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ENDORSED
FILED
ALAMEDA COUNTY

APR - 9 2009

CLERK OF THE SUPERIOR COURT
By Dorothy E. Lee, Deputy

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8 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**
9 **COUNTY OF ALAMEDA**

10)
11 MARY HEDRICK & NEIL HEDRICK,)
SHIRLEY BOXELL (Personal)
12 Representative of the Estate of Decedent)
MEGAN BOXELL) and BRUCE)
13 HARWELL,)

14 Plaintiffs,)

15 v.)

16 GENENTECH, INC. and XOMA, LTD,)
17 and DOES 1 through 10, inclusive,)

18 Defendants.)
19)
20)

Case No. 09 - 446158

COMPLAINT FOR DAMAGES
[PRODUCTS LIABILITY]

- 1. Strict Liability—Failure to Warn
- 2. Strict Products Liability
- 3. Negligence
- 4. Breach of Implied Warranty
- 5. Breach of Express Warranty
- 6. Fraud
- 7. Fraud by Concealment
- 8. Negligent Misrepresentation
- 9. Loss of Consortium
- 10. Wrongful Death

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22 **DEMAND FOR JURY TRIAL**

23 Plaintiffs herewith request a trial by jury as to all issues of material fact.

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27 **JURISDICTION AND VENUE**
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- 1 1. This Court has jurisdiction over these claims pursuant to California Code of Civil
2 Procedure §§25-29.
- 3 2. This Court has jurisdiction over Defendants pursuant to California Code of Civil
4 Procedure §410.10 because Defendants conduct business and have extensive contacts throughout
5 California, including Alameda County.
- 6 3. Venue is proper in this Court under California Code of Civil Procedure §§395 and 395.5
7 because Defendants do business in Alameda County, and because Defendant XOMA, Ltd. has its
8 principal place of business in Berkeley, California.
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PARTIES

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- 13 4. Plaintiffs MARY HEDRICK and NEIL HEDRICK are citizens of the United States and
14 the State of Iowa, currently residing in Franklin County, Iowa.
- 15 5. Plaintiff SHIRLEY BOXELL is a citizen of the United States and the State of Indiana,
16 currently residing in Wells County, Indiana. Plaintiff Boxell is the Personal Representative of
17 the Estate of her daughter, decedent Megan Boxell (“DECEDENT”).
- 18 6. Plaintiff BRUCE HARWELL is a citizen of the United States and the State of California,
19 currently residing in Kings County, California.
- 20 7. Defendant GENENTECH, INC. (“GENENTECH”) is a Delaware corporation with its
21 principal place of business in South San Francisco, California. At all times herein mentioned,
22 GENENTECH designed, developed, manufactured, tested, analyzed, distributed, recommended,
23 merchandised, advertised, promoted, supplied and sold to distributors, and retailers for resale to
24 physicians, hospitals, medical practitioners and the general public, a certain pharmaceutical
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1 product, hereinafter referred to as RAPTIVA (also know as Efalizumab) nationwide and in the
2 State of California.

3 8. Defendant XOMA, LTD. (“XOMA”) is a business entity formed under the laws of
4 Bermuda with its principal place of business in Berkeley, California. XOMA researches,
5 develops and manufactures antibody and other protein-based biopharmaceuticals for disease
6 targets that include immunological and inflammatory disorders. At all times herein mentioned,
7 XOMA has been engaged in the research, development and manufacturing of RAPTIVA in
8 collaboration with GENENTECH.
9

10 9. The true names and capacities, whether individual, corporate, partnership, associate or
11 otherwise, of DEFENDANTS DOES 1 through 10, inclusive, are presently unknown to Plaintiffs
12 who therefore sues these DEFENDANTS by fictitious names. Plaintiffs are informed and
13 believe and thereupon allege that each of the fictitiously named DEFENDANTS are responsible
14 in some manner for the occurrences alleged herein and Plaintiffs’ damages were proximately
15 caused by such DEFENDANTS’ acts and omissions. Each reference in this Complaint to
16 “DEFENDANTS” or a specifically named DEFENDANT shall also refer to all DEFENDANTS
17 sued under fictitious names. Plaintiffs will amend this Complaint to assert true names and
18 capacities of fictitiously named DEFENDANTS when such has been ascertained.
19

20 10. At all times relevant to this Complaint, each of the aforementioned DEFENDANTS
21 (GENENTECH, XOMA and DOES 1 through 10) were the agents, employees, associates,
22 partners, joint venturers, shareholders, owners, and/or representatives or each other and,
23 engaging in acts alleged herein, and were, at all times, acting within the purpose and scope of
24 such agency and with the consent and approval by said DEFENDANTS.
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COMMON FACTUAL ALLEGATIONS

11. RAPTIVA is a once-weekly injection approved for adults with moderate to severe plaque psoriasis. The drug works by suppressing T-cells (blood cells that help fight infection) in the immune system. These cells, when activated, migrate to the skin and cause psoriasis, resulting in thick, red, scaly inflamed patches on the skin surface. Psoriasis is a chronic, non-contagious autoimmune disease which affects the skin. Plaque psoriasis, the most common form of the disease, is characterized by inflamed patches of skin (“lesions”) topped with silvery white scales. According to the National Institutes of Health, as many as 7.5 million Americans have psoriasis; approximately 2.3 million Americans have the more severe plaque psoriasis. While there are a number of medications that may help control the symptoms of psoriasis, there is currently no cure.

12. RAPTIVA (formerly known as Xanelim) was developed by GENENTECH and XOMA in the United States. In April of 1996, XOMA entered into a collaboration agreement with GENENTECH for the development of RAPTIVA. XOMA initially produced RAPTIVA and completed the Phase I and Phase II trials for RAPTIVA in 1999.

13. In December 1999, GENENTECH and XOMA announced initiation of Phase III Clinical Trials for RAPTIVA. GENENTECH then switched manufacturing of RAPTIVA from XOMA to a GENENTECH facility to allow for large-scale material production. DEFENDANTS intended to file a biologics license application (BLA) with the U.S. Food and Drug Administration (FDA) by the end of 2001, in order to compete with rival drugs, Biogen’s Amevive (alefacept) and Immunex Corp./Wyeth’s Enbrel (etanercept) in the lucrative psoriasis market. RAPTIVA was expected to reach peak annual sales of \$400 million, if approved.

1 14. In May 2001, DEFENDANTS announced preliminary positive results from an initial 12-
2 week treatment period of two-Phase III clinical trials of RAPTIVA. Common adverse events
3 reported from the two short-term trials were mild to moderate headache, nausea, chills and pain.

4 15. In April 2002, DEFENDANTS started a Phase II trial of RAPTIVA for treatment of
5 patients with mild to moderate rheumatoid arthritis.
6

7 16. In April 2002, DEFENDANTS reported that a RAPTIVA pharmacokinetic study failed to
8 show comparability between the XOMA-produced RAPTIVA and the Genentech-produced
9 RAPTIVA. The study suggested that the GENENTECH material achieved a higher serum
10 concentration than the XOMA material. The comparability failure delayed RAPTIVA's filing
11 with the FDA (December 2002) and further eroded RAPTIVA's sales potential behind its
12 competitors.
13

14 17. In January 2003, the FDA approved the marketing of Biogen's Amevive for the treatment
15 of psoriasis, one of DEFENDANTS main competitors in the biologics psoriasis market.

16 18. In April 2003, GENENTECH loaned XOMA \$95 million under amended terms in their
17 deal to develop RAPTIVA.
18

19 19. On May 15, 2003, XOMA recorded a net quarterly loss of \$13 million due in part to
20 increased research and development fees related to RAPTIVA. The success of XOMA was
21 critically tied to the success of RAPTIVA. XOMA had no product to market and RAPTIVA
22 represented the company's first attempt at commercial product which in turn would generate
23 much needed revenue into the company. For that reason, DEFENDANTS invested in the cross
24 development of RAPTIVA for uses in other highly profitable disease markets, namely
25 rheumatoid and psoriatic arthritis.
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1 20. In May 2003, DEFENDANTS halted a clinical study developing RAPTIVA for the
2 treatment of rheumatoid arthritis. An evaluation of the trial outcomes determined that RAPTIVA
3 did not result in any noticeable clinical benefit in the patients receiving the drug. The results
4 were disappointing for DEFENDANTS' strategic visions of competing with the new biologic
5 rheumatoid arthritis drugs two of which, Amgen's Enbrel and Johnson & Johnson's Remicade,
6 total sales were approximately \$2 billion in 2002. (One year later, DEFENDANTS announced
7 RAPTIVA failed to show a significant benefit in patients suffering from psoriatic arthritis.)
8

9 21. On September 9, 2003, DEFENDANTS falsely and fraudulently represented to the
10 Dermatologic and Ophthalmic Drugs Advisory Committee of the FDA that RAPTIVA was a
11 safe drug:
12

13 Extended therapy with RAPTIVA provides increased clinical
14 efficacy with no adverse events. Overall, there were few serious
15 adverse events associated with RAPTIVA therapy, no evidence
16 of organ toxicity, and no evidence of increased malignancies or
infections.

17 22. On October 23, 2003, the FDA approved the biologics license application for RAPTIVA.
18 The FDA's approval decision was based on data from four randomized, placebo-controlled
19 Phase III studies. The Phase III results included efficacy and safety data for 12 and 24 weeks of
20 treatment. At the time of approval, a total of 2,764 patients had been treated with RAPTIVA. Of
21 those 2,764 patients, 2,400 had been treated for three months, 904 for six months, and only 218
22 for one year or more. While the panel approved RAPTIVA, several members raised concerns
23 about long-term or interrupted use of the product. Sustained responses to RAPTIVA beyond 24
24 weeks were unknown at the time of approval.
25

26 23. Despite these safety concerns, the danger of prolonged or interrupted immunosuppression
27 was ignored by DEFENDANTS and RAPTIVA was launched on November 17, 2003.
28

1 24. On July 20, 2005, the FDA announced a new warning on RAPTIVA following reports of
2 four cases of hemolytic anemia that were diagnosed four to six months after patients started on
3 the monoclonal antibody. Two of the cases occurred during clinical trials of RAPTIVA, and the
4 other two were reported as post-marketing events, according to the FDA. The package insert for
5 RAPTIVA was modified to include a warning to stop use of the drug should hemolytic anemia
6 occur. In addition, the information sheet was updated to include news of post marketing reports
7 of necrotizing fasciitis, tuberculous pneumonia, bacterial sepsis, severe pneumonia, and
8 worsening of infections such as pneumonia despite antimicrobial therapy.

9
10 25. In October 2008, the FDA issued a boxed warning, the FDA's highest level of warning,
11 about the risk of life-threatening infections including Progressive Multifocal
12 Leukoencephalopathy (PML), a rare brain infection. The FDA had received reports of serious
13 infection leading to hospitalization, and death in patients using RAPTIVA. The new boxed
14 warning also highlighted the risks of bacterial sepsis, viral meningitis, invasive fungal disease
15 and other opportunistic infections, as well as increased risk of cancer.

16
17 26. In February 2009, the FDA issued a Public Health Advisory concerning three deaths in
18 patients treated with RAPTIVA. Two involved people with confirmed cases of progressive
19 multifocal leukoencephalopathy. The third death was a person believed to have contracted the
20 brain infection, according to the advisory.

21
22 27. On February 20, 2009, the European Medicines Agency (EMA) recommended to the
23 European Commission the suspension of the marketing for RAPTIVA. After reviewing a
24 comprehensive benefit-risk re-assessment, the EMA's Committee for Medicinal Products for
25 Human Use (CHMP) concluded that the benefits of RAPTIVA no longer outweighed its risks. In
26 the European Union, physicians were advised not to issue any new prescriptions for RAPTIVA.
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1 28. On February 20, 2009, Canada suspended the sales of RAPTIVA due to safety concerns.

2 29. On April 8, 2009, DEFENDANTS announced a phased withdrawal of RAPTIVA from
3 United States markets due to safety concerns.

4 30. At all times material hereto, Defendants knew that RAPTIVA had a strong potential to
5 increase the risk of serious life-threatening infection and reactivate latent, chronic infections.
6 DEFENDANTS also had knowledge that RAPTIVA had the potential to increase the risk of
7 lymphomas and other malignancies.

8 31. At all times material hereto, DEFENDANTS failed to warn patients of RAPTIVA's risk
9 of serious life-threatening infections including PML, encephalitis and meningitis, as well as
10 lymphomas, malignancies and/or death. Despite knowing that RAPTIVA posed serious injuries
11 for anyone who took the drug, DEFENDANTS decided to push RAPTIVA to market on claimed
12 efficacy and safety trials while downplaying its inherent dangers.

13 32. Further, DEFENDANTS intentionally diverted attention from RAPTIVA's risks and
14 dangers by providing the bare minimum of information on the issue without having performed
15 any significant studies on long term usage of RAPTIVA. Had Plaintiffs in this action had known
16 the risks and dangers associated with RAPTIVA, Plaintiffs would not have taken RAPTIVA and
17 consequently would not have been subject to its dangerous side effects.

18 33. The physicians who prescribed RAPTIVA to Plaintiffs relied on the representations made
19 by DEFENDANTS, prior to the date of prescribing RAPTIVA for use. The physicians relied on
20 the representations regarding the safety of RAPTIVA, and would not have recommended for use
21 or prescribed RAPTIVA if they had known the true fact regarding the safety of RAPTIVA.

22 34. Prior to the date upon which RAPTIVA was prescribed to Plaintiffs, DEFENDANTS
23 knew, or should have known, that the product was extremely dangerous and unsafe for use by the
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1 general public. The dangers of this product included, by way of example, the likelihood of
2 developing serious infections such as PML, encephalitis and meningitis, as well as lymphomas,
3 malignancies and/or death. DEFENDANTS failed to take appropriate action to cure the nature
4 of these defects or to appropriately warn users of the product or their physicians of such
5 dangerous characteristics.
6

7 35. DEFENDANTS thereby acted with malice toward Plaintiffs, who accordingly request
8 that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake
9 of example and for the purpose of punishing DEFENDANTS for its conduct, in an amount
10 sufficiently large to be an example to others and to deter these DEFENDANTS and others from
11 engaging in similar conduct in the future. The aforesaid wrongful conduct was done with the
12 advance knowledge, authorization, and/or ratification of an officer, director, and/or managing
13 agent of DEFENDANTS.
14

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16 **SPECIFIC FACTUAL ALLEGATIONS to PLAINTIFF MARY HEDRICK**
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18 36. From on or about February 2004 until on or about August 2006, Mary Hedrick took
19 RAPTIVA manufactured and distributed by DEFENDANTS for the treatment of moderate to
20 severe psoriasis. Because of the misleading information that DEFENDANTS, and each of them,
21 provided to physicians and the FDA about the true risks associated with the use of RAPTIVA
22 and because of the failure of DEFENDANTS to adequately inform physicians generally
23 including Plaintiff's physicians, about the true risks associated with the use of RAPTIVA, at all
24 times relevant to this lawsuit, while Mary Hedrick was taking RAPTIVA, her physicians never
25 informed her of the risk of developing serious and permanent injuries associated with RAPTIVA.
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1 37. On or about August 2006, Mary Hedrick began to experience flu like symptoms. Her
2 condition got dramatically worse within days, when she fainted and was taken to the Emergency
3 Room at Mercy Hospital in Mason City, Iowa. An MRI and spinal tap revealed Mary Hedrick
4 had Herpes Viral Encephalitis.

6 38. Herpes viral encephalitis is a rare neurological disorder characterized by inflammation of
7 the brain (encephalitis). Brain damage occurs as the inflamed brain pushes against the skull, and
8 can lead to death.

9 39. In Mary Hedrick's case, she was near death when she was airlifted from Mercy Hospital
10 in Iowa to the Mayo Clinic in Minnesota. At that time, Mary Hedrick was admitted into ICU
11 where she remained for over a month on a ventilator. When Mary Hedrick was discharged from
12 ICU, she had completely lost her ability to speak and walk. Mary Hedrick required several
13 weeks of intensive in-patient rehabilitation including physical therapy and speech therapy. She
14 had to re-learn how to eat, stand, walk and use her hands for grasping and writing. Plaintiff Mary
15 Hedrick continued outpatient physical and speech therapy for an additional three months
16 subsequent to her release from the hospital.

19 40. Use of RAPTIVA caused Mary Hedrick to suffer serious, permanent and disabling
20 injuries but not limited to injuries associated with the brain damage and her nervous system.
21 Because of injuries Mary Hedrick suffered from the use of RAPTIVA, Mary Hedrick has
22 experienced and will continue to experience medical and related expenses, loss of income and
23 career, disability, pain and suffering, psychological injury and other injuries and damages.

1 **SPECIFIC FACTUAL ALLEGATIONS to PLAINTIFF SHIRLEY BOXELL**

2 41. From on or about June 22, 2005 until on or about June 30, 2006, MEGAN BOXELL took
3 RAPTIVA manufactured and distributed by DEFENDANTS for the treatment of moderate to
4 severe psoriasis. Because of the misleading information that DEFENDANTS, and each of them,
5 provided to physicians and the FDA about the true risks associated with the use of RAPTIVA
6 and because of the failure of DEFENDANTS to adequately inform physicians generally
7 including Plaintiff's physicians, about the true risks associated with the use of RAPTIVA, at all
8 times relevant to this lawsuit, while Megan Boxell was taking RAPTIVA, her physicians never
9 informed her of the risk of developing serious and permanent injuries, including death,
10 informed her of the risk of developing serious and permanent injuries, including death,
11 associated with RAPTIVA.
12

13 42. On or about June 29, 2006, Megan Boxell began to experience flu like symptoms. She
14 presented to the Bluffton Emergency Room with abdominal pain, back pain, nausea and
15 vomiting. The next day Megan Boxell went into a coma. A CT was obtained which revealed
16 diffuse edema with questionable basilar leptomeningeal enhancement. Her neurologist felt that
17 her examination was compatible with brain death with Leptomeningeal Encephalitis (viral
18 encephalitis) as the culprit. Plaintiff Shirley Boxell made the decision to withdraw life support
19 from her daughter on June 30, 2006.
20

21 43. Use of RAPTIVA caused Megan Boxell to die at age 26.

22 44. Because of the wrongful death of Megan Boxell from the use of RAPTIVA, her mother,
23 Plaintiff Shirley Boxell has been deprived of a kind and loving daughter and has incurred
24 reasonable and necessary expenses for decedent's funeral, burial and memorial services to their
25 damage in a presently unascertained sum.
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1 **SPECIFIC FACTUAL ALLEGATIONS to PLAINTIFF BRUCE HARWELL**

2 45. From on or about May 2004 until on or about October 2004, Bruce Harwell took
3 RAPTIVA manufactured and distributed by DEFENDANTS for the treatment of moderate to
4 severe psoriasis. Because of the misleading information that DEFENDANTS, and each of them,
5 provided to physicians and the FDA about the true risks associated with the use of RAPTIVA
6 and because of the failure of DEFENDANTS to adequately inform physicians generally
7 including Plaintiff's physicians, about the true risks associated with the use of RAPTIVA, at all
8 times relevant to this lawsuit, while Bruce Harwell was taking RAPTIVA, his physicians never
9 informed him of any serious and permanent injuries associated with RAPTIVA.
10

11
12 46. From on or about June 2004 to on or about July 2004, Bruce Harwell experienced flu-like
13 symptoms, including fevers, chills, and aches. In approximately October 2004, Bruce Harwell's
14 symptoms increased in severity. He experienced constant diarrhea mixed with blood, significant
15 weight loss, abdominal pain and severely painful camping. A colonoscopy was ultimately
16 performed which revealed ulcerative colitis. Ulcerative colitis, like psoriasis, is an autoimmune
17 disease, a disease in which the immune system malfunctions attacking some part of the body,
18 such as the colon. Bruce Harwell's prescribing physician discontinued RAPTIVA, an
19 immunosuppressant. Following discontinuation of RAPTIVA, Bruce Harwell experienced
20 leukopenia, an abnormal deficiency in white blood cells count caused by immunosuppression, as
21 well as recurrent and severely debilitating psoriasis which required hospitalization for several
22 weeks.
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24
25 47. Use of RAPTIVA caused Bruce Harwell to suffer serious and disabling injuries described
26 herein. Because of injuries Bruce Harwell suffered from the use of RAPTIVA, Bruce Harwell
27 has experienced and will continue to experience medical and related expenses, pain and
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1 suffering, psychological injury and other injuries and damages. Bruce Harwell missed
2 approximately 5 months of work as a community college professor.

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4
5 **FIRST CAUSE OF ACTION**

6 **[Strict Liability in Tort: Failure to Warn]**

7 48. Plaintiff Mary Hedrick, Plaintiff Shirley Boxell and Plaintiff Bruce Harwell (Plaintiffs)
8 hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth
9 herein and further alleges as follows.

10 49. At all times herein mentioned RAPTIVA was defective and unsafe in manufacture, and
11 was so at the time it was distributed by Defendants and injected by Plaintiff. RAPTIVA was
12 defective in that it was not properly prepared and/or was not accompanied by proper warnings,
13 regarding all possible adverse side effects associated with the use of RAPTIVA, and given the
14 severity of the adverse effects, the warnings given did not accurately reflect the symptoms and
15 severity of the adverse effects. The product was also defective in that the product manufactured
16 and distributed differed from the manufacturer's intended results. These defects caused serious
17 injury to the user when used in its intended and foreseeable manner, and in the manner
18 recommended by Defendants.
19
20

21 50. Defendants knew that RAPTIVA was to be used by the user without inspection for
22 defects therein.

23 51. RAPTIVA was unaccompanied by warnings of its dangerous propensities that were
24 known or reasonably scientifically knowable at the time of distribution. The reasonably
25 foreseeable use of RAPTIVA involved substantial dangers not readily recognizable by the
26 ordinary user of the product. Defendants, and each of them, failed to warn of the known or
27 knowable likelihood of injury including but no limited to the likelihood the user would develop
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1 serious infections such as PML, encephalitis and meningitis, as well as lymphomas,
2 malignancies and/or death.

3 52. RAPTIVA was designed, manufactured, tested, analyzed, distributed, recommended,
4 merchandised, advertised, promoted, supplied and sold to distributors by Defendants, and each of
5 them, was further defective due to inadequate post-marketing warning or instruction because,
6 after Defendants, and each of them, knew or should have known of the risks of injury from
7 RAPTIVA, they failed to promptly respond to and warn about the likelihood of serious injury as
8 described herein.
9

10 53. Plaintiffs did not know, nor had reason to know, at the time of the use of RAPTIVA, or at
11 any time prior thereto, of the existence of the foregoing described defects. These defects caused
12 the herein described injuries to Plaintiffs.
13

14 54. The Defendants, and each of them, knew that RAPTIVA was to be used by the user
15 without inspection for defects therein and that RAPTIVA was unaccompanied by warnings of its
16 dangerous propensities that were known or reasonably scientifically knowable at the time of
17 distribution.
18

19 55. Plaintiffs neither knew, nor had reason to know, at the time of the use of RAPTIVA, or at
20 any time prior thereto, of the existence of the foregoing described defect.
21

22 WHEREFORE, Plaintiffs pray for judgment as hereinafter set forth.
23

24 SECOND CAUSE OF ACTION

25 [Strict Products Liability Pursuant to Restatement Second of Torts §402A]

26 56. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if
27 fully set forth herein and further alleges as follows:
28

1 57. The RAPTIVA manufactured and/or supplied by Defendants, and each of them, herein
2 was placed into the stream of commerce by these Defendants in a defective and unreasonably
3 dangerous condition in that the foreseeable risks exceeded the benefits associated with the design
4 or formulation.

5
6 58. Alternatively, the RAPTIVA manufactured and/or supplied by Defendants, and each of
7 them, was defective in design or formulation in that when it was placed in the stream of
8 commerce, it was unreasonably dangerous and it was more dangerous than an ordinary consumer
9 would expect and more dangerous than other forms of alternative traditional plaque psoriasis
10 treatment.

11
12 59. The RAPTIVA manufactured and/or supplied by Defendants, and each of them, was
13 defective due to inadequate warning or instruction because the Defendants and each of them
14 knew or should have known that the product created a serious risk of harm to consumers and
15 these Defendants failed to adequately warn of said risks.

16
17 60. The RAPTIVA manufactured and/or supplied by Defendants, and each of them, was
18 defective due to inadequate warning and/or inadequate testing.

19 61. The RAPTIVA manufactured and/or supplied by Defendants, and each of them, was
20 defective due to inadequate post-marketing warnings and instructions, because the Defendant
21 knew or should have know of the risk of serious injury from RAPTIVA, however they failed to
22 provide adequate warnings to users or consumers of the product and continued to promote the
23 product.

24
25 62. As a proximate and legal result of the defective and unreasonably dangerous condition of
26 RAPTIVA manufactured and/or supplied by Defendants, and each of them, Plaintiffs were
27 caused to suffer the herein described injuries.
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1 68. As a result of the carelessness and negligence of Defendants, and each of them,
2 RAPTIVA caused Plaintiffs to thereby sustain injuries as herein alleged.

3 WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.
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6 **FOURTH CAUSE OF ACTION**

7 **[Breach of Implied Warranty]**

8 69. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if
9 fully set forth herein and further alleges as follows:

10 70. At all times mentioned herein, Defendants, and each of them, manufactured,
11 compounded, packaged, distributed, recommended, merchandised, advertised, promoted,
12 supplied and sold RAPTIVA, and prior to the time it was prescribed to Plaintiffs, Defendants
13 impliedly warranted to Plaintiffs, and to their agents, that the product was of merchantable
14 quality and safe for the use for which it was intended.
15

16 71. Plaintiffs and their agents relied on the skill and judgment of the Defendants, and each of
17 them, in using RAPTIVA.
18

19 72. The product was unsafe for its intended use, and it was not of merchantable quality, as
20 warranted by Defendants in that it had very dangerous propensities when put to its intended use
21 and would cause severe injury to the user. RAPTIVA was unaccompanied by warnings of its
22 dangerous propensities that were either known or reasonably scientifically knowable at the time
23 of distribution. RAPTIVA did cause the Plaintiffs to sustain injuries as herein alleged.
24

25 73. After Plaintiffs were made aware that their injuries were a result of RAPTIVA, notice
26 was duly given to Defendants of the breach of said warranty.

27 WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.
28

1 **FIFTH CAUSE OF ACTION**

2 **[Breach of Express Warranty]**

3 74. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if
4 fully set forth herein and further alleges as follows:

5 75. The aforementioned manufacturing, compounding, packaging, designing, distributing,
6 testing, constructing, fabricating, analyzing, recommending, merchandizing, advertising,
7 promoting, supplying and selling of RAPTIVA was expressly warranted to be safe for use by
8 Plaintiffs, and other members of the general public.

9 76. At the time of the making of the express warranties, Defendants had knowledge of the
10 purpose for which RAPTIVA was to be used and warranted the same to be in all respects, fit,
11 safe, and effective and proper for such purpose. RAPTIVA was unaccompanied by warnings of
12 its dangerous propensities that were either known or knowable at the time of distribution.

13 77. Plaintiffs and their physicians reasonably relied upon the skill and judgment of
14 Defendants, and upon said express warranty, in using RAPTIVA. The warranty and
15 representations were untrue in that the product caused severe injury to Plaintiffs and was unsafe
16 and, therefore, unsuited for the use for which it was intended. RAPTIVA could and did thereby
17 cause Plaintiffs to sustain injuries as herein alleged.

18 78. As soon as the true nature of the product, and the fact that the warranty and
19 representations were false, were ascertained, said Defendants were notified of the breach of said
20 warranty.

21 WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

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1 SIXTH CAUSE OF ACTION

2 [Fraud]

3 79. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if
4 fully set forth herein and further alleges as follows:

5 80. The Defendants falsely and fraudulently represent to Plaintiffs, their physicians and
6 members of the general public, that RAPTIVA was safe for use in treating plaque psoriasis. The
7 representations by said Defendants were, in fact, false. The true facts include, but are not limited
8 to the fact that RAPTIVA was not safe for said purpose and were, in fact, dangerous to the health
9 and bodies of Plaintiffs.

10 81. The representations by said Defendants were, in fact, false. The true facts were that
11 RAPTIVA was not adequately tested, that there were frequent, sever, protracted, debilitating,
12 difficult, life threatening and disabling side effects and adverse effects of RAPTIVA, including
13 but not limited to serious infections such as PML, encephalitis and meningitis, as well as
14 lymphomas, malignancies and/or death, and Defendants did not disclose or warn users and their
15 physicians about the known risk of injury in using the product. Defendants misrepresented the
16 safety of RAPTIVA, represented that the product was safe for use in psoriasis treatment and
17 concealed warnings of the known or knowable risks of injury in using RAPTIVA.

18 82. When said Defendants made these representations, they knew that they were false.
19 Defendants made said representations with the intent to defraud and deceive Plaintiffs with the
20 intent to induce them to act in the manner herein alleged.

21 83. At the time Defendants made the aforesaid representations, and at the time Plaintiffs took
22 the actions herein alleged. Plaintiffs and their physicians were ignorant of the falsity of these
23 representations and reasonably believed them to be true. In reliance upon said representations,
24 Plaintiffs were induced to, and did, use RAPTIVA as herein described. If Plaintiffs had known
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1 the actual facts, they would not have taken such action. The reliance of Plaintiffs and their
2 physicians upon Defendants' representations was justified because said representations were
3 made by individuals and entities that appeared to be in a position to know the true facts.

4
5 84. As a result of Defendants' fraud and deceit, Plaintiffs was caused to sustain the herein
6 described injuries.

7 85. In doing the acts herein alleged, the Defendants acted with oppression, fraud, and malice,
8 and Plaintiffs are therefore entitled to punitive damages to deter Defendants and others from
9 engaging in similar conduct in the future. Said wrongful conduct was done with the advance
10 knowledge, authorization and/or ratification of an officer, director and/or managing agent of
11 Defendants.
12

13 WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.
14

15 **SEVENTH CAUSE OF ACTION**

16 **[Fraud by Concealment]**

17 86. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if
18 fully set forth herein and further alleges as follows:
19

20 87. At all times mentioned in this Complaint, Defendants had the duty and obligation to
21 disclose to Plaintiffs and to their physicians, the true facts concerning RAPTIVA, that is, that
22 RAPTIVA was dangerous, and defective, and how likely it was to cause serious consequences to
23 users, including injuries as described in this Complaint, and the true level of risk involved in
24 prescribing RAPTIVA for the purposes indicated. Defendants made the affirmative
25 representations as set forth above to Plaintiffs, their prescribing physicians, and the general
26 public prior to the date RAPTIVA was prescribed to Plaintiffs, while concealing the following
27 material facts.
28

1 88. At all times mentioned herein, Defendants had the duty and obligation to disclose to
2 Plaintiffs and to their physicians the true facts concerning RAPTIVA, that is, that use would
3 cause injuries including but not limited to serious infections such as PML, encephalitis and
4 meningitis, as well as lymphomas, malignancies and/or death.

6 89. At all times herein mentioned, Defendants intentionally, willfully, and maliciously
7 concealed or suppressed the facts set forth above from Plaintiff's physicians, and therefore from
8 Plaintiffs, with the intent to defraud as herein alleged.

9 90. At all times herein mentioned, neither Plaintiffs nor their physicians were aware of the
10 facts set forth above, and had they been aware of said facts, they would not have acted as they
11 did, that is, would not have utilized the product to aid in the relief of psoriasis.

12 91. As a result of the concealment or suppression of the facts set forth above, Plaintiffs
13 sustained injuries as hereinafter set forth.

14 92. In doing the action herein alleged, Defendants acted with oppression, fraud, and malice
15 and Plaintiffs are therefore entitled to punitive damages in an amount reasonably related to
16 Plaintiffs' actual damages, and to Defendants' wealth, and sufficiently large to be an example to
17 others, and to deter these Defendants and others from engaging in similar conduct in the future.

18 93. That at all times herein mentioned, Defendants intentionally, willfully, and maliciously
19 concealed or suppressed the facts set forth above from Plaintiffs' physicians and therefore from
20 Plaintiffs, with the intent to defraud Plaintiffs as herein alleged.

21 94. At all times herein mentioned, neither Plaintiffs, nor their physicians were aware of the
22 facts set forth above, and had they been aware of said facts, they would not have acted as they
23 did, that is, that RAPTIVA would not have been prescribed to Plaintiffs and they would not have
24 injected it.
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1 95. As a result of the concealment or suppression of the facts set forth above, Plaintiff
2 MARY HEDRICK suffered injuries as hereinafter set forth.

3 96. In doing the action herein alleged, Defendants acted with oppression, fraud, and malice
4 and Plaintiffs are entitled to punitive damages in an amount reasonably related to Plaintiffs actual
5 damages, and to Defendants' wealth, and sufficiently large to be an example to others, and to
6 deter these Defendants and others from engaging in similar conduct in the future.
7

8 Wherefore, Plaintiff prays for judgment against Defendants as hereinafter set forth.
9

10 **EIGHTH CAUSE OF ACTION**

11 **[Negligent Misrepresentation]**

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13 97. Plaintiffs hereby incorporates by reference all previous paragraphs of this Complaint as if
14 fully set forth herein and further alleges as follows:.

15 98. The Defendants had an absolute duty to disclose the true facts regarding the safety of
16 RAPTIVA as the only entities capable of knowing and reporting the true facts regarding the
17 safety and testing of RAPTIVA. Furthermore, Defendants had a duty to ensure it had a
18 reasonable basis for making the representations as set forth above.
19

20 99. The Defendants made the aforesaid representations with no reasonable ground for
21 believing them to be true. They did not have accurate or sufficient information concerning these
22 representations. Furthermore, Defendants were aware that without such information they could
23 not accurately make the aforesaid representation.
24

25 100. The aforesaid representations were made to the physicians prescribing RAPTIVA prior to
26 the date it was prescribed to Plaintiffs and their physician relied on those representations about
27 the safety of RAPTIVA when prescribing RAPTIVA to Plaintiffs.
28

1 101. At the time the aforesaid representations were made, Defendants concealed from
2 Plaintiffs and their physicians their lack of information on which to base their representations
3 regarding the safety of RAPTIVA and their consequent inability to make the aforesaid
4 representations accurately.

5
6 102. The aforesaid representations were made by Defendants with the intent to induce
7 Plaintiffs to act in the manner herein alleged, that is, to inject RAPTIVA as prescribed.

8 103. The Defendants falsely represented to Plaintiffs, their physicians and members of the
9 general public, that RAPTIVA was safe for in psoriasis treatment. The representations by said
10 Defendants were, in fact, false. The true facts were that RAPTIVA was not safe for said purpose
11 and was, in fact, dangerous to the health and body of Plaintiffs and there by caused injury to
12 Plaintiffs.

13
14 104. The Defendants made the aforesaid representations with no reasonable ground for
15 believing them to be true. They did not have accurate or sufficient information concerning these
16 representations. Furthermore, Defendants were aware that without such information it could not
17 accurately make the aforesaid representations.

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19 105. At the time Defendants made the aforesaid representations, and at the time RAPTIVA
20 was prescribed to Plaintiffs, Plaintiffs and their physicians were ignorant of the falsity of these
21 representations and reasonably believed them to be true. In reliance upon said representations,
22 Plaintiffs injected RAPTIVA as herein described. If Plaintiffs had known the actual facts, they
23 would not have taken such action. The reliance of Plaintiffs and their physicians upon
24 Defendants' representations was justified because said representations were made by individuals
25 and entities that appeared to be in a position to know the true facts.
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1 106. As a result of Defendants' false representations and concealment, Plaintiffs were caused
2 to sustain the herein described injuries.

3 107. As a proximate result of the Defendants' misrepresentations, Plaintiffs have suffered an
4 ascertainable loss in an amount to be determined at trial.
5

6
7 **NINTH CAUSE OF ACTION**

8 **[Loss of Consortium]**

9 108. Plaintiffs Mary Hedrick and Neil Hedrick re-allege and incorporate by reference all
10 previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows

11 109. Plaintiff Neil Hedrick is and at all times relevant hereto has been the lawful spouse of
12 Plaintiff Mary Hedrick, and as such he is entitled to the comfort and enjoyment of her society
13 and services.
14

15 110. As a direct and proximate result of the foregoing misconduct of the Defendants, Plaintiff
16 Neil Hedrick has been deprived of his spouse's companionship, services, solace, consortium,
17 affection and attention to which he is entitled. As a result of the foregoing, Plaintiff Neil Hedrick
18 has been and will continue to be injured and damaged.
19

20 Wherefore, Plaintiff Neil Hedrick pray for judgment against Defendants as hereinafter set
21 forth.

22 **TENTH CAUSE OF ACTION**

23 **[Wrongful Death]**

24 111. Plaintiff Shirley Boxell re-alleges and incorporates by reference all previous paragraphs
25 of this Complaint as if fully set forth herein and further alleges as follows:
26

27 112. As a direct and proximate result of the Defendants' actions as described above, decedent
28 was seriously injured while using the RAPTIVA in the manner for which it was intended.

1 113. The injuries so inflicted on the decedent resulted in the decedent's death on June 30,
2 2006.

3 114. As a further direct and proximate result of the foregoing death of Megan Boxell, Plaintiff
4 Shirley Boxell has been deprived of a kind and loving daughter and her daughter's care, comfort,
5 love, protection, advice, society, physical assistance, and financial support.
6

7 115. As a further direct and proximate result of the foregoing, Plaintiff Shirley Boxell has
8 been generally damaged in a sum to be established according to proof, as provided by Code of
9 Civil Procedure sections 425.10 and 425.11.
10

11 116. As a further direct and proximate result of the death of the Megan Boxell, Plaintiff
12 Shirley Boxell has incurred reasonable and necessary expenses for decedent's funeral, burial, and
13 memorial services to their damage in a presently unascertained sum. Plaintiff Shirley Boxell
14 requests permission to insert the amount when it is finally determined.

15 Wherefore, Plaintiff Shirley Boxell demands judgment against Defendants as set forth
16 below.
17

18 **PLAINTIFFS REQUEST A TRIAL BY JURY ON ALL COUNTS.**

19 **PRAYER FOR RELIEF**


20 WHEREFORE, Plaintiffs pray for judgment as follows:
21

- 22 1. for general damages in a sum within the jurisdiction of this Court;
- 23 2. for medical, hospital, and incidental expenses, according to proof;
- 24 3. for loss of earnings and for loss of earning capacity, according to proof;
- 25 4. for punitive or exemplary damages;
- 26 5. for costs of suit herein;
- 27 6. for attorney's fees;
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- 7. for such other relief as the Court deems just and proper; and
- 8. for all applicable statutory remedies provided by law in California that assert liability for Defendants wrongdoings and improper conduct.

DATED: 4/9/2009

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