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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

DAVID LUCHSINGER and CHERYL LUCHSINGER, Plaintiffs, vs. REGENERON PHARMACEUTICALS, INC., and SANOFI-AVENTIS U.S. LLC, Defendants.	Case No.: **COMPLAINT FOR DAMAGES** **JURY DEMAND**

COMPLAINT

Plaintiffs David Luchsinger and Cheryl Luchsinger ("Plaintiffs"), by and through the undersigned attorneys, hereby brings this action against the above-captioned Defendants, Regeneron Pharmaceuticals, Inc. and Sanofi-Aventis U.S. LLC, to recover damages, pursuant to and under the laws of the State of Nevada, arising from personal injuries suffered as a proximate result of injection of Defendants' prescription drug Dupixent® (dupilumab) (hereinafter "Dupixent" or "dupilumab"), and allege as follows:

INTRODUCTION

1. This is an action for damages relating to Defendants' wrongful conduct in connection with the development, testing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of dupilumab as Defendants' brand prescription drug Dupixent.

2. Defendants manufactured, promoted and sold Dupixent as a biologic medication for the treatment of multiple conditions, including atopic dermatitis (AD), asthma, and other inflammatory diseases of the skin and respiratory tract in adult and pediatric patients. Dupixent is a biologic medication administered by subcutaneous injection with an initial dose administered at two different injection sites and subsequent doses administered every two to four weeks, depending on age and body weight.

3. Dupixent caused the development and/or aggravation and accelerated progression of cutaneous T-cell lymphoma (CTCL) in Plaintiff. CTCL is a rare type of cancer that affects white blood cells called T cells, or T lymphocytes. T-cell lymphomas like CTCL are a subtype of non-Hodgkin lymphoma (NHL).

4. CTCL is a T-cell lymphoma that starts in the skin. Mycosis fungoides and Sezary syndrome are the two most common subtypes of CTCL. Plaintiff has been diagnosed with Mycosis fungoides.

5. Defendants knew or should have known that Dupixent, when taken as prescribed and intended, causes the development and/or rapid clinical progression of T-cell lymphoma, including CTCL.

6. Numerous case reports and scientific studies have established that Dupixent causes T-cell lymphoma, including CTCL, and/or accelerates its progression.

7. Defendants failed to warn, instruct, advise, educate, or otherwise inform Dupixent users and prescribers, including Plaintiff and Plaintiff's treating physicians, about the risk of development and/or rapid exacerbation of CTCL. The U.S. label for Dupixent makes no mention of these risks.

8. As a proximate result of Defendants' wrongful actions and inactions, Plaintiff suffered and continues to suffer serious personal injuries, including severe pain, loss of enjoyment of life, economic loss, and out-of-pocket costs of medical tests and treatment.

9. Plaintiff brings this action for personal injuries suffered as a proximate result of injection of Defendants' prescription drug Dupixent. Plaintiff seeks compensatory damages, punitive damages, and all other available remedies provided to Plaintiff under the law due to the Defendants' negligent, reckless, and wrongful conduct.

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PARTIES

10. Plaintiff DAVID LUCHSINGER is, and at all times relevant to this action was, a citizen and resident of the State of Nevada who resides in Clark County, Nevada.

11. Plaintiff CHERYL LUCHSINGER is, and at all times relevant to this action, a citizen and resident of the State of Nevada who resides in Clark County, Nevada.

12. Plaintiff DAVID LUCHSINGER was injected with Defendants' Dupixent (dupilumab) product from October 2024 until March 2025. As a direct and proximate result of use of Defendants' Dupixent product, Plaintiff DAVID LUCHSINGER incurred and continues to incur medical expenses and suffered and continues to suffer severe pain and physical and emotional injuries, including the development and/or acceleration and exacerbation of CTCL and loss of enjoyment of life.

13. At all times material to this Complaint, Plaintiff DAVID LUCHSINGER and Plaintiff CHERYL LUCHSINGER were lawfully married as husband and wife.

14. Defendant REGENERON PHARMACEUTICALS, INC. (hereinafter, "Regeneron") is a corporation organized under New York law with its principal place of business located at 777 Old Saw Mill River Road, Tarrytown, NY 10591.

15. Defendant SANOFI-AVENTIS U.S. LLC (hereinafter "Sanofi-Aventis") is a limited liability company organized and existing under the laws of the state of Delaware, with its principal place of business at 55 Corporate Drive, Bridgewater, NJ 08807. Sanofi-Aventis is a wholly-owned subsidiary of Sanofi US Services, Inc., a Delaware corporation.

16. Defendant Regeneron submitted a Biologics License Application (BLA) for Dupixent (dupilumab) which was initially approved on March 28, 2017 for the indication of treatment of adult patients with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable (BLA 761055).

17. Defendant Regeneron subsequently submitted and obtained approval of multiple supplemental biologics license applications (sBLAs) to expand the indications for Dupixent to atopic dermatitis in pediatric patients; to asthma, chronic rhinosinusitis with nasal polyps

(CRSwNP), and eosinophilic esophagitis (EoE) in adult and pediatric patients; and to the treatment of prurigo nodularis (PN) and chronic obstructive pulmonary disease (COPD) in adult patients.

18. As the official sponsor of the BLA for Dupixent in the United States, Defendant Regeneron maintains significant responsibility and control over the drug and all activities and materials related thereto.

19. Defendant Sanofi-Aventis, individually and/or through its parent and/or subsidiaries, funded and continues to fund research conducted by Defendant Regeneron related to the development of Dupixent. Defendant Sanofi-Aventis markets and sells Dupixent in the United States including in the state of Georgia. Upon information and belief, Sanofi employs sales representatives throughout Georgia and in this District to promote and sell Dupixent.

20. At all times relevant hereto, Defendants include and have included any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

21. Defendants jointly developed, manufactured, marketed and distributed Dupixent throughout the United States including in the state of Georgia.

22. Upon information and belief, profits and losses associated with the sale of Dupixent in the United States are split equally (50/50) between Defendant Sanofi-Aventis (individually and/or through its parent and/or subsidiaries) and Defendant Regeneron.

23. Dupixent is a top-selling, blockbuster drug and a flagship product of both Sanofi-Aventis and Regeneron.[1] Sales of Dupixent were $11.6 billion in 2023, $14.1 billion in 2024 and at or above $4 billion per quarter for the first three quarters of 2025.2

24. Defendants directed and continue to direct advertising and informational materials to Georgia physicians and potential users of Dupixent for the specific purpose of selling Dupixent in Georgia including in this District.

25. Defendants manufactured, marketed and distributed the Dupixent injected into Plaintiff.

26. At all times relevant to this action, Defendants tested, studied, researched, designed, formulated, developed, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold Dupixent worldwide and throughout the United States, including in and throughout the state of Georgia, and generated substantial revenue as a result.

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JURISDICTION AND VENUE

27. Plaintiffs reallege and incorporate by reference all of the foregoing allegations as if repeated in full here.

28. This suit alleges causes of action seeking relief arising under the laws of the State of Nevada, including but not limited to the allegation that as a direct and proximate result of the Defendants' products and each Defendant's negligent, deceptive, willful, immoral, reckless, and

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[1] https://www.accio.com/business/sanofi-top-selling-drugs; https://synapse.patsnap.com/article/what-are-the-top-selling-drugs-of-regeneron.

[2] https://firstwordpharma.com/story/5952354; https://finance.yahoo.com/news/dupixent-sales-spur-sanofi-growth-165640339.html; https://www.fiercepharma.com/pharma/sanofi-and-regenerons-dupixent-course-inflection-year-copd; https://investor.regeneron.com/news-releases/news-release-details/regeneron-reports-fourth-quarter-and-full-year-2023-financial; https://investor.regeneron.com/news-releases/news-release-details/regeneron-reports-third-quarter-2025-financial-and-operating.

unlawful actions and inactions, representations and misrepresentations, including by omission, Plaintiffs suffer and continue to suffer injuries and damages within the State of Nevada.

29. Plaintiffs have suffered and continue to suffer both injuries and damages within the State of Nevada that exceed the sum or value of $75,000, exclusive of interest and costs.

30. This Court has original subject matter jurisdiction over the claims pursuant to 28 U.S.C. § 1332 because the controversy is between citizens of different states.

31. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. §1391(b)(2) because, at all times material hereto, a substantial part of the events or omissions giving rise to this claim occurred in this District, and 28 U.S.C. §1391(b)(1) because at all times material hereto, both defendants conducted substantial business in this District related to Dupixent.

32. Each Defendant purposefully availed itself of the privilege of conducting activities in Nevada, such as marketing, promoting, distributing, and selling its products (including Dupixent) in Nevada including in this District.

33. Defendant Regeneron is registered to do business in Nevada and established an agent to receive service of process in Nevada and is therefore amenable to suit on any claim in Nevada.

34. Defendant Regeneron Pharmaceuticals, Inc. can be served at its registered agent for service of process, CT Corporation System, at 701 S Carson St Ste 200, Carson City, NV, 89701.

35. Defendant Sanofi-Aventis U.S. LLC is registered to do business in Nevada and established an agent to receive service of process in Nevada and is therefore amenable to suit on any claim in Nevada.

36. Defendant Sanofi-Aventis U.S. LLC can be served at its registered agent for service of process, Corporation Service Company, 112 North Curry Street, Carson City, NV, 89703.

GENERAL FACTUAL ALLEGATIONS

A. Atopic Dermatitis

37. Dupixent was initially developed and approved to treat moderate to severe atopic dermatitis when topical treatments (treatments applied to the skin) are not sufficient or appropriate.

38. Atopic dermatitis, also known as eczema, is a chronic inflammatory skin disease characterized by upregulation of the type 2 immune response and a dysfunctional skin barrier in which the skin is itchy, red and dry.

39. Atopic dermatitis may present with similar morphology (i.e., erythema, lichenification, fissuring with pruritus, disruption of the skin barrier, and impetiginization) as mycosis fungoides and Sezary syndrome, which are the two most common subtypes of CTCL.

B. Dupixent

40. Dupixent (dupilumab) is a biologic medication – a human monoclonal antibody – used to treat inflammatory health conditions. Dupixent inhibits the signaling of interleukin-4 (IL-4) and interleukin-13 (IL-13) by specifically binding to the IL-4 receptor alpha subunit that is shared by the IL-4 and IL-13 complexes.[3]

41. Dupixent is now indicated for the treatment of multiple conditions, including atopic dermatitis (AD), asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), and eosinophilic esophagitis (EoE) in adult and pediatric patients and for the treatment of prurigo nodularis (PN) and chronic obstructive pulmonary disease (COPD) in adult patients. The mechanism of action

[3] Sokumbi, et al., Evolution of dupilumab-associated cutaneous atypical lymphoid infiltrates. *Am J Dermatopathol*. 2021;43(10):714-20.

through which Dupixent exerts a therapeutic effect in patients with these conditions has not been definitively established.

42. Biologics are specialty medications made inside living cells and designed to target specific parts of the immune system involved in a particular disease.

43. Upon information and belief, at no time after receiving approval did Defendants take initiative to update their package insert or request permission from the FDA to warn about the development, acceleration or exacerbation of T-cell lymphoma including CTCL. Nor did Defendants use the "changes being effected" ("CBE") labeling changes provision of 21 C.F.R. § 314.70(c)(6)(iii)(A), (C); 21 C.F.R § 314.3(b) to add or strengthen the warning and precautions or adverse reactions sections of the Dupixent label to alert patients and physicians of these increased dangers of Dupixent.

44. At all relevant times, there were safer and reasonably effective treatments and/or other FDA-approved medications for the treatment of atopic dermatitis and/or eczema which healthcare providers could have prescribed as an alternative treatment to Dupixent.

C. Dangers of Dupixent: CTCL

45. CTCL is a chronic condition that is generally considered incurable, and accordingly, treatment generally aims to put the disease into remission, leaving the patient with fewer signs and symptoms. CTCL can cause severe itching, pain and physical disfigurement which can significantly impair health-related quality of life, especially in the later stages of the disease. CTCL can also metastasize to affect tissues and organs other than the skin. Survival rates for CTCL patients vary depending on the stage at time of diagnosis; patients with moderate to advanced CTCL experience markedly reduced survival. CTCL stages range from I to IV, and include substages indicated by letters A and B, with higher numbers and letters indicating greater severity.

46. Shortly after Dupixent was released to the market, concerned clinical and academic physicians began publishing case reports and case series linking dupilumab use with T-cell lymphoma, including CTCL (including mycosis fungoides and Sezary syndrome).[4] The reports have increased over time and have included diagnoses of new, primary CTCL as well as an unexpected "unmasking" or severe and rapid clinical progression of otherwise subclinical and undiagnosed CTCL occurring weeks to years following initiation of Dupixent use.

47. On November 30, 2018, a published case report described the development of CTCL in a patient treated with dupilumab.[5] After 3 months of dupilumab treatment for atopic dermatitis, the patient developed right inguinal lymph node enlargement, plaques on her neck, elbow and lower back, and a rapidly ulcerated lesion under her right nipple. Biopsy revealed CD30+ ALK1-negative cutaneous anaplastic large cell lymphoma, a subtype of CTCL. In their discussion the authors noted that prior research had shown Th2 pathway involvement in oncogenesis via IL-4 and IL-13.

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[4] *E.g.*, Yoo, et al., Three cases of new diagnosis of mycosis fungoides following commencement on biologic therapies for presumed psoriasis/eczema. *European Journal of Cancer*. 2019; 119SI:S41; Tran, et al., Development of Sezary syndrome following the administration of dupilumab. *Dermatol Online J*. 2020; 26(4); Hollins, et al., Long-Standing dermatitis treated with dupilumab with subsequent progression to cutaneous T-cell lymphoma. *Cutis*. 2020; 106(2):E8-E11; Du-Thanh, et al., Lethal anaplastic large-cell lymphoma occurring in a patient treated with dupilumab. *JAAD Case Reports*. 2021; 18:4-7; Nakazaki, et al., Discordant lymphomas of classic Hodgkin lymphoma and peripheral T-cell lymphoma following dupilumab treatment for atopic dermatitis. *International Journal of Hematology*. 2022;116:446-452; Poyner, et al., Dupilumab unmasking cutaneous T-cell lymphoma: report of a fatal case. *Clinical and Experimental Dermatology*. 2022;47:974-976; Choo, et al., Angioimmunoblastic T-cell lymphoma unmasked by treatment with dupilumab. *JAAD Case Reports*. 2023;33:87-90; Hamp, et. al., Dupilumab-Associated Sezary Syndrome, *Indian Journal of Dermatology*. 2023;68(4):459-462; Park, et al., Cutaneous T-cell lymphoma following dupilumab use: a systematic review. *International Journal of Dermatology*. 2023; 62:862-876 (collecting and analyzing case studies).

[5] Bozon, et al., Lymphome a grandes cellules ALK1 negatif CD 30+ avec atteintes ganglionnaire et cutanee sous dupilumab. *Annales de Dermatologie et de Vénéréologie.* 2018; 145(12):S272-S273.

48. In 2019, a published case report described rapid progression of mycosis fungoides following nine weeks of use of dupilumab for treatment of atopic eczema.[6]

49. At least 29 studies (case reports, case series and cross-sectional studies) regarding 124 patients who developed lymphoproliferative disorders after dupilumab use had been published by the end of 2024.[7]

50. Following temporary, minimal or no benefit from Dupixent, doctors have observed, inter alia, worsening dermatitis, lymphadenopathy (swollen lymph nodes) and disease progression with rapid tumor growth.[8] Irreversible and aggressive cutaneous lymphoma disease acceleration in previously undiagnosed patients has also been reported.[9]

51. The published medical literature contains multiple documented cases of atopic dermatitis transforming into CTCL in response to dupilumab therapy.[10] Performance of serial histopathologic evaluation of lymphoid infiltrates before and during dupilumab treatment in seven

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[6] Poyner, et al., A case of mycosis fundoides with large cell transformation following dupilumab treatment. *European Journal of Cancer*. 2019;119SI:S42-S43.

[7] Li, et al., Dupilumab-associated lymphoproliferative disorders: a comprehensive review on clinicohistopathologic features and underlying mechanisms. *Current Opinion in Immunology*. 2025; 94:102563.

[8] *E.g.*, Espinosa, et al., Progression of cutaneous T-cell lymphoma after dupilumab: Case review of 7 patients. *J Am Acad Dermatol*. 2020; 83(1):197-199; Hollins, et al., Long-Standing dermatitis treated with dupilumab with subsequent progression to cutaneous T-cell lymphoma. *Cutis*. 2020; 106(2):E8-E11; Umemoto, et al., Dupilumab therapy in Sezary syndrome misdiagnosed as atopic dermatitis: A case report. *J Dermatol*. 2020;47(10); Russomanno, et al., Acceleration of cutaneous T-cell lymphoma following dupilumab administration. *JAAD Case Reports*. 2021;8:83-85; Ahatov, et al., A rare case of aggressive cytotoxic T-cell lymphoma in a patient on dupilumab. *JAAD Case Reports*. 2022; 24:112-114; Amagai, et al., Nodal anaplastic large cell lymphoma with lymphomatoid papulosis following treatment of initially presumed atopic dermatitis with dupilumab: A case report. *Dermatologic Therapy*. 2022;35(3); Hamp, et al., Dupilumab-associated Sezary Syndrome. *Indian J Dermatol*. 2023;68:459-62 (identifying dupilumab as "a catalyst for the progression of SS in this patient"); Malick, et al., Cutaneous T-cell Lymphoma Progression: A Potential Dupilumab Pitfall. *Cureus*. 2023;15(8):e42959.

[9] *E.g.*, Jfri, et al. Diagnosis of mycosis fungoides or Sezary syndrome after dupilumab use: A systematic review. *J Am Acad Dermatol*. 2023; 88(5):1164-1166; Espinosa, et al., Progression of cutaneous T-cell lymphoma after dupilumab: Case review of 7 patients. *J Am Acad Dermatol*. 2020; 83(1):197-199.

[10] Cison, et al., Mycosis fungoides unveiled following dupilumab treatment in a patient with a history of atopic dermatitis. Usefulness of HFUS in monitoring skin features. A review with a case report. *Advances in Dermatology and Allergology*. 2025; 1.

patients demonstrated that dupilumab causes progressive transformation of atopic dermatitis to CTCL.[11]

52. Even well before these published case reports, upon information and belief, dermatologists and oncologists apprised defendants' sales representatives and/or other agents and employees about their observation of and concern about patients developing CTCL after their use of Dupixent.

53. A recent retrospective cohort study from Memorial Sloan Kettering Cancer Center identified 30 patients with dupilumab exposure for atopic dermatitis or eczema followed by confirmed CTCL and two patients with CTCL following use of both Dupixent and the JAKi upadacitinib, but no patients with CTCL following other biologic treatments (JAKi alone or tralokinumab), which the authors noted "challenge[s] the hypothesis that severe chronic AD is the cause of CTCL in patients exposed to dupilumab."[12]

54. A retrospective study performed by researchers from Johns Hopkins University School of Medicine investigated the clinical presentation and outcomes of patients with a documented history of atopic dermatitis who developed CTCL following the use of biologics. These researchers found that patients treated with Dupixent were at a significantly higher risk of advanced-stage CTCL at the time of diagnosis and patients treated with a combination of Dupixent and other biologics were at a significantly higher risk of CTCL progression following initial diagnosis.[13]

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[11] Sokumbi, et al., Evolution of dupilumab-associated cutaneous atypical lymphoid infiltrates. *Am J Dermatopathol*. 2021;43(10):714-20.

[12] Liao, et al., Diagnosis of cutaneous T-cell lymphoma following exposure to biologic agents for atopic dermatitis: A retrospective cohort study from a single tertiary cancer center. *J Am Acad Dermatol*. 2025;92(6):1394-1395.

[13] Fleischli, et al., Abstract #183: Presentation and Outcomes of cutaneous T-cell lymphoma following the use of dupilumab compared to other biologic therapies. 5th World Congress of Cutaneous Lymphomas, April 11-13, 2024. Pasadena, California.

55. Several recent studies investigated the association between dupilumab and the exacerbation of pre-existing CTCL or its development by using a large deidentified electronic health record database (TriNetX) to compare the incidence of CTCL in patients who have used dupilumab with those who have never used it. The first analysis compared atopic dermatitis patients who were prescribed dupilumab to patients who did not use the drug, adjusting for age only. A second analysis was performed which controlled for age, sex, ethnicity and race and excluded patients who had prior usage of a group of disease-modifying antirheumatic drugs which may confound the relationship between dupilumab and CTCL. The study found that patients with atopic dermatitis who were prescribed dupilumab had a four-fold higher risk of developing CTCL (OR 4.1003, 95% confidence interval 2.055-8.192), and a high increased risk remained statistically significant after exclusion of prior disease-modifying antirheumatic drug use (OR 3.202, 95% confidence interval 1.573-6.514).[14]

56. A second study using the TriNetX database compared patients with atopic dermatitis who were treated with dupilumab with those who were treated with alternative therapies and found that patients treated with dupilumab had an almost five-fold statistically significant increased relative risk (RR) of developing CTCL compared to those who never treated with dupilumab (RR = 4.59, 95% confidence interval 2.459-8.657, $P < 0.0001$).[15] These investigators found that the risk of developing CTCL is highest in the first year of therapy with dupilumab and in adult patients.[16]

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[14] Hasan, et al., Dupilumab therapy for atopic dermatitis is associated with increased risk of cutaneous T cell lymphoma: A retrospective cohort study. *J Am Acad Dermatol*. 2024; 91(2):255-258.
[15] Mandel, et al., Increased risk of cutanteous T-cell lymphoma development after dupilumab use for atopic dermatitis. *Dermatol Ther*. 2024:1-8.
[16] *Id.*

57. A third study used the TriNetX database to compare three separate groups of patients (those treated with dupilumab, ruxolitinib and upadacitinib) to atopic dermatitis patients who did not receive that drug. Dupilumab was associated with significant increased odds of CTCL (OR 2.86; 95% CI 1.93-4.22).[17] CTCL odds were not significantly elevated among the groups treated with the JAK inhibitors ruxolitinib (OR 1.70; 95% CI 0.78-3.71) and upadacitinib (OR 1.20; 95% CI 0.52-2.78). These findings are noteworthy given that ruxolitinib and upadacitinib both have boxed warnings regarding lymphomas and other malignancies. The authors concluded: "Our findings reinforce previous reports linking dupilumab to increased CTCL risk in AD patients."

58. The findings from the TriNetX studies "closely align" with a phase 3, 5-year open-label extension study evaluating the long-term safety of dupilumab that was sponsored by Defendants.[18] In that international, multicenter study, three out of 2677 adult patients developed CTCL (mycosis fungoides) and one patient developed T-cell lymphoma as a treatment emergent adverse event.[19] Mycosis fungoides was noted to be one of the 5 most common treatment-emergent adverse events leading to discontinuation of Dupixent in this study.

59. Another recent population-based cohort study using the TriNetX database compared patients with asthma treated with dupilumab with those treated with the combination of inhaled corticosteroids and long-acting beta agonists. After propensity score matching, dupilumab-treated patients were found to have a statistically significantly higher risk of CTCL (HR 5.63, 95%

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[17] Ahmed, et al., Risk of Cutaneous T-cell lymphoma in atopic dermatitis patients treated with dupilumab and JAK inhibitors: a TriNetX cohort study." *Archives of Dermatological Research*. 2026; 318:37.

[18] Hasan, et al., Response to Flynn et al., "Dupilumab therapy for atopic dermatitis is associated with increased risk of cutaneous T cell lymphoma: A retrospective cohort study." *J Am Acad Dermatol*. 2025; e7-e8.

[19] Beck, at al., Dupilumab in adults with moderate to severe atopic dermatitis: a 5-year open-label extension study. *JAMA Dermatol*. 2024; 160:805-812; https://clinicaltrials.gov/study/NCT01949311.

CI 1.16-27.37), Mycosis fungoides and Sezary syndrome (HR 5.79; 95% CI 1.22-27.42), and peripheral T-cell lymphoma (HR 6.14, 95% CI 1.29-29.17).[20]

60. Per the FDA Adverse Event Reporting System (FAERS), Defendants were notified of reports of cutaneous lymphoma in patients injected with Dupixent shortly after they began selling the drug. For example, in 2018 alone, at least 10 reports of cutaneous lymphoma, of which at least 7 were T-cell lymphoma, were reported. By the end of April 2021, at least 64 reports of cutaneous lymphoma, of which 59 were specified as T-cell lymphoma, had been reported.

61. In the following years, a steady stream of CTCL adverse events in patients taking Dupixent continued to flow in. Upon information and belief, over 200 such cases were reported to the Defendants by the end of 2024.

62. Upon information and belief, many of the adverse event reports contained causal attributions to Dupixent use by the reporting physicians.

63. Based on well-established principles, these adverse event numbers vastly underestimate the true number of CTCL events occurring with Dupixent. Additionally, as FDA has made clear in its Guidance to industry, even a single well-documented post-marketing adverse event report can constitute a safety signal requiring action by the manufacturer, including a potential label change, particularly if the report involves an event that is extremely rare in the absence of drug use.

64. Multiple published analyses of the FAERS database of dupilumab-related adverse events reported between 2017 and 2023 found a strong safety signal for CTCL with dupilumab.[21]

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[20] Sheng-Kai Ma, et al., Dupilumab and lymphoma risk among patients with asthma: a population-based cohort study. *Eur Resp J.* 2025; 66:2500139.

[21] Cabrera-Perez, et al., Integrative epidemiology and immunotranscriptomics uncover a risk and potential mechanism for cutaneous lymphoma unmasking or progression with dupilumab therapy. *J. Allergy Clin*

"Compared to other therapies used in AD [atopic dermatitis], dupilumab had the most case reports and the highest RORs [reporting odds ratio] for CTCL."[22] The higher the ROR, the greater the extent to which the reporting of a given adverse event is observed to be disproportionately reported with a given drug.

65. Analysis of the World Health Organization global database of individual case safety reports (VigiBase) found a statistically significant odds ratio of 11.11 (95% confidence interval 6.77-18.23) of CTCL with dupilumab use.[23] This finding indicates that patients were over ten times more likely to report CTCL as an adverse event with Dupixent than other biologic medications between 2008 and 2020.

66. On January 15, 2025, the FDA notified Defendant Regeneron via email that it had identified and begun evaluating a newly identified safety signal (NISS) regarding "dupilumab therapy for atopic dermatitis being associated with increased risk of cutaneious T cell lymphoma" as of December 26, 2024. The FDA further noted that the agency had classified this NISS as a potential risk.

67. On March 31, 2025, the FDA published its quarterly report "Potential Signals of Serious Risks/New Safety Information Identified by the FDA Adverse Event Reporting System

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Immunol. 2025; 155(5):1584-1594; Lavin, et al., Cutaneous T-cell lymphoma after dupilumab use: a real-world pharmacovigilance study of the FDA Adverse Event Reporting System, *Journal of Investigative Dermatology*. 2025; 145:211-214; Gao, et al. Analysis and mining of Dupilumab adverse events based on FAERS database. *Scientific Reports.* 2025;15(1):8597 (finding significant safety signals for CTCL Stage III and CTCL Stage IV). *See also* Zhou, et al., Analysis of differences in dupilumab-associated adverse drug event signals between children and adults based on the FAERS database. *European Journal of Pharmacology* 2025; 1005:178103 (finding "notably high" signal intensity for association between CTCL and dupilumab in adults).

[22] Cabrera-Perez, et al., Integrative epidemiology and immunotranscriptomics uncover a risk and potential mechanism for cutaneous lymphoma unmasking or progression with dupilumab therapy. *J. Allergy Clin Immunol*. 2025; 155(5):1584-1594, at 1592.

[23] Mota, et al, Real-world evidence on the risk of cancer with anti-IL-5 and anti-IL-4Ra biologicals. *Allergy*. 2022;78(5):1375-1377.

(FAERS)" for the 4th quarter of 2024. In this report the FDA listed Dupixent as having a potential signal of serious risk of CTCL based on safety information identified by the FAERS. The FDA noted that it is "evaluating the need for regulatory action."

68. Upon information and belief, physicians who treat patients who have developed CTCL after use of Dupixent have presented their results at national and international conferences, which have been attended by employees of Defendants.

69. Upon information and belief, physicians who have prescribed Dupixent to patients who then were diagnosed with CTCL after use of Dupixent have reported their concern to sales representatives of Defendants.

70. The causal link between dupilumab and CTCL has been found to be biologically plausible. Specifically, dupilumab may cause initiation and/or progression of CTCL via the same mechanism through which it improves atopic dermatitis: the IL-13 receptor blockade which leads to increased IL-13 in the local milieu, driving CTCL stimulation and progression.[24] Dupilumab may also disrupt the equilibrium phase maintained by IL-4 leading to the progression of CTCL by triggering an "escape phase" of tumor cells.[25]

71. The data, analyses and information described in this Complaint that was received prior to Plaintiff's use of Dupixent constitutes newly acquired information pursuant to C.F.R. §

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[24] Cabrera-Perez, et al., Integrative epidemiology and immunotranscriptomics uncover a risk and potential mechanism for cutaneous lymphoma unmasking or progression with dupilumab therapy. *J. Allergy Clin Immunol*. 2025; 155(5):1584-1594, at 1584, 1589-93; Hollins, et al., Long-Standing dermatitis treated with dupilumab with subsequent progression to cutaneous T-cell lymphoma. *Cutis*. 2020; 106(2):E8-E11; Nakazaki, et al., Discordant lymphomas of classic Hodgkin lymphoma and peripheral T-cell lymphoma following dupilumab treatment for atopic dermatitis. *International Journal of Hematology*. 2022;116:446-452.

[25] Guglielmo, et al., Mycosis fungoides and IL-4/13 inhibitors: what is known and unmet needs. *Expert Review of Clinical Immunology*. 2025; 21(6):723-729.

601.12(f)(6), which supported a label change to Dupixent in order to properly warn about CTCL with Dupixent use.

72. Upon information and belief, Defendants have not informed the FDA of all of the newly-acquired, mounting evidence that use of Dupixent results in the development, accelerated progression and/or exacerbation of T-cell lymphoma, including CTCL. Defendants had such newly acquired information at least as early as 2018 upon receipt of multiple adverse event reports of CTCL development and/or rapid progression with use of Dupixent. These reports are a stark contrast from what Defendants reported to the FDA to obtain drug approval.[26]

73. Upon information and belief, at no time did Defendants request permission from the FDA to warn physicians and patients about the newly acquired information related to the development, accelerated progression and/or exacerbation of CTCL with Dupixent use, nor did Defendants use the CBE labeling changes provision to alert physicians and patients of same.

D. Defendants' Failure to Test Dupixent

74. Defendants knew or should have known of the potential of Dupixent to exacerbate or accelerate pre-existing T-cell lymphoma, including CTCL, or increase susceptibility to its development.

[26] Defendants downplayed the risk of CTCL when communicating with the FDA prior to receiving drug approval. For example, Defendants designated mycosis fongoides and cutaneous T-cell dyscrasias as "adverse events of special interest" because "they may be misdiagnosed as chronic AD." Clinical Review, Brenda Carr, MD, at 166, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/761055Orig1s000MedR.pdf; *See also* 11/14/14 CDER Medical Policy Council, Breakthrough Therapy Designation Requests at 1-2 at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/761055Orig1s000OtherR.pdf ("The adverse event of concern with dupilumab is cutaneous T-cell lymphoma (CTCL) reported in one patient on therapy in trial #1225, open label long term. Lymphoma is difficult to diagnosis in these patients. DDDP also noted that CTCL was seen in a placebo patient in the another [sic] trial, 1026, phase 2 sequential ascending dose trial. This patient may have had CTCL when entering the trial. For the patient on study drug, the event seen may regress once the patient is off study drug.").

75. Despite the fact that peer-reviewed case reports, case series, epidemiologic articles and studies emerged providing evidence of the carcinogenic dangers of Dupixent,27 Defendants failed to adequately test Dupixent to investigate the risks, including the potential of exacerbating or accelerating the progression of pre-existing T-cell lymphoma or increasing susceptibility to its development.

76. Defendants did not conduct any experimental carcinogenicity studies of Dupixent in any animal species prior to its approval by FDA for marketing in the United States. Upon information and belief, since receiving approval for marketing in the United States, Defendants still have not conducted any formal testing to evaluate the carcinogenic properties of Dupixent, nor have they conducted any formal testing to identify potential mechanisms through which Dupixent exposure might cause "unmasking" or severe and rapid progression of subclinical CTCL.

E. Defendants' Failure to Warn

73. As case reports, case series, observational studies, and analytical cohort studies evidencing a strong risk of CTCL with Dupixent use accumulated, researchers expressed concern, advised caution and strongly recommended that atopic dermatitis patients undergo multiple skin biopsies to rule out underlying cutaneous malignancy prior to prescribing Dupixent. Furthermore, these clinicians recommended ongoing monitoring and repeat screening through serial biopsies and other means to detect changes in pathology during the course of Dupixent treatment that may be indicative of disease transformation. Additionally, researchers advised healthcare providers to maintain a high degree of clinical suspicion for CTCL when a patient shows signs of non-responsiveness or brief, initial responsiveness to Dupixent treatment followed by exacerbation of

[27] *E.g.*, Hollins, et al., Long-Standing dermatitis treated with dupilumab with subsequent progression to cutaneous T-**cell** lymphoma. *Cutis*. 2020; 106(2):E8-E11.

symptoms. Despite calls from these researchers year after year, Defendants provided no such recommendation to aid in the appropriate screening and monitoring of patients to reduce or eliminate their risk of Dupixent-induced CTCL or Dupixent-induced progression of CTCL.

74. Defendants failed to warn physicians and patients that Dupixent should not be prescribed or administered to patients with confirmed or suspected T-cell lymphoma, including CTCL, and that these diagnoses should be ruled out, by skin biopsies, testing for T-cell receptor gene arrangement, flow cytometry of the blood, or otherwise, prior to Dupixent administration, especially with atypical presentations such as adult-onset atopic dermatitis, patients without personal or familial atopic medical history, and/or erythrodermic and other uncharacteristic presentations like plaques, nodules or sparing flexural sites.[28]

75. Defendants failed to warn physicians and patients that due to the risks of development, acceleration and exacerbation of T-cell lymphoma with dupilumab, careful clinical, histopathologic and immunohistochemical evaluation should be performed before and during treatment with dupilumab.[29] Early detection of CTCL is of critical importance because a delay in diagnosis contributes to disease progression and high risk of mortality.[30]

76. Defendants failed to warn physicians and patients that use of Dupixent in patients with adult-onset atopic dermatitis and no history of atopy may result in development, acceleration

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[28] *See* Mandel, et al., Increased risk of cutaneous T-cell lymphoma development after dupilumab use for atopic dermatitis. *Dermatol Ther*. 2024:1-8; Guitart J, Dupilumab, Atopic Dermatitis, and Mycosis Fungoides-New Insights on an Evolving Story, *JAMA Dermatology*. 2023; 159(11):1177-1178; Guglielmo, et al., Mycosis fungoides and IL-4/13 inhibitors: what is known and unmet needs. *Expert Review of Clinical Immunology*. 2025; 21(6):723-729.

[29] *See* Sokumbi, et al., Evolution of dupilumab-associated cutaneous atypical lymphoid infiltrates. *Am J Dermatopathol*. 2021;43(10):714-20.

[30] Park, et al., Cutaneous T-cell lymphoma following dupilumab use: a systematic review. *International Journal of Dermatology*. 2023; 62:862-876.

and/or exacerbation of CTCL.[31] Defendants failed to warn that these patients should be closely monitored and that multiple biopsies of skin lesions should be performed when clinical improvement is minimal or absent.[32]

77. Defendants failed to warn physicians and patients to diligently monitor disease course via close clinical follow-up after Dupixent initiation for both dupilumab responders and nonresponders.[33] Treaters and patients should have been warned to be on the lookout for inadequate treatment response (including following initial improvement) and/or signs and symptoms of CTCL and to promptly evaluate for T-cell lymphoma following detection of same. Defendants should have warned that signs and symptoms that merit prompt evaluation for T-cell lymphoma in patients on Dupixent with presumed atopic dermatitis include new eczematous plaques in locations different than original sites, worsening pruritus (itching), lymphadenopathy, and new-onset moderate to severe "atopic dermatitis" in the elderly.[34]

78. From its original approval in 2017 to the present, the United States prescribing information for Dupixent has been deficient in that it has failed to provide adequate instructions for its safe prescription and use. At all times relevant hereto, the United States prescribing information for Dupixent has contained (1) no BOXED WARNING advising patients and their healthcare providers of the risk of CTCL or any other form of cancer with Dupixent treatment; (2)

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[31] *See* Hollins, et al., Long-Standing dermatitis treated with dupilumab with subsequent progression to cutaneous T-cell lymphoma. *Cutis*. 2020; 106(2):E8-E11.

[32] Li., et al., Dupilumab-associated lymphoproliferative disorders: a comprehensive review on clinicohistopathologic features and underlying mechanisms. *Current Opinion in Immunology*. 2025: 94:102563.

[33] Park, et al., Cutaneous T-cell lymphoma following dupilumab use: a systematic review. *International Journal of Dermatology*. 2023; 62:862-876; Mandel, et al., Increased risk of cutanteous T-cell lymphoma development after dupilumab use for atopic dermatitis. *Dermatol Ther*. 2024:1-8; Jfri, et al. Diagnosis of mycosis fungoides or Sezary syndrome after dupilumab use: A systematic review. *J Am Acad Dermatol*. 2023; 88(5):1164-1166.

[34] Espinosa, et al., Progression of cutaneous T-cell lymphoma after dupilumab: Case review of 7 patients. *J Am Acad Dermatol*. 2020; 83(1):197-199.

no warnings in section 5, WARNINGS AND PRECAUTIONS, advising patients and their healthcare providers of the risk of CTCL or any other form of cancer with Dupixent treatment; (3) no reference to CTCL in section 6, ADVERSE REACTIONS, advising patients and their healthcare providers that clinically significant CTCL adverse reactions have been reported with the use of Dupixent; (4) no contraindication for use in patients with a history of CTCL or active CTCL; (5) no instructions directing healthcare providers to perform adequate testing of patients (through biopsy or other means) to confirm a clinical diagnosis of atopic dermatitis, particularly in equivocal cases, before commencing treatment with Dupixent; (6) no instructions directing healthcare providers to perform adequate testing of patients (through biopsy, cytometry or other means) to rule out the presence of subclinical or smoldering CTCL before commencing treatment with Dupixent; (7) no instructions directing healthcare providers to perform regular and continuous monitoring during treatment with Dupixent for the development of signs and symptoms of CTCL and repeat biopsies to detect changes in pathologies during treatment with Dupixent consistent with CTCL development; and (8) no instructions directing healthcare providers to discontinue use of Dupixent when a patient exhibits signs of non-responsiveness to treatment or worsening of disease, or otherwise develops signs and symptoms consistent with CTCL.

79. Defendants failed to add the above-referenced information to the United States prescribing information for Dupixent despite sufficient notice of reasonable evidence of a causal association between Dupixent use and CTCL that would have supported inclusion of this information well before Plaintiff's use of Dupixent.

80. Defendants' failure to appropriately revise the United States prescribing information for Dupixent to reflect the clinically important risk of CTCL with Dupixent treatment continued in the face of mounting evidence from postmarketing adverse events, published case reports,

published case studies, descriptive observational studies, analytic cohort studies and disproportionality analyses.

81. The vast body of scientific evidence discussed *supra* establishes that there exists a strong and consistent causal relationship between the use of Dupixent and incident CTCL, to include both new cases of CTCL and rapid exacerbation of subclinical CTCL, which was known or knowable to Defendants at all times relevant hereto. Further, at all times relevant hereto, numerous practical measures to prevent, mitigate and/or reduce the risk of Dupixent-induced CTCL were known or knowable to Defendants.

82. At all times relevant hereto, Defendants were responsible for the content of the United States Prescribing Information for Dupixent.

83. At all times relevant hereto, Defendants were under a duty to advise healthcare providers within Section 5, WARNINGS AND PRECAUTIONS of the United States Prescribing Information for Dupixent, of clinically significant adverse reactions associated with the use of Dupixent, including any that are potentially fatal, that are serious even if infrequent or that can be prevented or mitigated through appropriate use of the drug, along with limitations in use imposed by such reactions. (21 CFR 201.57(c)(6)(i)).

84. At all times relevant hereto, Defendants were under a duty to advise healthcare providers within Section 5, WARNINGS AND PRECAUTIONS of the United States Prescribing Information for Dupixent, of laboratory tests that should be performed before, during and after therapy to follow patient responses or identify possible adverse reactions associated with the use of Dupixent. (21 CFR 201.57(c)(6)(iii)).

85. At all times relevant hereto, Defendants were under a duty to advise healthcare providers within a BOXED WARNING in the United States Prescribing Information for Dupixent,

of clinically significant adverse reactions, particularly those that may lead to death or serious injury, associated with the use of Dupixent. (21 CFR 201.57(c)(1)).

86. At all times relevant hereto, Defendants were under a duty to promptly revise the United States Prescribing Information for Dupixent to add warnings regarding clinically significant hazards as soon as there is reasonable evidence of a causal association with the drug. (21 CFR 201.57(c)(6)(i)). Importantly, however, a causal relationship need not have been definitely established in order to add such a warning to the United States Prescribing Information.

87. At all times relevant hereto, through submitting to the FDA a Changes Being Effected (CBE) Supplement, Defendants had available to them the option to unilaterally add new warnings regarding the risk of CTCL to the United States Prescribing Information for Dupixent reflecting newly-acquired information during the postmarketing period evidencing this clinically significant risk. (21 CFR 314.70(c)).

88. Similarly, through submitting a CBE Supplement to the FDA, Defendants had available to them the option to add new contraindications for use of Dupixent in patients without histopathologically confirmed atopic dermatitis or at risk of developing or experiencing exacerbation of subclinical CTCL and/or to add or strengthen instructions concerning dosage and administration of Dupixent that would serve to increase the safety of its use. (21 CFR 314.70(c)).

89. Notwithstanding, Defendants chose not to undertake any such actions.

90. Further, at all times relevant hereto, Defendants failed to take other reasonable and prudent steps within their capacity, including, but not limited to sending "Dear Healthcare Provider" (DHCP) letters or issuing and disseminating safety alerts, to advise patients and healthcare providers that Dupixent treatment carries a significant risk of CTCL and to convey appropriate mitigation strategies to reduce or eliminate the risk of Dupixent-induced CTCL.

Similarly, Defendants failed to advise patients and healthcare providers of new research evidencing a significant risk of CTCL with Dupixent use through prudent and reasonable means within their capacity.

91. Instead of warning physicians to monitor and test for CTCL before and during use of Dupixent, Defendants' marketing materials and websites for Dupixent expressly advertised: "NO INITIAL LAB TESTING OR ONGOING LAB MONITORING" is required for prescription and treatment with Dupixent.[35]

92. Defendants have aggressively promoted Dupixent as a necessary, life-changing therapy for patients suffering from atopic dermatitis and other inflammatory health conditions in order to drive prescriptions for Dupixent. Defendants have spent billions of dollars on direct-to-consumer advertising depicting Dupixent as being highly safe and effective and capable of greatly improving the quality of patients' lives.

93. Defendants marketed Dupixent in television advertisements, social media, the internet, and print brochures as providing clearer skin, fast itch relief, and better breathing. For patients with eczema, Defendants claim that Dupixent "help[s] heal your skin from within"[36] and "helps you feel the heal and see the difference with less itch and clearer skin."[37] They encouraged patients to "show off your skin."[38] For patients with asthma, Defendants claim that Dupixent

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[35] *E.g.*, https://www.dupixenthcp.com/atopicdermatitis/ (last visited Jan. 16, 2026); *see also* https://www.dupixenthcp.com/eoe/about/frequently-asked-questions (last visited Jan. 16, 2026).

[36] Dupixent Patient Brochure, 2023, Sanofi and Regeneron Pharmaceuticals, Inc., "Stay ahead of eczema with Dupixent"; Dupixent "No Matter What" TV spot, https://www.andrewjeske.com/dupixent; Dupixent "Stay Ahead" TV spot, https://www.ispot.tv/ad/50Bs/dupixent-stay-ahead; Dupixent "Show Off: Pool and Party" TV spot, https://www.ispot.tv/ad/6Jz9/dupixent-show-off-pool-and-party; Dupixent "One Step Ahead" TV spot, https://www.ispot.tv/ad/OGzj/dupixent-one-step-ahead.

[37] *E.g.*, Dupixent Patient Brochure, 2025, Sanofi and Regeneron Pharmaceuticals, Inc., "Dupixent helps you feel the heal and see the difference." *See also* https://www.dupixent.com/atopicdermatitis/.

[38] *E.g.*, Dupixent "Show Off: Pool and Party" TV spot, https://www.ispot.tv/ad/6Jz9/dupixent-show-off-pool-and-party.

"helps people with asthma breathe easier" and will allow them to "get more out of [their] lungs," to "Du [sic] more with less asthma" and "achieve better breathing that lasts."[39] Defendants promote Dupixent as providing "Benefits with every breath."[40] For patients with COPD, Defendants claim that Dupixent is "proven to help reduce flareups so you can do more with less COPD" and that it "helps adults breathe easier starting in as little as two weeks. That could mean more places visited, more dogs walked, more gardens tended, more to look forward to. It's amazing what can happen when you can do more."[41]

94. In their 2024 "Welcome to Dupixent" guide, Defendants claim that "Dupixent acts like a firefighter – it aims to dampen down the fire. It can do this by calming certain immune cells down and making them less active than before."

95. Defendants made repeated representations that Dupixent is safe and effective, including references to "safety results" from clinical trials.[42] Defendants made these false and misleading statements even though they knew Dupixent had lymphoproliferative disorder risks that had not been adequately studied with respect to its effect on the development and progression of T-cell lymphoma, including CTCL.

96. Defendants should have warned patients and prescribers, including Plaintiff and Plaintiff's treating physicians, that use of Dupixent may result in the development or exacerbation of T-cell lymphoma, which can lead to accelerated disease progression and death. Defendants were on notice of these risks from the peer-reviewed literature, reports of adverse events, presentations

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[39] Dupixent TV Spot, "Better Days", https://www.ispot.tv/ad/BTY3/dupixent-asthma-better-days; Dupixent TV Spot, "This is Better: Roller Disco", https://www.ispot.tv/ad/TRbU/dupixent-this-is-better-roller-disco. *See also* https://www.dupixent.com/asthma/.

[40] https://www.dupixent.com/asthma/.

[41] Dupixent TV Spot, "More", https://www.ispot.tv/ad/Tj_6/dupixent-more. *See also* https://www.dupixent.com/copd/.

[42] *E.g.*, Dupixent Patient Brochure, 2025, Sanofi and Regeneron Pharmaceuticals, Inc., "Dupixent helps you feel the heal and see the difference."

at professional conferences, and their own studies.

97. As of the filing of this complaint, Defendants still have failed to implement appropriate labeling revisions to add necessary information regarding the risk of CTCL with Dupixent use or appropriate mitigation strategies to reduce or eliminate the risk of Dupixent-induced or Dupixent-aggravated CTCL.

98. Defendants' ongoing failure to warn, misrepresentations, and omissions, as set forth *supra,* regarding the safety of Dupixent and the risks of development or aggravation of CTCL from same constitute a continuing tort.

PLAINTIFF-SPECIFIC ALLEGATIONS

99. Plaintiff DAVID LUCHSINGER developed a skin rash as an adult. The rash was diagnosed and treated as eczema / atopic dermatitis.

100. Plaintiff DAVID LUCHSINGER was prescribed Dupixent for treatment of his atopic dermatitis in or around October 2024. Plaintiff DAVID LUCHSINGER then self-administered his Dupixent injections until March 2025. Thus, Plaintiff received multiple injections of Dupixent over a five-month period and was repeatedly exposed to the drug.

101. At all relevant times, Defendants represented Dupixent to be appropriate, safe and suitable for such purposes.

102. Plaintiff DAVID LUCHSINGER had not been diagnosed with lymphoma of any kind (including CTCL) prior to initiation of Dupixent.

103. After brief, minor improvement, Plaintiff DAVID LUCHSINGER's skin condition became worse with use of Dupixent.

104. Plaintiff DAVID LUCHSINGER was first diagnosed with CTCL on or about October 3, 2025. Plaintiff has been diagnosed with both Mycosis fungoides based on biopsies on his right inferior upper back and left lateral abdomen.

105. Plaintiff DAVID LUCHSINGER's treatment has included radiation therapy and chemotherapy (including Mechlorethamine, which is derived from the compound in production of mustard gas).

106. Plaintiff's Mycosis fungoides has progressed over time as a result of injection of Dupixent.

107. Plaintiff DAVID LUCHSINGER did not know that his CTCL / Mycosis fungoides was or could have been caused by Defendants until October 2025 when they first learned via internet and/or television advertisements that Dupixent can cause, exacerbate or accelerate CTCL. Prior to October 2025, no healthcare provider suggested to Plaintiff DAVID LUCHSINGER that his CTCL / Mycosis fungoides may have been caused by Dupixent. Plaintiff DAVID LUCHSINGER had no reason to believe that his CTCL had been caused, exacerbated or accelerated by Dupixent until October 2025. Plaintiff DAVID LUCHSINGER had no reason to investigate whether Defendants or Dupixent had caused his CTCL / Mycosis fungoides until October 2025.

108. Defendants failed to timely and adequately warn Plaintiff DAVID LUCHSINGER and his medical providers of the propensity of Dupixent to cause the development or accelerate the progression of CTCL and the need to get appropriate diagnostic tests before initiating Dupixent treatment, despite Defendants' knowledge of same. Defendants also failed to warn Plaintiff DAVID LUCHSINGER and his medical providers to cease use of Dupixent and/or to get

appropriate diagnostic tests to diagnose or rule out CTCL if Dupixent did not improve his condition or if his skin condition became worse while on Dupixent.

109. Defendants' failure to warn resulted in Plaintiff DAVID LUCHSINGER being diagnosed with late-stage CTCL / Mycosis fungoides, which has impeded his treatment alternatives and left him with a grim prognosis.

110. Defendants' Dupixent was at all times utilized and prescribed in a manner foreseeable to Defendants.

111. Plaintiff DAVID LUCHSINGER and Plaintiff DAVID LUCHSINGER's physicians used Dupixent in the manner in which it was intended and recommended to be used and did not misuse or alter Dupixent in an unforeseeable manner, making such use reasonably foreseeable to Defendants.

112. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff DAVID LUCHSINGER and Plaintiff DAVID LUCHSINGER's physicians the true and significant risks associated with Dupixent injections.

113. Due to Defendants' concealment of Dupixent's connection with CTCL, and their failure to warn physicians and patients of this risk, as alleged herein, Plaintiff DAVID LUCHSINGER did not discover and could not reasonably have discovered the connection between Plaintiff DAVID LUCHSINGER's injuries and Dupixent until after the public dissemination of information related to the FDA's posting of a newly identified potential safety signal (NISS) on March 31, 2025.

114. Throughout the relevant period, Plaintiff DAVID LUCHSINGER exercised reasonable diligence by seeking medical care, undergoing diagnostic testing, and following the advice of his treating physicians. Plaintiff DAVID LUCHSINGER further discussed the potential

cause of his CTCL with his treating physicians following his diagnosis and he was not advised of any potential role involving Dupixent by his treating physicians.

115. Plaintiff DAVID LUCHSINGER reasonably relied on Defendants' representations and omissions and the absence of warnings in Dupixent's prescribing information or any other publicly disseminated information in not connecting Plaintiff's CTCL diagnosis with Dupixent until after the public dissemination of information related to the FDA's posting of a newly identified potential safety signal (NISS) on March 31, 2025.

116. Through Defendants' affirmative misrepresentations and/or omissions, Defendants concealed from Plaintiff DAVID LUCHSINGER the causal connection between Dupixent and CTCL.

117. As a result of Defendants' actions, Plaintiff DAVID LUCHSINGER and Plaintiff DAVID LUCHSINGER's physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff DAVID LUCHSINGER would be exposed to the risks identified in this Complaint and that those risks were the direct and proximate result of Defendants' conduct.

118. At the time that Plaintiff DAVID LUCHSINGER was first prescribed Dupixent, Defendants were or should have been on notice that there existed reasonable evidence of a causal association between Dupixent and development and/or progression of CTCL.

119. As a direct and proximate result of the dangerous and defective nature of Dupixent as described herein, Plaintiff DAVID LUCHSINGER suffered and continues to suffer CTCL and resulting severe pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. Plaintiff

DAVID LUCHSINGER's injuries are permanent and he will continue to suffer these losses in the future.

PLAINTIFFS' CLAIMS

COUNT I – STRICT PRODUCT LIABILITY – FAILURE TO WARN
(Against All Defendants)

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

121. At all relevant times, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, distributing, and/or promoting Dupixent and placed Dupixent into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

122. At all relevant times, Dupixent was defective and unreasonably dangerous when it left the possession of Defendants in that it failed to contain warnings of an adequate or sufficient nature as to alert consumers and physicians, including Plaintiff DAVID LUCHSINGER and Plaintiff DAVID LUCHSINGER's healthcare providers, to the dangerous risks associated therewith, including, but not limited, to its propensity to cause serious and permanent injuries including those which Plaintiff DAVID LUCHSINGER sustained. These risks and dangers were known and/or reasonably knowable by Defendants prior to and during the time which Plaintiff DAVID LUCHSINGER was prescribed and ingested Dupixent.

123. Defendants, as manufacturers, distributers, and marketers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks associated with the use of Dupixent were inadequate.

124. Plaintiff DAVID LUCHSINGER and Plaintiff DAVID LUCHSINGER's treating and prescribing physicians did not have the same knowledge as Defendants and no adequate warning was communicated to Plaintiff DAVID LUCHSINGER or to his physicians.

125. Defendants had a duty to provide adequate warnings and instructions for Dupixent and to adequately understand, test, and monitor their product.

126. Defendants had a duty to distribute, market, and/or sell Dupixent with adequate warnings that did not present an unreasonable risk of harm or injury to users who took the drug, including Plaintiff DAVID LUCHSINGER.

127. Defendants had a continuing duty to provide consumers, including Plaintiff DAVID LUCHSINGER and Plaintiff DAVID LUCHSINGER's physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with Dupixent, as it became or could have become available to Defendants.

128. The warnings that accompanied Dupixent and the corresponding Label, Full Prescribing Information, Instructions for Use, and Patient Information were defective, thereby making the product not reasonably safe for its expected, intended, and/or foreseeable uses, functions and purposes.

129. Dupixent and its corresponding Label, Full Prescribing Information, Instructions for Use, and Patient Information were not reasonably safe as distributed, marketed, delivered and/or sold by Defendants.

130. Defendants marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, Dupixent, to health care providers empowered to prescribe and dispense Dupixent, and to consumers, including Plaintiff DAVID LUCHSINGER, without adequate warnings and other clinically relevant information and data. Through both omissions and

affirmative misstatements in its labeling, full prescribing information, instructions for use, patient information, brochures, marketing and promotional materials and advertisements, Defendants misled users, including Plaintiff DAVID LUCHSINGER, and the medical community about the risk and benefit balance of Dupixent, which resulted in injury to Plaintiff.

131. Defendants knew or should have known through testing, scientific knowledge, advances in the field, published research in peer-reviewed journals, or otherwise, that Dupixent created a risk of serious injury, including the development or exacerbation of CTCL, which can lead to accelerated disease progression and death.

132. Despite the fact that Defendants knew or should have known that Dupixent caused unreasonable and dangerous serious injuries, they continued to promote and market Dupixent without providing adequate clinically relevant information and data.

133. Defendants knew or should have known that consumers, including Plaintiff DAVID LUCHSINGER, would foreseeably and needlessly suffer injury as a result of Defendants' failures.

134. The Dupixent supplied to Plaintiff DAVID LUCHSINGER by Defendants was defective, unreasonably dangerous, and had inadequate warnings and instructions at the time it was sold, and Defendants also acquired additional knowledge and information confirming the defective and unreasonably dangerous nature of Dupixent. Despite this knowledge and information, Defendants failed and neglected to issue adequate warnings that Dupixent causes serious injury including the development or exacerbation of CTCL, which can lead to accelerated disease progression and death.

135. Defendants' failure to provide adequate warnings and instructions rendered Dupixent unreasonably dangerous in that it failed to perform as safely as an ordinary patient, prescriber, and/or other consumer would expect when used as intended and/or in a manner

reasonably foreseeable by the Defendants, and in that the risk of danger outweighs the benefits in certain patient populations, including Plaintiff DAVID LUCHSINGER.

136. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiff DAVID LUCHSINGER and Plaintiff DAVID LUCHSINGER's treating physicians.

137. Plaintiff DAVID LUCHSINGER's prescribing physicians, nurse practitioners, and physician assistants (hereinafter collectively referred to as "Plaintiff's Prescribing Healthcare Providers") would not have prescribed Dupixent to Plaintiff DAVID LUCHSINGER or would have ceased injecting it had they been apprised by Defendants of the increased risk of development, exacerbation or acceleration of CTCL in patients similar to Plaintiff, including those who have been diagnosed with adult-onset atopic dermatitis or eczema.

138. Upon information and belief, had they been provided adequate warnings and instructions by Defendants, Plaintiff DAVID LUCHSINGER's Prescribing Healthcare Providers would have administered appropriate testing to rule out CTCL prior to prescribing Dupixent to Plaintiff DAVID LUCHSINGER.

139. Upon information and belief, had they been provided adequate warnings and instructions by Defendants, Plaintiff's Prescribing Healthcare Providers would have performed multiple biopsies and other testing when his clinical improvement with Dupixent was minimal to nonexistent, which would have resulted in earlier detection of Plaintiff's CTCL and allowed time for treatment to occur prior to advancement to late-stage disease.

140. Alternatively, even if Defendants had apprised Plaintiff DAVID LUCHSINGER's Prescribing Healthcare Providers of the increased risk of development, acceleration or exacerbation of CTCL in individuals with Plaintiff DAVID LUCHSINGER's presentation with

usage of Dupixent and these Prescribing Healthcare Providers had still recommended usage of Dupixent to Plaintiff DAVID LUCHSINGER, the Prescribing Healthcare Providers would have relayed the information concerning the increased risk to Plaintiff DAVID LUCHSINGER, and Plaintiff DAVID LUCHSINGER as an objectively prudent person would not have chosen to inject Dupixent, notwithstanding Plaintiff's Prescribing Healthcare Providers' recommendation.

141. Similarly, if Defendants had warned of the increased risk of development, acceleration or exacerbation of CTCL associated with the usage of Dupixent in individuals with Plaintiff DAVID LUCHSINGER's presentation in the Patient Information handout, brochures, marketing and promotional materials and advertisements directed to users like Plaintiff DAVID LUCHSINGER, Plaintiff as an objectively prudent person would not have chosen to take Dupixent, notwithstanding Plaintiff's Prescribing Healthcare Providers' recommendation.

142. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff DAVID LUCHSINGER and Plaintiff DAVID LUCHSINGER's Prescribing Healthcare Providers to the dangerous risks of Dupixent including, among other things, increased risk of the development or exacerbation of CTCL, which can lead to accelerated disease progression and death, and the need to diligently monitor disease course via close clinical follow-up after Dupixent initiation.

143. Defendants failed to provide adequate post-marketing warnings and instructions after Defendants knew or should have known of the significant risks of, among other things, the development or exacerbation of CTCL, which can lead to accelerated disease progression and death.

144. Defendants continued to aggressively promote and sell Dupixent without adequate warnings, even after they knew or should have known of the unreasonable risks of serious injury

including the development or exacerbation of CTCL, which can lead to accelerated disease progression and death from the drug.

145. Defendants had an obligation to provide Plaintiff DAVID LUCHSINGER and Plaintiff DAVID LUCHSINGER's Prescribing Healthcare Providers with adequate clinically relevant information, data and warnings regarding the adverse health risks associated with exposure to Dupixent, and/or that there existed safer and more or equally effective alternative drug products, and/or that diligent monitoring of disease course via close clinical follow-up after Dupixent initiation was necessary.

146. Defendants' failure to adequately test and research harms associated with Dupixent, and Defendants' failure to provide appropriate warnings and instructions about Dupixent use, resulted in patients and the medical community, including Plaintiff DAVID LUCHSINGER's Prescribing Healthcare Providers, being inadequately informed about the true risk-benefit profile of Dupixent and not being sufficiently aware that serious injury and death might be associated with use of Dupixent.

147. The Dupixent designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, even after Defendants knew or should have known of the risks of severe injury and death from Dupixent, Defendants failed to provide adequate warnings to users or consumers of the products, and continued to improperly advertise, market and/or promote Dupixent.

148. Dupixent is defective and unreasonably dangerous to Plaintiff DAVID LUCHSINGER and other consumers regardless of whether Defendants had exercised all possible care in its preparation and sale.

149. The inadequate warnings for Dupixent existed when the drug left the Defendants' control.

150. Dupixent as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff DAVID LUCHSINGER without substantial change in its condition.

151. The foreseeable risk of serious injury caused by Dupixent could have been reduced or avoided by Plaintiff DAVID LUCHSINGER and/or Plaintiff DAVID LUCHSINGER's Prescribing Healthcare Providers had Defendants provided reasonable instructions or warnings of these foreseeable risks of harm.

152. Plaintiff DAVID LUCHSINGER could not, by the exercise of reasonable care, have discovered Dupixent's defects or perceived its dangers or avoided injury.

153. Inadequate warnings, labeling, and instructions accompanying Dupixent received by Plaintiff DAVID LUCHSINGER and Plaintiff DAVID LUCHSINGER's prescribing physicians were a substantial factor in causing Plaintiff's injuries.

154. Defendants concealed the causal relationship between Dupixent and CTCL from Plaintiff DAVID LUCHSINGER and Plaintiff DAVID LUCHSINGER's treating physicians resulting in Plaintiff being unaware of such connection until October 2025.

155. The Defendants are strictly liable for providing inadequate warnings accompanying Dupixent; for the distribution, marketing, and/or sale of Dupixent; and for the injuries sustained by Plaintiff DAVID LUCHSINGER.

156. As a direct and proximate result of Defendants' conduct, including the inadequate warnings, lack of adequate testing and research, and the defective and dangerous nature of Dupixent, Plaintiff DAVID LUCHSINGER suffered CTCL, and resulting severe pain and

suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. Plaintiff DAVID LUCHSINGER's injuries are permanent and he will continue to suffer these losses in the future.

157. Defendants consciously disregarded the increased risks of harm by failing to adequately warn of such risks; unlawfully concealing the dangers associated with Dupixent; and continuing to market, promote, sell, and defend Dupixent.

158. Defendants' acts and omissions as alleged in this Complaint were intentional, oppressive, malicious, reckless, wanton, fraudulent, beyond all standards of decency, and without regard for human life or Plaintiffs' rights, thereby warranting the imposition of punitive damages. Thus, Plaintiffs seek actual and punitive damages according to proof.

COUNT II – NEGLIGENCE
(Against All Defendants)

159. Plaintiffs hereby incorporate by reference paragraphs 1-119 of this Complaint as if fully set forth herein and further allege as follows:

160. At all relevant times, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, distributing, and/or promoting Dupixent for use by consumers, such as Plaintiff DAVID LUCHSINGER.

161. At all times relevant to this action, Defendants had a duty to exercise reasonable care in testing, study, research, formulation, manufacture, labeling, promotion, advertisement, marketing, distribution, and sale of Dupixent for use by consumers, such as Plaintiff DAVID LUCHSINGER.

162. At all times relevant to this action, Defendants owed a duty to consumers,

physicians, and the general public to assess, manage, and communicate the risks, dangers, and adverse effects of Dupixent, and to warn consumers and the medical community, including Plaintiff DAVID LUCHSINGER and Plaintiff DAVID LUCHSINGER's Prescribing Healthcare Providers, of those risks, dangers, and adverse effects.

163. Defendants' duties include, but are not limited to, carefully and properly advertising, analyzing, designing, developing, distributing, formulating, labeling, manufacturing, marketing, promoting, researching, selling, and testing Dupixent, which was placed in the stream of commerce, and providing adequate information regarding the appropriate use of Dupixent.

164. Prior to and during the time frame of Plaintiff DAVID LUCHSINGER's use of Dupixent, Defendants breached these duties, failed to exercise reasonable care, and were grossly negligent and careless in the testing, study, research, manufacture, labeling, promotion, advertisement, marketing, distribution, and sale of Dupixent.

165. At all times material hereto, the Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers associated with Dupixent.

166. Defendants had access to clinical trial and registry data and were aware of complaints that Dupixent caused serious complications including but not limited to the development, exacerbation or acceleration of CTCL.

167. Despite the fact that Defendants knew or should have known that Dupixent posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the drug without revising any warning language.

168. Defendants breached the above-described duties to Plaintiff DAVID LUCHSINGER and failed to exercise due care under the circumstances causing Plaintiff injury,

and their negligence, gross negligence and recklessness includes the following acts and omissions:

a. Negligently failing to properly and adequately test Dupixent before releasing the drug to market;

b. Negligently failing to conduct sufficient post-market testing and surveillance of the drug;

c. Failing to adequately test Dupixent on patients typical of the atopic dermatitis population especially in light of the plan to market precisely to that population of patients;

d. Negligently manufacturing, marketing, advertising, distributing, and selling the drug;

e. Continuing to negligently manufacture and distribute the drug without adequate warnings and instructions after the Defendants knew or should have known of Dupixent's adverse effects;

f. Negligently manufacturing, marketing, advertising, distributing, and selling the drug to consumers, including Plaintiff DAVID LUCHSINGER, without an adequate warning of the dangerous risks of the drug;

g. Negligently failing to notify and warn the public, including Plaintiff, and physicians of reported incidents involving injury and the negative health effects attendant to the use of the drug;

h. Negligently failing to conduct sufficient clinical analysis of Dupixent, which if properly performed would have shown that Dupixent had serious side effects, including but not limited to the increased risks of the development or acceleration of CTCL;

i. Negligently failing to conduct adequate pharmacovigilance and prepare a pharmacovigilance assessment and plan to mitigate the risks of the development or exacerbation of CTCL;

j. Negligently misrepresenting the safety of Dupixent;

k. Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of Dupixent and how to avoid same;

l. Negligently failing to exercise due care in the advertisement and promotion of Dupixent;

m. Negligently disseminating information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the serious risks of Dupixent;

n. Negligently failing to adequately warn Plaintiff DAVID LUCHSINGER's Prescribing Healthcare Providers regarding the increased risks of the development or acceleration of CTCL through various communication vehicles, including Dupixent's labeling, patient medication guides, Dear Healthcare Provider letters, press releases, and other risk communication options;

o. Aggressively and recklessly promoting Dupixent without adequate warnings and instructions even after Defendants knew or should have known of the unreasonable risks from the drug;

p. Negligently diminishing or hiding the risks associated with Dupixent; and

q. Negligently violating applicable state and federal laws and regulations.

164. A reasonable manufacturer, distributor, promoter, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

165. Plaintiff DAVID LUCHSINGER and Plaintiff DAVID LUCHSINGER's Prescribing Healthcare Providers reasonably relied upon the skill, superior knowledge, and judgment of Defendants. Defendants had a continuing duty to warn Plaintiff DAVID LUCHSINGER and his Prescribing Healthcare Providers of the dangers associated with Dupixent. Had Plaintiff DAVID LUCHSINGER and Plaintiff DAVID LUCHSINGER's Prescribing Healthcare Providers received adequate warnings regarding the risks of Dupixent, Plaintiff DAVID LUCHSINGER would not have been prescribed and used the product or would have discontinued use at an earlier date.

166. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff DAVID LUCHSINGER would suffer injuries as a result of Defendants' failure to exercise ordinary care in the testing, labeling, supplying, marketing, selling, advertising, and warning of the risks and dangers of Dupixent, and otherwise distributing the drug.

167. As a direct and proximate result Defendants' negligence, Plaintiff DAVID LUCHSINGER suffered injury, and resulting severe pain and suffering, disability, mental anguish,

loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. Plaintiff DAVID LUCHSINGER's injuries are permanent and he will continue to suffer these losses in the future.

168. Defendants' acts and omissions as alleged in this Complaint were intentional, oppressive, malicious, reckless, wanton, fraudulent, beyond all standards of decency, and without regard for human life or Plaintiffs' rights, thereby warranting the imposition of punitive damages. Thus, Plaintiffs seek actual and punitive damages according to proof.

COUNT III – LOSS OF CONSORTIUM
(Against All Defendants)

169. Plaintiff hereby incorporates by reference paragraphs 1-119 of this Complaint as if fully set forth herein and further allege as follows:

170. As a direct and proximate cause of the carelessness and negligence of the Defendants, as set forth above, the Plaintiff CHERYL LUCHSINGER, as wife of Plaintiff, DAVID LUCHSINGER has suffered consequential damages and has been deprived of her husband's full society, care, comfort, companionship, and has otherwise suffered a loss of consortium. Thus, Plaintiff CHERYL LUCHSINGER seeks actual and punitive damages according to proof.

PRAYER

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendants, and each of them, individually, jointly, and severally, as follows:

1. Judgment in favor of Plaintiffs and against each Defendant, for damages in such amounts as may be proven at trial;

2. Compensation for past and future economic and non-economic losses, including but not limited to medical expenses, pain and suffering, loss of earnings and ability to earn money, mental anguish, and emotional distress, in such amounts as may be proven at trial;

3. Exemplary and punitive damages in an amount to be proven at trial, and sufficient to punish Defendants or to deter Defendants and others from repeating the injurious conduct alleged herein;

4. Pre-judgment and post-judgment interest on the above general and special damages;

5. For Plaintiffs' costs of suit and attorneys' fees herein; and

6. For such other and further relief, whether at law or in equity, to which this Court deems just and proper.

JURY DEMAND

TAKE NOTE that Plaintiff demands trial by jury as to all issues herein.

DATED: February 10, 2026

AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC

/s/ Chelsie Warner
Chelsie Warner, Esq.

Attorney for Plaintiff

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Attorney has complied with LR IA 11-2.