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9 **UNITED STATES DISTRICT COURT**
10 **NORTHERN DISTRICT OF CALIFORNIA**
11 **SAN FRANCISCO DIVISION**

12 NATALIE BAUM,

13 Plaintiff,

14 v.

15 JANSSEN PHARMACEUTICALS, INC.
16 f/k/a JANSSEN PHARMACEUTICA INC.
17 f/k/a ORTHO-MCNEIL-JANSSEN
18 PHARMACEUTICALS, INC.; JANSSEN
19 ORTHO LLC; JANSSEN RESEARCH &
20 DEVELOPMENT LLC f/k/a JOHNSON
21 AND JOHNSON PHARMACEUTICAL
22 RESEARCH AND DEVELOPMENT LLC;
23 ORTHO-MCNEIL PHARMACEUTICALS,
24 INC.; JOHNSON & JOHNSON
25 COMPANY; TEVA BRANDED
26 PHARMACEUTICAL PRODUCTS R&D,
27 INC.; TEVA PHARMACEUTICALS USA,
28 INC.; CENTOCOR RESEARCH &
DEVELOPMENT, INC.; BAKER NORTON
PHARMACEUTICALS, INC. f/k/a Baker
Cummins Pharmaceuticals, Inc.; and IVAX
CORPORATION,

Defendants.

Case No.: 3:21-cv-00985

COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

1 Plaintiff Natalie Baum (“Plaintiff”), through her undersigned counsel, and based on
2 personal knowledge, investigation of counsel, and information and belief, files this Complaint for
3 Damages and Demand for Jury Trial and alleges as follows.

4 **NATURE OF THE ACTION**

5 1. This is an action for damages suffered by Plaintiff as a direct and proximate result
6 of Defendants JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA
7 INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; JANSSEN ORTHO
8 LLC; JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON
9 PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC; ORTHO-MCNEIL
10 PHARMACEUTICALS, INC.; JOHNSON & JOHNSON COMPANY; TEVA BRANDED
11 PHARMACEUTICAL PRODUCTS R&D, INC.; TEVA PHARMACEUTICALS USA, INC.;
12 CENTOCOR RESEARCH & DEVELOPMENT, INC.; BAKER NORTON
13 PHARMACEUTICALS, INC. f/k/a Baker Cummins Pharmaceuticals, Inc.; and IVAX
14 CORPORATION (collectively “Defendants”)’s negligent and wrongful conduct in connection
15 with the design, development, manufacture, testing, packaging, promoting, marketing,
16 distribution, labeling, and/or sale of ELMIRON® (hereafter “ELMIRON”) for the relief of
17 bladder pain or discomfort associated with interstitial cystitis.
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21 2. As a result of the defective nature of ELMIRON, persons who were prescribed and
22 ingested ELMIRON, including Plaintiff, have suffered and may continue to suffer severe and
23 permanent personal injuries, including but not limited to retinal pigmentary changes, vision
24 changes, and potentially irreversible vision damage.
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26 3. After beginning treatment with ELMIRON, and as a direct and proximate result
27 of Defendants’ actions and inaction, Plaintiff suffered retinal and macular damage,
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1 maculopathy/macular disorder, and retinal and macular pigmentary changes. Plaintiff's ingestion
2 of the defective and unreasonably dangerous drug ELMIRON has caused and will continue to
3 cause injury and damage to Plaintiff.

4 4. Defendants concealed, and continue to conceal, their knowledge of ELMIRON's
5 unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

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7 5. Plaintiff brings this action for personal injuries suffered as a proximate result of
8 Plaintiff being prescribed and ingesting ELMIRON. Plaintiff accordingly seeks compensatory
9 and punitive damages, monetary restitution, and all other available remedies as a result of injuries
10 caused by ELMIRON.

11 **PARTIES**

12 **A. Plaintiff**

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14 6. Plaintiff Natalie Baum is a citizen and a resident of Livermore, Alameda County,
15 California.

16 7. Plaintiff began taking ELMIRON in or about 2005.

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18 8. Plaintiff was prescribed, purchased, and ingested ELMIRON that was researched
19 by, developed, designed, licensed, manufactured, distributed, supplied, packaged, labeled, sold,
20 marketed, and/or introduced into interstate commerce by Defendants in the State of California,
21 and Plaintiff sustained serious injuries as a result in the State of California.

22 9. Plaintiff was given no warning by Defendants of the serious risk of vision-
23 threatening retinal changes, including vision loss, retinal and macular damage,
24 maculopathy/macular disorder, and retinal and macular pigmentary changes posed by
25 ELMIRON.
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1 10. Plaintiff was given no warnings by her physicians of the serious risks of vision-
2 threatening retinal changes, including vision loss, retinal and macular damage,
3 maculopathy/macular disorder, and retinal and macular pigmentary changes posed by
4 ELMIRON.

5 11. Plaintiff had no knowledge of the serious risk of vision-threatening retinal
6 changes, including vision loss, retinal and macular damage, maculopathy/macular disorder, and
7 retinal and macular pigmentary changes posed by ELMIRON.

8 12. Plaintiff's prescribing physicians were given no warning by Defendants of the
9 serious risk of vision-threatening retinal changes, including vision loss, retinal and macular
10 damage, maculopathy/macular disorder, and retinal and macular pigmentary changes posed by
11 ELMIRON.

12 13. Plaintiff was given no warning by Defendants of the need for ophthalmologic
13 monitoring before taking, while taking, and after discontinuing ELMIRON.

14 14. Plaintiff was given no warning by her physicians of the need for ophthalmologic
15 monitoring before taking, while taking, and after discontinuing ELMIRON.

16 15. Plaintiff had no knowledge of the need for ophthalmologic monitoring before
17 taking, while taking, and after discontinuing ELMIRON.

18 16. Plaintiff's prescribing physicians were given no warning by Defendants of the
19 need for ophthalmologic monitoring before taking, while taking, and after discontinuing
20 ELMIRON.

21 17. As result of using Defendants' ELMIRON, Plaintiff was caused to suffer vision
22 loss and visual symptoms including but not limited to difficult adapting to dim lighting, dark spots
23 in the center of her vision, straight lines appearing curved or squiggly, muted, less vivid colors,
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1 distorted vision, and vision disturbances; retinal and macular damage; maculopathy/macular
2 disorder; and retinal and macular pigmentary changes.

3 18. As a result of using Defendants' ELMIRON, Plaintiff was caused to sustain severe
4 and permanent personal injuries, pain, suffering, and emotional distress.

5 19. The injuries and damages sustained by Plaintiff were caused by Defendants'
6 ELMIRON.

7 20. Plaintiff may continue to suffer a progression of retinal and vision changes even
8 though Plaintiff is no longer taking ELMIRON.

9 21. Plaintiff has incurred and will continue to require and incur medical and related
10 expenses in connection with these injuries, which were caused by Defendants' ELMIRON, and
11 Defendants' unlawful conduct with respect to ELMIRON's design, manufacture, marketing,
12 distribution, and sale.

13 22. Plaintiff has endured and will continue to endure pain, suffering, mental anguish,
14 and loss of enjoyment of life as a result of her injuries, has suffered lost earnings and/or a loss of
15 earning capacity, and other injuries and damages to be proven at trial.

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18 **B. Defendants**

19 23. Upon information and belief, Defendant JANSSEN PHARMACEUTICALS,
20 INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN
21 PHARMACEUTICALS, INC. (hereinafter referred to as "JANSSEN PHARM") is a Pennsylvania
22 corporation having a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New
23 Jersey 08560, and is a wholly-owned subsidiary of Defendant JOHNSON & JOHNSON
24 COMPANY.

25 24. As part of its business, Defendant JANSSEN PHARM is involved in the
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1 research, development, design, licensing, manufacture, distribution, supply, sales and/or
2 marketing, and introduction into interstate commerce, either directly or indirectly through third
3 parties or related entities, of pharmaceutical products including ELMIRON and pentosan
4 polysulfate sodium.

5 25. Upon information and belief, Defendant JANSSEN PHARM has transacted and
6 conducted business in the State of California.
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8 26. Upon information and belief, Defendant JANSSEN PHARM has derived
9 substantial revenue from goods and products used in the State of California.

10 27. Upon information and belief, Defendant JANSSEN PHARM expected or
11 should have expected its acts to have consequence within the United States of America and the
12 State of California, and derived substantial revenue from interstate commerce within the United
13 States and the State of California, more particularly.
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15 28. Upon information and belief, and at all relevant times, Defendant JANSSEN
16 PHARM was in the business of and did design, research, manufacture, test, advertise, promote,
17 market, sell, and distribute the drug ELMIRON for the relief of bladder pain or discomfort
18 associated with interstitial cystitis.
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20 29. Upon information and belief, Defendant JANSSEN ORTHO LLC (hereinafter
21 referred to as “JANSSEN ORTHO”) is a limited liability company organized under the laws
22 of Delaware, having a principal place of business at Stateroad 933 Km 0 1, Street Statero, Gurabo,
23 Puerto Rico 00778. Defendant JANSSEN ORTHO is a wholly-owned subsidiary of JOHNSON &
24 JOHNSON COMPANY, which is a New Jersey corporation with its principal place of business
25 in New Jersey. JOHNSON & JOHNSON COMPANY is the sole member of JANSSEN ORTHO.
26 Accordingly, JANSSEN ORTHO is a citizen of New Jersey for purposes of determining diversity
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1 under 28 U.S.C. § 1332

2 30. As part of its business, Defendant JANSSEN ORTHO is involved in the
3 research, development, sales, and marketing of pharmaceutical products including ELMIRON
4 and pentosan polysulfate sodium.

5 31. Upon information and belief, Defendant JANSSEN ORTHO has transacted and
6 conducted business in the State of California.

7 32. Upon information and belief, Defendant JANSSEN ORTHO has derived
8 substantial revenue from goods and products used in the State of California.

9 33. Upon information and belief, Defendant JANSSEN ORTHO expected or
10 should have expected its acts to have consequence within the United States of America and the
11 State of California, and derived substantial revenue from interstate commerce within the United
12 States and the State of California.

13 34. Upon information and belief, and at all relevant times, Defendant JANSSEN
14 ORTHO was in the business of and did design, research, manufacture, test, advertise, promote,
15 market, sell, and distribute the drug ELMIRON for the relief of bladder pain or discomfort
16 associated with interstitial cystitis.

17 35. Upon information and belief, Defendant JANSSEN RESEARCH &
18 DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL
19 RESEARCH AND DEVELOPMENT LLC (hereinafter referred to as “JANSSEN R&D”) is a
20 limited liability company organized under the laws of New Jersey, having a principal place of
21 business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.
22 Defendant JANSSEN R&D’s sole member is CENTOCOR RESEARCH & DEVELOPMENT,
23 INC., which is a Pennsylvania corporation with its principal place of business in Pennsylvania.
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1 Accordingly, JANSSEN R&D is a citizen of Pennsylvania for purposes of determining diversity
2 under 28 U.S.C. § 1332.

3 36. Upon information and belief, Defendant JANSSEN R&D has transacted and
4 conducted business in the State of California.

5 37. Upon information and belief, Defendant JANSSEN R&D has derived substantial
6 revenue from goods and products used in the State of California.

7 38. Upon information and belief, Defendant JANSSEN R&D expected or should have
8 expected its acts to have consequence within the United States of America and the State of
9 California, and derived substantial revenue from interstate commerce within the United States
10 and the State of California, more particularly.

11 39. Upon information and belief, and at all relevant times, Defendant JANSSEN
12 R&D was in the business of and did design, research, manufacture, test, advertise, promote,
13 market, sell, and distribute the drug ELMIRON for the relief of bladder pain or discomfort
14 associated with interstitial cystitis.

15 40. Upon information and belief, Defendant ORTHO-MCNEIL
16 PHARMACEUTICALS, INC. (hereinafter referred to as “ORTHO PHARMA”) is a corporation
17 organized under the laws of Delaware with its principal place of business at 1000 US Highway
18 202, Raritan, New Jersey 08869, and is a wholly-owned subsidiary of Defendant JOHNSON &
19 JOHNSON COMPANY.

20 41. Upon information and belief, Defendant ORTHO PHARMA has transacted and
21 conducted business in the State of California.

22 42. Upon information and belief, Defendant ORTHO PHARMA has derived
23 substantial revenue from goods and products used in the State of California.

1 43. Upon information and belief, Defendant ORTHO PHARMA expected or
2 should have expected its acts to have consequence within the United States of America and the
3 State of California, and derived substantial revenue from interstate commerce within the United
4 States and the State of California, more particularly.

5 44. Upon information and belief, and at all relevant times, Defendant ORTHO
6 PHARMA was in the business of and did design, research, manufacture, test, advertise, promote,
7 market, sell, and distribute the drug ELMIRON for the relief of bladder pain or discomfort
8 associated with interstitial cystitis.

9 45. Upon information and belief, Defendant JOHNSON & JOHNSON COMPANY
10 (hereinafter referred to as “J&J”) is a corporation organized under the laws of New Jersey with
11 its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex
12 County, New Jersey 08933.

13 46. Upon information and belief, and at all relevant times, Defendants JANSSEN
14 PHARM, ORTHO PHARMA, and JANSSEN R&D were wholly-owned subsidiaries of
15 Defendant J&J.

16 47. As part of its business, Defendant J&J is and at all relevant times was involved
17 in the research, development, design, licensing, manufacture, distribution, supply, packaging,
18 labeling, sales, and/or marketing and introduction into interstate commerce, either directly or
19 indirectly through third parties or related entities, of pharmaceutical products including
20 ELMIRON. Defendant J&J manufactures, markets, and sells a wide range of pharmaceutical
21 products including ELMIRON and pentosan polysulfate sodium.

22 48. Upon information and belief, Defendant J&J has transacted and conducted
23 business in the State of California.
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1 49. Upon information and belief, Defendant J&J has derived substantial revenue from
2 goods and products used in the State of California.

3 50. Upon information and belief, Defendant J&J expected or should have expected
4 its acts to have consequence within the United States of America and the State of California,
5 and derived substantial revenue from interstate commerce within the United States and the State of
6 California.

7 51. Upon information and belief, and at all relevant times, Defendant J&J was in the
8 business of and did design, research, manufacture, test, advertise, promote, market, sell, and
9 distribute the drug ELMIRON for the relief of bladder pain or discomfort associated with
10 interstitial cystitis.

11 52. Upon information and belief, Defendant TEVA BRANDED
12 PHARMACEUTICAL PRODUCTS R&D, INC. (hereinafter referred to as “TEVA R&D”) is a
13 corporation organized under the law of Delaware, having a principal place of business at 41
14 Moores Road, Frazer, Pennsylvania 19355.

15 53. As part of its business, Defendant TEVA R&D is involved in the research,
16 development, sales, and marketing of pharmaceutical products including ELMIRON and pentosan
17 polysulfate sodium.

18 54. Upon information and belief, Defendant TEVA R&D has transacted and
19 conducted business in the State of California.

20 55. Upon information and belief, Defendant TEVA R&D has derived substantial
21 revenue from goods and products used in the State of California.

22 56. Upon information and belief, Defendant TEVA R&D expected or should have
23 expected its acts to have consequence within the United States of America and the State of
24 California.

1 California, and derived substantial revenue from interstate commerce within the United States and
2 the State of California, more particularly.

3 57. Upon information and belief, and at all relevant times, Defendant TEVA R&D
4 was in the business of and did design, research, manufacture, test, advertise, promote, market,
5 sell, and distribute the drug ELMIRON for the relief of bladder pain or discomfort associated with
6 interstitial cystitis.

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8 58. Upon information and belief, Defendant TEVA PHARMACEUTICALS USA,
9 INC. (hereinafter referred to as “TEVA USA”) is a corporation organized under the laws of
10 Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey
11 07054.

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13 59. As part of its business, Defendant TEVA USA is involved in the research,
14 development, sales, and marketing of pharmaceutical products including ELMIRON and pentosan
15 polysulfate sodium.

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17 60. Upon information and belief, Defendant TEVA USA has transacted and conducted
18 business in the State of California.

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20 61. Upon information and belief, Defendant TEVA USA has derived substantial
21 revenue from goods and products used in the State of California.

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23 62. Upon information and belief, Defendant TEVA USA expected or should have
24 expected its acts to have consequence within the United States of America and the State of
25 California, and derived substantial revenue from interstate commerce within the United States and
26 the State of California, more particularly.

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28 63. Upon information and belief, and at all relevant times, Defendant TEVA USA
was in the business of and did design, research, manufacture, test, advertise, promote, market,

1 sell, and distribute the drug ELMIRON for the relief of bladder pain or discomfort associated with
2 interstitial cystitis.

3 64. Upon information and belief, CENTOCOR RESEARCH & DEVELOPMENT,
4 INC. (hereinafter “CENTOCOR”) is a Pennsylvania corporation with its principal place of
5 business in Pennsylvania. JANSSEN R&D’s sole member is CENTOCOR.

6 65. CENTOCOR purposefully availed itself to California because it had marketed, co-
7 marketed, sold, and distributed the defective product, ELMIRON, in California. CENTOCOR,
8 together with its co-Defendants, packaged, labeled, promoted, advertised, marketed, co-marketed,
9 distributed, and sold ELMIRON in the State of California. Plaintiff’s claims directly arise out of
10 these forum-related activities by CENTOCOR. Plaintiff used ELMIRON in the State of California,
11 and Plaintiff had suffered and continues to suffer injuries in the State of California.

12 66. Defendant BAKER NORTON PHARMACEUTICALS, INC. f/k/a Baker
13 Cummins Pharmaceuticals, Inc. (hereinafter “BAKER NORTON”) is a corporation organized
14 under Florida law with its principal place of business in Florida.

15 67. BAKER NORTON submitted the NDA for ELMIRON to the FDA and was the
16 named sponsor on the approval of ELMIRON by the FDA. In support of the NDA for ELMIRON,
17 BAKER NORTON conducted the clinical trials, including clinical trials in the State of California.
18 The validity of two of these clinical trials were seriously questioned by the FDA.

19 68. BAKER NORTON held the NDA for ELMIRON from the date of approval,
20 September 26, 1996, until approximately September 1997.

21 69. BAKER NORTON purposefully availed itself to California because it had
22 developed the defective product, ELMIRON, in California, including conducting clinical trials in
23 California. Plaintiff’s claims directly arise out of these forum-related activities by BAKER
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1 NORTON as Plaintiff used this defective product that was tested in California, and Plaintiff had
2 suffered and continues to suffer injuries in California. The clinical trials, including the testing
3 performed in California, were integral to bringing ELMIRON to market nationwide. But for the
4 pre-FDA development of the drug, and clinical trials conducted within California, ELMIRON
5 would not have been sold and marketed throughout the U.S. nor ingested by Plaintiff.
6

7 70. Additionally, BAKER NORTON purposefully availed itself to California because
8 it had manufactured, packaged, labeled, promoted, advertised, marketed, distributed, and sold
9 ELMIRON in the State of California from September 26, 1996, until approximately September
10 1997. Plaintiff's claims directly arise out of these forum-related activities by BAKER NORTON
11 as BAKER NORTON'S early marketing, advertising, and distributing of ELMIRON in
12 California contributed to the popularity and extensive use of ELMIRON by medical professionals
13 such as Plaintiff's healthcare providers in California. Plaintiff's claims directly arise out of these
14 forum-related activities by BAKER NORTON as Plaintiff was prescribed, purchased, and
15 ingested ELMIRON in the State of California.
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17 71. Defendant IVAX CORPORATION (hereinafter "IVAX") is a corporation
18 organized under Florida law with its principal place of business in Florida.
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20 72. Upon information and belief, BAKER NORTON is and has been during all
21 relevant time periods a wholly-owned subsidiary of IVAX.
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23 73. Upon information and belief, IVAX was and is actively involved in BAKER
24 NORTON's business operations, including the early testing, developing, manufacturing,
25 marketing, distributing, and selling of ELMIRON. IVAX purposefully availed itself to California
26 because, together with its subsidiary BAKER NORTON, it had developed the defective product,
27 ELMIRON, in California, including by conducting clinical trials in California. Plaintiff's claims
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1 directly arise out of these forum-related activities by IVAX as Plaintiff used this defective product
2 that was tested in the State of California, and Plaintiff had suffered and continues to suffer injuries
3 in the State of California. The clinical trials, including the testing performed in the State of
4 California, were integral to bringing ELMIRON to market nationwide. But for the pre-NDA
5 development of the drug and clinical trials conducted within the State of California, ELMIRON
6 would not have been sold and marketed throughout the U.S. nor ingested by Plaintiff.
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8 74. Additionally, IVAX purposefully availed itself to California because, together
9 with its subsidiary BAKER NORTON, it had manufactured, packaged, labeled, promoted,
10 advertised, marketed, distributed, and sold ELMIRON in the State of California from September
11 26, 1996, until approximately September 1997. Plaintiff's claims directly arise out of these
12 forum-related activities as IVAX's early marketing, advertising, and distributing of ELMIRON
13 in the State of California contributed to the popularity and extensive use of ELMIRON by medical
14 professionals such as Plaintiff's physicians and healthcare providers in the State of California.
15 Plaintiff's claims directly arise out of these forum-related activities by IVAX as Plaintiff was
16 prescribed, purchased, and ingested ELMIRON in the State of California.
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18 75. Upon information and belief, in September 1997, IVAX licensed the rights to
19 ELMIRON in the United States and Canada to California-based Alza Pharmaceuticals, a division
20 of Alza Corporation, a California Corporation, for \$75 million in up-front payments. Upon
21 information and belief, and at times hereinafter relevant, Alza made the \$75 million up-front
22 payment and additional payments required under the agreement to IVAX from California. IVAX
23 later licensed ELMIRON to Ortho-McNeil Pharmaceuticals, Inc. n/k/a Defendant JANSSEN
24 PHARM.
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26 76. Upon information and belief, IVAX continues to receive milestone and royalty
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1 payments as a result of the sales of ELMIRON.

2 77. Upon information and belief, IVAX manufactured ELMIRON for non-party Alza
3 Pharmaceuticals, a division of Alza Corporation, a California Corporation, after licensing the
4 rights to ELMIRON to Alza in September 1997.

5 **JURISDICTION**

6 78. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a)(1)
7 because this case is a civil action where the matter in controversy exceeds the sum or value of
8 \$75,000, exclusive of interest and costs, and the parties are citizens of different States.

9 79. This Court has personal jurisdiction over Defendants consistent with the United
10 States Constitution as Plaintiff's claims arise out of Defendants' transaction of business and
11 tortuous acts within the State of California; by virtue of Defendants' substantial, continuous, and
12 systematic contacts within the State of California related to Plaintiff's claims; and Plaintiff
13 ingested and suffered injuries as a result of ingesting Defendants' drug ELMIRON in the State of
14 California.

15 80. JOHNSON & JOHNSON COMPANY and its subsidiaries manufactured,
16 packaged, labeled, promoted, co-promoted, advertised, marketed, distributed, and sold
17 ELMIRON to patients and physicians in the State of California, including Plaintiff, from the time
18 of its merger with Alza Corporation until the present.

19 81. Defendants BAKER NORTON and IVAX conducted the clinical trials used to
20 support approval of ELMIRON in the State of California.

21 82. Defendant BAKER NORTON manufactured, packaged, labeled, promoted,
22 advertised, marketed, distributed, and sold ELMIRON in the State of California from September
23 26, 1996, until approximately September 1997.

1 83. In September 1997, Defendants BAKER NORTON and IVAX sold the licensing
2 rights to ELMIRON to Alza Pharmaceuticals, a division of Alza Corporation, corporations
3 located in Vacaville, California.

4 84. At times hereafter relevant, Alza made the \$75 million up-front payment and
5 additional payments required under the agreement to IVAX from California.

6 85. Defendants BAKER NORTON and IVAX continued to receive royalty payments
7 for ELMIRON after the licensing rights to ELMIRON were sold to Alza Pharmaceuticals, a
8 division of Alza Corporation.
9

10 **VENUE**

11 86. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c), because
12 Defendants transact business within, are found in, and/or have agents in this judicial district; and
13 Plaintiff was prescribed, purchased, and ingested ELMIRON and suffered injuries as a result of
14 ingesting the drug ELMIRON in this District.
15

16 **INTRADISTRICT ASSIGNMENT**

17 87. Upon information and belief, assignment of this action to the San Francisco
18 Division in this District is appropriate because Plaintiff's purchase, use, and injuries arising out
19 of Plaintiff's purchase and use of the drug ELMIRON occurred in Alameda County, California.
20

21 **FACTUAL BACKGROUND**

22 **A. History of ELMIRON**

23 88. Pentosan polysulfate sodium (hereinafter referred to as "PPS") is a semi-
24 synthetically produced low molecular weight heparin-like compound and is and has been
25 marketed in the United States by Defendants under the name ELMIRON.
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1 89. Upon information and belief, Defendant TEVA R&D licenses ELMIRON to
2 Defendant JANSSEN PHARM, a wholly-owned subsidiary of Defendant J&J, for manufacture,
3 marketing, advertising, distribution, and sale of ELMIRON in the United States, including in the
4 State of California.

5 90. Upon information and belief, the original New Drug Application (hereinafter
6 referred to as “NDA”) for ELMIRON was submitted by BAKER NORTON, which was owned
7 by IVAX. IVAX later licensed ELMIRON to Ortho-McNeil Pharmaceuticals, Inc. n/k/a
8 Defendant JANSSEN PHARM. Defendant TEVA R&D then purchased IVAX and continued to
9 license ELMIRON to Defendant JANSSEN PHARM.
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11 91. ELMIRON sales in the United States total more than \$150 million each year.

12 92. ELMIRON was the first oral medication approved for use to relieve bladder pain
13 or discomfort associated with interstitial cystitis.
14

15 93. But under interstitial cystitis guidelines established by the American Urological
16 Association (AUA), ELMIRON is not a first-line treatment for interstitial cystitis. Rather,
17 ELMIRON is one of ten suggested second-line treatments, including three other oral medications:
18 amitriptyline, cimetidine, and hydroxyzine. The guidelines further include numerous third, fourth,
19 fifth, and sixth-line treatments. According to the AUA, “first-line treatments” should be suggested
20 to all patients and “sixth-line treatments” should be reserved for the most severe cases, with the
21 remaining treatment options falling in-between.
22

23 94. Interstitial cystitis is a chronic bladder condition affecting millions of people in
24 the United States, mainly women, that causes increased bladder pressure, bladder pain, and even
25 pelvic pain that can often be severe. There is currently no cure for interstitial cystitis.
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1 95. On August 7, 1985, the United States Food and Drug Administration (hereinafter
2 referred to as the “FDA”) designated ELMIRON an orphan drug product due to the rarity of
3 interstitial cystitis.

4 96. BAKER NORTON submitted its first NDA for approval on June 11, 1991, which
5 included data from two clinical trials (referred to as study 001 and 002).

6 97. On January 27, 1993, the FDA issued its first non-approval letter due to numerous
7 problems with the clinical trial analyses and results, as well as interaction between the clinical
8 trial investigators. Specifically, the FDA stated that the NDA lacked the requisite two (2) adequate
9 and well-controlled studies for determining the effects of ELMIRON. The FDA requested that
10 BAKER NORTON conduct another well-controlled, ideally blinded and randomized, clinical
11 trial and to exclude certain investigators.
12

13 98. At least one of the investigators was located and conducted his portion of the
14 clinical trials for ELMIRON in the State of California, and upon information and belief, had a
15 financial interest in ELMIRON; had connections with BAKER NORTON, the sponsor of
16 ELMIRON; and received and continues to receive in the State of California royalty payments
17 from Defendants from the sale of ELMIRON, including from sales of ELMIRON in California.
18

19 99. BAKER NORTON declined to perform additional clinical trials and instead re-
20 analyzed the data from the two pivotal studies already submitted.
21

22 100. On October 28, 1994, the FDA issued a second non-approval letter due to
23 insufficient clinical trial evidence to establish efficacy. Once again, the FDA emphasized that the
24 studies could not be considered independent due to issues with the investigators. In removing the
25 data generated by those investigators, neither study was powered to show statistical significance
26 for any of the primary efficacy endpoints. While the FDA did find that study 002 provided some
27

1 evidence of efficacy, it once again encouraged BAKER NORTON to perform another well-
2 controlled, sufficiently powered clinical trial and to exclude any investigators involved in study
3 002.

4 101. BAKER NORTON continued to decline to perform an additional clinical trial and
5 instead proposed an analysis of the database from its Compassionate Use program established in
6 1986, which it submitted to the FDA on August 31, 1995.

7
8 102. Ultimately, for its third resubmission of the NDA, BAKER NORTON relied on
9 two clinical studies. The first study (study 002) was a blinded, randomized, placebo-controlled
10 trial that evaluated only 151 patients for three (3) months. Of the patients receiving ELMIRON,
11 38% reported greater than 50% improvement in bladder pain compared to 18% of the placebo
12 patients. The FDA noted that the study indicated a statistically significant treatment effect for
13 only two (2) of six (6) identified efficacy endpoints—the patient’s evaluation of bladder pain and
14 the investigator’s evaluation of overall improvement—both of which allow for bias that
15 undermines the validity of the results. Further, the FDA also noted that one investigator in
16 particular influenced the results, and when the data from that investigator were removed, the
17 results still favored ELMIRON over placebo but were no longer statistically significant.
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20 103. The second clinical trial was an unblinded retrospective analysis of 2,499 patients,
21 mostly women, in the ELMIRON Compassionate Use program. After three (3) months, over half
22 of the patients dropped out or were deemed ineligible for the trial; importantly, 31% of those
23 patients reported lack of efficacy and 17% reported an adverse event. The percentage of patients
24 reporting improvement in pain after three (3) months of treatment was 61% but dropped to only
25 13% after six (6) months of treatment.
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1 104. In reviewing the NDA for a third time, the FDA accepted the Compassionate Use
2 data in lieu of a randomized controlled clinical trial, the typical gold standard. However, the FDA
3 noted that only a subset of the patients was analyzed, and any observed efficacy from ELMIRON
4 use could be enhanced by placebo effect since the study was unblinded and uncontrolled.

5 105. In reviewing the clinical trial data overall, the FDA noted that 75% of interstitial
6 cystitis patients could be classified as non-responders to ELMIRON therapy and recommended a
7 three (3) month trial period after drug initiation to determine if a patient will respond to
8 ELMIRON.
9

10 106. On September 26, 1996, the FDA ultimately approved the NDA for ELMIRON
11 based on these two studies despite the significant concerns. The FDA reviewers noted that, while
12 the studies had fatal flaws, the unique situation of interstitial cystitis, the apparent lack of
13 significant clinical safety concerns based on these short-term studies, and the appearance of
14 efficacy in a subset of patients resulted in a small risk/benefit ratio, provided BAKER NORTON
15 agreed to an indication with a three-month initial treatment trial and continued to monitor the
16 safety and efficacy of ELMIRON.
17

18 107. In September 1997, Alza Corporation acquired all rights to ELMIRON from
19 BAKER NORTON, which at this point in time was still owned by IVAX. BAKER
20 NORTON/IVAX sold the rights to ELMIRON to Alza Corporation for \$75 million up front and
21 continued to receive milestone and royalty payments thereafter.
22

23 **B. The Dangers of ELMIRON**

24 108. Following approval in 1996, Defendants have received multiple Adverse Event
25 Reports (hereinafter referred to as “AERs”) detailing injuries including serious visual symptoms
26 and/or damage both in the United States and internationally.
27
28

1 109. Nearly 150 cases of eye disorders were reported to the FDA as adverse effects of
2 ELMIRON ranging from blurred vision to maculopathy to blindness. Other reported symptoms
3 include visual impairment, halo vision, and reduced visual acuity.

4 110. In the Spring of 2018, a team at Emory Eye Center submitted a letter to the editor
5 of the Journal of Urology reporting findings of unusual retinal pigmentary changes or
6 maculopathy (i.e., any condition affecting the macula at the center of the retina) in six (6) female
7 patients on long-term ELMIRON treatment (median use of 15.5 years) *that did not resemble any*
8 *other type of retinal disease.*¹ That case series was published online at the end of April 2018.²
9 None of the patients had a family history of retinal disease or any pathogenic process that would
10 predispose them to such a disease. Of the six (6), five (5) had received 400mg daily of ELMIRON
11 (but two reduced their dose to 200mg per day after 17 years of treatment), and one (1) received
12 300mg daily. The youngest patient was 23 years old when diagnosed with interstitial cystitis,
13 began showing visual symptoms at 30, and by 37 had the most severe eye damage in the study.
14 The authors also highlighted the results of the Compassionate Use study that showed vision-
15 related adverse events, including optic neuritis, amblyopia, and retinal hemorrhage.
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18 111. In May 2019, the same Emory team presented an update to their study at the
19 American Urological Association annual meeting in Chicago. The study identified 10 patients
20 with pigmentary maculopathy at the Emory Eye Center. The patients ranged in age from 38 to 68
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25 ¹ Pearce WA, et al. *Re: FDA BRUDAC 2018 Criteria for Interstitial Cystitis/Bladder Pain Syndrome Clinical Trials: Future Direction for Research.* J Urol 2018;200(5):1122-1123.

26
27 ² Pearce WA, et al. *Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate Sodium.* Ophthalmology. May 22, 2018.
28

1 years old and once again had a median treatment duration of 15.5 years (with the shortest duration
2 of a little over two (2) years). The poster presentation concluded:

3 We describe a potentially avoidable retinal degeneration
4 phenomenon associated with chronic PPS exposure. Structural
5 changes occur at the level of the retinal pigment epithelium,
6 manifesting as characteristic pigmentary changes. While it remains
7 unclear whether drug cessation will alter the course of retinal
8 disease, we encourage affected patients to discontinue use, and
patients with suggestive visual symptoms to undergo a
comprehensive ophthalmic examination with OCT and FAF
imaging.³

9 112. The Emory researchers also presented at the Association for Research in Vision
10 and Ophthalmology Annual Meeting at the end of Spring 2019, where they reported results from
11 a retrospective cross-sectional study that included all patients at Emory Eye Center who had been
12 diagnosed with interstitial cystitis within a four (4)-year period. The authors found 14 cases of
13 this characteristic maculopathy in 80 patients exposed to ELMIRON and no cases in 139
14 unexposed patients. The only statistically significant risk factor was ELMIRON exposure, with
15 median use of 18.3 years in affected patients. The authors thereby concluded a strong association
16 between ELMIRON exposure and this specific type of vision-threatening maculopathy.⁴

17
18 113. The Emory research group then teamed with researchers at other institutions to
19 conduct a multi-institutional case series published in September 2019 that analyzed 35 patients
20 with ELMIRON-associated maculopathy. The median duration of use was 14.5 years at a median
21 dose of 300mg per day. The most common referral diagnosis was macular or pattern dystrophy
22
23

24
25 ³ Foote, et al. 2019. *Chronic Exposure to Pentosan Polysulfate Sodium is Associated with Retinal
26 Pigmentary Changes and Vision Loss*. AUA 2019 Abstract MP47-03.

27 ⁴ Hanif AM, et al. *Strength of Association between Pentosan Polysulfate and a Novel Maculopathy*.
28 JAMA Ophthalmology, October 2019; 126(10):1464-1466.

1 and/or age-related macular degeneration, and the most common symptoms included blurred
2 vision and prolonged dark adaptation. This study focused on diagnostic methods (i.e., multimodal
3 imaging) and presentation of this specific form of maculopathy, which proved distinctive from
4 other retinal diseases and conditions.⁵

5
6 114. In October 2019, a research team at Kaiser Permanente in Oakland, California
7 found that out of 140 patients currently using ELMIRON for an average of 15 years (and a
8 minimum of five (5) years), 24% had eye damage and/or retinal toxicity that increased with the
9 total amount of ELMIRON taken. That team presented their research at the 2019 Annual meeting
10 for the American Academy of Ophthalmology (AAO) in San Francisco.⁶ The researchers then
11 performed multimodal image screening on 117 patients exposed to ELMIRON, of which 23%
12 had definite indications of maculopathy and demonstrated a dose-response relationship.
13 Specifically, approximately one quarter of patients with an intake of greater than 500g developed
14 retinal changes consistent with ELMIRON-associated maculopathy.⁷

15
16 115. Another presentation at the October 2019 AAO meeting was “the first study to
17 demonstrate a *dose-response correlation* between exposure to [ELMIRON] and retinal toxicity.”⁸
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22 ⁵ Hanif AM, et al. *Phenotypic Spectrum of Pentosan Polysulfate Sodium-Associated Maculopathy:
23 A Multicenter Study*. JAMA Ophthalmology, 2019; 137(11):1275-1282.

24 ⁶ “More Evidence Linking Common Bladder Medication to a Vision-threatening Eye Condition.”
AAO Press Release. October 12, 2019.

25 ⁷ Vora RA, et al. *Prevalence of Maculopathy Associated with Long-Term Pentosan Polysulfate
26 Therapy*. Ophthalmology, June 2020; 127(6):835-836.

27 ⁸ Schaal, S. and Hadad, A. “Qualitative and Quantitative Analysis of Pentosan Polysulfate Sodium
28 Retinal Toxicity Demonstrates a Dose-Response Curve.” AAO PA068 – 2019.

1 116. In November 2019, the Emory Eye Center team released results from a U.S.
2 retrospective cohort study using a medical claims database from 2002 to 2016 comparing
3 ELMIRON users to matched controls at five (5) and seven (7) years of use. At the seven (7) year
4 follow-up, ELMIRON users had *significantly increased risk* of developing atypical maculopathy
5 and age-related macular degeneration. Therefore, this study concluded that ELMIRON “exposure
6 was associated with a new diagnosis of macular disease at the 7-year follow-up in a large national
7 cohort.”⁹

9 117. Also in November 2019, a researcher at Harvard published a case study of
10 ELMIRON-associated maculopathy that progressed over six (6) years after discontinuing the
11 medication. The female patient used 200mg per day of ELMIRON for 18 years. She first
12 presented with a year of visual symptoms at the age of 62 and stopped using ELMIRON shortly
13 thereafter. She continued to be seen for increasing visual damage over the course of the next six
14 (6) years and was determined to have retinal atrophy and damage that could not be associated
15 with any genetic or other potential cause. Upon release of the Emory case study in 2018, her
16 healthcare providers determined her case was consistent with ELMIRON-associated
17 maculopathy. The authors stated that this case “adds a new layer of concern by demonstrating
18 progressive maculopathy continuing for up to 6 years after the cessation of [ELMIRON],” and
19 called for screening that “balances the demands of patients and physicians with the importance of
20 prompt identification of early toxicity.”¹⁰

23
24
25 ⁹ Jain N, et al. *Association of macular disease with long-term use of pentosan polysulfate sodium: findings from a US cohort*. British Journal of Ophthalmology, November 6, 2019.

26 ¹⁰ Huckfeldt R, et al. *Progressive Maculopathy After Discontinuation of Pentosan Polysulfate Sodium*. Ophthalmic Surgery, Lasers & Imaging Retina. 2019;50(10):656-659. Similar screening
27 guidelines have been established for another drug, hydroxychloroquine, that has been similarly
28

1 118. In July 2020, researchers at Emory and other institutions published a retrospective
2 case series to evaluate the disease course of retinal pigmentary changes and maculopathy
3 associated with ELMIRON use (referred to as “PPS-associated maculopathy”) after drug
4 cessation. Of the 11 patients included in the study with confirmed PPS-associated maculopathy,
5 none of the patients exhibited demonstrable improvement after discontinuing ELMIRON; in fact,
6 nine (9) of the patients reported worsening visual symptoms. Imaging confirmed expansion of the
7 affected areas of the retina over time and even atrophy encroaching on the foveal center, which
8 suggests that “PPS-associated maculopathy continues to evolve after drug cessation for at least
9 10 years . . . [and] may pose a long-term threat to central vision.”¹¹

11 **C. The ELMIRON Label**

12 119. Despite this overwhelming body of research and literature, as well as evidence
13 from AERs received since approval, it was not until June 16, 2020 that the ELMIRON label was
14 updated to include a warning regarding retinal pigmentary changes and to recommend initial and
15 periodic retinal screening both during and following ELMIRON use.

16 120. Notably, the ELMIRON labels in Canada and Europe were updated in 2019 to
17 include warnings regarding pigmentary maculopathy.

18 121. Despite Defendants’ knowledge of the increased risk of severe injury and retinal
19 pigmentary changes among ELMIRON users, Defendants did not warn patients and physicians
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associated with vision damage. See Ferguson TJ, et al. *Chronic use of pentosan polysulfate sodium associated with risk of vision-threatening disease*. International Urogynecology Journal, 2019, 30:337-338.

¹¹ Shah, R., et al. *Disease Course in Patients With Pentosan Polysulfate Sodium-Associated Maculopathy After Drug Cessation*. JAMA Ophthalmology, July 9, 2020.

1 until June 16, 2020, and instead continued to defend ELMIRON, mislead physicians and the
2 public, and minimize unfavorable findings.

3 122. Despite numerous studies and other information in the possession of the
4 Defendants providing clear evidence of the dangers of ELMIRON, the Defendants have failed to
5 adequately investigate the threat that ELMIRON poses to patients' vision.
6

7 123. Despite numerous studies and other information in the possession of the
8 Defendants providing clear evidence of the dangers of ELMIRON, the Defendants failed to warn
9 physicians in any way of the risk that their patients could suffer retina injury and vision
10 impairment prior to on or about June 16, 2020.
11

12 124. Despite numerous studies and other information in the possession of the
13 Defendants providing clear evidence of the dangers of ELMIRON, the Defendants failed to warn
14 patients in any way of the risk that they could suffer retinal injury and vision impairment prior to
15 or on about June 16, 2020.
16

17 125. Clear evidence that ELMIRON use is associated with ocular damage, including
18 macular damage and maculopathy, dates back to the initial evaluations of compassionate use
19 experience conducted in the late 1980s and early 1990s and submitted in support of the NDA.
20 Indeed, during this analysis, adverse reactions were noted such as atrophic macular degeneration,
21 retinal disorder, retinal artery occlusion, optic atrophy, optic neuritis, eye hemorrhage, and eye
22 disorder. Defendants relied upon this study while seeking FDA approval and therefore had direct
23 knowledge of the adverse effects.
24

25 126. Available medical research also identified as early as 1991 that PPS inhibits
26 regrowth and proliferation of retinal pigment epithelial (RPE) cells and could impair an important
27 physiological pathway for retinal health.
28

1 127. There is no indication that any of the Defendants ever advised the FDA that
2 available medical research from as early as 1991 identified that PPS affects fibroblast growth
3 factors (FGF) as well as other growth factors, inhibits regrowth and proliferation of retinal
4 pigment epithelial (RPE) cells, and could impair an important physiological pathway for retinal
5 health.

6 128. There is no indication that any of the Defendants ever advised the FDA that the
7 medical research continued to build since 1991 as to the effects of ELMIRON on the fibroblast
8 growth factors (FGF) as well as other growth factors that inhibit regrowth and proliferation of
9 retinal pigment epithelial (RPE) cells and could impair an important physiological pathway for
10 retinal health.

11 129. Despite numerous signs of the potential for severe retinal side effects, multiple
12 studies conducted at top institutes, research published in peer-reviewed journals, public warnings
13 from prominent EU health agencies and Health Canada, and a warning placed in the European
14 and Canadian ELMIRON labeling, at all times Plaintiff was prescribed, purchased, and ingested
15 ELMIRON, Defendants were silent in the United States as to the harm.

16 130. Under what is known as the Changes Being Effectuated (“CBE”) regulation, a
17 manufacturer with an approved NDA can, among other things, add or strengthen a
18 contraindication, warning, precaution, or adverse reaction in its label without prior FDA approval
19 simply by sending the FDA a “supplemental submission.” 21 C.F.R. § 314.70(c)(6)(iii).

20 131. Specifically, the manufacturer can “add or strengthen a contraindication, warning,
21 precaution, or adverse reactions for which the evidence of causal association satisfies the standard
22 for inclusion in the labeling under § 201.57(c) of this chapter” and “to add or strengthen an
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1 instruction about dosage and administration that is intended to increase the safe use of the drug
2 product.” 21 C.F.R. § 314.70(c)(6)(iii)(A) and (C).

3 132. The Warnings and Precautions section of a drug’s label “must describe clinically
4 significant adverse reactions (including any that are potentially fatal, are serious even if infrequent
5 or can be prevented or mitigated through appropriate use of the drug), other potential safety
6 hazards (including those that are expected for the pharmacological class or those resulting from
7 drug/drug interactions), limitations in use imposed by them (e.g., avoiding certain concomitant
8 therapy) and steps that should be taken if they occur (e.g., dosage modification). The frequency
9 of all clinically significant adverse reactions and the approximate mortality and morbidity rates
10 for patients experiencing the reaction, if known and necessary for the safe and effective use of the
11 drug, must be expressed as provided under paragraph (c)(7) of this section.” 21 C.F.R. §
12 201.57(c)(6)(i).
13
14

15 133. A manufacturer must also revise its label “to include a warning about a clinically
16 significant hazard as soon as there is reasonable evidence of a causal association with a drug; a
17 causal relationship need not have been definitively established.” 21 C.F.R. § 201.57(c)(6)(i).
18

19 134. The Warnings and Precautions “section must contain information regarding any
20 special care to be exercised by the practitioner for safe and effective use of the drug (e.g.,
21 precautions not required under any other specific section or subsection).” 21 C.F.R. §
22 201.57(c)(6)(ii).
23

24 135. The Warnings and Precautions section of the label “must identify any laboratory
25 tests helpful in following the patient’s response or in identifying possible adverse reactions.” 21
26 C.F.C. § 201.57(c)(6)(iii). According to an FDA Guidance for Industry on the Warnings and
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28

1 Precautions section of the labeling, “[i]nformation about the frequency of testing and expected
2 ranges of normal and abnormal values should also be provided if available.”

3 136. An August 22, 2008 amendment to these regulations provides that a CBE
4 supplement to amend the labeling for an approved product must reflect “newly acquired
5 information.” Fed. Reg. 49609, *see also* 21 C.F.R. § 314.70. “Newly acquired information” is not
6 limited to new data but also includes “new analysis of previously submitted data.” *Id.* at 49606.
7 “[I]f a sponsor submits adverse event information to FDA and then later conducts a new analysis
8 of data showing risks of a different type or of greater severity or frequency than did reports
9 previously submitted to FDA, the sponsor meets the requirement for ‘newly acquired
10 information.’” *Id.* at 49607.
11

12 137. Defendants could have strengthened the ELMIRON label at any time under the
13 CBE regulation without prior FDA approval. Defendants received significant “newly acquired
14 information” on many occasions after the launch of ELMIRON that should have resulted in a
15 label change warning, through the CBE regulation, of the risks of vision-threatening retinal
16 changes, vision loss, retinal and macular damage, maculopathy/macular disorder, and retinal and
17 macular pigmentary changes associated with ELMIRON. The newly acquired information came
18 in forms such as post-market adverse events, newly-published peer-reviewed studies, and
19 government announcements and updated labeling.
20

21 22 138. Due to the nature of the serious and irreversible injuries, as well as the need for
23 ophthalmological monitoring while taking ELMIRON and after discontinuing ELMIRON, the
24 method used to update the label with this new warning should have been the method that would
25 have updated the label in the quickest period of time.
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1 139. The CBE regulation provides for the fastest method to update prescription drug
2 labeling.

3 140. While Defendants had ample opportunity to strengthen their label to add a warning
4 regarding PPS-associated maculopathy, vision loss, retinal and macular damage,
5 maculopathy/macular disorder, and retinal and macular pigmentary changes before June 16, 2020,
6 they declined to do so.

7 141. There is no evidence that the FDA would not have approved a label change adding
8 a warning regarding vision-threatening retinal changes, including vision loss, retinal and macular
9 damage, maculopathy/macular disorder, and retinal and macular pigmentary changes at any time
10 from the date of approval (September 26, 1996) to the present.

11 142. There is no clear evidence that the FDA would not have approved a warning
12 regarding vision-threatening retinal changes, including vision loss, retinal and macular damage,
13 maculopathy/macular disorder, and retinal and macular pigmentary changes to be included in the
14 original label at the time of approval.

15 143. On June 24, 2019, Defendants submitted a Supplemental New Drug Application
16 (“sNDA”) seeking to revise the Warnings and Post-Marketing Experience sections of the label
17 and to update the Patient labeling for ELMIRON to include warnings relating to vision-
18 threatening retinal changes and maculopathy.
19

20 144. Defendants’ NDA was not approved until June 16, 2020.

21 145. The new label for ELMIRON included warnings about “Retinal Pigmentary
22 Changes” in the “Warnings” section of the label.
23

24 146. The “Post-Marketing Experience” section of the label was also amended to include
25 information about “pigmentary changes in the retina (see WARNINGS)” with ELMIRON use.
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1 147. The new label for ELMIRON also stated that a “[d]etailed ophthalmologic history
2 should be obtained in all patients prior to starting treatment” with ELMIRON, and that a “baseline
3 retinal examination (including OCT [ocular coherence tomography] and auto-fluorescence
4 imaging is suggested for all patients within six months of initiating treatment and periodically
5 while continuing treatment.”

6 148. While Defendants had the opportunity to immediately update the label for
7 ELMIRON under the CBE regulation by simply sending the FDA a “supplemental submission,”
8 Defendants instead chose to submit a sNDA, which is a much lengthier and time-consuming
9 process, thereby delaying the dissemination of this important safety information to physicians and
10 patients.
11

12 149. Defendants’ failure to amend the ELMIRON label under the CBE regulations
13 resulted in unnecessary further delay in disseminating important safety information to physicians
14 and patients. This additional, needless delay prevented physicians and patients from obtaining
15 this critical information in the timeliest manner possible, which could have guided their care and
16 treatment and allowed for an earlier diagnosis of the relevant condition.
17

18 150. Consumers, including Plaintiff, who have used ELMIRON for the relief of bladder
19 pain or discomfort associated with interstitial cystitis, have alternative safer treatments available
20 to treat this condition.
21

22 151. Defendants knew of the significant risk of retinal pigmentary changes caused by
23 ingestion of ELMIRON.
24

25 152. However, Defendants did not adequately and sufficiently warn consumers
26 including Plaintiff, or the medical community, of the severity of such risks until June 16, 2020.
27
28

1 153. To the contrary, Defendants conducted nationwide sales and marketing campaigns
2 to promote the sale of ELMIRON and willfully deceived Plaintiff, Plaintiff's healthcare
3 professionals, the medical community, and the general public as to the health risks and
4 consequences of the use of ELMIRON.

5 154. As a direct result, in or about 2005, Plaintiff was prescribed and began taking
6 ELMIRON, primarily for the relief of bladder pain or discomfort associated with interstitial
7 cystitis.

8 155. Plaintiff ingested and used ELMIRON as prescribed and in a foreseeable manner.

9 156. The ELMIRON used by Plaintiff was provided to her in a condition substantially
10 the same as the condition in which it was manufactured and sold.

11 157. Plaintiff agreed to initiate treatment with ELMIRON in an effort to relieve bladder
12 pain and discomfort associated with interstitial cystitis.

13 158. In agreeing to initiate treatment with ELMIRON, Plaintiff relied on claims made
14 by Defendants that ELMIRON was safe and effective for the relief of bladder pain and discomfort
15 associated with interstitial cystitis.

16 159. Instead, ELMIRON can cause severe injuries, including retinal pigmentary
17 changes.

18 160. After beginning treatment with ELMIRON, and as a direct and proximate result
19 thereof, Plaintiff suffered from retinal and macular damage, maculopathy/macular disorder, and
20 retinal and macular pigmentary changes.

21 161. Defendants knew or should have known of the risks associated with the use of
22 ELMIRON, including the risk of retinal pigmentary changes, retinal and macular damage,
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1 maculopathy/macular degeneration/macular disorder, and pigmentary maculopathy (among other
2 injuries).

3 162. The development of Plaintiff's injuries was preventable and resulted directly from
4 Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and
5 publicize safety signals, suppression of information revealing serious risks, willful and wanton
6 failure to provide adequate instructions, and willful misrepresentations concerning the nature and
7 safety of ELMIRON. This conduct, as well as the product defects complained of herein, was a
8 substantial factor in bringing about and exacerbating Plaintiff's injuries.

9
10 163. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants'
11 conduct and ELMIRON's defects.

12
13 164. At all times material hereto, Defendants, by and through their agents, servants, and
14 employees, negligently, recklessly, and carelessly marketed, distributed, and sold ELMIRON
15 without adequate instructions or warning of its serious side effects and unreasonably dangerous
16 risks.

17
18 165. Plaintiff Natalie Baum would not have used ELMIRON had Defendants properly
19 disclosed the risks associated with the drug. Thus, had Defendants properly disclosed the risks
20 associated with ELMIRON, Plaintiff Natalie Baum would have avoided the risk of developing
21 the injuries complained of herein by not ingesting ELMIRON, and Plaintiff Natalie Baum's
22 physicians and healthcare providers would not have prescribed ELMIRON to Plaintiff.

23
24 166. Defendants, through their affirmative misrepresentations and omissions, actively
25 concealed from Plaintiff Natalie Baum and her physicians and healthcare providers the true and
26 significant risks associated with taking ELMIRON.

1 **B. Fraudulent Concealment Tolling**

2 171. All applicable statutes of limitations have also been tolled by Defendants’ knowing
3 and active fraudulent concealment and denial of the vision-threatening retinal changes, including
4 retinal and macular damage, maculopathy/macular disorder, and retinal and macular pigmentary
5 changes associated with ELMIRON throughout the time period relevant to this action.

6 172. Defendants are under a continuing duty to disclose the true character, quality,
7 safety issues, and safety concerns of ELMIRON to its users and Plaintiff specifically. Defendants
8 failed to adequately and fully inform patients such as Plaintiff and doctors about the vision-
9 threatening retinal changes, including retinal and macular damage, maculopathy/macular
10 disorder, and retinal and macular pigmentary changes, and their potential irreversibility,
11 associated with ELMIRON.

12 173. Plaintiff reasonably relied upon Defendants’ knowing, affirmative, or active
13 concealment when she continued to use ELMIRON as prescribed.

14 174. Because Defendants actively concealed the true risk of vision-threatening retinal
15 changes, including retinal and macular damage, maculopathy/macular disorder, and retinal and
16 macular pigmentary changes associated with ELMIRON, they are estopped from relying on any
17 statutes of limitations defense.

18 **C. Estoppel**

19 175. Defendants were and are under a continuous duty to disclose to Plaintiff the vision-
20 threatening retinal changes, including retinal and macular damage, maculopathy/macular
21 disorder, and retinal and macular pigmentary changes associated with ELMIRON. Instead, at all
22 relevant times, Defendants actively concealed the true character, quality, and nature of
23 ELMIRON and knowingly made misrepresentations and/or omissions about the safety of
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1 ELMIRON and the vision-threatening retinal changes, including retinal and macular damage,
2 maculopathy/macular disorder, and retinal and macular pigmentary changes associated with
3 ELMIRON.

4 176. Plaintiff reasonably relied upon Defendants’ knowing and affirmative
5 misrepresentations and active concealment of material facts and safety issues with ELMIRON.
6 Therefore, Defendants are estopped from relying on any defense based on statutes of limitations
7 in this action.
8

9 177. As a result of Defendants’ conduct as set forth above, Defendants have waived
10 and/or lost whatever right they may claim to the “learned intermediary defense.”
11

12 **COUNT I**
STRICT LIABILITY – FAILURE TO WARN

13 178. Plaintiff realleges and incorporates the allegations made above as if fully set forth
14 below.
15

16 179. Under California’s strict liability law, a plaintiff asserting a claim for failure to
17 warn is required to prove only that the defendant did not adequately warn of a particular risk that
18 was known or knowable in light of the generally recognized and prevailing best scientific and
19 medical knowledge available at the time of manufacture and distribution. Thus, in strict liability,
20 as opposed to negligence, the reasonableness of the defendant’s failure to warn is immaterial.
21

22 180. Under California’s strict liability law, a manufacturer is required to provide the
23 user adequate warnings to give the user the option to either refrain from using the product or to
24 use it in such a way as to minimize the degree of danger.
25

26 181. As more fully alleged above and incorporated herein by reference, Defendants
27 failed to warn Plaintiff and her physicians and healthcare providers of the unavoidable risks and
28

1 side effects associated with ELMIRON that Defendants knew or should have known. Specifically,
2 the risk of vision-threatening retinal changes, including vision loss, retinal and macular damage,
3 maculopathy/macular disorder, and retinal and macular pigmentary changes. Defendants
4 therefore failed to provide Plaintiff with the option to make an informed choice whether to use
5 the product or refrain.

6
7 182. At all times Plaintiff was prescribed, purchased, and ingested ELMIRON,
8 Defendants failed to warn physicians, including Plaintiff's physicians, and consumers, including
9 Plaintiff, of:

- 10 a. the risks of vision-threatening retinal changes, including vision loss, retinal
11 and macular damage, maculopathy/macular disorder, and retinal and
12 macular pigmentary changes associated with ELMIRON;
- 13 b. the need for an ophthalmologic history prior to starting treatment with
14 ELMIRON;
- 15 c. the need for genetic testing if a family history of maculopathy or pattern
16 dystrophy exists;
- 17 d. the need for a comprehensive baseline retinal examination for patients with
18 pre-existing ophthalmologic conditions prior to starting ELMIRON;
- 19 e. the need for ophthalmological monitoring commencing shortly after
20 starting to take ELMIRON, including but not limited to:
- 21 i. a baseline retinal examination within six months of starting
22 treatment and periodically while continuing and after ceasing
23 treatment;
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- 1 ii. the need to re-evaluate the risks and benefits of continuing
- 2 treatment if pigmentary changes in the retina develop, as they may
- 3 be irreversible;
- 4 f. the need for ophthalmological monitoring after discontinuing ELMIRON;
- 5 g. the ophthalmological imaging, testing, treatment, and/or monitoring
- 6 required for patients already taking ELMIRON;
- 7 h. the increased risks associated with higher doses of ELMIRON; and
- 8 i. the increased risks associated with longer duration of use of ELMIRON.
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10 183. At all times Plaintiff was prescribed, purchased, and ingested ELMIRON, the
11 labeling for ELMIRON did not contain any information regarding:

- 12 a. the risks of vision-threatening retinal changes, including vision loss, retinal
- 13 and macular damage, maculopathy/macular disorder, and retinal and
- 14 macular pigmentary changes associated with ELMIRON;
- 15 b. the need for an ophthalmologic history prior to starting treatment with
- 16 ELMIRON;
- 17 c. the need for genetic testing if a family history of maculopathy or pattern
- 18 dystrophy exists;
- 19 d. the need for a comprehensive baseline retinal examination for patients with
- 20 pre-existing ophthalmologic conditions prior to starting ELMIRON;
- 21 e. the need for ophthalmological monitoring commencing shortly after
- 22 starting to take ELMIRON, including but not limited to:
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- i. a baseline retinal examination within six months of starting treatment and periodically while continuing and after ceasing treatment;
- ii. the need to re-evaluate the risks and benefits of continuing treatment if pigmentary changes in the retina develop, as they may be irreversible;
- f. the need for ophthalmological monitoring after discontinuing ELMIRON;
- g. the ophthalmological imaging, testing, treatment, and/or monitoring required for patients already taking ELMIRON; and
- h. the increased risks associated with longer duration of use of ELMIRON.

184. The “WARNINGS” section in the ELMIRON label in the United States during the relevant time period when Plaintiff was prescribed, purchased, and ingested ELMIRON stated: “None.”

185. At all times Plaintiff was prescribed, purchased, and ingested ELMIRON, the labeling for ELMIRON did not list vision-threatening retinal changes, vision loss, retinal and macular damage, maculopathy/macular disorder, and retinal and macular pigmentary changes despite the fact that it did list other serious side effects reported with the use of ELMIRON.

186. Had Plaintiff been provided with a warning regarding the risk of vision-threatening retinal changes, including vision loss, retinal and macular damage, maculopathy/macular disorder, and retinal and macular pigmentary changes, she would not have chosen to take ELMIRON, and Plaintiff’s physicians would not have prescribed ELMIRON to Plaintiff.

187. As more fully alleged above and incorporated herein by reference, Defendants failed to adequately instruct Plaintiff and her physicians as to how ELMIRON should be used,

1 including how to properly evaluate ELMIRON patients, in order to eliminate or reduce the risk
2 of harm. Defendants therefore failed to provide information that could have allowed Plaintiff to
3 use the product in a way that would minimize the degree of danger.

4 188. Had Plaintiff been adequately instructed on how ELMIRON should be used in
5 order to eliminate or reduce the risk of harm, her injuries could have been avoided or prevented
6 from developing into the retinal and macular damage, maculopathy/macular disorder, retinal and
7 macular pigmentary changes, and vision loss and vision disturbances that she suffers today.

8 189. At the time Plaintiff was prescribed, purchased, and ingested ELMIRON, no
9 section of the label, including the “Warnings and Precautions” and the “Adverse Reactions”
10 sections, contained any warnings regarding the risk of vision-threatening retinal changes,
11 including vision loss, retinal and macular damage, maculopathy/macular disorder, and retinal and
12 macular pigmentary changes.

13 190. At the time Plaintiff was prescribed, purchased, and ingested ELMIRON, the
14 “Elmiron Patient Brochure,” the ELMIRON “Patient Education Flyer,” the “Patient Leaflet,” and
15 the www.orthoelmiron.com website for ELMIRON did not contain a warning regarding vision-
16 threatening retinal changes, including vision loss, retinal and macular damage,
17 maculopathy/macular disorder, and retinal and macular pigmentary changes associated with
18 ELMIRON, and they did not contain instructions regarding how ELMIRON should be used,
19 including how to properly evaluate ELMIRON patients in order to eliminate or reduce the risk of
20 harm.

21 191. By publishing direct-to-patient information in the “ELMIRON Patient Brochure,”
22 the ELMIRON “Patient Education Flyer,” the “Patient Leaflet,” and on the
23 www.orthoelmiron.com website for ELMIRON, including important safety information,
24

1 Defendants assumed the duty to directly warn patients such as Plaintiff of all the risks associated
2 with ELMIRON that were known or should have been known by Defendants.

3 192. Defendants knew or should have known through testing, scientific knowledge,
4 advances in the field, adverse events, communications with patients, communications with
5 physicians and otherwise, that ELMIRON created a risk of serious and potentially irreversible
6 vision-threatening retinal changes, including vision loss, retinal and macular damage,
7 maculopathy/macular disorder, and retinal and macular pigmentary changes, and was unsafe and
8 dangerous to Plaintiff and other consumers, all about which Defendants failed to warn.
9

10 193. The ELMIRON supplied to Plaintiff by Defendants was unsafe, dangerous, and
11 had inadequate warnings and/or instructions at the time it was sold to Plaintiff.
12

13 194. The dangerous propensities associated with ELMIRON were either known by
14 Defendants, or reasonably scientifically knowable, at the time Plaintiff was prescribed, purchased,
15 and ingested ELMIRON.

16 195. At times after ELMIRON was supplied to Plaintiff, Defendants acquired
17 additional knowledge and information confirming the dangerous nature of ELMIRON.
18

19 196. Despite having this knowledge and information, as more fully alleged above and
20 incorporated herein by reference, Defendants failed to issue adequate warnings and/or post-sale
21 warnings or notifications to physicians that ELMIRON causes serious and potentially irreversible
22 vision-threatening retinal changes, including vision loss, retinal and macular damage,
23 maculopathy/macular disorder, and retinal and macular pigmentary changes.
24

25 197. Despite having this knowledge and information, as more fully alleged above and
26 incorporated herein by reference, Defendants failed to issue adequate warnings and/or post-sale
27 warnings or notifications to Plaintiff that ELMIRON causes serious and potentially irreversible
28

1 vision-threatening retinal changes, including vision loss, retinal and macular damage,
2 maculopathy/macular disorder, and retinal and macular pigmentary changes.

3 198. Despite having this knowledge and information, as more fully alleged above and
4 incorporated herein by reference, Defendants failed to issue adequate warnings and/or post-sale
5 warnings or notifications to physicians such as Plaintiff's treating and ELMIRON-prescribing
6 physicians regarding how ELMIRON should be used, including how to properly evaluate
7 ELMIRON patients, in order to eliminate or reduce the risk of harm.

8
9 199. Defendants failed to provide adequate warnings to users, purchasers, or prescribers
10 of ELMIRON, including Plaintiff and Plaintiff's prescribing physicians, and instead continued to
11 sell ELMIRON in an unreasonably dangerous form without adequate warnings or instructions.

12
13 200. By failing to adequately test and research harms associated with ELMIRON use,
14 patients such as Plaintiff and the medical community, including prescribing doctors such as
15 Plaintiff's prescribing physicians, were inadequately informed about the true risk-benefit profile
16 of ELMIRON and were not sufficiently aware that serious and potentially irreversible vision-
17 threatening retinal changes, including vision loss, retinal and macular damage,
18 maculopathy/macular disorder, and retinal and macular pigmentary changes might be associated
19 with ELMIRON use.

20
21 201. By failing to provide appropriate precautions about ELMIRON use, patients such
22 as Plaintiff and the medical community, including prescribing doctors such as Plaintiff's
23 prescribing physicians, were inadequately informed about the true risk-benefit profile of
24 ELMIRON and were not sufficiently aware that serious and potentially irreversible vision-
25 threatening retinal changes, including vision loss, retinal and macular damage,
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1 maculopathy/macular disorder, and retinal and macular pigmentary changes might be associated
2 with ELMIRON use.

3 202. Nor were the medical community, patients, patients' families, or regulators,
4 including Plaintiff and Plaintiff's physicians, appropriately informed and/or warned by
5 Defendants that serious and potentially irreversible vision-threatening retinal changes, including
6 vision loss, retinal and macular damage, maculopathy/macular disorder, and retinal and macular
7 pigmentary changes might be a side effect of ELMIRON use and should or could be reported as
8 an adverse event.
9

10 203. As a direct and proximate result of Defendants' conduct, including the inadequate
11 warnings, dilution or lack of information, lack of adequate testing and research, and the dangerous
12 nature of ELMIRON, Plaintiff suffered bodily injury and resulting pain and suffering, disability,
13 mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and
14 nursing care and treatment, loss of earnings, loss of ability to earn money, and other economic
15 losses and aggravation of previously existing conditions. The losses are either permanent or
16 continuing and Plaintiff will suffer the losses in the future.
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18

19 **COUNT II**
20 **STRICT LIABILITY – DESIGN DEFECT**

21 204. Plaintiff realleges and incorporates the allegations made above as if fully set forth
22 below.

23 205. Defendants designed, developed, researched, tested, licensed, manufactured,
24 packaged, labeled, promoted, marketed, sold, and/or distributed ELMIRON, including the
25 ELMIRON used by Plaintiff, in a defective and unreasonably dangerous condition.
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1 206. Defendants expected ELMIRON to reach, and it did in fact reach, Plaintiff without
2 substantial change in the condition in which it was designed, researched, manufactured, and sold
3 by the Defendants.

4 207. At all times relevant hereto, Defendants' ELMIRON was manufactured, designed,
5 and labeled in an unsafe, defective, and inherently dangerous condition and was dangerous for
6 use by the public and in particular by Plaintiff.
7

8 208. At all times relevant to this action, ELMIRON, as designed, developed,
9 researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or
10 distributed by the Defendants, was defective in design and formulation in one or more of the
11 following particulars:

- 12 a. When placed in the stream of commerce, ELMIRON contained
13 unreasonably dangerous design defects and was not reasonably safe as
14 intended to be used, subjecting Plaintiff to risks that exceeded the benefits
15 of the drug;
16
17 b. When placed in the stream of commerce, ELMIRON was defective in
18 design and formulation, making use of the drug more dangerous than an
19 ordinary consumer would expect and more dangerous than other risks
20 associated with treatment for the relief of bladder pain or discomfort
21 associated with interstitial cystitis;
22
23 c. ELMIRON was insufficiently tested;
24
25 d. ELMIRON caused harmful side effects that outweighed any potential
26 utility;
27
28

1 e. Defendants were aware at the time ELMIRON was marketed that ingestion
2 of ELMIRON would result in an increased risk of retinal pigmentary
3 changes and other injuries;

4 f. ELMIRON was subject to inadequate post-marketing surveillance; and/or

5 g. There were safer alternative designs and formulations that were not
6 utilized.
7

8 209. ELMIRON was defective, failed to perform safely, and was unreasonably
9 dangerous when used by ordinary consumers, including Plaintiff, as intended and in a reasonably
10 foreseeable manner.

11 210. ELMIRON, as designed, developed, researched, tested, licensed, manufactured,
12 packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in
13 its design or formulation, in that it was unreasonably dangerous and its foreseeable risks exceeded
14 the alleged benefits associated with ELMIRON's design or formulation.
15

16 211. ELMIRON, as designed, developed, researched, tested, licensed, manufactured,
17 packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in
18 design or formulation in that it posed a greater likelihood of injury than other treatments for the
19 relief of bladder pain or discomfort associated with interstitial cystitis and was more dangerous
20 than an ordinary consumer could reasonably foresee or anticipate.
21

22 212. At all times relevant to this action, Defendants knew or had reason to know that
23 ELMIRON was in a defective condition and was inherently dangerous and unsafe when used in
24 the manner instructed, provided, and/or promoted by Defendants.
25

26 213. Defendants had a duty to properly test, develop, design, manufacture, inspect,
27 package, label, market, promote, sell, distribute, maintain supply, provide proper warnings, and
28

1 otherwise ensure that ELMIRON was not unreasonably dangerous for its normal, common,
2 intended use, or for use in a form and manner instructed and provided by Defendants.

3 214. When Defendants placed ELMIRON into the stream of commerce, they knew it
4 would be prescribed for the relief of bladder pain or discomfort associated with interstitial cystitis,
5 and they marketed and promoted ELMIRON as safe for the relief of bladder pain or discomfort
6 associated with interstitial cystitis.

7
8 215. Plaintiff was prescribed, purchased, and used ELMIRON.

9 216. Plaintiff used ELMIRON for its intended purpose and in the manner
10 recommended, promoted, marketed, and reasonably anticipated by Defendants.

11 217. Neither Plaintiff nor Plaintiff's physicians and health care professionals, by the
12 exercise of reasonable care, could have discovered the defects and risks associated with
13 ELMIRON before Plaintiff's ingestion of ELMIRON.

14
15 218. The harm caused by ELMIRON far outweighed its benefit, rendering ELMIRON
16 more dangerous than an ordinary consumer or health care professional would expect and more
17 dangerous than alternative products. Defendants could have designed ELMIRON to make it less
18 dangerous. When Defendants designed ELMIRON, the state of the industry's scientific
19 knowledge was such that a less risky design was attainable.

20
21 219. At the time ELMIRON left Defendants' control, there was a practical, technically
22 feasible, and safer alternative design that would have prevented the harm Plaintiff suffered
23 without substantially impairing the reasonably anticipated or intended function of ELMIRON.
24 This was demonstrated by the existence of other treatments for the relief of bladder pain or
25 discomfort associated with interstitial cystitis that had a more established safety profile and a
26 considerably lower risk profile.
27

1 220. Defendants’ defective design of ELMIRON was willful, wanton, fraudulent,
2 malicious, and done with reckless disregard for the health and safety of users of ELMIRON.
3 Defendants’ conduct was motivated by greed and the intentional decision to value profits over
4 the safety and well-being of the consumers of ELMIRON such as Plaintiff.

5 221. The defects in ELMIRON were substantial and contributing factors in causing
6 Plaintiff’s injuries. But for Defendants’ acts and omissions, Plaintiff would not have suffered the
7 injuries complained of herein.
8

9 222. Due to the unreasonably dangerous condition of ELMIRON, Defendants are liable
10 to Plaintiff.

11 223. Defendants’ conduct, as described above, was reckless. Defendants risked the lives
12 of consumers and users of ELMIRON, including Plaintiff, with knowledge of the safety problems
13 associated with ELMIRON, and suppressed this knowledge from the general public. Defendants
14 made conscious decisions not to redesign, adequately warn, or inform the unsuspecting public.
15 Defendants’ reckless conduct warrants an award of punitive damages.
16

17 224. As a foreseeable, direct, and proximate consequence of Defendants’ actions,
18 omissions, and misrepresentations, Plaintiff suffered and will continue to suffer retinal and
19 macular damage, maculopathy/macular disorder, retinal and macular pigmentary changes, and
20 other related health complications. In addition, Plaintiff requires and will continue to require
21 healthcare and services. Plaintiff has incurred and will continue to incur medical and related
22 expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the
23 enjoyment of life, a diminished quality of life, aggravation of preexisting conditions, activation
24 of latent conditions, and other losses and damages. Plaintiff’s direct medical losses and costs
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1 include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur
2 mental and physical pain and suffering.

3 **COUNT III**
4 **BREACH OF EXPRESS WARRANTY**

5 225. Plaintiff realleges and incorporates the allegations made above as if fully set forth
6 below.

7 226. Under Cal. Com. Code § 2313, any affirmation of fact or promise made by the
8 seller to the buyer that relates to the goods and becomes part of the basis of the bargain creates an
9 express warranty that the goods shall conform to the affirmation or promise.
10

11 227. Here, Defendants expressly warranted to physicians and consumers, including
12 Plaintiff and Plaintiff's physicians, that ELMIRON was safe, well-tolerated, and does not carry
13 serious and potentially irreversible vision-threatening retinal changes, including vision loss,
14 retinal and macular damage, maculopathy/macular disorder, and retinal and macular pigmentary
15 changes.
16

17 228. ELMIRON does not conform to these express representations because it is neither
18 safe nor well-tolerated, and it significantly increases the risk of serious and potentially irreversible
19 vision-threatening retinal changes, including vision loss, retinal and macular damage,
20 maculopathy/macular disorder, and retinal and macular pigmentary changes.
21

22 229. The risk was either known or reasonably scientifically knowable to Defendants at
23 the time Plaintiff was prescribed, purchased, and ingested ELMIRON.

24 230. As a direct and proximate result of the breach of Defendants' warranties, Plaintiff
25 suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity
26 for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss
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1 of earnings, loss of ability to earn money, and other economic losses and aggravation of
2 previously existing conditions. The losses are either permanent or continuing, and Plaintiff will
3 suffer the losses in the future.

4 **COUNT IV**
5 **BREACH OF IMPLIED WARRANTY**

6 231. Plaintiff realleges and incorporates the allegations made above as if fully set forth
7 below.

8 232. Under Cal. Com. Code § 2314, a warranty that the goods are merchantable is
9 implied. In order for goods to be considered merchantable, they must at least, among other things,
10 be fit for the ordinary purpose for which such goods are used; be adequately contained, packaged,
11 and labeled; and conform to the promises or affirmations of fact made on the container or label.

12 233. At the time Defendants marketed, sold, and distributed ELMIRON, Defendants
13 knew of the use for which ELMIRON was intended, and they impliedly warranted ELMIRON to
14 be of merchantable quality, safe, and fit for such use.

15 234. Defendants knew, or had reason to know, that Plaintiff and Plaintiff's physicians
16 would rely on Defendants' judgment and skill in providing ELMIRON for its intended use.

17 235. Plaintiff and Plaintiff's physicians reasonably relied upon the skill and judgment
18 of Defendants as to whether ELMIRON was of merchantable quality, safe, and fit for its intended
19 use.

20 236. Contrary to such implied warranty, ELMIRON was not of merchantable quality or
21 safe or fit for its intended use, because the product was and is, unreasonably dangerous and unfit
22 for the ordinary purposes for which ELMIRON was used and was not adequately labeled, as it
23 failed to warn of risks reasonably scientifically knowable to Defendants or instruct users how to
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1 minimize the degree of danger, and did not conform to the promises or affirmations of fact made
2 in the label.

3 237. As a direct and proximate result of the breach of implied warranty, Plaintiff
4 suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity
5 for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss
6 of earnings, loss of ability to earn money and other economic losses and aggravation of previously
7 existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the
8 losses in the future.
9

10 **COUNT V**
11 **NEGLIGENCE**

12 238. Plaintiff realleges and incorporates the allegations made above as if fully set forth
13 below.

14 239. At all times material herein, Defendants had a duty to exercise reasonable care and
15 had the duty of an expert in all aspects of the testing, inspection, packaging, labeling, distribution,
16 marketing, promotion, advertising, sale, warning, post-sale warning, testing, and research to
17 assure the safety of the product when used as intended or in a way that Defendants could
18 reasonably have anticipated and to assure that the consuming public, including Plaintiff and
19 Plaintiff's physicians, obtained accurate information and adequate instructions for the safe use or
20 non-use of ELMIRON.
21

22 240. As more fully alleged above and incorporated herein by reference, Defendants had
23 a duty to warn Plaintiff, Plaintiff's physicians, and the public in general of ELMIRON's dangers
24 and serious side effects, including serious and potentially irreversible vision issues and retinal
25 harm, and how ELMIRON should be used, including how to properly evaluate ELMIRON
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1 patients, in order to eliminate or reduce the risk of harm and because it was reasonably foreseeable
2 that an injury could occur because of ELMIRON's use.

3 241. At all times material herein, Defendants failed to exercise reasonable care and the
4 duty of an expert and knew, or in the exercise of reasonable care should have known, that
5 ELMIRON was not properly tested, inspected, packaged, labeled, warned about, distributed,
6 marketed, advertised, formulated, promoted, examined, maintained, sold, prepared, or a
7 combination of these acts.
8

9 242. Each of the following acts and omissions herein alleged was negligently and
10 carelessly performed by Defendants, resulting in a breach of the duties set forth above. These acts
11 and omissions include, but are not limited to:

- 12 a. Negligent and careless research and testing of ELMIRON;
- 13 b. Negligent and careless failure to give adequate warnings that would attract
14 the attention of Plaintiff, Plaintiff's physicians, and the public in general of
15 the potentially dangerous, defective, unsafe, and deleterious propensity of
16 ELMIRON and of the risks associated with its use;
- 17 c. Negligent and careless failure to provide instructions on ways to safely use
18 ELMIRON to avoid injury, including how to properly evaluate ELMIRON
19 patients;
- 20 d. Negligent and careless failure to provide instructions regarding the need
21 for ophthalmological monitoring while taking ELMIRON;
- 22 e. Negligent and careless failure to provide instructions regarding the need
23 for ophthalmological monitoring after discontinuing ELMIRON;
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- 1 f. Negligent and careless failure to explain the mechanism, mode, and types
- 2 of adverse events associated with ELMIRON;
- 3 g. Negligent representations that ELMIRON was safe or well-tolerated; and
- 4 h. Negligent and careless failure to issue adequate post-sale warnings that
- 5 ELMIRON causes an increased risk of serious and potentially irreversible
- 6 vision-threatening retinal changes, including vision loss, retinal and
- 7 macular damage, maculopathy/macular disorder, and retinal and macular
- 8 pigmentary changes.
- 9

10 243. As a direct and proximate result of Defendants' negligence, Plaintiff suffered
11 bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the
12 enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of
13 earnings, loss of ability to earn money, and other economic losses and aggravation of previously
14 existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the
15 losses in the future.
16

17 **COUNT VI**
18 **NEGLIGENT FAILURE TO WARN**

19 244. Plaintiff realleges and incorporates the allegations made above as if fully set forth
20 below.
21

22 245. Defendants formulated, tested, packaged, labeled, produced, created, made,
23 constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted
24 ELMIRON, including ELMIRON that Plaintiff was prescribed, purchased, and ingested.
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1 246. Defendants had a duty under California state law to exercise reasonable care to
2 provide adequate warnings about the risks and dangers of ELMIRON that were known or
3 knowable to Defendants at the time of distribution.

4 247. Defendants breached their duty in that they failed to warn Plaintiff and Plaintiff's
5 physicians by not reporting the risk of serious defects and life-altering complications described
6 herein that Defendants knew or should have known were associated with ELMIRON prior to and
7 during the times that Plaintiff was prescribed, purchased, and ingested ELMIRON.
8

9 248. At all times Plaintiff was prescribed, purchased, and ingested ELMIRON,
10 Defendants negligently failed to warn physicians, including Plaintiff's physicians, and
11 consumers, including Plaintiff, of:

- 12 a. the risks of vision-threatening retinal changes, including vision loss, retinal
13 and macular damage, maculopathy/macular disorder, and retinal and
14 macular pigmentary changes associated with ELMIRON;
- 15 b. the need for an ophthalmologic history prior to starting treatment with
16 ELMIRON;
- 17 c. the need for genetic testing if a family history of maculopathy or pattern
18 dystrophy exists;
- 19 d. the need for a comprehensive baseline retinal examination for patients with
20 pre-existing ophthalmologic conditions prior to starting ELMIRON;
- 21 e. the need for ophthalmological monitoring commencing shortly after
22 starting to take ELMIRON, including but not limited to:
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- 1 e. the need for ophthalmological monitoring commencing shortly after
2 starting to take ELMIRON, including but not limited to:
- 3 i. a baseline retinal examination within six months of starting
4 treatment and periodically while continuing and after ceasing
5 treatment;
- 6 ii. the need to re-evaluate the risks and benefits of continuing
7 treatment if pigmentary changes in the retina develop, as they may
8 be irreversible;
- 9 f. the need for ophthalmological monitoring after discontinuing ELMIRON;
- 10 g. the ophthalmological imaging, testing, treatment, and/or monitoring
11 required for patients already taking ELMIRON; and
- 12 h. the increased risks associated with longer duration of use of ELMIRON.

13
14
15 250. The “WARNINGS” section in the ELMIRON label in the United States during the
16 relevant time period when Plaintiff was prescribed, purchased, and ingested ELMIRON stated:
17 “None.”

18
19 251. At all times Plaintiff was prescribed, purchased, and ingested ELMIRON, the
20 labeling for ELMIRON did not list vision-threatening retinal changes, vision loss, retinal and
21 macular damage, maculopathy/macular disorder, and retinal and macular pigmentary changes
22 despite the fact that it did list other serious side effects reported with the use of ELMIRON.

23
24 252. Had Plaintiff been provided with a warning regarding the risk of vision-threatening
25 retinal changes, including vision loss, retinal and macular damage, maculopathy/macular
26 disorder, and retinal and macular pigmentary changes, she would not have chosen to take
27 ELMIRON, and Plaintiff’s physicians would not have prescribed ELMIRON to Plaintiff.

1 253. As more fully alleged above and incorporated herein by reference, Defendants
2 negligently failed to adequately instruct and warn Plaintiff and her physicians as to how
3 ELMIRON should be used, including how to properly evaluate ELMIRON patients, in order to
4 eliminate or reduce the risk of harm. Defendants therefore negligently failed to provide
5 information that could have allowed Plaintiff to use the product in a way that would minimize the
6 degree of danger.
7

8 254. Had Plaintiff been adequately instructed on how ELMIRON should be used in
9 order to eliminate or reduce the risk of harm, her injuries could have been avoided or prevented
10 from developing into the retinal and macular damage, maculopathy/macular disorder, retinal and
11 macular pigmentary changes, and vision loss and vision disturbances that she suffers today.
12

13 255. At the time Plaintiff was prescribed, purchased, and ingested ELMIRON, no
14 section of the label, including the “Warnings and Precautions” and the “Adverse Reactions”
15 sections, contained any warnings regarding the risk of vision-threatening retinal changes,
16 including vision loss, retinal and macular damage, maculopathy/macular disorder, and retinal and
17 macular pigmentary changes.
18

19 256. At the time Plaintiff was prescribed, purchased, and ingested ELMIRON, the
20 “Elmiron Patient Brochure,” the ELMIRON “Patient Education Flyer,” the “Patient Leaflet,” and
21 the www.orthoelmiron.com website for ELMIRON did not contain a warning regarding vision-
22 threatening retinal changes, including vision loss, retinal and macular damage,
23 maculopathy/macular disorder, and retinal and macular pigmentary changes associated with
24 ELMIRON, and they did not contain instructions regarding how ELMIRON should be used,
25 including how to properly evaluate ELMIRON patients in order to eliminate or reduce the risk of
26 harm.
27
28

1 257. By publishing direct-to-patient information in the “ELMIRON Patient Brochure,”
2 the ELMIRON “Patient Education Flyer,” the “Patient Leaflet,” and on the
3 www.orthoelmiron.com website for ELMIRON, including important safety information,
4 Defendants also assumed the duty to directly warn patients such as Plaintiff of all the risks
5 associated with ELMIRON that were known or should have been known by Defendants.
6

7 258. Defendants knew or should have known through testing, scientific knowledge,
8 advances in the field, adverse events, communications with patients, communications with
9 physicians and otherwise, that ELMIRON created a risk of serious and potentially irreversible
10 vision-threatening retinal changes, including vision loss, retinal and macular damage,
11 maculopathy/macular disorder, and retinal and macular pigmentary changes, and was unsafe and
12 dangerous to Plaintiff and other consumers, all about which Defendants failed to warn.
13

14 259. The ELMIRON supplied to Plaintiff by Defendants was unsafe, dangerous, and
15 had inadequate warnings and/or instructions at the time it was sold to Plaintiff.
16

17 260. The dangerous propensities associated with ELMIRON were either known by
18 Defendants, or reasonably scientifically knowable, at the time Plaintiff was prescribed, purchased,
19 and ingested ELMIRON.
20

21 261. At times after ELMIRON was supplied to Plaintiff, Defendants acquired
22 additional knowledge and information confirming the dangerous nature of ELMIRON.
23

24 262. Despite having this knowledge and information, as more fully alleged above and
25 incorporated herein by reference, Defendants negligently failed to issue adequate warnings and/or
26 post-sale warnings or notifications to physicians that ELMIRON causes serious and potentially
27 irreversible vision-threatening retinal changes, including vision loss, retinal and macular damage,
28 maculopathy/macular disorder, and retinal and macular pigmentary changes.

1 263. Despite having this knowledge and information, as more fully alleged above and
2 incorporated herein by reference, Defendants negligently failed to issue adequate warnings and/or
3 post-sale warnings or notifications to Plaintiff that ELMIRON causes serious and potentially
4 irreversible vision-threatening retinal changes, including vision loss, retinal and macular damage,
5 maculopathy/macular disorder, and retinal and macular pigmentary changes.

6 264. Despite having this knowledge and information, as more fully alleged above and
7 incorporated herein by reference, Defendants negligently failed to issue adequate warnings and/or
8 post-sale warnings or notifications to physicians such as Plaintiff's treating and ELMIRON-
9 prescribing physicians regarding how ELMIRON should be used, including how to properly
10 evaluate ELMIRON patients, in order to eliminate or reduce the risk of harm.

11 265. Defendants negligently failed to provide adequate warnings to users, purchasers,
12 or prescribers of ELMIRON, including Plaintiff and Plaintiff's prescribing physicians, and
13 instead continued to sell ELMIRON in an unreasonably dangerous form without adequate
14 warnings or instructions.

15 266. By negligently failing to adequately test and research harms associated with
16 ELMIRON use, patients such as Plaintiff and the medical community, including prescribing
17 doctors such as Plaintiff's prescribing physicians, were inadequately informed about the true risk-
18 benefit profile of ELMIRON and were not sufficiently aware that serious and potentially
19 irreversible vision-threatening retinal changes, including vision loss, retinal and macular damage,
20 maculopathy/macular disorder, and retinal and macular pigmentary changes might be associated
21 with ELMIRON use.

22 267. By negligently failing to provide appropriate precautions about ELMIRON use,
23 patients such as Plaintiff and the medical community, including prescribing doctors such as
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1 Plaintiff's prescribing physicians, were inadequately informed about the true risk-benefit profile
2 of ELMIRON and were not sufficiently aware that serious and potentially irreversible vision-
3 threatening retinal changes, including vision loss, retinal and macular damage,
4 maculopathy/macular disorder, and retinal and macular pigmentary changes might be associated
5 with ELMIRON use.

6
7 268. Nor were the medical community, patients, patients' families, or regulators,
8 including Plaintiff and Plaintiff's physicians, appropriately informed and/or warned by
9 Defendants that serious and potentially irreversible vision-threatening retinal changes, including
10 vision loss, retinal and macular damage, maculopathy/macular disorder, and retinal and macular
11 pigmentary changes might be a side effect of ELMIRON use and should or could be reported as
12 an adverse event.

13
14 269. As a direct and proximate result of Defendants' negligent failure to warn,
15 including the inadequate warnings, dilution or lack of information, lack of adequate testing and
16 research, and the dangerous nature of ELMIRON, Plaintiff suffered bodily injury and resulting
17 pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense
18 of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn
19 money, and other economic losses and aggravation of previously existing conditions. The losses
20 are either permanent or continuing, and Plaintiff will suffer the losses in the future.

21
22 **COUNT VII**
23 **NEGLIGENCE PER SE**
24 **(Violations of 21 U.S.C. §§ 331, 352 and 21 C.F.R. §§ 201.56, 201.57, 202.1)**

25 270. Plaintiff realleges and incorporates the allegations made above as if fully set forth
26 herein.

1 271. At all times herein mentioned, Defendants had an obligation to abide by the law,
2 including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the
3 manufacture, testing, production, processing, assembling, inspection, research, promotion,
4 advertising, distribution, marketing, labeling, packaging, preparation for use, consulting, sale,
5 warning and post-sale warning, and other communications of the risks and dangers of ELMIRON.
6

7 272. By reason of its conduct as alleged herein, Defendants violated provisions of
8 statutes and regulations, including, but not limited to, the following:

- 9 a. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C.
10 §§ 331 and 352, by misbranding ELMIRON;
- 11 b. Defendants failed to follow the “[g]eneral requirements on content and
12 format of labeling for human prescription drugs” in violation of 21 C.F.R.
13 § 201.56;
- 14 c. Defendants failed to follow the “[s]pecific requirements on content and
15 format of labeling for human prescription drugs” in violation of 21 C.F.R.
16 § 201.57;
- 17 d. Defendants advertised and promoted ELMIRON in violation of 21 C.F.R.
18 § 202.1; and
- 19 e. Defendants violated 21 C.F.R. § 201.57(e) by failing to timely and
20 adequately change the ELMIRON label to reflect the evidence of an
21 association between ELMIRON and the serious and potentially irreversible
22 vision-threatening retinal changes, including vision loss, retinal and
23 macular damage, maculopathy/macular disorder, and retinal and macular
24 pigmentary changes affecting Plaintiff.
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1 279. California Civil Code § 1709 provides that one who willfully deceives another
2 with intent to induce her to alter her position to her injury or risk is liable for any damages that
3 she thereby suffers.

4 280. California Civil Code § 1710 provides, in part, that a deceit within the meaning of
5 § 1709 is the suppression of fact by one who is bound to disclose it, or who gives information of
6 other facts that are likely to mislead for want of communication of that fact.
7

8 281. Defendants willfully deceived Plaintiff, her physicians and healthcare providers,
9 the medical community, and the public in general, by concealing and/or omitting material
10 information concerning ELMIRON, which Defendants had a duty to disclose, thus
11 misrepresenting the true nature of the medication.
12

13 282. Indeed, Defendants' omission of important safety data served as a
14 misrepresentation to consumers and physicians, including Plaintiff, Plaintiff's physicians and
15 healthcare providers, and the public in general, that ELMIRON was safe or well-tolerated, when,
16 in fact, ELMIRON was dangerous to the well-being of patients.
17

18 283. Specifically, as more fully alleged above and incorporated herein by reference,
19 Defendants intentionally suppressed, concealed, and omitted material facts in the promotional,
20 marketing, and labeling communications about the risks and benefits of ELMIRON to Plaintiff
21 and Plaintiff's physicians and healthcare providers, including but not limited to, the risk of serious
22 and potentially irreversible vision-threatening retinal changes, including vision loss, retinal and
23 macular damage, maculopathy/macular disorder, and retinal and macular pigmentary changes
24 associated with ELMIRON and instructions on how to safely use ELMIRON, including how to
25 properly evaluate ELMIRON patients, in order to eliminate or reduce the risk of harm.
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1 284. Defendants had exclusive possession and/or knowledge of this information and
2 these material facts.

3 285. As more fully alleged above and incorporated herein by reference, at the time
4 Defendants promoted ELMIRON without disclosing the material facts described above they knew
5 or should have known that ELMIRON carried a risk of serious and potentially irreversible vision-
6 threatening retinal changes, including vision loss, retinal and macular damage,
7 maculopathy/macular disorder, and retinal and macular pigmentary changes.

8 286. As more fully alleged above and incorporated herein by reference, at the time
9 Defendants promoted ELMIRON without disclosing the material facts described above, they
10 knew or should have known that patients taking ELMIRON should be provided with instructions
11 regarding how to safely use ELMIRON, including how to properly evaluate ELMIRON patients,
12 in order to eliminate or reduce the risk of harm.

13 287. Defendants failed to exercise reasonable care and competence in obtaining or
14 communicating information regarding the safe use of ELMIRON and otherwise failed to exercise
15 reasonable care in transmitting information to Plaintiff, Plaintiff's physicians and healthcare
16 providers, and the public in general.

17 288. Defendants made the aforesaid misrepresentations by omission in the course of
18 Defendants' business as manufacturers and distributors of ELMIRON despite having no
19 reasonable basis to omit this critical information.

20 289. At the time the aforesaid misrepresentations by omission were made, Defendants
21 intended to induce Plaintiff or Plaintiff's physicians and healthcare providers to rely upon such
22 misrepresentations.

1 misrepresented the properties and effects of ELMIRON with the intention that health care
2 professionals and consumers such as Plaintiff's physicians and Plaintiff would rely upon that
3 information in their decisions concerning whether to prescribe or ingest ELMIRON.

4 296. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors
5 of ELMIRON, knew or reasonably should have known that health care professionals and
6 consumers of ELMIRON such as Plaintiff's physicians and Plaintiff would rely on that
7 information disseminated and marketed to them regarding the product when weighing the
8 potential benefits and potential risks of prescribing or ingesting ELMIRON.

9 297. Defendants failed to exercise reasonable care to ensure that the information they
10 disseminated to health care professionals and consumers such as Plaintiff's physicians and
11 Plaintiff concerning the properties and effects of ELMIRON were accurate, complete, and not
12 misleading. As a result, Defendants disseminated information to health care professionals and
13 consumers such as Plaintiff's physicians and Plaintiff that was negligently and materially
14 inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

15 298. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors of
16 ELMIRON, knew or reasonably should have known that health care professionals including
17 Plaintiff's physicians would write prescriptions for ELMIRON in reliance on the information
18 disseminated by Defendants, and that the patients including Plaintiff receiving prescriptions for
19 ELMIRON would be placed in peril of developing serious injuries if the information disseminated
20 by Defendants and relied upon was materially inaccurate, misleading, or otherwise false.

21 299. From the time ELMIRON was first tested, studied, researched, evaluated,
22 endorsed, manufactured, marketed, and distributed and up to the present, Defendants failed to
23 disclose material facts regarding the safety of ELMIRON. Defendants made material
24

1 misrepresentations to Plaintiff, Plaintiff’s health care professionals, the healthcare community,
2 and the general public, including:

- 3 a. Stating that ELMIRON had been tested and found to be safe and effective
4 for the relief of bladder pain or discomfort associated with interstitial
5 cystitis;
6
7 b. Concealing, misrepresenting, and actively downplaying the severe risks of
8 harm to users of ELMIRON when compared to comparable or superior
9 alternative drug therapies; and
10
11 c. Misrepresenting ELMIRON’s risk of unreasonable, dangerous, and
12 adverse side effects.

13 300. Defendants made the foregoing representations without any reasonable ground for
14 believing them to be true.

15 301. These representations were made directly by Defendants, their sales
16 representatives, and other authorized agents, and in publications and other written materials
17 directed to health care professionals, medical patients, and the public.

18 302. Defendants made these representations with the intent to induce reliance thereon,
19 and to encourage the prescription, purchase, and use of ELMIRON.

20 303. Defendants had a duty to accurately and truthfully represent to medical
21 professionals and consumers, including Plaintiff’s physicians and healthcare providers and
22 Plaintiff, the truth regarding Defendants’ claims that ELMIRON had been tested and found to be
23 safe and effective for the relief of bladder pain or discomfort associated with interstitial cystitis.
24

25 304. The misrepresentations made by Defendants were, in fact, false and known by
26 Defendants to be false at the time the misrepresentations were made.
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1 305. Defendants failed to exercise ordinary care in making their representations
2 concerning ELMIRON and in the manufacture, sale, testing, quality assurance, quality control,
3 and distribution in interstate commerce of ELMIRON.

4 306. Defendants engaged in a nationwide marketing campaign, over-promoting
5 ELMIRON in written marketing literature, in written product packaging, and in direct-to-
6 consumer advertising via written and internet advertisements and television commercial
7 advertisements. Defendants' over-promotion was undertaken by touting the safety and efficacy
8 of ELMIRON while concealing, misrepresenting, and actively downplaying the serious and
9 severe risks of harm to users of ELMIRON when compared to comparable or superior alternative
10 drug therapies. Defendants negligently misrepresented ELMIRON's risk of unreasonable and
11 dangerous adverse side effects.
12

13 307. Defendants' conduct, as described above, was reckless. Defendants risked the lives
14 of consumers and users of ELMIRON, including Plaintiff. Defendants had knowledge of the
15 safety problems and suppressed this knowledge from Plaintiff, Plaintiff's physicians and
16 healthcare providers, and the general public. Defendants made conscious decisions not to
17 redesign, re-label, adequately warn, or inform Plaintiff, Plaintiff's physicians and healthcare
18 providers, and the unsuspecting public. Defendants' reckless conduct warrants an award of
19 punitive damages.
20

21 308. As a foreseeable, direct, and proximate consequence of Defendants' actions,
22 omissions, and misrepresentations, Plaintiff suffered retinal and macular damage,
23 maculopathy/macular disorder, retinal and macular pigmentary changes, and other related health
24 complications. In addition, Plaintiff requires and will continue to require healthcare and services.
25 Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff has also
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1 suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished
2 quality of life, aggravation of preexisting conditions, activation of latent conditions, and other
3 losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring,
4 and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and
5 suffering. Plaintiff suffered damages in an amount to be determined at trial.

6
7 **REQUEST FOR PUNITIVE DAMAGES**

8 309. Plaintiff realleges and incorporates the allegations made above as if fully set forth
9 below.

10 310. At all times relevant herein, Defendants:

- 11 a. knew or should have known that ELMIRON was dangerous and
12 ineffective;
- 13 b. concealed the dangers and health risks associated with ELMIRON from
14 Plaintiff, Plaintiff's physicians, other medical providers, the FDA, and the
15 public at large;
- 16 c. attempted to misrepresent and did knowingly make misrepresentations to
17 Plaintiff, Plaintiff's physicians, other medical providers, and the public in
18 general, as previously stated herein, as to the safety and efficacy of
19 ELMIRON; and
- 20 d. with full knowledge of the health risks associated with ELMIRON and
21 without adequate warnings of the same, manufactured, formulated, tested,
22 packaged, labeled, produced, created, made, constructed, assembled,
23 promoted, marketed, advertised, distributed, and sold ELMIRON for use.
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1 311. Defendants, by and through their officers, directors, managing agents, authorized
2 sale representatives, employees, and/or other agents who engaged in malicious, fraudulent, and
3 oppressive conduct towards Plaintiff, Plaintiff’s physicians, and the public, acted with willful,
4 wanton, conscious, and/or reckless disregard for the safety of Plaintiff and the general public.

5 312. Defendants’ misrepresentations including knowingly withholding material
6 information from the medical community and the public, including Plaintiff and Plaintiff’s
7 physicians, concerning the safety of ELMIRON. Defendants’ conduct was willful, wanton, and
8 undertaken with a disregard for Plaintiff’s rights.

9 313. Defendants acted with oppression, fraud, and/or malice, and their actions were
10 carried on with a willful and conscious disregard of the safety of others, including Plaintiff.
11

12 314. Defendants were fully aware of the safety risks of ELMIRON dating back to their
13 clinical trials. Nonetheless, Defendants deliberately crafted their label, marketing, and promotion
14 to mislead consumers such as Plaintiff and their physicians on these serious and permanent life-
15 altering injuries.
16

17 315. This conduct by the Defendants was not done by accident. Rather, Defendants
18 knew that they could turn a profit by convincing physicians and consumers that ELMIRON came
19 without any serious harmful risks. Defendants further knew that full disclosure of the true risks
20 of ELMIRON would limit the amount of money they would make selling the drug. Defendants’
21 object was accomplished not only through inadequate warnings in their label, but also through a
22 comprehensive scheme of misleading marketing and deceptive omissions more fully alleged
23 throughout this pleading. Plaintiff’s physicians and Plaintiff were denied the opportunity and the
24 right to have a discussion in order to make an informed decision about whether to prescribe and
25 take ELMIRON. Defendants accomplished this by failing to provide and warn about the serious
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1 risks, and specifically those affecting vision and the fact that the damage may be irreversible,
2 and/or ELMIRON's lack of efficacy. Such conduct was done with conscious disregard of
3 Plaintiff's rights and Plaintiff's safety.

4 316. Notwithstanding the foregoing, Defendants continued to market ELMIRON to
5 consumers, including Plaintiff, without disclosing the risks.

6
7 317. Defendants knew of ELMIRON's lack of warnings, but intentionally concealed
8 and/or recklessly failed to disclose the risks and continued to market, distribute, and sell
9 ELMIRON without said warnings so as to maximize sales and profits at the expense of the health
10 and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the
11 foreseeable harm caused by ELMIRON.

12
13 318. Defendants' intentional and/or reckless failure to disclose information deprived
14 Plaintiff of necessary information to enable her to weigh the risks of using ELMIRON against its
15 benefits.

16
17 319. As a direct and proximate result of one or more of these wrongful acts or omissions
18 of Defendants, Plaintiff suffered profound injuries that required and will require in the future
19 medical treatment, and Plaintiff incurred and will incur in the future medical expenses.

20
21 320. Defendants are liable jointly and/or severally for all general, special and
22 compensatory damages and equitable relief to which Plaintiff is entitled by law. Plaintiff seeks
23 actual and punitive damages from Defendants and alleges that the conduct of Defendants was
24 committed with knowing, conscious, careless, reckless, willful, wanton, deliberate, and grossly
25 negligent disregard for the rights and safety of consumers, including Plaintiff, thereby entitling
26 Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from
27 similar conduct in the future.

1 Respectfully submitted this 8th day of February, 2021.

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