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UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

JANE and JOSEPH DOE, **Plaintiffs,** **v.** **BAUSCH & LOMB, INC., BAUSCH & LOMB HOLDINGS INC., VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS INTERNATIONAL,VALEANT PHARMACEUTICALS INTERNATIONAL, INC., AND DOES 1 THROUGH 50, INCLUSIVE,** **Defendants.**	**CASE NO. 3:18-cv-00352-VLB** **FIRST AMENDED COMPLAINT FOR INJUNCTIVE RELIEF AND DAMAGES** **JURY DEMAND**

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Plaintiffs Jane and Joseph Doe (hereinafter collectively "Plaintiffs"), by and through their counsel, bring this action as a result of defective intraocular lenses manufactured and sold by Bausch & Lomb Inc., which caused and continue to cause Plaintiff Jane Doe to suffer permanent vision loss and continuous deterioration of both eyes. Plaintiffs bring these claims under state laws to obtain injunctive relief to cease the sale of this product and for compensatory and punitive damages; and, allege as follows:

I. PARTIES

A. Plaintiffs

1. Plaintiff Jane Doe and Joseph Doe, wife and husband, are individuals and residents of Fairfield County, Connecticut.

B. Defendants

2. Defendants in this case have various names but form one connected corporate structure. The locus of Defendants' activity regarding the design, manufacture, distribution, and communication with the FDA occurred out of Defendants' offices and facilities in Southern California.

i. Bausch & Lomb Inc.

3. Defendant Bausch & Lomb Inc. ("Bausch & Lomb" or "B&L")) has its headquarters at 1400 Goodman St. N, Rochester, NY 14609. However, the optical lens business that Bausch & Lomb conducts is based in Southern California out of its office in Irvine, Orange County, California.

4. The lenses at issue in this case were manufactured at 10574 Acacia Street, #D1, Rancho Cucamonga, Orange County, CA 91730. Defendant Bausch & Lomb, formerly Bausch & Lomb Surgical, Inc., manufactures contact lenses and

lens care products, ophthalmic surgical devices and instruments, and ophthalmic pharmaceuticals.

5. Bausch & Lomb Surgical, Inc. was formerly known as IOLAB Corp.

6. Bausch & Lomb Surgical, Inc. was incorporated in 1976 and is based in Irvine, California. Bausch & Lomb Surgical, Inc. was a subsidiary of Bausch & Lomb.

7. Bausch & Lomb Inc. acquired EYEONICS, which originally developed the predecessor product called the Chrystalens Accommodating Intraocular Lens.

8. The specific products manufactured at Bausch & Lomb in Rancho Cucamonga, CA include the BL1UT Trulign Toric; Model: BL1UT Trulign Toric. (Source: http://www.bausch.com/ecp/edfu?udt_19771_param_page=2.)

9. This product at issue in this case is the Trulign Toric intraocular lens ("Trulign", "Trulign Lens", "Trulign Toric Lens", "Trulign Toric Intraocular Lens", or "Lens"). It is the subject of this lawsuit. Its predecessor product, the Crystalens Accommodating Intraocular Lens ("Crystalens"), was also manufactured at Rancho Cucamonga, CA (UVAM). (Source: http://www.bausch.com/ecp/edfu?udt_19771_param_page=3.)

10. Bausch & Lomb maintains its California headquarters through the present at 50 Technology Drive in Irvine, CA 92618.

11. The entity at this address is registered with the FDA and is listed as the PMA Applicant for both the Crystalens and the Trulign products (see below).

Establishment:

Bausch & Lomb, Inc.
50 Technology Dr.
Irvine, CA 92618

Registration Number: 3004343135
FEI Number*: 3004343135
Status: Active
Date of Registration Status: 2017

Source: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs /cfRL`/rl.cfm?rid=91006

Device: CRYSTALENS ACCOMMODATING INTRAOCULAR LENS & TRULIGN TORIC INTRAOCULAR LENS
Classification Name: Intraocular, Toric Optics
Generic Name: Lens, Intraocular, Toric Optics
Regulation Number: 886.3600

12. Applicant:

Bausch & Lomb, Inc.
50 Technology Dr.
Irvine, CA 92618
PMA Number: P030002
Supplement Number: S038
Date Received: 02/01/2016
Decision Date: 07/27/2016
Source: https//www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfpma/pma.cfm?id=P030002S038

13. The MAUDE Adverse Event Reports submitted by Bausch & Lomb in connection with the Crystalens products and with the Trulign Toric Intraocular Lens lists the manufacturer as Bausch & Lomb in Rancho Cucamonga, CA and the manufacturer contact at 50 Technology Drive, Irvine CA.

14. On March 20, 2016, the FDA approved moving the manufacturing site to Clearwater, Florida. However, all the conduct that led to the defective lens being marketed and sold to Plaintiff Mrs. Doe occurred when Bausch & Lomb was operating out of its Southern California headquarters.

15. Bausch & Lomb continues to operate its ocular business from California, and in particular, in its Irvine, California facility.

16. On its website, Bausch & Lomb states: "In August 2013, Bausch + Lomb became the eye care division of Valeant Pharmaceuticals International, Inc." *See* "The Bausch + Lomb Story," Bausch & Lomb, http://www.bausch.com/our-company/about-bausch-lomb/the-bausch-lomb-story (last accessed Mar. 15, 2015).

17. As recently as March 15, 2017, Bausch & Lomb advertised its interest to hire employees for the Irvine, California facility; a Sacramento, California facility; and a Petaluma, California facility.

a. One advertisement was for a position was called "Director Medical Affairs – Ophthalmology" for B&L Surgical stated:

> **Valeant Pharmaceuticals International, Inc. is a diverse pharmaceutical company that is committed to focusing on our key stakeholders while delivering consistently high performance. Our values provide the overall direction for our company, and provide us with the tools necessary to rise to any challenge by leveraging our collective hard work and effort along with our unwavering competitive spirit. These values help us set goals based on our organization's potential and what we hope it will become.**
>
> **Responsibilities**
>
> **Serve as medical expert for the B+L Surgical Division, in support of the following activities . . . .**
>
> **See Valeant.com, https://jobs-valeant.icims.com/jobs/8499/director-medical-affairs---ophthalmology/job?mobile=false&width=990&height=500&bga=true&needsRedirect=false&jan1offset=-480&jun1offset=-420 (last accessed Mar. 15, 2018).**

b. At the time of this filing, the following other positions advertised on Glassdoor.com for Bausch & Lomb and Valeant Pharmaceutical International, Inc.:

i. National Accounts Manager - Surgical in Irvine, CA ("Responsible for business development and sales growth of Integrated Delivery Networks, ASC groups, Mobile Service Providers, and other strategic healthcare entities. These objectives and sales growth initiatives are predicated on the successful execution of national contracts by the B+L sales force, working in conjunction with the Regional Business Directors, Marketing, and the contracts department.");

ii. Director Medical Affairs in Irvine, CA ("Serve as medical expert for the B+L Surgical Division");

iii. Quality Specialist Petaluma, CA;

iv. Senior Principal Scientist (Team Leader) Petaluma, CA;

v. Surgical Equipment Specialist - Northern California in Sacramento, CA ("The Surgical Equipment Specialist (SES) is a professional sales position whose primary purpose is the presentation, promotion, and sale of the Bausch + Lomb portfolio of surgical equipment products such as cataract surgical equipment, vitreoretinal surgical equipment and related instruments and disposable products. The SES reports to the Regional Business Director (RBD).");

and

vi. Customer Relations Associate, in Irvine, CA.

18. In particular, the oversight over the Trulign Lens has been and is still conducted out of Bausch & Lomb's Irvine location:

a. A July 30, 2013 adverse event report concerning the Trulign Lens also reflects the manufacturer's address as B&L in Rancho Cucamonga,

California. and the contact for the FDA as Sharon Spencer at B&L, 30 Enterprise, Ste. 450, Aliso Viejo, California. Sharon Spencer was B&L's contact with FDA concerning all of the significantly delayed adverse event reports in violation of the conditional approval that demonstrate that B&L in 2013 and 2014 knew of the failures of the Trulign but failed to report those adverse events to FDA until 2017.

b. In the end of February 23, 2017, an adverse event report for the Trulign Lens reported on the MAUDE database lists Sharon Spencer as the manufacturer's contact, who is associated with B&L's Aliso Viejo facility.

c. As recently as January 2018, the new manufacturer contact for adverse event reports for the Trulign is Faranak Gomarooni out of B&L's Irvine, California facility.

ii. <u>Bausch & Lomb Holdings, Inc., Valeant Pharmaceuticals International, and Valeant Pharmaceuticals International, Inc.</u>

19. Bausch & Lomb, Inc. was a division of Bausch & Lomb Holdings, Inc.

20. In 2013, Bausch & Long was absorbed in a merger with Valeant Pharmaceuticals International ("VPI"), a division of Valeant Pharmaceutical International, Inc. ("VPII").

21. On its website today, Bausch & Lomb refers to itself as "Bausch + Lomb, a division of Valeant Pharmaceuticals International, Inc. (NYSE: VRX) (TSX: VRX)." *See* "About Bausch & Lomb," Bausch & Lomb, http://www.bausch.com/our-company/about-bausch-lomb (last accessed Mar. 15, 2018). VRX is the ticker symbol for VPII.

22. In the merger agreement filed with the SEC, along with the Form 8-K, Defendants showed how Bausch & Lomb would be subsumed as a division of VPII:

> **Bausch + Lomb will retain its name and become a division of Valeant. Valeant's existing ophthalmology businesses will be integrated into the Bausch + Lomb division, creating a global eye health platform with estimated pro forma 2013 net revenue of more than $3.5 billion. The acquisition positions Valeant to capitalize on growing eye health trends driven by an aging patient population, an increased rate of diabetes and demand from emerging markets. The combined business will also benefit from access to a strong product portfolio and a late stage pipeline of innovative, new products.**
>
> **Valeant's Chairman and Chief Executive Officer, J. Michael Pearson, said, "We are excited to announce the acquisition of Bausch + Lomb, which will transform Valeant into a global leader in eye health by significantly strengthening our capabilities in ophthalmic pharmaceuticals, contact lenses and lens care products, and ophthalmic surgical devices and instruments. Bausch + Lomb's world-renowned brand, comprehensive portfolio of leading eye care products, and promising late stage pipeline are an ideal strategic fit for our current ophthalmology business and we are strongly committed to continuing to build a sustainable eye health business. With this transaction, Valeant will be a worldwide leader in both dermatology and eye health.**
>
> **. . .**
>
> **Following the closing, Mr. Saunders will join Valeant in an advisory role to help ensure a seamless transition and integration and Fred Hassan, Chairman of Bausch + Lomb's Board of Directors, will join Valeant's Board of Directors. In addition, Dan Wechsler, Executive Vice President and President of Bausch + Lomb's Global Pharmaceuticals, will join Valeant as Executive Vice President and Company Group Chairman, Ophthalmology and Eye Health. Bausch + Lomb's Chief Medical Officer Calvin W. Roberts, M.D. will also join Valeant as its Chief Medical Officer, Ophthalmology and Eye Health. We also anticipate additional members of the senior management team to join Valeant."**

23. VPI is a company registered in Delaware. However, its filings with the SEC indicate that until 2015, VPI was located at One Enterprise, Aliso Viejo, CA 92656, the same address as Bausch & Lomb's manufacturing facilities, where the Trulign Toric Lens was manufactured.

iii. Valeant Pharmaceuticals North America

24. Bausch & Lomb's business in the U.S. is operated as a division of Valeant Pharmaceuticals North America LLC ("VPNA"), a division of VPII. VPNA is a Delaware company with its business offices and headquarters located in Bridgewater, New Jersey.

25. VPNA also is listed as the post-market Trulign Lens study sponsor.

iv. Valeant Pharmaceuticals International, Inc.

26. Valeant Pharmaceutical International, Inc. ("VPII") is a Canadian Corporation, with its United States headquarters and principal place of business in Bridgewater, New Jersey.

27. Defendant VPII acquired Bausch & Lomb and all of its divisions and subsidiaries and included all of them as part of the VPII business. Defendant VPII holds itself out as a global company that does business around the world and throughout the United States.

28. Defendant VPII describes itself on its website as "a multinational, specialty pharmaceutical and medical device company anchored by a collection of world-class franchises and 22,000 employees worldwide who come to work each day with a common goal of improving people's lives through VPII's healthcare products. VPII develops, manufactures and markets a broad range of branded, generic and branded generic pharmaceuticals, over-the-counter (OTC) products and medical devices, which are marketed directly or indirectly in more than 100 countries."

29. After the acquisition in 2013, Bausch & Lomb became a division of VPII.

30. The headquarters for the newly-acquired, wholly-owned division of VPII, Bausch & Lomb, which develops, manufactures and sells the intraocular lenses at issue, is based in Irvine, California.

31. Bausch & Lomb holds itself out as a division of VPII.

32. VPII directly owns and oversees all of the other Defendants in this action and therefore, is the responsible party for the harm the subject device caused Mrs. Doe and Mr. Doe.

v. Doe Defendants

33. Plaintiffs are ignorant of the true names and capacities of the Defendants sued by fictitious names, who are described throughout as DOES 1 through 50, and such names are fictitious. Each of these fictitiously named DOE Defendants is responsible in some manner for the acts complained of in this Complaint, and each proximately caused Plaintiffs' injuries and damages, and each was acting as the agent for the others.

34. Plaintiffs, by and through their undersigned counsel, hereby institute this civil action against Bausch & Lomb, Inc. and DOES 1 through 50 (collectively, "Bausch & Lomb" or "Defendants").

II. JURISDICTION AND VENUE

35. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1332 and 1367 because this is a personal injury/products liability action in which the matter or controversy exceeds the sum of $5,000,000, exclusive of interest and costs, and in which the parties are citizens of different states.

36. This Court has personal jurisdiction over Defendants because they transact business in the United States, including in the District of Connecticut;

have substantial aggregate contacts with the United States, including within this District; engaged and are engaging in conduct that has and had a direct, substantial, reasonably foreseeable, and intended effect of causing injury to persons throughout the United States, and specifically in this District where the devices were sold to Plaintiff's doctor; and, Defendants purposely availed themselves of the laws of the United States.

37. In accordance with 28 U.S.C. § 1391, venue is proper in the this District because a substantial part of the conduct giving rise to Plaintiffs' claims occurred in that District. Defendants transact business in this District.

III. INTRODUCTION

38. This products liability action arises as a result of defective Lenses sold by VPII through its wholly-owned subsidiary Bausch & Lomb.

39. The dangerously defective Lenses caused Plaintiff Mrs. Doe to suffer permanent vision impairment and permanent and irreparable damage to both of her eyes. As a result of the defective Lenses, Plaintiff Mrs. Doe has been forced to endure more than eight painful and ultimately unsuccessful surgeries and significant remedial procedures, more than forty visits with specialists and more than 100 tests and procedures in an effort to remediate the loss of vision.

40. Plaintiff Mrs. Does continues to suffer extremely painful and debilitating complications from the defective Lenses and is likely to continue to suffer further complications and the loss of her remaining vision in the future.

41. The defective product at issue is Defendants' Trulign Toric Intraocular Lens model BL1UT ("Trulign", "Trulign Lens":, "Trulign Toric Lens(es)", "Trulign Toric Intraocular Lens(es)" or "Lens(es), which is the 2013 model of Defendants'

"Crystalens" lenses. The Trulign Lens is the latest in a line of "accommodating" lenses that are surgically implanted in the eyes to replace one's natural lens after the natural lens is removed during cataract surgery.

42. The Trulign Lens suffers defects and risks unique to accommodating lenses manufactured and sold by Defendants; defects that Defendants failed to disclose, and in so doing, violated regulations issued by the U.S. Food & Drug Administration ("FDA") as well as the applicable state laws, including California where the Lenses were manufactured and distributed, and Connecticut and New York laws where Plaintiff Mrs. Doe was injured and sought treatment and care.

43. Because of Bausch & Lomb's wrongful conduct, which occurred in California at its intraocular lens headquarters and manufacturing facility, thousands of patients, like Mrs. Doe, underwent implants of these devices without knowing the defects and risks that they faced. These patients' ophthalmic surgeons were persuaded by Bausch & Lomb and Bausch & Lomb's "Opinion Leaders" who are paid physician promoters, and Bausch & Lomb's sales representatives to use Trulign Lenses for cataract surgery and to correct patients' astigmatism and presbyopia.

44. Representatives from Bausch & Lomb were physically present during Mrs. Doe's surgery to implant at least one of these devices. Representatives of Bausch & Lomb were also physically present when Plaintiff underwent the procedure in which the doctors attempted to remove the broken lens from her eye.

45. As a result, Plaintiff Mrs. Doe has suffered grievous personal injuries to her eyes that significantly impaired her vision and permanently and irreparably damaged both of her eyes.

46. Her husband, Plaintiff Joseph Doe, has suffered the loss of consortium, assistance and support of his wife; and their son and three daughters have suffered the loss of consortium, assistance, and support of their mother.

47. Plaintiff Mrs. Doe has been unable to work to her full capacity and is at risk for diminished earning capacity for the remainder of her life.

IV. FACTUAL BACKGROUND

A. Trulign Lenses for Cataract Surgery

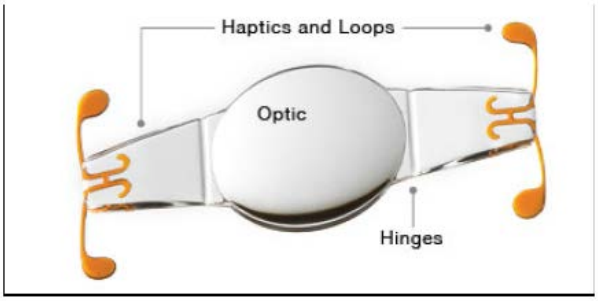
48. A cataract occurs when the naturally clear lens of the eye becomes cloudy. A lens implant is an artificial lens made of clear plastic that takes the place of the natural lens of the eye. The typical implant has a clear lens called the optic and two extensions called haptics that hold the lens in position within the eye. The haptic has a solid attachment with the optic. Figure A displays the typical cataract lens implant:

Figure A

49. Defendants' Trulign Lens is manufactured and sold in only one size and is not available in a selection of sizes to match patients' eyes. Instead, the "one-size-fits-all" Trulign Lens is sold to patients regardless of patients' varying eye sizes and shapes.

50. Defendants' Trulign Lens also differs from other intraocular lenses, because it has relatively large haptics that connect with the optic by a hinge. The hinge allows the Lens to flex. Flexing allows the Lens to change focus from close-up to distance. This is known as "accommodation". Bausch & Lomb's original accommodating lens was the Crystalens, introduced in 2003. The Trulign Lens was introduced in 2013 as the first accommodating lens that also corrects for astigmatism. Figure B shows a Trulign Lens:

Figure B



51. The hinge design that distinguishes this Lens makes this uniquely dangerous in the event it is necessary to remove or replace the Lens from the eye following implantation. After implantation, removal of the hinges may not be possible without causing permanent damage to the eye.

52. The hinge design that distinguishes this Lens also makes it uniquely dangerous by allowing one haptic of the implanted Lens to be pulled forward, while the other remains either in the normal position or is pushed backward, resembling the letter Z with the tilted optic in the middle. This asymmetric vaulting, known as "Z Syndrome", is a post-operative complication unique to the Trulign and Crystalens lenses ("IOLs"). Even a small degree of Trulign Lens tilt can have profoundly negative refractive effect. Z Syndrome can occur "despite perfect placement of the IOL during surgery," according to Dr. William B. Trattler, a physician with financial ties to Bausch & Lomb. Figure C demonstrates Z Syndrome:

Figure C

B. <u>Plaintiffs' Experience with Trulign Lenses</u>

53. On September 11, 2014, Plaintiff Mrs. Doe presented at her ophthalmologist in Connecticut with symptoms consistent with cataracts.

Mrs. Doe underwent cataract surgery with implantation of Trulign Lenses for her left eye on September 17, 2014, and for her right eye on September 24, 2014.

54. As of September 25, 2014, she had 20/20 vision in her right eye, and 20/25 vision in her left eye.

55. Some weeks after September 25, 2014, Mrs. Doe began to experience severe complications from the Trulign Lenses, including significant loss in visual acuity, blurriness, hazing, halos and significant eye pain. Mrs. Doe was diagnosed ultimately with Z Syndrome in both of her eyes.

56. As a result of the defective Lenses, Plaintiff Mr. Doe endured eight painful and ultimately unsuccessful surgical, medical and other interventions, more than 40 visits to specialists and more 100 tests and other procedures in an unsuccessful effort to correct her vision and remediate the considerable damage to her eyes. These unsuccessful efforts included YAG capsulotomies in both eyes, additional follow up YAG procedures, three extremely painful reconstructive surgeries, including an intraocular lens exchange and vitrectomy (replacement of natural vitreous gel with artificial gel), and two painful follow-up surgeries to truncate the broken lenses that remain embedded in Mrs. Doe's eyes. The surgeries were extremely painful and required large needles to be injected directly into Mrs. Doe's eye, while she was awake.

57. Despite the dedicated efforts of Mrs. Doe's ophthalmic surgeons to restore her vision loss from the defective Lenses, Mrs. Doe has suffered significant vision impairment, including the loss of visual acuity in both eyes, complete loss of depth perception, extreme photosensitivity, limited ability to see at night and

double vision. She also suffers continuously from the loss of balance, vertigo, headaches, extreme eye pain, eye fatigue and tearing. As a result of her vision impairment caused by the defective Lenses, Mrs. Doe falls frequently and has fallen down flights of stairs, narrowly missed being hit by cars and buses, suffered bruises, burns and other injuries from routine daily activities.

58. Plaintiff Mrs. Doe has also suffered continuous deterioration of the structure of both her eyes, including posterior vitreous detachments in both eyes, both requiring emergency care on weekends with attendant increased risks of retinal detachment, optic nerve damage, copper wool spots and other retina complications and a notable increase in macular thickening which significantly increases the risk of complete loss of vision in the future. As a result of the posterior vitreous detachments and optic nerve damage, Mrs. Doe struggles to see through a sea of floaters, flashes of lights, and shadows that continuously impair her visual field.

59. Moreover, despite eight surgical, medical and other procedural efforts to restore vision in Mrs. Doe's eyes, the twisted and vaulted lenses and haptics remain embedded in Mrs. Doe's eyes. The broken, embedded and twisted Lenses continuously and significantly obscure, distort and skew vision in both her eyes, resulting in significant higher order aberrations that make it even more difficult to see. The haptics from both Lenses cannot be safely removed from Mrs. Doe's eyes which further limits, and in many respects completely forecloses, corrective measures that would otherwise have been available if the Lenses were not defectively designed and manufactured.

60. As the primary source of support for her family, including four children (one of whom is profoundly disabled), Mrs. Doe has remained committed to supporting and caring for her family. Despite the challenges she faces from the significant vision loss, Mrs. Doe has remained working (with support from adaptive equipment) to care for her family. She is extremely concerned that she will completely lose her ability to see in the future and will be unable to support or care for her family.

61. At the time these Lenses were implanted, Plaintiff Mrs. Doe did not know of the dangers and increased risk of vaulting or Z Syndrome or that Trulign Lenses posed a significantly increased risk of vaulting or Z Syndrome. At the time the Lenses were implanted, Mrs. Doe did not know that, if complications occurred, it may not be possible to remove, replace or exchange the Lenses or haptics from her eyes or that it could require numerous painful surgeries and procedures to try to correct the problem. She did not know that her vision would become significantly impaired and that her eyes would become irreparably and permanently damaged.

62. Plaintiff and her ophthalmic surgeon were not informed by Defendants that these Lenses and the predecessor lenses, the Crystalens, had an increased risk of vaulting and that vaulting caused by the Lenses was a known and probable risk, not an extremely rare risk.

C. Defendants Knew and Failed to Warn about Z Syndrome Complications for Crystalens, and Later for Trulign Toric Intraocular Lenses.

i. Crystalens

63. Bausch & Lomb's predecessor, Eyeonics, Inc., knew as early as 2006 that Z Syndrome was a complication unique to its AT45 Crystalens IOL Lens. Indeed, Barrie Soloway, M.D., one of the authors of a paper coining the term "Z Syndrome" was a faculty member for Eyeonics.

D. Defendant Bausch & Lomb Acquired Crystalens Developer to Build and Expand the Intraocular Lens Business.

64. Crystalens was developed by Eyeonics, Inc., a privately held medical device company headquartered in Aliso Viejo, California.

65. Eyeonics, founded in 1998, developed and markets the Crystalens intraocular lens (IOL), the first and only FDA-approved accommodating IOL for the treatment of cataracts. The Crystalens IOL replaces the eye's natural lens and has been implanted in more than 95,000 eyes worldwide.

66. In November 2003, the Crystalens was approved for sale in the U.S. by FDA as a Class III medical device. The FDA's initial pre-market approval required the sponsor, then Eyeonics, to conduct post-marketing surveillance, to submit an adverse event report within ten days of receiving information concerning any injury attributable to the device if the injury was not addressed by the device's labeling, or if it was addressed by the labeling, if the injury was occurring with unexpected severity or frequency.

67. Similarly, FDA required device manufacturers to establish internal procedures for reviewing complaints and event reports,[1] and to report to FDA within thirty days after becoming aware of information suggesting that one of the manufacturer's devices may have caused or contributed to a death or serious injury, or has malfunctioned and would likely cause death or serious injury if the malfunction were to recur[2].

68. On February 1, 2008, Bausch & Lomb acquired Eyeonics, Inc.™, the rapidly growing, privately-held ophthalmic medical device company headquartered in Aliso Viejo, California.

69. Upon completion of the acquisition, Eyeonics' operations became part of Bausch & Lomb's surgical business, which offered a line of standard intraocular lenses, phacoemulsification equipment, vitreoretinal and refractive products to ophthalmologists worldwide.

70. The Crystalens was considered a huge innovation in 2003.

71. Accommodation is the eye's method to achieve near-distance focusing by altering the curvature of the natural crystalline lens, allowing a person to easily read small type used in books, restaurant menus, and on computer monitors. As the natural lens ages, accommodation decreases. This results in a condition known as presbyopia for most people over age 40, for which reading glasses are commonly required. Other approved IOLs only permit focusing at a fixed distances, while the Crystalens IOL is intended to mimic the accommodating characteristics of a natural lens.

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[1] See C.F.R. §820.198(a)

[2] See C.F.R. §803.50(a)

> **"This represents our first acquisition since Bausch & Lomb became a private company in a transaction led by Warburg Pincus," said Ronald L. Zarrella, chairman and CEO, Bausch & Lomb. "We are excited to enter a new phase of growth and innovation, and believe the Eyeonics acquisition is another sign of our commitment to delivering innovative, high-quality products to ophthalmologists and patients worldwide."**

72. Zarrella continued, "[t]his acquisition immediately places Bausch & Lomb into the rapidly expanding premium IOL market. The Crystalens technology complements our existing cataract surgical business, including our Stellaris Vision Enhancement System and our portfolio of monofocal IOLs. The acquisition also adds leadership depth, as Andy and his team bring a strong track record of product innovation and growth to the company. We look forward to their contributions as part of the Bausch & Lomb family."

http://www.visionmonday.com/latest-news/article/bausch-lomb-to-acquire-eyeonics-inc-maker-of-crystalens-accommodating-iol-5944/

73. In 2007, Eyeonics generated revenues of approximately $34 million, an increase of 100 percent over the prior year revenues of approximately $17 million. Its Crystalens IOL is estimated to represent approximately 30 percent of the presbyopic IOL market in the U.S.

74. By 2008, Defendants knew that Z Syndrome was a complication unique to all Bausch & Lomb's accommodating IOL Lenses, not just to the initial model.

75. According to an article published in 2008 in the Journal of Cataract & Refractive Surgery, "[Z Syndrome] is a unique complication with this type of hinged accommodating IOL. * * * Because Z Syndrome is caused by capsule fibrosis primarily, every effort to reduce the occurrence of capsule fibrosis

intraoperatively must be made using appropriately sized capsulorhexis, cortical removal, and potentially capsule polishing."

76. The article suggested steps that could be taken to minimize the risk of Z Syndrome at the time of implantation.

77. More than four incidents of Z Syndrome were reported. However, in April 2009, Bausch & Lomb submitted one adverse event report to FDA reporting on the occurrence of Z Syndrome.

78. Regarding "potential complications" for Crystalens implants circulated in or around 2009, Bausch & Lomb's advertising circular stated as follows: "The risks of implantation with Crystalens are generally the same potential risks that exist for implanting all intraocular lenses."

79. As of April 2010, Bausch & Lomb apparently considered Z Syndrome to be sufficiently serious and widespread that it began working with Dr. Stephen Safran, an American Board Certified, fellowship-trained cornea specialist. His special interest is in cataract surgery with premium lenses. He was called upon by Bausch & Lomb "to create an instrument to help aid the surgical correction of Z Syndrome."

80. On January 2, 2018, Bausch & Lomb announced it received FDA 510(k) clearance for its Crystalsert 2.6, that surgical device Dr. Safran had been working on since 2010:

> **The CI-26 injector includes several enhancements designed to assist IOL delivery through a smaller incision," Chuck Hess, vice president and general manager, U.S. Surgical, Bausch + Lomb, said in the release. "Surgeons already know the benefits of our Crystalens accommodating and Trulign toric lenses, and we are happy to provide them with a smaller incision option to**

deliver these benefits to their patients."

81. Nevertheless, throughout 2010 and later, Defendants placed advertising circulars intended for patients in ophthalmologists' offices throughout the U.S. for potential buyers of Crystalens to read, and did so knowing that Crystalens posed a unique risk—"Z" Syndrome—which risk was never disclosed to the public and the medical community. The risk was inadequately disclosed to the FDA.

ii. <u>Trulign Lenses</u>

82. When Defendants announced the "Trulign" Lens model of their accommodating lenses in a 2013 presentation to FDA seeking approval for the device, Bausch & Lomb claimed that the Trulign Lenses "did not introduce new safety or effectiveness concerns compared with Parent IOL" (referring to the Crystalens).

83. Based on that representation, neither Plaintiff nor her ophthalmologist were made aware of the increased risk of vaulting.

84. Bausch & Lomb presented its pre-market clinical study, downplaying both the risk and the severity of asymmetric vaulting/Z Syndrome, suggesting that non-complying doctors and subjects were the real cause, and not the defect in its design of the lens. Bausch & Lomb also assured the FDA that asymmetric vaulting (Z Syndrome) can be successfully treated, citing exactly the procedures and modalities that failed to resolve Mrs. Doe's symptoms.

85. These representations were knowingly false and constituted misbranding in violation of 21 U.S.C. §352(q), 21 C.F.R. §801.6, among others.

86. At the time the FDA considered whether to approve Trulign, the FDA's Advisory Panel noted that it had the following information available regarding vaulting and Z Syndrome:

a. Trulign Toric Accommodating IOL

i. 2 reports in the P030002/S027 clinical study

b. Crystalens Accommodating IOL

ii. 1 report in P030002 clinical study;

87. However, the reality was that there were approximately 270 medical device reports potentially related to vaulting and 5 cases were reported in the medical literature.

88. While the FDA Advisory Panel ultimately agreed to approve the Trulign lenses, several panel members said it was hard to judge the benefits versus risks because of faulty/missing data: "The missing data issue was an important one because there's more missing data than there are vaulting events," said Scott R. Evans, Ph.D., a senior research scientist in the Department of Biostatistics at Harvard University in Boston, Massachusetts.

89. Consequently, as a condition of approval, the FDA required a post-market safety study of the Trulign Lenses, specifically regarding the vaulting/Z Syndrome risk:

a. Trulign™ Toric IOL New Enrollment Study:

> **"The study will be a single arm, multi-site, prospective study with a sample size of 500 eyes at the end of 3 year follow-up. The specific question to be answered is the incidence of IOL vaulting (i.e., position change such as clinically significant anterior vaulting, clinically significant tilt, and secondary surgical intervention related to such vaulting) up to three years post implant. Follow-up assessments will occur at 1 day, 1**

> **week, 1 month, 6 month, 1 year, and then every year until the 3rd year of follow-up. Data collection will include observations, symptoms, diagnosis, treatment, sequelae, and resolution."**

90. Bausch & Lomb was required to submit a PMA supplement including a complete protocol of its post-approval study within 30 days and "to submit separate PAS Progress Reports every six months during the first two years of the study and annually thereafter." FDA also advised that "the results from these studies should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement."

91. Bausch & Lomb had claimed that no such study was necessary, because: "the Trulign™ Toric Accommodating IOL does not present new issues of safety or effectiveness compared to the known profile of the Crystalens IOL." Specifically, with respect to Z Syndrome, Bausch & Lomb told the FDA that "concerns about "anterior vaulting" and "Z Syndrome" relate to rare issues that have been apparent for many years."

92. Nevertheless, the post-market safety study began in March 2015, nearly two years after Bausch & Lomb began selling Trulign Lenses, and *six months after* Mrs. Doe had the Trulign Lenses implanted into her eyes.

93. Bausch & Lomb failed to timely provide its mandatory PAS Progress Reports to the FDA four times, including as of the date of this lawsuit. While the findings have not been published, in February 2016, Bausch & Lomb proposed changes to its Trulign and Crystalens labels.

94. When the Trulign Lenses were implanted by Mrs. Doe's ophthalmic surgeon in Connecticut, neither Plaintiffs nor her ophthalmic surgeon were

informed of the increased risk of vaulting from the Lenses. Plaintiffs Mr. and Mrs. Doe were not aware of the actual risk of Z Syndrome until years after the Lenses were implanted.

95. As a result of Bausch & Lomb failure to comply with its duty to conduct post-market surveillance and failure to comply with its duty to file adverse event reaction reports for all known incidents of Z Syndrome, information furnished to ophthalmologists and their patients was misleading, inaccurate, erroneous and incomplete. Bausch & Lomb's failure to comply with its reporting requirements diminished the ophthalmologist's ability to assess and warn the patient of the risk of Z Syndrome, so that these statements constituted misbranding in violation of 21 C.F.R. §801.6.

96. There is no mention in the Warnings or the Precautions on the Instructions for Use (labeling) for the Trulign Lens approved by the FDA in May 2013 of an irreparable damage caused by the significant risk of "vaulting" or "Z Syndrome."

97. The 2013 Trulign Lens warning fails to state that if vaulting does occur, the ophthalmic surgeon is required to realign and/or reposition the lens. There is no information about how an ophthalmologist can avoid Z Syndrome at time of implantation; that was crucial information that Bausch & Lomb already had in its possession and concealed from the ophthalmologist community, Plaintiff's ophthalmic surgeons, Plaintiffs and other patients.

98. There is no mention of a substantially increased risk of vaulting.

99. There is no mention that vaulting of the Lenses may destroy the patient's visual acuity and result in a permanent loss of vision.

100. There is no mention of the number of failures of the device or of its predecessor device noted anywhere on the labeling.

101. There is no mention that it may not be possible to remove the defective Lenses after implantation without causing extensive eye damage and continuous vision deterioration, thus precluding any future Lens replacement or exchange. There is no mention of the number of vaulted cases and/or Lens haptics that could not be safely removed.

102. When the Trulign Lenses were implanted by the Mrs. Doe's ophthalmic surgeon in Connecticut in September of 2014, Bausch & Lomb had not disclosed the true risks and dangers of vaulting and the permanent loss of vision and other complications that could result.

103. After the Lenses were implanted in Mrs. Doe's eyes in September of 2015, Mrs. Doe's vision initially was 20/20 and 20/25. However, within a short period of time, the Lenses vaulted.

104. Mrs. Doe's ophthalmic surgeon diligently attempted to correct the vaulted Lenses, by performing five YAG procedures on her eyes to attempt to reposition the Lenses. Those procedures occurred at the Connecticut facilities. Despite the dedicated efforts of Mrs. Doe's ophthalmic surgeon, Mrs. Doe's vision was not recovered.

105. Upon the advice of Mrs. Doe's ophthalmic surgeon in Connecticut, Mrs. Doe sought treatment with another specialist in New York, who explained to her that the Lenses were out of position.

106. New expanded warnings were finally added regarding the risk of Z Syndrome in the fall of 2016. This was the first time that Mr. and Mrs. Does knew of the true risks of vaulting and that the risks were risks caused by the defective Lenses. Upon review of medical research, counsel for Plaintiffs discovered that Trulign Lenses presented precisely the same problems for patients as had the Crystalens product, despite Bausch & Lomb's representation that the Trulign Lens had corrected all the health and safety problems.

107. The 2016 "Adverse Events" section of the new labeling explains "vaulting", including what vaulting is, how a clinician should diagnose vaulting with specificity following implantation of the Trulign Lenses, additional clinical factors that support the diagnosis of vaulting, what vaulting looks like to the clinician, causes of vaulting, as well as sequelae of vaulting.

108. The Warning section of the 2016 label addresses vaulting at point seven.

109. None of this information or detail was made available to the clinicians such as Mrs. Doe's ophthalmic surgeon, despite Bausch & Lomb possession of evidence of precisely these problems long before the Trulign Lenses were first sold to and implanted in Mrs. Doe's eyes.

110. The new expanded warnings remain grossly inadequate, despite Bausch & Lomb's knowledge that (a) the Lenses may be difficult (and in some

cases impossible) to safely remove, exchange or replace and/or may result in permanently embedded or broken haptics or Lenses, (b) multiple surgeries and procedures may not successful remediate the vaulted and twisted Lenses or broken or embedded haptics, (c) such remedial efforts may result in related complications including without limitation posterior vitreous detachments, optic fiber damage and macular thickening, and (d) in certain cases, implantation of the Lenses and efforts to correct the vaulted and twisted Lenses may result in significant vision loss and irreparable and permanent damage to the eyes.

E. Bausch & Lomb's Failed to Report Timely all Adverse Events to the FDA.

111. The FDA's initial premarket approval ("PMA") of the Crystalens required Bausch & Lomb to provide to the FDA all "Adverse Reaction Reports," within 10 days after the applicant [i.e., Bausch & Lomb] receives or has knowledge of information concerning: "[a]ny . . . injury . . . that is attributable to the device and (a) has not been addressed by the device's labeling; or (b) has been addressed by the device's labelling but is occurring with unexpected severity or frequency."

112. Likewise, the supplemental PMA for Trulign required Bausch & Lomb to submit adverse event reports within 30 days after receiving or otherwise becoming "aware of information, from any source, that reasonably suggests that one of their marketed devices:

a. may have caused or contributed to a death or serious injury; or

b. has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur."

113. Bausch & Lomb ignored and neglected its responsibilities to the FDA and the conditional approval it had received to market the Trulign Lenses when it failed to timely file adverse event reports for all known incidents of Z Syndrome with Bausch & Lomb's Crystalens and Trulign Lenses, violating its federal duties under 21 C.F.R. § 803.50(a).

114. Moreover, Bausch & Lomb failed to timely file numerous adverse event reports in Mrs. Doe's case, despite that Bausch & Lomb were informed of these adverse results on numerous occasions.

115. By failing to comply with its obligation to file adverse event reports involving Z Syndrome after implantation of Crystalens and Trulign Lenses, Bausch & Lomb violated the conditions set by the FDA in the FDA's initial approval for Bausch & Lomb to market Crystalens, and the FDA's supplemental approval to market Trulign Lenses in the United States.

116. In the physician labeling available at the time of Mrs. Doe's implants in 2014, there was no mention of vaulting or Z Syndrome reported in the adverse events section. Today, however, there is an entire section in the physician labeling devoted to describing adverse events involving "vaulting," including "Z Syndrome." Specifically, doctors are told that: "[v]aulting events occurred at a rate of 0.3% (1 event / 324 subjects) in the clinical study conducted for the original Crystalens IOL (Model AT-45), and at a rate of 0.9% (2 events / 227 subjects; both arms combined) in the clinical study conducted for the Trulign Toric IOL (a modification having the same hinged haptic design; Model AT50T)." These figures indicate that Trulign Lenses are more dangerous than the parent Crystalens

Lenses and that Defendant had reason to know of these dangers at the time it first marketed the Trulign Lenses.

117. Further, when Mrs. Doe had her implant surgery, the Trulign patient brochure claimed that "[t]he risks of implantation with the Trulign Toric IOL are the same risks that exist for all intraocular lenses."

118. The brochure did not discuss the unique, enhanced risk of Z Syndrome, nor the inadequacy of available treatments, but rather noted only that if the lens becomes stuck in an undesired position, you may need glasses or to have the lens removed. However, in Mrs. Doe's case, the defective Lenses cannot be safely removed or adjusted; and glasses have been at best only marginally effective.

119. Beginning in mid-2016, however, patients have been told that the Trulign hinge design poses an additional risk of vaulting, beyond those risks that exist with IOL implantation. As of 2016, patients are further warned that vaulting "is most commonly treated via a secondary surgery, which has additional risks."

120. When Mrs. Doe's implanting physician considered using Trulign Lenses, the only mention of vaulting in the physician labeling was that "a wound leak could cause forward vaulting of the optic."

121. As of 2016, the above described new adverse event section and warning was added that provides detailed information regarding adverse events involving asymmetric vaulting (Z Syndrome); notes that patients have experienced "higher order aberrations;" and, provides instructions for minimizing risk, recognizing symptoms and treatment.

F. The Trulign Lens is a Very Profitable Part of Bausch & Lomb's Business.

122. The Trulign has become a best seller for Bausch & Lomb. One market analyst has publicly estimated that the product's sales were significant for the fiscal year ended in April, 2016. Bausch & Lomb has been depending heavily on Trulign since sales in so many of its other products, such as the Crystalens, have slowed because of the recalls of those defective cataract lenses.

G. Plaintiffs have suffered damages as a result of Trulign' s defect and Defendants' Failures to Warn and to Report Adverse Events to the FDA.

123. Had Bausch & Lomb complied with their post-market obligations and adequately reported adverse event reports for Crystalens and Trulign Lenses, Mrs. Doe and her physician would not have selected Trulign. At the time of implant, neither Mrs. Doe, nor her physician had any reason to believe that the risk of Z Syndrome associated with Crystalens and Trulign Lenses were anything but rare, or that that the available treatments would not be successful.

124. Had Plaintiff or her physician been aware of the adverse event reports showing that the Trulign Lenses were more dangerous than the parent Crystalens IOL Lenses, or reports of Z Syndrome with higher order aberrations, or that the available treatment options including removal of Lenses, may not be successful, Mrs. Doe would not have had the Trulign Lenses implanted.

125. In addition to Plaintiff's physical and emotional injuries, including a significant reduction in her ability to see, continuous deterioration in her vision, disfigurement, pain and suffering, mental anguish and emotional distress, Plaintiffs have suffered financial losses because of Bausch & Lomb's false and misleading

statements and omissions regarding the "Z" Syndrome risk unique to Bausch & Lomb's Trulign Toric Lens and before that, the Crystalens.

126. Those losses include Plaintiff's out-of-pocket cost for the Trulign Lenses, as well as the cost of surgical procedures to implant and to try and correct the "Z" Syndrome. Mrs. Doe has incurred significant medical, surgical, therapeutic and consequential medical expenses, and will likely incur significant out-of-pocket losses in the future with continuous deterioration to Mrs. Doe's vision as a result of the defective Trulign Lenses. Those losses also include Mrs. Doe's diminished earning capacity and lost earnings resulting from the Trulign Lenses, resulting complications, and resulting continuous deterioration to Mrs. Doe's vision.

127. Mrs. Doe has served as the primary source of financial support for her children and the family relies upon her for their financial future. Their eldest son is profoundly disabled and requires round-the-clock home care, personal supports and services. Mrs. Doe's three school-age daughters are all actively involved in their schools, sports, church, and community activities. All of the family's children are extremely close with and dependent upon their mother. Mrs. Doe is extremely concerned about her continued ability to support and care for her future and the significant impact that her vision loss and future vision loss will have upon her family.

128. Plaintiff Joseph Doe has suffered a loss of consortium, assistance, care and support as a result of Defendants' misdeeds and negligence. In addition,

Mr. DOE is required as a result of the injuries to Mrs. Doe to provide additional care for his wife, and even greater responsibility caring for their family.

H. Equitable Estoppel – Tolling Of The Statute Of Limitations

129. Defendants are estopped from asserting time-based defenses where Plaintiffs did not discover nor reasonably could not, at any earlier time, discovered that their manifested injuries had a causal connection to the Defendants' fraud, misstatements, and omissions about this defective product.

130. At times, places, and involving participants known exclusively to Defendants and third parties and concealed from the Plaintiffs, Defendants engaged in fraudulent conduct which caused irreparable harm to Mrs. Doe.

131. Defendants had more than a decade's worth of science and research linking their intraocular lenses to an increased risk of vaulting resulting in substantially diminished if not completely destroyed vision.

132. Defendants knew or should have known of the risks and dangers of these intraocular lenses.

133. Defendants knew or should have known of the science and research well before Plaintiff was ever implanted with these Lenses.

134. Defendants have concealed from or failed to notify Plaintiffs and her ophthalmic surgeon of the full and complete nature of true risks, symptoms and dangers of the Lenses.

135. Although Defendants have recently acknowledged some of the risks and dangers of Z Syndrome and some related complications resulting from the Lenses in the 2016 Instructions for Use, Defendants did not disclose and still have not fully disclosed the seriousness of the issue. Despite Defendant's knowledge

of the risks of Z Syndrome and other significant complications, Defendants continue to downplay the widespread prevalence of the significant problems caused by the Lenses.

136. In fact, there are more than five hundred MAUDE Adverse Event Reports to FDA from 2013 through early 2016, linking vaulting to the Trulign Lenses. In each report, there is no mention of the final medical outcome or whether Lenses were successfully repositioned or removed. That is because most of these MAUDE Adverse Event Reports indicate the same pattern of harm suffered by Plaintiff. And Defendants failed to provide accurate and complete information to FDA in full violation of the applicable federal regulations.

137. This failure to provide accurate information continues through the present.

138. Any applicable statute of limitation has been tolled by Defendants' knowledge, active concealment, and denial of the facts alleged herein, which behavior is ongoing.

139. Defendants were and are under a continuous duty to disclose to Plaintiffs the true character, quality, and nature of risks and dangers of the Lenses. Defendants actively concealed the true character, quality, and nature of the risks and dangers and knowingly made misrepresentations about the characteristics, risks, and dangers. Plaintiffs and Plaintiff's physician reasonably relied upon Defendants' knowing and affirmative misrepresentations and/or active concealment of these facts. Based on the foregoing, Defendants are estopped from relying on any statutes of limitation in defense of this action.

I. Connecticut Discovery Rule

140. The causes of action alleged herein did not accrue until Plaintiff discovered and/or was diagnosed the devastating symptoms that Plaintiff suffered without any knowledge of the cause and the true risk that she would never regain her vision. Plaintiff, however, had no realistic ability to discern that the symptoms from which she suffered were linked to the defective Lenses until – at the earliest – after Defendants released the updated labeling for the Trulign Lenses.

J. Continuous Injury

141. Plaintiff Mrs. Doe continues to suffer harm as a result of the defective Lenses. The extent of the damage to her eyes has not been determined and whether there remains any remedy or modality that the ophthalmologists can use to improve her vision remains unknown.

142. Plaintiffs continue to be deprived of knowledge or information as to the extent of Plaintiff Mrs. Doe's lifelong injuries, damages and losses.

V. SUMMARY OF ALLEGATIONS

143. Plaintiffs suffered grievous personal injuries and damages and losses as a direct and proximate result of Defendants' misconduct.

144. Plaintiff would not have chosen to be treated with Trulign Lenses had she known of or been informed by Defendants of the true risks of the use of Trulign Lenses.

145. At all relevant times, Trulign was researched, developed, manufactured, marketed, promoted, advertised and sold by Defendants and their predecessors in interest.

146. At all times relevant, Defendants manufactured and sold the Trulign Lens in only one size, regardless of patients' varying eye sizes and shapes, thus impairing the Lens' safety and effectiveness.

147. At all times relevant, Defendants misrepresented the safety of Trulign Lenses to consumers and patients, including Mrs. Doe, and recklessly, willfully, or intentionally failed to alert Mrs. Doe or her ophthalmologists to the extreme danger to patients of the use of the Trulign Lenses.

148. At all times relevant, Defendants negligently manufactured, marketed, advertised, promoted, sold and distributed it as a safe and effective device to be used for cataract surgery. Defendants negligently, recklessly, and/or intentionally over-promoted Trulign Lenses to ophthalmologists and consumers, including to Mrs. Doe's ophthalmic surgeons and Mrs. Doe, and downplayed to ophthalmologists and patients its dangerous and permanent effects, including but not limited to the failure to warn of dangerous effects of Trulign Lenses used for cataract surgery and inability to remove defective lenses.

149. At all times relevant, Defendants misrepresented the safety of Trulign Lenses to consumers and patients, including Mrs. Doe, and recklessly, willfully, or intentionally failed to alert Mrs. Doe to the extreme danger to patients of a permanent Z Syndrome resulting from the implantation of these Lenses.

150. Any warnings Defendants may have issued concerning the implantation of the Trulign Lenses were insufficient in light of Bausch & Lomb's contradictory prior, contemporaneous and continuing promotional efforts and

over-promotion of the Trulign Lenses, even as Defendants knew of the serious adverse events caused by the Trulign and by its predecessor, the Crystalens.

151. At all relevant times, Defendants knew, and/or had reason to know, that Trulign Lenses were not safe for the patients, because its safety and efficacy for use was either unknown, or was known by these Defendants to be unsafe and ineffective.

152. At all relevant times, Bausch & Lomb knew, and/or had reason to know, that its representations and suggestions to ophthalmologists that Trulign Lenses were safe and effective for use in the eyes were materially false and misleading.

153. Defendants knew and/or had reason to know of this likelihood and the resulting risk of injuries and blindness, but concealed this information and did not warn Plaintiffs' ophthalmic surgeon or Plaintiffs, preventing Plaintiff and her ophthalmic surgeon from making informed choices about the selection of other lenses, treatments or therapies.

154. Plaintiff and her ophthalmic surgeon relied on Defendants' misrepresentations regarding the safety and efficacy of Trulign Lenses in connection with their decisions to use the lenses in Plaintiff's cataract surgery. Plaintiff and her ophthalmic surgeon did not know of the specific risks, and/or were misled by Defendants as to the nature and incidence of the true specific risks related to the use of Trulign Lenses in cataract surgery.

155. Defendants improperly promoted and marketed Trulign to Plaintiff's ophthalmic surgeon, and this promotion and marketing caused Plaintiff's

ophthalmic surgeon to decide to implant these defective intraocular Lenses in Plaintiff's eyes.

156. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venture of each of the other Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

157. At all times herein mentioned, Defendants and each of them, were fully informed of the actions of their agents and employees, and thereafter no officer, director or managing agent of Defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions and all Defendants and each of them, thereby ratified those actions.

158. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

159. At all times herein mentioned, Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by the Plaintiff and her ophthalmologists. As such, each of the Defendants is individually, as well as jointly and severally, liable to the Plaintiffs for their damages.

160. The harm which has been caused to Plaintiffs resulted from the conduct of one, or various combinations of the Defendants, and, through no fault of the Plaintiffs. There may be uncertainty as to which one or combination of Defendants caused the harm. Defendants have superior knowledge and information on the subject of which one or combination of Defendants caused Plaintiffs' injuries and damages.

161. Plaintiffs' claims exceed the jurisdictional limits of the Court.

VI. CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

Fraudulent Omission and Concealment

162. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

163. Defendants had a confidential and special relationship with Plaintiffs due to (a) Defendants' vastly superior knowledge of the health and safety risks relating to the Trulign Lenses and (b) Defendants' sole and/or superior knowledge

of their dangerous and irresponsible practices of improperly promoting to ophthalmologists the use of the Trulign Lenses.

164. As a result, Defendants had an affirmative duty to fully and adequately warn Plaintiff and her ophthalmologists of the true health and safety risks related to the use of the Trulign Lenses, and Defendants had a duty to disclose their dangerous and irresponsible practices of improperly promoting to ophthalmologists the use of these Lenses without adequate testing, adequate information about the history of failures and adequate and accurate information about the true risks and dangers of the Lenses.

165. Independent of any special relationship of confidence or trust, Defendants had a duty not to conceal the dangers of the Lenses to Plaintiff and her ophthalmologists.

166. Misrepresentations made by the Defendants about the safety of the Lenses independently imposed a duty upon Defendants to fully and accurately disclose to Plaintiff and her ophthalmologists the true health and safety risks related to the Trulign Lenses, and a duty to disclose their dangerous and irresponsible promotion and marketing practices.

167. In connection with their products, Defendants fraudulently and intentionally concealed important and material health and safety product risk information from Plaintiff and her ophthalmologists, all as alleged in this Complaint.

168. Any of the following is sufficient to independently establish Defendants' liability for fraudulent omission and/or concealment:

a. Defendants fraudulently concealed the health and safety hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the use of their Trulign Lenses in cataract surgeries;

b. Defendants fraudulently concealed their practice of promoting and marketing to ophthalmologists, including Plaintiff's physician, the use of their Trulign Lenses in cataract surgeries;

c. Defendants fraudulently concealed information about the known comparative risks and benefits of the use of the use of their Trulign Lenses in cataract surgeries and the relative benefits and availability of alternate products, treatments and/or therapies;

d. In connection with their Trulign products, Bausch & Lomb fraudulently and intentionally misrepresented material and important health and safety product risk information from Plaintiffs and Plaintiff's ophthalmologist; all as alleged in this Complaint. Plaintiff and Plaintiff's ophthalmologists would not have decided to use Trulign had they known of the safety risks related to the Trulign.

e. Bausch & Lomb marketed their product to and for the benefit of Plaintiff, and marketed it to Plaintiff's ophthalmologists. Defendants knew or had reason to know of the unreasonable dangers and defects in their Trulign product, and knew or had reason to know that Plaintiff and Plaintiff's ophthalmologists would use the product.

f. Bausch & Lomb fraudulently concealed and misrepresented the health and safety hazards, symptoms, constellation of symptoms, diseases

and/or health problems associated with the Trulign Lenses in the 2013 labeling otherwise known as the Instructions for Use, and concealed from Plaintiff's doctor and Plaintiff that the Trulign Lenses presented substantial problems, including problems doctors had confronted with the Crystalens.

g. Bausch & Lomb fraudulently concealed and misrepresented information about the known comparative risks and benefits of the use of the Trulign Lenses and the relative benefits and availability of alternate lenses, products, treatments and/or therapies.

h. Bausch & Lomb knew, or should have known, that it was concealing and misrepresenting true information about the known comparative risks and benefits of the use of Trulign Toric Lenses and the relative benefits and availability of alternate lenses products, treatments and/or therapies.

i. Bausch & Lomb knew that Plaintiff and Plaintiff's ophthalmologists would regard the matters Defendants concealed and misrepresented to be important in determining the course of treatment for the Plaintiff, including Plaintiff and Plaintiff's physician's decision whether or not to use the Trulign Toric Lenses.

j. Bausch & Lomb intended to cause Plaintiff and Plaintiff's ophthalmologists to rely on their concealment of information and misrepresentations about the safety risks related to the Trulign Lenses to induce them to use them in the surgeries on Plaintiff.

k. Plaintiffs and Plaintiff's ophthalmologists were justified in relying, and did rely, on Bausch & Lomb's concealment of information and

misrepresentations about the safety risks related to Trulign Lenses in connection with Plaintiff's cataract surgeries.

169. As the direct, proximate and legal cause and result of Defendants' fraudulent concealment and misrepresentations and suppression of material health and safety risks relating to Trulign Toric Lenses and Defendants' dangerous and irresponsible marketing and promotion practices, Plaintiffs have been injured and have incurred damages including, but not limited to, medical and hospital expenses, lost wages and lost earning capacity, physical and mental pain and suffering, loss of the enjoyment of life and loss of consortium.

170. Plaintiff Mrs. Doe has been injured and suffers injuries to her eyes, the exact nature of which are not completely known to date; Plaintiffs have sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown; Plaintiff will be required to incur additional medical expenses in the future to care for herself as a result of the continuously degrading injury and damages she has suffered; and, Plaintiff Joseph Doe has lost the society, comfort and consortium of his beloved wife.

171. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

172. Plaintiffs seek injunctive relief to force Defendants to cease sales of these dangerous and defective Lenses.

173. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety

of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

SECOND CAUSE OF ACTION

Strict Products Liability – Failure To Warn under the Connecticut Products Liability Act

174. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

175. Defendants had a duty to warn Plaintiff and her ophthalmologists about the dangers of the Trulign Lenses of which they knew, or in the exercise of ordinary care, should have known, at the time the Trulign Lenses left the Defendants' control.

176. Defendants did know of these dangers of use of the Lenses, and breached this duty by failing to warn Plaintiff and her ophthalmologists of the dangers of its use in cataract surgery.

177. As a direct and proximate result of one or more of the above listed dangerous conditions and defects, Plaintiffs sustained serious injuries of a personal and pecuniary nature from approximately the date of the first surgery through the present and long into the future.

178. Plaintiff sustained extreme pain, suffering, and anguish from the date of her cataract surgeries through the present.

179. As the direct, proximate and legal cause and result of Defendants' misconduct relating to Trulign Toric Lenses and Defendants' dangerous and irresponsible marketing and promotion practices, Plaintiffs have been injured and have incurred damages including, but not limited to, medical and hospital

expenses, lost wages and lost earning capacity, physical and mental pain and suffering, loss of the enjoyment of life and loss of consortium.

180. Plaintiff Mrs. Doe has been injured and suffers injuries and continuously degrading injuries to her eyes, the exact nature of which are not completely known to date; Plaintiffs have sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown; Plaintiff will be required to incur additional medical expenses in the future to care for herself as a result of the injury and damages she has suffered; and, Plaintiff Mr. Doe has lost the society, comfort and consortium of his beloved wife.

181. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

182. Plaintiffs seek injunctive relief to force Defendants to cease sales of these dangerous and defective Lenses.

183. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

THIRD CAUSE OF ACTION

Strict Products Liability – Manufacturing Defect Under the Connecticut Products Liability Act (CPLA)

184. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

185. Defendants were in the business of manufacturing and selling the Trulign Lenses.

186. Defendants' Trulign Lenses were defectively manufactured at the time that it left the Defendants' control.

187. The Trulign Lenses were unreasonably dangerous in that it was unsafe when used as it was promoted by Defendants for use in cataract surgeries including promotion to Plaintiff's ophthalmologist in Connecticut.

188. The Lenses were not manufactured in conformity with the manufacturer's design or in conformity with the FDA approved design that Defendants had submitted to FDA.

189. The Lenses failed to perform as safely as an ordinary consumer would expect

190. Defendants' unreasonably dangerous and defectively manufactured Trulign Lenses were the direct, legal and proximate cause of Plaintiff's injuries and damages including, but not limited to, medical hospital expenses and future medical expenses and future lost earnings and lost earning capacity.

191. The Lenses were expected to and did reach the consumers without substantial change in condition. Conn. Gen. Stat. Ann. § 52-572n(a).

192. As a direct and proximate result of one or more of the above listed dangerous conditions and defects, Plaintiffs sustained serious injuries of a personal and pecuniary nature from the development of the Z Syndrome to the present and far into the future.

193. Plaintiff sustained extreme pain, suffering, and anguish from the date of her surgeries through the present.

194. Plaintiffs seek injunctive relief to force Defendants to cease sales of these dangerous and defective Lenses.

195. Plaintiffs are entitled to compensatory damages in an amount determined at trial.

196. Defendants' conduct was wilful, wanton and oppressive and warrants an imposition of punitive damages.

FOURTH CAUSE OF ACTION

Negligence – Under Connecticut Products Liability Act

197. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

198. Defendants marketed their Trulign Lenses to and for the benefit of Plaintiff, and additionally marketed it to her ophthalmologists, and these Defendants knew or should have known that Plaintiff and her ophthalmologists would use their product for cataract surgery.

199. Defendants owed Plaintiff and her ophthalmologists duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge.

200. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, Defendants breached their duties to Plaintiff and to her ophthalmologists.

201. The following sub-paragraphs summarize, *inter alia*, these Defendants' breaches of duties to Plaintiff and her ophthalmologists and describe categories of acts or omissions constituting breaches of duty by these Defendants. Each and/or any of these acts or omissions establishes an independent basis for these Defendants' liability in negligence:

a. Unreasonable and improper promotion and marketing Trulign Lenses to ophthalmologists, including but not limited to the promotion and marketing of the Lenses without testing;

b. Failure to warn ophthalmologists and Plaintiff of the dangers associated with the Lenses including, but not limited to, development of the Z Syndrome, permanent scarring of the eye, and permanent and impairment of vision, and inability to remove, replace or exchange implanted Lenses from the eye as well as the need for painful therapies to attempt to repair the eyes;

c. Failure to exercise reasonable care by not complying with federal law and regulations applicable to the sale and marketing of Trulign Lenses;

d. Failure to maintain adequate records of complaints having to do with the implantation of the Lenses;

e. Failure to report adverse events to the FDA as required by the conditional approval of the devices;

f. Failure to investigate reported adverse events and inform the FDA and the medical community about those adverse events;

g. Failure to adhere to FDA's requirements; and

h. Failure to manufacture the Lenses employing the required good manufacturing practices.

202. Defendants knew, or should have known, that, due to their failure to use reasonable care, Plaintiff and her ophthalmologists would use and did use the Trulign Lenses to the detriment of Plaintiff's health, safety and well-being.

203. As the direct, producing, proximate and legal cause and result of Defendants' negligence, Plaintiffs suffered severe injuries and losses.

204. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

205. Plaintiffs seek injunctive relief to force Defendants to cease sales of these dangerous and defective Lenses.

206. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs and was such as warrants an award of punitive damages.

FIFTH CAUSE OF ACTION

Negligent Misrepresentation

207. Plaintiffs hereby incorporate each of the preceding paragraphs as if fully set forth herein.

208. Defendants had a duty to accurately and truthfully represent to the Plaintiff, her physician, the medical community and the public, that the Trulign Lenses had been tested and found to be safe and effective for use. The representations made by Defendants, in fact, were false.

209. Defendants failed to exercise ordinary care in the representations concerning the Trulign Lenses while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Trulign Lenses' high risk of unreasonable, dangerous, adverse side effects.

210. Defendants breached their duty in representing that the Trulign Lenses have no serious side effects.

211. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Trulign Lenses had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects.

212. As a proximate result of Defendants' conduct, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care and comfort, and economic damages.

213. As a result of the foregoing fraudulent and deceitful conduct by Defendants, and each of them, Plaintiffs suffered injuries and damages as alleged in this Complaint.

SIXTH CAUSE OF ACTION

Fraud

214. Plaintiffs hereby incorporate each of the preceding paragraphs as if fully set forth herein.

215. Defendants, and each of them, from the time that the Trulign Lenses were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed in September 2014 among other times, willfully deceived the Plaintiffs, the Plaintiffs' physician, the medical community and the public in general, by concealing from them, the true facts concerning the risks of vaulting of the Trulign Lenses, and the risks of inability to remove, replace or exchange the Trulign Lenses, which the Defendants had a duty to disclose.

216. At all times relevant hereto and in August and September of 2014, Bausch & Lomb, through its sales and marketing, conducted a sales and marketing campaign to promote the sale of the Trulign Lenses and willfully deceived the Plaintiff, Plaintiff's ophthalmologist, and the medical community as to the health risks and consequences of the use of the Trulign Lenses including, but not limited to, the following false, deceptive, misleading, and untruthful advertisements, public statements, marketing campaigns, and promotions:

a. In failing to warn Plaintiff's physician of the hazards associated with the use of the Trulign Lenses in the increased risk of vaulting, the proper diagnosis of vaulting, the cause of vaulting, the appropriate response to vaulting, the increased risk of vaulting presented by the Trulign Lenses, and the risks of inability to remove, replace or exchange the Trulign Lenses, about which Defendant knew and was aware;

b. In failing to properly test their products to determine adequacy and effectiveness or safety measures, if any, prior to releasing the Trulign Lenses for consumer use in May, 2013;

c. In failing to properly test their products to determine the increased risk of Z Syndrome, vaulting and severe vision impairment and in failing to properly test the ability to remove, replace or exchange the Trulign Lenses, during the normal and/or intended use of the Trulign Lenses when the Lenses were first approved in May of 2013 and through September of 2014, when the Connecticut physician implanted them into Plaintiff's eyes;

d. In failing to remove the Trulign Lenses from the market when the Defendants knew or should have known the Trulign Lenses were defective.

217. Defendants, pursuant Connecticut law on fraud, as the manufacturer of these products, owed Plaintiffs a duty to not allow fraudulent misinformation and disinformation to injure Plaintiffs.

218. Defendants concealed and/or suppressed any information that would have informed Plaintiffs, their physician, the medical community and the others of the true risks and dangers of the Trulign Lenses. As a result of Defendants' fraudulent concealment and omissions, Plaintiffs were deprived of information important to Jane Doe's ability to even provide care for herself.

219. Bausch & Lomb made false representations as a statement of fact that the Trulign Toric Lens did not carry the same risks and dangers of its predecessor, the Crystalens.

220. The statement was untrue and known to be so by Bausch & Lomb and its representatives, however, the Connecticut ophthalmologist relied on this representation by Bausch & Lomb;

221. Bausch & Lomb's failure to include the true risk of vaulting in its promotions, statements, and labeling were made with the intent of inducing reliance by doctors, like the Does' doctor in Connecticut;

222. The ophthalmologist in Connecticut relied on the statement to his detriment and to the detriment of his patient, Jane Doe because based on these misrepresentations, he used and implanted the Trulign Lenses into both of Plaintiff's eyes.

223. As a result of the Defendants' failures as described, Plaintiffs sustained the injuries, losses and damages described above.

224. As a direct and proximate result of Defendants' fraudulent conduct and omissions, Plaintiff Jane Doe suffered physical injuries, including, but not limited to, severe visual impairment.

225. Plaintiff Jane Doe was harmed because Defendants fraudulently concealed the fact that Trulign Lenses failed in the manners described above.

226. Plaintiff would never had consented to the use of the Trulign Lenses had Plaintiff known of the true risks and dangers concealed from Plaintiff and her doctor.

227. As a result of the Defendants' misconduct as alleged herein, Defendants are liable to Plaintiffs for, and Plaintiffs seek, the full measure of damages allowed under applicable law.

228. Plaintiffs seek injunctive relief to force Defendants to cease sales of these dangerous and defective Lenses.

229. As a result of direct result of the foregoing fraudulent and deceitful conduct by Defendants, and each of them, Plaintiffs suffered injuries, losses and damages as alleged.

230. Defendants' conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and other patients like Plaintiff Jane Doe and warrants an award of punitive damages.

SEVENTH CAUSE OF ACTION

Deceit by Concealment
California Civil Code §§ 1709, 1710

231. Plaintiffs hereby incorporate each of the preceding paragraphs as if fully set forth herein.

232. Defendants, and each of them, from the time that the Trulign Toric Lenses were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, willfully deceived the Plaintiff and the public in general, by concealing from them, the true facts concerning the Trulign Toric Lenses, which the Defendants had a duty to disclose.

233. At all times relevant hereto, Defendants, and each of them, conducted a sales and marketing campaign to promote the sale of the Trulign Toric Lenses and willfully deceived the Plaintiff, and the public in general as to the health risks and consequences of the use of the Trulign Toric Lenses including, but not limited to, the following false, deceptive, misleading, and untruthful advertisements, public statements, marketing campaigns, and promotions:

- **In failing to warn Plaintiff of the hazards associated with the use of the Trulign Toric Lenses;**
- **In failing to properly test their Trulign Toric Lenses to determine adequacy and effectiveness or safety measures, if any, prior to releasing the Trulign Toric Lenses for consumer use;**
- **In failing to properly test their Trulign Toric Lenses to determine the increased risk of vaulting during the normal and/or intended use of the Trulign Toric Lenses;**
- **In failing to inform ultimate users, such as Plaintiff, as to the safe and proper methods of handling and using the Trulign Toric Lenses;**
- **In failing to remove the Trulign Toric Lenses from the market when the Defendants knew or should have known the Trulign Toric Lenses were defective;**
- **In failing to instruct the ultimate users, such as Plaintiff, as to the methods for reducing the type of exposure to the Trulign Toric Lenses which caused increased risk of vaulting and ultimately, severe visual impairment;**
- **In failing to inform the public in general and the Plaintiff in particular of the known dangers of using the Trulign Toric Lenses;**
- **In failing to advise ophthalmologists how to prevent or reduce exposure that caused increased risk for vaulting and/or severe visual impairment;**

- **In marketing and labeling the Trulign Toric Lenses as safe for all uses despite knowledge to the contrary; and**
- **In failing to act like a reasonably prudent company under similar circumstances.**

234. Defendants, and each of them, were aware of the foregoing, and that the Trulign Toric Lenses were not safe, fit, and effective for use as intended. Furthermore, Defendants were aware that the intended and marketed and promoted use of the Trulign Toric Lenses was hazardous to health, and that the Trulign Toric Lenses carry a significant propensity to cause serious injuries to users including, but not limited to, the injuries suffered by Plaintiff as alleged in this Complaint.

235. Defendants intentionally concealed and suppressed the true facts concerning the Trulign Toric Lenses with the intent to defraud the Plaintiff, other consumers, and the public in general, in that Defendants knew that Plaintiff would not have consented to the use of Trulign Toric Lenses if she had known the true facts concerning the risks and dangers of the Trulign Toric Lenses.

236. As a result of the foregoing fraudulent and deceitful conduct by Defendants, and each of them, Plaintiff suffered injuries and damages as alleged.

EIGHTH CAUSE OF ACTION

Violation of Cal. Bus. & Prof. Code §§ 17200, et seq.

237. Plaintiffs hereby incorporate each of the preceding paragraphs as if fully set forth herein.

238. Plaintiff brings this cause of action pursuant to California Business & Professions Code §17204, in her individual capacity, and not on behalf of the general public.

239. California Business & Professions Code §17200 provides that unfair competition shall mean and include "all unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising."

240. The acts and practices described in the Paragraphs above were and are likely to mislead Plaintiff and the general public, and were conducted in California and elsewhere, and therefore constitute unfair business practices within the meaning of Business & Professions Code §17200. The acts of untrue and misleading advertising and marketing set forth in the preceding paragraphs are incorporated by reference and are, by definition, violations of Business & Professions Code §17200. This conduct includes, but is not limited to:

a. failing to warn Plaintiff of the hazards associated with the use of the Trulign Toric Lenses;

b. failing to properly test their Trulign Toric Lenses to determine adequacy and effectiveness or safety measures, if any, prior to releasing the Trulign Toric Lenses for consumer use;

c. failing to properly test their Trulign Toric Lenses to determine the increased risk of vaulting during the normal and/or intended use of the Trulign Toric Lenses;

d. failing to inform ultimate users, such as Plaintiff, as to the safe and proper methods of handling and using the Trulign Toric Lenses;

e. failing to remove the Trulign Toric Lenses from the market when the Defendants knew or should have known the Trulign Toric Lenses were defective;

f. failing to instruct the ultimate users, such as Plaintiff, and/or her ophthalmologist as to the methods for reducing the type of exposure to the Trulign Toric Lenses which caused increased risk of vaulting and severe visual impairment;

g. failing to inform the medical community and the Plaintiff's ophthalmologist in particular of the known dangers of using the Trulign Toric Lenses of the increased risk of vaulting and severe visual impairment;

h. marketing and labeling the Trulign Toric Lenses as safe for all uses despite knowledge to the contrary;

i. aggressively promoting the Trulign Toric Lenses despite knowledge of the increased risks; and

j. recklessly and/or intentionally minimizing and/or downplaying the health hazards and risks of serious side effects related to the use of the Trulign Toric Lenses from Plaintiff, the scientific community, and the general public.

241. These practices constitute unlawful, unfair and fraudulent business acts or practices, within the meaning of California Business & Professions Code §17200, as well as unfair, deceptive, untrue and misleading advertising as prohibited by California Business & Professions Code §17500.

242. As a result of their conduct described above, Defendants have been and will be unjustly enriched. Specifically, Defendants have been unjustly

enriched by their receipt of millions of dollars in ill-gotten gains for their design of, sale of, promotion of, and marketing of Trulign Toric Lenses, sold in large part as a result of the acts and omissions described herein. Defendants have been unjustly enriched by their receipt of millions of dollars in ill-gotten gains in the form of revenues and profits from the sale of Trulign Toric Lenses in California and throughout the United States, sold in large part as a result of the acts and omissions described herein.

243. Because of the fraudulent misrepresentations made by Defendants as detailed above, and the inherently unfair practice of committing a fraud against the public by intentionally misrepresenting and concealing material information, Defendants' acts and omissions described herein constitute unfair or fraudulent business practices.

244. Plaintiff, pursuant to California Business & Professions Code §17203, seeks an order of this court compelling Defendants to disgorge the monies collected and profits realized by them as a result of their unfair business practices and to cease sales of the Trulign Toric Lenses.

NINTH CAUSE OF ACTION

Violation of Cal. Bus. & Prof. Code §§ 17500, et seq.

245. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

246. Plaintiffs brings this cause of action pursuant to California Business & Professions Code §17535, in her individual capacity and not on behalf of the general public.

247. California Business & Professions Code §17500 provides that it is unlawful for any person, firm, corporation or association to dispose of property or perform services, or to induce the public to enter into any obligation relating thereto, through the use of untrue or misleading statements.

248. At all times herein mentioned, Defendants, through their conduct in California and elsewhere, have committed acts of disseminating untrue and misleading statements as defined by Business & Professions Code §17500 by engaging in the following acts and practices with intent to induce members of the public to purchase and use Trulign Toric Lenses:

a. failing to warn Plaintiff of the hazards associated with the use of the Trulign Toric Lenses;

b. failing to inform ultimate users, such as Plaintiff, as to the safe and proper methods of handling and using the Trulign Toric Lenses;

c. failing to instruct the ultimate users, such as Plaintiff, as to the methods for reducing the type of exposure to the Trulign Toric Lenses which caused increased risk of severe and potentially permanent visual impairment;

d. failing to inform the public in general and the Plaintiff in particular of the known dangers of using the Trulign Toric Lenses for cataract surgery;

e. failing to advise users how to prevent or reduce exposure that caused increased risk for vaulting and resulting medical problems;

f. marketing and labeling the Trulign Toric Lenses as safe for all uses despite knowledge to the contrary;

g. aggressively promoting the Trulign Toric Lenses, despite knowledge that such use would increase the risk of severe and permanent visual impairment; and

h. recklessly and/or intentionally minimizing and/or downplaying the health hazards and risks of serious side effects related to the use of the Trulign Toric Lenses from Plaintiff, her ophthalmologist, the medical community, and the general public.

249. Defendants, and each of them, have made numerous misrepresentations and misleading omissions to Plaintiff, the scientific community and the general public. Among Defendants' numerous misrepresentations and misleading omissions are the gross underestimations and under reporting of the incidence of vaulting and resulting permanent and severe visual impairment caused by implanting Trulign Toric Lenses.

250. Despite their knowledge of serious health hazards posed by Trulign Toric Lenses, Defendants did not warn consumers, the ophthalmologists, the medical community, or the general public about the serious risks and side effects associated with Trulign Toric Lenses and continued to promote, market, sell and defend Trulign Toric Lenses.

251. The foregoing practices constitute false and misleading advertising within the meaning of California Business & Professions Code §17500.

252. As a result of their conduct described above, Defendants have been and will be unjustly enriched. Specifically, Defendants have been unjustly enriched by their receipt of millions of dollars in ill-gotten gains for their design of,

sale of, promotion of, and marketing of Trulign Toric Lenses, sold in large part as a result of the acts and omissions described herein. Defendants have been unjustly enriched by their receipt of millions of dollars in ill-gotten gains in the form of revenues and profits from the sale of Trulign Toric Lenses in California and throughout the United States, sold in large part as a result of the acts and omissions described herein.

253. Pursuant to California Business & Professions Code §17535, Plaintiff seeks an order of this court compelling Defendants to disgorge the monies collected and profits realized by Defendants as a result of their unfair business practices and to cease the sale of the Trulign Toric Lenses.

254. Plaintiffs seek the imposition of a constructive trust over, and disgorgement of, the monies collected and profits realized by Defendants.

TENTH CAUSE OF ACTION

Loss of Consortium

255. Plaintiffs hereby incorporate each of the preceding paragraphs as if fully set forth herein.

256. Plaintiff Joseph Doe is, and at all times herein mentioned was, the lawful spouse of Plaintiff Jane Doe.

257. As a direct, legal, and proximate result of the culpability and fault of Defendants, be such fault through strict liability or negligence, Plaintiff Joseph Doe suffered the loss of support, service, society, and other elements of consortium, all to his general damage in an amount in excess of the jurisdictional minimum of this Court.

258. As alleged above, the Defendants knew and had reason to know that the implantation of the Trulign Lenses could cause serious injuries to Plaintiff Jane Doe, and other consumers like her, and to Joseph Doe and other spouses like him. Defendants consciously disregarded this increased risk of harm by failing to warn of such risks and by continuing to market, promote, sell and defend the Trulign Lenses.

VII. EQUITABLE TOLLING OF STATUTES OF LIMITATIONS AND PUNITIVE DAMAGES ARE PROPER IN THIS CASE.

259. Plaintiffs hereby incorporate by reference all other paragraphs of this Complaint.

260. Plaintiffs suffered illnesses that have latency periods and do not arise until many years after exposure. Plaintiff's illnesses did not distinctly manifest as having been caused by the Trulign Toric Lenses until Plaintiff was made aware that her injuries could be caused by use of the Defendants' Trulign Toric Lenses. Consequently, the discovery rule applies to this case and the statute of limitations has been tolled until the day that Plaintiff knew or had reason to know that ovarian cancer was linked to the use of the Trulign Toric Lenses.

261. Furthermore, the running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and conduct. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff the true risks associated with Trulign Toric Lenses.

262. As a result of Defendants' actions, Plaintiff was unaware, and could not reasonably know, or could not have reasonably learned through reasonable

diligence, that Plaintiff has been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

263. Furthermore, Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of Trulign Toric Lenses. Defendants were under a duty to disclose the true character, quality and nature of Trulign Toric Lenses because this was non-public information which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to Plaintiff.

264. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting profitable Trulign Toric Lenses, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on Defendants' representations.

265. In representations to the Plaintiff and the public in general, Defendants also fraudulently concealed and intentionally omitted the following material information:

- **that the Trulign Toric Lenses were not as safe as other products available;**
- **that the Trulign Toric Lenses were dangerous; and**
- **that the Trulign Toric Lenses were defectively and negligently designed and had defective, inadequate, and insufficient warnings and instructions.**

266. Defendants were under a duty to disclose to Plaintiff, and the public in general, the defective nature of the Trulign Toric Lenses.

267. Defendants made the misrepresentations and actively concealed information concerning the safety and efficacy of the Trulign Toric Lenses with the intention and specific desire to induce the consumers, including the Plaintiff, to rely on such misrepresentations in selecting, purchasing and using the Trulign Toric Lenses.

268. Defendants made these misrepresentations and actively concealed information concerning the safety and efficacy of the Trulign Toric Lenses in the labeling, advertising, promotional material or other marketing efforts.

269. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

270. The misrepresentations and active concealments by Defendants were perpetuated directly and indirectly by Defendants, its sales representative, employees, distributors, agents, marketers and detail persons.

271. At the time the representations were made, Plaintiff did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Trulign Toric Lenses. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts or Defendants' misrepresentations.

272. Defendants knew that Plaintiffs, and the public in general, had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the Trulign Toric Lenses, as set forth herein.

273. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of the Trulign Toric Lenses, Plaintiff would not have purchased, used, or relied on Defendants' Trulign Toric Lenses.

274. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and Plaintiff.

275. The information distributed to the public and Plaintiff by Defendants included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Trulign Toric Lenses.

276. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of the Trulign Toric Lenses, specifically that the Trulign Toric Lenses did not have dangerous and/or serious adverse health safety concerns, and that the Trulign Toric Lenses were as safe as other products.

277. Defendants' intent and purpose in making these misrepresentations was to deceive the Plaintiffs; to gain the confidence of the public, the medical

community, and Plaintiffs, to falsely assure them of the quality and fitness for use of the Trulign Toric Lenses; and induce Plaintiffs and the public to use the Trulign Toric Lenses.

278. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Trulign Toric Lenses to the public at large, for the purpose of influencing the sales of Trulign Toric Lenses known to be dangerous and defective, and/or not as safe as other alternatives.

279. At all times relevant to this action, Defendants knew that the Trulign Toric Lenses were not safe for consumers.

280. The misrepresentations and active concealment by Defendants constitute a continuing tort. Indeed, Defendants continue to misrepresent the potential risks and serious side effects associated with the use of the Trulign Toric Lenses.

281. As a result of the Defendants' advertising and marketing efforts, misrepresentations and omissions, the Trulign Toric Lenses are and continue to be pervasively manufactured and used in California and throughout the United States.

282. The acts, conduct, and omissions of Defendants, and each of them, as alleged throughout this Complaint were fraudulent, willful and malicious and were done with a conscious disregard for the rights of Plaintiffs and other users of the Trulign Toric Lenses and for the primary purpose of increasing Defendant's profits from the sale and distribution of the Trulign Toric Lenses. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive

damages against each Defendant in an amount appropriate to punish and make an example of each Defendant.

283. Prior to the manufacturing, sale and distribution of the Trulign Toric Lenses, Defendants, and each of them, knew that the Trulign Toric Lenses were in a defective condition as previously alleged herein and knew that those who were prescribed the Trulign Toric Lenses would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants and each of them through its officers, directors, managers, and agents, had knowledge that the Trulign Toric Lenses presented a substantial and unreasonable risk of harm to the public, including Plaintiff and, as such, consumers of the Trulign Toric Lenses were unreasonably subjected to risk of injury.

284. Despite such knowledge, Defendants, and each of them, acting through its officers, directors and managing agents for the purpose of enhancing Defendant's profits, knowingly and deliberately failed to remedy the known defects in the Trulign Toric Lenses and failed to warn the public, including the Plaintiff, of the extreme risk of injury occasioned by said defects inherent in the Trulign Toric Lenses. Defendants and its individual agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution and marketing of the Trulign Toric Lenses knowing that the public, including Plaintiff, would be exposed to serious danger in order to advance Defendants' own pecuniary interest and monetary profits.

285. Defendants' conduct was despicable, and so contemptible that it would be looked down upon and despised by ordinary decent people, and was

carried on by Defendants with willful and conscious disregard for safety, entitling Plaintiffs to exemplary damages.

286. Plaintiffs filed this lawsuit within the applicable limitations period of first suspecting that the Trulign Toric Lenses were the cause of any appreciable harm sustained by Plaintiffs, within the applicable limitations period of first suspecting or having reason to suspect any wrongdoing, and within the applicable limitations period of first discovering the injuries. Plaintiffs could not, by the exercise of reasonable diligence, have discovered any wrongdoing and could not have discovered the causes of the injuries at an earlier time because the injuries occurred without initial perceptible trauma or harm and, when the injuries were discovered, the causes were not immediately known. Plaintiffs did not suspect, nor did they have reason to suspect, that wrongdoing had caused the injuries until recently. Plaintiffs filed the original action within one-year of discovering the causes of action and identities of Defendants.

287. Plaintiff had no knowledge of the defects in the Trulign Toric Lenses or of the wrongful conduct of Defendants as set forth herein, nor did Plaintiffs have access to information regarding other injuries and complaints in the possession of Defendants. Additionally, Plaintiffs were prevented from discovering this information sooner because Defendants misrepresented and continue to misrepresent to the public that the Trulign Toric Lenses are safe and free from defects. Defendants fraudulently concealed information to allow Plaintiffs to discover a potential cause of action sooner.

288. Plaintiff has reviewed their potential legal claims and causes of action against the Defendants and intentionally choose only to pursue claims based on state law. Any reference to any federal agency, regulation or rule is stated solely as background information and does not raise a federal question. Plaintiffs choose to only pursue claims based on state law and are not making any claims that raise federal questions.

WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, and as appropriate to each cause of action alleged, as follows:

a. For injunctive relief, including removal of the dangerous and defective Trulign lens from the market;

b. For declaratory relief, declaring that the Trulign Toric Lenses are defective as a matter of law;

c. Past and future general damages, the exact amount of which has yet to be ascertained, in an amount which will conform to proof at time of trial;

d. Past and future economic and special damages according to proof at the time of trial;

e. Loss of earnings and impaired earning capacity according to proof at the time of trial;

f. Medical expenses, past and future, according to proof at the time of trial;

g. For past and future mental and emotional distress, according to proof;

h. For loss of consortium;

i. For punitive or exemplary damages according to proof at the time of trial;

j. For attorneys' fees and costs of suit incurred herein;

k. For pre-judgment interest as provided by law; and

l. For such other and further relief as the Court deems equitable or appropriate under the circumstances.

DEMAND FOR A JURY TRIAL

Plaintiffs demand a trial by jury on all issues stated.

Respectfully submitted,

Dated: March 23, 2018

/s/ Wendy R. Fleishman
Wendy R. Fleishman

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Attorneys for Plaintiffs Jane and Joseph Doe

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 28th day of March, 2018, a copy of the foregoing First Amended Complaint For Injunctive Relief And Damages was filed electronically and served by mail on anyone unable to accept electronic filing. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system or by mail on anyone unable to accept electronic filing. Parties may access this filing through the Court's system.

/s/ Wendy R. Fleishman
Wendy R. Fleishman
(*pro hac vice*)