UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

MICHAEL DURKIN,

Plaintiff,

vs.

SANOFI-AVENTIS U.S. LLC; and REGENERON PHARMACEUTICALS, INC.,

Defendants.

Civil Action No.: _____

JURY TRIAL DEMANDED

COMPLAINT

NOW COMES Plaintiff MICHAEL DURKIN ("Plaintiff"), by and through the undersigned attorneys, and bring this action against SANOFI-AVENTIS U.S. LLC and REGENERON PHARMACEUTICALS, INC. (hereinafter, collectively, "Defendants"), for personal injuries suffered as a proximate result of injection of Defendants' prescription drug Dupixent® (dupilumab) (hereinafter "Dupixent" or "dupilumab"), and allege as follows:

I. 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 Michael Durkin. 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 Michael Durkin 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 bring this action for personal injuries suffered as a proximate result of

injection of Defendants' prescription drug Dupixent. Plaintiff seek compensatory damages, punitive damages, and all other available remedies provided to Plaintiff under the law due to the Defendants' negligent, reckless, and wrongful conduct.

II. THE PARTIES

10. Plaintiff Michael Durkin was injected with and physically harmed by the Defendants' product Dupixent.

11. At all relevant times since Michael Durkin's initial injection of Dupixent, Plaintiff was and is a resident and citizen of Cape Coral, Florida, located in Lee County.

12. Plaintiff Michael Durkin was injected with Defendants' Dupixent (dupilumab) product from May 2023 until October 2025. As a direct and proximate result of use of Defendants' Dupixent product, Plaintiff 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. 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.

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 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).

16. 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.

17. 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.

18. 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 Florida. Upon information and belief, Sanofi employs sales representatives throughout Florida and in this District to promote and sell Dupixent.

19. 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.

20. Sanofi-Aventis and Regeneron operate under a global "IO License and Collaboration Agreement." Under this agreement, the companies effectively operate as a joint venture for Dupixent throughout the United States including in the state of Florida. They share profits and losses from Dupixent sales in the U.S. on a 50/50 basis. They jointly oversee the

development, regulatory approval, pharmacovigilance, and commercialization of the drug. Both companies are responsible for the content of the drug's labeling and marketing materials. Therefore, the acts and omissions of one Defendant regarding Dupixent are attributable to the others.

21. 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]

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

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

24. 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 Florida, and generated substantial revenue as a result.

III. JURISDICTION & VENUE

25. This Court has diversity jurisdiction over this action pursuant to 28 U.S.C. § 1332,

[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.

as the amount in controversy exceeds $75,000.00 exclusive of interest and costs and the Parties are citizens of different States.

26. 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.

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

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

29. Defendant Regeneron Pharmaceuticals, Inc. can be served at its registered agent for service of process, CT Corporation System, at 1200 South Pine Island Road, Plantation, Florida 33324.

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

31. Defendant Sanofi-Aventis U.S. LLC can be served at its registered agent for service of process, Corporation Service Company, 1201 Hays Street, Tallahassee, Florida 32301.

IV. FACTUAL BACKGROUND

A. Atopic Dermatitis

32. 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.

33. 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.

34. 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

35. 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]

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

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

38. 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

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

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.

39. 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

40. 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.

41. 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

[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

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.

42. 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.

43. 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]

44. 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]

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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.

[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.

45. 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]

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

47. 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.

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[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.

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

48. 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]

49. 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]

50. 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

[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.

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]

51. 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]

52. 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."

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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.*
[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.

53. 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.

54. 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% 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]

55. 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.

[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.
[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.

56. 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.

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

58. 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.

59. 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] "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.

[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 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.

60. 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.

61. 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.

62. 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 (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."

63. 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.

64. 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.

[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.

65. 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]

66. 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. § 601.12(f)(6), which supported a label change to Dupixent in order to properly warn about CTCL with Dupixent use.

67. 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]

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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.

[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*

68. 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

70. 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.

71. 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.

72. 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, Defendant 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

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.").

[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.

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 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]

[28] *See* Mandel, et al., Increased risk of cutanteous 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,

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 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.

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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.

[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.

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) 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

[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.

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.

[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).

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 "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,

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[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.

[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/.

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 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.

V. FACTS SPECIFIC TO PLAINTIFF

99. Plaintiff developed a skin rash as an adult, with an eight-year history of chronic recurrent dermatitis reported as of May 2023. The rash was diagnosed and treated as eczema and atopic dermatitis. Prior treatments included various topical steroids such as clobetasol, triamcinolone, and halobetasol, as well as pimecrolimus and intramuscular Kenalog.

100. Plaintiff was prescribed Dupixent for the treatment of his atopic dermatitis in or

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

around May 2023. Plaintiff received an initial loading dose consisting of two 300 mg injections on May 26, 2023, during which he was trained by a nurse on self-administration. Following this, he was prescribed 300 mg injections to be self-administered every two weeks. Plaintiff continued regular use of Dupixent through at least October 2025, receiving repeated exposure to the drug over a period of more than two years.

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

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

103. Specifically, Plaintiff underwent skin biopsies twice prior to his CTCL diagnosis. On February 5, 2019, prior to initiation of Dupixent therapy, a biopsy was performed which showed subacute spongiotic dermatitis. On July 26, 2024, a subsequent biopsy was performed while Plaintiff was using Dupixent, which specifically ruled out CTCL at that time, reporting negative results for TCR-gamma and TCR-beta studies.

104. After brief improvement following the initial dose, Plaintiff's skin condition persisted and later flared. By February 2024, while still on Dupixent, he reported a flare-up and developed new systemic symptoms including fatigue and joint pain.

105. Plaintiff was first diagnosed with CTCL on or about October 9, 2025. A biopsy of a lesion on his right proximal dorsal forearm confirmed Cutaneous T-Cell Lymphoma, Mycosis Fungoides type, patch stage.

106. Plaintiff's treatment has included phototherapy (nbUVB), and following the failure of Dupixent and topical steroids, he was transitioned to other systemic treatments including Rinvoq in January 2026.

107. Plaintiff did not know that his CTCL was or could have been caused by Defendants until October 2025 when he 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 that his CTCL may have been caused by Dupixent. Plaintiff had no reason to believe that his CTCL had been caused, exacerbated or accelerated by Dupixent until October 2025. Plaintiff had no reason to investigate whether Defendants or Dupixent had caused his CTCL until October 2025.

108. Defendants failed to timely and adequately warn Plaintiff 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 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' Dupixent was at all times utilized and prescribed in a manner foreseeable to Defendants.

110. Plaintiff and Plaintiff'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.

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

112. 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 did not discover and

could not reasonably have discovered the connection between Plaintiff Michael Durkin'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.

113. Throughout the relevant period, Plaintiff exercised reasonable diligence by seeking medical care, undergoing diagnostic testing, and following the advice of her treating physicians. Plaintiff further discussed the potential cause of her CTCL with her treating physicians following her diagnosis and she was not advised of any potential role involving Dupixent by her treating physicians.

114. Plaintiff 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 his 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.

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

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

117. At the time that Plaintiff 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.

118. As a direct and proximate result of the dangerous and defective nature of Dupixent

as described herein, Plaintiff 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's injuries are permanent and he will continue to suffer these losses in the future.

VI. CAUSES OF ACTION

FIRST CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN
Against All Defendants

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

120. 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.

121. 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 and Plaintiff'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 sustained. These risks and dangers were known and/or reasonably knowable by Defendants prior to and during the time which Plaintiff was prescribed and ingested Dupixent.

122. 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.

123. Plaintiff and Plaintiff's treating and prescribing physicians did not have the same knowledge as Defendants and no adequate warning was communicated to Plaintiff or to her physicians.

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

125. 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.

126. Defendants had a continuing duty to provide consumers, including Plaintiff and Plaintiff'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.

127. 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.

128. 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.

129. 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, 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, and the medical community about the risk and benefit balance of Dupixent, which resulted in injury to Plaintiff.

130. 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.

131. 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.

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

133. The Dupixent supplied to Plaintiff 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.

134. 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.

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

136. Plaintiff'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 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.

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

138. 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 her 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.

139. Alternatively, even if Defendants had apprised Plaintiff's Prescribing Healthcare Providers of the increased risk of development, acceleration or exacerbation of CTCL in individuals with Plaintiff's presentation with usage of Dupixent and these Prescribing Healthcare

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

140. 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's presentation in the Patient Information handout, brochures, marketing and promotional materials and advertisements directed to users like Plaintiff, Plaintiff as an objectively prudent person would not have chosen to take Dupixent, notwithstanding Plaintiff's Prescribing Healthcare Providers' recommendation.

141. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiff'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.

142. 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.

143. 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.

144. Defendants had an obligation to provide Plaintiff and Plaintiff'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.

145. 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'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.

146. 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.

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

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

149. Dupixent as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, promoted, advertised, marketed, distributed, and/or sold by Defendants reached

Plaintiff without substantial change in its condition.

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

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

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

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

154. 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.

155. 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 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's injuries are permanent and she will continue to suffer these losses in the future.

156. 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.

SECOND CAUSE OF ACTION
NEGLIGENCE
Against All Defendants

157. Plaintiff hereby incorporates by reference Sections I through V of this Complaint as if fully set forth herein and further allege as follows:

158. 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.

159. 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.

160. 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 and Plaintiff's Prescribing Healthcare Providers, of those risks, dangers, and adverse effects.

161. 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.

162. Prior to and during the time frame of Plaintiff'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.

163. 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.

164. 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.

165. 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.

166. Defendants breached the above-described duties to Plaintiff 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, 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'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 and Plaintiff's Prescribing Healthcare Providers reasonably relied upon the

skill, superior knowledge, and judgment of Defendants. Defendants had a continuing duty to warn Plaintiff and her Prescribing Healthcare Providers of the dangers associated with Dupixent. Had Plaintiff and Plaintiff's Prescribing Healthcare Providers received adequate warnings regarding the risks of Dupixent, Plaintiff 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 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 of one or more of the above-stated acts, omissions, and conduct committed by the Defendants, Plaintiff 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's injuries are permanent and she will continue to suffer these losses in the future.

THIRD CAUSE OF ACTION
BREACH OF POST-MARKET DUTY TO WARN
Against All Defendants

168. Plaintiff hereby incorporates by reference Sections I through V of this Complaint as if fully set forth herein and further allege as follows:

169. Defendants are engaged in the business of selling or otherwise distributing Dupixent and have a duty to provide a warning after the time of sale or distribution for defects they reasonably become aware of or should have become aware of after the sale.

170. After the sale of Dupixent to Plaintiff, Defendants knew or reasonably should have

known that the drug posed a substantial risk of harm—specifically the risk of T-cell Lymphoma—based on internal data, published literature, and adverse event reports.

171. Plaintiff, Plaintiff's physicians, and others to whom a warning might be provided could be identified and could reasonably be assumed to be unaware of this specific carcinogenic risk.

172. Defendants could have easily and effectively communicated to Plaintiff and prescribing physicians through "Dear Healthcare Provider" letters, label updates, or direct patient notification.

173. Defendants failed to provide such warnings after the time of sale, including but not limited to:

a. Failing to issue a "Dear Healthcare Provider" letter warning of the acceleration risk;

b. Failing to update the label to include a "Black Box" warning regarding lymphoma and/or CTCL and its subtypes; and

c. Failing to notify the FDA of the true extent of the safety signal.

174. As a direct and proximate cause of Defendants' negligent failure to provide a Post-Sale warning, Plaintiff sustained injuries and damages as described above.

FOURTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION
Against All Defendants

175. Plaintiff hereby incorporates by reference Sections I through V of this Complaint as if fully set forth herein and further allege as follows:

176. Defendants owed a duty to prescribing physicians, other healthcare providers, and to consumers of Dupixent to accurately and truthfully represent the risks of the drug.

177. Defendants made statements to Plaintiff's physicians and the medical community

concerning material facts regarding Dupixent which Defendants knew were false, or believed to be true but were in fact false, including:

a. Representing that Dupixent was "safe" and did not carry the cancer risks of older immunosuppressants;

b. Representing that Dupixent was a "targeted" therapy that did not broadly suppress the immune system; and

c. Failing to disclose that the drug blocks the IL-13R alpha 1 receptor while leaving the tumor-promoting IL-13R alpha 2 receptor uninhibited.

178. Defendants failed to exercise reasonable care or competence in obtaining and communicating the information supplied for the guidance of others.

179. Plaintiff and Plaintiff's prescribing physician justifiably relied upon the information provided by Defendants.

180. As a direct and proximate result of Defendants' false information and misrepresentations, Plaintiff sustained injuries and damages as described above.

FIFTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
Against All Defendants

181. Plaintiff hereby incorporates by reference Sections I through V of this Complaint as if fully set forth herein and further allege as follows:

182. Defendants expressly warranted that Dupixent was a safe and effective biologic medication.

183. As set forth in greater detail throughout this Complaint, Defendants made express representations and warranties, including but not limited to:

a. That Dupixent had a superior safety profile compared to traditional

immunosuppressants;

b. That Dupixent helps patients "heal from within" and targets only the inflammatory pathway; and

c. That routine blood monitoring for malignancy was unnecessary.

184. At the time Defendants manufactured, marketed, sold, and/or distributed Dupixent, they knew that the drug was intended for human use and that Plaintiff was a foreseeable user.

185. The express warranties were a part of the basis for Plaintiff's use of Dupixent, and Plaintiff relied on these warranties in deciding to use the drug.

186. Dupixent did not conform to these express representations because it carried a latent, high-risk potential for causing or accelerating fatal T-cell malignancies.

187. As a direct and proximate cause of Defendants' breach of express warranties, Plaintiff sustained injuries and damages as described above.

SIX CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY
Against All Defendants

188. Plaintiff hereby incorporates by reference Sections I through V of this Complaint as if fully set forth herein and further allege as follows:

189. Defendants impliedly warranted, through their marketing, advertising, and sales representatives, that Dupixent was of merchantable quality and fit for the ordinary purposes and uses for which it was sold (the safe treatment of atopic dermatitis).

190. In fact, Dupixent was not of merchantable quality nor fit for the ordinary purposes for which it was sold.

191. Dupixent was not fit for its ordinary purpose because it posed an unreasonable risk of causing a life-threatening injury (CTCL) when used as directed for a non-life-threatening

condition (atopic dermatitis).

192. Plaintiff and/or Plaintiff's physician reasonably relied upon the skill and judgment of Defendants.

193. As a direct and proximate cause of Defendants' breach of implied warranties, Plaintiff sustained injuries and damages.

SEVENTH CAUSE OF ACTION
VIOLATION OF FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT
Against all Defendants

194. Plaintiff hereby incorporates by reference Sections I through V of this Complaint as if fully set forth herein and further allege as follows:

195. This cause of action is brought pursuant to the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, *et seq.* ("FDUTPA").

196. At all times relevant hereto, Plaintiff was a "consumer" within the meaning of Fla. Stat. § 501.203(7), and Defendants were engaged in "trade or commerce" within the meaning of Fla. Stat. § 501.203(8).

197. The acts by Defendants in this cause of action include, but are not limited to, the following unfair, unconscionable, or deceptive acts or practices:

a. Representing Dupixent as safe and effective while knowing those claims were false and without sufficient medical support regarding long-term cancer risk;

b. Representing Dupixent to be of a higher quality and safety profile than other available alternatives (e.g., JAK inhibitors);

c. Failing to disclose adequate information about the safety and efficacy of Dupixent either before or after Plaintiff's prescription;

d. Knowingly providing inadequate warnings about the drug's dangerous

propensity to accelerate lymphoma;

e. Failing to inform Plaintiff and the public of the risk of injury after being informed of the massive safety signal (PRR 30.0) in the FAERS database;

f. Failing to report knowledge of adverse events (atopic dermatitis patients developing CTCL) to the FDA and the public; and

g. Doing all of the above with the sole intent of selling more prescriptions and creating demand for their blockbuster franchise.

198. The above acts constitute unfair and deceptive trade practices because they constitute false, unfair, misleading, and deceptive conduct that not only creates the likelihood of confusion but also the inherent capacity to deceive consumers.

199. Defendants' conduct offends established public policy and is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers.

200. As a direct and proximate result of Defendants' violations of FDUTPA, Plaintiff has suffered actual damages, including the purchase price of the drug, medical expenses, and other economic losses.

201. Plaintiff is entitled to recover actual damages, attorneys' fees, and costs pursuant to Fla. Stat. §§ 501.211(2) and 501.2105.

EIGHTH CAUSE OF ACTION
PUNITIVE DAMAGES
Against All Defendants

202. Plaintiff hereby incorporates by reference Sections I through V of this Complaint as if fully set forth herein and further allege as follows:

203. Defendants have engaged in aggressive and reckless marketing efforts, including highlighting the lack of a requirement for initial laboratory testing and ongoing laboratory

monitoring as a favorable attribute of Dupixent in promotional materials to physicians and patients despite the fact that such testing was necessary to avoid serious adverse health outcomes, such as Plaintiff's CTCL, and this was known or knowable to Defendants.

204. Defendants have engaged in marketing efforts seeking to induce healthcare providers to switch their patients from other medications to Dupixent despite lacking the necessary evidence to demonstrate that Dupixent is safe and effective in the adult-onset atopic dermatitis population and despite affirmative evidence that the drug is not safe in this patient population.

205. Defendants have engaged in marketing efforts seeking to induce healthcare providers to prescribe Dupixent to their patients without first obtaining diagnostic confirmation of an underlying indicated health condition.

206. Defendants have engaged in marketing efforts seeking to induce patients to specifically request a prescription of Dupixent from their healthcare provider when its use is not necessary.

207. Defendants have intentionally misled healthcare providers and the general public in making superiority claims for Dupixent as compared to other medications despite possessing the knowledge that these claims are false.

208. Defendants have intentionally failed to properly warn healthcare providers about the true risk of CTCL related to Dupixent use despite possessing knowledge that Dupixent causes these serious adverse events.

209. Defendants' actions were willful and malicious in that Defendants' conduct was carried on with a conscious disregard for the safety and rights of Plaintiff. Defendants' unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendants in an amount appropriate to punish Defendants, and deter similar conduct in

the future.

210. As a direct and proximate result of the defective and dangerous nature of Dupixent, Plaintiff 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. The losses are permanent, and Plaintiff will continue to suffer the losses in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment in his favor and against Defendants, and each of them, individually, jointly, and severally, as follows:

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

b. 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, loss of consortium and emotional distress, in such amounts as may be proven at trial;

c. Treble damages as may be awarded under the Florida Deceptive and Unfair Trade Practices Act in an amount to be proven at trial;

d. 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;

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

f. Costs of this suit and attorneys' fees; and

g. Any and all other relief, both legal and equitable, that the Court may deem just and proper.

PLAINTIFF DEMANDS A TRIAL BY JURY OF ALL ISSUES SO TRIABLE.

Dated: February 4, 2026

Respectfully Submitted,

FARR LAW FIRM P.A.

/s/ George T. Williamson
George T. Williamson
FL Bar: 85585
99 Nesbit Street
Punta Gorda, Florida 33950
(941) 639-1158
(941) 639-0028 (Facsimile)
gwilliamson@farr.com

Attorney for Plaintiff

JS 44 (Rev. 08/18)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Michael Durkin

(b) County of Residence of First Listed Plaintiff Lee
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Farr Law Firm P.A., 99 Nesbit Street, Punta Gorda, FL 33950

DEFENDANTS

Sanofi-Aventis U.S. LLC, et al.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
Diversity 28 USC 1332

Brief description of cause:
Dupixent pharmaceutical product liability action

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE
02/04/2026

SIGNATURE OF ATTORNEY OF RECORD
/s/ George T. Williamson

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Florida

MICHAEL DURKIN

Plaintiff(s)

v.

SANOFI-AVENTIS U.S. LLC; and REGENERON PHARMACEUTICALS, INC.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Sanofi-Aventis U.S. LLC
c/o Corporation Service Company
1201 Hays Street
Tallahassee, Florida 32301

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

George T. Williamson
Farr Law Firm P.A.
99 Nesbit Street
Punta Gorda, FL 33950
gwilliamson@farr.com
(941) 639-1158

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: 02/04/2026

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Florida

MICHAEL DURKIN

Plaintiff(s)

v.

SANOFI-AVENTIS U.S. LLC; and REGENERON PHARMACEUTICALS, INC.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Regeneron Pharmaceuticals, Inc.
c/o CT Corporation System
1200 South Pine Island Road
Plantation, Florida 33324

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

George T. Williamson
Farr Law Firm P.A.
99 Nesbit Street
Punta Gorda, FL 33950
gwilliamson@farr.com
(941) 639-1158

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: 02/04/2026

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: