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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
HELENA DIVISION

CHANTEELE NASH, Plaintiff, vs. SANDOZ, Inc., and John Does I-II Defendants.	Case No. **ORIGINAL COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff CHANTELLE NASH, for her Original Complaint against Defendant SANDOZ, INC. ("Sandoz"), alleges:

PARTIES

1. At all times relevant to this complaint, Plaintiff was a citizen of Montana and resident of Clancy, Jefferson County, Montana.

2. Defendant SANDOZ, INC. (hereinafter "Sandoz") is, and at all times pertinent hereto was, a business incorporated in Princeton, New Jersey, doing business in the State of Montana.

3. John Does I-II are either akas or aliases of Sandoz or are any other entities known or unknown involved with the incident or who may be jointly or severally liable for Plaintiff's damages.

4. Jurisdiction and venue are appropriate in this Court as there is a diversity in the parties and the amount in controversy is in excess of $75,000.00.

INTRODUCTION

5. Sandoz has for years manufactured and sold a chemotherapy drug called Docetaxel Injection, which is administered to many who suffer primarily from breast cancer. While it is one of many drugs effective at treating breast cancer, Sandoz has known for years that the drug carries a significant risk of causing permanent damage to the lacrimal system, including canalicular stenosis. Canalicular stenosis is the narrowing and/or occlusion of the canaliculus, a narrow canal in the lacrimal drainage system, which results in the inability of the tears to drain properly. In a healthy eye, the lacrimal gland produces basal tears throughout the day, to lubricate the cornea and eliminate debris. However, in a person with canalicular stenosis, the occluded canaliculus prevents these basal tears from draining properly, resulting in epiphora, or excessive tearing.

6. A simple preventative procedure at the onset of chemotherapy-induced tearing, involving the temporary placement of silicone stents, allows a patient to continue her Docetaxel Injection regimen while removing the likelihood of permanent damage to the lacrimal system. Although Sandoz warns that "excessive tearing which may be attributable to lacrimal duct obstruction has been reported," Sandoz failed to warn patients and oncologists of the risk that the damage can occur quickly and can be **permanent.** Further, Sandoz failed to report the severity and frequency of this risk to the Food and Drug Administration ("FDA"). Worse, Sandoz 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. Nash suffers from permanent injuries because she used Docetaxel Injection.

7. 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. Nash, the irritated, swollen, watering eyes and the ongoing medical

management of the condition affect their work, 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. As a Senior Vice President and Chief Officer of Risk Management at a bank, Mrs. Nash's tearing impacts her interactions with investors and the likelihood of future career advancements.

FACTUAL ALLEGATIONS

Development and Approval of Docetaxel Injection

8. Taxotere and Docetaxel Injection are drugs used in the treatment of various forms of cancer, including breast cancer, and are 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.

9. The FDA first 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.

10. In August 2004, the manufacturer of Taxotere obtained FDA approval for an expanded use of the drug "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.

11. 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.

12. On September 16, 2010, Sandoz filed NDA application #201525 to market its Docetaxel Injection under §505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA"), codified at §21 U.S.C. 355(b)(2).

13. Sandoz received FDA approval for NDA #201525 on June 29, 2011 and began marketing the drug in the United States on August 15, 2011.

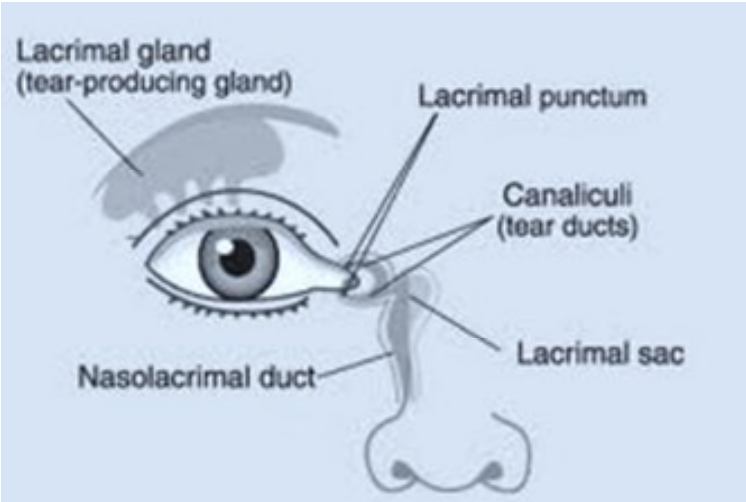
14. Since approval, Sandoz has submitted multiple Changes Being Effected Supplemental New Drug Applications ("CBE sNDA") to update its labeling. It submitted a CBE sNDA (S-002) on July 29, 2011 that was approved on March 15, 2012, and a CBE sNDA (S-003) on August 15, 2013 that was approved on April 23, 2014. Neither submission, however, updated its labeling concerning permanent epiphora or canalicular stenosis.

15. Docetaxel Injection 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.

Anatomy of Lacrimal System

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



17. Docetaxel Injection is secreted in the tear film, thereby causing fibrosis in areas of the lacrimal system, including the lacrimal punctum, canaliculi 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.

Docetaxel Injection's Labeling

18. At the time Mrs. Nash was administered Docetaxel Injection, 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, Sandoz includes "redness of the eye, excess tearing" among "the most common side effects of Docetaxel Injection." *Id*. Sandoz'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, Sandoz downplays the significance of the underlying injury causing epiphora.

20. Sandoz'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. Sandoz did not provide such adequate notice to oncologists. To the contrary, the labeling leads oncologists, like Mrs. Nash's, to believe that excessive

[1] https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/201525s016s017lbl.pdf

tearing is merely a transitory side effect and will end after the cessation of chemotherapy. This failure to provide notice resulted in thousands of women, like Mrs. Nash, suffering daily from a permanent condition that could have easily been prevented with adequate warning.

Sandoz's Duty to Monitor and Update Labeling

22. The primary responsibility for timely communicating complete, accurate, and current safety and efficacy information related to Docetaxel Injection rests with Sandoz 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, Sandoz 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.

Sandoz Knew That Docetaxel Injection Can Cause Permanent Canalicular Stenosis.

36. After Sandoz submitted its NDA for approval to FDA, accumulating data demonstrated that the warning advising of "lacrimal duct obstruction" failed to adequately communicate to oncologists the severity and permanency of Docetaxel Injection-related epiphora. This accumulating data highlighted concerns of the increased frequency and severity of docetaxel-induced permanent stenosis in cancer

patients, the increased need for monitoring, and the lack of awareness among oncologists and their patients regarding the true nature of the damage caused. The following excerpts are just a sampling of the accumulating data:

- The second most common adverse event [of docetaxel administration] was watery eyes and tearing (epiphora), affecting 55 patients (50.9%) in the one week group… this side effect was very specific for the weekly regimen and the frequency increased for every consecutive treatment cycle.[2]

- In conclusion, it is important for oncologists to be aware of this adverse event, and ophthalmologists should be consulted in cases in which tears appear during docetaxel therapy.[3]

- Both retrospective and prospective studies have shown that the schedule of administration of docetaxel significantly affects the incidence and severity of canalicular stenosis. Unfortunately, these relationships are not appreciated by many oncologists or ophthalmologists.[4]

37. Following the approval of Sandoz's NDA, published studies highlighted an ongoing problem that oncologists did not appreciate the seriousness of potential **permanent** damage to the lacrimal system as a result of Docetaxel

[2] Sorbe, Bengt, et al., *A Study of Docetaxel Weekly or Every Three Weeks in Combination with Carboplatin as First Line Chemotherapy in Epithelial Ovarian Cancer: Hematological and Non-Hematological Toxicity Profiles*, 5(4) ONCOLOGY LETTERS 1140-1148 (2013).

[3] Yamagishi, T., Ochi, N., Yamane, H. et al. *Epiphora in Lung Cancer Patients Receiving Docetaxel: A Case Series,* 7 BMC RES NOTES 322 (2014).

[4] Esmaeli, Bita, et al., *Evaluation and Management of Chemotherapy-Induced Epiphora, Punctal and Canalicular Stenosis and Nasolacrimal Duct Obstruction*, 33 THE AMERICAN SOCIETY OF OPHTHALMIC PLASTIC AND RECONSTRUCTIVE SURGERY, 9-12 (2017).

Injection. Despite the prevalence of accumulating data, Sandoz took no efforts to analyze this data and take measures to add a stronger warning to the oncological community. Sandoz's decision to willfully ignore this data resulted in an increase of cases of permanent injuries to the end users of its product. Sandoz had ample opportunity to utilize the CBE process and unilaterally strengthen its label to raise awareness among oncologists as recommended by the studies.[5] This accumulating data showing an increase in advanced cases of canalicular stenosis is de facto evidence that Sandoz's warning was inadequate. Logic dictates if Sandoz's warning adequately advised oncologists of the serious **but preventable** nature of canalicular stenosis, there would no accumulating data showing this increased frequency of Docetaxel Injection-related canalicular stenosis.

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

[5] Of note, in 2016 Sandoz utilized the CBE process to change its warning label regarding the side effect of alopecia. Specifically, Sandoz sought to strengthen the warning to include the word "**permanent**."

Docetaxel Injection Caused Mrs. Nash's Permanent Canalicular Stenosis

39. Mrs. Nash was diagnosed with breast cancer and was initially given chemotherapy with Taxol. However, after six rounds of Taxol, she developed neuropathy and her regimen was switched to Docetaxel Injection.

40. Mrs. Nash 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. Nash looked forward to no longer suffering from constantly irritated, watering eyes. But as the effects of chemotherapy wore off, the epiphora continued; however Mrs. Nash remained hopeful that it would eventually resolve. To her dismay, it never has.

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

42. As a result of this permanent side effect, Mrs. Nash 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. Nash's self-image, negatively impacted her relationships, and others' perceptions of her, leading to social isolation and depression even long after fighting cancer.

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

44. Mrs. Nash 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.

45. Mrs. Nash is a Senior Vice President and Risk Management Officer at Eagle Bancorp Montana, Inc. Her responsibilities include personally meeting with clients and investors and giving presentations regularly. Now, however, she is embarrassed and feels that her tearing is a distraction, undermining her credibility and efficiency as a presenter. She has taken time off for multiple doctor appointments attempting to repair the damage already done. Mrs. Nash is concerned that her tearing will prevent her from further career advancement.

46. Mrs. Nash's injuries could have been prevented had Sandoz simply

warned that permanent canalicular stenosis is a common but preventable side effect of Docetaxel Injection. Specifically, had Sandoz properly warned Mrs. Nash's oncologist of the rapid onset of permanent damage, her oncologist would have advised her to inform him immediately at the onset of her symptoms and referred her to the appropriate lacrimal specialist. Mrs. Nash thus seeks recovery for her mental and physical suffering stemming from permanent, but easily preventable, canalicular stenosis.

47. Mrs. Nash files this lawsuit within the applicable statute of limitations.

Tolling of the Statute of Limitations.

48. Alternatively, Mrs. Nash files this lawsuit within the applicable statute of limitations period of first suspecting that Sandoz's wrongful conduct caused the appreciable harm she sustained. Due to Sandoz's fraudulent concealment of the true nature of "excessive tearing which may be attributable to lacrimal duct obstruction," Mrs. Nash could not, by the exercise of reasonable diligence, have discovered that Sandoz wrongfully caused her injuries since she was unaware of the severity and permanency of her injury. Specifically in its warning label, which Sandoz intended for oncologists to read and rely on, Sandoz 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. Nash was unaware that Sandoz knew of the devastating and permanent consequences of stenosis, or that Sandoz concealed this information from her oncologist. Because Mrs. Nash's oncologist was unaware of the permanent nature of this side effect, Mrs. Nash was also unaware that her condition was permanent.

49. Sandoz to this day does not warn that Docetaxel Injection can cause permanent obstruction of the lacrimal system. Therefore Mrs. Nash did not suspect, nor did she have reason to suspect, that she had been permanently injured. Furthermore, Mrs. Nash 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.

50. Additionally, Mrs. Nash was prevented from discovering this information at an earlier date because Sandoz: (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. Nash to discover Sandoz's liability; and (5) still has not disclosed to the public, the FDA, and the medical profession that Docetaxel Injection 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)

51. Mrs. Nash incorporates by reference the above paragraphs as if set forth herein.

52. At all relevant times, Sandoz was in the business of designing, researching, manufacturing, testing, promoting, marketing, selling, and/or distributing pharmaceutical products, including the Docetaxel Injection used by Mrs. Nash.

53. The Docetaxel Injection designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Sandoz failed to provide adequate warnings to users and their healthcare providers, including Mrs. Nash 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 Sandoz and ultimately administered to Mrs. Nash lacked such warnings when it left Sandoz's control.

54. The risks of developing disfiguring, permanent canalicular stenosis

were known to or reasonably knowable by Sandoz at the time the Docetaxel Injection left Sandoz's control.

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

56. Any warnings actually provided by Sandoz 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.

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

58. Mrs. Nash was a reasonably foreseeable user of Docetaxel Injection who used the drug in a reasonably anticipated manner.

59. Mrs. Nash 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 Sandoz of the risk of these side effects.

60. As a direct and proximate result of Sandoz's failure to warn of the potentially severe adverse effects of Docetaxel Injection, Mrs. Nash 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.

COUNT II – STRICT PRODUCTS LIABILITY (MISREPRESENTATION)

61. Mrs. Nash incorporates by reference the above paragraphs as if set forth herein.

62. Sandoz sold the Docetaxel Injection that Mrs. Nash's healthcare providers prescribed for Mrs. Nash and that Mrs. Nash used.

63. Sandoz was engaged in the business of selling the Docetaxel Injection for resale, use, or consumption.

64. Sandoz misrepresented facts as set forth herein concerning the character or quality of the Docetaxel Injection that would be material to potential prescribers and purchasers or users of the product.

65. Sandoz's misrepresentations were made to potential prescribers and/or purchasers or users as members of the public at large.

66. As purchasers or users, Mrs. Nash and/or her healthcare providers reasonably relied on the misrepresentations.

67. Mrs. Nash was a person who would reasonably be expected to use, consume, or be affected by the Docetaxel Injection.

68. As a direct and proximate result of the foregoing acts and omissions, Sandoz caused Mrs. Nash 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 punctal 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.

COUNT III - NEGLIGENCE

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

70. Sandoz had a duty to exercise reasonable care in the design, research, formulation, manufacture, production, marketing, testing, supply, promotion, packaging, sale, and/or distribution of Docetaxel Injection, including a duty to assure

that the product would not cause users to suffer unreasonable, disfiguring, and dangerous side effects.

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

72. The negligence of Sandoz, 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 Docetaxel Injection 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 Docetaxel Injection to Mrs. Nash, 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 Docetaxel Injection 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, Docetaxel Injection;

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

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

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

(g) Concealing from and/or misrepresenting information to Mrs. Nash, her healthcare providers, other medical and healthcare professionals, and/or the FDA concerning the existence and severity of risks and dangers of Docetaxel Injection; and

(h) Encouraging the sale of Docetaxel Injection, either directly or indirectly, orally or in writing, to Mrs. Nash 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 Sandoz knew or should have known that Docetaxel Injection caused unreasonably dangerous side effects, Sandoz continues to market, manufacture, distribute, and/or sell Docetaxel Injection to consumers.

74. Mrs. Nash 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 Docetaxel Injection and measures that could have been taken to prevent severe and permanent disfigurement from the use of Docetaxel Injection.

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

76. Sandoz's negligence was a proximate cause of Mrs. Nash's injuries,

harms, damages, and losses, in connection with the use of Docetaxel Injection, 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.

COUNT IV – NEGLIGENT MISREPRESENTATION

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

78. Sandoz had a duty to represent to Mrs. Nash, her healthcare providers, the healthcare community, and the public in general that Docetaxel Injection 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 Docetaxel Injection, Sandoz negligently represented to Mrs. Nash, her healthcare providers, the healthcare community, and the public in general that Docetaxel Injection had been tested and was found to be safe and/or effective for its indicated use.

80. Sandoz concealed its knowledge of Docetaxel Injection defects from Mrs. Nash, her healthcare providers, and the public in general and/or the healthcare

community specifically.

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

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

83. Sandoz breached its duty in misrepresenting Docetaxel Injection's serious side effects to Mrs. Nash, her healthcare providers, the healthcare community, the FDA, and the public in general.

84. Mrs. Nash and her healthcare providers reasonably relied on Sandoz to fulfill its obligations to disclose all facts within its knowledge regarding the serious side effects of Docetaxel Injection 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,

Sandoz caused Mrs. Nash 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.

COUNT V– FRAUDULENT MISREPRESENTATION

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

87. In its labeling information, Sandoz communicated to Mrs. Nash, 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, Sandoz fraudulently omitted from this vague warning of "lacrimal duct obstruction" and/or "excessive tearing" that Docetaxel Injection could and did cause **permanent** damage to the lacrimal system, including canalicular stenosis.

89. These representations were material and false.

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

92. At the time Sandoz made the aforesaid representations, and, at the time Mrs. Nash used Docetaxel Injection, Mrs. Nash and Mrs. Nash's healthcare providers were unaware of the falsity of Sandoz's representations, statements and/or

implications and justifiably and reasonably relied on Sandoz's representations, statements, and implications, believing them to be true.

93. In reliance on Sandoz's representations, Mrs. Nash and her healthcare providers were induced to and did use and prescribe Docetaxel Injection, which caused Mrs. Nash 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.

COUNT VI – FRAUDULENT CONCEALMENT

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

95. At all times during the course of dealing between Sandoz and Mrs. Nash and her healthcare providers, Sandoz misrepresented the design characteristic and safety of Docetaxel Injection for their intended use.

96. Sandoz knew or was reckless in not knowing that its representations

were false due to Sandoz's access to ongoing studies and reports that disclosed serious, but preventable damage to the lacrimal system caused by Docetaxel Injection. In representations made to Mrs. Nash and her healthcare providers, Sandoz 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. Sandoz had a duty to disclose to Mrs. Nash and her healthcare providers the defective nature of Docetaxel Injection, including, but not limited to, the heightened risks of disfiguring, permanent canalicular stenosis.

98. Sandoz had a duty to disclose to Mrs. Nash and her healthcare providers that the disfiguring, permanent canalicular stenosis caused by the use of Docetaxel Injection could have been prevented by early identification and treatment of epiphora during chemotherapy.

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

100. Sandoz's concealment and omissions of material fact concerning the

safety of Docetaxel Injection were made purposefully, willfully, wantonly, and/or recklessly to mislead Mrs. Nash and her healthcare providers into reliance on the continued use of the drugs and to cause them to purchase, prescribe, and/or dispense Docetaxel Injection and/or use it.

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

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

103. As a result of the foregoing acts and omissions, Sandoz caused Mrs. Nash 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, Chantelle Nash 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.

JURY DEMAND

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

Dated this 3rd day of January, 2022.

By: /s/ Shane Colton

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