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12
13 **UNITED STATES DISTRICT COURT**
14 **SOUTHERN DISTRICT OF CALIFORNIA**

15 KELLY S. PFAFF, individually, on behalf of
16 J.A.P. and C. P., minors, and as Trustee of the
PFAFF FAMILY TRUST,

17 Plaintiffs,

18 v.

19 MERCK & CO., INC. and MERCK SHARP &
20 DOHME, CORP.,

21 Defendants.
22

No. **'15CV509 DMS BLM**

COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

23 Plaintiff Kelly Pfaff, as trustee of the Pfaff Family Trust and individually and on behalf of
24 her minor children, Plaintiffs J.A.P. and C. P., through their undersigned counsel, based on their
25 individual experiences, the investigation of Counsel, and on information and belief, respectfully
26 submits the following Complaint for damages arising from the injury to and wrongful death of her
27 husband and the father of her children, John D. Pfaff.
28

I. INTRODUCTION

1
2 1. This suit arises out of the failure of Defendants Merck & Co., Inc. and Merck Sharp &
3 Dohme Corp. (together, “Merck” or “Defendant Merck”) to warn of dangerous side effects in its
4 prescription hair loss drug, Propecia. Propecia has known depression and suicide ideation side
5 effects. But from the drug’s inception in 1997 through late 2010, Defendant Merck never included
6 these side effects, or the risk of developing them, on the Propecia label or literature distributed with
7 the drug, even though these were reported side effects known or knowable to Defendant Merck.
8 And to this day, Merck has never disclosed or explained the risks related to suicide ideation or
9 suicidality.

10 2. John D. Pfaff, the husband and father of Plaintiffs Kelly, J.A.P., and C. P., was prescribed
11 Propecia by his dermatologist in May 2008. Over the next two years of ingesting the drug as
12 prescribed, John spiraled into a deep depression that lingered even after he stopped taking the drug
13 in 2012. The Propecia-induced depression was followed by suicide ideation, and eventually, John
14 took his own life. Because of Defendant Merck’s strict negligence, negligence, and breach of
15 express and implied warranties in failing to warn of these dangerous side effects, they are liable for
16 the injury to and wrongful death of John D. Pfaff.

17 3. This case seeks wrongful death and survival action damages on behalf of Plaintiffs Kelly
18 Pfaff, J.A.P., C. P., and the Pfaff Family Trust stemming from Defendant Merck’s failure to warn
19 of potential depression and suicide ideation side effects in prescription hair loss drug, Propecia. It
20 does not seek damages stemming from Defendant Merck’s failure to warn of the sexual
21 dysfunction side effects caused by Propecia.

II. PARTIES

22
23 4. Plaintiff Kelly Pfaff, the surviving spouse of decedent John D. Pfaff, was a resident of
24 Encinitas, California, in San Diego County, at all relevant times to this lawsuit. She resides in Park
25 City, Utah with her two children. Kelly is also the sole, currently acting Trustee of the Pfaff Family
26 Trust, of which the beneficiaries are Kelly Pfaff, J.A.P., and C. P.

1 5. Plaintiff J.A.P., the minor son of decedent John D. Pfaff and Kelly Pfaff, was a resident of
2 Encinitas, California, in San Diego County, at all relevant times to this lawsuit. He resides in Park
3 City, Utah with his mother and sister.

4 6. Plaintiff C.P., the minor daughter of decedent John D. Pfaff and Kelly Pfaff, was a resident
5 of Encinitas, California, in San Diego County, at all relevant times to this lawsuit. She resides in
6 Park City, Utah with her mother and brother.

7 7. On information and belief, Defendant Merck & Co., Inc. (“Merck & Co.”) is a publicly-
8 traded, global pharmaceutical corporation incorporated in the State of New Jersey and
9 headquartered at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033, in Union County.

10 8. On information and belief, Defendant Merck Sharp & Dohme, Corp. (“Merck Sharp”) is a
11 wholly owned subsidiary of Defendant Merck & Co. On information and belief, Merck Sharp is
12 incorporated in the State of New Jersey and headquartered at 2000 Galloping Hill Road,
13 Kenilworth, New Jersey 07033, in Union County.

14 9. Merck is a global health care company, which claims to “deliver innovative health solutions
15 through its prescription medicines, vaccines, biologic therapies and animal health products, which
16 it markets directly and through its joint ventures.”¹ Comprised of three operating segments, “[t]he
17 Pharmaceutical segment includes human health pharmaceutical and vaccine products marketed
18 either directly by the Company or through joint ventures.”² Merck’s pharmaceutical products
19 include therapeutic and preventive agents, generally sold by prescription, for the treatment of
20 human disorders.³ Merck sells these products to drug wholesalers and retailers, hospitals,
21 government agencies and managed health care providers such as health maintenance organizations,
22 pharmacy benefit managers and other institutions.⁴

23 10. Merck’s U.S. sales alone topped more than \$17.1 billion in 2014. Propecia sales made up
24 \$264 million of Merck’s total U.S. sales in 2014.

25 _____
26 ¹ MERCK.COM, Annual Form 10-K dated Feb. 27, 2015 *available at* <http://www.merck.com/investors/financial-reports/sec-filings.html> (last visited Mar. 3, 2015).

27 ² *Id.*

28 ³ *Id.*

⁴ *Id.*

1 **III. JURISDICTION AND VENUE**

2 11. This Court has diversity jurisdiction over this action under 28 U.S.C. § 1332(a) because the
3 amount in controversy exceeds \$75,000, and Plaintiffs are citizens of a different state than
4 Defendant Merck.

5 12. This Court has personal jurisdiction over Plaintiffs because Plaintiff Kelly Pfaff submits to
6 the Court’s jurisdiction. This Court has personal jurisdiction over Defendant Merck because it
7 conducts substantial business in California.

8 13. Defendant Merck is headquartered in Kenilworth, New Jersey, but, on information and
9 belief, it conducts or conducted substantial business in this District by marketing and selling its
10 prescription drug products, including Propecia.

11 14. Venue is proper in this District under 28 U.S.C. § 1391(2) because “a substantial part of the
12 events or omissions giving rise to the claim occurred in this District.” Decedent John D. Pfaff, the
13 subject of this wrongful death suit, was prescribed, purchased, and ingested Defendant Merck’s
14 prescription drug in this District. He also committed suicide in this District. Finally, venue is
15 proper under 28 U.S.C. § 1391(3) because Defendant Merck, as a corporation, is “deemed to reside
16 in any judicial district in which they are subject to personal jurisdiction,” and because of Defendant
17 Merck’s numerous contacts with this District described in the preceding paragraph.

18 **IV. FACTUAL ALLEGATIONS**

19 **A. Merck Develops, Manufactures, Markets, and Sells Propecia, But Fails To Warn**
20 **About Its Dangerous Mental Health Side Effects.**

21 15. In or around December 1997, after receiving Federal Drug Administration (“FDA”)
22 approval, Merck began manufacturing, marketing, and selling the prescription drug Propecia
23 throughout the United States.

24 16. Propecia is a one (1) milligram tablet of finasteride for prescription use in males only to
25 treat male pattern hair loss.

26 17. Finasteride belongs to a class of prescription medicines called 5 α -reductase inhibitors (“5-
27 ARIs”) used primarily to treat benign prostatic hyperplasia and androgenic alopecia. Finasteride is
28 a Type II 5-ARI that prevents the conversion of testosterone into dihydrotestosterone (“DHT”).

1 The primary cause of androgenic alopecia, or male pattern balding, is the conversion of
2 testosterone to dihydrotestosterone (“DHT”). By inhibiting 5 α -reductase, finasteride prevents
3 conversion of testosterone to DHT in the hair follicles. Because DHT affects an insulin-like growth
4 factor in the hair follicles important in the development of healthy hair shafts, by blocking DHT
5 production, finasteride reduces hair loss.

6 18. At the time of Propecia’s approval and release, Merck did not include the side effects of
7 depression, suicide ideation, or similar cognitive issues, or the risks of developing these, associated
8 with the drug in its labeling.

9 19. In fact, Merck promoted the use of Propecia for treatment of male pattern hair loss as safe
10 for its intended use.

11 20. Suicide ideation is defined as “thinking about, considering, or planning for suicide” by the
12 Centers for Disease Control and Prevention.⁵

13 21. Depression, by contrast, is characterized by “depressed or sad mood, diminished interest in
14 activities which used to be pleasurable, weight gain or loss, psychomotor agitation or retardation,
15 fatigue, inappropriate guilt, difficulties concentrating, as well as recurrent thoughts of death.”⁶ The
16 “diagnostic criteria established by the American Psychiatric Association dictate that five or more of
17 the above symptoms must be present for a continuous period of at least two weeks.”⁷ While
18 depression can lead to suicide ideation, the two are distinct, as suicide ideation presents a separate
19 side effect with a heightened risk to the afflicted person.

20 22. For other drugs on the market with links to suicide ideation, the FDA has proposed warning
21 labels clearly outlining the side effects, and risk of developing them, to the drug’s users. For
22 example, in antidepressants, the FDA proposed updates in the box warning at the beginning of the
23 package insert, in the “WARNINGS-Clinical Worsening and Suicide Risk,” and in the
24

25
26 ⁵ Injury Prevention & Control: Division of Violence Prevention, CDC.GOV, <http://www.cdc.gov/violenceprevention/suicide/definitions.html> (last visited Mar. 4, 2015).

27 ⁶ Mental Illness, Centers for Disease Control and Prevention, CDC.GOV, <http://www.cdc.gov/mentalhealth/basics/mental-illness/depression.htm> (last visited Mar. 4, 2015).

28 ⁷ *Id.*

1 “PRECAUTIONS-Information for Patients” sections of the products’ labels. The proposed
2 language conveyed the dangers in a clear, comprehensive manner:

- 3 • **“Suicidality and Antidepressant Drugs - Antidepressants increased the risk
4 compared to placebo of suicidal thinking and behavior (suicidality) in children,
5 adolescents, and young adults in short-term studies of major depressive disorder
6 (MDD) and other psychiatric disorders. Anyone considering the use of [Insert
7 established name] or any other antidepressant in a child, adolescent, or young adult
8 must balance this risk with the clinical need. Short-term studies did not show an
9 increase in the risk of suicidality with antidepressants compared to placebo in
10 adults beyond age 24; there was a reduction in risk with antidepressants compared
11 to placebo in adults aged 65 and older. Depression and certain other psychiatric
12 disorders are themselves associated with increases in the risk of suicide. Patients of
13 all ages who are started on antidepressant therapy should be monitored
14 appropriately and observed closely for clinical worsening, suicidality, or unusual
15 changes in behavior. Families and caregivers should be advised of the need for close
16 observation and communication with the prescriber.”** (Emphasis in original.)⁸
- 17 • “Patients with major depressive disorder (MDD), both adult and pediatric, may
18 experience worsening of their depression and/or the emergence of suicidal ideation and
19 behavior (suicidality) or unusual changes in behavior, whether or not they are taking
20 antidepressant medications, and this risk may persist until significant remission occurs.”⁹
- 21 • “There has been a longstanding concern, however, that antidepressants may have a role
22 in inducing worsening of depression and the emergence of suicidality in certain patients
23 during the early phases of treatment. Pooled analyses of short-term placebo-controlled
24 trials of antidepressant drugs (SSRIs and others) showed that these drugs increase the
25 risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young
26 adults (ages 18-24) with major depressive disorder (MDD) and other psychiatric
27 disorders. Short-term studies did not show an increase in the risk of suicidality with
28 antidepressants compared to placebo in adults beyond age 24; there was a reduction with
antidepressants compared to placebo in adults aged 65 and older.”¹⁰
- **“All patients being treated with antidepressants for any indication should be
monitored appropriately and observed closely for clinical worsening, suicidality,
and unusual changes in behavior, especially during the initial few months of a
course of drug therapy, or at times of dose changes, either increases or decreases.”**¹¹
(Emphasis in original.)

25 ⁸ Antidepressant Use in Children, Adolescents, and Adults, FDA.GOV, [http://www.fda.gov/-
26 downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM173233.pdf](http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM173233.pdf) (Last visited Mar. 5,
2015).

27 ⁹ *Id.*

28 ¹⁰ *Id.*

¹¹ *Id.*

- “Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers. Such monitoring should include daily observation by families and caregivers.”¹² (Emphasis in original.)

23. Similarly, in 2005, after reports of suicide ideation in the prescription drug Accutane—a cosmetic drug, like Propecia—the manufacturer updated the label to include these side effects even though the mechanism of action was not yet known:

Psychiatric Disorders

Accutane (isotretinoin) may cause depression, psychosis and, rarely, suicidal ideation, suicide attempts, suicide, and aggressive and/or violent behaviors. No mechanism of action has been established for these events (see ADVERSE REACTIONS: Psychiatric). Prescribers should read the brochure, *Recognizing Psychiatric Disorders in Adolescents and Young Adults: A Guide for Prescribers of Isotretinoin*. Prescribers should be alert to the warning signs of psychiatric disorders to guide patients to receive the help they need. Therefore, prior to initiation of Accutane (isotretinoin) therapy, patients and family members should be asked about any history of psychiatric disorder, and at each visit during therapy patients should be assessed for symptoms of depression, mood disturbance, psychosis, or aggression to determine if further evaluation may be necessary. Signs and symptoms of depression, as described in the brochure (“Recognizing Psychiatric Disorders in Adolescents and Young Adults”), include sad mood, hopelessness, feelings of guilt, worthlessness or helplessness, loss of pleasure or interest in activities, fatigue, difficulty concentrating, change in sleep pattern, change in weight or appetite, suicidal thoughts or attempts, restlessness, irritability, acting on dangerous impulses, and persistent physical symptoms unresponsive to treatment. Patients should stop Accutane (isotretinoin) and the patient or a family member should promptly contact their prescriber if the patient develops depression, mood disturbance, psychosis, or aggression, without waiting until the next visit. Discontinuation of Accutane (isotretinoin) therapy may be insufficient; further evaluation may be necessary. While such monitoring may be helpful, it may not detect all patients at risk. Patients may report mental health problems or family history of psychiatric disorders. These reports should be discussed with the patient and/or the patient's family. A referral to a mental health professional may be necessary. The physician should consider whether Accutane (isotretinoin) therapy is appropriate in this setting; for some patients the risks may outweigh the benefits of Accutane (isotretinoin) therapy.

(Emphasis in original.)

¹² *Id.*

1 24. In October 2006, BioMed Central, a scientific publisher specializing in open access journal
2 publication, published a study indicating that Propecia may cause depression.¹³ The study was
3 prompted by previous animal studies, and some human case reports, suggesting finasteride could
4 alter 5-ARI activity in some regions of the brain, leading to behavioral and mood changes.¹⁴
5 Researchers enrolled 128 men with androgenic alopecia who were prescribed 1 mg/day of
6 finasteride.¹⁵ To gather information on depressed mood and anxiety, participants completed Beck
7 Depression Inventory (“BDI”) and Hospital Anxiety and Depression Scale (“HADS”)
8 questionnaires before beginning the finasteride treatment, and again two months after it.¹⁶ The
9 preliminary study concluded finasteride might induce depressive symptoms, and therefore these
10 behavioral side effects should be considered specially when prescribed for patients more
11 susceptible to them.¹⁷ The study also recommended further studies “to elucidate behavioral effects
12 of finasteride in higher doses and in high risk groups...”¹⁸

13 25. On information and belief, Merck failed to warn U.S. clinicians and patients of depression
14 and suicide ideation side effects associated with Propecia in or around May 2008.

15 26. Merck’s failure to warn of these cognitive side effects contradicted its response to new
16 information about the sexual side effects associated with the drug. When Merck first released
17 Propecia in 1997, some sexual side effects, such as decreased libido, erectile dysfunction, and
18 ejaculate disorder, were reported in the initial Propecia labeling, but Merck represented these were
19 only temporary. After the Swedish Medical Products Agency commenced an investigation into
20 Merck’s representations and concluded Propecia can cause permanent sexual dysfunction, in 2008,
21 Merck changed its Swedish label to warn of these effects, and on information and belief, later
22 changed Propecia labels in the United Kingdom and Italy. Finally, around June 2011 and again in
23

24 ¹³ BMC Pharmacology & Toxicology, BIOMEDCENTRAL.COM, [http://www.biomedcentral-](http://www.biomedcentral.com/-1472-6904/6/7)
25 [com/-1472-6904/6/7](http://www.biomedcentral.com/-1472-6904/6/7) (last visited Mar. 3, 2015).

26 ¹⁴ *Id.*

27 ¹⁵ *Id.*

28 ¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

1 April 2012, Merck made significant and well-publicized updates to the Propecia label, admitting
2 many of the reported sexual side effects persisted after discontinuation of the drug.

3 27. But when it came to Propecia's depression and suicide ideation side effects, Merck largely
4 ignored clinical findings it knew or should have known about. It was not until December 2010, at
5 earliest, when Merck updated Propecia's professional label to include "depression" as a side effect
6 in the Adverse Reactions Postmarketing Experience section of the labeling and the Patient Package
7 Insert.¹⁹

8 28. The December 2010 label omits suicide ideation altogether.

9 29. Even after Merck's significant updates in April 2012 in light of the sexual dysfunction
10 findings, the new Propecia label made scant mention of the depression in the Adverse Reactions
11 Postmarketing Experience section of the labeling and the Patient Package Insert, and did not
12 mention suicide ideation.²⁰

13 30. In August 2012, Dr. Michael Irwig of George Washington University published a
14 retrospective study highlighting a link between Propecia and depression and suicide ideation, and
15 concluding men who took Propecia for hair loss and experienced its sexual side effects also had
16 high rates of depressive symptoms, even after stopping the drug.²¹

17 31. Among the group of former Propecia users who developed persistent sexual dysfunction, 75
18 percent reported symptoms of depression compared with 10 percent of controls who never took the
19 drug.²² The symptoms were moderate-to-severe in 64 percent of the former Propecia users and in
20 none of the controls.²³

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22
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24 ¹⁹ Ex. A, Propecia Label dated December 2010.

25 ²⁰ Ex. B, Propecia Label dated April 2012.

26 ²¹ Michael S. Irwig, M.D., *Depressive Symptoms and Suicidal Thoughts Among Former Users*
27 *of Finasteride With Persistent Sexual Side Effects*, J. CLINICAL SOC'Y, Aug. 7, 2012, available at
[http://www.psychiatrist.com/_layouts/PPP.Psych.Controls/ArticleViewer.ashx?ArticleURL=/JCP/a](http://www.psychiatrist.com/_layouts/PPP.Psych.Controls/ArticleViewer.ashx?ArticleURL=/JCP/article/Pages/2012/v73n09/v73n0911.aspx)
rticle/Pages/2012/v73n09/v73n0911.aspx (last visited Mar. 3, 2015).

28 ²² *Id.*

²³ *Id.*

1 32. Significantly, 39 percent of the former Propecia users reported having thoughts of suicide,
2 and 5 percent agreed with the statement, “I would like to kill myself.”²⁴ Only one member of the
3 control group, which was less than half the size of the former Propecia users’ sample, reported
4 suicidal thoughts.²⁵

5 33. Dr. Irwig’s study was prompted by earlier studies and reports suggesting the link between
6 Propecia and depression and suicide ideation. To reach his results, Dr. Irwig administered
7 standardized interviews to 61 men who were former users of finasteride with persistent sexual side
8 effects for over three months, gathering demographic information, medical and psychiatric
9 histories, and information on medication use, sexual function, and alcohol consumption.²⁶ All of
10 the former finasteride users were otherwise healthy men with no baseline sexual dysfunction,
11 medical conditions, psychiatric conditions or use of oral prescription medications.²⁷ Dr. Irwig also
12 conducted interviews with a control group of 29 men who had male pattern hair loss but who had
13 never used finasteride and denied any history of psychiatric conditions or use of psychiatric
14 medications.²⁸ Both groups self-administered the Beck Depression Inventory II (BDI-II), a widely
15 used, validated instrument that measures the severity of depression in adults.²⁹

16 34. Based on his findings, Dr. Irwig recommended clinicians and potential users of Propecia be
17 warned of the potential risk of depressive symptoms and suicidal thoughts. He also suggested
18 further research on the topic was warranted.³⁰

19 35. On information and belief, Merck has yet to update its Propecia label to adequately address
20 the dangerous depression side effect, nor warn of suicide ideation as a side effect.
21
22
23

24 ²⁴ *Id.*

25 ²⁵ *Id.*

26 ²⁶ *Id.*

27 ²⁷ *Id.*

28 ²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

1 **B. The Pfaff Family**

2 36. John and Kelly met on April 12, 1996, in San Diego, California. The two were married June
3 8, 2002. They purchased their first home, a fixer-upper, in Encinitas, California. It was here they
4 welcomed their first child on July 26, 2005.

5 37. John was finding success at his job at the EMC Corporation, a computer data storage
6 company, which afforded the couple the ability to purchase a coastal home.

7 38. An avid team sport player in high school and college, John maintained his active lifestyle
8 after college. He loved to surf and snow ski whenever he had the chance, and he worked out with a
9 trainer once or twice per week. He often helped Kelly around the home, and enjoyed coaching his
10 child's soccer team.

11 39. In or around May 2005, John took a position with a smaller, innovative IT consulting firm,
12 Trace3. The role gave John the opportunity to build something from scratch, something he relished.
13 John was a leader and communicator. While at Trace3, John helped expand the business into San
14 Diego, from a single-run territory to a full office of people. He was later promoted to President of
15 Trace3 in January 2010.

16 40. When Kelly became pregnant with their second child in 2007, the couple decided to buy a
17 nearby property and contemplated a remodel of their original Encinitas cottage or building a brand
18 new home. The move made sense given a second child was coming. Their daughter was born on
19 August 13, 2008.

20 **C. John Starts Taking Propecia And His Mental Health Begins To Steadily Decline**

21 41. On May 6, 2008, John visited Dr. David E. Thomas at the Dermatologist Medical Group of
22 North County in Encinitas, California. After evaluation, Dr. Thomas prescribed Propecia for John's
23 hair loss, and John filled his first prescription on May 7, 2008. John was diligent about taking his
24 Propecia as prescribed—1 milligram pill daily.

25 42. Defendant Merck and the Propecia labeling did not warn Dr. Thomas or John that
26 depression or suicide ideation were potential side effects associated with the drug.

27 43. In 2009, John, for the first time, displayed an odd and troublesome attitude. He and Kelly
28 would begin fighting over something small and insignificant, and then things escalated from there,

1 which was atypical because they rarely argued before this issue emerged. These fights left Kelly
2 confused, hurt, and angry because she did not understand the change in her husband. Usually calm
3 and confident, John expressed anxiety, extreme worry, and negative feelings. His sex drive also
4 dwindled, which Kelly initially attributed to having young children.

5 44. From there, John's temperament drastically changed and his suffering intensified. By 2011,
6 things unraveled and Kelly no longer recognized the man she married. Over the next two years
7 John would suffer from a lack of sex drive, anxiety, depression, short temper, uncharacteristic
8 weight gain despite being active and healthy, alarmingly repetitious behavior, impaired decision-
9 making, low confidence, extreme insomnia, anger, suicide ideation, and social withdrawal.

10 45. In or around September 2011, John suffered a panic attack. The panic attack concerned
11 John because it was the first he had ever experienced and it happened suddenly. He was also
12 concerned because he did not understand what triggered it. It was around the same time of this first
13 panic attack that John's decreased libido grew progressively worse.

14 46. A few months later, around December 2011, John suffered a second panic attack. John was
15 excessively sweating, shaking, and making suicidal comments during this panic attack.

16 47. John filled his Propecia prescription for the last time on February 22, 2012. After he and
17 Kelly discussed their diminished sex life, they decided he should stop taking the prescription in
18 case it might be contributing to his decreased libido.

19 48. Around May 2012, John was increasingly angry and aggressive, yelling at family members,
20 and acting outside his normal behavior. John also suffered from severe insomnia. By this time, his
21 libido problems had escalated. John uncharacteristically gained weight despite his active and
22 healthy lifestyle.

23 49. Still, John's odd behavior only worsened. He was fatigued and often napped during the day.
24 He complained of unexplained muscle twitching and shaking in his legs and abnormal body
25 temperatures. John also experienced cognitive dysfunction. His thought processing slowed, he
26 often repeated himself over and over again, and his problem-solving skills were impaired,
27 preventing him from resolving simple matters. He was "checked-out" emotionally, and Kelly
28 describes John as "in a fog," highly depressed, and numb.

1 50. Before taking Propecia, John never suffered from depression, suicide ideation, anxiety, or
2 other cognitive issues. He never experienced insomnia or a diminished libido either.

3 51. John's symptoms worsened and persisted, and on January 7, 2013, he suddenly resigned as
4 President of Trace3. After he quit, Kelly remembers John acting confused and without any
5 confidence, direction, or hope.

6 52. Still perplexed and shocked by his own abrupt resignation, John sent a bizarre and
7 uncharacteristic email to Trace3 executives on January 10, 2013, confessing he had erred in
8 resigning, begging for his job back, and asking for forgiveness. Trace3 declined to re-hire John.

9 53. During January and February 2013, John could not sleep more than a few hours each night
10 for approximately 45 days. This was John's most prolonged and disturbing bout of insomnia.

11 **D. John Ends His Life**

12 54. On the morning of March 5, 2013, John left the Pfaff home without notice. When he left,
13 Kelly was driving Aidan to school and the family's housekeeper had just arrived at the home.
14 John's absence was noted by Kelly when she returned and she discovered John failed to take their
15 daughter to school as planned.

16 55. John walked approximately one block from the house to the nearby Amtrak railroad tracks.
17 He stepped in front of an oncoming train and was immediately killed on impact. John was 40 years
18 old.

19 **E. The Pfaff Family Without John**

20 56. John's untimely death left Kelly, the children, and their extended family devastated and
21 traumatized. Kelly was suddenly without her husband, and her children without their father. John
22 had been the family patriarch and sole bread-winner. Compounding this loss was that Kelly could
23 not understand or explain what had so drastically changed her husband, leading him to take his
24 own life.

25 57. Immediately after learning of John's death, Kelly fell into a deep state of shock and panic.
26 Her entire body visibly shook for several days after he died. Aside from her grief, she was fearful
27 for the future of her family. Kelly was a stay-at-home mom to the kids, and without John, she had
28 many expenses to cover but no income and no resume or career to fall back on.

1 58. Around May 2013, the Pfaff family learned of the depression and suicide ideation side
2 effects associated with Propecia use.

3 59. Providing for her children weighs heavily on Kelly, and she struggles to support them. As
4 leftover income and assistance depletes, Kelly must find a job that will permit her to monetarily
5 support her growing children while also caring for them physically and emotionally.

6 60. Kelly and the children continue to see therapists to deal with the grief of this loss. But their
7 lives are forever changed by John's absence. While playing games, their daughter, now 6-years-
8 old, often pretends John is playing with her. Their son, now 9-years-old, has struggled with
9 anxiety, anger, and worry. He feels pressure to protect Kelly and his sister as the only male in the
10 house. Kelly worries about the impact the loss of such an important relationship will have on the
11 kids' lives. Kelly is crippled by loneliness and sadness from losing the love of her life.

12 **V. CAUSES OF ACTION**

13 **FIRST CAUSE OF ACTION**

14 **(Strict Product Liability – Failure to Warn)**

15 61. Plaintiffs incorporate by reference all allegations in the foregoing paragraphs.

16 62. Defendant Merck developed, manufactured, marketed, and sold Propecia during all relevant
17 times alleged herein.

18 63. As a prescription drug manufacturer, Defendant Merck had a duty to warn of known or
19 reasonably scientifically knowable side effects posed by Propecia, and the risk thereof.

20 64. As a drug manufacturer, Defendant Merck had a duty to maintain the content of its drug
21 labels, including Propecia. Defendant Merck was required to both craft an adequate label for
22 Propecia, and ensure that its warnings remain adequate if Propecia is on the market.

23 65. Propecia had potential side effects of depression and suicide ideation that were known or
24 knowable to Defendant Merck in light of the scientific and medical knowledge that was generally
25 accepted in the scientific community at the relevant times of Propecia's manufacture, marketing,
26 distribution, and sale.

27 66. The side effects of depression and suicide ideation, and the risks thereof, present substantial
28 dangers when Propecia is used or misused in an intended or reasonably foreseeable way.

1 67. Ordinary consumers would not have recognized the potential side effects of depression and
2 suicide ideation posed by Propecia, nor the risk thereof.

3 68. John D. Pfaff used Propecia in a foreseeable manner.

4 69. Defendant Merck failed to warn John D. Pfaff, individually and/or through his prescribing
5 physicians, about Propecia's potential side effects of depression and suicide ideation, and the risk
6 of developing such side effects, and Defendant Merck continues to conceal that Propecia has the
7 potential side effect of suicide ideation, and the risks thereof.

8 70. John D. Pfaff was harmed, and ultimately killed, by Propecia as described.

9 71. Defendant Merck's lack of sufficient warning was a substantial factor in causing John's
10 injuries and death.

11 **SECOND CAUSE OF ACTION**

12 **(Negligence – Failure to Warn)**

13 72. Plaintiffs incorporate by reference all allegations in the foregoing paragraphs.

14 73. Defendant Merck developed, manufactured, marketed, and sold Propecia during all relevant
15 times alleged herein.

16 74. As a prescription drug manufacturer, Defendant Merck had a continuing duty to exercise
17 due care in warning of Propecia's potential side effects of depression and suicide ideation, and the
18 risk thereof.

19 75. Defendant Merck knew or reasonably should have known that Propecia was dangerous or
20 was likely to be dangerous when used or misused in a reasonably foreseeable manner.

21 76. Defendant Merck knew or reasonably should have known that John D. Pfaff, individually
22 and/or through his prescribing physicians, would not realize the dangers posed by Propecia of
23 potential depression or suicide ideation, or both.

24 77. Defendant Merck failed to warn John D. Pfaff, individually and/or through his prescribing
25 physicians, of the dangers of potential depression and/or suicide ideation posed by Propecia.

26 78. A reasonable prescription drug manufacturer, under the same or similar circumstances,
27 would have warned of the dangers of potential depression or suicide ideation, or both, posed by
28 Propecia.

1 79. Defendant Merck's failure to warn was a substantial factor in causing John's psychological
2 condition.

3 80. Propecia harmed, and ultimately caused the death of, John D. Pfaff, as described.

4 **THIRD CAUSE OF ACTION**

5 **(Breach of Implied Warranties – Failure to Warn)**

6 81. Plaintiffs incorporate by reference all allegations in the foregoing paragraphs.

7 82. At all relevant times, Defendant Merck was in the business of manufacturing and selling
8 Propecia and other pharmaceuticals to physicians and their patients.

9 83. At all relevant times, Defendant Merck knew of the intended use of Propecia and impliedly
10 warranted the product to be of merchantable quality and safe and fit for such use.

11 84. John D. Pfaff, individually and/or by and through his prescribing physicians, reasonably
12 relied upon the skill, superior knowledge, and judgment of Defendant Merck.

13 85. John D. Pfaff purchased Propecia manufactured by Defendant Merck.

14 86. Defendant Merck breached these representations and warranties, as they were false,
15 misleading, and inaccurate in that Propecia was not safe for its intended use and was not of
16 merchantable quality because Defendant Merck failed to warn that Propecia could (1) lead to
17 depression or (2) induce suicide ideation and increase the risk thereof, or both.

18 87. As a direct and proximate result of Defendant Merck's breach of implied warranties, John
19 D. Pfaff was harmed, and ultimately killed, as described herein.

20 88. Propecia's failure to be as warranted by Defendant Merck was a substantial factor in
21 causing John's injuries and death.

22 **FOURTH CAUSE OF ACTION**

23 **(Breach of Express Warranties – Failure to Warn)**

24 89. Plaintiffs incorporate by reference all allegations in the foregoing paragraphs.

25 90. Defendant Merck expressly represented to John D. Pfaff, individually and/or by and
26 through his prescribing physicians, that Propecia was safe and fit for its intended purposes to treat
27 male pattern hair loss.

28

1 91. John D. Pfaff, individually and/or by and through his prescribing physicians, reasonably
2 relied upon Defendant Merck's express warranties and guarantees that Propecia was safe,
3 merchantable, and reasonably fit for its intended purpose in choosing to treat male pattern hair loss.

4 92. Propecia did not conform to these express representations because its labeling failed to
5 adequately warn of the potential side effects of depression and suicide ideation, and the risks
6 thereof.

7 93. Defendant Merck breached its express warranties because Propecia was not as Merck had
8 represented.

9 94. As a direct and proximate result of Defendant Merck's breach of express warranties, John
10 D. Pfaff was harmed, and ultimately killed, as described herein.

11 95. Propecia's failure to be as warranted by Defendant Merck was a substantial factor in
12 causing John's injuries and death.

13 **FIFTH CAUSE OF ACTION**

14 **(Wrongful Death – On behalf of Kelly Pfaff, J.A. Pfaff, and C. Pfaff)**

15 96. Plaintiffs incorporate by reference all allegations in the foregoing paragraphs.

16 97. The death of John D. Pfaff was directly and proximately caused by the strict negligence,
17 negligence, and breach of warranties by Defendant Merck, as alleged herein.

18 98. Plaintiff Kelly Pfaff, the surviving spouse of John D. Pfaff, suffered pecuniary damages,
19 loss of John's services, guidance, and advice, and loss of John's love, society, comfort, care,
20 affection, solace, moral support, protection, companionship, and consortium arising from the death
21 of her husband.

22 99. Plaintiffs J.A.P. AND C.P., the surviving children of John D. Pfaff, suffered pecuniary
23 damages, loss of John's services, guidance, training, and advice, and loss of John's love, society,
24 comfort, care, affection, solace, moral support, protection, and companionship arising from the
25 death of their father.

SIXTH CAUSE OF ACTION

**(Survival Action – Kelly Pfaff, as Trustee and Surviving Spouse,
on behalf of John D. Pfaff’s Estate)**

100. Plaintiffs incorporate by reference all allegations in the foregoing paragraphs.

101. Defendant Merck was strictly negligent, negligent, and breached warranties in failing to warn or adequately warn of Propecia’s potential side effects, and the risks thereof, as described herein.

102. Defendant Merck’s acts and conduct directly and proximately caused injury to John D. Pfaff, as described herein.

103. Because of Defendant Merck’s actions described herein, John D. Pfaff suffered pecuniary and punitive damages.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, pray for judgment against Defendants as follows:

- A. For all compensatory damages caused by Defendants’ conduct;
- B. For all incidental and consequential damages caused by Defendants’ conduct;
- C. For exemplary or punitive damages;
- D. For the maximum interest provided by law on such monetary relief, including but not limited to, Cal. Civ. Code § 3291;
- E. Attorney’s fees;
- F. Costs of suit; and
- G. For such other and further relief as the Court deems proper and just.

VII. JURY TRIAL DEMANDED

Plaintiff demands a trial by jury on all issues triable of right by jury.

DATED: March 5, 2015

HAGENS BERMAN SOBOL SHAPIRO LLP

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