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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF SAN FRANCISCO

CGC-24-619197

TREBOR HARDIMAN,

Plaintiff,

-vs.-

GLOBAL BLOOD THERAPEUTICS, INC.,

Defendant.

CASE NO.:

COMPLAINT FOR DAMAGES FOR

1) **STRICT LIABILITY, DESIGN DEFECT;**
2) **STRICT LIABILITIY, FAILURE TO WARN;**
3) **NEGLIGENCE;**
4) **BREACH OF EXPRESS WARRANTIES;**
5) **BREACH OF IMPLIED WARRANTIES;**
6) **UNJUST ENRICHMENT;**
7) **FALSE AND MISLEADING ADVERTISING IN VIOLATION OF BUSINESS & PROFESSIONS CODE §17200, et seq.;**
8) **FALSE AND MISLEADING ADVERTISING IN VIOLATION OF BUSINESS & PROFESSIONS CODE §17500, et seq.; and**
9) **VIOLATION OF CALIFORNIA CIVIL CODE §1750, et seq.**

DEMAND FOR JURY TRIAL

Plaintiff Trebor Hardiman, by and through the undersigned counsel, brings this civil action against Defendant Global Blood Therapeutics, Inc. (hereinafter Defendant) for personal injuries and damages suffered by Plaintiff, and alleges the following:

INTRODUCTION

1) This is an action for damages related to Defendant's wrongful conduct in connection with the development, design, testing, manufacturing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of Oxbryta (generic name: voxelotor), a prescription medication used to treat sickle cell disease (herein after SCD) in adults and children aged 4 and older.

2) Oxbryta is manufactured as an oral, once-daily therapy for patients with SCD.

3) On September 25, 2024, Pfizer, Inc. announced that it was voluntarily withdrawing all lots of Oxbryta, in all markets where it is approved (hereinafter the Recall).[1] The decision came after "data showed an imbalance in Vaso-occlusive crises, a complication of the disease and "fatal events" that required further assessment."[2]

4) Oxbryta injured Plaintiff Trebor Hardiman (hereinafter "Plaintiff") by causing or substantially contributing to the onset of a vaso-occlusive crisis (VOC) as well as significant pain and swelling throughout the body.

5) Defendant knew or should have known for decades that Oxbryta, when administered and prescribed as intended, can cause or substantially contribute to VOCs and even death.

6) Nevertheless, Defendant failed to warn, instruct, advise, educate, or otherwise inform Oxbryta users and prescribers about the risk of VOCs and/or death.

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

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

[1] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-voluntarily-withdraws-all-lots-sickle-cell-disease
[2] https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-withdraws-sickle-cell-disease-treatment-all-markets-2024-09-25/

PARTIES

9) At all relevant times hereto, Plaintiff was a resident and citizen of Illinois.

10) Defendant Global Blood Therapeutics, Inc. is a Delaware corporation, with its principal executive offices located at 181 Oyster Point Boulevard, South San Francisco, California 94080.

11) Defendant Global Blood Therapeutics, Inc. "discovered and developed" Oxbryta, which was granted accelerated approval by the FDA in November 2019.[3]

12) Upon information and belief, Defendant Global Blood Therapeutics is a wholly owned subsidiary of Pfizer, Inc.

13) Defendant does business in California by, among other things, distributing, marketing, selling and/or profiting from Oxbryta in California as well as throughout the United States.

14) At all times material herein, Defendant was, and is, a pharmaceutical companies involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Oxbryta, in California, and throughout the United States.

JURISDICTION AND VENUE

15) Jurisdiction over this matter is proper in this Court pursuant to California Constitution Article VI, Section 10 because this case is a cause not given by statute to other trial courts.

16) This Court has jurisdiction over Defendant Global Blood Therapeutics, Inc. because its principal place of business is in San Francisco County, California.

17) Venue of this case is proper in this case because a substantial part of the events and omissions giving rise to the Plaintiff's claims occurred in San Francisco County, California.

18) This venue is also proper because Defendant Global Blood Therapeutics, Inc.'s principal place of business is located in San Francisco County, California.

PLAINTIFF TREBOR HARDIMAN'S SPECIFIC FACTS

19) Plaintiff Trebor Hardiman is sixty-seven years old and was diagnosed with SCD as a child.

20) In approximately 2020, he began taking Oxbryta for the treatment of SCD after seeing

[3] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-completes-acquisition-global-blood-therapeutics

numerous advertisements by Defendant Global Blood Therapeutics, Inc.

21) While on Oxbryta, Plaintiff suffered a higher rate of VOCs than prior to starting the medication and had more blood transfusions, in addition to other debilitating symptoms caused by the medication including pain and swelling.

22) Additionally, in the Fall of 2024, while still on Oxbryta, Plaintiff suffered a stroke. As a result of the stroke, Plaintiff's vision significantly decreased, and he is no longer able to drive or do normal everyday activities.

23) Around September 25, 2024, he received a call from an employee of Defendant informing him about the recall. After that call, he stopped taking the medication.

24) In the short time since stopping the medication, Plaintiff has suffered multiple VOCs and has been hospitalized for approximately a week at Advocate Christ Medical Center in Oak Lawn, Illinois. As of the filing of this lawsuit, Plaintiff is still hospitalized with complications from stopping the medication.

25) As a result of Defendant's actions and inactions, Plaintiff has suffered serious injuries and damages due to taking Oxbryta.

26) Plaintiff was unaware until the Recall that Oxbryta had a higher rate of vaso-occlusive crisis. He was also unaware that there were more deaths in the Oxbryta treatment group as compared to the placebo group in post-marketing studies or that there were higher rates of vaso-occlusive crisis in patients with sickle cell disease receiving Oxbryta in two real-world registry studies.

GENERAL ALLEGATIONS

SICKLE CELL DISEASE

27) SCD is a group of inherited red blood cell disorders. Red blood cells contain hemoglobin, a protein that carries oxygen. Healthy red blood cells are round, and they move through small blood vessels to carry oxygen to all parts of the body.

28) In someone who has SCD, the hemoglobin is abnormal, which causes the red blood cells to become hard and sticky and look like a C-shaped farm tool called a sickle. The sickle cells die early, which causes a constant shortage of red blood cells. Also, when they travel through small blood vessels,

sickle cells get stuck and clog the blood flow. This can cause pain and other serious complications (health problems) such as infection, acute chest syndrome, and stroke.

29) There are several types of SCD. The specific type of SCD a person has depends on the genes they inherited from their parents. People with SCD inherit genes that contain instructions, or code, for abnormal hemoglobin, including:

HbSS: People who have this form of SCD inherit two genes, one from each parent, that code for hemoglobin "S." Hemoglobin S is an abnormal form of hemoglobin that causes the red cells to become rigid, and sickle shaped. This is commonly called sickle cell anemia and is usually the most severe form of the disease.

HbSC: People who have this form of SCD inherit a hemoglobin S gene from one parent and a gene for a different type of abnormal hemoglobin called "C" from the other parent. This is usually a milder form of SCD.

HbS beta thalassemia: People who have this form of SCD inherit a hemoglobin S gene from one parent and a gene for beta thalassemia, another type of hemoglobin abnormality, from the other parent. There are two types of beta thalassemia: "zero" (HbS beta0) and "plus" (HbS beta+). Those with HbS beta0-thalassemia usually have a severe form of SCD. People with HbS beta+-thalassemia tend to have a milder form of SCD.

30) SCD is diagnosed with a simple blood test. In children born in the United States, it most often is found at birth during routine newborn screening tests at the hospital. In addition, SCD can be diagnosed while the baby is in the womb. Diagnostic tests before the baby is born, such as chorionic villus sampling and amniocentesis, can check for chromosomal or genetic abnormalities in the baby. Chorionic villus sampling tests a tiny piece of the placenta called chorionic villus. Amniocentesis tests a small sample of amniotic fluid surrounding the baby.[4]

Oxbryta

31) The active substance in Oxbryta, was supposed to work by improving the ability of the

[4] https://www.cdc.gov/sickle-cell/about/index.html#:~:text=Sickle%20cell%20disease%20(SCD)%20is,some%20more%20severe%20than%20others.

hemoglobin to hold on to oxygen, and preventing it from forming chains. In theory, this would help the red blood cells to maintain normal shape and flexibility, reducing their excess breakdown and improving their lifespan.

32) The FDA approved Oxbryta under the accelerated approval pathway in 2019 for the treatment of sickle cell disease in adults and pediatric patients 12 years of age and older. In 2021, FDA granted accelerated approval of Oxbryta for the treatment of sickle cell disease in patients 4 to 11 years of age. Accelerated approval is based on a surrogate or intermediate clinical endpoint that is reasonably likely to predict clinical benefit, allowing for earlier approval of drugs that treat serious conditions and fill an unmet medical need. In general, FDA requires post-marketing studies to verify and describe the clinical benefit of medications approved under this program. *Id.*

33) Defendant marketed Oxbryta through various forms of media and promised its purchasers would "experience less sickling."[5]

34) Defendant called Oxbryta a "firsts-of-its-kind tablet that treats sickle cell. . ." and would lead to "less sickling" by "address[ing] sickling at its source." [6]

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[5] https://www.mmm-online.com/home/channel/first-look-oxbryta-spot-aims-to-empower-patients-with-sickle-cell/

[6] https://sicklecellconsortium.org/wp-content/uploads/2020/06/Oxbryta-Core-Patient-Leave-Behind-Electronic-Version-2.pdf

TREAT SICKLE CELL AT ITS SOURCE

Oxbryta is the first-of-its-kind tablet that treats sickle cell in a different way—by working directly on hemoglobin S to interfere with the sickling process (polymerization).

With a different way to treat sickle cell, now you can imagine less sickling. Talk to your doctor about Oxbryta or visit **Oxbryta.com**

IMPORTANT SAFETY INFORMATION

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines may affect how OXBRYTA works. OXBRYTA may also affect how other medicines work.

Please see Important Safety Information on pages 20-21 and included full Prescribing Information.

GBT

Oxbryta (voxelotor) 500mg tablets

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Id.

35) On September 25, 2024, Pfizer, Inc. announced it was voluntarily withdrawing the medication from the market, ceasing distribution, and discontinuing all active clinical trials and expanded access programs for Oxbryta "because recent data indicate the benefit of Oxbryta does not outweigh the risks for the sickle cell patient population."[7]

36) Pfizer, Inc. noted that the decision was "based on the totality of clinical data that now indicates the overall benefit of OXBRYTA no longer outweighs the risk in the approved sickle cell patient population. The data suggest an imbalance in vaso-occlusive crises and fatal events which require further assessment."[8]

37) According to the European Medicines Agency, Study GBT440-032 is assessed the effects of voxelotor on the transcranial doppler ultrasound measurements of cerebral arterial blood flow in children from 2 to 15 years of age with SCD and are at high risk of stroke. The study recruited 236 patients from Egypt, Ghana, Kenya, Nigeria, Oman, Saudi Arabia, the United States and the United Kingdom. There were 8 deaths in people taking voxelotor and 2 deaths in people taking placebo.[9]

38) Study GBT440-042 assessed the effects of voxelotor on leg ulcers in 88 patients from 12 years of age recruited from Brazil, Kenya and Nigeria. Eight deaths occurred in the open-label part of this study. *Id.*

39) "The initiation of the review follows an imbalance of deaths between voxelotor and placebo observed in clinical trials," the European Medicines Agency said in an agenda of the meeting posted on its website.[10]

40) Oxbryta was at all times utilized and prescribed in a manner foreseeable to Defendant, as Defendant generated the instructions for use. Plaintiff and Plaintiff's physicians foreseeably used Oxbryta, and did not misuse or alter Oxbryta in an unforeseeable manner.

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[7] https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerting-patients-and-health-care-professionals-about-voluntary-withdrawal-oxbryta-market-due

[8] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-voluntarily-withdraws-all-lots-sickle-cell-disease

[9] https://www.ema.europa.eu/en/documents/referral/oxbryta-article-20-procedure-review-started_en.pdf

[10] https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-withdraws-sickle-cell-disease-treatment-all-markets-2024-09-25/

41) As a direct result of being prescribed and consuming Oxbryta, Plaintiff has been permanently and severely injured, having suffered serious consequences.

42) As a direct and proximate result of his Oxbryta use, Plaintiff suffered severe physical pain and has sustained permanent injuries and emotional distress, along with economic loss including past and future medical expenses.

CAUSE OF ACTION

COUNT 1

STRICT LIABILITY-DESIGN DEFECT

43) Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

44) Plaintiff brings this strict liability claim against Defendant for defective design with respect to its Oxbryta products.

45) At all relevant times, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting Oxbryta products, which are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Oxbryta products into the stream of commerce. These actions were under the ultimate control and supervision of Defendant. At all relevant times, Defendant designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, and/or distributed the Oxbryta products used by Plaintiff, as described herein.

46) At all relevant times, Defendant's Oxbryta products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public, including Plaintiff.

47) At all relevant times, Defendant's Oxbryta products reached the intended consumers, handlers, and users or other persons coming into contact with these products within this judicial district and throughout the United States, including Plaintiff, without substantial change in its condition as designed, manufactured, sold, distributed, labeled, and/or marketed by Defendant. At all relevant times, Defendant registered, researched, manufactured, distributed, marketed, packaged, and/or sold Oxbryta

products within this judicial district and aimed at a consumer market within this judicial district. Defendant was at all relevant times involved in the sales and promotion of Oxbryta products marketed and sold in this judicial district.

48) Defendant's Oxbryta products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and/or marketed by Defendant were defective in design and formulation in that, when they left the control of Defendant's manufacturers and/or suppliers, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate.

49) Defendant's Oxbryta products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and/or marketed by Defendant were defective in design and formulation in that, when they left the hands of Defendant's manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with its design and formulation.

50) At all relevant times, Defendant knew or had reason to know that Oxbryta products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendant.

51) Therefore, at all relevant times, Defendant's Oxbryta products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and/or marketed by Defendant were defective in design and formulation, in one or more of the following ways:

a. When placed in the stream of commerce, Defendant's Oxbryta products were defective in design and formulation, and, consequently, dangerous to an extent beyond that whichan ordinary consumer would contemplate;

b. When placed in the stream of commerce, Defendant's Oxbryta products were unreasonably dangerous in that they were hazardous and posed a grave risk of VOCs and other serious illnesses when used in a reasonably anticipated manner;

c. When placed in the stream of commerce, Defendant's Oxbryta products contained unreasonably dangerous design defects and were not reasonably safe when used in areasonably anticipated or intended manner;

d. Defendant did not sufficiently test, investigate, or study its Oxbryta products;

e. Exposure to Oxbryta products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

f. Defendant knew or should have known at the time of marketing/selling Oxbryta products that exposure to Oxbryta could result severe illnesses and injuries and even death;

g. Defendant did not conduct adequate post-marketing surveillance of its Oxbryta products;

h. Defendant could have employed safer alternative designs and formulations.

52) Plaintiff used and was exposed to Defendant's Oxbryta products without knowledge of Oxbryta's dangerous characteristics.

53) At all times relevant to this litigation, Plaintiff used and/or was exposed to the use of Defendant's Oxbryta products in an intended or reasonably foreseeable manner without knowledge of Oxbryta's dangerous characteristics.

54) Plaintiff could not reasonably have discovered the defects and risks associated with Oxbryta products before or at the time of exposure due to the Defendant's suppression or obfuscation of scientific information.

55) The harm caused by Defendant's Oxbryta products far outweighed its benefit, rendering Defendant's product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendant's Oxbryta products were and are more dangerous than alternative products, and Defendant could have designed Oxbryta products to make them less dangerous. Indeed, at the time Defendant designed Oxbryta products, the state of the industry's scientific knowledge was such that a less risky design or formulation was attainable.

56) At the time Oxbryta products left Defendant's control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendant's Oxbryta products.

57) Defendant's defective design of Oxbryta products was willful, wanton, malicious, and

conducted with reckless disregard for the health and safety of users of the Oxbryta products, including Plaintiff.

58) Therefore, as a result of the unreasonably dangerous condition of its Oxbryta products, Defendant is strictly liable to Plaintiff.

59) The defects in Defendant's Oxbryta products were substantial and contributing factors in causing Plaintiff's injuries, and, but for Defendant's misconduct and omissions, Plaintiff would not have sustained injuries.

60) Defendant's conduct, as described herein, was reckless. Defendant risked the lives of consumers and users of its products, including Plaintiff, with knowledge of the safety problems associated with Oxbryta products, and suppressed this knowledge from the general public. Defendant made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendant's reckless conduct warrants an award of punitive damages.

61) As a direct and proximate result of Defendant placing its defective Oxbryta products into the stream of commerce, and the resulting injuries, Plaintiff sustained pecuniary loss including general damages in a sum which exceeds the jurisdictional minimum of this Court.

62) As a proximate result of Defendant placing its defective Oxbryta products into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Plaintiff has suffered great mental anguish and other personal injury and damages.

63) As a proximate result of the Defendant placing its defective Oxbryta products into the stream of commerce, as alleged herein, Plaintiff sustained loss of income and/or loss of earning capacity.

64) WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendant for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT II

STRICT LIABILITY-FAILURE TO WARN

65) Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

66) Plaintiff brings this strict liability claim against Defendant for failure to warn.

67) At all relevant times, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting Oxbryta products which are defective and unreasonably dangerous to consumers, including Plaintiff, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Oxbryta. These actions were under the ultimate control and supervision of Defendant. At all relevant times, Defendant registered, researched, manufactured, distributed, marketed, and sold within this judicial district and aimed at a consumer market. Defendant was at all relevant times involved in the retail and promotion of Oxbryta products marketed and sold in in this judicial district.

68) Defendant researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce its Oxbryta products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiff, and therefore had a duty to warn of the risks associated with the use of Oxbryta products.

69) At all relevant times, Defendant had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure its Oxbryta products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendant had a continuing duty to warn Plaintiff of dangers associated with Oxbryta. Defendant, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

70) At the time of manufacture, Defendant could have provided warnings or instructions regarding the full and complete risks of Oxbryta products because it knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

71) At all relevant times, Defendant failed and deliberately refused to investigate, study, test, or promote safety or to minimize the dangers to users and consumers of its product and to those who would foreseeably use or be harmed by Defendant's Oxbryta products, including Plaintiff.

72) Even though Defendant knew or should have known that Oxbryta posed a grave risk of

harm, it failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure. The dangerous propensities of its products and as a result of ingesting Oxbryta, as described above, were known to Defendant, or scientifically knowable to Defendant through appropriate research and testing by known methods, at the time it distributed, supplied or sold the product, and were not known to end users and consumers, such as Plaintiff.

73) Defendant knew or should have known that its products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendant failed to adequately warn consumers, i.e., the reasonably foreseeable users, of the risks of exposure to its products. Defendant has wrongfully concealed information concerning the dangerous nature of Oxbryta, and further, have made false and/or misleading statements concerning the safety of Oxbryta products.

74) At all relevant times, Defendant's Oxbryta products reached the intended consumers, handlers, and users or other persons coming into contact with these products within this judicial district and throughout the United States, including Plaintiff, without substantial change in its condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendant.

75) Plaintiff was exposed to Defendant's Oxbryta products without knowledge of its dangerous characteristics.

76) At all relevant times, Plaintiff used and/or was exposed to the use of Defendant's Oxbryta products while using it for its intended or reasonably foreseeable purposes, without knowledge of its dangerous characteristics.

77) Plaintiff could not have reasonably discovered the defects and risks associated with Oxbryta products prior to or at the time of Plaintiff consuming Oxbryta. Plaintiff relied upon the skill, superior knowledge, and judgment of Defendant to know about and disclose serious health risks associated with using Defendant's products.

78) Defendant knew or should have known that the minimal warnings disseminated with its Oxbryta products were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for its ordinary, intended and reasonably foreseeable uses.

79) The information Defendant did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to utilize the products safely and with adequate protection. Instead, Defendant disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to Oxbryta; continued to aggressively promote the efficacy of its products, even after it knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Oxbryta.

80) This alleged failure to warn is not limited to the information contained on Oxbryta's labeling. Defendant should have warned the public about risks associated with Oxbryta through other non-labeling mediums, i.e., promotion, advertisements, public service announcements, and/or public information sources. But Defendant did not disclose these known risks through any medium.

81) Defendant is liable to Plaintiff for injuries caused by its negligent or willful failure, as described above, to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of its products and the risks associated with the use of Oxbryta.

82) Had Defendant provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with its Oxbryta products, Plaintiff could have avoided the risk of developing injuries and could have obtained or used alternative medication.

83) As a direct and proximate result of Defendant placing defective Oxbryta products into the stream of commerce, Plaintiff was injured and has sustained pecuniary loss resulting and general damages in a sum exceeding the jurisdictional minimum of this Court.

84) As a proximate result of Defendant placing defective Oxbryta products

85) into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish and other personal injuries and damages.

86) As a proximate result of Defendant placing defective Oxbryta products into the stream of

commerce, as alleged herein, Plaintiff sustained loss of income and/or loss of earning capacity.

87) WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendant for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT III

NEGLIGENCE

88) Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

89) Defendant or indirectly, caused Oxbryta products to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff. At all relevant times, Defendant registered, researched, manufactured, distributed, marketed and sold Oxbryta within this judicial district and aimed at a consumer market within this district.

90) At all relevant times, Defendant had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and distribution of Oxbryta products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to consumers and users of the product.

91) At all relevant times, Defendant had a duty to exercise reasonable care in the marketing, advertisement, and sale of the Oxbryta products. Defendant's duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using Oxbryta and appropriate, complete, and accurate warnings concerning the potential adverse effects of Oxbryta.

92) At all relevant times, Defendant knew or, in the exercise of reasonable care, should have known of the hazards and dangers of Oxbryta.

93) Accordingly, at all relevant times, Defendant knew or, in the exercise of reasonable care, should have known that use of Oxbryta products could cause or be associated with Plaintiff's injuries, and thus, create a dangerous and unreasonable risk of injury to the users of these products, including Plaintiff.

94) Defendant also knew or, in the exercise of reasonable care, should have known that users and consumers of Oxbryta were unaware of the risks and the magnitude of the risks associated with use of Oxbryta.

95) As such, Defendant breached its duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, marketing, supply, promotion, advertisement, packaging, sale, and distribution of Oxbryta products, in that Defendant manufactured and produced defective Oxbryta; knew or had reason to know of the defects inherent in its products; knew or had reason to know that a user's or consumer's use of the products created a significant risk of harm and unreasonably dangerous side effects; and failed to prevent or adequately warn of these risks and injuries.

96) Defendant was negligent in its promotion of Oxbryta, outside of the labeling context, by failing to disclose material risk information as part of its promotion and marketing of Oxbryta, including the internet, television, print advertisements, etc. Nothing prevented Defendant from being honest in its promotional activities, and, in fact, Defendant had a duty to disclose the truth about the risks associated with Oxbryta in its promotional efforts, outside of the context of labeling.

97) Despite its ability and means to investigate, study, and test the products and to provide adequate warnings, Defendant failed to do so. Indeed, Defendant wrongfully concealed information and further made false and/or misleading statements concerning the safety and use of Oxbryta.

98) Defendant's negligence included:

a. Manufacturing, producing, promoting, formulating, creating, developing,designing, selling, and/or distributing Oxbryta products without thorough and adequate pre- and post-market testing;

b. Manufacturing, producing, promoting, formulating, creating, developing,designing, selling, and/or distributing Oxbryta while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of Oxbryta;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Oxbryta products were safe for its intended consumer use;

d. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Oxbryta products so as to avoid the risk of serious harm associated with the prevalent use of Oxbryta products;

e. Failing to design and manufacture Oxbryta products so as to ensure they were at least as safe and effective as other medications on the market intended to treat the same symptoms;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons Defendant could reasonably foresee would use Oxbryta products;

g. Failing to disclose to Plaintiff, users/consumers, and the general public that use of Oxbryta presented severe risks of VOCs and other grave illnesses;

h. Failing to warn Plaintiff, consumers, and the general public that the product'srisk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiff and other consumers;

i. Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of Oxbryta products;

j. Representing that its Oxbryta products were safe for its intended use when, in fact, Defendant knew or should have known the products were not safe for its intended purpose;

k. Declining to make or propose any changes to Oxbryta products' labeling or other promotional materials that would alert consumers and the general publicof the risks of Oxbryta;

l. Advertising, marketing, and recommending the use of the Oxbryta products, while concealing and failing to disclose or warn of the dangers known (by Defendant) to be associated with or caused by the use of or exposure to Oxbryta;

m. Continuing to disseminate information to its consumers, which indicate or imply that Defendant's Oxbryta products are not unsafe for regularconsumer use; and

n. Continuing the manufacture and sale of its products with the knowledge thatthe

products were unreasonably unsafe and dangerous.

99) Defendant knew and/or should have known that it was foreseeable consumers such as Plaintiff would suffer injuries as a result of Defendant's failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Oxbryta.

100) Plaintiff did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to Oxbryta.

101) Defendant's negligence was the proximate cause of Plaintiff's injuries.

102) Defendant's conduct, as described above, was reckless. Defendant regularly risked the lives of consumers and users of its products, including Plaintiff, with full knowledge of the dangers of its products. Defendant have made conscious decisions not to redesign, re- label, warn, or inform the unsuspecting public, including Plaintiff. Defendant's reckless conduct therefore warrants an award of punitive damages.

103) As a direct and proximate result of Defendant placing defective Oxbryta products into the stream of commerce, Plaintiff was injured and has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

104) As a proximate result of Defendant placing defective Oxbryta products into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish and other personal injury and damages.

105) As a proximate result of Defendant placing defective Oxbryta products into the stream of commerce, as alleged herein, Plaintiff sustained a loss of income, and loss of earning capacity.

106) WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendant for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT IV

BREACH OF EXPRESS WARRANTIES

107) Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

108) At all relevant times, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting Oxbryta products, which are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Oxbryta products into the stream of commerce. These actions were under the ultimate control and supervision of Defendant.

109) Defendant had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of Oxbryta products, including a duty to:

a. ensure that its products did not cause the user unreasonably dangerous side effects;

b. warn of dangerous and potentially fatal side effects; and

c. disclose adverse material facts, such as the true risks associated with the use of and exposure to Oxbryta, when making representations to consumers and the general public, including Plaintiff.

110) Oxbryta's label confirms that it was "indicated for the treatment of sickle cell disease in adults and pediatric patients 4 years of age and older."[11]

111) As alleged throughout this pleading, the ability of Defendant to properly disclose those risks associated with Oxbryta is not limited to representations made on the labeling.

112) Defendant marketed Oxbryta through various forms of media and promised its purchasers would "experience less sickling."[12]

113) At all relevant times, Defendant expressly represented and warranted to the purchasers of its products, by and through statements made by Defendant in labels, publications, package inserts, and other written materials intended for consumers and the general public, that Oxbryta products were safe to human health and the environment, effective, fit, and proper for its intended use. Defendant advertised, labeled, marketed, and promoted Oxbryta products, representing the quality to consumers and the public in such a way as to induce its purchase or use, thereby making an express warranty that Oxbryta products would conform to the representations.

[11] https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213137s006lbl.pdf
[12] https://www.mmm-online.com/home/channel/first-look-oxbryta-spot-aims-to-empower-patients-with-sickle-cell/

114) These express representations include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Oxbryta. Defendant knew and/or should have known that the risks expressly included in Oxbryta warnings and labels did not and do not accurately or adequately set forth the risks of developing the serious injuries complained of herein. Nevertheless, Defendant expressly represented that Oxbryta products were safe and effective, that they were safe and effective for use by individuals such as the Plaintiff, and/or that they were safe and effective as consumer medication.

115) The representations about Oxbryta, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

116) Defendant placed Oxbryta products into the stream of commerce for sale and recommended its use to consumers and the public without adequately warning of the true risks of developing the injuries associated with the use of Oxbryta.

117) Defendant breached these warranties because, among other things, Oxbryta products were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with its use, and were not merchantable or safe for its intended, ordinary, and foreseeable use and purpose. Specifically, Defendant breached the warranties in the following ways:

a. Defendant represented through its labeling, advertising, and marketing materials that Oxbryta products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Oxbryta and by expressly limiting the risks associated with use within its warnings and labels; and

b. Defendant represented that Oxbryta products were safe for use and intentionally concealed information that demonstrated that Oxbryta could lead to higher risks of VOCs and death.

118) Plaintiff detrimentally relied on the express warranties and representations of Defendant concerning the safety and/or risk profile of Oxbryta in deciding to purchase the product. Plaintiff

reasonably relied upon Defendant to disclose known defects, risks, dangers, and side effects of Oxbryta. Plaintiff would not have purchased or used Oxbryta had Defendant properly disclosed the risks associated with the product, either through advertising, labeling, or any other form of disclosure.

119) Defendant had sole access to material facts concerning the nature of the risks associated with its Oxbryta products, as expressly stated within its warnings and labels, and knew that consumers and users such as Plaintiff could not have reasonably discovered that the risks expressly included in Oxbryta warnings and labels were inadequate and inaccurate.

120) Plaintiff had no knowledge of the falsity or incompleteness of Defendant's statements and representations concerning Oxbryta.

121) Plaintiff used and/or was exposed to Oxbryta as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by Defendant.

122) Had the warnings, labels, advertisements, or promotional material for Oxbryta products accurately and adequately set forth the true risks associated with the use of such products, including Plaintiff's injuries, rather than expressly excluding such information and warranting that the products were safe for its intended use, Plaintiff could have avoided the injuries complained of herein.

123) As a direct and proximate result of Defendant's breach of express warranty, Plaintiff has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

124) As a proximate result of Defendant's breach of express warranty, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish and other personal injury and damages.

125) As a proximate result of Defendant's breach of express warranty, as alleged herein, Plaintiff sustained a loss of income and/or loss of earning capacity.

126) WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendant for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT V

BREACH OF IMPLIED WARRANTIES

127) Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

128) At all relevant times, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting Oxbryta products, which were and are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Oxbryta products into the stream of commerce.

129) Before the time Plaintiff used Oxbryta products, Defendant impliedly warranted to its consumers, including Plaintiff, that Oxbryta products were of merchantable quality and safe and fit for the use for which they were intended; specifically, as consumer medication.

130) But Defendant failed to disclose that Oxbryta has dangerous propensities when used as intended and that use of Oxbryta products carries an increased risk of developing severe injuries, including Plaintiff's injuries.

131) Plaintiff was an intended beneficiary of the implied warranties made by Defendant to purchasers of its Oxbryta products.

132) The Oxbryta products were expected to reach and did in fact reach consumers and users, including Plaintiff, without substantial change in the condition in which they were manufactured and sold by Defendant.

133) At all relevant times, Defendant were aware that consumers and users of its products, including Plaintiff, would use Oxbryta products as marketed by Defendant, which is to say that Plaintiff was a foreseeable user of Oxbryta.

134) Defendant intended that Oxbryta products be used in the manner in which Plaintiff, in fact, used them and which Defendant impliedly warranted to be of merchantable quality, safe, and fit for this use, even though Oxbryta was not adequately tested or researched.

135) In reliance upon Defendant's implied warranty, Plaintiff used Oxbryta as instructed and labeled and in the foreseeable manner intended, recommended, promoted, and marketed by Defendant.

136) Plaintiff could not have reasonably discovered or known of the risks of serious injury associated with Oxbryta.

137) Defendant breached its implied warranty to Plaintiff in that Oxbryta products were not of merchantable quality, safe, or fit for its intended use, or adequately tested. Oxbryta has dangerous propensities when used as intended and can cause serious injuries, including those injuries complained of herein.

138) The harm caused by Defendant's Oxbryta products far outweighed its benefit, rendering the products more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

139) As a direct and proximate result of Defendant's breach of implied warranty, Plaintiff has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

140) As a proximate result of the Defendant's breach of implied warranty, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish and other personal injury and damages.

141) As a proximate result of Defendant's breach of implied warranty, as alleged herein, Plaintiff sustained a loss of income and/or loss of earning capacity.

142) WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendant for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT VI

UNJUST ENRICHMENT

143) Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

144) At all relevant times, Defendant designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold, or otherwise released Oxbryta products into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that

consumed it, including Plaintiffs.

145) Defendant was unjustly enriched as a result of its wrongful conduct, including through the false and misleading marketing, promotions, and advertisements that omitted disclosure that the products presented an unreasonable risk of substantial bodily injury resulting from its use.

146) Defendant appreciated, recognized, and chose to accept the monetary benefits Plaintiff conferred onto Defendant at Plaintiff's detriment. These benefits were the expected result of Defendant acting in its pecuniary interests at the expense of Plaintiffs.

147) There is no justification for Defendant's enrichment. It would be inequitable, unconscionable, and unjust for Defendant to be permitted to retain these benefits because the benefits were procured as a result of its wrongful conduct.

148) Defendant wrongfully obfuscated the harm caused by its Oxbryta products. Thus, Plaintiffs, who mistakenly enriched Defendant by relying on Defendant's misrepresentations of product safety, could not and did not know the effect that using Oxbryta products would have on Plaintiffs' health.

149) Plaintiff is entitled to restitution of the benefits Defendant unjustly retained and/or any amounts necessary to return Plaintiff to the position they occupied prior to dealing with Defendant. Plaintiff would expect compensation from Defendant's unjust enrichment stemming from its wrongful actions.

150) WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendant for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT VII

FALSE AND MISLEADING ADVERTISIN IN VIOLATION OF BUSINESS & PROFESSIONS CODE §17200, *et seq.*

151) Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

152) This cause of action is brought pursuant to Business and Professions Code §17200, *et seq.*

153) In the advertising of the Oxbryta Products, Defendant made false and misleading

statements and material omissions including, as set forth above, the representation that its Oxbryta products would lead to "less sickling" by "address[ing] sickling at its source."

154) Defendant is aware that the claims that it makes about its Oxbryta products are false, misleading, and unsubstantiated.

155) As alleged in the preceding paragraphs, Defendant's misrepresentations and omissions of the material facts detailed above constitute an unfair and fraudulent business practice within the meaning of California Business & Professions Code §17200.

156) In addition, Defendant's use of various forms of advertising media to advertise, call attention to or give publicity to the sale of goods or merchandise, which are not as represented in any manner, constitute unfair, deceptive, untrue or misleading advertising, unfair competition, and an unlawful business practice within the meaning of Business & Professions Code §§17531 and 17200, which advertisements have deceived and are likely to deceive the consuming public, in violation of Business & Professions Code §17500.

157) There were reasonably available alternatives to further Defendant's legitimate business interests, other than the conduct described herein.

158) All of the conduct alleged herein occurs and continues to occur in Defendant's business. Defendant's wrongful conduct is part of a pattern or generalized course of conduct repeated on thousands of occasions daily.

159) Pursuant to Business & Professions Code §§17203 and 17535, Plaintiff seeks an order requiring Defendant to disclose such misrepresentations, and additionally seeks an order awarding Plaintiff restitution of the money Defendant wrongfully acquired by means of responsibility attached to Defendant's failure to disclose the existence and significance of said misrepresentations.

160) Thus, Plaintiff has suffered and will continue to suffer injuries and damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

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COUNT VIII

FALSE AND MISLEADING ADVERTISING IN VIOLATION OF BUSINESS & PROFESSIONS CODE §17500, *et seq.*

161) Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

162) This cause of action is brought pursuant to Business and Professions Code §17500, et seq. (the "FAL"). The FAL prohibits the dissemination of any advertisement which is untrue or misleading, and which is known, or which by exercise of reasonable care should be known, to be untrue or misleading. Cal. Bus. & Prof. Code §17500.

163) In its advertising of Oxbryta products, Defendant made false and misleading statements. Specifically, as set forth above, Defendant labeled its products as safe and effective for the treatment of SCD.

164) In fact, the Oxbryta products injurious to consumers. Defendant is aware that its claims regarding the Oxbryta products are false, misleading, and unsubstantiated.

165) As alleged in the preceding paragraphs, the Defendant's misrepresentations of the material facts detailed above constitute an unfair and fraudulent business practice within the meaning of the FAL.

166) In addition, Defendant's use of various forms of advertising media to advertise, call attention to, or give publicity to the sale of goods or merchandise, which are not as represented in any manner, constitutes unfair, deceptive, untrue or misleading advertising, unfair competition, and an unlawful business practice within the meaning of Business & Professions Code §§ 17531 and 17200, which advertisements have deceived and are likely to deceive the consuming public, in violation of the FAL.

167) Pursuant to Business & Professions Code §§17203 and 17535, Plaintiff seeks an order requiring Defendant to disclose such misrepresentations, and additionally request an order awarding Plaintiff restitution of the money that Defendant wrongfully acquired by means of responsibility attached to Defendant's failure to disclose the existence and significance of said misrepresentations.

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COUNT IX

VIOLATION OF CALIFORNIA CIVIL CODE §1750, *et seq.*

168) Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

169) This cause of action is brought pursuant to Civil Code §1750, et seq., the Consumers Legal Remedies Act.

170) Plaintiff constitutes a "consumer" within the meaning of Civil Code §1761(d).

171) Defendant's sales of the Oxbryta products constitute "transactions" within the meaning of Civil Code §1761(e).

172) The Oxbryta products purchased by Plaintiff constitutes "goods" under Civil Code §1761(a).

173) The policies, acts, and practices heretofore described were intended to result in the sale of Oxbryta products to the consuming public and violated and continue to violate: (1) Section 1770(a)(5) of the Act which prohibits, inter alia, "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have;" (2) Section 1770(a)(7) of the Act, which prohibits, "[r]epresenting that goods or services are of a particular standard, quality, grade, or that goods are of a particular style or model , if they are of another;" (3) Section 1770(a)(9), which prohibits, '[a]advertising goods or services with intent not to sell them as advertised" and section 1770(a)(14) which prohibits "representing that a transaction confers or involves rights, remedies, or obligations which it does not have or involve."

174) Defendant fraudulently deceived Plaintiff by representing that Oxbryta products have certain characteristics, benefits, uses and qualities which it does not have. In doing so, Defendant intentionally misrepresented and concealed material facts from Plaintiff, specifically and not limited to the fact that its Oxbryta products promote health and are fit for consumption. Said misrepresentations and concealment were done with the intention of deceiving Plaintiff and depriving him of his legal rights and money.

175) Defendant knew that the Oxbryta products were not safe for consumption.

176) Defendant's actions as described hereinabove were done with conscious disregard of Plaintiff's rights and Defendant was wanton and malicious in its concealment of the same.

177) Pursuant to California Civil Code §1780(a) of the Act, Plaintiff seeks injunctive relief in the form of an order enjoining the above-described wrongful acts and practices of Defendant including, but not limited to, an order enjoining Defendant from distributing such false advertising and misrepresentations. Plaintiff shall be irreparably harmed if such an order is not granted.

178) Plaintiff reserves the right to amend this complaint to include a request for damages under the CLRA after complying with California Civil Code §1782(a) within thirty days after the commencement of this action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for a jury trial and for judgment against Defendant as follows **FOR ALL CAUSES OF ACTION:**

1) For past, present and future general damages in an amount to be determined at trial;

2) For past, present and future special damages, including but not limited to past, present and future lost earnings, economic damages and others, in an amount to be determined at trial;

3) Any appropriate punitive or exemplary damages;

4) Any appropriate statutory damages;

5) For costs of suit;

6) For interest as allowed by law;

7) For attorney's fees and costs as applicable;

8) For treble damages as applicable;

9) For such other and further relief as the court may deem proper.

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Respectfully submitted,

Dated: October 22, 2024,

BRADLEY/GROMBACHER LLP
AYLSTOCK, WITKIN, KREIS & OVERHOLTZ

By: */s/ Kiley Grombacher*
Marcus J. Bradley, Esq.
Kiley L. Grombacher, Esq.
S. Mary Lie, Esq.
Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff Trebor Hardiman demands a jury trial in this matter.

Dated: October 22, 2024,

BRADLEY/GROMBACHER LLP
AYLSTOCK, WITKIN, KREIS & OVERHOLTZ

By: */s/ Kiley Grombacher*
Marcus J. Bradley, Esq.
Kiley L. Grombacher, Esq.
S. Mary Lie, Esq.
Attorneys for Plaintiff