UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

[redacted],	)	
	)	
Plaintiff,	)	Civil Action No. 1:22-cv-06375
	)	
v.	)	
	)	Judge Nancy L. Maldonado
HORIZON THERAPEUTICS USA, INC.	)	
	)	
Defendant.	)	
	)	

DEFENDANT HORIZON'S MEMORANDUM IN SUPPORT OF MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT

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Pursuant to Fed. R. Civ. P. 8(a) and Fed. R. Civ. P. 12(b)(6), Defendant Horizon Therapeutics USA, Inc. ("Horizon"), submits this Motion to Dismiss on grounds that Plaintiff's claims are preempted by federal law and because Plaintiff has failed to state plausible warnings and design defect claims against Horizon under Arizona law.

I. INTRODUCTION

This product liability action arises out of Plaintiff [redacted]'s alleged use of TEPEZZA®, a prescription biologic approved by the U.S. Food and Drug Administration ("FDA") in January 2020 as a safe and effective treatment for Thyroid Eye Disease.[1] Biologics are medications that come from living sources. They can be composed of sugars, proteins, nucleic acids, or complex combinations of these substances. In contrast to drugs that are chemically synthesized with known structures, biologics are complex mixtures that are not easily identified or characterized.[2] TEPEZZA® is a human monoclonal antibody that targets a receptor that has been shown to play a significant role in Thyroid Eye Disease.

Plaintiff alleges that she received TEPEZZA® infusions between June and November 2020 to treat her unspecified medical condition which she describes as Thyroid Eye Disease and/or Graves' Disease. First Amended Complaint ("FAC") ¶ 10. In her FAC, she claims that she developed permanent hearing loss and/or tinnitus at an unspecified time after receiving TEPEZZA®. *Id.* at ¶ 12. TEPEZZA®'s FDA-approved labeling disclosed hearing impairment, including deafness, among the most common adverse reactions, occurring in 10% of patients

[1] The FDA BLA Approval for TEPEZZA® is attached as Exhibit A and is available publicly at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/761143Orig1s000ltr.pdf (last accessed 2/6/23). Horizon requests this Court take judicial notice of the BLA Approval. Publicly available government agency determinations that appear on an agency website are subject to judicial notice. *See Vincent v. Medtronic Inc.*, 221 F.Supp. 3d 1005, 1009 (N.D. Ill. 2016) (internal citations omitted).

[2] *What Are "Biologics" Questions and Answers*, available at https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers (last accessed 2/6/23).

participating in clinical trials.[3] While framed in various causes of action, including strict liability and negligence for alleged warnings failures and design defect, the gravamen of Plaintiff's claims is that Horizon is liable for having failed to adequately warn healthcare professionals of the risk of hearing loss associated with the use of TEPEZZA® and that Horizon should have redesigned TEPEZZA® to prevent hearing loss. Plaintiff's FAC fails to state a claim upon which relief may be granted against Horizon.

First, Plaintiff's warning-based claims are preempted because she fails to allege facts that, if proven, would be sufficient to demonstrate that Horizon could have added desired warnings consistent with federal law. Claims that a defendant should have updated a prescription drug label unilaterally without prior approval by the FDA are preempted unless the defendant could have made the change pursuant to the "changes being effected" ("CBE") regulation. *See* 21 C.F.R. § 314.70(c)(6)(iii); *see also Wyeth v. Levine*, 555 U.S. 555, 568 (2009). That regulation requires there to be "newly acquired information," defined as information that "reveal[s] risks of a different type or greater severity or frequency" than previously known by the FDA. 21 C.F.R. § 601.12(f)(6). Simply put, her FAC does not allege any newly acquired information concerning "risks of a different type or greater severity or frequency" that would have permitted Horizon to change the TEPEZZA® label in accordance with the CBE regulation between the date of the FDA's approval of the TEPEZZA® label in January 2020 and Plaintiff's treatment with TEPEZZA® in June 2020. Indeed, all but one of Plaintiff's allegations concerning "newly acquired information" post-date Plaintiff's treatment with TEPEZZA® and, thus, cannot support

[3] FDA-Approved labeling for TEPEZZA® is publicly available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761143s000lbl.pdf. (last accessed 2/6/23). A copy is attached as Exhibit B. Horizon requests the Court take judicial notice of the publicly available warnings on FDA's website. *See Sellers v. Boehringer Ingelheim Pharm., Inc.*, 881 F.Supp. 2d 992, 999 (S.D. Ill. 2012) (taking judicial notice of warnings on a drug label).

her warning defect claims. In addition, the alleged "newly acquired information" that pre-dates Plaintiff's treatment, a single adverse event report dated May 13, 2020, does not reveal risks of a "different type or greater severity or frequency" than previously disclosed to the FDA and included on the TEPEZZA® label, nor is the alleged information based on "reasonable evidence" of a causal association between the biologic and some adverse effect. (FAC, ¶56(a)).

Second, Plaintiff's design defect claims are preempted under Supreme Court precedent because any change to TEPEZZA®'s design to conform with state tort law obligations as advocated by Plaintiff would conflict with federal law, which precludes any change in formulation absent prior FDA approval. For these reasons, Plaintiff's FAC should be dismissed in its entirety as preempted.

Third, Plaintiff's claims fail to state a claim under Arizona law, which applies to this case. The FAC does not allege facts sufficient to render her strict liability and negligent warnings and design claims plausible under the *Twombly-Iqbal* standard.[4] Nor is any claim for punitive damages allowed under Arizona law.

II. RELEVANT FACTUAL BACKGROUND

A. TEPEZZA® is an FDA-approved biologic infusion for treatment of Thyroid Eye Disease.

In January 2020, FDA approved TEPEZZA® as the first-ever drug for adults with Thyroid Eye Disease. FAC ¶ 41. Thyroid Eye Disease is a rare condition where the muscles and fatty

[4] This case is one of 11 currently pending in the Northern District of Illinois Court, include two pending before this Court, related to TEPEZZA®. *See Leeds v. Horizon Therapeutics, USA, Inc.* (Case No.: 22-cv-06837). On December 21, 2022, Plaintiffs filed a Motion for Reassignment of Cases to a Single Judge pursuant to Local Rule 40.4 and Internal Operating Procedure 13(e) in *Weibel v. Horizon Therapeutics, USA, Inc.* (Case No.: 22-cv-4518) (Dkt. No. 23). That motion is now fully briefed with Horizon's Response filed on January 13, 2023 (Dkt. No. 34) and Plaintiffs' Reply filed on January 20, 2023 (Dkt. No. 35). The motion is set for hearing before Judge Leinenweber on February 14, 2023. Horizon denies that these cases are "related" for purposes of Rule 40.4 because they involve different underlying medical conditions, infusion dates, infusion dosage and administration, learned intermediaries, treatment facilities, adverse events, and the operative state law product liability standards are different in each jurisdiction.

tissues behind the eye become inflamed, causing the eyes to be pushed forward and bulge outwards (proptosis). *Id.* at ¶ 30. Although this condition impacts relatively few individuals, Thyroid Eye Disease can be incapacitating. *Id.* at ¶ 30. Individuals suffering from moderate-to-severe Thyroid Eye Disease may experience impaired vision and eventually require surgery, which involves removing bone between the eye socket and the sinuses. *Id.* at ¶ 33.

B. TEPEZZA®'s FDA-approved label warned of the risk of hearing impairment, including deafness.

The FDA ultimately approved TEPEZZA® based on the results of two studies. *Id.* at ¶¶ 41, 45. And Plaintiff admits, the label discloses hearing loss (specifically, deafness) as one of the most common adverse reactions observed in patients treated with TEPEZZA®. *See id.* ¶ 47.

The label reads:

> **----------ADVERSE REACTIONS----------**
>
> Most common adverse reactions (incidence greater than 5%) are muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, **hearing impairment**, dry skin, dysgeusia and headache (6.1)[5]

Additionally, the label provides data concerning adverse reactions, including hearing impairment at an incidence of around 10%, documented in the clinical trials:

Table 1. Adverse Reactions Occurring in 5% or More of Patients Treated with TEPEZZA® and Greater Incidence than Placebo

Adverse Reactions	TEPEZZA® N=84 N (%)	Placebo N=86 N (%)
Muscle spasms	21 (25%)	6 (7%)
Nausea	14 (17%)	8 (9%)
Alopecia	11 (13%)	7 (8%)
Diarrhea	10 (12%)	7 (8%)
Fatigue [a]	10 (12%)	6 (7%)
Hyperglycemia [b]	8 (10%)	1 (1%)
Hearing Impairment [c]	**8 (10%)**	**0**

[5] *See* Exhibit B, FDA-Approved labeling for TEPEZZA®, at p. 8. (emphasis added).

Dysgeusia	7 (8%)	0
Headache	7 (8%)	6 (7%)
Dry skin	7 (8%)	0

a Fatigue includes asthenia
b Hyperglycemia includes blood glucose increase
c **Hearing impairment (includes deafness, eustachian tube dysfunction, hyperacusis, hypoacusis and autophony)**[6]

Moreover, the FDA Dermatologic and Ophthalmic Drugs Advisory Committee (the "FDA Committee") discussed the risk of hearing loss associated with TEPEZZA® and monitoring before the FDA approved TEPEZZA® or its label.[7] FDA Committee members[8] considered whether to recommend audiologic testing on TEPEZZA®'s label but decided against it. In discussions, Dr. Chambers, FDA Deputy Director of Division of Transplant and Ophthalmology, noted:

> the usual way that way we [FDA] would do that would be to identify it either in the adverse reaction section of the label or in the precaution warning so that people are aware it's an event that's been associated, at least temporally, with the product, but not necessarily advocate testing or monitoring. But again, you've identified that it's a potential issue, and let the individual patient and physician decide what the appropriate plan is for that patient.

As Harvard Ophthalmology professor Dr. Chodosh summarized, "everybody thinks that hearing loss is potentially important. There were some differences of opinion in how that should be addressed" and concluded that "mandatory testing" was the "minority opinion."[9] In reaching this conclusion, the Committee determined that it did not have enough information to make audiologic

[6] *See* Exhibit B, FDA-Approved labeling for TEPEZZA®, at p. 12 (emphasis added).
[7] This court may take judicial notice of the transcript of the Meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee, at pp. 1-7; 79-81, 122-23, 248-49, 264-272, 295, 298-300 (December 13, 2019) ("FDA Transcript"), available at https://www.fda.gov/media/135336/download (last accessed 2/6/23), relevant portions attached as Exhibit C) in connection with analyzing a motion to dismiss. Fed. R. Evid. 201. *U.S. ex rel Dan Abrams Co., LLC v. Medtronic, Inc.*, No. LA CV15-01212, 2018 WL 4023092, at fn 1 (C.D. Cal. Sept. 11, 2017) (taking judicial notice of FDA Panel Transcript as a record and report of an administrative body).
[8] The FDA Committee was chaired by Dr. James Chodosh, a Harvard Ophthalmology professor, and committee members included other Ophthalmology professors, practicing ophthalmologists, Endocrinology professors, biostatisticians, and FDA members, including the FDA Deputy Director of Division of Transplant and Ophthalmology, Dr. Wiley Chambers.
[9] *Id.* at pp. 264-272; *see also* Exhibit B, FDA-Approved labeling for TEPEZZA®.

testing recommendations for TEPEZZA®. Members discussed the lack of information on the mechanism of hearing loss from TEPEZZA®, risk factors for hearing loss with TEPEZZA® use (*e.g.* pre-existing hearing loss or tinnitus), the association of hearing loss with the conditions that TEPEZZA® treats, and lack of data on how to identify and address audiologic symptoms (*e.g.* a time line for measuring hearing loss and how to address hearing loss symptoms).[10]

C. Federal Regulation of Biologic License Applications.

To obtain FDA approval for a new biologics product, a manufacturer must submit a biologics license application ("BLA"). 21 U.S.C. § 355(b); 42 U.S.C. § 262(a). The BLA must include data from nonclinical laboratory and clinical studies demonstrating that the product meets prescribed requirements for safety, purity, and potency, a full description of manufacturing methods, specifications, data establishing product stability, samples of the product, product labeling, containers, and summaries of product test results. 21 C.F.R. §§ 601.2(a); 600.3(kk).

Following approval, the FDA continues to regulate all changes to biologic products, including product labeling. As with FDA-approved drugs, manufacturers must notify the FDA about "each change in the product … labeling established in the approved license application(s)." *Id*. § 601.12(a)(1). Although the FDA can direct a manufacturer to change a BLA's label after it has entered the market, regulations strictly limit a manufacturer's ability to unilaterally change FDA-approved labels. Generally, "a manufacturer may only change a drug label after the FDA approves a supplemental application." *Wyeth*, 555 U.S. at 568 (citing 21 C.F.R. § 314.70(c)(6)(iii); *see also* 21 U.S.C. § 355(o)(4). However, the regulation does permit a manufacturer to make labeling changes outside of a supplemental application under the CBE provision. Specifically, the CBE "permits a manufacturer to make certain changes to its label before receiving the agency's

[10] *See* Exhibit C, FDA Transcript at 79-81, 122-23, 248-49, 264-272, 295, 298-300.

approval" based on "newly acquired information." *Wyeth*, 555 U.S. at 568.

D. Plaintiff's treatment with TEPEZZA® and Claims in this Lawsuit.

In this case, Plaintiff alleges that she was prescribed and received TEPEZZA® infusions from June through November 2020 and subsequently suffered from permanent hearing loss and/or tinnitus. FAC at ¶¶ 10-11. The FAC fails to specify when Plaintiff experienced hearing loss and/or tinnitus. Despite the warnings in TEPEZZA®'s label regarding hearing impairment and deafness, Plaintiff alleges that Horizon failed to adequately warn about the risk of hearing loss in patients taking TEPEZZA® and/or the risk of permanent hearing loss. *Id.* at ¶ 48. Plaintiff does not allege that Horizon failed to provide adequate warnings to the FDA or in its labeling about the incidence of hearing loss in patients receiving TEPEZZA®; instead, Plaintiff's claims are premised on the alleged permanency of her hearing impairment and/or a need for more specific guidance to physicians to conduct audiologic screenings during treatment.[11] *See e.g.*, FAC ¶¶ 6, 48, 61, 77, 78, 84. Plaintiff asserts causes of action for Strict Liability – Failure to Warn, Strict Liability – Design Defect, Negligent Failure to Warn, Negligent Design, and Punitive Damages.

In support of her claims, Plaintiff cites to Adverse Events reported to the FDA in 2020, only one of which was received before Plaintiff received TEPEZZA®, purportedly involving incidents of hypoacusis (hearing loss), deafness, and tinnitus in patients after using TEPEZZA®. *See id.* at ¶¶ 56(a)-(m), 57. None of these reports allege information that the FDA did not have at the time of approval, and FDA regulations are explicit that adverse event reports do not represent "that the drug caused or contributed to an adverse effect." 21 C.F.R. § 314.80(l). And the remaining case studies and publications Plaintiff alleges are not "reasonable evidence" of a risk not previously disclosed to the FDA. Thus, although Plaintiff claims that Horizon "should have

[11] *See* Exhibit C, FDA Transcript at pp. 79-81, 122-23, 248-49, 264-272, 295, 298-300.

changed the TEPEZZA® label to include warnings and instructions associated with the drug" using the CBE process, she fails to identify or allege any "newly acquired information" that Horizon could have used to unilaterally update the label prior to her treatment. Finally, FDA granted approval to TEPEZZA®'s design – and federal law prohibits a manufacturer from redesigning a prescription drug or biologic without FDA approval.

III. ARGUMENT

Dismissal is warranted under Rule 12(b)(6) when a plaintiff fails to allege facts sufficient "to raise a right to relief above the speculative level" or "fails to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545, 547 (2007). This "plausibility" standard applies to all claims brought in federal court. *See Ashcroft v. Iqbal*, 556 U.S. 662, 684 (2009). Although a court generally must accept well-pleaded facts as true on a motion to dismiss for failure to state a claim, this principle does *not* apply to legal conclusions, conclusory allegations, or unwarranted factual inferences. *See Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 555. "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Iqbal*, 556 U.S. at 679. Assuming their veracity, the court must determine whether plaintiff's well-pleaded factual allegations "plausibly give rise to an entitlement to relief." *Id.* Put another way, the complaint must present sufficient factual material to allege a claim that is "plausible on its face." *Twombly*, 550 U.S. at 570. Such facial plausibility exists "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

A. Plaintiff's Claims Fail Because They Are Preempted by Federal Law.

Plaintiff's claims are preempted by the FDA's approval of TEPEZZA® under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 601, *et seq.* The Supremacy Clause of the U.S. Constitution directs that the laws of the United States "shall be the supreme Law of the Land ... any Thing in

the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. This case concerns impossibility preemption, which is a type of conflict preemption that occurs when it is "impossible for a private party to comply with both state and federal requirements." *Mut. Pharma. Co. v. Bartlett*, 570 U.S. 472, 480 (2013).

In the context of pharmaceutical drugs litigation, the Supreme Court held in *Wyeth* that a state law claim that a drug manufacturer failed to warn consumers of a risk associated with using its drug is preempted by the FDCA and related labeling regulations, if there is "clear evidence" that the FDA would not have approved a change to the drug's label. 555 U.S. at 571. In *Merck Sharp & Dohme Corp. v. Albrecht*, the Supreme Court clarified that courts should treat the question of whether clear evidence is met "not as a matter of fact for a jury, but as a matter of law for the judge to decide." 139 S.Ct. 1668, 1679 (2019); *see also In re Celexa & Lexapro Mktg. & Sales Prac. Litig. v. Forest Lab'y*, 779 F.3d 34, 42-43 (1st Cir. 2015). The *Albrecht* court did "not further define *Wyeth's* use of 'clear evidence' in terms of evidentiary standards, such as 'preponderance of the evidence' or 'clear and convincing evidence.'" *Id.* Instead, a judge must simply answer the question of "whether the relevant federal and state laws 'irreconcilably conflic[t].'" *Id.*

To that end, the Supreme Court explained that because the FDA's CBE regulations permit drug manufacturers to add or strengthen a label without prior approval, 21 C.F.R. § 314.70(c)(6)(iii)(A), "a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both." *Id.* at 1679. Importantly, however, the Supreme Court recognized that even under this general principle, a plaintiff must demonstrate that a manufacturer could have availed itself of the CBE regulations, noting that "manufacturers cannot propose a change that is not based on reasonable evidence." *Id.* There must be sufficient evidence of a causal association between the

drug and the information sought to be added. *Id.*; *See also In re In re Incretin-Based Therapies Prod. Liab. Litig.*, 524 F.Supp. 3d 1007, 1017 (S.D. Cal. 2021) (declining to limit preemption to cases where the manufacturer has proposed a label change).

With respect to Plaintiff's warnings claims, the FAC fails to identify any newly acquired information, much less newly acquired information based on reasonable evidence, for Horizon to have unilaterally changed the TEPEZZA® label using the CBE procedure before Plaintiff's treatment in June 2020, and Plaintiff's warnings-based claims are therefore preempted. And because Horizon could not have altered the contents of TEPEZZA® without the FDA's prior approval, Plaintiff's design claims are preempted and must also fail.

1. The First Amended Complaint does not allege "newly acquired information" that could have allowed a change to TEPEZZA®'s label and therefore Plaintiff's warnings claims are preempted.

In the context of a Motion to Dismiss, the plaintiff must allege "newly acquired information" that would trigger the applicability of the CBE regulation and the potential resulting labeling change. *In re Celexa*, 779 F.3d at 41; *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708 (2d Cir. 2019). However, here, none of the "reports" and studies Plaintiff alleges reveal risks of a different type or greater severity or frequency than previously included in Horizon's submissions to the FDA and discussed by the FDA Committee prior to approval.

Whether a state-law failure-to-warn claim against a manufacturer of a branded prescription medication is preempted is a question of law that may be resolved by the Court at the pleadings stage. *McGrath v. Bayer HealthCare Pharms., Inc.*, 393 F.Supp. 3d 161, 167 (E.D.N.Y. 2019). To resolve that question, the Court must decide whether "federal law (including the appropriate FDA actions) prohibited [Horizon] from adding any and all warnings to the drug label [for TEPEZZA®] that would satisfy state law." *Albrecht*, 139 S.Ct. at 1678; *accord Wyeth*, 555 U.S. at 571; *Bartlett*, 570 U.S. at 488-89; *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613-15 (2011).

Drug and biologics manufacturers are limited in their ability to unilaterally change labels on their products. To make a unilateral change to a drug's label without FDA approval, a manufacturer must comply with the CBE regulation. *Gibbons*, 919 F.3d at 707 (citing 21 C.F.R. § 314.70(c)(6)(iii)); *see also Albrecht*, 139 S.Ct. at 1673. The CBE process is only available to make label changes based on "newly acquired information." *In re Incretin-Based Therapies*, 524 F.Supp. 3d at 1018; *In re Celexa*, 779 F.3d at 41-42 (citing 21 C.F.R. 314.70(c)(6)(iii)). "Newly acquired information" means:

> [D]ata, analyses, or other information **not previously submitted to the [FDA]** which may include (but are not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events or analyses **reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA**.

21 C.F.R. § 601.12(f)(6) (emphasis added).

The Second Circuit has articulated the requirements to adequately plead and then prove a state law failure-to-warn claim based on post-drug-release information:

> [T]o state a claim for failure-to-warn that is not preempted by the FDCA, a plaintiff must plead a labeling deficiency that Defendant could have corrected using the CBE regulation. If the plaintiff meets that standard, the burden shifts to the party asserting a preemption defense to demonstrate that there is clear evidence that the FDA would not have approved a change to the prescription drug's label.

Gibbons, 919 F.3d at 708 (internal citations omitted); *McGrath*, 393 F.Supp. 3d at 167 (E.D.N.Y. 2019); *see also Mahnke v. Bayer Corp.*, No. 2:19-cv-07271, 2020 WL 2048622 (C.D. Cal. March 10, 2020).

In *Gibbons*, the plaintiffs alleged that manufacturers of Eliquis (a blood-thinning medication used to reduce the risk of stroke in patients with atrial fibrillation) provided insufficient warnings in the labeling regarding the risk of bleeding. 919 F.3d at 702. For the preemption analysis, the district court examined the plaintiffs' allegations regarding "newly acquired

information" to determine if the information was "such that the defendants could unilaterally change the label pursuant to the CBE regulation without FDA approval." *Utts v. Bristol-Myers Squibb Co.*, 251 F.Supp. 3d 644, 661 (S.D.N.Y. 2017). The district court examined adverse event data and found no newly acquired information because it "d[id] not suggest—nor d[id]the plaintiffs allege—that the real-world signal data for Eliquis shows a greater severity or frequency of bleeding events or deaths than previously disclosed in Eliquis' submissions to the FDA." *Id.* at 665.

Ultimately, the district court dismissed the complaint concluding that the plaintiffs had failed to "demonstrate that any newly acquired information exists to support a label change pursuant to CBE regulations" and that the plaintiffs were not entitled to discovery on preempted claims. *Id*. at 673. The Second Circuit affirmed and held that plaintiffs' allegations of "reports" and "studies" related to serious hemorrhaging and "about serious bleeding events associated with Eliquis" did "not constitute newly acquired information, as the term is defined in 21 C.F.R. §314.3(b)" as they must have "reveal[ed] risks of a different type or greater severity or frequency than previously included in submissions to the FDA." *Gibbons*, 919 F.3d at 708. The Second Circuit concluded that the complaints were properly dismissed because the operative complaint provided "no basis upon which the court could conclude that the bleeding events covered by the alleged "reports" and "studies" presented a different type of risk than those the company had discussed with the FDA or were more severe or more frequent than bleeding events that the government already knew about. *Id.*

Here, Plaintiff's FAC is devoid of any plausible allegations that newly acquired information existed that would have permitted Horizon to unilaterally amend the TEPEZZA® label that was in effect when Plaintiff received TEPEZZA® in June 2020. The FDA Committee that evaluated TEPEZZA® was fully aware of both the frequency and severity of the potential

hearing impairment, including deafness. In fact, Dr. Weng, Baylor Ophthalmology professor, noted that "hearing-related adverse effects … were noted in approximately 10 percent of the study patients," she was then also advised that in one of the earlier studies, the rate of hearing impairment was 13 percent. [12] Dr. Weng also reminded the FDA Committee regarding concern about potential permanency of hearing loss, noting that "there was a proportion of patients that did not recover, at least during the observation period thus far, who are still dealing with impacts …. So there's a potential for irreversible change in one sense."[13] Nevertheless, that same FDA Committee recommended approval of TEPEZZA® and its label, and considered and expressly rejected a labeling recommendation that audiologic testing should be conducted on patients receiving TEPEZZA®.[14] Given the FDA's analysis of the data and guidance related to labeling, there is no labeling deficiency that could have been corrected using the CBE regulation.

a. Adverse Event Reports to the FDA are not "newly acquired information."

Plaintiff's FAC attempts to salvage her warnings claims by pointing to submissions to FDA's Adverse Event Reporting System ("FAERS") in 2020 for incidents involving hearing loss, tinnitus, and deafness following use of TEPEZZA®, which Plaintiff claims constitute "newly acquired information" under the CBE regulation. FAC ¶¶ 56(a)-(m), 57. Notably, only one of the adverse events was reported prior to Plaintiff's treatment and all of these adverse events are of the same type disclosed on the TEPEZZA® label (*i.e.*, hearing loss, deafness) and considered by the FDA Committee, and there is no allegation that the FAERS data shows a more severe risk of these outcomes. FDA regulations require pharmaceutical companies to submit reports for "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related."

[12] *See* Exhibit C, FDA Transcript at pp. 11; 122-123; and 265.
[13] *Id.*
[14] *See supra, p. 6* and Exhibit C, FDA Transcript at 79-81, 122-23, 248-49, 264-272, 295, 298-300.

21 C.F.R. § 314.80(a). Importantly, the regulation contains a disclaimer that "[a] report or information submitted by an applicant under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse effect." 21 C.F.R. § 314.80(l). FAERS data also cannot demonstrate a greater frequency of adverse events because the database may contain duplicate reports where the same report was submitted by a consumer and by the sponsor. "Therefore, FAERS data cannot be used to calculate the incidence of an adverse event … in the U.S. population."[15] *N.J. Carpenters Pension & Annuity Funds v. Biogen Idec. Inc.*, 537 F.3d 35, 53 (1st Cir. 2008) ("The receipt of an adverse report does not in and of itself show a causal relationship between [a drug] and the illness mentioned in a report.")

Against this regulatory backdrop, many courts have held that adverse event reports are not "newly acquired information." To qualify as "newly acquired information," the information must demonstrate "reasonable evidence of a causal association with a drug…." 21 C.F.R. § 201.57. But "[t]he fact that a user of a drug has suffered an adverse event, standing alone, does not mean that the drug caused the event." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011); *see also Gayle v. Pfizer Inc.*, 452 F.Supp. 3d 78, 88 (S.D.N.Y. 2020) (finding that "6,000 adverse event reports relating to diabetes sent from Pfizer to the FDA" do not constitute "newly acquired information" because they do not indicate casual association); *Ignacuinos v. Boehringer Ingelheim Pharm., Inc.*, 490 F.Supp. 3d 533, 543 (D. Conn. 2020) (finding that adverse event reports are not "newly acquired information" unless they are "grounded in scientific research" such that they "provide reasonable evidence of a causal association"). In this case, the FAERS data alleged in

[15] *Questions and Answers on FDA's Adverse Event Reporting System (FAERS)* https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers (last accessed 2/6/23).

the FAC provides no evidence of causal association and does not reveal risks of a different type or greater severity or frequency than previously included in submissions to the FDA. Therefore, Horizon could not have altered the TEPEZZA® label under the CBE regulation, and Plaintiff's claims are preempted as a matter of law.

b. The "newly acquired information" Plaintiff alleges is not based on "reasonable evidence," which is required to add warnings through the CBE procedure.

Plaintiff's claims fail for the additional reason that she has not and cannot identify any evidence-based studies that "reveal risks of a different type or greater severity or frequency than previously included in [labeling] submissions to FDA." 21 C.F.R. § 314.3(b). FDA's guidance on this issue underlies the statutory language. In its guidance, FDA declared that it "undertakes a detailed review of the proposed labeling, allowing only information for which there is scientific basis to be included in the FDA-approved labeling." Supplemental Application Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2851 (Jan. 16, 2008). Further, FDA "would not allow a change to labeling to add a warning in the absence of reasonable evidence of an association between the product and an adverse event." *Id.* (internal citations omitted). By expressly requiring that a label change under the CBE regulation only reflect newly acquired information and "there is sufficient evidence of a causal association" with the biologic, the FDA ensures "that only scientifically justified information is provided in the labeling of an approved product." *Id.* Further, if a company were to propose an unwarranted CBE, the submission could be deemed "false, untrue, and inaccurate" in violation of 18 U.S.C. § 1001.

The alleged "newly acquired information" does not meet these criteria. Adverse event reports are, by definition, not demonstrative of causation. 21 C.F.R. § 314.80(l). Other than the peer-reviewed articles reporting on the FDA-mandated clinical trials, the "Reports in Published Medical Literature" Plaintiff cites are not peer-reviewed studies using statistically significant data;

they are case studies, most of which report on only a handful of individuals. *See e.g.*, FAC ¶ 66 (two cases); ¶ 68 (four cases); ¶¶ 65, 69, 72, 73 (one case). None of the "newly acquired information" Plaintiff alleges explains the mechanism of hearing loss from TEPEZZA® or how it might be distinguished from hearing loss from the conditions that TEPEZZA® treats or from simply aging.

In sum, Plaintiff has not alleged any facts that would permit (much less require) a different warning at the time of her treatment with TEPEZZA® in June 2020. Moreover, based on the facts alleged, Horizon could not have unilaterally altered the FDA-approved label of TEPEZZA® so as to provide her or her treating physician a different warning. Thus, Plaintiff's claims premised on failure to warn are preempted and fail to state an actionable claim against Horizon.

2. Plaintiff's design defect claims require a change to TEPEZZA®'s design that federal law forbids.

While Plaintiff seeks to enforce a purported state law duty to change the design of TEPEZZA®, federal law prohibits a drug manufacturer from unilaterally changing a drug's formulation without prior FDA approval. As the Supreme Court confirmed in *Bartlett*, once the FDA approves a drug, "the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" 570 U.S. at 472 (citing 21 C.F.R. § 314.70(b)(2)(i)). The Sixth Circuit applied the Supreme Court's guidance on preemption in prescription drug cases to find that design defect claims involving the branded prescription drug Ortho Evra were preempted. *See Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 298-300 (6th Cir. 2015) (holding that plaintiff's post-FDA approval design defect "is clearly preempted by federal law" because "defendants could not have altered the dosage of estrogen" in Ortho Evra without FDA's prior approval, and holding further that plaintiff's pre-FDA approval

design defect claim is preempted because it "is too attenuated" and because defendants "could not have complied with whatever pre-approval duty might exist without ultimately seeking the FDA's prior approval to marketing" the drug). The *Utts* court summarized the speculation inherent in a design defect claim against a drug manufacturer as follows:

> To imagine that [a duty to submit a differently designed drug for FDA approval] exists, the Court would have to speculate that the defendants designed Eliquis differently, the FDA would have approved the alternate design; that Mr. Utts would have been prescribed this alternately designed Eliquis; and that this alternate design would not have caused Mr. Utts to suffer severe internal bleeding.

Utts v. Bristol-Myers Squibb Co., 226 F.Supp. 3d 166, 186 (S.D.N.Y. 2016). Multiple other courts, including this one, have reached similar conclusions in cases involving branded prescription drugs.[16]

The *Bartlett* Court confirmed that "[i]n the drug context, either increasing the 'usefulness' of a product or reducing its 'risk of danger' would require redesigning the drug: A drug's usefulness and its risk of danger are both direct results of its chemical design and, most saliently, its active ingredients." 570 U.S. at 483. And biologics are far more complex than lab-synthesized drugs. TEPEZZA® is a human monoclonal antibody that is not chemically synthesized. Thus, scientifically speaking, Horizon did not design TEPEZZA® the way other manufacturers design a standard prescription drug. To change TEPEZZA®'s design by changing it in any way would be to turn it into an entirely different substance—one which would not have TEPEZZA®'s properties and would likely not even be an effective treatment for thyroid eye disease for which TEPEZZA® has been approved by the FDA. Without pre-approval from the FDA, Horizon is prohibited from modifying any of the prescribed requirements for safety, purity, and potency, manufacturing and

[16] *See e.g.*, *Shah v. Forest Labs Inc.*, No. 10 C 8163, 2015 WL 3396813, at *5 (N.D. Ill. May 26, 2015) (claim that "Lexapro is inherently dangerous based on its design … would be preempted by federal law"); *In re Testosterone*, No. 14 C 1748, 2017 WL 1836435 (N.D. Ill. May 8, 2017) (applying *Yates* to enter summary judgment on design defect claims).

methods. *See* 21 C.F.R. §§ 601.2(a); 600.3(kk). Because Plaintiff alleges that TEPEZZA® should have been formulated or designed differently to reduce its risk of danger related to hearing impairment, she necessarily contends that state law required unilateral action that federal law forbids. Horizon cannot change the design of TEPEZZA® without the FDA's approval because "the altered chemical would be a new drug that would require its own NDA to be marketed in interstate commerce." *Bartlett*, 570 U.S. at 484 (quoting 21 C.F.R. § 310.3(h) (giving examples of when FDA considers a drug to be new, including cases involving "newness of drug use of any substance which composes such drug, in whole or in part")).

Because the FDA approved TEPEZZA®'s current design, and Horizon could not have changed its design or formulation without first seeking and receiving FDA approval, the Court should dismiss Plaintiff's design defect claims with prejudice.

B. Plaintiff's Claims Must be Dismissed for Failure to State a Claim under Arizona law.

In addition to preemption, Plaintiff's claims must be dismissed because they are not viable under Arizona law, which applies to all claims in this case. Plaintiff has failed to state a plausible failure to warn claim because the FDA-approved labeling adequately warned of the risk of hearing impairment, and even deafness, and Horizon has no duty to warn Plaintiff directly. Plaintiff has failed to plead allegations sufficient for a claim under Arizona's learned intermediary doctrine. Moreover, Horizon has satisfied its duties under the learned intermediary doctrine because the TEPEZZA® label disclosed hearing impairment, including deafness, among the most common adverse reactions. Plaintiff's design defect claims must be dismissed because she fails to allege *how* the biologic is unsafe and any alleged "defect" in design was adequately warned against. Finally, punitive damages are not a "claim" under Arizona law, nor are punitive damages even allowed in this case, where the biologic is FDA-approved.

1. Arizona law applies to plaintiff's claims.

The FAC does not allege which state's law applies, and Plaintiff's products liability claims are generically pled without reference to any statute or supporting law. Federal courts sitting in diversity apply the choice of law rules of the forum state. *See Hinc v. Lime-O-Sol Co.*, 382 F.3d 716, 719 (7th Cir. 2004). Thus, the "conflict of laws" rules of Illinois apply to this case. The Illinois Supreme Court uses the "most significant relationship" test to choose the applicable law in tort cases. *Fredrick v. Simmons Airlines, Inc.*, 144 F.3d 500, 503-04 (7th Cir. 1998). This means "***the law of the place of injury controls*** unless another state has a more significant relationship with the occurrence and with the parties with respect to the particular issue." *Townsend v. Sears, Roebuck & Co.*, 879 N.E.2d 893, 903 (Ill. 2007)(emphasis added).

Here, Plaintiff alleges that she was a resident and citizen of Arizona "***at all times relevant"*** to this action. FAC ¶ 9 (emphasis added). Based on the allegations in the FAC, the Court may presume that Plaintiff received TEPEZZA® in Arizona as prescribed by her Arizona treating physician at a facility in Arizona where the alleged injury occurred. Therefore, Arizona has the most significant relationship to the causes of action and the parties. *See Paulsen v. Abbott Lab'y*, No. 15-cv-4144, 2018 WL 1508532, at *12 (N.D. Ill. Mar. 27, 2018) (upon a motion to dismiss, the Court found that Georgia law applied to drug defect claim when Plaintiff resided and the treatment and injury occurred in Georgia); *Gray v. Abbott Lab'y, Inc.*, No. 10 cv 6377, 2011 WL 3022274, at *3 (N.D. Ill. July 22, 2011) (finding at motion to dismiss stage that Georgia law applied because "Georgia is where Gray presumably purchased any Similac products and where the alleged injury to her son occurred"). Arizona law applies to Plaintiff's claims.

2. Plaintiff's failure to warn claims fail as a matter of law.

a. *Horizon adequately warned of the risk of hearing loss and deafness associated with TEPEZZA®.*

Under Arizona law, a failure to warn claim is also known as an "informational defect claim." "A prima facie case of strict liability for informational defect requires a plaintiff to show (1) that the defendant had a duty to warn, (2) that the missing warning made the product defective and unreasonably dangerous, (3) that the warnings were absent when the product left defendant's control, and (4) that the failure to warn caused plaintiff's injury." *Baca v. Johnson & Johnson*, No. CV-20-01036-PHX-DJH, 2020 WL 6450294, at *3 (D. Ariz. Nov. 2, 2020) (citing references omitted). In Arizona, "[m]anufacturers generally have a duty to warn consumers of foreseeable risks of harm from using their products" for both strict liability and negligence claims. *Conklin v. Medtronic, Inc.*, 431 P.3d 571, 577 (Ariz. 2018) (citing *Watts v. Medicis Pharm. Corp.*, 365 P.3d 944, 949 (Ariz. 2016); Restatement (Third) of Torts: Prods. Liab. § 2 (Am. Law Inst. 1998)).

Plaintiff has not pled a plausible failure-to-warn claim because the FDA-approved TEPEZZA® label warned of the risk of hearing impairment — the exact adverse reaction that is the subject of her FAC. Plaintiff claims that Horizon "fail[ed] to adequately warn and advise of adverse reactions involving hearing, tinnitus, and other audiologic symptoms" and "failed to properly warn prescribing physicians … of the risk of serious and potentially irreversible hearing loss and tinnitus." *E.g.*, FAC ¶¶ 168(f)-(g). However, as admitted in Plaintiff's FAC, TEPEZZA®'s FDA-approved labeling disclosed hearing impairment among the most common adverse reactions, occurring in 10% of patients participating in clinical trials.[17] Plaintiff has not plausibly alleged that Horizon failed to provide an adequate warning or instruction about the risk of hearing loss associated with TEPEZZA®. *See Jones v. Medtronic Inc.*, 411 F.Supp. 3d 521,

[17] *See* Exhibit B, FDA-Approved labeling for TEPEZZA®, at pp. 8, 12; FAC at ¶ 47.

534 (D. Ariz. 2019), *aff'd sub nom. Jones v. Medtronic*, 830 F. App'x 925 (9th Cir. 2020)(dismissing Plaintiff's failure to warn claim, finding that "the allegedly missing warnings are clearly present in the [product] label."). Her failure to warn claims must be dismissed.

b. *Horizon has no duty to warn Plaintiff directly under Arizona law, and Plaintiff has failed to state a claim under the Learned Intermediary Doctrine.*

Plaintiff's informational defect claim also fails to the extent it is premised on a failure to warn Plaintiff directly about a risk of hearing loss. *See e.g.*, FAC at ¶¶ 75-78, 134, Additionally, Plaintiff has failed to state a claim based on failure to warn Plaintiff's treating healthcare providers under the learned intermediary doctrine. Arizona has adopted the learned intermediary doctrine as set forth in the Restatement (Third) of Torts, which applies to prescription drug and medical device manufacturers. *See Conklin*, 431 P.3d at 577 (citing *Watts*, 365 P.3d at 949). "Under the learned intermediary doctrine, a medical device manufacturer satisfies its duty to warn patients of the foreseeable risks involved with its products if it provides a complete, accurate, and appropriate warning to the patient's health-care provider." *Baca*, 2020 WL 6450294, at *3 (citing *Watts*, 365 P.3d at 949); *Conklin*, 431 P.3d at 577. "[B]ecause of the learned intermediary doctrine, a defendant's duty to warn ends once it provides an adequate warning to the healthcare provider." *Baca*, 2020 WL 6450294, at *3 (citing *Watts*, 365 P.3d at 947).

In *Baca*, the Arizona district court dismissed the plaintiff's informational defect claims because the complaint failed to name the treating physicians and failed to explain how the physicians would have acted differently with a different warning:

> [B]ecause of the learned intermediary doctrine, a defendant's duty to warn ends once it provides an adequate warning to the healthcare provider. Therefore, **the focus of this failure to warn claim is on what Defendants told the health-care provider and whether inadequacies in those warnings caused Plaintiff's injuries. On this point, the Complaint is silent. It does not name the treating physicians who received the allegedly inadequate warning, nor does it state that these physicians would have**

> **acted differently had they received a different warning.** Therefore, the Court finds that Complaint fails to allege facts raising a plausible failure to warn claim.

2020 WL 6450294, at *3 (emphasis added). Though the plaintiff argued that the complaint provided a list of warnings that should have been provided to plaintiff and her health care providers, the court rejected that argument, as it "misse[d] the point." *Id.* Instead, "[t]he Complaint needs to show how the alleged failure to warn caused the injury, and simply alleging warnings that Defendants should have included does not satisfy this element." *Id.*

As in *Baca*, Plaintiff here fails to identify how any alleged deficiency in product warnings caused her injury. She fails to name her treating physicians in the FAC. She also fails to state how her treating physicians would have acted differently if they had received different warnings. Without these elements, Plaintiff has failed to sufficient plead breach of duty or causation under Arizona's learned intermediary doctrine, requiring dismissal of Plaintiff's failure to warn claim.

As another basis for dismissal, the warnings were present on TEPEZZA®'s FDA-approved labeling, such that her treating physician was adequately warned of the risk of hearing loss associated with the biologic. *See Baca*, 2020 WL 6450294, at *3; *Watts v. Medicis Pharm. Corp.*, 365 P.3d 944, 949 (Ariz. 2016); *Conklin*, 431 P.3d at 577. The label lists hearing impairment, including deafness, among the most common adverse reactions, occurring in 10% of patients participating in clinical trials.[18] Because Horizon satisfied its duty under Arizona's learned intermediary doctrine, Plaintiff's failure to warn claim must be dismissed as a matter of law.

c. *Plaintiff's treatment pre-dated any alleged "new information" about risks of hearing impairment.*

Moreover, Plaintiff's claim fails to the extent it is premised on a failure to warn Plaintiff's prescribing physician about a risk of permanent hearing loss and/or tinnitus, which Plaintiff claims

[18] *See* Exhibit B, FDA-Approved labeling for TEPEZZA®, at pp. 8, 12; FAC at ¶ 47.

she experienced after receiving TEPEZZA® from June through November 2020. *See* FAC at ¶¶ 10-11. However, all of Plaintiff's allegations concerning studies on the risk of hearing loss associated with TEPEZZA®, which are consistent with the labeling, post-date her treatment in June 2020. *See* FAC at ¶¶ 62-74. As discussed in detail above, TEPEZZA®'s label included hearing impairment as one of the most common adverse reactions. And to be clear, none of the information relied upon by Plaintiff is sufficient to change the label. But even if Plaintiff's faulty argument was considered, the studies she points to were published over a one year after she began treatment. Further, as described above, FAERS data cannot show a causal link between an adverse event and a product, nor can it show an increased incidence of an adverse outcome. Moreover, the FDA Committee highlighted the uncertainties surrounding audiologic testing in its discussion and decided not to recommend screening for TEPEZZA® patients. Thus, Plaintiff has not and cannot allege sufficient facts to support a reasonable inference that Horizon should have warned Plaintiff based on the results of studies that had not yet occurred and information rejected by FDA. For the above reasons, Plaintiff's Negligent Failure to Warn claim also fails as a matter of law.

3. Plaintiff's design defect claims fail as a matter of law.

Plaintiff likewise has failed to plead a plausible design defect claim. The FAC is devoid of any facts alleging *how* TEPEZZA®'s design was defective or *how* any defect in that design caused her alleged injuries. While Plaintiff alleges that TEPEZZA® "was not properly manufactured, designed, compounded, tested, inspected, … formulated … [or] prepared" and caused Plaintiff's injuries (FAC ¶¶ 182 and 183), these conclusory allegations are insufficient to support a plausible claim under the *Twombly-Iqbal* standard. This is especially true here, where Plaintiff's FAC relates to a complex, cutting edge medical technology that is not easily characterized and cannot be "redesigned" to address some actual or perceived problem. "A claim

of design defect entails a showing that a product's design was defective, unreasonably dangerous, and that the defect proximately caused the plaintiff's injury." *Baca*, 2020 WL 6450294, at *4 (citing *Barnes v. Sandoz Crop Prot. Corp*., 938 P.2d 95, 97 (Ariz. Ct. App. 1997); *Vineyard v. Empire Mach. Co., Inc*., 581 P.2d 1152, 1155 (Ariz. Ct. App. 1978)). Plaintiff fails to adequately plead how TEPEZZA®'s design caused her injuries. The FAC does not describe how the biologic allegedly failed. Plaintiff's design defect claims fail and should be dismissed as a matter of law.

C. Punitive Damages are Not a Cause of Action and Not Permitted under Arizona law.

In addition to her design defect and failure to warn claims, Plaintiff asserts a "claim" for punitive damages. *See* FAC at ¶¶ 188-201. But a prayer for punitive damages is not, itself, a cause of action; punitive damages are merely a type of remedy. *See Quiroga v. Allstate Ins. Co.*, 726 P.2d 224, 226 (Ariz. Ct. App. 1986). Punitive damages are also precluded because "[u]nder Arizona law, manufacturers are not liable for punitive damages if the product was approved by a government agency." *Baca*, 2020 WL 6450294, at *6 (citing A.R.S. § 12-689(A)(1)). TEPEZZA® was FDA-approved, and therefore no claim for punitive damages is permitted in this case. Nor does any exception apply that would allow for punitive damages in this case. Arizona law allows punitive damages only if a manufacturer "[i]ntentionally, and in violation of applicable regulations **as determined by final action of the government agency**, withheld from or misrepresented to the government agency information material to the approval or maintaining of approval of the product ... and the information is relevant to the harm that the claimant allegedly suffered." A.R.S. § 12-689(B)(2) (emphasis added). Here, the FAC does not allege and cannot allege how Horizon intentionally withheld or misrepresented any such information. And, as in *Baca*, the Plaintiff's FAC "fails to allege that the FDA determined by final action that Defendants withheld or misrepresented information relevant to the Product's approval." *Baca*, 2020 WL 6450294, at *6.

Therefore, no statutory exception applies, and the Punitive Damages claim must be dismissed as a matter of law.

IV. CONCLUSION

For these reasons, Plaintiff's First Amended Complaint against Horizon should be dismissed in its entirety.

Dated: February 6, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a copy of this Memorandum in support of Motion to Dismiss was filed via the Court's E-Filing System and sent electronically on February 6, 2023, which will send an electronic copy to e-filers.

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