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UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA

JENNIFER BURNS, Plaintiff, v. SANOFI US SERVICES, INC. f/k/a SANOFI-AVENTIS U.S., INC., and SANOFI-AVENTIS U.S., LLC, Defendants.	Case No. **COMPLAINT** JURY TRIAL DEMANDED

Plaintiff Jennifer Burns, for her Original Complaint against Defendants SANOFI US SERVICES, INC., f/k/a SANOFI-AVENTIS U.S., INC. and SANOFI-AVENTIS U.S., LLC (collectively "Sanofi"), alleges:

I. INTRODUCTION

1. Sanofi manufactures and sells a chemotherapy drug named Taxotere (generic name docetaxel), which is administered to many who suffer primarily from breast cancer. While it is one of many drugs effective at treating breast cancer, Sanofi has known for years that the drug carries a significant risk of causing permanent damage to the lacrimal system, including canalicular stenosis.

2. A simple preventative procedure at the onset of chemotherapy-induced tearing, involving the temporary placement of silicone stents, allows a patient to continue her Taxotere regimen while removing the likelihood of permanent damage to the lacrimal system. Although Sanofi warns that "excessive tearing which may be attributable to lacrimal duct obstruction has been reported," Sanofi failed to warn patients and oncologists of the risk that the damage can occur quickly and can be **permanent.** Further, Sanofi failed to report the severity and frequency of this risk to the Food and Drug Administration ("FDA"). Worse, Sanofi misled patients and oncologists about the severity and frequency of this devastating side effect even though this condition can be entirely preventable with early intervention and treatment during chemotherapy. As a result, Mrs. Burns suffers from permanent injuries because she used Taxotere.

3. Plaintiff is grateful for the chemotherapy that helped to save her life; however, that gratitude is diminished by the fact that she now must endure a permanent and life-altering condition that could have been prevented with an adequate warning to her physicians. Plaintiff's permanent injuries to her lacrimal system, specifically canalicular stenosis, cause daily disruption to her life due to excessive tearing, or epiphora. For those who have never experienced epiphora, the condition might seem like a minor annoyance. However, for cancer survivors like Mrs. Burns, the irritated, swollen, watering eyes and the ongoing medical management of the condition affect their work, their self-esteem, interpersonal relationships, daily activities like driving or reading a book, and their general ability to return to a normal life after defeating cancer.

II. PARTIES

A. Plaintiff

4. Plaintiff Jennifer Burns is an individual residing in Woodland Hills, California who received Taxotere as part of a chemotherapy regimen after being diagnosed with breast cancer. She was

administered Taxotere at Kaiser Permanente in Woodland Hills, California. She was prescribed weekly treatment and received a total of twelve rounds of chemotherapy with Taxotere. During chemotherapy, she complained of excessively watery eyes. Mrs. Burns was told that her watery eyes were a side effect of the chemotherapy. Unfortunately, because no measures were taken to intervene, the epiphora continued and she was ultimately diagnosed with permanent canalicular stenosis.

B. Sanofi Defendants

5. Defendant Sanofi US Services Inc. f/k/a Sanofi-Aventis U.S. Inc. is a Delaware corporation, with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi US Services Inc. is a wholly owned subsidiary of Sanofi S.A. Sanofi S.A. is engaged in research and development, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of prescription drugs, including Taxotere. Defendant Sanofi US Services Inc. engages in research and development, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of prescription drugs, including Taxotere.

6. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company, with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC is a wholly owned subsidiary of Defendant Sanofi S.A., and Sanofi S.A. is Sanofi-Aventis U.S., LLC's sole member. Defendant Sanofi-Aventis U.S. LLC engages in research and development, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of prescription drugs, including Taxotere.

7. Since 2006, defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. have collectively served as the U.S. operational front for Sanofi S.A. in the U.S. prescription drug market.

III. JURISDICTION AND VENUE

8. Federal subject matter jurisdiction is based on 28 U.S.C. §1332(a) due to the complete diversity of Mrs. Burns and Defendants and the amount in controversy exceeds $75,000.

9. A substantial part of the acts and omissions giving rise to this cause of action occurred in this district and therefore venue is proper here pursuant to 28 U.S.C. §1391(a).

10. The Sanofi Defendants are subject to personal jurisdiction in this Court due to their ongoing and substantial contacts in this forum.

IV. FACTUAL ALLEGATIONS

A. Development and Approval of Taxotere (Docetaxel)

11. Taxotere is a drug used in the treatment of various forms of cancer, including breast cancer, and is a part of a family of cytotoxic drugs referred to as taxanes. Taxanes are derived from yew trees, and unlike other cytotoxic drugs, taxanes inhibit the multiplication of cancer cells by over-stabilizing the structure of a cancer cell, which prevents the cell from breaking down and reorganizing for cell reproduction. They are widely used as chemotherapy agents.

12. The FDA approved Taxotere on May 14, 1996 for limited use—namely, for the treatment of patients with locally advanced or metastatic breast cancer that had either (1) progressed during anthracycline-based therapy or (2) relapsed during anthracycline-based adjuvant therapy.

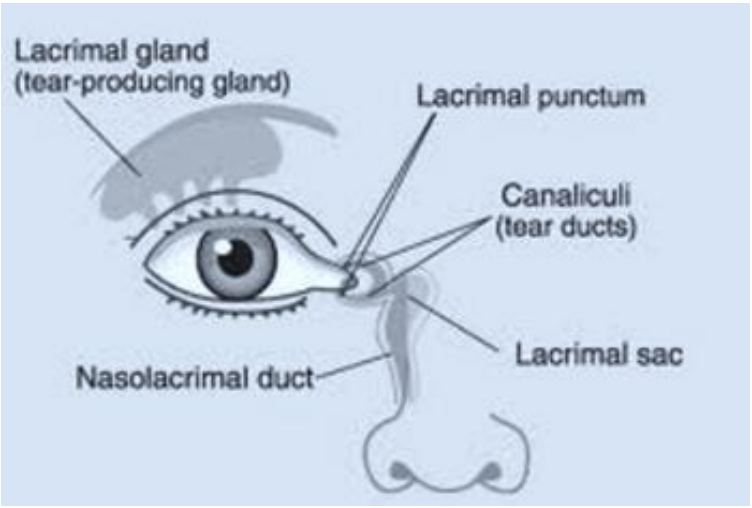
13. In August 2004, Sanofi obtained FDA approval for an expanded use of Taxotere "in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-positive breast cancer." This resulted in a greater number of patients being treated with Taxotere.

14. As the universe of patients taking Taxotere expanded to include patients with a higher survivability rate, more cancer survivors taking Taxotere would now experience a permanent disabling (but preventable) condition – namely, permanent damage to the lacrimal system.

15. Taxotere is not purchased by patients at a pharmacy; rather, patients' use of this drug occurs via administration through injection and/or intravenously at a physician's office or medical treatment facility.

B. Anatomy of Lacrimal System

16. The following image depicts the anatomy of the lacrimal system.



17. Taxotere is secreted in the tear film, thereby causing fibrosis in areas of the lacrimal system, including the puncta, canaliculus and/or nasolacrimal duct. This scarring can cause permanent occlusion, causing an inability for tears to drain naturally through the lacrimal system. Because the eyes are constantly producing tears, this results in persistent epiphora.

C. Taxotere's Labeling

18. At the time Mrs. Burns was administered Taxotere, its labeling information stated in relevant part under **Post-Marketing Experiences**:

> **Ophthalmologic**: conjunctivitis, lacrimation or lacrimation with or without conjunctivitis. Excessive tearing which may be attributable to lacrimal duct obstruction has been reported. Rare cases of transient visual disturbances (flashes, flashing lights, scotomata) typically occurring during drug infusion and in association with hypersensitivity reactions have been reported. These were reversible upon discontinuation of the infusion.

and under **Patient Counseling Information**:[1]

> • Explain to patients that side effects such as nausea, vomiting, diarrhea, constipation, fatigue, excessive tearing, infusion site reactions, and hair loss are associated with docetaxel administration.

19. Additionally, in the *Patient Information* section of the label, Sanofi includes "redness of the eye, excess tearing" among "the most common side effects of Taxotere." *Id.* Sanofi's inclusion of this potentially permanent side effect in a laundry list of common but notably transitory side effects effectively misrepresents the risk of harm associated with tearing. By failing to fully inform patients and physicians of the potential for serious permanent damage to the lacrimal system, Sanofi downplays the significance of the underlying injury causing the patient to tear.

20. Sanofi's labeling information at all times relevant to this lawsuit, and even to date, does not identify the risk of stenosis as a cause of excessive tearing, the rapid onset at which stenosis can occur, the potentially permanent nature of the injury, the need to refer patients to a lacrimal specialist, nor does it identify the condition as preventable with timely intervention during chemotherapy.

21. Sanofi did not provide such adequate notice to oncologists. To the contrary, the labeling leads oncologists, like Mrs. Burns's, to believe that excessive tearing is merely a transitory side effect and will

[1] https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020449s063lbl.pdf

end after the cessation of chemotherapy. This failure to provide notice resulted in thousands of women, like Mrs. Burns, suffering daily from a permanent condition that could have easily been prevented with adequate warning.

D. Sanofi's Duty to Monitor and Update Labeling

22. The primary responsibility for timely communicating complete, accurate, and current safety and efficacy information related to Taxotere rests with Sanofi because it has superior, and in many cases exclusive, access to the relevant safety and efficacy information, including post-market complaints and data.

23. To fulfill its essential responsibilities, Sanofi must vigilantly monitor all reasonably available information. It must closely evaluate the post-market clinical experience of its drugs and timely provide updated safety and efficacy information to the healthcare community and to consumers.

24. When monitoring and reporting adverse events, as required by both federal regulations and state law, time is of the essence. The purpose of monitoring a product's post-market experience is to detect potential safety signals that could indicate to drug sponsors and the medical community that a public safety problem exists.

25. If, for example, a manufacturer was to delay reporting post-market information, that delay could mean that researchers, FDA, and the medical community are years behind in identifying a public safety issue associated with the drug.

26. In the meantime, more patients are harmed by using the product without knowing, understanding, and accepting its true risks, which is why drug sponsors must not only completely and accurately monitor, investigate and report post-market experiences, but must also report the data in a timely fashion.

27. A drug is "misbranded" in violation of the FDCA when its labeling is false and misleading or does not provide adequate directions for use and adequate warnings. *See* 21 U.S.C. §§ 321(n); 331(a), (b), (k); 352(a), (f). A drug's labeling satisfies federal requirements if it gives physicians and pharmacists sufficient information—including indications for use and "any relevant hazards, contraindications, side effects, and precautions"—to allow those professionals "to use the drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.100(c)(1).

28. As part of their responsibility to monitor post-market clinical experiences with the drug and

provide updated safety and efficacy information to the healthcare community and to consumers, each approved NDA applicant "must promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, post marketing clinical investigations, post marketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers." 21 C.F.R. § 314.80(b).

29. Any report of a "serious and unexpected" drug experience, whether foreign or domestic, must be reported to the FDA within 15 days and must be promptly investigated by the manufacturer. 21 C.F.R. § 314.80(c)(1)(i-ii).

30. Most other adverse event reports must be submitted quarterly for three years after the application is approved and annually thereafter. 21 C.F.R. § 314.80(c)(2)(i). These periodic reports must include a "history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated)." 21 C.F.R. § 314.80(c)(2)(ii).

31. Federal law requires labeling to be updated as information accumulates: "labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." 21 C.F.R. § 201.57(c)(6)(i). Thus, for example, drug manufacturers must warn of an adverse effect where there is "some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." 21 C.F.R. § 201.57(c)(7).

32. All changes to drug labels require FDA assent. 21 C.F.R. § 314.70(b)(2)(v)(A). Brand-name drug sponsors may seek to change their approved labels by filing a supplemental application. 21 C.F.R. § 314.70.

33. One regulation, the "Changes Being Effected" (CBE) regulation, permits a manufacturer to unilaterally change a drug label to reflect "newly acquired information," subject to later FDA review and approval. 21 C.F.R. § 314.70(c)(6)(iii). Newly acquired information includes "new analyses of previously submitted data." 21 C.F.R. § 314.3(b).

34. Thus, for instance, if a drug sponsor determined that a warning was insufficient based on a new analysis of previously existing data, it could submit a CBE and change its labeling.

35. The longer a drug sponsor delays updating its labeling to reflect current safety information, the more likely it is that medical professionals will prescribe the drug without advising patients of harmful adverse reactions, and the more likely it is that patients will suffer harmful side effects without the opportunity to evaluate risks for themselves.

E. Sanofi Knew That Taxotere Can Cause Permanent Canalicular Stenosis.

36. Since 2002, Sanofi's Taxotere label has advised that "excessive tearing which may be attributable due to lacrimal obstruction has been reported."[2] Despite this language, medical literature has continued to accumulate and raise concerns that oncologists are not being properly warned of the severity of this permanent side effect – and in response, Sanofi has done nothing to notify oncologists or patients.

37. The following studies, published after 2002, highlight concerns of the increased frequency and severity of permanent stenosis in cancer patients taking Taxotere, the increased need for monitoring, and the lack of awareness among oncologists and their patients regarding the true nature of the damage caused:

a) From *American Society of Ophthalmic Plastic and Reconstructive Surgery*:

> Better education of oncologists who prescribe docetaxel is needed as we continue to encounter new cases of advanced canalicular blockage.[3]

b) From *American Cancer Society*:

> Despite the previous publication of several articles by our group regarding canalicular stenosis and lacrimal obstruction resulting from docetaxel therapy, we still frequently encounter advanced cases of this condition because of delayed diagnosis. Thus it appears that oncologists need to become better educated regarding this side effect.
>
> All patients receiving weekly docetaxel should be monitored closely by an ophthalmologist so that the timely management of canalicular stenosis can be offered.

[2] https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020449s063lbl.pdf

[3] Bita Esmaeli, et al., *Docetaxel-Induced Histologic Changes in the Lacrimal Sac and Nasal Mucosa*, 19 OPTHALMIC PLASTIC AND RECONSTRUCTIVE SURGERY 4, pp. 305-308 (2003)

> We recommend silicone intubation [stents] in all symptomatic patients who are receiving weekly docetaxel if they are to continue receiving the drug.[4]

c) From *Pharmacotherapy*:

> Moreover, epiphora may be an underrecognized adverse effect of docetaxel because excess tearing after chemotherapy administration is not as stringently monitored as life-threatening toxicities . . . This adverse effect warrants evaluation because weekly administration is being used more commonly for the treatment of advanced solid tumors, and epiphora can interfere with the activities and quality of daily life.[5]

d) From the *Journal of Clinical Oncology*:

> Despite substantial literature documenting canalicular stenosis as an adverse effect of docetaxel, the exact incidence of this important adverse effect is unknown. All previous publications were based on retrospective studies at tertiary ophthalmology practices, and only patients whose symptoms of epiphora were evaluated. We report the finding of prospective, single-center study designed to determine the incidence and severity of epiphora and its anatomic correlate, canalicular stenosis, in patients receiving docetaxel weekly or every 3 weeks.
>
> Previous retrospective studies and our clinical experience suggested that the incidence of epiphora might be as high as 50% in patients treated with weekly docetaxel and less than 10% in patients who receive docetaxel every 3 weeks.
>
> In this prospective, observational study, epiphora was seen in 64% of patients in the weekly docetaxel group and in 39% of the docetaxel every 3 weeks group.
>
> Patients who experience epiphora associated with docetaxel should be promptly referred to an ophthalmologist familiar with this adverse effect. Frequent [approximately every 4-6 weeks] probing and irrigation in the office and judicious use of topical steroids on a tapering dose can eliminate the need for silicone intubation or other lacrimal procedures in

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[4] Bita Esmaeli, et al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*, 98 CANCER 504-7 (2003)

[5] Polly Kintzel, et al., *Docetaxel-related Epiphora*, 26 PHARMACOTHERAPY 6 (2006).

> approximately 80% of patients taking docetaxel every 3 weeks and in approximately 50% of patients taking docetaxel weekly. [6]

38. Prominent medical researchers have described this side effect as follows: "canalicular stenosis may be the most important side effect of weekly docetaxel;"[7] "cancer patients . . . view epiphora as one of the worst side effects because of their inability to read, drive, or wear make-up;"[8] "visually disabling;"[9] "misleading appearance of emotional tears;"[10] "canalicular stenosis can negatively impact the quality of life . . . and should be considered when choosing the chemotherapy regimen;"[11] "epiphora may be a major disability. It interferes with daily activities and causes emotional disturbances;"[12] "the potential risk of this complication should be carefully weighed;"[13] "epiphora may be an underrecognized adverse effect;"[14] and "the high incidence of this adverse effect has an impact on several aspects of daily living."[15]

39. Medical literature is clear that: (1) the onset of damage to the lacrimal system can be rapid upon

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[6] Bita Esmaeli, et al., *Prospective Study of Incidence and Severity of Epiphora and Canalicular Stenosis in Patients With Metastatic Breast Cancer Receiving Docetaxel*, 24 JOURNAL OF CLINICAL ONCOLOGY 22 (2006).

[7] Bita Esmaeli, et. al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*, 98 AM. CANCER SOC'Y., 504 (2003).

[8] *Id.*

[9] Bita Esmaeli, et. al., *Canalicular Stenosis Secondary to Weekly versus Every-3-Weeks Docetaxel in Patients with Metastatic Breast Cancer*, 109 AM ACAD. OF OPHTHALMOLOGY, 1188 (2002).

[10] Bita Esmaeli, et. al., *Canalicular Stenosis Secondary to Weekly Docetaxel: A Potentially Preventable Side Effect*, 13 EUROPEAN SOC'Y. FOR MED. ONCOLOGY, 218 (2001).

[11] Bita Esmaeli, et. al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*, 98 AM. CANCER SOC'Y., 504 (2003).

[12] Medy Tsalic, et al., *Epiphora (Excessive Tearing) and Other Ocular Manifestations Related to Weekly Docetaxel*, 23 MEDICAL ONCOLOGY (2005).

[13] *Id.*

[14] Polly Kintzel, et al., *Docetaxel-related Epiphora*, 26 PHARMACOTHERAPY 6 (2006).

[15] Arlene Chan, et al., *Prevalence of Excessive Tearing in Women with Early Breast Cancer Receiving Adjuvant Docetaxel-based Chemotherapy*, 31 JOURNAL OF CLINICAL ONCOLOGY, 17 (2013)

initiation of Taxotere administration, (2) immediate referral to a lacrimal specialist for monitoring is essential, (3) damage to the lacrimal system can be permanent, (4) this side effect is preventable, and (5) oncologists are not aware of the severity of this side effect. Unfortunately this lack of awareness often results in oncologists counseling their patients that their tearing is a temporary side effect and will eventually subside.

F. Taxotere Caused Mrs. Burns' Permanent Canalicular Stenosis

40. Mrs. Burns was diagnosed with breast cancer and given chemotherapy with Taxotere, receiving a total of twelve infusions over the course of four months.

41. At her sixth Taxotere infusion, Mrs. Burns notified her oncologist that she was experiencing severe watery eyes. Although he visited her during her chemotherapy session, he did not advise her to seek treatment from a lacrimal specialist. The next day, she scheduled an appointment with an optometrist who diagnosed her with dry eye and advised her that watery eyes were a side effect of chemotherapy.

42. After completing chemotherapy, Mrs. Burns reported to her physician that the persistently tearing eyes were her primary concern, and two weeks after her final Taxotere infusion she was referred to an ophthalmologist. The ophthalmologist inserted punctal plugs in an attempt to alleviate the tearing; however, the near constant tearing continued.

43. Three and a half months after her last chemotherapy treatment, Mrs. Burns saw an oculoplastic surgeon, who diagnosed her with canaliculus obstruction in both eyes. She was advised that Taxotere had caused scarring in her tear ducts and was causing her eyes to excessively tear.

44. Over the next several months, Mrs. Burns endured multiple surgeries involving tube insertion but the tubes continued to migrate into her nose and the tearing persisted. Subsequently, a left eye tube was removed and was unable to be reinserted after persistent infections in that eye. Her medical records indicate that her right eye continued to tear as well, despite the repeated surgeries.

45. Mrs. Burns completed chemotherapy and was excited to be cancer free and rid of all of the side effects she suffered as a result of the cancer treatment. Among these, Mrs. Burns looked forward to no longer suffering from constantly irritated, watering eyes. But as the effects of chemotherapy wore off, her watery eyes remained.

46. Mrs. Burns continues to experience persistent tearing and a disruption of her life. As a direct and proximate result of Sanofi's conduct in connection with the design, development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, warning, and sale of Taxotere, Mrs. Burns suffers from epiphora due to permanent canalicular stenosis. This condition is a known permanent side effect of taking Taxotere.

47. As a result of this permanent side effect, Mrs. Burns has struggled to return to normalcy, even after surviving cancer, because she continues to suffer from persistent tearing on a daily basis, interfering with her ability to perform basic activities and enjoy life. This permanent change has altered Mrs. Burns's self-image, negatively impacted her relationships, and others' perceptions of her, leading to social isolation and depression even long after fighting cancer.

48. When Mrs. Burns underwent chemotherapy with Taxotere, her eyes unexpectedly became irritated and red and began to tear constantly. Throughout her ordeal, Mrs. Burns remained hopeful that, like other chemotherapy side effects, the epiphora would eventually resolve. Indeed, she was advised that the tearing would get better. To her dismay, it never has.

49. Mrs. Burns's tearing impacts all aspects of her daily life. Prior to developing permanent canalicular stenosis, Mrs. Burns was self-confident and enjoyed social and professional interactions with other people. Now she lacks the confidence she previously enjoyed.

50. Mrs. Burns is anxious about social interactions because she fears people will perceive her as sad and crying. Her tears spill out over her cheeks, making her skin irritated and she is unable to keep makeup on her face. She is aware of the concerned looks from well-intentioned friends, colleagues and strangers who perceive her to be emotional and upset.

51. Throughout her ordeal, Mrs. Burns was advised that, like other chemotherapy side effects, the epiphora would eventually resolve and was reassured that the treatments would work. Mrs. Burns was advised by her healthcare providers that the epiphora could be fixed and no one advised this may be a condition she would have to live with the rest of life.

52. Mrs. Burns's injuries could have been prevented had Sanofi simply warned that permanent canalicular stenosis is a common but preventable side effect of Taxotere. Specifically, had Sanofi properly warned Mrs. Burns's oncologist of the rapid onset of permanent damage, her oncologist would

have referred her to a lacrimal specialist immediately at the onset of her symptoms, rather than advising her that the symptoms would go away when she completed her chemotherapy. Mrs. Burns thus seeks recovery for her mental and physical suffering stemming from permanent, but easily preventable, canalicular stenosis.

53. Mrs. Burns files this lawsuit within the applicable statute of limitations.

G. Tolling of the Statute of Limitations.

54. Alternatively, Mrs. Burns files this lawsuit within the applicable statute of limitations period of first suspecting that Sanofi's wrongful conduct caused the appreciable harm she sustained. Due to Sanofi's fraudulent concealment of the true nature of "excessive tearing which may be attributable to lacrimal duct obstruction," Mrs. Burns could not, by the exercise of reasonable diligence, have discovered that Sanofi wrongfully caused her injuries since she was unaware of the severity and permanency of her injury. Specifically in its warning label, which Sanofi intended for oncologists to read and rely on, Sanofi fraudulently concealed (1) the rapid onset at which stenosis can occur, (2) the potentially permanent nature of the injury, (3) the need to immediately refer patients to a lacrimal specialist and (4) that the condition is highly preventable with timely intervention during chemotherapy. As a result, Mrs. Burns was unaware that Sanofi knew of the devastating and permanent consequences of stenosis, or that Sanofi concealed this information from her oncologist. Because Mrs. Burns's oncologist was unaware of the permanent nature of this side effect, Mrs. Burns was also unaware that her condition was permanent.

55. Sanofi to this day does not warn that Taxotere can cause permanent obstruction of the lacrimal system. Therefore Mrs. Burns did not suspect, nor did she have reason to suspect, that she had been permanently injured. Furthermore, Mrs. Burns did not and could not suspect the tortious nature of the conduct causing her injuries until a date before filing this action that is less than the applicable limitations period for filing suit.

56. Upon presentation of tearing, Mrs. Burns was advised that tearing was a common side effect of Taxotere chemotherapy that, like most other side effects of chemotherapy, would resolve.

57. In February of 2020, a friend reached out to Mrs. Burns after seeing a blog post on the website of the law firm of Hotze Runkle, PLLC regarding Sanofi's negligence in failing to warn of the risk of canalicular stenosis. Only then did Mrs. Burns discover that the manufacturers of Taxotere were aware

of permanent canalicular stenosis, but they intentionally withheld this information from healthcare practitioners and consumers. Mrs. Burns felt as though she had an epiphany. For the first time, based on the information she read on the law firm's website, she appreciated that the manufacturer of her chemotherapy drug failed to inform her and her oncologist of the risk of permanent damage to her lacrimal system, as well as its knowledge that her injury could have been prevented. Mrs. Burns could not have discovered Sanofi's wrongdoing earlier, because to this date, Sanofi's warning fails to fully advise of the nature of the injury, resulting in oncologists and their patients remaining in the dark. Mrs. Burns was only able to discover that her tearing was never going to go away after Hotze Runkle published these facts on the internet.

58. Additionally, Mrs. Burns was prevented from discovering this information at an earlier date because Sanofi: (1) misrepresented to the public, the FDA, and the medical profession the permanent nature of "lacrimal duct obstruction;" (2) failed to disclose to the public, the FDA, and the medical profession its knowledge of the risk of permanent but reversible side effects; (3) failed to disclose to the public, the FDA, and the medical profession its knowledge that these side effects were preventable with early intervention during chemotherapy; (4) fraudulently concealed facts and information that could have led Mrs. Burns to discover Sanofi's liability; and (5) still has not disclosed to the public, the FDA, and the medical profession that Taxotere can cause permanent punctal, canalicular and nasolacrimal duct stenosis which can be prevented with early intervention during chemotherapy.

COUNT I – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)

59. Mrs. Burns incorporates by reference the above paragraphs as if set forth herein.

60. At all relevant times, Sanofi was in the business of designing, researching, manufacturing, testing, promoting, marketing, selling, and/or distributing pharmaceutical products, including the Taxotere used by Mrs. Burns.

61. The Taxotere designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Sanofi failed to provide adequate warnings to users and their healthcare providers, including Mrs. Burns and her healthcare providers, of the risk of side effects associated with the use of Taxotere, particularly the risk of developing disfiguring, permanent canalicular stenosis, or the measures that could have been taken to prevent it. The Taxotere designed,

formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Sanofi and ultimately administered to Mrs. Burns lacked such warnings when it left Sanofi's control.

62. The risks of developing disfiguring, permanent canalicular stenosis were known to or reasonably knowable by Sanofi at the time the Taxotere left Sanofi's control, because of "newly acquired information" available to Sanofi after the 2002 label change.

63. A reasonably prudent company in the same or similar circumstances would have provided a warning that communicated the dangers and safe use of Taxotere.

64. Any warnings actually provided by Sanofi did not sufficiently and/or accurately reflect the symptoms, type, scope, severity, and/or duration of these side effects, particularly the risks of developing disfiguring, permanent canalicular stenosis or how it could have been prevented during administration of the chemotherapy.

65. Without adequate warning of these side effects, Taxotere is not reasonably fit, suitable, or safe for its reasonably anticipated or intended purposes.

66. Mrs. Burns was a reasonably foreseeable user of Taxotere who used the drug in a reasonably anticipated manner.

67. Mrs. Burns would have taken preventative measures during the course of her chemotherapy to prevent canalicular stenosis had she (and her physicians) been provided an adequate warning by Sanofi of the risk of these side effects.

68. As a direct and proximate result of Sanofi's failure to warn of the potentially severe adverse effects of Taxotere, Mrs. Burns suffered and continues to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including canalicular stenosis; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Plaintiff Jennifer Burns respectfully requests judgment in her favor and against

Defendants in an amount that exceeds $75,000, plus the costs of this suit and any other and further relief this Court deems just and proper.

COUNT II - NEGLIGENCE

69. Mrs. Burns incorporates by reference the above paragraphs as if set forth herein.

70. Sanofi had a duty to exercise reasonable care in the design, research, formulation, manufacture, production, marketing, testing, supply, promotion, packaging, sale, and/or distribution of Taxotere, including a duty to assure that the product would not cause users to suffer unreasonable, disfiguring, and dangerous side effects.

71. Sanofi breached these duties when it put Taxotere into interstate commerce, unreasonably and without adequate and/or proper warning to Mrs. Burns and her healthcare providers, a product that Sanofi knew or should have known created a high risk of unreasonable, disfiguring, and dangerous side effects.

72. The negligence of Sanofi, its agents, servants, and/or employees, included but was not limited to, the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, and/or designing Taxotere without thoroughly, adequately, and/or sufficiently testing it — including pre-clinical and clinical testing and post-marketing surveillance — for safety and fitness for use and/or its dangers and risks;

(b) Marketing Taxotere to Mrs. Burns, her healthcare providers, the public, and the medical and healthcare professions without adequately and correctly warning and/or disclosing the existence, severity, and duration of known or knowable side effects, including permanent canalicular stenosis;

(c) Marketing Taxotere to the public, and the medical and healthcare professions without providing adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Taxotere;

(d) Advertising and recommending the use of Taxotere without sufficient knowledge of its safety profile;

(e) Designing, manufacturing, producing, and/or assembling Taxotere in a manner that was dangerous to its users;

(f) Concealing information from Mrs. Burns, her healthcare providers, the public, other medical and healthcare professionals, and the FDA that Taxotere was unsafe, dangerous, and/or non-conforming with FDA regulations;

(g) Concealing from and/or misrepresenting information to Mrs. Burns, her healthcare providers,

other medical and healthcare professionals, and/or the FDA concerning the existence and severity of risks and dangers of Taxotere; and

(h) Encouraging the sale of Taxotere, either directly or indirectly, orally or in writing, to Mrs. Burns and her healthcare providers without warning about the need for more comprehensive and regular medical monitoring than usual to ensure early discovery of potentially serious side effects such as punctal, canalicular and nasolacrimal duct stenosis.

73. Despite the fact that Sanofi knew or should have known that Taxotere caused unreasonably dangerous side effects, Sanofi continues to market, manufacture, distribute, and/or sell Taxotere to consumers.

74. Mrs. Burns and her healthcare providers were therefore forced to rely on safety information that did not accurately represent the risks and benefits associated with the use of Taxotere and measures that could have been taken to prevent severe and permanent disfigurement from the use of Taxotere.

75. Sanofi knew or should have known that consumers such as Mrs. Burns would use its product and would foreseeably suffer injury as a result of Sanofi's failure to exercise reasonable care, as set forth above.

76. Sanofi's negligence was a proximate cause of Mrs. Burns's injuries, harms, damages, and losses, in connection with the use of Taxotere, including but not limited to: past and future medical expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement including permanent canalicular stenosis; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Jennifer Burns respectfully requests judgment in her favor and against Defendants in an amount that exceeds $75,000, plus the costs of this suit and any other and further relief this Court deems just and proper.

COUNT III – NEGLIGENT MISREPRESENTATION

77. Mrs. Burns incorporates by reference the above paragraphs as if set forth herein.

78. Sanofi had a duty to represent to Mrs. Burns, her healthcare providers, the healthcare community, and the public in general that Taxotere had been tested and found to be safe and effective for the treatment of various forms of cancer.

79. When warning of safety and risks of Taxotere, Sanofi negligently represented to Mrs. Burns, her healthcare providers, the healthcare community, and the public in general that Taxotere had been tested and was found to be safe and/or effective for its indicated use.

80. Sanofi concealed its knowledge of Taxotere defects from Mrs. Burns, her healthcare providers, and the public in general and/or the healthcare community specifically.

81. Sanofi concealed this information with the intent of defrauding and deceiving Mrs. Burns, her healthcare providers, the public in general, and the healthcare community in particular, and were made with the intent of inducing Mrs. Burns, her healthcare providers, the public in general, and the healthcare community in particular, to recommend, dispense, and/or purchase Taxotere.

82. Sanofi failed to exercise ordinary and reasonable care in its representations of Taxotere in its sale, testing, quality assurance, quality control, and/or distribution into interstate commerce, and Sanofi negligently misrepresented Taxotere's high risks of unreasonable, dangerous side effects. These side effects were unreasonable because they could have been entirely prevented with adequate warning.

83. Sanofi breached its duty in misrepresenting Taxotere's serious side effects to Mrs. Burns, her healthcare providers, the healthcare community, the FDA, and the public in general.

84. Mrs. Burns and her healthcare providers reasonably relied on Sanofi to fulfill its obligations to disclose all facts within its knowledge regarding the serious side effects of Taxotere and the ability to prevent those side effects with appropriate precautionary measures.

85. As a direct and proximate result of the foregoing acts and omissions, Sanofi caused Mrs. Burns to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent canalicular stenosis; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Jennifer Burns respectfully requests that judgment in her favor and against Defendants in an amount that exceeds $75,000, plus the costs of this suit and any other and further relief

this Court deems just and proper.

COUNT IV – FRAUDULENT MISREPRESENTATION

86. Mrs. Burns incorporates by reference the above paragraphs as if set forth herein.

87. In its labeling information, Sanofi communicated to Mrs. Burns, her healthcare providers, the healthcare community, and the public in general that "excessive tearing which may be attributable to lacrimal duct obstruction has been reported" and that excessive tearing is a common side effect. These statements misrepresented the true risk of harm to patients, in that they failed to fully inform oncologists and patients of (1) the rapid onset at which stenosis can occur, (2) the potentially **permanent** nature of the injury, (3) the need to immediately refer patients to a lacrimal specialist and (4) that the condition is highly preventable with timely intervention during chemotherapy.

88. Despite having knowledge of this side effect, Sanofi fraudulently omitted from this vague warning of "lacrimal duct obstruction" and/or "excessive tearing" that Taxotere could and did cause **permanent** damage to the lacrimal system, including canalicular stenosis.

89. These representations were material and false.

90. Sanofi made these representations and omissions:

(a) with knowledge or belief of their falsity, and/or in the case of omissions, with knowledge or belief of falsity of the resulting statements;

(b) positively and recklessly without knowledge of their truth or falsity;

(c) with knowledge that they were made without any basis; and/or

(d) without confidence in the accuracy of the representations or statements resulting from the omissions.

91. Sanofi made these false representations with the intention or expectation that Mrs. Burns, her healthcare providers, the public in general, and the healthcare community in particular, would recommend, dispense, and/or purchase Taxotere, all of which evidenced a callous, reckless, willful, wanton, and depraved indifference to the health, safety, and welfare of Mrs. Burns.

92. At the time Sanofi made the aforesaid representations, and, at the time Mrs. Burns used Taxotere, Mrs. Burns and Mrs. Burns's healthcare providers were unaware of the falsity of Sanofi's representations, statements and/or implications and justifiably and reasonably relied on Sanofi's representations,

statements, and implications, believing them to be true.

93. In reliance on Sanofi's representations, Mrs. Burns and her healthcare providers were induced to and did use and prescribe Taxotere, which caused Mrs. Burns to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent canalicular stenosis; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Jennifer Burns respectfully requests judgment in her favor and against Defendants in an amount that exceeds $75,000, plus the costs of this suit and any other and further relief this Court deems just and proper.

COUNT V – FRAUDULENT CONCEALMENT

94. Mrs. Burns incorporates by reference the above paragraphs as if set forth herein.

95. At all times during the course of dealing between Sanofi and Mrs. Burns and her healthcare providers, Sanofi misrepresented the design characteristic and safety of Taxotere for their intended use.

96. Sanofi knew or was reckless in not knowing that its representations were false due to Sanofi's access to ongoing studies and reports that disclosed serious, but preventable damage to the lacrimal system caused by Taxotere. In representations made to Mrs. Burns and her healthcare providers, Sanofi fraudulently concealed and intentionally omitted the following material information: (1) the rapid onset at which stenosis can occur, (2) the potentially permanent nature of the injury, (3) the need to immediately refer patients to a lacrimal specialist and (4) that the condition is highly preventable with timely intervention during chemotherapy.

97. Sanofi had a duty to disclose to Mrs. Burns and her healthcare providers the defective nature of Taxotere, including, but not limited to, the heightened risks of disfiguring, permanent canalicular stenosis.

98. Sanofi had a duty to disclose to Mrs. Burns and her healthcare providers that the disfiguring, permanent canalicular stenosis caused by the use of Taxotere could have been prevented by early

identification and treatment of epiphora during chemotherapy.

99. Sanofi had sole access to material facts concerning the defective nature of Taxotere and its propensity to cause serious and dangerous side effects, and therefore cause damage to persons who used the drugs at issue, including Mrs. Burns.

100. Sanofi's concealment and omissions of material fact concerning the safety of Taxotere were made purposefully, willfully, wantonly, and/or recklessly to mislead Mrs. Burns and her healthcare providers into reliance on the continued use of the drugs and to cause them to purchase, prescribe, and/or dispense Taxotere and/or use it.

101. Sanofi knew that Mrs. Burns and her healthcare providers had no way to determine the truth behind its concealment and omissions, including the material omissions of fact surrounding Taxotere set forth herein.

102. Mrs. Burns and her healthcare providers reasonably relied on information disclosed by Sanofi that negligently, fraudulently, and/or purposefully did not include facts that were concealed and/or omitted by Sanofi.

103. As a result of the foregoing acts and omissions, Sanofi caused Mrs. Burns to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent canalicular stenosis; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Jennifer Burns respectfully requests judgment in her favor and against Defendants in an amount that exceeds $75,000, plus the costs of this suit and any other and further relief this Court deems just and proper.

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V. JURY DEMAND

Plaintiff has requested a trial by jury pursuant to rule 38 of the Federal Rules of Civil Procedure.

Dated: November 15, 2021

FITZPATRICK & SWANSTON
RMP LAW GROUP LLC
HOTZE RUNKLE PLLC

By: /s/ B. James Fitzpatrick
B. James Fitzpatrick
Richard M. Paul (*pro hac* forthcoming)
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