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

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| IN RE: TEPEZZA MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION | No. 1:23−cv−03568<br>MDL No. 3079 |
| This Document Relates to Member Cases:<br>No. 1:22-cv-06562 (*Pledger*)<br>No. 1:23-cv-02503 (*Polanco*)<br>No. 1:23-cv-02659 (*Stern*)<br>No. 1:23-cv-02703 (*Ford*)<br>No. 1:23-cv-02714 (*Merriweather*)<br>No. 1:23-cv-03033 (*Chryssos*)<br>No. 1:23-cv-03585 (*Meyers*)<br>No. 1:23-cv-06423 (*Bounds*)<br>No. 1:23-cv-15306 (*Egger*)<br>No. 1:23-cv-15501 (*Meilleur*)<br>No. 1:23-cv-15994 (*Perkett*) | Judge Thomas M. Durkin<br><br>Magistrate Judge M. David Weisman |

**DEFENDANT HORIZON THERAPEUTICS USA, INC.'S MEMORANDUM IN SUPPORT OF ITS OMNIBUS MOTION TO DISMISS THE DESIGN DEFECT CLAIMS IN ELEVEN INITIAL BELLWETHER DISCOVERY COMPLAINTS PURSUANT TO FED. R. CIV. P. 12(b)(6)**

TABLE OF CONTENTS

TABLE OF AUTHORITIES

**Cases**

**Statutes**



**Other Authorities**

**Rules**

Horizon Therapeutics USA, Inc. ("Horizon") moves this Court to dismiss the strict liability and negligent design defect claims asserted in eleven[1] of the Initial Bellwether Discovery plaintiffs' First Amended Complaints ("FACs") under the laws of the states where each plaintiff alleges exposure. Plaintiffs allege that Tepezza® (teprotumumab), a first-of-its-kind biologic approved by the U.S. Food and Drug Administration ("FDA") for the treatment of thyroid eye disease ("TED"), caused hearing impairment injuries. The Court previously dismissed plaintiffs' post-approval design defect claims as preempted. *See* Mem. & Order at 3, 9 (ECF No. 70).[2] Plaintiffs are, therefore, left with an exceedingly narrow claim—that, despite FDA's approval of Horizon's design of Tepezza®, Horizon should have somehow designed Tepezza® differently, but in a way that still would have gained FDA approval, been prescribed by plaintiffs' physicians, and avoided plaintiffs' alleged injuries. *See id.* at 1, 6. Plaintiffs fail to adequately state such a claim under any relevant state law.

The eleven plaintiffs are from nine different states: California (*Egger*), Florida (*Bounds* and *Perkett*), Maryland (*Pledger*), Michigan (*Merriweather*), New Jersey (*Polanco*), New York (*Chryssos* and *Stern*), Pennsylvania (*Ford*), Utah (*Meyers*), and Tennessee (*Meilleur*). Of the eleven:

- **Three** of the plaintiffs (*Egger*, *Ford*, *and Meyers*) assert solely negligent design defect claims, following their voluntary dismissal of strict liability design defect claims as not recognized under California (*Egger*), Pennsylvania (*Ford*), and Utah (*Meyers*) law; and

[1] Although there are twelve Initial Bellwether Discovery cases, only eleven plaintiffs are the subject of this Motion because plaintiff *Kanesta-Rychner* voluntarily dismissed her only design defect claim. *See* Notice of Dismissal of Claim 2 (strict liability design defect), *Kanesta-Rychner*, No. 1:23-cv-03575 (ECF No. 17); *infra* Background § II n.8.

[2] Unless otherwise indicated, citations to documents filed in this case refer to the MDL docket: *In re Tepezza Mktg., Sales Pracs., & Prods. Liab. Litig.*, No. 1:23-cv-03568 (N.D. Ill.).

- **Eight** of the plaintiffs (*Bounds*, *Perkett*, *Pledger*, *Merriweather*,[3] *Polanco*, *Chryssos*, *Stern*, and *Meilleur*) assert both strict liability and negligent design defect claims.[4]

All eleven of the Initial Bellwether Discovery plaintiffs' design defect claims should be dismissed under applicable law because they fail to identify a specific aspect of the design of Tepezza® that rendered Tepezza® unreasonably dangerous and could have been changed prior to FDA approval to eliminate a specific risk. Plaintiffs allege only in a conclusory fashion that Tepezza® is defective because it poses a risk of hearing injuries. This is not enough.

Plaintiffs *Pledger*, *Chryssos*, *Stern*, *Ford*, and *Meyers*'s claims additionally fail because they do not allege facts to support an allegation that their proposed alternative design—a half-dose regime—would have been equally efficacious, eliminated the risk of hearing impairment, and been approved by FDA, as required by Maryland, New York, Pennsylvania, and Utah law. Plaintiffs' *Egger*, *Merriweather*, *Pledger*, *Polanco*, and *Meilleur*'s design defect claims fail for the additional reason because they do not allege facts to support an allegation that Tepezza®'s risks of hearing impairment outweighed its utility—despite being the first and only FDA-approved treatment for thyroid eye disease—under a risk-utility analysis, as required under California, Illinois, Maryland, New Jersey, and Tennessee law.

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[3] In a separate motion, Horizon moves to dismiss plaintiff Merriweather's FAC in its entirety because her claims are not recognized under Michigan law. Should that Motion not be granted, plaintiff Merriweather's design defect claims should be dismissed for failure to state a claim for the reasons herein.

[4] *See* ***Chryssos***, No. 1:23-cv-03033: FAC Claims 3 and 4 (ECF No. 12); ***Egger***, No. 1:23-cv-15306: FAC Claim 4 (ECF No. 3); Notice of Dismissal of Claim 3 (strict liability design defect) (ECF No. 5); ***Meyers***, No. 1:23-cv-03585: FAC Claim 4 (ECF No. 6); Notice of Dismissal of Claim 3 (strict liability design defect) (ECF No. 8); ***Meilleur***, No. 1:23-cv-15501: FAC Claims 3 and 4 (ECF No. 10); ***Merriweather***, No. 1:23-cv-02714: FAC Claims 3 and 4 (ECF No. 10); ***Perkett***, No. 1:23-cv-15994: FAC Claims 3 and 4 (ECF No. 6); ***Polanco***, No. 1:23-cv-02503: FAC Claims 3 and 4 (ECF No. 10); ***Stern***, No. 1:23-cv-02659: FAC Claims 3 and 4 (ECF No. 14); ***Bounds***, No. 1:23-cv-06423: FAC Claims 3 and 4 (ECF No. 4); ***Ford***, No. 1:23-cv-02703: FAC Claim 4 (ECF No. 11); Notice of Dismissal of Claim 3 (strict liability design defect) (ECF No. 13); ***Pledger***, No. 1:22-cv-06562: FAC Claims 3 and 4 (ECF No. 36).

For the reasons set forth below, Horizon respectfully requests the Court dismiss the strict liability and negligent design defect claims asserted in eleven of the Initial Bellwether Discovery plaintiffs' FACs for failure to state a claim under the relevant state laws.

## BACKGROUND

### I. Plaintiffs' Allegations

Tepezza® is the first FDA-approved medication indicated to treat TED, a rare autoimmune disease "characterized by progressive inflammation in the tissues around the eyes." *See, e.g.*, FAC ¶¶ 28, 30, 33, 42 (Ex. A).[5] Inflammation causes proptosis or exophthalmos (wherein the eyes push forward and bulge from the eye sockets), eyelid and eye redness or "bloody eyes," and immense pain. *Id.* ¶¶ 28, 31. TED may also cause: eyelid retraction (wherein patients cannot fully shut their eyelids); dry eyes; eye pain; difficulty or an inability to look around; impaired vision, including blurred or double vision (diplopia); eye misalignment or strabismus (wherein the two eyes point in different directions); inflamed white area of eye; excessive eye watering or tearing; an intolerance to bright lights; and eyelid swelling. *See id.*

Tepezza® is an insulin-like growth factor-1 ("IGF-1") inhibitor that blocks the growth factor protein, which is believed to play a significant role in the development of TED. *Id.* ¶¶ 42, 103. Following years of development and two randomized clinical trials, FDA approved Horizon's Biologics License Application ("BLA") for Tepezza® in January 2020. *Id.* ¶¶ 42, 48-49. All plaintiffs allege that they were prescribed Tepezza® after FDA approval.[6]

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[5] Horizon refers to the FAC in *Chryssos*, No. 1:23-cv-03033, ECF No. 12, as Exhibit A. The allegations set forth in the *Chryssos* FAC are representative of the FACs of all the Initial Bellwether Discovery plaintiffs subject to this motion.

[6] *See* FAC ¶ 10, *Meyers*, No. 1:23-cv-03585 (alleging Tepezza® infusions from April 2020 through September 2020) (ECF No. 6); FAC ¶ 10, *Stern*, No. 1:23-cv-02659 (May 2021 through October 2021) (ECF No. 14); FAC ¶ 10, *Ford*, No. 1:23-cv-02703 (August 2021 through October 2021) (ECF No. 11); FAC ¶ 10, *Pledger*, No. 1:22-cv-06562 (June 2021 through December 2021) (ECF No. 36); FAC ¶ 10,

Plaintiffs allege that Horizon designed Tepezza® "in such a way that posed an unreasonable risk of permanent hearing injuries," but nowhere do they specify what about Tepezza®'s design was defective or unreasonably dangerous. *Id.* ¶ 227. Specifically, plaintiffs allege:

- Tepezza® is defective and unreasonably dangerous because Horizon failed to conduct "pharmacodynamic studies" to "determine [Tepezza®'s] mechanism of action," *id.* ¶¶ 46-47, 242, 251(c);
- Had Horizon exercised reasonable care in testing and studying Tepezza®, it would have known prior to approval that Tepezza® "can cause serious and irreversible hearing loss and/or tinnitus," *id.* ¶ 162;
- Horizon placed Tepezza® "into the stream of commerce in a defective and unreasonably dangerous condition," *id.* ¶¶ 225, 231;
- Horizon breached its duty to design Tepezza® free from a defective condition by designing Tepezza® "in such a way that posed an unreasonable risk of permanent hearing injuries," *id.* ¶¶ 226-28;
- Tepezza was "defective in design or formulation because . . . it was in an unreasonably and dangerous condition because it failed to perform as safely as an ordinary consumer would expect . . ., posing a risk of serious and potentially irreversible hearing damage," *id.* ¶¶ 232, 234 (Tepezza was in a condition "not contemplated" by plaintiff), 237 (plaintiff "would not expect" a TED drug to cause hearing loss);
- Tepezza® "causes serious and potentially irreversible hearing loss," *id.* ¶ 236; and
- Tepezza® "was defective in design or formulation in that its limited and unproven effectiveness and low efficacy did not outweigh the risks of serious and potentially irreversible hearing issues," *id.* ¶ 239.

Plaintiffs dedicate two-pages of their FACs to Horizon's "design" of Tepezza® to treat TED, but that section contains ***zero*** allegations of any specific defect in Tepezza®'s design. *See id.* ¶¶ 37-45 (header: "Defendant designs and seeks FDA approval for Tepezza to treat thyroid eye disease").

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*Polanco*, No. 1:23-cv-02503 (November 2021 through May 2022) (ECF No. 10); FAC ¶ 10, *Egger*, No. 1:23-cv-15306 (March 2022 through August 2022) (ECF No. 3); FAC ¶ 10, *Chryssos*, 1:23-cv-03033 (June 2022 through September 2022) (ECF No. 12); FAC ¶ 10, *Perkett*, No. 1:23-cv-15994 (April 2022 through September 2022) (ECF No. 6); FAC ¶ 10, *Merriweather*, No. 1:23-cv-02714 (September 2022 through May 2023) (ECF No. 10); FAC ¶ 10, *Meilleur*, No. 1:23-cv-15501 (July 2022 through December 2022) (ECF No. 10); FAC ¶ 10, *Bounds*, No. 1:23-cv-06423 (November 1, 2022 to April 3, 2023) (ECF No. 4).

Plaintiffs' sole allegation regarding a proposed "alternative design" of Tepezza® consists of a single paragraph alleging that "[r]easonable alternative designs existed" by way of "using a half dose" of Tepezza®. *Id.* ¶ 243; *see also id.* ¶ 255 (identical allegation). Plaintiffs do not (and cannot) allege that this alternative design "existed" prior to FDA approval in January 2020. Plaintiffs' only alleged support for this "alternative design" is a single case report published in 2023 regarding a single patient who had pre-Tepezza® hearing loss and achieved substantial improvement of her TED symptoms after her first four Tepezza® infusions of the FDA-approved dose. *See id.* (citing Ragini Phansalkar, *Reduction of Teprotumumab-Induced Hearing Loss With Comparable Efficacy Using Half-Dose Therapy*, 39 Ophthalmic Plas. Reconstr. Surg. e101-04 (2023) (Ex. B) ("Phansalkar Case Report")).[7] The patient stopped treatment after four of the eight infusions prescribed in accordance with the FDA-approved dose. *See* Phansalkar Case Report at e101-02 (Ex. B). One year later, the patient restarted Tepezza® using eight half-dose infusions over an unknown period of time. *See id.* at e103.

## II. Procedural History as to Design Defect Claims

On June 2, 2023, the Judicial Panel for Multidistrict Litigation centralized eighteen actions alleging permanent hearing loss and tinnitus associated with the use of Tepezza® in the Northern District of Illinois before the Honorable Thomas M. Durkin (the "MDL Court"). *See generally* Transfer Order (ECF No. 1). The MDL Court considered pre-existing 12(b)(6) briefing that had

[7] *See also* Horizon's concurrently filed Request for Judicial Notice ("RJN") asking that the Court take judicial notice of the Exhibits that are referenced in the FACs or are matters of public record. When deciding a motion to dismiss, "courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 322 (2007); *see also Jackson v. Kane Cnty.*, No. 09 C 4154, 2010 WL 4719713, at *2 n.2 (N.D. Ill. Nov. 9, 2010) ("In ruling on a 12 (b)(6) motion to dismiss, the court may take judicial notice of matters of public record.") (citing *Cancer Found., Inc. v. Cerberus Cap. Mgmt.*, 559 F.3d 671, 675, n.2 (7th Cir. 2009)); Fed. R. Evid. 201(b).

been pending in the transferor court in one of those actions, *Williams v. Horizon Therapeutics USA, Inc.*, No. 1:22-cv-06838 (N.D. Ill.) to consider the sole issue of whether plaintiffs' state-law design defect claims are preempted by federal law. The Court found that plaintiffs' post-FDA approval design defect claims are preempted. *See* Mem. Op. & Order 3, 9 (ECF No. 70). The Court found that plaintiffs' "pre-approval design defect claims"—*i.e.*, that Horizon should have designed Tepezza® differently *before* it sought FDA approval—are not preempted. *Id.* at 1. The Court took "no position on whether [plaintiffs'] design defect claims warrant dismissal on any other ground," including whether plaintiffs adequately alleged design defect claims under the appropriate state law. *Id.* at 1, 6 n.5, 9.

The eleven Initial Bellwether Discovery plaintiffs all filed FACs that assert strict liability and negligent design defect claims under nine state laws. Plaintiffs in three cases (*Egger*, *Ford*, and *Meyers*) voluntarily dismissed strict liability design defect claims that are not cognizable under applicable state laws but continue to assert negligent design defect claims.[8] The remaining eight plaintiffs (*Bounds*, *Perkett*, *Pledger*, *Merriweather*, *Polanco*, *Chryssos*, *Stern*, and *Meilleur*) assert both strict liability and negligent design defect claims. Horizon thus moves to dismiss the following remaining claims in eleven Initial Bellwether Discovery Cases: (1) the strict liability and negligence design defect claims asserted under Florida (*Bounds* and *Perkett*), Michigan

[8] Certain states—relevant here, California, Michigan, Pennsylvania, Utah, and Washington—have clearly recognized that strict liability design defect claims against prescription drug manufacturers do not exist. *See* Restatement (Second) of Torts § 402A, comment k (1965). In response to Horizon's request that specific plaintiffs voluntarily dismiss their alleged strict liability claims that are not recognized by the states where each plaintiff alleges exposure, regardless of how they are pleaded, plaintiffs agreed to voluntarily dismiss the following: strict liability design defect under California law, *Egger*, No. 1:23-cv-15306; strict liability design defect under Utah law, *Meyers*, No. 1:23-cv-03585; strict liability design defect under Washington law, *Kanesta-Rychner*, No. 1:23-cv-03575; and strict liability failure to warn and strict liability design defect under Pennsylvania law, *Ford*, No. 1:23-cv-02703. *See* Email from T. Becker to C. Thurman et al. (June 27, 2024) (Ex. C); *supra* n. 1,4.

(*Merriweather*),[9] Maryland (*Pledger*), New Jersey (*Polanco*), New York (*Chryssos* and *Stern*) and Tennessee (*Meilleur*) law; and (2) the negligent design defect claims asserted under California (*Egger*), Pennsylvania (*Ford*), and Utah (*Meyers*) law.

## III. Federal Regulation of Biologics

The Federal Food, Drug, & Cosmetic Act ("FDCA") and related regulations create a comprehensive regulatory scheme for the development and approval of biological products such as Tepezza®. FDA has exclusive regulatory authority to approve biological products that are shown to be "safe, pure, and potent." 21 U.S.C. § 355(a)-(d); 42 U.S.C. § 262(a)(2)(C)(i) (providing the Secretary of Health and Human Services with regulatory approval of biologics). "The entire statutory scheme envisages that the FDA will perform the difficult task of investigation and scientific evaluation usually required to determine whether a drug product is safe and effective." *Premo Pharm. Lab'ys, Inc. v. United States*, 629 F.2d 795, 803 (2d Cir. 1980).

FDA involvement in a biologic's development was particularly acute here, as it granted Tepezza® "Orphan Drug" designation in 2013, "Fast Track" designation in 2015, and "Breakthrough" designation in 2016. *See* FAC ¶¶ 37-40. Where the biologic, like Tepezza®, aims to prevent, diagnose, or treat a rare disease with populations of under 200,000 people (*i.e.*, "Orphan Drug" designation), FDA "provide[s] . . . written recommendations for the non-clinical and clinical investigations . . . necessary for approval of such drug." 21 U.S.C. § 360aa-bb; FAC ¶¶ 37-38 (FDA granted Tepezza® Orphan Drug designation in 2013). If the biologic "demonstrates the potential to address unmet medical needs," or "preliminary clinical evidence indicates that the drug

[9] *See generally* Horizon's concurrently filed Mem. Supp. Mot. Dismiss All Claims of Initial Bellwether Disc. Pl. *Merriweather* Pursuant to Fed. R. Civ. P. 12(b)(6). Regardless of the choice-of-law determination, plaintiff *Merriweather*'s strict liability and negligent design defect claims are inadequately pleaded under either Illinois or Michigan law.

may demonstrate substantial improvement over existing therapies," FDA may grant "Fast Track" or "Breakthrough" designation to the drug—as it did for Tepezza®—which expedites the drug's development and makes it subject to intensive and frequent guidance from FDA. *See* 21 U.S.C. § 356(a)-(b)[10]; FAC ¶¶ 39-40 (FDA granted Tepezza® Fast Track designation in 2015 and Breakthrough designation in 2016). Such designation reflects a policy decision to promote the development of important drugs that treat serious but rare diseases.

When considering a manufacturer's BLA (even for biologics not granted Orphan Drug, Fast Track, or Breakthrough status), FDA reviews every aspect of the biologic, its design and labeling, including detailed reports of nonclinical laboratory studies and clinical trials evaluating the biologic's safety and efficacy, its composition, and the drug's proposed labeling. *See* 21 C.F.R. § 601.2. FDA's regulation of biologics is so "pervasive[]" that it extends "down to the requirements for plumbing and ventilation systems at each manufacturing facility." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 237 (2011). In deciding whether to approve a biologic, an FDA Advisory Committee may hold a public hearing after evaluating the available data for "a determination of safety and effectiveness." 21 C.F.R. §§ 14.160, 14.171. An FDA Advisory Committee held such a hearing to assess the BLA for Tepezza®. *See* Transcript of *December 13, 2019 Meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee,* U.S Food & Drug

[10] *See also Fast Track*, U.S. Food & Drug Admin. (Jan. 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track (Ex. E) (stating that Fast Track designation makes a biologic eligible for "frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval" and "frequent communication from FDA about such things as the design of the proposed clinical trials"); *Breakthrough Therapy*, U.S. Food & Drug Admin (Jan. 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy (Ex. F) (stating Breakthrough Designation makes the biologic eligible for all "Fast Track" designation benefits and "[i]ntensive guidance on efficient drug development program, beginning as early as Phase 1").

Admin. (Dec. 13, 2019), https://www.fda.gov/media/135336/download (Ex. G).[11] FDA could have required additional clinical trials—for example, to examine different dosing regimes—before granting Tepezza® approval, but did not do so.

FDA will approve a BLA only if it finds that the application meets its strict requirements for licensure. 21 C.F.R. § 601.20. FDA approval of a BLA constitutes a determination that the product is safe and effective. *See id.* § 601.2(d). FDA approval represents a decision that the benefits of the biologic outweigh the risks. *See Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 476 (2013) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000)). That decision takes into account the proposed label because biologics—and in particular, "new and experimental drugs"—are "unavoidably unsafe," or "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement (Second) of Torts § 402A, comment k (1965)[12]; *see also* 21 C.F.R. § 601.2(a) (safety determination made based on, *inter alia*, clinical trial data and proposed labeling); *United States v. Rutherford*, 442 U.S. 544, 555 (1979) ("Few if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk."); *Wyeth v. Levine*, 555 U.S. 555, 608 (2009) (Alito, J., dissenting) ("[A] drug's warning label 'serves as the standard under which the FDA determines whether a product is safe and effective.'" (quoting 50 Fed. Reg. 7470 (1985))).

[11] The FDA Advisory Committee unanimously voted that the potential benefits of Tepezza® outweigh the potential risks. *See* Exhibit G at 309:20-310:06, 312:14-313:2.

[12] Comment k explains that new prescription drugs accompanied by proper warnings are "not defective, nor . . . *unreasonably* dangerous," because due to "lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, . . . but such experience as there is justifies the marketing and use of the drug not withstanding a medically recognizable risk." *See* Restatement (Second) of Torts § 402A (1965); *see also Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991) (holding that drug manufacturers cannot be strictly liable for design defect claims relating to an FDA-approved prescription drug under Utah law); *Brown v. Superior Ct.*, 751 P.2d 470 (Cal. 1988) (same under California law).

Once approved, the drug's label becomes an integral part of the biologic's design and claims for design defect merge with those for failure-to-warn. *See* Restatement (Second) of Torts § 402A, comment k (1965) (imposing an exception from strict liability for FDA-approved prescription drug products that are properly prepared and accompanied by proper direction and warning); *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 41 (1st Cir. 2015) ("*Wyeth* effectively reserves the launch of new drugs to the expertise of the FDA, but then preserves a wide scope for the states in requiring manufacturers to respond to information not considered by the FDA.").

## LEGAL STANDARD

Federal Rule of Civil Procedure 8 requires "a short and plain statement of the claim showing that the pleader is entitled to relief." The Rule "contemplates the statement of circumstances, occurrences, and events in support of the claim presented" and does not authorize a plaintiff's "bare averment that he wants relief and is entitled to it." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 n.3 (2007). "[M]ore than labels and conclusions" are required "and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 555 (internal citations omitted); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 681 (2009). "[T]he pleading standard Rule 8 announces does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id.* at 678 (internal citations omitted). A complaint is insufficient under Rule 12 where it does not contain sufficient factual allegations to "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570.

## ARGUMENT

Plaintiffs' design defect claims fail under the laws of each state where plaintiffs allege exposure. Plaintiffs fail to plausibly allege: *any* defect in Tepezza®'s design that existed when

Tepezza® was approved by FDA, a feasible alternative design, and any facts to support a reasonable inference that Tepezza®'s risks outweighed its benefits.

## I. The Law of The Place Where Plaintiffs Suffered Injury Applies to All of Plaintiffs' Design Defect Claims.

Plaintiffs agree that the law of the state where each plaintiff resides applies to that plaintiff's design defect claims. *See* Email from T. Becker to C. Thurman (June 27, 2024) (Ex. C); *supra* Background § II (plaintiffs agreed to dismiss claims where the states of injury did not recognize such claims); June 10, 2024 Status Hr'g Tr. 6:8-7:4 (Ex. D) (PLC explaining that "[n]o more than 12" states are implicated in the Motions to Dismiss). Illinois choice-of-law rules yield the same result because there is a "*strong* presumption" that the law of the place of the injury applies. *Townsend v. Sears, Roebuck & Co.*, 879 N.E.2d 893, 904-05 (Ill. 2007) (emphasis in original); *see Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941) (stating that federal courts sitting in diversity apply the choice-of-law rules of the forum state); *see also, e.g.*, *In re Abbott Lab'ys Preterm Infant Nutrition Prods. Liab. Litig.*, No. 22 C 71, 2023 WL 4273701, at *5 (N.D. Ill. June 29, 2023) (MDL court applying New Jersey law to New Jersey plaintiffs' product liability claims who alleged injury in New Jersey); *Paulsen v. Abbott Lab'ys*, No. 15-cv-4144, 2018 WL 1508532, at *12-13 (N.D. Ill. Mar. 27, 2018) (applying Georgia law to product liability claims where plaintiff was a resident of, and alleged injury in, Georgia); *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14 C 1748, 2014 WL 7365872, at *10-11 (N.D. Ill. Dec. 23, 2014) (applying law of each MDL plaintiff's state of residence).

## II. Plaintiffs Do Not Plausibly Allege Either Strict Liability or Negligent Design Defect Claims Under Any Relevant State Laws.

### A. Plaintiffs' Design Defect Claims Fail Under the Law of All 9 States Because Plaintiffs Do Not Identify Any Specific Design Defect in Tepezza®.

In the pharmaceutical context, plaintiffs must allege Tepezza®'s design (*i.e.*, its composition or formulation) rendered it unreasonably dangerous to state a design defect claim. The design flaw cannot be inadequate warnings. It is unclear how plaintiffs assert a defective design claim because plaintiffs have failed to identify a specific aspect of Tepezza®'s design that renders it unreasonably dangerous. Thus, plaintiffs' design defect claim fails at the most basic level: there is no plausible allegation of a defective design.

#### *1. Plaintiffs Fail to Allege a Specific Defect in Tepezza®'s Design.*

To plausibly state a claim for design defect of an FDA-approved medication under either a strict liability or negligence theory under applicable state law, plaintiffs must identify a specific defect in Tepezza® that caused plaintiffs' harm. *See Marroquin v. Pfizer*, 367 F. Supp. 3d 1152, 1163-64 (E.D. Cal. 2019) (citing *Merrill v. Navegar, Inc.*, 28 P.3d 116 (Cal. 2001)) (under **California** law, "[i]f a design defect is at issue, [plaintiff] must identify what aspect of amiadarone makes it defective."); *Shapiro v. NuVasive, Inc.*, No. 19-23163, 2019 WL 5742159, at *1-2 (S.D. Fla. Nov. 5, 2019) (under **Florida** law, for both strict liability and negligent design defect theories, the complaint "must contain allegations about what was in fact defective," or unreasonably dangerous "about the product" (citations omitted)).[13]

[13] *See also* **Maryland**: *Grinage v. Mylan Pharms., Inc.*, 840 F. Supp. 2d 862, 869 n.6 (D. Md. 2011) (quoting *Pease v. Am. Cyanamid Co.*, 795 F. Supp. 755, 759, 759 n.3 (D. Md. 1992)) (negligence and strict liability design defect inquiries both require product to be in a defective condition, *i.e.*, "unreasonably dangerous"); **New Jersey**: *Hindermyer v. B. Braun Med., Inc.*, 419 F. Supp. 3d 809, 823 (D.N.J. 2019) (design defect claims under NJPLA require plaintiff to show the product was defective); **New York**: *Oden v. Bos. Sci. Corp.*, 330 F. Supp. 3d 877, 887-88 (E.D.N.Y. 2018) (design defect inquiries under strict liability and negligence theories require plaintiff to identify a defect that "posed a substantial likelihood of harm"); **Pennsylvania**: *McGrain v. C.R. Bard, Inc.*, 551 F. Supp. 3d 529, 541-42 (E.D. Pa. 2021)

Moreover, plaintiffs are required to demonstrate that a defect existed at the time the product was placed on the market (*i.e.*, at the time of FDA approval). *See* Mem. Op. & Order 3, 9 (ECF No. 70) (holding that post-approval design defect claims are preempted); *supra* Background § I (all plaintiffs' use dates are post-approval).[14] To do so, plaintiffs must plausibly allege facts that support a reasonable inference that Horizon could have designed a safer product *prior* to approval and that its failure to do so rendered Tepezza® unreasonably dangerous when FDA approved

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(allegations must address the design of defendants' product in a "level of meaningful detail"); **Utah**: *Henrie v. Northrop Gunman Corp.*, 502 F.3d 1228, 1236-37 (10th Cir. 2007) (under Utah law, negligent design claim requires the product be unreasonably dangerous under the same statutory standard as a strict liability claim); **Tennessee**: *Maness v. Bos. Sci.*, 751 F. Supp. 2d 962, 967-69 (E.D. Tenn. 2010) (to allege negligent or strict liability design defect under Tennessee Product Liability Act of 1978 ("TPLA"), allegations must include specific facts as to how the product was defective or unreasonably dangerous); *see also* **Illinois**: *Grzanecki v. Smith & Nephew, Inc.*, No. 18-CV-00204, 2019 WL 2297452, at *2-3 (N.D. Ill. Oct. 5, 2017) (negligent and strict liability design defect claims require plaintiffs to state a "condition" of the drug that makes it "unreasonably dangerous"). *But see* **Utah:** *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991) (holding that a drug properly prepared and accompanied by FDA-approved directions and warnings could not, as a matter of law, be "defective nor . . . *unreasonably* dangerous" (emphasis in original)). Just one court has held in an unpublished decision that the "exemption on design defect liability for prescription drugs is . . . limited to strict liability," rationalizing that "Utah courts have consistently limited the application of this exemption to strict liability claims." *See Lake-Allen v. Johnson & Johnson, L.P.*, No. 2:08CV00930, 2009 WL 2252198, at *3 (D. Utah July 27, 2009) (citing no cases). Such a holding is contrary to the controlling line of precedent requiring defects to be "unreasonably dangerous" to support negligent design defect claims.

[14] *See also* **California:** *Jiminez v. Sears, Roebuck & Co.*, 482 P.2d 681, 683 (Cal. 1971) (requiring defect to exist when product "left the hands of the retailer or manufacturer" for both negligent and strict liability design defect claims under California law); **Florida:** *Bailey v. Janssen Pharmaceutica*, 288 F. App'x 597, 608 (11th Cir. 2008) (applying Florida law) (same for strict liability design defect claims); *Witt v. Stryker Corp.*, 648 F. App'x 867, 875 (11th Cir. 2016) (applying Florida law) (same for negligent design defect claims); **Maryland:** *Conway v. Am. Med. Sys.*, No. GLR-18-1466, 2021 WL 6126293, at *7 (D. Md. Dec. 28, 2021) (same for both under Maryland law); **New Jersey:** *Barrett v. Tri-Coast Pharm., Inc.*, 518 F. Supp. 3d 810, 825-26 (D.N.J. 2021) (same for all product liability claims under NJPLA); **Pennsylvania:** *Lance v. Wyeth*, 85 A.3d 434, 458 (Pa. 2014) (same for negligent design under Pennsylvania law); **New York:** *Suez Water N.Y. Inc. v. E.I. du Pont de Nemours & Co.*, 578 F. Supp. 3d 511, 560 (S.D.N.Y. 2022) (quoting *Robinson v. Reed-Prentice Div. of Package Mach. Co.*, 49 N.Y.2d 471, 479 (1980)) (same for strict liability under New York law); *Kennedy v. Covidien, LP*, No. 1:18-cv-01907, 2019 WL 1429979, at *3, 5 (S.D.N.Y. Mar. 29, 2019) (same for negligent design under New York law); **Tennessee:** *King v. Danek Med., Inc.*, 37 S.W.3d 429, 435 (Tenn. Ct. App. 2000) (same for all product liability actions under TPLA (citing Tenn. Code Ann. § 29-28-105(a))); **Utah:** Utah Code Ann. § 78-15-6 (same for all product liability actions under Utah law); *see also* **Illinois:** *Tillman v. Taro Pharm. Indus. Ltd.*, No. 10-cv-04202, 2011 WL 3704762, at *3 (N.D. Ill. Aug. 17, 2011) (quoting *Faucett v. Ingersoll-Rand Min. & Mach. Co.*, 960 F.2d 653, 655 (7th Cir. 1992) (same for strict product liability under Illinois law).

Tepezza® as safe and effective to treat TED in January 2020, and at the time when plaintiffs first used the medicine. *See* Mem. Op. & Order at 3 (ECF No. 70); FAC ¶ 42.

Plaintiffs allege only in a conclusory fashion that Tepezza®, an FDA-approved biologic medication, is defective, and fail to identify in their pleading any specific defect. *See, e.g.*, FAC ¶¶ 225-26, 232 (Ex. A) (labeling Tepezza® "defective and unreasonably dangerous" without explanation). Plaintiffs' allegations regarding Tepezza®'s allegedly defective design contain only legal conclusions, without *any* factual allegations as to Tepezza®'s design, let alone *what* specifically about Tepezza®'s design makes it defective. *See* FAC ¶¶ 37-45 (Ex. A) (header: "Defendant designs and seeks FDA approval for Tepezza to treat thyroid eye disease"). The lack of factual support to plausibly allege an aspect of Tepezza®'s design that renders it unreasonably dangerous requires dismissal of these claims. *See, e.g.*, *Marroquin v. Pfizer, Inc.*, 367 F. Supp. 3d 1152, 1164 (E.D. Cal. 2019) (dismissing plaintiff's negligent design defect claim for failing to "identify what aspect of amiodarone makes it defective"); *McDonald v. Schriner*, No. 2:18-cv-02084, 2019 WL 1040978, at *6 (W.D. Tenn. Mar. 5, 2019) (dismissing design defect claims supported by allegations that FDA-approved medication Ropinirole "induced [plaintiff's] heavy gambling" because complaint failed to allege any facts sufficiently explaining *how* Ropinirole's design is defective).[15]

[15] *See also* **New York:** *Oden*, 330 F. Supp.3d at 887-88 (dismissing plaintiff's design defect claim because plaintiff alleged the medical device was "defective in design" but failed to include "any *facts* indicating the particular component that was defective or otherwise identifying a specific problem . . . that caused it to be unreasonably dangerous"); **Pennsylvania:** *McGrain*, 551 F. Supp.3d at 541-42 (E.D. Pa. 2021) (same); **Florida:** *Dimieri v. Medicis Pharms. Corp.*, No. 2:14-cv-176, 2014 WL 3417364, at *5 (M.D. Fla. July 14, 2014) (dismissing claims that acne medication caused hair loss because plaintiff failed to "identify the source of an alleged defect in Solodyn or disclose any possible defects which could exist in Solodyn"); *cf. Bailey v. Janssen Pharmaceutica, Inc.*, 288 F. App'x 597, 607-08 (11th Cir. 2008) (holding complaint that suggested "several possible defects existing at the time of [plaintiff's] use of the Duragesic patch," including its pace of medication release and protective liner and functional layers susceptible to leak, sufficiently alleged a defect that made the patch unreasonably dangerous); **Maryland:** *Thomas v. Ethicon*,

### *2. Plaintiffs Allegation That Tepezza® is an IGF-IR Inhibitor Does Not Identify a Defect.*

At most, plaintiffs allege that Tepezza® is an inhibitor of IGF-1, a hormone "associated with mammalian hearing and deficiencies [of which] result in hearing loss." FAC ¶¶ 103-06 (describing IGF-1R inhibitors as posing a risk of hearing impairment). The fact itself that Tepezza® is an IGF-1 inhibitor does not constitute a "defect"; such logic leads to the impermissible conclusion that all IGF-1 inhibitors are defective *per se*. Accepting plaintiffs' logic would require the court to conclude that Tepezza® should not have been marketed at all—a conclusion foreclosed by the Supreme Court's "stop-selling" rationale in *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472, 488 (2013). There, the Court held that a claim that a manufacturer should have "pulled the drug from the market . . . is no solution." *Id.* at 475. *Bartlett* forbids requiring a manufacturer to "cease acting altogether in order to avoid liability." *Id.* at 488; *see also Trisvan v. Heyman*, 305 F. Supp. 3d 381, 405 (E.D.N.Y. 2018) ("'An outright ban' cannot be a viable alternative to sustain a design-defect claim." (quoting *S.F. v. Archer Daniels Midland Co.*, 594 F. App'x 11, 12 (2d Cir. 2014))).

### *3. Plaintiffs' Allegations That Tepezza® Causes Hearing Impairment Do Not Support a Design Defect Claim.*

Plaintiffs' allegations that Tepezza® is defective simply because plaintiffs allege hearing impairment adverse reactions fare no better. FAC ¶¶ 227-28, 232, 234, 237 (Ex. A) (calling Tepezza® "defectively designed in that it posed a serious risk of severe and permanent hearing injuries"). "The fact that plaintiff allegedly suffered an injury from the [product] does not show that the [product] was defective." *Maness v. Bos. Sci.*, 751 F. Supp. 2d 962, 969 (E.D. Tenn. 2010);

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No. 20-3729, 2021 WL 6126300, at *5-6 (D. Md. Dec. 28, 2021) (finding plaintiff sufficiently stated a design defect when she identified fifteen potential problems with the product's design).

*see also Gomez v. Pfizer, Inc.*, 675 F. Supp. 2d 1159 (S.D. Fla. 2009) (allegations that Motrin and Tylenol were defectively designed because their "intended use resulted in a substantial and unreasonable likelihood of causing Stevens-Johnson syndrome, which rendered [them] unreasonably dangerous" were insufficient to adequately plead a design defect because "[s]uch allegations amount to no more than bare legal conclusions"); *Grinage*, 840 F. Supp. at 870 ("While she does allege injury, a plaintiff's right to recovery in a design defect case 'may not rest on any presumption from the happening of an event.'" (quotation omitted)). Plaintiffs' circular reasoning—using the injury to support an inference of the defect—cannot meet plaintiffs' burden under Rule 12(b)(6).

#### *4. Plaintiffs' Allegations That Tepezza® Is Defective Because They Did Not Expect The Risk Of Hearing Impairment Is A Failure-to-Warn Claim But Cannot Allege Design Defect.*

Plaintiffs' allegations concerning what plaintiffs "expect[ed]," FAC ¶¶ 232, 237 (Ex. A), or "contemplated," *id.* ¶ 234, are nothing more than failure-to-warn claims. All biologics have medically recognized risks—both known and unknown—because clinical trials represent a limited patient population. *See* Restatement (Second) of Torts § 402A, comment k (1965). What a consumer expects about a product is the FDA-approved label, which is an integral part of the "design" of an FDA-approved pharmaceutical product. *See, e.g.*, *Wyeth,* 555 U.S. at 608 (Alito, J., dissenting) (calling a drug's warning label the "centerpiece of risk management"). Claims that hinge on consumer expectations are not design defect but rather failure-to-warn claims. *See Grinage*, 840 F. Supp. 2d at 870 (under consumer expectations test, a design defect claim merges with a failure-to-warn claim because "[a]n ordinary consumer forms her expectations regarding the safety of drugs from her doctor or from the drug's label"); *Trisvan v. Heyman*, 305 F. Supp. 3d 381, 404 (E.D.N.Y. 2019) (plaintiff's concession that adequate warnings would have minimized

any harm demonstrates that "plaintiff's complaint does not lie with the *design* of the medications but the harms flowing from a lack of knowledge of their side-effects" (emphasis in original)). Because plaintiffs' design defect claims hinge on their expectations (*i.e.*, the FDA approved label), plaintiffs fail to assert a plausible claim.

#### *5. Plaintiffs Cannot and Do Not Allege that FDA Would Have Approved a Different Design of Tepezza®.*

Even if plaintiffs had plausibly alleged the existence of a pre-approval design defect, plaintiffs fail to allege that any supposed defect proximately caused plaintiffs' injuries. All plaintiffs were prescribed Tepezza® after FDA approval. *See supra* Background § I n.4 (plaintiffs' use dates). Plaintiffs cannot claim that Tepezza®'s design was defective after FDA approval. *See* Mem. & Order at 3, 9 (ECF No. 70) (dismissing plaintiffs' post-approval design defect claims as preempted). As such, plaintiffs must allege how the supposed defect that existed *prior* to FDA approval caused their injuries years *after* FDA approval. Plaintiffs' allegations are silent as to proximate causation. Plaintiffs fail to allege that had Horizon designed Tepezza® differently, FDA would have approved the alternative design. Nor do plaintiffs allege that their physician would have prescribed any alleged different design. Plaintiffs also fail to allege that the alternative design would have avoided plaintiffs' alleged injury. *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 299 (6th Cir. 2015) (noting the elements of a supposed design defect claim that a plaintiff would be required to prove to be successful on a pre-approval design defect claim). *Cf. Gaetano v. Gilead Scis., Inc.*, 529 F. Supp. 3d 333, 343 (D.N.J. 2021) (finding plaintiff satisfied *Yates*'s requirements when the alternative design *was* approved by the FDA).

#### *6. Conclusion as to Plaintiffs' Failure to Allege a Specific Design Defect*

At bottom, rather than identifying a specific defect in Tepezza®'s design, plaintiffs proffer nothing more than conclusory allegations that parrot the elements of a design defect claim. *See,*

*e.g.*, FAC ¶ 232 (Ex. A) ("The Tepezza supplied to Plaintiff by Defendant was defective in design or formulation because, when it left the hands of the manufacturer or supplier, it was in an unreasonably dangerous and defective condition because it failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendant, posing a risk of serious and potentially irreversible hearing damage to Plaintiff and other consumers."). It is well-established that "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555.

Because plaintiffs fail to describe a specific defect in Tepezza®'s design that renders it unreasonably dangerous, plaintiffs' claims for strict liability and negligent design defect fail.

**B. Plaintiffs *Pledger*, *Chryssos*, *Stern*, *Ford,* and *Meyers's* Design Defect Claims Additionally Fail under Relevant State Laws Because They Do Not Plausibly Allege A Feasible Alternative Design.**

Plaintiff's *Pledger*, *Chryssos*, *Stern*, *Ford,* and *Meyers's* claims fail for the additional reason that the laws of the states where they suffered injury require plaintiffs to allege a feasible alternative design to support their design defect claims. The alleged alternative design must have existed prior to FDA approval to support pre-approval design defect claims. *See* Mem. & Order 3, 9 (ECF No. 70). Plaintiffs propose an alternative dosing regime as their alternative design, relying on the Phansalkar Case Report as the basis for their allegation. *See* FAC ¶¶ 243, 255. This allegation is insufficient because (1) the proposed alternative dosing regime did not exist prior to FDA approval; (2) there is no evidence that a half-dose on its own would be efficacious at treating TED; and (3) there is no evidence that a half-dose of Tepezza® would be safer than Tepezza® at its FDA-approved dose.

Maryland (*Pledger*), New York (*Chryssos* and *Stern*), Pennsylvania (*Ford*), and Utah (*Meyers*) require sufficient factual allegations of a feasible alternative design to state a plausible design defect claim. *See Grinage*, 840 F. Supp. 2d at 870 (dismissing plaintiff's complaint for

failure to state design defect claim under Maryland law because plaintiff "alleges nothing with regard to the utility of Allopurinol or availability of less dangerous alternatives"); *MacSwan v. Merck & Co., Inc.*, 602 F. Supp. 3d 466, 474-75 (W.D.N.Y. 2022) (dismissing plaintiff's strict liability and negligent design defect claims for failure to plausibly allege a feasible alternative design); *Salvio v. Amgen, Inc.*, 810 F. Supp. 2d 745, 754 (W.D. Pa. 2011) (same for negligent design claims); *Tingey v. Radionics*, 193 F. App'x 747, 756 (10th Cir. 2006) (applying Utah law) (negligent design claim against medical device possible where plaintiff "has made a sufficient showing of the practicality of a safer design").[16]

Plaintiffs fail to adequately plead an alternative design that is safer, equally efficacious, and feasible because they fail to allege *facts* that show an alternative design was technologically feasible, available at the time FDA approved Tepezza®, and would have reduced or prevented the plaintiffs' harm. Relying solely on the Phansalkar Case Report, which is dated three years after Tepezza®'s FDA approval, plaintiffs allege that "using half the dose of Tepezza" is their purported "reasonable alternative design." *See* FAC ¶¶ 243, 255 (Ex. A). Plaintiffs contend that Horizon should have tested and sought FDA approval for a "half dose" regimen of Tepezza® that was never studied before FDA approval, remains untested to this day, and has never been approved by FDA as safe and effective to treat TED. *See In re Alloderm Litig.*, No. 0295, 2015 WL 5022618, at *12 (N.J. Super. L. Div. Aug. 14, 2015) (claimed alternative could not be considered for plaintiffs who

[16] In Utah, the availability of a safer design alone does *not* mean that a product was defective because "Utah law imposes 'no duty to make a safe [product] safer,' and does not 'requir[e] manufacturers to discontinue manufacturing less safe but [still] non-defective products.'" *Groesbeck v. Bumbo Int'l Trust*, 718 F. App'x 604, 622 (10th Cir. 2017) (alterations in original) (quoting *Slisze v. Stanley-Bostitch*, 979 P.2d 317, 320 (Utah 1999)). Even if the Court finds plaintiff *Meyers* adequately alleged a feasible alternative design, her claims are still subject to dismissal because pharmaceutical drugs are not unreasonably dangerous as a matter of law. *See Grundberg*, 813 P.2d at 92 (holding that pharmaceutical products meet the "unavoidably dangerous" exception to "unreasonably dangerous" products).

"had their surgeries prior to the commercial availability of" the claimed alternative); *Salvio*, 810 F. Supp. 2d at 754 ("[B]aldly stating that there were safer alternatives to [a drug], without providing factual support that they exist, is insufficient to survive a 12(b)(6) motion"); *Wolfe v. McNeil-PPC, Inc.*, 773 F. Supp. 2d 561, 572 (E.D. Pa. 2011) ("There exists no FDA-approved alternative form of [the drug], meaning there is no available alternative design of the drug for defendants to adopt.").[17]

The Phansalkar Case Report simply does not plausibly support an inference that there is a safer alternative with equal efficacy or reduced harms. *See* Phansalkar Case Report (Ex. B); *e.g.*, *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989-90 (8th Cir. 2001) (rejecting case reports as reliable scientific evidence). The Phansalkar Case Report does not support an inference of equal efficacy as it concerns a single patient that—before she took the half-dose of Tepezza® that plaintiffs point to as their supposed alternative design—had previously taken four infusions of the FDA-approved dose of Tepezza® (half of the FDA-approved and prescribed dosage), and already saw substantial efficacy from the medication. *See* Phansalkar Case Report at e101-02 (Ex. B). A year later, the patient restarted Tepezza® using plaintiffs' proposed half-dose and noted only "similar efficacy of the half dose." *See id.* at e103.

Even assuming that a half-dose of Tepezza® would be efficacious and would have been approved by FDA, plaintiffs fail to allege that such a design would be safer. The Phansalkar Case Report cannot support an inference of reduced harms because the patient suffered from

[17] Plaintiffs' alternative design amounts to a failure-to-test theory, namely, that Horizon should have tested different doses of Tepezza®. *See* FAC ¶¶ 243, 255 (alleging that "*if* [Horizon] had properly tested the drug," the different design "could feasibly be implemented"); Phansalkar Case Report at e104 (Ex. B) ("To date, there are no dosing studies of teprotumumab for TED."). Such an allegation cannot suffice. *See DiBartolo*, 914 F. Supp. 2d at 622 (allegations that Abbott was negligent in the design and testing of Humira were insufficient to plausibly allege feasible alternative design).

pretreatment hearing loss. *See id.* An allegation that one patient's hearing loss did not worsen after receiving a half-dose of Tepezza® does not suffice to allege that a half-dose design would be safer than the FDA-approved design. Further, plaintiffs allege that *all* IGF-1R inhibitors adversely impact hearing, regardless of dose. *See* FAC ¶ 106 (Ex. A); *MacSwan*, 602 F. Supp. 3d at 475 (dismissing design defect claims for failure to provide a feasible alternative design when complaint alleged Fosamax could be designed without nitrogen because it alleged that "all bisphosphonates—not just those containing nitrogen—cause atrial fibrillation"). As the Supreme Court stated in *Bartlett*, a design defect claim may not survive where "the drug is chemically incapable of being redesigned." 570 U.S. 472, 484 (2013).

Because plaintiffs fail to allege a reasonable alternative design, the design defect claims in *Pledger*, *Merriweather*, *Chryssos*, *Stern*, *Ford*, and *Meyers* should be dismissed.

### C. Plaintiffs *Egger*, *Merriweather*, *Pledger*, *Polanco*, and *Meilleur*'s Design Defect Claims Additionally Fail Under Relevant State Laws Because They Do Not Plausibly Allege That Tepezza®'s Risks Outweighed Its Benefits.

Plaintiffs *Egger*, *Merriweather*, *Pledger*, *Polanco*, and *Meilleur* additionally fail to adequately plead a design defect because the applicable state law requires that plaintiffs allege facts sufficient to support a risk-utility analysis. Plaintiffs allege only in a conclusory fashion that Tepezza®'s risks outweighed its utility, *e.g.*, FAC ¶ 239, but they allege no *facts* to support such an analysis. Tepezza® continues to be approved by FDA as safe and effective to treat TED to this day. Since its approval in January 2020, the "Highlights of Prescribing Information" section on the first page of the January 2020 label listed "hearing impairment" as one of the "[m]ost common adverse reactions."[18] The "Clinical Trials Experience" section of the label also always included

[18] *Drug Label for Tepezza®*, U.S Food & Drug Admin. (Jan. 2020), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/761143Orig1s000lbl.pdf (Ex. H).

information about reports of hearing impairment, including "deafness."[19] FDA's approval of Tepezza® amounts to a finding that Tepezza®'s benefits in its treatment of TED outweigh its risks (including of hearing impairment), particularly because the warning label is the "centerpiece of risk management." *Wyeth*, 555 U.S. at 608; *In re Celexa & Lexapro*, 779 F.3d at 41 ("To the extent that the underlying policy issue is one of who decides whether and how a drug can be marketed, the line so drawn lets the FDA be the exclusive judge of safety and efficacy based on information available at the commencement of marketing . . . .").

California (*Egger*), Maryland (*Pledger*), New Jersey (*Polanco*), Tennessee (*Meilleur*), and Illinois require factual allegations to support a risk-utility analysis, *i.e.*, that Tepezza®'s risks outweigh its utility.[20] Plaintiffs have not adequately plead under a risk-utility analysis that Tepezza®'s harm outweighs its utility. In conducting a risk-utility analysis, courts weigh up to seven factors across the relevant state laws:

> (1) the usefulness and desirability of the product-its utility to the user and to the public as a whole; (2) the safety aspects of the product-the likelihood that it will cause injury, and the probable seriousness of the injury; (3) the availability of a substitute product that would meet the need and not be as unsafe; (4) the manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility; (5) the user's ability to avoid danger by the exercise of care in the use of the product; (6) the user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product or of the existence of suitable warnings or instructions; and (7) the feasibility, on

[19] *Id.*

[20] **California:** *Nichols v. Covidien LP*, No. 20-cv-06836, 2021 WL 764134, at *5 (N.D. Cal. Feb. 26, 2021) (citing *Merrill v. Navegar, Inc.*, 28 P.3d 116, 125 (Cal. 2001)); **Maryland:** *Pease v. Am. Cyanamid Co.*, 795 F. Supp. 755, 759 (D. Md. 1992) (citations omitted); **New Jersey:** *Gremo v. Bayer Corp.*, 469 F. Supp. 3d 240, 255 (D.N.J. 2020) (citations omitted); **Tennessee:** *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 397 (6th Cir. 2013) (quoting *Brown v. Crown Equip. Corp.*, 181 S.W.3d 268, 282-83 (Tenn. 2005)); *see also* **Illinois:** *Tillman*, 2011 WL 3704762, at *3.

> the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.[21]

Plaintiffs simply allege in a conclusory fashion that Tepezza® "was defective in design or formulation in that its limited and unproven effectiveness and low efficacy did not outweigh the risks of serious and potentially irreversible hearing issues posed by the drug." FAC ¶ 239 (Ex. A). "Such conclusory allegations, without more, fail to state a design defect claim." *Tsavaris v. Pfizer*, No. 1:15-cv-21826, 2016 WL 375008, at *2 (S.D. Fla. Feb. 1, 2016) (dismissing design defect claims when allegation was merely that the product was "'unreasonably dangerous,' that its 'risks . . . exceeded any benefits or utility associated with the design or formulation,' and that the drug is 'much more dangerous than other available . . . drugs'"). Plaintiffs' only allegation to support a risk-utility analysis is an unsupported alternative design (which, as previously discussed, is not sufficient). *See supra* Argument § II.B. Because plaintiffs do "not plead any of these factors," they do not sufficiently allege that Tepezza®'s harm outweighs its utility under a risk-utility analysis. *Hindermyer*, 419 F. Supp. 3d at 825 n.3.

## CONCLUSION

Horizon requests that the Court dismiss the design defect claims asserted in all of the First Amended Complaints of eleven Initial Bellwether Discovery cases under either negligence or strict liability theories because they fail to specifically plead an identifiable design defect.

The Court should dismiss the design defect claims in the following Initial Bellwether Discovery cases for the additional reason of failing to allege facts to support a reasonable inference that a feasible alternative design existed, as required by the applicable state law: *Pledger*, 1:22-cv-

[21] *See, e.g.*, *Hindermyer*, 419 F. Supp. 3d at 825 n.3; *Conway v. Am. Med. Sys., Inc.*, No. CV GLR-18-1466, 2021 WL 6126293, at *7 (D. Md. Dec. 28, 2021); *Strayhorn*, 737 F.3d at 397; *see also Merrill v. Navegar, Inc.*, 28 P.3d 116, 125 (Cal. 2001) (considering some factors).

06562; *Chryssos*, 1:23-cv-03033; *Stern*, 1:23-cv-02659; *Ford*, 1:23-cv-02703; and *Meyers*, 1:23-cv-03585.

The Court should dismiss the design defect claims in the following Initial Bellwether Discovery cases for the additional reason that plaintiffs failed to adequately plead facts supporting a risk-utility analysis, as required under applicable state law: *Egger*, 1:23-cv-15306; *Merriweather*, 1:23-cv-02714; *Pledger*, 1:22-cv-06562; *Polanco*, 1:23-cv-02503; and *Meilleur*, 1:23-cv-15501.

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Respectfully Submitted,

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