UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

AMARILIS POLANCO, **Plaintiff,** **v.** **HORIZON THERAPEUTICS USA, INC,** **Defendant.**	**Case No.** **COMPLAINT WITH JURY DEMAND**

I. PRELIMINARY STATEMENT

1. Plaintiff Amarilis Polanco brings this action for damages caused by Defendant Horizon Therapeutics, Inc.'s wrongful conduct in connection with the development, design, testing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of teprotumumab as Defendant's prescription drug Tepezza®.

2. Defendant manufactures, promotes, and sells Tepezza as a prescription drug that treats thyroid eye disease ("TED"). Tepezza is manufactured as an infusion treatment given by physicians intravenously.

3. Tepezza injured Plaintiff by causing permanent hearing damage.

4. Defendant knew or should have known that Tepezza, when used as prescribed and intended, causes harmful hearing loss and other symptoms including tinnitus.

5. Numerous patient reports, including significant newly acquired reports immediately following Defendant's launch of Tepezza, scientific studies, and even Defendant's post-marketing studies establish that Tepezza causes hearing loss and tinnitus.

6. Nevertheless, Defendant failed to warn, instruct, advise, educate, or otherwise inform Tepezza users, Tepezza prescribers, or United States governmental regulators about the

risk of hearing loss, or the need for medical and/or audiological monitoring. At all relevant times, the U.S. label for Tepezza contained no warning of permanent hearing loss or tinnitus.

7. As a proximate result Defendant's wrongful actions and inactions, Plaintiff was injured and suffered damages from Plaintiff's use of Tepezza.

8. Plaintiff accordingly demands judgment against Defendant and requests, among other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, and costs.

II. PARTIES

A. Plaintiff

9. Plaintiff Amarilis Polanco is a resident and a citizen of the state of New Jersey. Plaintiff suffered severe injuries as a direct result of infusion of Defendant's biological product Tepezza.

10. Plaintiff was diagnosed with TED and/or Graves' disease and received Tepezza infusions from a physician from November 2021 through May 2022.

11. During the relevant time periods, Plaintiff and Plaintiff's physicians were given no warning and had no knowledge of the serious risk of permanent hearing loss and/or tinnitus Tepezza posed. Specifically, and as discussed fully below, there is no warning or indication that Tepezza can, and in fact does, cause permanent hearing damage. Nor are physicians directed to conduct baseline audiology testing before treatment with Tepezza or monitor hearing acuity during treatment.

12. Subsequently, and as a result of Plaintiff's infusions of Tepezza, Plaintiff now suffers from permanent hearing loss and/or tinnitus.

13. As a proximate result of Defendant's acts and omissions, Plaintiff suffered the

injuries described above due to Plaintiff's infusions of Tepezza. Plaintiff accordingly seeks damages associated with these injuries.

B. Defendant

14. Defendant Horizon Therapeutics USA, Inc. f/k/a Horizon Pharma USA, Inc. is a corporation organized under the laws of Delaware with its principal place of business at 1 Horizon Way, Deerfield, Illinois 60015.

15. Horizon Therapeutics USA, Inc. is a wholly owned subsidiary of Horizon Therapeutics PLC organized under the laws of Ireland with a principal place of business located at 70 St. Stephen's Green, Dublin 2, D02 E2X4, Ireland.

16. Defendant, together with its parent company Horizon Therapeutics PLC (collectively "Horizon") were responsible for the sales and marketing in the United States of the drug Tepezza from Horizon's U.S. headquarters in Deerfield, Illinois.

17. On information and belief, Defendant has transacted and conducted business within the State of Illinois and has derived substantial revenue from goods and products disseminated and used throughout Illinois and the United States.

18. Horizon held the Biologic License Application ("BLA") for Tepezza from approximately January 2020 to the present.

19. At all relevant times, Horizon was, and still is, a pharmaceutical company involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Tepezza, in Illinois and throughout the United States.

20. Defendant was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Tepezza, and

controlling the Tepezza BLA.

21. The term "Defendant" as used in the complaint shall include any and all named or unnamed parent companies, parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and any organizational units of any kind, their predecessors, successors, successors in interest, assignees, and their officers, directors, employees, agents, representatives, and any and all other persons acting on their behalf.

III. JURISDICTION AND VENUE

22. The Court has jurisdiction under 28 U.S.C. § 1332(a)(1) because the amount in controversy exceeds $75,000, exclusive of interest and costs, and is between citizens of different states.

23. Venue is proper in this Court under 28 U.S.C. § 1391(b)(2), because Defendant resides in this district, conducts business in this district, and a substantial part of the acts and omissions giving rise to this complaint occurred in this district.

IV. STATEMENT OF THE CASE

24. Plaintiff brings this case against Defendant for damages associated with Plaintiff's use of the biologic product Tepezza, which was designed, manufactured, sold, and/or distributed by Defendant. Plaintiff suffered various injuries, serious physical pain, emotional distress, and medical expenses as a direct result of Plaintiff's use of Tepezza.

25. At all relevant times, Defendant was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Tepezza for the treatment of TED.

26. Defendant's fraudulent and illegal conduct with respect to Tepezza caused

hundreds, if not thousands, of individuals—including Plaintiff—to develop severe and permanent hearing damage.

V. FACTS

A. Thyroid Eye Disease

27. TED is characterized by progressive inflammation in the tissues around the eyes. This can cause the eyelids to become red, swollen, and uncomfortable and the eyes can push forward or bulge ("proptosis"). Notwithstanding Horizon's marketing materials suggesting vision impairment is common amongst those diagnosed with TED, that outcome is exceedingly rare—impacting a mere 3– 5% of TED patients. On information and belief, Horizon was aware of these facts at all times, but nonetheless promoted Tepezza's use for anyone diagnosed with TED and for early treatment of the disease.

28. TED is an autoimmune disease usually associated with hyperthyroidism. The exact mechanism of the disease is not fully understood.

29. The signs and symptoms of TED can vary greatly from one person to another. Symptoms range from mild to severe and include redness, irritation, and discomfort of the eyes and eyelids. Dry eyes and pain when moving the eyes may also occur. Eyelid retraction is also common, which is when the upper eyelid is positioned too high and/or the lower eyelid too low thus exposing the eye. The most noticeable symptom can be exophthalmos or proptosis, which means the eyes bulge or protrude outward of the eye socket. Additional symptoms and signs can include blurred vision, double vision ("diplopia"), misalignment of the eyes ("strabismus"), chronic bloody eyes, white area of eye inflamed, watery eyes due to excessive formation of tears, swelling near the upper and lower eyelids, an intolerance of bright lights, and difficulty moving the eyeballs.

30. TED is divided into two stages; the "active phase," which involves a progressive worsening of symptoms and visible inflammation followed by an "inactive phase" that is characterized by no further deterioration in the patient's condition. The active phase typically lasts for six months to two years.

31. TED mostly commonly occurs as part of Graves' disease, which is an autoimmune disease that affects the thyroid, skin, and eyes. TED can also occur in people with overactive or underactive thyroid (hyperthyroidism and hypothyroidism respectively).

32. In affected individuals who have underlying Graves' disease, treatment includes reversing hyperthyroidism. Some individuals with mild TED may be treated with supportive measures such as dark sunglasses to treat sensitivity to light, ointments, artificial tears, and/or prisms that are attached to glasses. Other therapies, such as corticosteroids, have been used to reduce inflammation and swelling in individuals with moderate-to-severe disease.

33. Some individuals with moderate-to-severe or severe disease may eventually require surgery. Generally, it is recommended to avoid surgery until after the active phase of the disease has ended.

34. According to the 2008 Consensus Statement of the European Group on Graves' Orbitopathy (EUGOGO) on Management of Graves' Orbitopathy, the disease is often mild and self-limiting, and probably declining in frequency, with only 3–5% of cases posing a threat to eyesight.

B. Defendant Designs and Seeks FDA Approval for Tepezza to Treat Thyroid Eye Disease

35. On May 6, 2013, the FDA granted teprotumumab the designation of Orphan Drug.

36. The FDA has authority to designate a drug or biologic product used to prevent,

diagnose, or treat a rare disease or condition with a population under 200,000 people as an Orphan Drug. Orphan Drug designations provide a separate pathway for approval and qualify sponsors for incentives including tax credits for qualified clinical trials, exemption from user fees, and up to seven years of market exclusivity post-approval.

37. On March 9, 2015, the FDA granted a Fast Track designation for teprotumumab.

38. On July 29, 2016, the FDA granted Breakthrough Therapy Designation for teprotumumab for active TED.

39. On approximately July 6, 2019, Defendant submitted the original BLA for teprotumumab-trbw (BLA: 761143).

40. In January 2020 the FDA approved Tepezza, making it the first approved drug indicated to treat TED. Tepezza inhibits (or blocks) the activity of the protein insulin-like growth factor-1 ("IGF-1"), which is believed to a play as significant role in the development of the disorder.

41. On approval of Tepezza, the FDA Risk Assessment and Risk Mitigation Review notes:

> Severity of TED is distinct from, but related to, disease activity. Severity of TED is best defined by functional or cosmetic impairment, which can be assessed by various criteria, such as is the Clinical Measures of Severity based on the European Group on Graves' Orbitopathy (EUGOGO) Consensus Statement. Clinical activity of TED is commonly measured by the Clinical Activity Score (CAS). Both activity and severity should be considered in the treatment of TED, as the 2 measurements are not interchangeable and don't follow a linear relationship.

42. In 2021, the EUGOGO issued clinical practice guidelines for the medical management of Graves' orbitopathy, which included first-line and second-line treatments for disease based on severity. The guidelines include simply that Tepezza be considered only as a

second-line treatment for moderate-to-severe and active Graves' orbitopathy. In making Tepezza a second-line treatment recommendation, the 2021 EUGOGO guidelines note, "although teprotumumab has become the first drug approved by the US Food and Drug Administration for the treatment of adult [Graves' Orbitopathy], its incorporation into routine clinical practice is currently limited by the lack of comprehensive long-term efficacy and safety data, absence of head-to-head comparison with i.v. glucocorticoids, restricted geographical availability, reimbursement (outside the US), and costs."

C. Defendant's Failure to Test Tepezza

43. According to the Tepezza label, "Teprotumumab-trbw's mechanism of action in patients with TED has not been fully characterized. Teprotumumab- trbw binds to IGF-1R and blocks its activation and signaling." Defendant failed to conduct tests to determine the mechanism of action of the drug.

44. Further, the Tepezza label admits "[n]o formal pharmacodynamic studies have been conducted with teprotumumab-trbw."

45. According to its label, "[t]he safety of TEPEZZA was evaluated in two randomized, double-masked, placebo-controlled clinical studies (Study 1 [NCT:01868997] and Study 2 [NCT:03298867]) consisting of **170** patients with TED (**84** received TEPEZZA and **86** received placebo)." (See **6.1 Clinical Trials Experience**) (emphasis added).

46. Elsewhere on the label, it reports that "TEPEZZA was evaluated in 2 randomized, double-masked, placebo-controlled studies in **171** patients with TED: Study 1 (NCT01868997) and Study 2 (NCT03298867)." Of those patients, "[a] total of **84** patients were randomized to TEPEZZA and **87** patients were randomized to placebo." (See 14 **CLINICAL STUDIES**) (emphasis added).

47. Regardless of which representation on the Tepezza label regarding the total number of study participants is accurate, Tepezza was submitted to FDA for approval with less than 100 patients enrolled in clinical trials actually receiving the drug.

48. The label for Tepezza contains warnings for "Infusion Reactions" (see 5.1), "Exacerbation of Preexisting Inflammatory Bowel Disease" (see 5.2), and "Hyperglycemia" (see 5.3).

49. The only reference on the Tepezza label related to hearing loss is listed among the "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." In a table listing the incidence of the adverse reactions in the experimental versus the control group of the clinical trials, "hearing impairment" was noted to have occurred in 8 Tepezza users and 0 of the placebo group (see 6.1, Table 1). Hearing impairment was noted to include "deafness, eustachian tube dysfunction, hyperacusis, hypoacusis, and autophony." Nothing on the label suggests that any of the adverse events might be of extended duration (e.g., permanent diarrhea). Nor does the label mention tinnitus.

D. The Dangers of Tepezza Post Marketing

50. Despite study after study providing clear evidence of the dangers of Tepezza, Defendant failed to adequately investigate the threat that Tepezza poses to patients' ears and hearing or warn patients of the risk that they would suffer ear injury and permanent or extended hearing impairment.

51. According to Defendant's 2021 Annual Report, it "delayed the start of an FDA-required post-marketing study to evaluate safety of TEPEZZA in a larger patient population and retreatment rates relative to how long patients receive the medicine. The FDA-required post-

marketing study was initiated in the fourth quarter of 2021." Defendant continued to market and sell Tepezza in the interim.

52. On February 22, 2022, Defendant issued a press release announcing results from a new post-marketing safety analysis of hearing events associated with Tepezza for the treatment of TED.

53. These findings were also presented at the 48th Annual Meeting of the North American Neuro-Ophthalmology Society (NANOS 2022), Feb. 12–17, in Austin, Texas.

54. Thousands of patients were included in this 19-month analysis and demonstrated approximately 10% of all cases reported to the safety database have included a hearing-related event.

55. The most frequently reported hearing event was hypoacusis (reduction in hearing), followed by tinnitus (ringing in the ears).

56. Defendant continues to represent the majority of hearing-related adverse events in the pivotal trials and post-approval have been mild to moderate and reversible.

57. In contrast to the public statements, almost immediately after the FDA approved Tepezza, patients and doctors began reporting serious complications relating to ear and permanent hearing problems in patients taking Tepezza.

E. Adverse Events Related to Tepezza

58. As noted above, Plaintiff was treated between November of 2021 and May of 2022. On information and belief, before the completion of Plaintiff's treatment, Horizon self-reported (or consumers reported) the following newly acquired information to the FDA, but Horizon took no action to seek a label change under the FDA's Changes Being Effected ("CBE") regulation (21 C.F.R. § 314.70(c)(3)):

a. On May 13, 2020, the FDA received a report of a consumer experiencing tinnitus following use of Tepezza;

b. On June 2, 2020, Horizon notified the FDA of a consumer reporting experiencing tinnitus following use of Tepezza;

c. On June 4, 2020, Horizon notified the FDA of a consumer reporting experiencing hypoacusis following use of Tepezza;

d. On June 8, 2020, Horizon notified FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

e. On June 15, 2020, Horizon notified FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

f. On July 1, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus and hypoacusis following use of Tepezza;

g. On July 14, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

h. On July 28, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

i. On August 6, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

j. On August 14, 2020, Horizon notified the FDA of a report from a patient experiencing hypoacusis following use of Tepezza;

k. On August 20, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing bilateral deafness following use of Tepezza;

l. On September 1, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

m. On September 7, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

n. On September 8, 2020, Horizon notified the FDA of two separate reports—one from a consumer and one from a healthcare professional— of patients experiencing hypoacusis following use of Tepezza;

o. On September 9, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

p. On September 10, 2020, Horizon notified the FDA of a report from a consumer of

experiencing hypoacusis following use of Tepezza;

q. On September 11, 2020, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

r. On September 15, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

s. On September 18, 2020, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis and tinnitus following use of Tepezza;

t. On September 18, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

u. On September 25, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

v. On September 28, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

w. On September 30, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

x. On September 30, 2020, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis and tinnitus following use of Tepezza;

y. On October 9, 2020, Horizon notified the FDA of a report from a consumer of experiencing deafness following use of Tepezza;

z. On October 16, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

aa. On October 21, 2020, the FDA received a report of a consumer experiencing deafness following use of Tepezza;

bb. On October 27, 2020, Horizon notified the FDA of two separate reports from consumers of experiencing deafness following use of Tepezza;

cc. On November 2, 2020, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

dd. dd. On November 10, 2020, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

ee. On November 16, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

ff. On November 19, 2020, Horizon notified the FDA of a report from a consumer of experiencing dysacusis and tinnitus following use of Tepezza;

gg. On December 4, 2020, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

hh. On December 17, 2020, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

ii. On December 28, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza; and

jj. On December 30, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza.

59. On information and belief, FDA received 45 adverse-event reports in 2020 related to Tepezza for ear and labyrinth disorders, which include tinnitus, hypoacusis, and deafness.

60. The adverse-event reports continued in 2021:

a. On January 13, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing dysphonia and hypoacusis following use of Tepezza;

b. On January 14, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient deafness following use of Tepezza;

c. On January 19, 2021, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

d. On February 9, 2021, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

e. On March 11, 2021, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

f. On April 9, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

g. On April 20, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

h. On May 17, 2021, Horizon notified the FDA of nine separate reports of adverse events following use of Tepezza:

i. One from a consumer reporting hypoacusis and tinnitus;

ii. One from a consumer reporting hypoacusis;

iii. One from a healthcare provider reporting a patient experiencing hypoacusis and tinnitus;

iv. Two from healthcare providers reporting a patient experiencing hypoacusis; and

v. Four from healthcare providers reporting a patient experiencing deafness following use of Tepezza;

i. On May 18, 2021, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

j. On May 19, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

k. On May 20, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

l. On May 20, 2021, Horizon notified the FDA of a report from a consumer experiencing deafness following use of Tepezza;

m. On May 31, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

n. On June 17, 2021, the FDA received a report from a consumer experiencing deafness following use of Tepezza;

o. On July 7, 2021, Horizon notified the FDA of a report from a consumer of experiencing deafness following use of Tepezza;

p. On July 13, 2021, the FDA received a report from a consumer of experiencing hypoacusis following use of Tepezza; and

q. On July 14, 2021, the FDA received a report from a consumer of experiencing tinnitus following use of Tepezza.

61. Each of the adverse events listed above were reported to the FDA before Plaintiff began her Tepezza infusions on July 15, 2021.

62. The adverse-event reporting continued through the conclusion of Plaintiff's treatment on December 22, 2021:

a. One July 21, 2021, the FDA received a report of a consumer experiencing deafness

following use of Tepezza;

b. On August 2, 2021, the FDA received a report from a consumer of experiencing tinnitus following use of Tepezza;

c. On August 10, 2021, Horizon notified the FDA of 16 separate reports of adverse events following use of Tepezza:

i. Four from consumers of experiencing hypoacusis;

ii. One from a consumer of experiencing hypoacusis and tinnitus;

iii. One from a consumer of experiencing deafness;

iv. Four from healthcare professionals of a patient experiencing deafness;

v. Four from healthcare professionals of a patient experiencing hypoacusis; and

vi. Two from healthcare professionals of a patient experiencing tinnitus.

d. On August 18, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

e. On August 18, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing autophony, deafness, and hypoacusis following use of Tepezza;

f. On August 18, 2021, Horizon notified the FDA of two separate reports from healthcare professionals of a patient experiencing hypoacusis following use of Tepezza;

g. On September 7, 2021, the FDA received a report from a consumer of experiencing deafness following use of Tepezza;

h. On September 10, 2021, the FDA received a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

i. On October 5, 2021, the FDA received a report from a consumer of experiencing tinnitus following use of Tepezza;

j. On October 7, 2021, the FDA received a report from a consumer experiencing hypoacusis following use of Tepezza;

k. On October 15, 2021, the FDA received a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

l. On October 20, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

m. On October 29, 2021, Horizon notified the FDA of three separate reports from a consumer of experiencing deafness following use of Tepezza;

n. On October 29, 2021, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

o. On October 29, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

p. On November 3, 2021, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

q. On November 3, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

r. On November 4, 2021, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

s. On November 4, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

t. On November 4, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

u. On November 5, 2021, Horizon notified the FDA of four separate reports from healthcare professionals of a patient experiencing hypoacusis following use of Tepezza;

v. On November 8, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

w. On November 8, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

x. On November 9, 2021, the FDA received a report from a consumer experiencing tinnitus following use of Tepezza;

y. On November 10, 2021, Horizon notified the FDA of a report from a consumer of experiencing tinnitus and hypoacusis following use of Tepezza;

z. On November 10, 2021, Horizon notified the FDA of three separate reports from a consumer of experiencing hypoacusis following use of Tepezza;

aa. On November 10, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

bb. On November 10, 2021, Horizon notified the FDA of three separate reports from healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

cc. On November 10, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

dd. On November 11, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

ee. On November 11, 2021, Horizon notified the FDA of a report from a consumer experiencing deafness following use of Tepezza;

ff. On November 12, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

gg. On November 12, 2021, Horizon notified the FDA of two separate reports from healthcare professionals of a patient experiencing hypoacusis following use of Tepezza;

hh. On November 12, 2021, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

ii. On November 15, 2021, Horizon notified the FDA of a report from a consumer of experiencing deafness following use of Tepezza;

jj. On November 15, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus and deafness following use of Tepezza;

kk. On November 17, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness and tinnitus following use of Tepezza;

ll. On November 17, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

mm. On December 6, 2021, the FDA received a report from a consumer of experiencing deafness and tinnitus following use of Tepezza;

nn. On December 12, 2021, the FDA received a report from a consumer of experiencing hypoacusis following use of Tepezza;

63. On information and belief, FDA received 106 adverse-event reports in 2021 and 92 adverse-event reports in 2022 (thus far) related to Tepezza for ear and labyrinth disorders, which include tinnitus, hypoacusis, and deafness.[1]

[1] *See e.g. FAERS Public Dashboard*, available at https://fis.fda.gov/sense/app/95239e26-e0be-42d9- a960-9a5f7f1c25ee/sheet/6b5a135f-f451-45be-893d-20aaee34e28e/state/analysis (last accessed November 18, 2022

F. Reports in the Published Medical Literature

64. The FDA has established reporting categories for post-approval changes to a drug's label. The CBE supplement allows for changes in the labeling of a drug product to reflect newly acquired information without prior approval from the FDA. 21 C.F.R. § 314.70(c)(3). The manufacturer may make these changes based on newly acquired information, which can include reevaluation of prior clinical trials, mounting adverse-event reports, and the peer-reviewed literature. The manufacturer is, at all times, responsible for the content of its label and may execute a CBE to the label with or without FDA approval.

65. The CBE process allows for drug manufacturers to change a drug label more quickly than the supplemental new drug application ("sNDA") process based on newly acquired information about the drug.

66. FDA has routinely approved manufacturers' CBEs imposing testing regimes for harms associated with a drug's use.

67. Before and during Plaintiff's treatment, the peer-reviewed literature, together with the mounting adverse event reports, and Horizon's own clinical trial data, required Defendant to implement a CBE warning physicians and consumers of the risk of irreversible hearing loss and tinnitus. To date, Horizon has failed to utilize the CBE process to modify the label to warn of risks associated with long-term hearing loss and/or impose a baseline testing regime to monitor patients for hearing loss.

68. Before and during Plaintiff's treatment, the peer-reviewed literature established that Horizon possessed newly acquired information sufficient to trigger its CBE obligations. For example:

a. In April 2021, an e-publication of a pooled analysis from the clinical trials was

funded and published by Horizon. Kahaly GJ, Douglas RS, Holt RJ, Sile S, and Smith TJ. Teprotumumab for patients with active [TED]: a pooled data analysis, subgroup analyses, and off- treatment follow-up results from two randomised, double-masked, placebo-controlled, multicentre trials. Lancet Diabetes Endocrinol 2021;9:360–72 (e-pub April 15, 2021). This data was available to Horizon at all times before and during Plaintiff's treatment. The authors include Horizon employee Saba Sile. The article notes that Horizon funded the study and played a pivotal role in constructing the analysis plan, study design, data collection, data analysis, data interpretation, and writing of the publication. The paper reported the hearing events in the clinical trials as: "[h]earing impairment events, reported as deafness, eustachian tube dysfunction, hyperacusis, hypoacusis, or autophony, were all classified as non-serious and all patients continued in the study without event worsening. No patients discontinued treatment because of these events. One hearing event continued but improved and was lost to follow-up, while another patient with a history of loud noise-induced tinnitus continued at the time of last-post study follow-up report." In other words, the authors' reanalysis of the clinical trial data could not rule out ongoing hearing issues after patients discontinued the treatment.

b. In October 2021, Douglas et al., published a follow-up open-label extension clinical trial report of the OPTIC-X study. As with the April 2021 publication, much, if not all, of the data from the study existed before Plaintiff's treatment and/or discontinuation of use.[2] The authors include three Horizon employees: Saba Sile, Megan Francis-Sedlak, and Robert J. Holt. The authors reported four patients experiencing hearing loss or tinnitus, one of which continued through the last visit. On information and belief, Horizon failed to conduct any additional follow-on investigation for the patient with ongoing hearing loss at the time of the clinical trials.

c. Teprotumumab (Tepezza) is an insulin-like growth factor I receptor (IGF-IR) inhibitor. On information and belief, Horizon knew when developing Tepezza that it was an IGF-IR inhibitor.[3]

d. It has been known since the early 2000s that IGF-1 is associated with mammalian hearing and deficiencies result in hearing loss. On information and belief, it was well known in the medical literature that IGF-1 plays a central role in hearing and low levels of IGF-I had been shown to correlate with human syndromes associated with hearing loss.[4]

e. Inhibition of IGF-1R as a mechanism for teprotumumab-induced ototoxicity has

[2] *See e.g.*Douglas et. al, *Teprotumumab efficacy, safety, and durability in longer-duration [TED] and re-treatment*: OPTIC-X. Ophthalmology 2022;129:438–449 (e-pub October 2021).
[3] *Id*.
[4] *See e.g.*, Murillo-Custa, S et al., *The role of insulin-like growth factor-I in the pathophysiology of hearing*. Front. Mol. Neurosci. 2011;4–11; Varela-Nieto I, Murillo-Cuesta S, Rodriguez de la Rosa L, Lassatetta L, Contreras J. *IGF-1 deficiency and hearing loss: molecular clues and clinical implications*. Pediatr. Endocrinol. Rev. 2013 Jul; 10(4):460–72; Varela-Nieto I, Morales-Garcia JA, Vigil P, Diaz-Casares A, Gorospe, I, Sanchez-Galiano S, Canon S, Camarero G, Contreras J, Cediel R, Leon Y. *Trophic effects of insulin-like growth factor-I (IGF-I) in the inner ear*. Hear Res. 2004 Oct;196(102):19–25; Cediel R, Riquelme R, Contreras J, Diaz A, Varela-Nieto I. *Sensorineural hearing loss in insulin-like growth factor I-null mice: a new model of human deafness*. Eur J. Neurosci. 2006 Jan;23(2):587–90.

been reported in the medical literature.[5]

69. This data, coupled with the fact that IGF-1Rs are well known to adversely impact cochlear development and maintenance, triggered Horizon's obligation to implement a CBE to warn of the risks of long-term hearing loss and tinnitus. To date, Horizon has yet to execute a CBE warning patients and their doctors that Tepezza may cause ongoing hearing loss and tinnitus after discontinuation of use and/or completion of treatment.

70. Beyond the information set forth above, there is mounting evidence in the peer-reviewed literature establishing that long-term hearing loss can occur following discontinuation of Tepezza treatments.[6]

71. In August 2021, Highland et al. published an article titled Ototoxicity and Teprotumumab reporting a case of a 61-year-old female with "one of the first descriptive cases of ototoxicity resulting in irreversible sensorineural hearing loss in the setting of treatment with teprotumumab." The authors suggested that audiologic evaluations should be recommended to patients on teprotumumab.[7]

72. In September 2021, Yu et al. reported a case series of two cases of subjective and objective hearing function changes associated with teprotumumab treatment for TED, including hearing loss and tinnitus. The authors noted that the potential for a risk of long-term irreversible

[5] *See e.g.*, Winn BJ, Kersten RC. *Teprotumumab: interpreting the clinical trials in the context of [TED] pathogenesis and current therapies*. Ophthalmology. 2021 Nov;128(11):1627–1651 (e-pub April 28, 2021); Teo HM, Smith TJ, Joseph SS. *Efficacy and safety of teprotumumab in thyroid eye disease*. Ther. Clin. Risk. Manag. 2021 Nov 25;17:1219–1230; Chern A, Dagi Glass LR, Gudis DA. *thyroid eye disease, teprotumumab, and hearing loss: an evolving role for otolaryngologists*. Otolaryngol Head Neck Surg. 2021 Dec;165(6):757–758; Girnita L, Smith TJ, Janssen JAML. *It takes two to tango: IGF-I and TSH receptors in thyroid eye disease*. J. Clin. Endocrinol. Metab. 2022 Aug 8;107(Supplement_1):S1–S12.

[6] *See e.g.* Chern et. al, *Teprotumumab and hearing loss: hear the warning*s. Orbit. 2021 Aug;40(4):355–56.(e-pub August, 2021)

[7] *See e.g.* Highland et al., *Ototoxicity and Teprotumumab*. Ann. Otol. Rhinol. Laryngol. 2022 Aug; 131(8):910– 913) (e-pub August 27, 2021)

hearing loss may exist.[8]

73. Chern et al. also published an article in December 2021 stating "clinicians who prescribe teprotumumab should strongly consider monitoring patients' hearing with an audiologist and otolaryngologist."[9]

74. In January 2022, an additional case series of four cases of Tepezza-associated hearing loss was reported based upon patients of three doctors who treated 28 patients. The authors proposed a mechanism and concluded:

> Teprotumumab may cause a spectrum of potentially irreversible hearing loss ranging from mild to severe, likely resulting from the inhibition of the insulin-like growth factor-1 and the insulin-like growth factor-1 receptor pathway. Due to the novelty of teprotumumab and the lack of a comprehensive understanding of its effect on hearing, the authors endorse prospective investigations of hearing loss in the setting of teprotumumab treatment. Until the results of such studies are available, the authors think it prudent to adopt a surveillance protocol to include an audiogram and tympanometry before, during and after infusion, and when prompted by new symptoms of hearing dysfunction.[10]

75. In February 2022, another case report noted that while hearing loss was noted as a side effect in clinical trials, no formal audiometric investigations of these patients had been reported, and the manufacturer offered no formal guidelines for audiometric monitoring. The authors concluded that, because guidelines exist for other known ototoxic medications, patients undergoing treatment with Tepezza should receive similar audiometric monitoring.[11]

76. In February 2022, Sears et al. reported on a prospective observational case series.

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[8] *See e.g.* Yu et al., *Audiology findings in patients with teprotumumab associated otologic symptoms*. Am.J. Ophthalmol. Case Rep. 2021 Sep 16;24:101202.
[9] Chern et al., *Thyroid eye disease, teprotumumab, and hearing loss: an evolving role for otolaryngologists*. Otolaryngol. Head Neck Surg. 2021 Dec;165(6):757–758.
[10] *See e.g.* Belinsky et al., *Teprotumumab and Hearing Loss: Case Series and Proposal for Audiologic Monitoring*. Ophthalmic Plast. Reconstr. Surg. 2022 Jan–Feb 01;38(1):73– 78
[11] *See e.g.* Ding et al., *Sensorineural Hearing Loss After Teprotumumab Therapy for Thyroid Eye Disease: A Case Report.* Otol. Neurotol. 2022 Feb 1;43(2):e148–e152.

In this series, 27 patients were analyzed (24 females, 3 males, average 56.3 years old). Twenty-two patients (81.5%) developed new subjective otologic symptoms. The results revealed three of the five patients with teprotumumab-related hearing loss had persistent subjective hearing loss at last follow-up. The authors also concluded that clinicians need screening, monitoring, and prevention guidelines for teprotumumab-related hearing loss.[12]

77. In March 2022, the e-publication of an Expert Consensus on the use of teprotumumab was released. The authors reported the results of three rounds of surveys taken between October 2020 and February 2021. Nine of the fifteen authors reported being consultants, speakers, or owners of Defendant in the publication. The consensus recommendations include: (1) a medical history including history of hearing loss must be completed before initiation of treatment (emphasis in original) because conditions can worsen during treatment; (2) baseline audiogram and patulous eustachian tube testing may be conducted before the initiation of treatment with teprotumumab to ensure patients undergo minimal adverse events (emphasis in original); and (3) hearing-impairment adverse effects should be discussed with patients before initiating treatment (emphasis in original).[13]

78. In April 2022, Chow and Silkiss published a case report of a woman in her 50s who developed tinnitus after the third dose of Tepezza, followed by frank hearing loss after the fifth dose. Repeat audiogram six weeks later showed no improvement in the hearing loss. The authors concluded "[g]iven potentially irreversible sensorineural hearing loss, we recommend close monitoring with regular audiometric testing before, during[,] and after teprotumumab therapy and

[12] *See e.g.*Sears et al., *Hearing dysfunction after treatment with teprotumumab for thyroid eye disease*. Am. J. Ophthalmol. 2022 Feb 25;240:1–13.
[13] *See e.g.* Douglas RS, Kossler et. al. *Expert consensus on the use of teprotumumab for the management of TED using a modified-Delphi approach*. J Neuro- Ophthalmol. 2022;42:334–339 (e-pub March 24, 2022).

propose potential treatment to reverse its effects in the ear."[14]

79. In April 2022, an additional case report of a woman with tinnitus and hearing loss was published by Najjar and Yu. The woman reported tinnitus after the second infusion and hearing loss by the fifth infusion. Audiograms after discontinuation revealed no improvement. The authors recommended a new prospective clinical trial be performed with comprehensive pretreatment audiologic testing and ongoing audiologic monitoring.[15]

80. In July 2022, Bartalena et al. continued the publication of reports in a peer-reviewed journal article titled to distill the danger to its essence.[16]

81. At all relevant times, Defendant failed to adequately warn or instruct patients, the medical community, or prescribers in the United States that Tepezza causes, is linked to, and is associated with permanent hearing loss and/or tinnitus.

82. At all relevant times, Defendant failed to adequately warn or instruct patients, the medical community, or prescribers in the United States that patients receiving Tepezza should undergo regular audiological testing to detect hearing loss.

83. At all relevant times, the labeling for Tepezza failed to provide adequate warnings and instructions, failed to caution that patients should be closely monitored, and failed to adequately inform patients and physicians that permanent hearing loss and/or tinnitus is associated with Tepezza use.

84. At all relevant times, Defendant also failed to alert patients of the need for

[14] *See e.g.* Chow & Silkiss, *Teprotumumab-associated chronic hearing loss screening and proposed treatments*. BMJ Case Rep. 2022 Apr 13;15(4):e248335.
[15] *See e.g.* Najjar & Yu, Audiologic Demonstration of Ototoxicity from Teprotumumab Treatment in a Patient with Thyroid Eye Disease. OTO Open. 2022 Apr 29;6(2):2473974X221097097.
[16] *See e.g.* Bartalena et al. *Teprotumumab for Graves' orbitopathy and ototoxicity: moving problems from eyes to ears?* J. Endocrinol. Invest. 2022 Jul;45(7):1455–57. (This article was e-published April 11, 2022.)

audiological monitoring while receiving Tepezza and whether risks for hearing- related injuries increase with higher doses or longer durations.

85. Other mediations affecting hearing have included instructions and warnings for users and prescribers. For example, the chemotherapeutic drug cisplatin is likewise associated with ototoxicity. In the labeling for cisplatin, the manufacturer provides the following warning:

> Cisplatin for injection can cause ototoxicity, which is cumulative and may be severe. Consider audiometric and vestibular function monitoring.
>
> Ototoxicity is manifested by tinnitus, hearing loss in the high frequency range (4,000 to 8,000 Hz) and/or decreased ability to hear normal conversational tones. Ototoxicity can occur during or after treatment and can be unilateral or bilateral. Deafness after the initial dose of cisplatin for injection has been reported. Vestibular toxicity has also been reported.
>
> Ototoxic effects can be more severe and detrimental in pediatric patients, particularly in patients less than 5 years of age. The prevalence of hearing loss in pediatric patients is estimated to be 40-60%. Additional risk factors for ototoxicity include simultaneous cranial irradiation, treatment with other ototoxic drugs and renal impairment. Consider audiometric and vestibular testing in all pediatric patients receiving cisplatin [see Use in Specific Populations (8.4)]. Genetic factors (e.g. variants in the thiopurine S-methyltransferase [TPMT] gene) may also contribute to the cisplatin-induced ototoxicity; although this association has not been consistent across populations and study designs.

86. The American Speech-Language-Hearing Association 2020 guidelines also suggest that baseline audiological monitoring should occur when using ototoxic medications. Specifically, the guidelines state:

> When possible, the baseline record should include (1) an audiologic hearing test focused on your ability to hear very high-pitched sounds; (2) word recognition tests; and (3) other tests. This information can help you and your doctor make any important decisions to stop or change the medication therapy before your hearing is affected.

87. As explained above, the FDA has established reporting categories for post-approval changes to a drug's label. The CBE supplement allows for changes in the labeling of a drug product to reflect newly acquired information without prior approval from the FDA.

88. The CBE process allows for drug manufacturers to change a drug label more quickly than the sNDA process based on newly acquired information about the drug.

89. Defendant should have changed the Tepezza label to include warnings and instructions addressing the risk of injury associated with the drug as soon as it had notice of adverse reports relating to the same.

90. By failing to use the FDA's CBE supplement to warn Plaintiff, consumers, and physicians of the risk of permanent hearing loss associated with using Tepezza, Defendant acted in a gross and flagrant character, evincing reckless disregard of the safety and welfare of persons exposed to its dangerous drug.

91. Additionally, by failing to use the FDA's CBE supplement to warn Plaintiff, consumers, and physicians of the risk of permanent hearing loss and/or tinnitus associated with using Tepezza, Defendant showed wantonness, recklessness, or a grossly careless disregard for the public's safety and welfare.

G. Rather Than Warn of the Dangers of Tepezza, Horizon Implemented an Aggressive Marketing Campaign to Encourage Its Use

92. As noted above, less than 5% of all persons with TED suffer any form of vision impairment. In this sense, Tepezza was, and is, a drug in search of a disease given that more than 95% of all users will experience no benefit related to vision impairment.

93. As a drug in search of a disease, Horizon launched an aggressive marketing campaign to fuel sales of its blockbuster drug. For example, according to Horizon's 2021 Annual

report:

> Our comprehensive post-launch commercial strategy for [Tepezza] aims to enable more [TED] patients to benefit from [Tepezza]. We are doing this by: (i) facilitating continued [Tepezza]uptake in the treatment of [TED] through continued promotion of [Tepezza]to treating physicians; (ii) continuing to develop the [TED] market by increasing physician awareness of the disease severity and the urgency to diagnose and treat it, as well as the benefits of treatment with [Tepezza]; (iii) driving accelerated disease identification and time to treatment through our digital and broadcast marketing campaigns; (iv) enhancing the patient journey with our high-touch, patient-centric model as well as support for the patient and site-of-care referral processes; and (v) pursuing more timely access to [Tepezza] for [TED] patients."

94. Similarly, Horizon's 2021 Annual Report reiterates:

> "It bears repeating: 2021 was a record-breaking year for Horizon. Full-year 2021 net sales were $3.23 billion, representing year-over-year growth of 47 percent, and our full-year 2021 adjusted EBITDA [earnings before interest, taxes, depreciation, and amortization] was $1.28 billion, representing year-over-year growth of 33 percent. Driving much of this growth was [Tepezza], which boasted one of the most successful rare disease medicine launches in history, and had full-year 2021 net sales of $1.66 billion, representing year-over-year growth of 103 percent."

On information and belief, this aggressive marketing campaign drove, in part, the astonishing Tepezza sales that followed.

95. Additionally, in the wake of the global COVID pandemic, Horizon launched an aggressive campaign to convert physician use. On May 14, 2021, PM360 reported the following:

> Within three months of its launch, 95% of target physicians were aware of the brand and more than 65% said they were highly likely to prescribe [Tepezza]. Due to COVID, the team also had to find ways to reach HCPs without an in-person sales force. The team developed a booth (TEPEZZAexperience.com) for virtual medical congresses that allows visitors to take a quiz about [TED], tour the [Tepezza]data, hear real patient stories, and connect with a Horizon representative. In just the month of November, the booth received over 2,800 visits and over 550 unique HCP engagements.

> As [Tepezza] is an infusion medication and the core prescriber base did not have infusion experience, a new field team was also developed to build a site of care network. The marketing team developed customized materials for the infusion center clinical and administrative staff to support rapid uptake at launch.[17]

96. But that was not all. At the same time, Horizon launched a massive direct-to-consumer campaign whose sole purpose was to build brand awareness and promote sales. Specifically, PM360 reported:

> On the patient front, the team launched a DTC campaign that spotlighted the extremely challenging symptoms of [TED] that cannot be ignored. Within a month, [Tepezza]achieved 82% aided awareness among patients, an increase of 68% prior to the campaign. Combined communication efforts also drove 157K unique visitors to TreatTED.com, a page created for the TEPEZZA.com website.[18]

97. On information and belief, the direct-to-consumer campaign included the development of websites masquerading as support groups for persons suffering from TED, promotion of the drug on Graves' disease websites, the creation of "more than 1,000 infusion centers," and a massive unbranded and branded televised direct-to- consumer advertisement campaign.[19]

98. At the time of approval, a spokesperson for the company said teprotumumab would cost $14,900 per vial, with full treatment over six months consisting of approximately 23 vials, and that the wholesale acquisition cost for that amount is $343,000, with an annual net realized price of $200,000. As a result, the cost of a course of treatment of Tepezza is hundreds of thousands of dollars per patient.

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[17] *See* https://www.pm360online.com/elite-2021-marketing-team-tepezza-marketing- team/ (last visited November 16, 2022) (emphasis in original).
[18] *Id.*
[19] *See generally* https://www.fiercepharma.com/marketing/horizon-uses-eye-catching-animation- for-ted-ads (last accessed November 16, 2022).

99. As a direct result of these efforts, annual sales of Tepezza soared. According to Horizon's April 28, 2022 Proxy Statement, the company's "excellence in commercial execution" continued for this dangerous drug, evidenced by "more than doubl[ing] the full-year net sales of [Tepezza] … to $1.7 billion in its second year post-launch, representing impressive growth of 103 percent."

100. In that 2022 Proxy Statement, Horizon continued to tout its "initiatives to drive increased awareness of [Tepezza] and [TED]…" and reported that it has "generated cumulative net sales of $2.5 billion, despite the negative impact of the COVID-19 pandemic, representing exceptional value creation for our shareholders" and sees "opportunities for continued growth for [Tepezza], projecting peak global annual net sales of more than $3.5 billion."

101. Yahoo Finance recently reported that Horizon's anticipated 2022 sales will likely exceed $3.6 billion. In short, Horizon's collective marketing efforts worked, resulting in nearly $6 billion in sales in less than three years.

H. Defendant Had a Duty to Protect American Consumers and Failed to Fulfill That Duty

102. At all relevant times, Defendant had a duty to craft an adequate label with respect to Tepezza.

103. At all relevant times, Defendant had a duty to ensure that the warnings in the Tepezza label were adequate—at all times—for as long as the drug remained available for sale in the United States.

104. At all relevant times, Defendant had a responsibility to conduct post- marketing surveillance and to continue to study the safety and efficacy of Tepezza, after the Tepezza BLA was approved, for as long as the drug remained available for sale in the United States.

105. At all relevant times, Defendant had a duty to revise the Tepezza label to include a warning regarding the risk of serious and permanent hearing-related injuries as soon as there was reasonable evidence of a causal association between such injuries and Tepezza use.

106. On information and belief, despite understanding Tepezza could cause hearing-related injuries, Defendant knowingly withheld and/or misrepresented information required to be submitted under the FDA BLA regulations concerning the safety and efficacy of Tepezza, including, but not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Tepezza users suffering hearing-related injuries as a result of their Tepezza use. Such information was material and relevant to the risk of patients, like Plaintiff, developing serious hearing-related injuries as a result of taking Tepezza.

I. How Horizon's Misconduct Endangered American Consumers

107. On information and belief, had Defendant exercised reasonable care in testing and studying Tepezza, it would have discovered—prior to seeking FDA approval— that Tepezza use can cause serious and irreversible hearing loss and/or tinnitus.

108. On information and belief, despite post-approval adverse-event reports and other clinical evidence, Defendant failed to continue to test and study the safety and efficacy of Tepezza.

109. On information and belief, from the date Defendant received FDA approval to market Tepezza in the United States, Defendant made, distributed, marketed, and sold Tepezza without adequate warning to Plaintiff's prescribing physicians or Plaintiff that Tepezza was associated with and/or could cause serious hearing loss in patients who used it, and that Defendant had not adequately conducted complete and proper testing and studies of Tepezza with regard to hearing loss and/or tinnitus, including as to duration.

110. On information and belief, Defendant concealed and/or failed to completely

disclose its knowledge that Tepezza was associated with and/or could cause hearing loss and/or tinnitus, including as to duration, as well as its knowledge that it had failed to fully test or study said risk.

111. On information and belief, Defendant ignored the association between the use of Tepezza and the risk of developing permanent hearing loss, including, but not limited to, hearing loss and tinnitus.

112. On information and belief, Defendant failed to warn Plaintiff and Plaintiff's healthcare providers regarding true risk of hearing damage of Tepezza, but similar efficacy compared to other products and/or treatment options.

113. On information and belief, Defendant failed to provide adequate instructions to healthcare professionals and patients in the United States regarding how to safely monitor and identify signs of potentially serious audiological complications associated with Tepezza infusions.

114. On information and belief, Defendant failed to warn healthcare professionals and patients in the United States, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely monitor and identify signs of potentially serious hearing complications associated with Tepezza infusions.

115. On information and belief, Defendant failed to warn and/or to provide adequate instructions to healthcare professionals and patients in the United States, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely stop receiving Tepezza when potentially serious hearing complications developed while using Tepezza.

116. On information and belief, Defendant failed to warn healthcare professionals and patients in the United States, including Plaintiff's prescribing physicians and Plaintiff, of the true risk of auditory damage to patients receiving Tepezza as compared to other similarly efficacious

pharmaceutical products or treatment options.

117. Defendant's failures to provide adequate instructions and/or disclose information—which Defendant possessed regarding the failure to adequately test and study Tepezza for the risk of serious hearing complications—further, rendered the Tepezza Package Insert, and other educational and/or promotional materials, inadequate.

118. Despite adverse-event reports from healthcare professionals and consumers around the world, Defendant never adequately warned of the risk of serious and irreversible hearing loss, including, but not limited to, hearing loss and tinnitus, associated with using Tepezza.

J. Equitable Tolling of Statutes of Limitations

119. Defendant willfully, wantonly, and intentionally conspired, and acted in concert, to withhold information from Plaintiff, Plaintiff's healthcare providers, and the general public concerning the known hazards associated with the use of Tepezza.

120. Defendant willfully, wantonly, and intentionally conspired, and acted in concert, to withhold safety-related warnings from Plaintiff, Plaintiff's healthcare providers, and the general public concerning the known hazards associated with the use of Tepezza.

121. Defendant willfully, wantonly, and intentionally conspired, and acted in concert, to withhold instructions from Plaintiff, Plaintiff's healthcare providers, and the general public concerning how to identify, mitigate, and/or treat known hazards associated with the use of Tepezza.

122. Defendant willfully, wantonly, and intentionally conspired, and acted in concert, to ignore relevant safety concerns and to deliberately not study the safety and efficacy of Tepezza.

123. Defendant failed to disclose a known risk and, instead, affirmatively misrepresented that Tepezza was safe for its intended use. Defendant disseminated labeling,

marketing, promotion, and/or sales information to Plaintiff, Plaintiff's healthcare providers, and the general public regarding the safety of Tepezza knowing such information was false, misleading, and/or inadequate to warn of the safety risks associated with Tepezza use. Defendant did so willfully, wantonly, and with the intent to prevent the dissemination of information known to it concerning Tepezza's safety.

124. Further, Defendant actively concealed the true risks associated with the use of Tepezza, particularly as they relate to the risk of serious hearing-related injuries, by affirmatively representing in numerous communications that there were no hearing-loss warnings required to safely prescribe and take Tepezza and no permanent hearing-related adverse side effects associated with use of Tepezza. These communications were disseminated to Plaintiff, Plaintiff's healthcare providers, and the general public and included, without limitation, the Package Insert.

125. Due to the absence of any warning by Defendant as to the significant permanent health and safety risks posed by Tepezza, Plaintiff was unaware that Tepezza could cause serious and permanent hearing-related injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

126. Due to the absence of any instructions for how to identify and/or monitor Tepezza patients for potential hearing-related complications, Plaintiff was unaware that Tepezza could cause serious and permanent hearing-related injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

127. Given Defendant's conduct and deliberate actions designed to deceive Plaintiff, Plaintiff's healthcare providers, and the general public with respect to the safety and efficacy of Tepezza, Defendant is estopped from relying on any statute-of-limitations defenses.

VI. CLAIMS

A. Count I: Strict Liability Failure to Warn

128. Plaintiff incorporates all prior allegations as if set forth herein.

129. At all relevant times, Defendant engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Tepezza and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendant.

130. Defendant, as a manufacturer and distributer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field, and further, Defendant knew or should have known that warnings and other clinically relevant information and data that it distributed regarding the risks associated with the use of Tepezza were inadequate.

131. Plaintiff did not have the same knowledge as Defendant, and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physicians.

132. Defendant had a duty to provide adequate warnings and instructions for Tepezza, to use reasonable care to design a product that is not unreasonably dangerous to users, and to adequately understand, test, and monitor its product.

133. Defendant had a continuing duty to provide consumers, including Plaintiff and Plaintiff’s physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with Tepezza as it became or could have become available to Defendant.

134. Defendant marketed, promoted, distributed, and sold an unreasonably dangerous

and defective prescription drug, Tepezza, to health care providers empowered to prescribe and dispense Tepezza to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omission and affirmative misstatements, Defendant misled the medical community about the risk and benefit balance of Tepezza, which resulted in injury to Plaintiff.

135. Defendant knew or should have known through testing, scientific knowledge, advances in the field, published research in major peer-reviewed journals, and its own post-marketing studies, that Tepezza created a risk of serious and potentially irreversible hearing issues, and/or could interfere with normal hearing.

136. Despite the fact that Defendant knew or should have known that Tepezza caused unreasonable and dangerous side effects, it continued to promote and market Tepezza without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

137. Defendant knew or should have known that consumers, Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Defendant's failures.

138. The Tepezza supplied to Plaintiff by Defendant was defective, unreasonably dangerous, and had inadequate warnings or instructions at the time it was sold, and Defendant also acquired additional knowledge and information confirming the defective and unreasonably dangerous nature of Tepezza. Despite this knowledge and information, Defendant failed and neglected to issue adequate warnings that Tepezza causes serious and potentially irreversible hearing issues and/or instructions concerning the need for audiological monitoring and potential discontinuation of use of Tepezza.

139. Defendant's failure to provide adequate warnings or instructions rendered Tepezza

unreasonably dangerous in that it failed to perform as safely as an ordinary patient, prescriber, and/or other consumer would expect when used as intended and/or in a manner reasonably foreseeable by Defendant, and in that the risk of danger outweighs the benefits.

140. Defendant failed to provide timely and adequate warnings to physicians and consumers, including Plaintiff and to Plaintiff's intermediary physicians, in the following ways:

a. Defendant failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiff's physicians to the dangerous risks of Tepezza including, among other things, potentially irreversible hearing issues;

b. Defendant failed to provide adequate post-marketing warnings and instructions after Defendant knew or should have known of the significant risks of, among other things, potentially irreversible hearing issues; and

c. Defendant continued to aggressively promote and sell Tepezza, even after it knew or should have known of the unreasonable risks of potentially irreversible hearing issues from the drug.

141. Defendant had an obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Tepezza, and/or that there existed safer and more or equally effective alternative drug products.

142. By failing to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information, data, and warnings regarding the adverse health risks associated with exposure to Tepezza, and/or that there existed safer and more or equally effective alternative drug products, Defendant breached its duty of reasonable care and safety.

143. By failing to adequately test and research harms associated with Tepezza, and by failing to provide appropriate warnings and instructions about Tepezza use, patients and the medical community—including Plaintiff and Plaintiff's prescribing doctors—were inadequately

informed about the true risk-benefit profile of Tepezza and were not sufficiently aware that serious and potentially irreversible hearing issues might be associated with use of Tepezza. Nor were the medical community, patients, patients' families, or regulators appropriately informed that serious and potentially irreversible hearing issues might be a side effect of Tepezza and should or could be reported as an adverse event.

144. The Tepezza designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective due to inadequate post-marketing surveillance and/or warnings because, even after Defendant knew or should have known of the risks and severe and permanent hearing injuries from receiving Tepezza, it failed to provide adequate warnings to users or consumers of the product and continued to improperly advertise, market and/or promote Tepezza.

145. Tepezza is defective and unreasonably dangerous to Plaintiff and other consumers regardless of whether Defendant had exercised all possible care in its preparation and sale.

146. The foreseeable risk of serious and potentially irreversible hearing issues caused by Tepezza could have been reduced or avoided by Plaintiff, prescribers, and/or other consumers if Defendant had provided reasonable instructions or warnings of these foreseeable risks of harm.

147. Defendant's actions described above were performed willfully, intentionally, and with reckless disregard of the health and safety of Plaintiff and the general public.

148. As a direct and proximate result of Defendant's conduct, including the inadequate warnings, dilution or lack of information, lack of adequate testing and research, and the defective and dangerous nature of Tepezza, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic

losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

B. Count II: Negligent Failure to Warn

149. Plaintiff incorporates all prior allegations as if set forth herein

150. At all relevant times, Defendant had a duty to exercise reasonable care and had the duty of an expert in all aspects of the warning and post-sale warning to assure the safety of Tepezza when used as intended or in a way that Defendant could reasonably have anticipated, and to assure that the consuming public, including Plaintiff and Plaintiff's physicians, obtained accurate information and adequate instructions for the safe use or non-use of Tepezza.

151. Defendant's duty of care was that a reasonably careful designer, manufacturer, seller, importer, distributor, and/or supplier would use under like circumstances.

152. Defendant had a duty to warn Plaintiff, Plaintiff's physicians, and consumers of Tepezza's dangers and serious side effects, including serious and potentially irreversible hearing loss and other clinically relevant information, as it was reasonably foreseeable to Defendant that Tepezza could cause such injuries.

153. At all relevant times, Defendant failed to exercise reasonable care and knew, or in the exercise of reasonable care should have known, that Tepezza had inadequate instructions and/or warnings.

154. Defendant's actions and omissions were negligent and careless, resulting in a breach of the duties set forth above. These acts and omissions include, but are not limited to:

a. Failing to accompany its product with proper and adequate warnings, labeling, or instructions concerning the potentially dangerous, defective, unsafe, and deleterious propensity of Tepezza and of the risks associated with its use, including the severity and potentially irreversible nature of such adverse effects;

b. Disseminating information to Plaintiff and Plaintiff's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;

c. Failing to provide warnings or other information that accurately reflected the symptoms, scope, severity, and permanence of the side effects and health risks;

d. Failure to accompany its product with proper or adequate rate of incidence or prevalence of hearing-related injuries;

e. Failing to adequately test and/or warn about the use of Tepezza, including, without limitations, the possible adverse side effects and health risks caused by using Tepezza;

f. Failure to adequately warn of the risks that Tepezza could interfere with the normal health and hearing;

g. Failure to adequately warn of the risk of serious and potentially irreversible hearing loss;

h. Failure to adequately warn and advise of adverse reactions involving hearing, tinnitus, and other audiologic symptoms;

i. Failure to instruct patients, prescribers, and consumers of the need for audiological monitoring when receiving Tepezza;

j. Failing to provide instructions on ways to safely use Tepezza to avoid injury;

k. Failing to explain the mechanism, mode, and types of adverse events associated with Tepezza;

l. Failing to provide adequate training or information to medical care providers for appropriate use of Tepezza and patients receiving Tepezza;

m. Failing to provide patients and/or physicians with adequate clinically relevant information, data, and warnings regarding the adverse health risks associated with exposure to Tepezza, as it became or could have become known to Defendant;

n. Failing to advise patients and/or physicians that there existed safer and more or equally effective alternative products or treatment options that do not carry the risks posed by Tepezza; and

o. Representing to physicians, including but not limited to Plaintiff's prescribing physicians, that this drug was safe and effective for use.

155. Tepezza was defective and unreasonably dangerous when it left the possession of Defendant in that it contained warnings insufficient to alert patients and prescribing physicians of

the dangerous risks associated with Tepezza, including but not limited to the risk of serious and potentially irreversible hearing loss and tinnitus despite Defendant's knowledge of the risk of these injuries over other TED therapies available.

156. Tepezza was defective due to inadequate post-marketing warnings and instruction because Defendant knew or should have known of the risk and danger of serious bodily harm from the use of Tepezza but failed to provide adequate warning to patients and prescribing physicians of the product, including Plaintiff and Plaintiff's prescribing physician, knowing the product could cause serious injury.

157. Plaintiff was prescribed and used Tepezza for its intended purpose.

158. Plaintiff could not have known about the dangers and hazards presented by Tepezza.

159. The warnings given by Defendant were not accurate, clear, or complete and/or were ambiguous.

160. The warnings, or lack thereof, that were given by Defendant failed to properly warn prescribing physicians, including Plaintiff's prescribing physician, of the risk of serious and potentially irreversible hearing loss and tinnitus, and failed to instruct prescribing physicians to test and monitor for the presence of the injuries for which Plaintiff and others had been placed at risk by using Tepezza.

161. The warnings that were given by Defendant failed to properly warn Plaintiff and prescribing physicians of the prevalence of permanent hearing loss.

162. Plaintiff and Plaintiff's prescribing physicians reasonably relied upon the skill, superior knowledge, and judgment of Defendant. Defendant had a continuing duty to warn Plaintiff and prescribing physicians of the dangers associated with Tepezza. Had Plaintiff received adequate

warnings regarding the risks of Tepezza, Plaintiff would not have used Tepezza. But Defendant failed to communicate adequate warnings and/or instruction for use of Tepezza.

163. Defendant's failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Tepezza was a proximate cause of Plaintiff's injuries and damages, which were foreseeable.

164. Plaintiff's injuries and damages are severe and permanent and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from Defendant.

165. As a direct and proximate result of Defendant's negligence, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

C. Count III: Strict Liability Design Defect

166. Plaintiff incorporates all prior allegations.

167. At all relevant times, Defendant engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Tepezza, and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendant.

168. Defendant, as a manufacturer, designer, distributer, marketer, and promoter of pharmaceutical drugs, had a duty to design a product free from a defective condition that was unreasonably dangerous to Plaintiff.

169. Defendant breached this duty by designing Tepezza in such a way that posed an unreasonable risk of permanent hearing injuries and by placing and keeping Tepezza on the market despite Tepezza's defective condition.

170. Defendant had a duty to create a product that was not unreasonably dangerous for its normal, intended, and foreseeable use. Defendant knew or should have known that Tepezza, which it developed, manufactured, labeled, marketed, sold, and/or promoted, was defectively designed in that it posed a serious risk of severe and permanent hearing injuries.

171. Defendant had a continuing duty to use reasonable care to design a product that is not unreasonably dangerous to users and to adequately understand, test, and monitor its product.

172. Defendant breached that duty when it created a product unreasonably dangerous for its intended and foreseeable use.

173. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product that created an unreasonable risk to the health of consumers, and Defendant is therefore strictly liable for the injuries sustained by Plaintiff.

174. 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.

175. The Tepezza administered to Plaintiff was expected to, and did, reach Plaintiff without substantial change in the condition in which it is sold.

176. The Tepezza administered to Plaintiff was in a condition not contemplated by

Plaintiff in that it was unreasonably dangerous, posing a serious risk of permanent hearing damage.

177. Tepezza is a medication prescribed primarily for TED.

178. Tepezza causes serious and potentially irreversible hearing issues, and/or could interfere with normal health and hearing, thus harming Plaintiff and other consumers.

179. Plaintiff, ordinary consumers, and prescribers would not expect a TED drug designed, marketed, and labeled for eye disease treatment to cause irreversible hearing loss.

180. The Tepezza supplied to Plaintiff by Defendant was defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it had not been adequately tested, was in an unreasonably dangerous and defective condition, and posed a risk of serious and potentially irreversible hearing issues to Plaintiff and other consumers.

181. The Tepezza supplied to Plaintiff by Defendant 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. Balancing the limited utility and high risk of the drug's use, the design of the Tepezza drug makes the product unreasonably dangerous.

182. The design defects render Tepezza more dangerous than other drugs and therapies designed to treat TED and causes an unreasonable increased risk of injury, including but not limited to potentially irreversible hearing loss.

183. Defendant knew or should have known through testing, scientific knowledge, advances in the field, published research in major peer-reviewed journals, its own post-marketing studies, or otherwise, that Tepezza created a risk of serious and potentially irreversible hearing loss and/or could interfere with normal health and hearing.

184. Tepezza is defective and unreasonably dangerous to Plaintiff and other consumers

in that, despite early indications and concerns that Tepezza use could result in permanent hearing damage, Defendant failed to adequately test or study the drug, including but not limited to: pharmacokinetics and pharmacodynamics of the drug, its effects on hearing, the potential effects and risks of long-term use, the potential for inter-patient variability, and/or the potential for a safer effective dosing regimen.

185. Defendant knew or should have known that consumers, and Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Tepezza's defective design.

186. Tepezza is defective and unreasonably dangerous to Plaintiff and other consumers even if Defendant had exercised all possible care in the preparation and sale of Tepezza.

187. Defendant's actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of Plaintiff and the general public.

188. As a direct and proximate result of Defendant's conduct, including the lack of adequate testing and research and the defective and dangerous nature of Tepezza, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

D. Count IV: Negligent Design Defect

189. Plaintiff incorporates all prior allegations.

190. At all relevant times, Defendant had a duty to exercise reasonable care and had the duty of an expert in all aspects of the design, formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, promotion, advertising, sale, testing, and

research to assure the safety of Tepezza when used as intended or in a way that Defendant could reasonably have anticipated, and to assure that the consuming public, including Plaintiff and Plaintiff's physicians, obtained accurate information and adequate instructions for the safe use or non-use of Tepezza.

191. At all relevant times, Defendant failed to exercise reasonable care and meet the duties of an expert and knew, or in the exercise of reasonable care should have known, that Tepezza was not properly manufactured, designed, compounded, tested, inspected, packaged, distributed, marketed, advertised, formulated, promoted, examined, maintained, sold, prepared, monitored, or a combination of these acts.

192. Defendant's actions and omissions were negligent and careless, resulting in a breach of the duties set forth above. These acts and omissions include, but are not limited to:

a. Failing to use due care in developing, testing, designing, monitoring, and manufacturing Tepezza so as to avoid the aforementioned risks to individuals when Tepezza was being used for treatment;

b. Failing to conduct adequate pre-clinical and clinical testing and post- marketing surveillance to determine the safety of Tepezza;

c. Failing to adequately test or study Tepezza, including but not limited to pharmacokinetics and pharmacodynamics of the drug, its effects on hearing, the potential effects of long-term use, the potential for inter- patient variability, and/or the potential for a safer effective dosing regimen;

d. Failing to independently and vigilantly protect against unreasonable health risks posed by Tepezza;

e. Promoting, advertising, marketing, and selling Tepezza without advising that there existed safer and more or equally effective alternative drug products or treatment options; and

f. Designing, manufacturing, and placing into the stream of commerce a product that was unreasonably dangerous for its reasonably foreseeable use, which Defendant knew or should have known could cause injury to Plaintiff.

193. Defendant's negligence and Tepezza's failures arise under circumstances precluding any other reasonable inference other than a defect in Tepezza.

194. Defendant's failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Tepezza was a proximate cause of Plaintiff's injuries and damages, which were foreseeable.

195. Plaintiff's injuries and damages are severe and permanent and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from Defendant.

196. As a direct and proximate result of Defendant's negligence, Plaintiff suffered bodily injury with resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer losses in the future.

E. Count V: Punitive Damages

197. Plaintiff incorporates all prior allegations.

198. Defendant's acts and omissions constituted oppression, fraud, malice, and/or recklessness and were done with advance knowledge, conscious disregard of the safety of others, and/or ratification by Defendant's officers, directors, and/or managing agents.

199. Defendant's actions amounted to actual malice or reckless indifference to the likelihood of harm associated with its acts and omissions.

200. Defendant misled both the medical community and the public, including Plaintiff and Plaintiff's physicians, by making false, misleading, or incomplete representations about the safety and effectiveness of Tepezza and by failing to provide adequate instructions and training

concerning its use.

201. Defendant marketed, promoted, distributed, and sold an unreasonably dangerous and defective prescription drug to healthcare providers empowered to prescribe and dispense Tepezza to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data and misled the medical community about the need for and the risk-benefit balance of Tepezza, which resulted in injury to Plaintiff.

202. Defendant downplayed, understated, and/or disregarded its knowledge of the serious and permanent side effects and risks associated with the use of Tepezza despite available information demonstrating that drug could interfere with normal health and hearing and cause potentially irreversible hearing loss and tinnitus.

203. Defendant were or should have been in possession of evidence demonstrating that Tepezza use could interfere with the normal health and hearing, cause irreversible damage to hearing, and cause tinnitus. Nevertheless, Defendant continued to market Tepezza by providing false and misleading information regarding its safety and effectiveness.

204. Defendant failed to provide warnings that would have dissuaded health care professionals from using Tepezza, thus preventing health care professionals, including Plaintiff's prescribing physician, and consumers, including Plaintiff, from weighing the true risks against the benefits of using Tepezza.

205. Defendant knew or should have known that consumers, and Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Tepezza's negligent failure to warn, negligent design, and/or negligent marketing, and consciously, deliberately and callously disregarded that knowledge in favor of maximizing sales and profits.

206. As a direct and proximate result of Defendant's acts and omissions, Plaintiff suffers

from hearing loss and other auditory symptoms caused by Plaintiff receiving Tepezza.

207. As a result of Plaintiff's injuries, Plaintiff has endured substantial pain and suffering, has incurred significant expenses for medical care, and will remain economically challenged and emotionally harmed.

208. Plaintiff has suffered and will continue to suffer economic loss and emotional harm.

209. Defendant's actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff and the public.

210. Plaintiff's injuries and damages are severe, permanent, and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from Defendant.

211. Defendant's conduct was committed with knowing, conscious, deliberate, or reckless disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendant and deter it from similar conduct in the future.

212. Consequently, Defendant is liable for punitive damages in an amount to be determined by the jury.

PRAYER FOR RELIEF

Plaintiff respectfully prays for the following relief:

a. Enter judgment in Plaintiff's favor on each claim;

b. Award Plaintiff compensatory damages for each of the following categories of harm:

i. Medical expenses (both to purchase Tepezza and resulting from its use);

ii. Pain and suffering;

iii. Mental anguish, anxiety, and discomfort;

iv. Physical impairment; and

v. Loss of enjoyment of life;

c. Award Plaintiff pre- and post-judgment interest;

d. Award exemplary and punitive damages;

e. Award reasonable and necessary attorneys' fees, costs, and expenses, of suit along with pre-judgment interest on those sums; and

f. Award such other relief to which Plaintiff may be justly entitled.

JURY DEMAND

Plaintiff demands a trial by jury as to all claims so triable.

Date: April 20, 2023

Respectfully submitted,

/s/ Mark A. DiCello
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**Pro Hac Vice to be filed*