IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND BALTIMORE DIVISION

HOWARD NOLL **3337 Kensington Square** **Manchester, Carrol County,** **Maryland 21102,** **Plaintiff,** **vs.** **NOVARTIS PHARMACEUTICALS CORPORATION,** **One Health Plaza** **East Hanover, Morris County** **New Jersey 07936,** **Defendant.**	§ § § § § § § § § § § § § § § §	**Case No.:** 22-3204

COMPLAINT

COMES NOW Plaintiff, **HOWARD NOLL,** by and through undersigned counsel, and hereby brings this action for damages against Defendant, Novartis Pharmaceuticals Corporation, and alleges as follows:

INTRODUCTION

1. This is an action for damages due to Plaintiff relating to Defendant's development, testing, manufacture, packaging, preparation, labeling, marketing, supply and/or sale of the dangerous and defective pharmaceutical product Beovu®.

2. Defendant misrepresented that Beovu was a safe and effective treatment for age-related macular degeneration when in fact the drug causes serious medical problems including retinal vasculitis, retinal vascular occlusion, and related sequelae.

3. Defendant failed to warn physicians and the public about Beovu's propensity to

cause vision related adverse events including, but not limited to, retinal vasculitis, retinal vascular occlusion, and related sequelae.

4. Consumers and physicians alike have been misled about Beovu's safety and efficacy, and as a result consumers, including Plaintiff, have suffered serious and permanent eye injuries including retinal vasculitis, retinal vascular occlusion, and related sequelae.

PARTIES

5. Plaintiff, Howard Noll is and was at all times relevant hereto, a resident of Manchester, Maryland which is located in Carroll County, Maryland. Plaintiff used Beovu, and was treated for his Beovu related injuries, in this judicial District.

6. Defendant, Novartis Pharmaceuticals Corporation, a subsidiary of Novartis AG, is and was at all times relevant hereto, a corporation organized under the laws of the State of Delaware with its principal place of business at One Health Plaza, East Hanover, New Jersey 07936. Defendant, Novartis Pharmaceuticals Corporation is the current sponsor of the Biologics License Application for Beovu, and thus maintains primary responsibility and control over the drug and all activities and materials relating thereto. Upon information and belief, Defendant, Novartis Pharmaceuticals Corporation has also been substantively involved in the design, funding, authoring, conduct and/or publication of medical research related to Beovu.

7. Defendants, Novartis Pharmaceuticals Corporation shall hereinafter be referred to as "Defendant" or "Novartis".

8. At all times relevant here, Defendant has been engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Beovu, and controlling the Investigational New Drug Application and Biologics License Application for Beovu.

9. At all times relevant hereto, Defendant was engaged in the business of developing,

designing, licensing, manufacturing, distributing, selling, marketing, and or introducing into interstate commerce throughout the United States, and in the State of Maryland, either directly or indirectly, through third-parties, subsidiaries and/or related entities, the pharmaceutical product Beovu.

JURISDICTION & VENUE

10. The jurisdiction of this Court over the subject matter of this action is predicated on 28 U.S.C. § 1332. The amount in controversy exceeds $75,000.00, exclusive of interest and costs and complete diversity of citizenship exists between the parties.

11. Venue in this Court is proper pursuant to 28 U.S.C § 1391 in that a substantial part of the events or omissions giving rise to the claims asserted herein occurred in this District, and Defendant is subject to personal jurisdiction in this District.

GENERAL ALLEGATIONS

12. This action is for damages brought on behalf of Plaintiff, Howard Noll, who was prescribed and supplied with and who has taken the prescription drug Beovu, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, or otherwise placed in the stream of commerce by Defendant.

13. Plaintiff was prescribed and injected with Beovu on January 29, 2020. Subsequently, Plaintiff developed retinal vasculitis and other related sequelae. Prior to using Beovu, Plaintiff had been prescribed and used other anti-VEGF therapies without incurring any material side effects.

14. Plaintiff, Howard Noll**,** brings this action against Defendant to recover damages for the injuries suffered as a result of his ingestion of Beovu and to recover for his individual economic

and non-economic damages which he sustained as a result therefrom.

15. Defendant's wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

16. At all times relevant, Defendant was engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale the prescription drug Beovu for use by physicians in treating their patients, including Plaintiff.

17. At all times relevant, Defendant was authorized to do business within Plaintiff's state of residence and did conduct such business.

18. At times relevant, the officers and directors of Defendant participated in, authorized, and directed the production and promotion of Beovu when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of Beovu and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff discussed herein.

FACTS COMMON TO ALL COUNTS

19. Beovu® (brolucizumab) is a human vascular endothelial growth factor ("VEGF") inhibitor indicated for the treatment of Neovascular (Wet) Age-Related Macular Degeneration ("AMD" or "nAMD") in adults.

20. Wet AMD, also referred to as exudative AMD ("eAMD"), is characterized by the presence of choroidal neovascularization, a pathologic form of angiogenesis that results in the leakage and accumulation of fluid within the retina. In general, the primary goal of treatment for wet AMD is to maintain visual acuity, which requires drying the retina through the inhibition of

new blood vessel growth and reduction of fluid leakage.

21. The Beovu molecule, formerly known as ESBA1800 and/or RTH258, was originally developed by Switzerland-based ESBATech AG. ESBATech AG was acquired by Alcon, Inc. in September 2009, after which Alcon, Inc. and its subsidiaries, including Alcon Research, LLC f/k/a Alcon Research, Ltd., assumed ownership and all future marketing rights to Beovu. Novartis Pharmaceuticals Corporation subsequently acquired Alcon, Inc. in April 2011, and with it, ownership and all future marketing rights to Beovu. During the premarketing development process, Beovu was regulated under Investigational New Drug Application number 112023 in the United States.

22. Novartis announced that the United States Food and Drug Administration ("FDA") accepted the Biologics License Application ("BLA") for Beovu on April 15, 2019. At that time, Novartis noted that it had used a priority review voucher to expedite review of Beovu in the U.S. in order to "make brolucizumab available as quickly as possible". This is despite the fact that safe and efficacious drugs for the treatment of wet AMD were already on the market in the United States.

23. Beovu received FDA approval on October 7, 2019 under BLA number 761125.

24. Approval of Beovu was based on the results of two prospective, randomized, double-blind, multicenter Phase III studies, HAWK (NCT02307682) and HARRIER (NCT02434328), which, based on the data as characterized to the FDA by Defendants, met the primary endpoint of non-inferiority to aflibercept in mean change in best-corrected visual acuity ("BCVA") from baseline to week 48.

25. Beovu is administered as an intravitreal injection and is intended to treat AMD by inhibiting the binding of VEGF to the VEGFR1 and VEGFR2 receptors, thereby suppressing the

growth of abnormal blood vessels and reducing the potential for fluid leakage into the retina.

26. Beovu is the third VEGF inhibitor to receive FDA approval for the treatment of wet AMD. Other VEGF inhibitors approved for the treatment of wet AMD include Lucentis® (ranibizumab) by Genentech, which was approved June 30, 2006, and Eylea® (aflibercept) by Regeneron Pharmaceuticals, which was approved November 18, 2011. Unlike Beovu, Lucentis and Eylea "have been well established as effective and safe anti-VEGF therapies for nAMD".

27. Although not approved by the FDA for this indication, Avastin® (bevacizumab) by Genentech is another VEGF inhibitor routinely utilized by ophthalmologists in the treatment of wet AMD. Avastin has been on the market since February 26, 2004.

28. Clinical treatment guidelines published by the American Academy of Ophthalmology currently state "intravitreal injection therapy using anti-vascular endothelial growth factor (VEGF) agents (e.g., aflibercept, bevacizumab, and ranibizumab) is the most effective way to manage neovascular AMD and represents the first line of treatment".

29. Novartis sought to acquire and develop a new drug for the treatment of wet AMD that they could promote as requiring less frequent injections than other VEGF inhibitors. This would be accomplished by creating a drug composed of a smaller molecule that would allow for delivery of a greater molar dose with more effective tissue penetration and greater durability, thereby allowing for longer intervals between injections.

30. According to the published article titled *Retinal vasculitis and intraocular inflammation after intravitreal injection of brolucizumab* by Baumal et al., Beovu's "molecular mass of 26 kDa is less than that of other commercially available anti-VEGF agents, allowing for a higher molar concentration with potential for greater anti-VEGF therapeutic performance per intravitreal injection. Increased molar concentration combined with a high binding affinity for

VEGF have been postulated to account for its potential for increased durability, and brolucizumab is the first agent in this class approved for a dosing interval range of 8 to 12 weeks after 3 loading doses."

31. The instant matter involves injuries of retinal vasculitis, retinal vascular occlusion, and other acute eye injuries associated with the administration of Beovu.

32. Retinal vasculitis is characterized by inflammation of the vessels of the retina typically leading to a decrease in vision. Retinal vasculitis can lead to retinal vascular occlusion and/or retinal artery occlusion. Retinal vascular occlusion is characterized by an obstruction of the venous or arterial system of the retina, usually by a thrombus or embolus, causing vision loss which can be severe and permanent. If the occlusion occurs in the veins of the retina, the occlusion is referred to as a retinal vein occlusion. If the occlusion occurs in the arteries of the retina, the occlusion is referred to as a retinal artery occlusion. Herein the term "retinal vascular occlusion" is used to refer to occlusions of either the arteries or the veins in the retina.

33. Retinal vasculitis and retinal vascular occlusion are injuries unique to Beovu use. These injuries have been widely reported in patients taking Beovu, but are not considered to be a risk with other VEGF inhibitors.

34. On January 23, 2020, American Society of Retina Specialists ("ASRS") issued an alert to its members that it had already begun to receive physician reports of intraocular inflammation caused by the use of Beovu.

35. During the 43rd Annual Meeting of the Macula Society from February 19-22, 2020 additional safety data from the HAWK and HARRIER trials was presented publicly. During this presentation it was indicated that six cases of retinal vascular occlusion occurred in those clinical trials in the Beovu treated groups. It was observed in the medical literature thereafter that these

numbers were "different than the published Phase 3 data of the HAWK and HARRIER studies which reported only 3 cases of retinal artery occlusion/thrombosis". Thus, the underreporting of clinical trial reports of retinal vasculitis and retinal vascular occlusion was known by Novartis by this date, at the latest.

36. On February 23, 2020, the ASRS issued an alert to its members in which it noted that it had received 14 reported cases of vasculitis related to Beovu injections, 11 of which were designated as occlusive retinal vasculitis.

37. On March 2, 2020, Novartis announced it was "conducting a comprehensive review of a limited number of reported cases of severe vision loss, inflammation and potential retinal vasculitis in patients treated with Beovu" and that it would commission an external Safety Review Committee to conduct safety evaluations for Beovu. The announcement cited to the February 23, 2020 ASRS alert clearly indicating Novartis was aware of those reports at that time.

38. On March 30, 2020, ASRS issued an update noting the number of cases of retinal vasculitis related to intravitreal injections of Beovu it had received had risen to 25, with 21 such cases involving retinal occlusion.

39. In an article titled Retinal arterial occlusive vasculitis following intravitreal brolucizumab administration, published on March 31, 2020 Haug et al. presented a published report of vascular occlusion with vasculitis after intravitreal injection of Beovu for wet AMD. The patient, who had received multiple intravitreal ranibizumab treatments previously in both eyes without complication, reported loss of vision with light sensitivity in both eyes four weeks after bilateral intravitreal Beovu injection. After excluding other potential etiologies, and given the temporal relationship with administration of Beovu, the retinal vascular occlusion suffered by the

patient in this case was causally attributed to her use of Beovu. This patient's presentation was also noted to be similar to the prior reports of retinal vasculitis and retinal vascular occlusion reported by ASRS.

40. In an April 2, 2020 publication titled Severe vision loss secondary to retinal arteriolar occlusion after multiple intravitreal brolucizumab administrations, Jain et al. reported on a patient who presented with sudden blurry vision and floaters without pain or redness following her third injection of Beovu. The patient had previously received treatment with bevacizumab, ranibizumab, and aflibercept without incident. Upon examination the patient was found to have multiple retinal vascular occlusions which caused "severe loss of vision". After a thorough work-up and exclusion of other potential causal factors, the patient was ultimately diagnosed with "retinal arteriolar occlusion associated with repeated intravitreal brolucizumab administrations". It was also prominently noted in this article that retinal vascular occlusion had not previously been seen with other anti-VEGF drugs.

41. In another retrospective case series by the ASRS Research and Safety in Therapeutics ("ReST") Committee published on April 7, 2020 and titled Occlusive retinal vasculitis following intravitreal brolucizumab, Witkin et al. analyzed the characteristics of 26 post-marketing cases of retinal vasculitis following intravitreal Beovu administration in 25 patients which were reported to ASRS through April 1, 2020. In this study, retinal vasculitis presented after one Beovu injection in 11 (42%) eyes, after two injections in 11 (42%) eyes, and after three injections in four (16%) eyes. Authors noted that 22 (85%) eyes were reported by the treating physician as having occlusive vasculitis, with a mean time to presentation of 26 days (range, 3-63 days) from the most recent Beovu injection, and 46 days (range, 15-146 days) from the first Beovu

injection. All patients had previously been treated with other anti-VEGF agents with no history of anti-VEGF-associated inflammation, and no Beovu injections were given in the presence of intraocular inflammation according to the reporting physicians. Of note, 20 (77%) patients included in this case series were stated to have switched from other VEGF inhibitors to Beovu for the purpose of "Extend[ing] treatment interval", consistent with Novartis' marketing efforts. Authors also noted that they found no identifiable associations with product lot numbers, as these events were reported with Beovu from eight different lots administered by 20 different physicians, and expressed that there was no indication of an association with any ocular disorders, autoimmune diseases, drug allergies, or other medical disorders, ruling out alternative causation.

42. The authors ultimately concluded that these events were causally related to Beovu use. The authors further advised, "[b]ecause of the potentially severe nature of the consequences of retinal vasculitis secondary to brolucizumab, caution is advised when considering injection of brolucizumab in monocular patients or when bilateral injections are being contemplated".

43. Post-marketing adverse event reports related to retinal vasculitis and retinal vascular occlusion began flowing into Novartis almost immediately after Beovu came on the market.

44. On or before November 13, 2019, Novartis received a report of retinal vascular occlusion in a patient taking Beovu. The report was made by a physician and the injuries were noted to be both serious and resulting in disability to the patient.

45. On or before November 14, 2019, Novartis received a report of retinal vasculitis in a patient taking Beovu. The report was made by a physician and the injuries were noted to be both serious and resulting in a hospitalization by the patient.

46. In December 2019, Novartis received 2 additional reports of retinal vasculitis in

patients taking Beovu.

47. In January 2020 and prior to Plaintiff's use of Beovu, Novartis received 4 additional reports of retinal vasculitis and/or retinal vascular occlusion in patients taking Beovu.

48. Many of the adverse event reports outlined in paragraphs 44-47 contained causal attributions to Beovu use by the reporting physicians.

49. Several of the adverse event reports were ultimately published in the peer reviewed medical literature and included discussions of Beovu's causal contribution to the patients' retinal vasculitis or retinal vascular occlusion injuries.

50. These adverse event numbers have been reported, although based on well-established reporting principles, these numbers vastly underestimate the true number of these events occurring in Beovu users. Further, as specifically noted by Mones et al. in their publication regarding Beovu-related retinal vasculitis and retinal vascular occlusion, when it comes to postmarketing adverse event data, there is a "considerable possibility of underreporting".

51. As FDA has made clear in its Guidance for Industry, even a single well-documented post-marketing adverse event report can constitute a safety signal requiring action by the manufacturer, including a potential label change, particularly if the report involves an event that is extremely rare in the absence of drug use.

52. Retinal vasculitis and retinal vascular occlusion are adverse events that occur extremely rarely in the absence of drug use.

53. On April 8, 2020 Novartis confirmed the existence of a safety signal involving rare adverse events of "retinal vasculitis and/or retinal vascular occlusion that may result in severe vision loss" for Beovu and further advised that it would be seeking to update its product labeling for Beovu worldwide based on this confirmed safety signal.

54. The information outlined in paragraphs 43-47, 127-132, and 136 of this Complaint among others both individually and certainly collectively constitute newly acquired information pursuant to 21 C.F.R. § 601.12(f)(6) and which supported a label change for Beovu in order to properly warn about the risk of retinal vasculitis and retinal vascular occlusion with Beovu use. This is true both because the frequency of retinal vasculitis and retinal vascular occlusion reports seen prior to Plaintiff's use of Beovu exceeded what was reported by Novartis from its phase 3 clinical trials and because the type and severity of these same post-marketing adverse events differed from what was reported by Novartis from its phase 3 clinical trials for Beovu. This is likewise true because the phase 3 clinical trials themselves had many more retinal vasculitis and retinal vascular occlusion adverse events than were reported by Novartis at the time of drug approval.

55. Novartis did not immediately and promptly seek a label change by way of the existing CBE regulation. Novartis' delay in seeking an appropriate label change substantially contributed to Plaintiff ultimately suffering from retinal vascular occlusion.

56. It was not until June 9, 2020 that Novartis revised the United States product labeling for Beovu to include a new warning regarding the risk of "Retinal Vasculitis and/or Retinal Vascular Occlusion" (§5.2), which reads as follows:

> Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation, have been reported with the use of BEOVU [*see Contraindications (4.2) and Adverse Reactions (6.1)*]. Patients should be instructed to report any change in vision without delay.

57. It is yet unclear when this new warning was widely disseminated to physicians utilizing Beovu with their patients.

58. Prior to June 2020, no warnings regarding the risk of retinal vasculitis or retinal

vascular occlusion were present in the United States product labeling for Beovu.

59. Data further supporting the causal relationship between administration of Beovu and retinal vasculitis and retinal vascular occlusion injuries have been documented in the peer-reviewed medical literature. Several publications beyond those discussed above have detailed these adverse health outcomes following Beovu administration since its approval in 2019.

60. For example, in a publication titled *Retinal vasculitis and intraocular inflammation after intravitreal injection of brolucizumab,* Baumal et al. presented a retrospective case series of retinal vasculitis and intraocular inflammation in 15 eyes from 12 patients following administration of Beovu. All eyes had received previous intravitreal injections of one or more anti-VEGF agents including aflibercept, bevacizumab, and ranibizumab. The diagnosis of retinal vasculitis and intraocular inflammation in this series was made at a mean of 35.5 days (range 14-56 days) in 10 eyes after receiving the first Beovu injection and 20 days (range 7-25 days) in five eyes after receiving more than one Beovu injection. The most severely affected eyes in the series featured occlusion of larger retinal arteries at the optic nerve or branches proximal to the fovea, and demonstrated severe visual loss at 20/200 or worse when vasculitis was diagnosed and showed limited improvement at the most recent follow-up. Authors noted that a history of recent Beovu intravitreal injection combined with examination demonstrating the spectrum of features observed in the case series likely rules out a systemic event, which otherwise could occur in this age group. Baumal and colleagues found that "retinal vasculitis after brolucizumab was typically occlusive and could involve the retinal arteries, veins, and potentially capillaries, with a range in the severity of findings" and declared, "Brolucizumab is the first FDA-approved anti-VEGF agent associated with noninfectious retinal vasculitis after intravitreal therapy".

61. In a publication titled *Retinal Vasculitis After Administration of Brolucizumab*

Resulting in Severe Loss of Visual Acuity, Kondapalli et al. reported on a patient who experienced immediate blurry vision with clinically-significant boxcarring of the retinal arteries following her second injection of Beovu. This patient had previously been treated with bevacizumab and aflibercept without experiencing any intraocular inflammation or other complications. The patient was noted to have no visual improvement at her most recent follow-up, approximately five weeks post-injection. Fungal and viral etiologies were ruled out, and the patient was diagnosed with "occlusive retinal vasculitis associated with intravitreal administration of brolucizumab in the setting of neovascular age-related macular degeneration".

62. In a publication titled *Brolucizumab-related retinal vasculitis with exacerbation following ranibizumab retreatment: A clinicopathologic case study*, Iyer et al. described a case involving a patient who was found to have retinal vasculitis and intraocular inflammation after presenting with pain, ocular aches, floaters and decreased visual acuity one week following her third injection of Beovu. As with other reports, this patient had previously received regular intravitreal treatments with bevacizumab, aflibercept, and ranibizumab without incident. In discussing the matter, authors commented, "Retinal occlusive vasculitis with intraocular inflammation has been a devastating adverse event for brolucizumab, leading to blinding visual outcomes for many patients. Although intraocular inflammation has been seen with other anti-VEGF medications, severe vision loss due to retinal occlusive vasculitis has not been reported."

63. Based on the significant safety issue related to retinal vasculitis and retinal vascular occlusion, Rosenfeld & Browning explained in their recent editorial titled *Is This a 737 Max Moment for Brolucizumab?,* "[w]e have stopped using brolucizumab because of the associated inflammation. Our patients have alternatives without incurring this risk". Making note of the unusual nature of the inflammation in that it is associated with "occlusive vasculitis and

irreversible severe vision loss", they pointed out that "[t]he retinal community had not reported this type of vision-threatening occlusive retinal vasculitis after intravitreal injections of other commonly used anti-VEGF drugs". Finally, the authors stressed, "[I]t is our view that intravitreal injections of brolucizumab should stop. Brolucizumab is not the only drug that can be used for the treatment of eAMD. In the face of the known risk, its use is unwarranted."

64. In response to the Rosenfeld & Browning editorial, Kayath & Sauer (two Novartis employees) used a public platform to attempt to defend Novartis' handling of the matter and made clear that Novartis did not appreciate independent ophthalmologists shedding light on the undisclosed safety issues with Beovu and advising against its further use. The authors noted, "we believe the choice of treatment should ultimately be left to individual treating physicians and their patients, after appropriate evaluation of the benefit-risk profile of the product" and "[a]t Novartis, we support individual physicians, who we believe, whether or not they choose to use brolucizumab, are able to make the best treatment choices for their patients". At no point in this published response did these Novartis employees take responsibility or apologize for their failure to present accurate data concerning adverse events in clinical trials or for putting patients at risk for severe vision loss that otherwise could have been prevented had they not been exposed to Beovu.

65. Rosenfeld & Browning subsequently issued a reply criticizing the published response letter by Kayath & Sauer. The authors pointed out that "Their letter fails to disclose the recent clarifications in the HAWK and HARRIER trial data, and by doing so they fail to reveal the true risks and benefits for the patients who might be given brolucizumab". Noting that the external Safety Review Committee found that incidences of retinal vasculitis and retinal vascular occlusion were higher in the HAWK and HARRIER trials than previously reported, Rosenfeld & Browning

commented, "[t]hese data, and the discrepancy from the previously released results, in addition to the cases arising from the community use of brolucizumab, raise red flags". In response to Novartis' contention that the overall rate of vision loss was comparable between Beovu and aflibercept groups in the clinical trials, the authors noted that "this comparison is flawed", and such an assessment must instead be "based on the risk of vision loss from the drug and not from the natural history of disease progression after anti–vascular endothelial growth factor injections". Mirroring their statements in the original editorial, Rosenfeld & Browning commented "we believe that the benefits of brolucizumab are not worth the risks compared with similarly effective therapies that do not have the same risk of an occlusive vasculitis" and stated "we reiterate our recommendation that a moratorium be imposed on the use of brolucizumab until the cause is discovered for these inflammatory side effects and until remedies are devised". The authors finally declared, "It comes down to a simple question for Novartis and the vitreoretinal community: how many more patients need to lose vision before this moratorium is implemented?"

66. Echoing the concerns expressed by Rosenfeld & Browning, other retinal practices have also made the decision not to use Beovu in light of the significant safety issues involving retinal vasculitis and retinal vascular occlusion. For example, California-based The Retina Partners explained in a recent article, "Given that other safe and effective therapies exist for neovascular AMD, and that we currently have no way of predicting who will be affected by occlusive vasculitis, we have elected to avoid Beovu until safety can be demonstrated". They further noted, "many retina specialists, including our group, believe that odds of 1 in 50 that an injection could result in vascular occlusion is unacceptable – especially when some of these patients will end up with severely and permanently reduced visual acuity, and/or scotoma".

67. Researchers have identified biologically plausible mechanisms though which

Beovu can cause retinal vasculitis and/or retinal vascular occlusion events.

68. Various theories have been proposed, including that the pathogenic mechanism involves the formation of local antibodies, or patient factors such as prior anti-VEGF treatment use, human leukocyte antigens, immune status, and causative comorbidities are potential culprits.

69. According to Novartis, "The proprietary innovative structure results in a small molecule (26 kDa) with potent inhibition of, and high affinity to, all VEGF-A isoforms. Beovu is engineered to deliver a high concentration of drug, thus providing more active binding agents."

70. Given these unique attributes, certain researchers have proposed that the distinct molecular structure of Beovu is responsible for the events of retinal vasculitis and retinal vascular occlusion. As noted by Jain et al. in *Severe vision loss secondary to retinal arteriolar occlusion after multiple intravitreal brolucizumab administrations*, "[i]t could be theorized that the observed adverse event is attributed to the more potent VEGF blockade, owing to the properties of the brolucizumab molecule." Similarly, in *Occlusive retinal vasculitis following intravitreal brolucizumab,* Witkin et al. stated "[i]t is possible that because of its more potent anti-VEGF effect, brolucizumab may have a high enough anti-VEGF effect to cause retinal arteriolar constriction and occlusive vasculopathy compared with other anti-VEGF agents."

71. In a publication titled *Brolucizumab-related retinal vasculitis with exacerbation following ranibizumab retreatment: A clinicopathologic case study*, Iyer et al. also discussed the potential for the unique characteristics of Beovu to confer greater immunological effects than other VEGF inhibitor products, as they postulated "Brolucizumab may be more immunogenic than other anti-VEGF agents by virtue of its relative small size and consequent ability to unfold which exposes epitopes that may not be recognized by the immune system. Alternatively during the post-translational modification process of protein fragments like brolucizumab, structural changes such

as cleavage and cross-linking of the protein may result in the creation of new protein epitopes. These new protein structures could lead to formation of aggregates, which can significantly enhance immunogenicity."

72. Several researchers have also proposed that the retinal vasculitis and/or retinal vascular occlusion observed following exposure to Beovu is potentially a result of a type III or type IV hypersensitivity reaction.

73. A hypersensitivity reaction is an inappropriate or over-reactive immune response to an antigen resulting in undesirable effects in the human body. In a type III hypersensitivity reaction, an abnormal immune response is mediated by the formation of antigen-antibody aggregates called immune complexes, which can precipitate in various tissues and trigger the classical complement pathway. Complement activation leads to the recruitment of inflammatory cells that release lysosomal enzymes and free radicals at the site of immune complexes, causing tissue damage. A type IV hypersensitivity reaction, also referred to as a delayed hypersensitivity reaction because it takes more than 12 hours to develop, is mediated by T cells that provoke an inflammatory reaction against exogenous or endogenous antigens. After antigen exposure, an initial local immune and inflammatory response occurs that attracts leukocytes. Then the antigen, engulfed by macrophages and monocytes, is presented to T cells, which then becomes sensitized and activated. Type IV drug hypersensitivity occurs when various drug particles bind to a T cell receptor, even if not metabolized by antigen-presenting cells or presented by major histocompatibility complex molecules.

74. Pathologic findings in patients presenting with retinal vasculitis and/or retinal vascular occlusion following Beovu administration that support the plausibility of a type III or type IV delayed hypersensitivity reaction include the presence of anti-drug antibodies and elevated

T cells and B cells.

75. According to Iyer et al., "Among findings favoring type III hypersensitivity are frequent demonstration of anti-drug antibodies in the Hawk and Harrier trials, delayed onset retinal vasculitis, and some clinical overlap with hemorrhagic occlusive retinal vasculitis which is also postulated to involve type III hypersensitivity." The case reported by Iyer and colleagues also demonstrated the presence of both T cells and B cells in vitreous sample staining.

76. Regarding the Phase III clinical trials for Beovu, the FDA also found, "Among subjects with treatment-emergent antibodies, a higher number of intraocular inflammation events were observed".

77. Novartis has also commented on anti-drug antibodies observed during clinical trials, noting "In a post-hoc unmasked assessment of the Phase III HAWK and HARRIER data, there was an observed trend toward increased incidence of [retinal vasculitis and/or retinal vascular occlusion] in patients with treatment emergent (boosted/induced) anti-drug antibodies (ADAs)".

78. Beovu is a monoclonal antibody, which are complex, laboratory-made proteins that mimic the body's immune system in order to fight off infections or suppress disease processes, and may cause immunogenicity. As pointed out by Sharma et al. in their publication *Brolucizumab and immunogenicity*, "Type III hypersensitivity reactions (HSR) to the [monoclonal antibodies] including anti-VEGF agents used for oncological indications have been reported to cause vasculitis".

79. In May 2021, Novartis halted three ongoing Beovu studies due to increased reporting of intraocular inflammation, retinal vasculitis, and retinal vascular occlusion among those taking Beovu in the study. Novartis specifically cited concerns for patient safety in making the decision to halt the studies. Novartis further concluded based on these safety concerns that

"physicians should not treat patients with Beovu 6mg at intervals less than 2 months beyond the first three doses".

80. Consistent with the large and growing body of evidence demonstrating a causal relationship between Beovu and retinal vasculitis and retinal vascular occlusion, and that Beovu confers a greater risk of vision-threatening inflammatory adverse effects than alternative anti-VEGF treatments, Novartis has itself admitted to such an association. In a Novartis-funded and authored review titled *Brolucizumab: evolution through preclinical and clinical studies and the implications for the management of neovascular age-related macular degeneration*, Nguyen et al. admit to the causal relationship between Beovu and the injuries complained of herein, stating, "Amidst the reports of ocular inflammation, including occlusive retinal vasculitis with significant visual loss, ***that is associated with brolucizumab administration*** in eyes with neovascular AMD" (emphasis added).

81. As a direct and proximate result of the dangerous and defective nature of Beovu as described herein, Plaintiff suffered severe bodily injury, and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and treatment. The losses are permanent and Plaintiff will continue to suffer the losses in the future.

FIRST CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN

82. Plaintiff re-alleges and incorporates by reference all of the allegations contained in paragraphs 1-81 as if fully set forth herein.

83. At all times relevant hereto, Beovu was defective and unreasonably dangerous when it left the possession of Defendant in that it failed to contain warnings of an adequate or

sufficient nature as to alert consumers and physicians, including Plaintiff and Plaintiff's healthcare providers, to the dangerous risks associated therewith, including, but not limited, to its propensity to cause serious and permanent eye injuries including those which Plaintiff sustained. These risks and dangers were known and/or reasonably knowable by Defendant prior to and during the time which Plaintiff was prescribed and ingested Beovu.

84. At all times relevant hereto, Defendant failed to provide sufficient warnings and instructions that would have put the general public, including Plaintiff and Plaintiff's physicians, on notice of the dangers and adverse effects caused by ingestion of Beovu, including, but not limited to retinal vasculitis, retinal vascular occlusion, and related sequelae.

85. Defendant failed to provide warnings of such risks and dangers to Plaintiff and Plaintiff's healthcare providers as described herein, and further, concealed the known risks and dangers and failed to warn of known or scientifically knowable risks and dangers associated with Beovu from patients, the medical community, and consumers, including Plaintiff, and Plaintiff's healthcare providers.

86. Plaintiff was prescribed and did ingest Beovu in a manner consistent with and as intended by Defendant.

87. Ordinary patients and consumers, such as Plaintiff, could not have discovered or recognized any relevant potential risks and dangerous defects in Beovu through the exercise of reasonable care within their capacity.

88. Defendant, as an entity materially involved in the development, testing, manufacture, sale and/or distribution of Beovu, is held to the level of knowledge of an expert in the field.

89. Plaintiff individually, and through his prescribing physician, reasonably relied upon

the skill, superior knowledge, and judgment of Defendant.

90. Despite its possession of knowledge regarding these risks and a its duty to adequately warn of severe and dangerous adverse events associated with use of Beovu, Defendant failed to properly warn the medical community and consumers, including Plaintiff and Plaintiff's healthcare providers, that use of Beovu was associated with an increased risk of serious vision problems including retinal vasculitis, retinal vascular occlusion, and related sequelae.

91. Beovu was designed, manufactured, distributed, sold and/or supplied by Defendant, and was marketed while defective due to inadequate warnings, instructions, labeling and/or inadequate testing in light of Defendant's knowledge of Beovu's innate risks and dangers and attributable serious vision related adverse events.

92. At all times up to the present, Defendant has failed to properly warn of the risk of serious vision problems including retinal vasculitis, retinal vascular occlusion, and related sequelae. No warning concerning retinal vasculitis or retinal vascular occlusion was contained in the product labeling prior to Plaintiff's use of Beovu and subsequent diagnosis with retinal vascular occlusion.

93. The only information contained on these conditions prior to June 2020, which could be found in the "Clinical Trials Experience" section of the label was inadequate and otherwise false and misleading because it failed to convey and still fails to convey the absolute risk of retinal vasculitis or retinal vascular occlusion from the Beovu clinical trials. The numbers conveyed in this section to this date reflect that 1% of clinical trial patients experienced these injuries while the number is and has always been at least 3.3%.

94. The product labeling for Beovu has at all times also failed to reflect that the clinical trials for Beovu demonstrated a 2,312% increased relative risk of retinal vasculitis or retinal

vascular occlusion in Beovu users as compared to those patients that used the active control (aflibercept) in the clinical trials.

95. Defendant had a post-sale duty to timely warn physicians including Plaintiff's healthcare providers, and consumers, such as Plaintiffs, about the potential risks and complications associated with use of Beovu.

96. As discussed herein, Defendant has intentionally misrepresented the clinical trial data for Beovu to healthcare providers and the general public in order to mask the true risk of retinal vascular occlusion, retinal vasculitis, intraocular inflammation, and other severe eye injuries related to Beovu use. Those misrepresentations continue to the present.

97. Specifically, at all times relevant to this case Defendant intentionally withheld from Plaintiff and his treating physicians the true number of retinal vasculitis, retinal vascular occlusion, and intraocular inflammation reports seen in the Beovu clinical trials.

98. Defendant further intentionally concealed information demonstrating a 2,312% increase in relative risk for retinal vasculitis or retinal vascular occlusion when comparing the patients in the clinical trials taking Beovu and the patients assigned to the active control (aflibercept).

99. Even more egregious than just concealing the aforementioned data, Defendant through its sales representatives has intentionally engaged in marketing efforts seeking to induce healthcare providers to switch their patients from other anti VEGF agents to Beovu despite lacking the necessary evidence to demonstrate that Beovu is safe and effective in this population and despite affirmative evidence that the drug is not safe in this patient population and without advising patients and physicians that switch to Beovu from these other agents actually poses a greater risk of harm to the patient, especially as it related to retinal vasculitis,

retinal vascular occlusion, and intraocular inflammation.

100. Defendant has intentionally misled healthcare providers and the general public in making non-inferiority claims for Beovu as compared to other anti VEGF agents despite possessing the knowledge that these claims are false.

101. Defendant has intentionally failed to properly warn healthcare providers about the true risk of retinal vasculitis, retinal vascular occlusion, intraocular inflammation, and other severe eye injuries related to Beovu use despite possessing knowledge that Beovu causes these serious adverse events.

102. Specifically, here Defendant publically acknowledged the need to change the product labeling for Beovu on April 8, 2020 to add a warning about retinal vasculitis and retinal vascular occlusion, which are serious life altering injuries. However, rather than immediately disseminate a warning concerning these injuries in the product labeling through the available Changes Being Effected process and other available sources Defendant intentionally and voluntarily chose to update their product labeling for Beovu through much slower means and didn't avail themselves of other available tools to disseminate the warning more quickly.

103. Defendant's actions were willful and malicious in that Defendant's conduct was carried on with a conscious disregard for the safety and rights of Plaintiff and others. Defendant's unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendant in an amount appropriate to punish Defendant, and deter similar conduct in the future.

104. As a direct and proximate result of the dangerous and defective nature of Beovu, Plaintiff suffered retinal vasculitis and other serious eye injuries, and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of

hospitalization, and medical treatment. The losses are permanent and the Plaintiff will continue to suffer the losses in the future.

SECOND CAUSE OF ACTION
NEGLIGENCE

105. Plaintiff re-alleges and incorporates by reference all of the allegations contained in paragraphs 1-81 as if fully set forth herein.

106. At all times relevant hereto, Defendant was under a duty to exercise reasonable care in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling, and testing Beovu to ensure that use of Beovu did not result in avoidable injuries.

107. At all times relevant hereto, Defendant owed a duty to consumers, physicians, and the general public to assess, manage, and communicate the risks, dangers, and adverse effects of Beovu, and to warn consumers and the medical community, including Plaintiff and Plaintiff's healthcare providers, of those risks, dangers, and adverse effects.

108. Defendant's duties include, but are not limited to, carefully and properly advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling, and testing Beovu, which was placed in the stream of commerce, and providing adequate information regarding the appropriate use of Beovu.

109. Defendant negligently breached the above-described duties to Plaintiff by committing negligent acts and/or omissions, including, but not limited to the following:

a. failing in their obligation to provide consumers and the medical community, including Plaintiff and Plaintiff's healthcare providers, with accurate, adequate and

clinically relevant information, data and warnings regarding the adverse health risks associated with use of Beovu, and/or that there existed safer alternative pharmaceutical drugs to treat AMD;

b. failing to provide adequate post-marketing warnings and instructions after Defendant knew or should have known of the significant risks of, among other things, adverse vision-related events and/or reactions, including, but not limited to an increased risk for retinal vasculitis, retinal vascular occlusion, and related sequelae associated with use of Beovu;

c. failing to review all medical literature regarding Beovu and failing to report data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Beovu;

d. failing to disclose the results of the testing and other information in their possession regarding the potential for Beovu to cause vision-related adverse events including, but not limited to, an increased risk for retinal vasculitis, retinal vascular occlusion, and related sequelae;

e. representing that Beovu was safe for use when, in fact, Defendant knew or should have known that it was unsafe for use and that Beovu use was associated with vision-related events and/or reactions, including, but not limited to an increased risk for retinal vasculitis, retinal vascular occlusion, and related sequelae;

f. promoting and marketing Beovu for use despite the fact that Defendant knew or should have known that Beovu use was associated with vision-related adverse events and/or reactions, including, but not limited to an increased risk for retinal vasculitis, retinal vascular occlusion, and related sequelae;

g. promoting and marketing Beovu as safe and effective for use when, in fact, it was unsafe, especially as compared to other available therapies to treat AMD;

h. failing to conduct adequate post-marketing studies, non-clinical and clinical testing, and post-marketing surveillance and analyses to determine and subsequently communicate the safety profile and side effects associated with the use of Beovu;

i. continuing to promote the safety and effectiveness of Beovu while downplaying its risks, even after Defendant knew or should have known of the significant risks of Beovu use;

j. failing to provide consumers and the medical community, including Plaintiff and Plaintiff's healthcare providers, with scientific data which indicated that Beovu was unreasonably dangerous due to its propensity to cause vision-related adverse events including, but not limited to, an increased risk for retinal vasculitis, retinal vascular occlusion, and related sequelae; and/or

k. failing to adequately test Beovu on patients that had a prior history of anti-VEGF

use especially in light of the plan to market precisely to that population of patients.

110. Although Defendant knew or should have known that Beovu causes unreasonably dangerous side effects, including an increased risk for retinal vasculitis, retinal vascular occlusion, and related sequelae, they continue to market Beovu, despite the fact there are safer and more or equally effective alternative therapies to treat AMD.

111. Defendant knew or should have known that failure to exercise ordinary care, as described herein, would result in serious injury to patients, such as Plaintiff.

112. Defendant had a post-sale duty to timely warn physicians including Plaintiff's healthcare providers, and consumers, such as Plaintiffs, about the potential risks and complications associated with use of Beovu.

113. As discussed herein, Defendant has intentionally misrepresented the clinical trial data for Beovu to healthcare providers and the general public in order to mask the true risk of retinal vascular occlusion, retinal vasculitis, intraocular inflammation, and other severe eye injuries related to Beovu use. Those misrepresentations continue to the present.

114. Specifically, at all times relevant to this case Defendant intentionally withheld from Plaintiff and his treating physicians the true number of retinal vasculitis, retinal vascular occlusion, and intraocular inflammation reports seen in the Beovu clinical trials.

115. Defendant further intentionally concealed information demonstrating a 2,312% increase in relative risk for retinal vasculitis or retinal vascular occlusion when comparing the patients in the clinical trials taking Beovu and the patients assigned to the active control (aflibercept).

116. Even more egregious than just concealing the aforementioned data, Defendant through its sales representatives has intentionally engaged in marketing efforts seeking to

induce healthcare providers to switch their patients from other anti VEGF agents to Beovu despite lacking the necessary evidence to demonstrate that Beovu is safe and effective in this population and despite affirmative evidence that the drug is not safe in this patient population and without advising patients and physicians that switch to Beovu from these other agents actually poses a greater risk of harm to the patient, especially as it related to retinal vasculitis, retinal vascular occlusion, and intraocular inflammation.

117. Defendant has intentionally misled healthcare providers and the general public in making non-inferiority claims for Beovu as compared to other anti VEGF agents despite possessing the knowledge that these claims are false.

118. Defendant has intentionally failed to properly warn healthcare providers about the true risk of retinal vasculitis, retinal vascular occlusion, intraocular inflammation, and other severe eye injuries related to Beovu use despite possessing knowledge that Beovu causes these serious adverse events.

119. Specifically, here Defendant publically acknowledged the need to change the product labeling for Beovu on April 8, 2020 to add a warning about retinal vasculitis and retinal vascular occlusion, which are serious life altering injuries. However, rather than immediately disseminate a warning concerning these injuries in the product labeling through the available Changes Being Effected process and other available sources Defendant intentionally and voluntarily chose to update their product labeling for Beovu through much slower means and didn't avail themselves of other available tools to disseminate the warning more quickly.

120. Defendant's actions were willful and malicious in that Defendant's conduct was carried on with a conscious disregard for the safety and rights of Plaintiff and others. Defendant's unconscionable conduct thereby warrants an assessment of exemplary and punitive damages

against Defendant in an amount appropriate to punish Defendant, and deter similar conduct in the future.

121. As a direct and proximate result of the dangerous and defective nature of Beovu Plaintiff suffered retinal vasculitis and other serious eye injuries, and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, and medical care and treatment. The losses are permanent and the Plaintiff will continue to suffer the losses in the future.

THIRD CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION

122. Plaintiff re-alleges and incorporates by reference all of the allegations contained in paragraphs 1-81 as if fully set forth herein.

123. Defendant's fraudulent, intentional and material misrepresentations and omissions regarding the safety and efficacy of Beovu and of Beovu's side effects, including that concerning an increased risk for retinal vasculitis, retinal vascular occlusion, and related sequelae were communicated to Plaintiffs directly through promotional materials, advertising, product inserts, and the product monograph with the intent that Plaintiff use Beovu. The safety and efficacy of Beovu was also fraudulently and intentionally misrepresented to Plaintiff's healthcare providers with the intent that such misrepresentations would result in Beovu being prescribed and administered to Plaintiff.

124. Defendant knew that the material representations they were making regarding the safety, efficacy, and side effects of Beovu were false.

125. Defendant fraudulently and intentionally made misrepresentations and/or actively concealed, suppressed, or omitted this material information with the intention and specific desire to induce consumers and the medical community, including Plaintiff and Plaintiff's healthcare

providers, to use, prescribe, and purchase Beovu.

126. Defendant fraudulently and intentionally knew that Plaintiff and/or Plaintiff's healthcare providers would rely upon such material misrepresentations and/or omissions in selecting Beovu for the treatment of Plaintiff.

127. Data from the HAWK and HARRIER Phase III clinical trials were published in January 2020. In their publication titled *HAWK and HARRIER: phase 3, multicenter, randomized, double-masked trials of brolucizumab for neovascular age-related macular degeneration*, Dugel et al. reported no cases of retinal vasculitis in any treatment group, two (0.6%) serious cases of retinal artery occlusion in the Beovu 3mg group, no serious cases of retinal artery occlusion in the Beovu 6mg groups, and one (0.3%) serious case of retinal artery occlusion in the aflibercept 2mg group. These events were simply listed in a table in the publication and were not discussed by authors in the text of the manuscript. Additionally, as noted below, these events were significantly underreported in this publication.

128. It should further be noted that Defendant, Novartis funded and "participated in the design of the study; management, analysis, and interpretation of the data; preparation, review, and approval of the manuscript" for this publication by Dugel and colleagues. Additionally, two of the authors of this study, James Warburton, MBBS and Andreas Weichselberger, PhD, were employees of Novartis and were noted to have contributed to the conception and design, data collection, analysis and interpretation, and maintained overall responsibility for the study. These two authors are also inventors of the brolucizumab molecule as reflected on United States Patent number US 2016/0130337 A1. Accordingly, at all times Defendant maintained control over the study data and manuscript, and thus had the ability to edit, revise, or correct any false or misleading information contained therein, however it chose not to do so.

129. On June 4, 2020, ASRS issued a report containing the external Safety Review Committee's initial findings regarding cases of retinal vasculitis and retinal vascular occlusion occurring during the Phase III HAWK and HARRIER trials. This review was conducted solely by using data provided to the Safety Review Committee by Novartis. This data was available to Novartis at all times relevant, including before the drug was first made available for use in the United States.

130. According to the report, out of a total 1,088 patients in premarket clinical trials assigned to Beovu treatment arms, the committee found that 36 (3.3%) experienced retinal vasculitis, 23 (2.1%) of which experienced concomitant vascular occlusion. Risk of ≥ 3 line vision loss and ≥ 6 line vision loss over two years in patients with retinal vasculitis was 22% (8/36) and 14% (5/36), respectively, and in those with occlusive retinal vasculitis was 30% (7/23) and 22% (5/23), respectively.

131. On a comparative basis, only 1 patient in the aflibercept group in the Beovu phase 3 clinical trials suffered from retinal vasculitis or retinal vascular occlusion.

132. In comparing the external Safety Review Committee's findings to the Beovu Phase III clinical trial data as originally reported by Novartis to the FDA, ASRS commented, "the [Safety Review Committee] found that their observed incidences of both retinal vasculitis and retinal vascular occlusion were higher than the incidences reported by the investigators".

133. Published ahead-of-press on June 20, 2020, just 16 days after the preliminary Safety Review Committee's report was issued, in a publication titled *HAWK and HARRIER: Ninety-Six-Week Outcomes from the Phase 3 Trials of Brolucizumab for Neovascular Age-Related Macular Degeneration*, Dugel et al. (2020) reported on 96-week outcomes from the HAWK and HARRIER Phase III clinical trials. In this updated data set, retinal vasculitis was simply noted to have occurred

during the trials, and the treatment assignments and number of patients affected were not reported. Four retinal arterial occlusive events were reported in the Beovu 3mg group and six retinal arterial occlusive events were reported in the Beovu 6mg groups. Total retinal arterial occlusive events occurring in the aflibercept 2mg group were not reported, but one case of retinal artery occlusion coded as a serious adverse event was listed in a table.

134. Dugel and colleagues did make a passing reference to postmarketing cases of intraocular inflammation, vasculitis, and retinal occlusive vasculitis as reported by ASRS, and noted that such reports are currently being investigated by Novartis and an external safety review committee. However, there was no mention by the authors that the safety review committee was reanalyzing the HAWK and HARRIER data and had already found numerous unreported cases of retinal vasculitis and retinal vascular occlusion. It should be noted that while this manuscript was originally submitted for publication in December 2019, it was last revised on June 4, 2020, the same day the Safety Review Committee report was issued, prior to its being accepted for publication by *Ophthalmology* on June 12, 2020.

135. Similar to the earlier publication by Dugel et al. discussed above, Novartis funded and "participated in the design of the study; management, analysis, and interpretation of the data; and preparation, review, and approval of the manuscript" for this updated publication by Dugel and colleagues. Again, two of the authors of the study, Georges Weissgerber, MD and Kinfemichael Gedif, PhD, were employees of Novartis and one or both were noted to have contributed to the conception and design, data collection, analysis and interpretation, and maintained overall responsibility for the study. Accordingly, at all times Defendant maintained control over the study data and manuscript, and thus had the ability to edit, revise, or correct any false or misleading information contained therein, however it chose not to do so.

136. The findings of the external Safety Review Committee, previously discussed above, were formally published in November 2020 in an article titled *Risk of Inflammation, Retinal Vasculitis and Retinal Occlusion-Related Events with Brolucizumag: Post-Hoc Review of HAWK and HARRIER.* In addition to reiterating the data previously disclosed in the June 2020 report, Mones et al. provided additional detail and context to the events of retinal vasculitis and retinal vascular occlusion that occurred in the clinical trials for Beovu. The authors took care to emphasize that their review was limited only to the 60 patients for whom investigators reported intraocular inflammation and did not include all patients enrolled in the clinical trials. As such, they noted "Additional cases may have been identified if the SRC had applied the conservative review to all patients in the two studies" and stated "The actual event rate may have been higher than reported by the investigators, particularly if some of the cases were minimally symptomatic or asymptomatic". Based on the data that was made available to the committee, there were eight cases of at least moderate visual acuity loss (≥15 ETDRS letters) among eyes with definite or probable intraocular inflammation, five of which were severe (≥30 ETDRS letters), and seven of these cases occurred in eyes with definite or probable intraocular inflammation with concomitant retinal vasculitis and retinal vascular occlusion. In eyes with definite or probable intraocular inflammation, the incidence of retinal vasculitis was 72.0%; in eyes with intraocular inflammation and retinal vasculitis, the incidence of retinal occlusion was 63.9%. Approximately three quarters of cases of each event occurred within six months of the first Beovu injection, and half of cases occurred within the first three months following the first Beovu injection. Mones et al. discussed some of the limitations of the imaging performed by the study investigators and made available for their review, commenting that "fluorescein angiograms were usually not widefield and limited in number, preventing the assessment of peripheral vasculitis signs and retinal blood flow".

Authors concluded, "this rigorous analysis of cases of definite/probable IOI that occurred in the phase 3 HAWK and HARRIER clinical trials identified a number of cases with signs of retinal vasculitis with or without signs of retinal vascular occlusion, and such events were associated with increased risk of visual acuity loss". In their discussion, Jain et al. pointed out that data from the HAWK and HARRIER clinical trials as presented at the 43rd Annual Meeting of the Macula Society indicated six cases of retinal artery occlusion (including terms of retinal artery thrombosis, retinal artery occlusion, and retinal artery embolism) occurred in the brolucizumab 6mg patients. They then made the observation that these data were "different than the published Phase 3 data of the HAWK and HARRIER studies which reported only 3 cases of retinal artery occlusion/thrombosis".

137. The only information contained in the product labeling for Beovu concerning retinal vasculitis or retinal vascular occlusion was contained in the "Clinical Trials Experience" subsection of the "Adverse Reactions" section of the Beovu label.

138. The relevant information contained in the "Clinical Trials Experience" section of the label has at all times been false as it relates to the occurrence of retinal vasculitis and retinal vascular occlusion. The information contained in that section of the label from the launch of the drug to present has indicated that these conditions occurred in 1% of clinical trial patients. However, as noted above, at a minimum, these conditions occurred in at least 3.3% of clinical trial patients receiving Beovu. To further mask the true incidence of retinal vasculitis in its clinical trials for Beovu, Novartis now lists these events, in part, in the Adverse Reactions section of the label with other unrelated adverse events under the medically incorrect label of "Intraocular Inflammation".

139. Defendant made these misrepresentations and/or omissions and actively concealed

adverse information at a time when they, their agents and/or their employees knew that Beovu had certain defects, dangers, and characteristics that differed from what had been represented to the medical community and the consuming public, including Plaintiff's healthcare providers and Plaintiff. In addition to the representations discussed above, those misrepresentations and omissions include, but are not limited to, the following:

a. Defendant failed to disclose or actively concealed data demonstrating that Beovu increased the risk of vision-related adverse events including, but not limited to, retinal vasculitis, retinal vascular occlusion, and related sequelae. Specifically, Defendant omitted from its product labeling data demonstrating a 2,312% increase in relative risk for retinal vasculitis or retinal vascular occlusion and related sequelae and misrepresented the incidence of retinal vasculitis and retinal vascular occlusion as occurring in 1% of clinical trial patients rather than a minimum of 3.3% of patients that actually suffered these injuries in the Beovu clinical trials. Plaintiff and his prescribing physician were misled by this in accurate information and detrimentally relied on this inaccurate information in deciding to prescribe and take Beovu;

b. Defendants failed to include or provide adequate warnings along with Beovu regarding potential and established risks, and the nature, scope, severity, and duration of any serious side effects of Beovu use, including, but not limited to, an increased risk of retinal vasculitis, retinal vascular occlusion, and related sequelae, when compared to other available therapies to treat AMD. Plaintiff and his prescribing physician relied on these lack of warnings to conclude that Beovu did not pose these risks when compared to other available therapies to treat AMD;

c. Since receiving FDA approval, Novartis has encouraged ophthalmologists to switch their patients to Beovu by marketing it as requiring less frequent injections than other VEGF inhibitors used in the treatment of AMD, thereby purporting to offer greater convenience and reduce patient non-adherence. While Novartis' marketing of Beovu has been primarily directed towards convincing doctors to switch patients who have previously been treated with other VEGF inhibitors to Beovu, none of the patients included in the premarket clinical trials had ever received prior treatment with other VEGF inhibitors. Instead, the study protocols for the HAWK and HARRIER clinical trials required all enrolled patients to be treatment-naïve. Therefore, Novartis failed to perform any testing in the very patient population to which it intended, and indeed did, specifically market Beovu to after it received FDA approval. As such, Defendant promoted Beovu as a safe and effective treatment for patients with a prior history of using other anti-VEGF therapies despite the fact that the Defendant had not properly studied Beovu in that patient population in its clinical trials for Beovu. This promotion occurred as to Plaintiff's prescribing physician prior to Plaintiff being prescribed Beovu and Plaintiff's prescribing physician detrimentally relied on these representations in

deciding to prescribe Beovu to Plaintiff.

d. Defendant failed to issue a safety communication like a Dear Healthcare Professional Letter or otherwise timely update its product labeling upon receipt of post-marketing adverse event reports involving retinal vasculitis, and/or retinal vascular occlusion. Given this material omission, Plaintiff and his prescribing physician used Beovu without an understanding that these events had been reported in the post-marketing setting and therefore prescribed and used the drug without possessing this knowledge.

140. In addition to misreporting the safety data from the HAWK and HARRIER clinical trials as demonstrated by the external Safety Review Committee reanalysis, Novartis has misled healthcare providers and the public by consistently downplaying the frequency at which retinal vasculitis and/or retinal vascular occlusion adverse events have occurred in patients treated with Beovu.

141. On March 2, 2020, Novartis issued a press release regarding "reported cases of severe vision loss, inflammation and potential retinal vasculitis in patients treated with Beovu" in which it stated, "[w]e believe the incidence of these events remains consistent with or below the package insert".

142. Again, on March 11, 2020, Novartis issued a press release in which it stated "[t]he rate of the reported post-marketing events remains consistent with or below the approved prescribing information". However, during March 2020 the United States prescribing information cited an incidence rate of 1% for retinal vascular occlusion occurring in the HAWK and HARRIER clinical trials and cited no incidence rate for, nor made any reference to retinal vasculitis.

143. In April 2020, Novartis' Chief Executive Officer Vas Narasimhan, citing the incidence of these adverse events, was quoted as stating they are "very rare, with about 1 to 2 cases in 10,000 injections". Despite this statement citing an incidence rate even lower than Novartis had cited just the month prior, Novartis nonetheless issued another press release on April 8, 2020 in

which it stated that it was initiating an update to the prescribing information for Beovu after it "concluded that there is a confirmed safety signal of rare adverse events of 'retinal vasculitis and/or retinal vascular occlusion that may result in severe vision loss'".

144. Also wildly inconsistent with Novartis' earlier statements, as reported by BioPharma Dive on April 9, 2020, after a review of Beovu postmarketing data "Novartis found retinal artery occlusion, inflammation of blood vessels in the eye — known as vasculitis — or severe vision loss occurred in 8.75 to 10.08 out of 10,000 injections for five weeks spanning Feb. 28 to March 27".

145. Following the emergence of the safety issues discussed herein, Novartis created a webpage which provides data on the incidence of events of retinal vasculitis and retinal vascular occlusion which have been reported in the postmarketing setting since October 2019. By reviewing the data presented on this website, it can be seen that Novartis has consistently downplayed and continues to downplay the frequency with which these adverse events have actually occurred in patients treated with Beovu, and that the frequency at which these events are occurring continues to rise.

146. As of July 24, 2020, Novartis' postmarketing data website for Beovu cited the following incidence rates for the adverse events of interest: 2.73 reports of retinal vasculitis per 10,000 injections; 2.64 reports of retinal vascular occlusion per 10,000 injections; 4.76 reports of concomitant retinal vasculitis and retinal vascular occlusion per 10,000 injections; and when all categories are combined, 10.13 reports of retinal vasculitis, retinal vascular occlusion, or retinal vasculitis with retinal vascular occlusion per 10,000 injections.

147. As of September 25, 2020, Novartis' postmarketing data website for Beovu cited the following incidence rates for the adverse events of interest: 4.50 reports of retinal vasculitis

per 10,000 injections; 3.00 reports of retinal vascular occlusion per 10,000 injections; 6.14 reports of concomitant retinal vasculitis and retinal vascular occlusion per 10,000 injections; and when all categories are combined, 13.64 reports of retinal vasculitis, retinal vascular occlusion, or retinal vasculitis with retinal vascular occlusion per 10,000 injections.

148. As of October 23, 2020, Novartis' postmarketing data website for Beovu cited the following incidence rates for the adverse events of interest: 5.13 reports of retinal vasculitis per 10,000 injections; 3.22 reports of retinal vascular occlusion per 10,000 injections; 6.12 reports of concomitant retinal vasculitis and retinal vascular occlusion per 10,000 injections; and when all categories are combined, 14.50 reports of retinal vasculitis, retinal vascular occlusion, or retinal vasculitis with retinal vascular occlusion per 10,000 injections.

149. As of November 20, 2020, Novartis' postmarketing data website for Beovu cited the following incidence rates for the adverse events of interest: 5.08 reports of retinal vasculitis per 10,000 injections; 3.24 reports of retinal vascular occlusion per 10,000 injections; 7.16 reports of concomitant retinal vasculitis and retinal vascular occlusion per 10,000 injections; and when all categories are combined, 15.47 reports of retinal vasculitis, retinal vascular occlusion, or retinal vasculitis with retinal vascular occlusion per 10,000 injections.

150. Defendant's material misrepresentations and/or active concealment, suppression, and omissions were perpetuated directly and/or indirectly by Defendant, their sales representatives, employees, distributors, agents and/or detail persons, through databases, printouts, monographs, product labeling and other information drafted, prepared, marketed, sold, and supplied by Defendant, their sales representatives, employees, distributors, agents and/or detail persons.

151. Defendant's material misrepresentations and/or active concealment, suppression, and omissions constitute a continuing tort.

152. Through its product inserts and other public statements, Defendant continues to misrepresent the serious potential vision-related risks and complications associated with use of Beovu.

153. Defendant had a post-sale duty to timely warn physicians including Plaintiff's healthcare providers, and consumers, such as Plaintiffs, about the potential risks and complications associated with use of Beovu.

154. Defendant fraudulently and intentionally misrepresented the safety and efficacy of Beovu in its labeling, advertising, product inserts, promotional materials, or other marketing resources and materials.

155. If Plaintiff's healthcare providers and Plaintiff had known the true facts concerning the risks of Beovu use, in particular, the risk of vision-related adverse events and/or reactions, including, but not limited to an increased risk for retinal vasculitis, retinal vascular occlusion, and related sequelae, they would not have prescribed or used Beovu and would have instead prescribed and used a safer alternative pharmaceutical drug or no drug at all.

156. Plaintiff and Plaintiff's healthcare providers' reliance upon Defendant's material misrepresentations were justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position of knowledge of the true facts concerning Beovu, while Plaintiff and Plaintiff's healthcare providers were not in a position to know the true facts concerning Beovu, and because Defendant overstated the benefits and safety of Beovu, and concomitantly downplayed the risks of its use, including, but not limited to, an increased risk for retinal vasculitis, retinal vascular occlusion, and related sequelae, thereby inducing Plaintiff's healthcare providers to prescribe and Plaintiff to use Beovu, in lieu of other safer alternatives, or no drug at all.

157. As discussed herein, Defendant has intentionally misrepresented the clinical trial data for Beovu to healthcare providers and the general public in order to mask the true risk of retinal vascular occlusion, retinal vasculitis, intraocular inflammation, and other severe eye injuries related to Beovu use. Those misrepresentations continue to the present.

158. Specifically, at all times relevant to this case Defendant intentionally withheld from Plaintiff and his treating physicians the true number of retinal vasculitis, retinal vascular occlusion, and intraocular inflammation reports seen in the Beovu clinical trials.

159. Defendant further intentionally concealed information demonstrating a 2,312% increase in relative risk for retinal vasculitis or retinal vascular occlusion when comparing the patients in the clinical trials taking Beovu and the patients assigned to the active control (aflibercept).

160. Even more egregious than just concealing the aforementioned data, Defendant through its sales representatives has intentionally engaged in marketing efforts seeking to induce healthcare providers to switch their patients from other anti VEGF agents to Beovu despite lacking the necessary evidence to demonstrate that Beovu is safe and effective in this population and despite affirmative evidence that the drug is not safe in this patient population and without advising patients and physicians that switch to Beovu from these other agents actually poses a greater risk of harm to the patient, especially as it related to retinal vasculitis, retinal vascular occlusion, and intraocular inflammation.

161. Defendant has intentionally misled healthcare providers and the general public in making non-inferiority claims for Beovu as compared to other anti VEGF agents despite possessing the knowledge that these claims are false.

162. Defendant has intentionally failed to properly warn healthcare providers about the

true risk of retinal vasculitis, retinal vascular occlusion, intraocular inflammation, and other severe eye injuries related to Beovu use despite possessing knowledge that Beovu causes these serious adverse events.

163. Specifically, here Defendant publically acknowledged the need to change the product labeling for Beovu on April 8, 2020 to add a warning about retinal vasculitis and retinal vascular occlusion, which are serious life altering injuries. However, rather than immediately disseminate a warning concerning these injuries in the product labeling through the available Changes Being Effected process and other available sources Defendant intentionally and voluntarily chose to update their product labeling for Beovu through much slower means and didn't avail themselves of other available tools to disseminate the warning more quickly.

164. Defendant's actions were willful and malicious in that Defendant's conduct was carried on with a conscious disregard for the safety and rights of Plaintiff and others. Defendant's unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendant in an amount appropriate to punish Defendant, and deter similar conduct in the future.

165. As a direct and proximate result of the dangerous and defective nature of Beovu Plaintiff suffered retinal vasculitis and other serious eye injuries, and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, and medical care and treatment. The losses are permanent and the Plaintiff will continue to suffer the losses in the future.

FOURTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

166. Plaintiff re-alleges and incorporates by reference all of the allegations contained in paragraphs 1-81 as if fully set forth herein.

167. Defendant's negligent material misrepresentations and omissions regarding the safety and efficacy of Beovu and of Beovu's side effects, including that concerning an increased risk for retinal vasculitis, retinal vascular occlusion, and related sequelae were communicated to Plaintiffs directly through promotional materials, advertising, product inserts, and the product monograph with the intent that Plaintiff use Beovu. The safety and efficacy of Beovu was also negligently misrepresented to Plaintiff's healthcare providers with the intent that such misrepresentations would result in Beovu being prescribed and administered to Plaintiff.

168. Defendant either knew or should have known that the material representations they were making regarding the safety, efficacy, and side effects of Beovu were false.

169. Defendant negligently made misrepresentations and/or actively concealed, suppressed, or omitted this material information with the intention and specific desire to induce consumers and the medical community, including Plaintiff and Plaintiff's healthcare providers, to use, prescribe, and purchase Beovu.

170. Defendant negligently knew or should have known that Plaintiff and/or Plaintiff's healthcare providers would rely upon such material misrepresentations and/or omissions in selecting Beovu for the treatment of Plaintiff.

171. Defendant made these material misrepresentations and/or omissions and actively concealed adverse information at a time when they, their agents and/or their employees knew or should have known that Beovu had certain defects, dangers, and characteristics that differed from what had been represented to the medical community and the consuming public, including Plaintiff's healthcare providers and Plaintiff. Those misrepresentations and omissions further include, but are not limited to, the following:

a. Defendant failed to disclose or actively concealed data demonstrating that Beovu increased the risk of vision-related adverse events including, but not limited to, retinal

vasculitis, retinal vascular occlusion, and related sequelae. Specifically, Defendant omitted from its product labeling data demonstrating a 2,312% increase in relative risk for retinal vasculitis or retinal vascular occlusion and related sequelae and misrepresented the incidence of retinal vasculitis and retinal vascular occlusion and related events as occurring in 1% of clinical trial patients rather than a minimum of 3.3% of patients. Plaintiff and his prescribing physician were misled by this in accurate information and detrimentally relied on this inaccurate information in deciding to prescribe and take Beovu;

b. Defendants failed to include or provide adequate warnings along with Beovu regarding potential and established risks, and the nature, scope, severity, and duration of any serious side effects of Beovu use, including, but not limited to, an increased risk of retinal vasculitis, retinal vascular occlusion, and related sequelae, when compared to other available therapies to treat AMD. Plaintiff and his prescribing physician relied on these lack of warnings to conclude that Beovu did not pose these risks when compared to other available therapies to treat AMD;

c. Since receiving FDA approval, Novartis has encouraged ophthalmologists to switch their patients to Beovu by marketing it as requiring less frequent injections than other VEGF inhibitors used in the treatment of AMD, thereby purporting to offer greater convenience and reduce patient non-adherence. While Novartis' marketing of Beovu has been primarily directed towards convincing doctors to switch patients who have previously been treated with other VEGF inhibitors to Beovu, none of the patients included in the premarket clinical trials had ever received prior treatment with other VEGF inhibitors. Instead, the study protocols for the HAWK and HARRIER clinical trials required all enrolled patients to be treatment-naïve. Therefore, Novartis failed to perform any testing in the very patient population to which it intended, and indeed did, specifically market Beovu to after it received FDA approval. As such, Defendant promoted Beovu as a safe and effective treatment for patients with a prior history of using other anti-VEGF therapies despite the fact that the Defendant had not properly studied Beovu in that patient population in its clinical trials for Beovu. This promotion occurred as to Plaintiff's prescribing physician prior to Plaintiff being prescribed Beovu and Plaintiff's prescribing physician detrimentally relied on these representations in deciding to prescribe Beovu to Plaintiff..

d. Defendant failed to issue a safety communication like a Dear Healthcare Professional Letter or otherwise timely update its product labeling upon receipt of post-marketing adverse event reports involving retinal vasculitis and/or retinal vascular occlusion. Given this material omission, Plaintiff and his prescribing physician used Beovu without an understanding that these events had been reported in the post-marketing setting and therefore prescribed and used the drug without possessing this knowledge.

172. Defendant's material misrepresentations and/or active concealment, suppression, and omissions were perpetuated directly and/or indirectly by Defendant, its sales representatives,

employees, distributors, agents and/or detail persons, through databases, printouts, monographs, product labeling and other information drafted, prepared, marketed, sold, and supplied by Defendant, its sales representatives, employees, distributors, agents and/or detail persons.

173. Defendant's material misrepresentations and/or active concealment, suppression, and omissions constitute a continuing tort.

174. Through its product inserts and other public statements, Defendant continue to misrepresent the serious potential vision-related risks and complications associated with use of Beovu.

175. Defendant had a post-sale duty to timely warn physicians including Plaintiff's healthcare providers, and consumers, such as Plaintiffs, about the potential risks and complications associated with use of Beovu.

176. Defendant negligently misrepresented the safety and efficacy of Beovu in their labeling, advertising, product inserts, promotional materials, or other marketing resources and materials.

177. If Plaintiff's healthcare providers and Plaintiff had known the true facts concerning the risks of Beovu use, in particular, the risk of vision-related adverse events and/or reactions, including, but not limited to, an increased risk for retinal vasculitis, retinal vascular occlusion, and related sequelae, they would not have prescribed or used Beovu and would have instead prescribed and used a safer alternative pharmaceutical drug or no drug at all.

178. Plaintiff and Plaintiff's healthcare providers' reliance upon Defendant's material misrepresentations were justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position of knowledge of the true facts concerning Beovu, while Plaintiff and Plaintiff's healthcare providers were not in a position

to know the true facts concerning Beovu, and because Defendant overstated the benefits and safety of Beovu, and concomitantly downplayed the risks of its use, including, but not limited to, an increased risk for retinal vasculitis, retinal vascular occlusion, and related sequelae, thereby inducing Plaintiff's healthcare providers to prescribe and Plaintiff to use Beovu, in lieu of other safer alternatives, or no drug at all.

179. As discussed herein, Defendant has intentionally misrepresented the clinical trial data for Beovu to healthcare providers and the general public in order to mask the true risk of retinal vascular occlusion, retinal vasculitis, intraocular inflammation, and other severe eye injuries related to Beovu use. Those misrepresentations continue to the present.

180. Specifically, at all times relevant to this case Defendant intentionally withheld from Plaintiff and his treating physicians the true number of retinal vasculitis, retinal vascular occlusion, and intraocular inflammation reports seen in the Beovu clinical trials.

181. Defendant further intentionally concealed information demonstrating a 2,312% increase in relative risk for retinal vasculitis or retinal vascular occlusion when comparing the patients in the clinical trials taking Beovu and the patients assigned to the active control (aflibercept).

182. Even more egregious than just concealing the aforementioned data, Defendant through its sales representatives has intentionally engaged in marketing efforts seeking to induce healthcare providers to switch their patients from other anti VEGF agents to Beovu despite lacking the necessary evidence to demonstrate that Beovu is safe and effective in this population and despite affirmative evidence that the drug is not safe in this patient population and without advising patients and physicians that switch to Beovu from these other agents actually poses a greater risk of harm to the patient, especially as it related to retinal vasculitis,

retinal vascular occlusion, and intraocular inflammation.

183. Defendant has intentionally misled healthcare providers and the general public in making non-inferiority claims for Beovu as compared to other anti VEGF agents despite possessing the knowledge that these claims are false.

184. Defendant has intentionally failed to properly warn healthcare providers about the true risk of retinal vasculitis, retinal vascular occlusion, intraocular inflammation, and other severe eye injuries related to Beovu use despite possessing knowledge that Beovu causes these serious adverse events.

185. Specifically, here Defendant publically acknowledged the need to change the product labeling for Beovu on April 8, 2020 to add a warning about retinal vasculitis and retinal vascular occlusion, which are serious life altering injuries. However, rather than immediately disseminate a warning concerning these injuries in the product labeling through the available Changes Being Effected process and other available sources Defendant intentionally and voluntarily chose to update their product labeling for Beovu through much slower means and didn't avail themselves of other available tools to disseminate the warning more quickly.

186. Defendant's actions were willful and malicious in that Defendant's conduct was carried on with a conscious disregard for the safety and rights of Plaintiff and others. Defendant's unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendant in an amount appropriate to punish Defendant, and deter similar conduct in the future.

187. As a direct and proximate result of the dangerous and defective nature of Beovu Plaintiff suffered retinal vasculitis and other serious eye injuries, and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of

hospitalization, and medical care and treatment. The losses are permanent and the Plaintiff will continue to suffer the losses in the future.

WHEREFORE, Plaintiff prays for judgment against Defendant as follows:

a. For general damages in an amount to be proven at the time of trial;

b. For special damages in an amount to be proven at the time of trial;

c. For statutory damages as set forth above, in an amount to be proven at trial;

d. For exemplary and punitive damages against Defendant in an amount to be proven at trial, and sufficient to punish or deter Defendant and others from repeating the injurious conduct alleged herein;

e. For pre-judgment and post-judgment interest on the above general and special damages;

f. For costs of this suit and attorneys' fees; and

g. All other relief that this Court deems necessary, proper, and just.

Respectfully submitted,

KETTERER, BROWNE & ASSOCIATES, LLC

/s/
Reza Davani, Esq.
Fed. Bar No. 30168
T: (410) 885-6267
F: (855) 334-5626
Reza@KBAattorneys.com
www.KBAattorneys.com
336 S. Main Street
Bel Air, MD 21014
Attorneys for Plaintiff

Pro Hac Vice Motion to-be-filed
Brandon Bogle, Esq.
Fed. Bar No. 52624

(T) 850-435-7042
(F) 850-436-6042
bbogle@levinlaw.com
Levin, Papantonio, Proctor, Buchanan,
O'Brien, Barr and Mougey, P.A.
316 S. Baylen St. Suite 600
Pensacola, Florida 32502-5996
Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiffs request that their claims in this case be tried by a jury.

KETTERER, BROWNE & ASSOCIATES, LLC

/s/
Reza Davani, Esq.
Fed. Bar No. 30168
T: (410) 885-6267
F: (855) 334-5626
Reza@KBAattorneys.com
www.KBAattorneys.com
336 S. Main Street
Bel Air, MD 21014
Attorneys for Plaintiff

Pro Hac Vice Motion to-be-filed
Brandon Bogle, Esq.
Fed. Bar No. 52624
(T) 850-435-7042
(F) 850-436-6042
bbogle@levinlaw.com
Levin, Papantonio, Proctor, Buchanan,
O'Brien, Barr and Mougey, P.A.
316 S. Baylen St. Suite 600
Pensacola, Florida 32502-5996
Attorneys for Plaintiff