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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

ANTHONY BAUM AND JEANETTE BAUM, Plaintiffs, vs. **REGENERON PHARMACEUTICALS, INC.; and SANOFI-AVENTIS U.S. LLC,** Defendants.	**COMPLAINT AND DEMAND FOR JURY TRIAL** **Civil Action No.: _____**

COMPLAINT

Plaintiffs Anthony Baum and Jeanette Baum, by and through the undersigned attorneys, bring this action against REGENERON PHARMACEUTICALS, INC. and SANOFI-AVENTIS U.S. LLC (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:

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® (hereinafter "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. Defendants misrepresented that Dupixent was a safe and effective treatment for atopic dermatitis, COPD, asthma, and other inflammatory health conditions when in fact the drug causes T-cell lymphoma and/or triggers a reaction leading to severe and rapid clinical progression of otherwise subclinical and undiagnosed T-cell lymphoma.

4. Defendants failed to warn physicians and the public about Dupixent's propensity to cause T-cell lymphoma or rapidly exacerbate subclinical T-cell lymphoma.

5. Dupixent caused the development and/or aggravation of peripheral T-cell lymphoma (PTCL) in Anthony Baum.

6. PTCL is a rare, aggressive type of non-Hodgkin lymphoma that originates from mature T-cells and natural killer (NK) cells.

7. 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 PTCL and CTCL.

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

9. 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 exacerbation of T-cell lymphoma. The U.S. label for Dupixent makes no mention of these risks.

10. 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.

11. Plaintiffs bring this action for personal injuries suffered as a proximate result of injection of Defendants' prescription drug Dupixent. Plaintiffs accordingly seek compensatory damages and all other available remedies provided to Plaintiffs under the law due to the Defendants' negligent, reckless, and wrongful conduct.

THE PARTIES

12. Plaintiff Anthony Baum was injected with and physically harmed by the Defendants' product Dupixent.

13. At all relevant times since Anthony Baum's initial injection of Dupixent, Plaintiffs were and are residents and citizens of Grayslake, Illinois located in Lake County.

14. Plaintiff was injected with Defendants' Dupixent (dupilumab) product in March and April 2022 on at least four occasions. 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 PTCL and loss of enjoyment of life.

15. 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.

16. 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.

17. 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).

18. 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.

19. 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.

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

21. 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.

22. Defendants jointly developed, manufactured, marketed and distributed Dupixent throughout the United States including the state of Illinois.

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

24. 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 $18.3 billion in 2025.[2]

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

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

27. At all times relevant to this action, Defendants tested, studied, researched, designed, formulated, developed, manufactured, inspected, labeled, packaged, promoted, advertised,

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

[2] https://firstwordpharma.com/story/5952354; https://finance.yahoo.com/news/dupixent-sales-spur-sanofi-growth-165640339.html; https://www.fiercepharma.com/pharma/sanofi-and-regenerons-dupixent-course-inflection-year-copd; https://investor.regeneron.com/news-releases/news-release-details/regeneron-reports-fourth-quarter-and-full-year-2023-financial; https://investor.regeneron.com/news-releases/news-release-details/regeneron-reports-third-quarter-2025-financial-and-operating; https://global.pharmcube.com/news/detail/f2590817763848dd808d006a9ba62820?type=dailyNews.

marketed, distributed, and/or sold Dupixent worldwide and throughout the United States, including in and throughout the state of Illinios, and generated substantial revenue as a result.

JURISDICTION & VENUE

28. This Court has diversity jurisdiction over this action pursuant to 28 U.S.C. § 1332, as the amount in controversy exceeds $75,000.00 exclusive of interest and costs and the Parties are citizens of different States.

29. 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.

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

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

32. Defendant Regeneron Pharmaceuticals, Inc. can be served at its registered agent for service of process, CT Corporation System, at 208 South LaSalle Street, Suite 814, Chicago, IL 60604-1101.

33. Defendant Sanofi-Aventis U.S. LLC can be served at its registered agent for service of process, Corporate Service Company, 251 Little Falls Drive, Wilmington, DE 19808.

FACTUAL BACKGROUND

A. Atopic Dermatitis

34. 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.

35. Atopic dermatitis, also known as atopic 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.

B. Dupixent

36. Dupixent (dupilumab) is a biologic medication – a human monoclonal antibody – that 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]

37. 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.

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

39. 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 PTCL or CTCL. Nor did Defendants use the "changes being effected" ("CBE") labeling changes provision of 21 C.F.R. § 314.70(c)(6)(iii)(A), (C); 21 C.F.R § 314.3(b) to add or strengthen the warning and precautions

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

or adverse reactions sections of the Dupixent label to alert patients and physicians of these increased dangers of Dupixent.

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

C. Dangers of Dupixent: T-cell Lymphoma

41. Shortly after Dupixent was released to the market, concerned independent clinical and academic physicians began publishing case reports and case series linking dupilumab use with T-cell lymphoma, including CTCL and PTCL.[4] The reports have increased over time and have included diagnoses of new, primary T-cell lymphoma as well as an unexpected "unmasking" or severe and rapid clinical progression of otherwise subclinical and undiagnosed T-cell lymphoma occurring weeks to years following initiation of Dupixent use. This large and growing body of research has expanded to cohort studies, cross-sectional studies and analyses of postmarketing adverse events.

[4] *E.g.*, Yoo, et al., Three cases of new diagnosis of mycosis fungoides following commencement on biologic therapies for presumed psoriasis/eczema. *European Journal of Cancer*. 2019; 119SI:S41; Tran, et al., Development of Sezary syndrome following the administration of dupilumab. *Dermatol Online J*. 2020; 26(4); Hollins, et al., Long-Standing dermatitis treated with dupilumab with subsequent progression to cutaneous T-cell lymphoma. *Cutis*. 2020; 106(2):E8-E11; Du-Thanh, et al., Lethal anaplastic large-cell lymphoma occurring in a patient treated with dupilumab. *JAAD Case Reports*. 2021; 18:4-7; Nakazaki, et al., Discordant lymphomas of classic Hodgkin lymphoma and peripheral T-cell lymphoma following dupilumab treatment for atopic dermatitis. *International Journal of Hematology*. 2022;116:446-452; Poyner, et al., Dupilumab unmasking cutaneous T-cell lymphoma: report of a fatal case. *Clinical and Experimental Dermatology*. 2022;47:974-976; Choo, et al., Angioimmunoblastic T-cell lymphoma unmasked by treatment with dupilumab. *JAAD Case Reports*. 2023;33:87-90; Hamp, et. al., Dupilumab-Associated Sezary Syndrome, *Indian Journal of Dermatology*. 2023;68(4):459-462; Park, et al., Cutaneous T-cell lymphoma following dupilumab use: a systematic review. *International Journal of Dermatology*. 2023; 62:862-876 (collecting and analyzing case studies); Amatore, et al., Cutaneous T-cell lymphomas and dupilumab for atopic dermatitis: A systematic review and expert consensus. *J Eur Acad Dermatol Venereol*. 2026; 00:1-15 (systematic review of 51 studies including data from 547 patients).

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]

45. Following temporary, minimal or no benefit from Dupixent, doctors have observed, *inter alia*, worsening dermatitis, lymphadenopathy (swollen lymph nodes) and disease progression

[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] Poynew, 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.

with rapid tumor growth.[8] Irreversible and aggressive 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 T-cell lymphoma after their use of Dupixent.

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

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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.

confirmed CTCL, but no patients with CTCL following other biologic treatments (JAKi and 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 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. In the first study, the first analysis compared atopic dermatitis patients who were prescribed dupilumab to patients who did not use the drug, adjusting for age only. A second analysis was performed which controlled for age, sex, ethnicity and race and excluded patients who had prior usage of a group of disease-modifying antirheumatic drugs which may confound the relationship between dupilumab and CTCL. The study found that patients with atopic dermatitis who were prescribed dupilumab had a four-fold higher risk of developing CTCL (OR 4.1003, 95% confidence interval 2.055-8.192), and a high increased risk remained statistically

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[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, Pennsylvania.

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 by a different group of scientists 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 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. In February 2026, researchers from the University of California San Diego published the results of a retrospective single-center cohort study examining CTCL risk in relation to Dupixent use for all indications.[21] Electronic health records maintained in the University of California San Diego Health system were used to identify patients with (n=1,374) or without (n=1,249,409) a history of Dupixent treatment and to ascertain incident cases of CTCL among groups, defined by diagnosis codes for Mycosis fungoides or Sezary syndrome. Using

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[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. In addition, two patients developed Hodgkin's disease and one patient developed Hodgkin's disease lymphocyte predominance type state III. 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.

[21] Baghdasarian S, et al., Dupilumab and Cutaneous T-Cell Lymphoma: A Retrospective Cohort Study. *JAAD International* (2026).

multivariable logistic regression models to adjust for age, sex, race, baseline atopic dermatitis, pain, rash, history of cutaneous squamous cell carcinoma and protocolized follow-up, these researchers found that Dupixent use was associated with 87% increased odds of CTCL (OR 1.87; 95% CI 1.08-3.23; p=0.025) compared to non-use. History of atopic dermatitis was not significantly associated with CTCL. The authors recommended vigilant baseline assessment and ongoing monitoring when initiating Dupixent, advising that physicians should exercise a low threshold for biopsy in atypical or refractory cases of atopic dermatitis and perform interval reassessments during Dupixent therapy.

56. 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. And in the first four months of 2019, Defendants received at least four more adverse event reports of CTCL in patients treated with Dupixent. 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.

57. In the following years, a steady stream of T-cell lymphome 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. 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 T-cell lymphoma 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.[22] "Compared to other therapies used in AD [atopic dermatitis], dupilumab had the most case reports and the highest RORs [reporting odds ratio] for CTCL."[23] 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.

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.[24] 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"

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[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; 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).

[23] 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.

[24] 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.

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. The causal link between dupilumab and T-cell lymphoma has been found to be biologically plausible. Specifically, dupilumab may cause initiation and/or progression of CTCL and PTCL 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 T-cell lymphoma stimulation and progression.[25] Dupilumab may also disrupt the equilibrium phase maintained by IL-4 leading to the progression of T-cell lymphoma by triggering an "escape phase" of tumor cells.[26]

64. 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 T-cell lymphoma with Dupixent use.

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[25] 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.

[26] *See* 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.

65. 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 PTCL and CTCL. Defendants had such newly acquired information at least as early as 2018 upon receipt of multiple adverse event reports of T-cell lymphoma 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.[27]

66. 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 T-cell lymphoma, including PTCL and 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

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

68. Despite the fact that peer-reviewed case reports, case series, epidemiologic articles

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

and studies emerged providing evidence of the carcinogenic dangers of Dupixent,[28] 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.

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

E. Defendants' Failure to Warn

70. As case reports, case series, observational studies, and analytical cohort studies evidencing a strong risk of T-cell lymphoma with Dupixent use accumulated, researchers expressed concern, advised caution and strongly recommended that atopic dermatitis patients undergo multiple skin biopsies to rule out underlying 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 T-cell lymphoma 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,

[28] *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.

Defendants provided no such recommendation to aid in the appropriate screening and monitoring of patients to reduce or eliminate their risk of Dupixent-induced T-cell lymphoma or Dupixent-induced progression of T-cell lymphoma.

71. Despite multiple peer-reviewed publications and Defendants' knowledge of adverse events, Defendants continued to manufacture, promote, advertise, market and distribute Dupixent without alerting prescribers or patients in labeling, marketing materials, product inserts or otherwise of the increased risks of serious injury, including development or accelerated progression of CTCL, from use of Dupixent.

72. On the contrary, Defendants, via their retained consultants, actually advocated for *increased* usage of Dupixent when the FDA-approved dosing regimen proved inadequate to relieve symptoms of atopic dermatitis.[29]

73. 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 PTCL, 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.[30]

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[29] *E.g.*, Hendricks, et al., Management Recommendations for Dupilumab Partial and Non-durable Responders in Atopic Dermatitis. *Am J Clin Dermatol*. 2019;20(4):565- 569 (Defendants' paid consultants Peter A. Lio, M.D. and Vivian Y. Shi, M.D. (along with Aleski Hentricks) recommending more aggressive prescribing of Dupixent, including increased dosages, increased dosing frequency and the addition of immunosuppressive agents to existing Dupixent regimens, in circumstances when patients exhibit an inadequate or incomplete response to Dupixent treatment).

[30] *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, et al., Mycosis fungoides and IL-4/13 inhibitors: what is known and unmet needs. *Expert Review of Clinical*

74. 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.[31] Early detection of T-cell lymphoma is of critical importance because a delay in diagnosis contributes to disease progression and high risk of mortality.[32]

75. 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 T-cell lymphoma.[33] 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.[34]

76. 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.[35] Treaters and patients should have been warned to be on the lookout for inadequate treatment response (including following initial improvement) and/or signs and

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Immunology. 2025; 21(6):723-729; Amatore, et al., Cutaneous T-cell lymphomas and dupilumab for atopic dermatitis: A systematic review and expert consensus. *J Eur Acad Dermatol Venereol.* 2026; 00:1-15.

[31] *See* Sokumbi, et al., Evolution of dupilumab-associated cutaneous atypical lymphoid infiltrates. *Am J Dermatopathol*. 2021;43(10):714-20; Amatore, et al., Cutaneous T-cell lymphomas and dupilumab for atopic dermatitis: A systematic review and expert consensus. *J Eur Acad Dermatol Venereol.* 2026; 00:1-15.

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

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

[34] Li., et al., Dupilumab-associated lymphoproliferative disorders: a comprehensive review on clinicohistopathologic features and underlying mechanisms. *Current Opinion in Immunology*. 2025: 94:102563; Amatore, et al., Cutaneous T-cell lymphomas and dupilumab for atopic dermatitis: A systematic review and expert consensus. *J Eur Acad Dermatol Venereol.* 2026; 00:1-15.

[35] 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.

symptoms of CTCL or PTCL and to promptly evaluate for T-cell lymphoma following detection of same. Defendants should have warned that signs and symptoms that merit prompt evaluation for T-cell lymphoma in patients on Dupixent with presumed atopic dermatitis include new eczematous plaques in locations different than original sites, worsening pruritus (itching), lymphadenopathy, and new-onset moderate to severe "atopic dermatitis" in the elderly.[36]

77. 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, PTCL, 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, PTCL, or any other form of cancer with Dupixent treatment; (3) no reference to CTCL or PTCL in section 6, ADVERSE REACTIONS, advising patients and their healthcare providers that clinically significant CTCL and PTCL adverse reactions have been reported with the use of Dupixent; (4) no contraindication for use in patients with a history of T-cell lymphoma or active T-cell lymphoma; (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 T-cell lymphoma before commencing treatment with Dupixent; (7) no instructions directing healthcare providers to perform regular and continuous

[36] 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.

monitoring during treatment with Dupixent for the development of signs and symptoms of T-cell lymphoma and repeat biopsies to detect changes in pathologies during treatment with Dupixent consistent with T-cell lymphoma 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 or PTCL.

78. 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 T-cell lymphoma that would have supported inclusion of this information well before Plaintiff's use of Dupixent.

79. Defendants' failure to appropriately revise the United States prescribing information for Dupixent to reflect the clinically important risk of T-cell lymphoma, including CTCL and PTCL, 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.

80. 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 T-cell lymphoma, to include both new cases of T-cell lymphoma and rapid exacerbation of subclinical T-cell lymphoma, 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 T-cell lymphoma were known or knowable to Defendants.

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

82. 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)).

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 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)).

84. 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)).

85. 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.

86. 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 T-cell lymphoma, including CTCL and PTCL, 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)).

87. 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 T-cell lymphoma 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)).

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

89. 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 T-cell lymphoma, including CTCL and PTCL, and to convey appropriate mitigation strategies to reduce or eliminate the risk of same. Similarly, Defendants failed to advise patients and healthcare providers of new research evidencing a significant risk of T-cell lymphoma, including CTCL and PTCL, with Dupixent use through prudent and reasonable means within their capacity.

90. Instead of warning physicians to monitor and test for T-cell lymphoma, including CTCL and PTCL, 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.[37]

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[37] *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). Atopic dermatitis clinical treatment guidelines funded by Defendants have similarly touted "[n]o laboratory

91. Defendants have aggressively promoted Dupixent as a necessary, life-changing therapy for patients suffering from atopic dermatitis, asthma, COPD 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.

92. Defendants have heavily 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"[38] and "helps you feel the heal and see the difference with less itch and clearer skin."[39] They encouraged patients to "show off your skin."[40] For patients with asthma, Defendants claim that Dupixent "helps people with asthma breath 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."[41] Defendants promote Dupixent as providing "Benefits with every breath."[42] 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 breath easier starting in as little as two weeks. That could

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monitoring is required before initiation or during treatment" with Dupixent. *E.g.*, Simpson, et al., When does atopic dermatitis warrant systemic therapy? Recommendations from an expert panel of the International Eczema Council. *J Am Acad Dermatol*. 2017;77(4):623-633.

[38] 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.

[39] *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/.

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

[41] 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/.

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

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."[43]

93. 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."

94. Defendants made repeated representations that Dupixent is safe and effective, including references to "safety results" from clinical trials.[44] 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 and PTCL.

95. 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.

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

FACTS SPECIFIC TO PLAINTIFF

97. On or about January 18, 2022, Plaintiff presented to his dermatologist, Dr. Jason B.

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

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

Waldinger, with itching all over, which started in late 2021. Plaintiff also had a rash on his back at that time.

98. After biopsy, Plaintiff was diagnosed with eczema.

99. Plaintiff had no prior history of atopic dermatitis or eczema.

100. Plaintiff was prescribed Dupixent for treatment of his eczema. Plaintiff received two injections of Dupixent on March 9, 2022. Per his doctor's instructions, Plaintiff self-administrered three more doses, the last of which was on April 20, 2022.

101. Plaintiff developed enlarged lymph nodes after taking Dupixent. Plaintiff did not have swelling of his lymph nodes prior to taking Dupixent.

102. In approximately May 2022 Plaintiff was diagnosed with PTCL. Plaintiff was initially diagnosed with angioimmunoblastic T-cell lymphoma (AITL), a type of peripheral T-cell lymphoma, by physicians at Northshore University HealthSystem. Plaintiff was subsequenetly treated by physicians at Northwestern who revised his diagnosis to PTCL.

103. Plaintiff's prescribing dermatologist Dr. Jason B. Waldinger explained in a May 24, 2022 message to Plaintiff Anthony Baum that he "would not continue with the Dupilumab/Dupixent injections any more because the best strategy to treat the itching is to treat the lymphoma."

104. At all relevant times, Defendants represented Dupixent to be appropriate, safe and suitable for the purposes for which it was prescribed to Plaintiff.

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

106. Plaintiff's treatment for his PTCL has included chemotherapy and a stem cell transplant. Plaintiff has suffered complications as a result of his stem cell transplant, including

graft vs. host disease (GvHD) and COPD incited by GvHD.

107. Plaintiffs did not know that Plaintiff Anthony Baum's PTCL was or could have been wrongfully caused until March 2025 when Plainitff Jeanette Baum first discovered a medical article that had been published about her husband without Plaintiffs' knowledge.

108. Plaintiffs believe that the patient discussed in Choo, et al., Angioimmunoblastic T-cell lymphoma unmasked by treatment with dupilumab. *JAAD Case Reports*. 2023;33:87-90 is Anthony Baum. Plaintiffs were not aware of the existence of this publication until Jeanette Baum found it on the internet in March 2025. None of the authors nor any of Plainitff's treating physicians alerted Plainitffs to this article or the contents thereof.

109. At or around the time of Anthony Baum's diagnosis with PTCL, Plaintiffs pointed out to Dr. Waldinger that Mr. Baum's lymph nodes swelled after starting Dupixent. Dr. Waldinger communicated to Plaintiffs at that time that he did not believe that Plaintiff's lymphoma was related to Dupixent.

110. Prior to March 2025, no healthcare provider suggested to Plaintiffs that Anthony Baum's PTCL might have been caused or exacerbated by Dupixent. In fact, Dr. Waldinger denied this.

111. At or around the time of Mr. Baum's diagnosis with PTCL, Plaintiff Jeanette Baum called Defendants to report what had happened to her husband after taking Dupixent. She asked whether swollen lymph nodes were a reaction to Dupixent and was told that there is no record of this having happened before.

112. 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 T-cell lymphoma, especially in individuals with adult-onset eczema, 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 T-cell lymphoma if Dupixent did not improve his condition, if his skin condition became worse while on Dupixent, or if he developed lymphadenopathy.

113. Defendants' failure to warn resulted in Plaintiff being diagnosed with and/or the accelerated progression of PTCL.

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

115. 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.

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

117. As a result of Defendants' actions, Plaintiffs 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.

118. 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 T-cell lymphoma.

119. As a direct and proximate result of the Defendants' wrongful actions and inactions

and the dangerous and defective nature of Dupixent as described herein, Plaintiff sustained and continues to sustain severe physical and emotional injuries, loss of capacity for enjoyment of life, aggravation and exacerbation of preexisting conditions, mental and physical pain and suffering, disability, past and future lost wages and loss of earning capacity, and cost of medical, hospital and other care and treatment. Plaintiff's injuries are permanent and he will continue to suffer these losses in the future.

CAUSES OF ACTION

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

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

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

122. 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. Plaintiffs 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 his 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 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 T-cell lymphoma, 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 T-cell lymphoma, 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.

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 T-cell lymphoma 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 T-cell lymphoma 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 biopsies and other testing when his clinical improvement with Dupixent was minimal to nonexistent, which would have resulted in earlier detection of Plaintiff's PTCL.

139. Alternatively, even if Defendants had apprised Plaintiff's Prescribing Healthcare Providers of the increased risk of development, acceleration or exacerbation of T-cell lymphoma in indivdiuals 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 T-cell lymphoma 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 T-cell lymphoma, 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 T-cell lymphoma, 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 T-cell lymphoma, 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. By failing to adequately test and research harms associated with Dupixent, and by

failing to provide appropriate warnings and instructions about Dupixent use, patients and the medical community, including Plaintiff's Prescribing Healthcare Providers, were inadequately informed about the true risk-benefit profile of Dupixent and were not 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. The 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 prescribers 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. 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.

154. 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 sustained serious bodily injuries 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 continuing, and Plaintiff will suffer the losses in the future.

155. 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

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

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

158. 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, to ensure that use of Dupixent did not result in avoidable injuries.

159. 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.

160. 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.

161. 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, inspection, labeling, promotion, advertisement, marketing, distribution, and sale of Dupixent.

162. 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.

163. 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 T-cell lymphoma.

164. 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.

165. Defendants breached the above-described duties to Plaintiff and failed to exercise due care under the circumstances causing Plaintiff injury, and Defendants' negligence, gross negligence and recklessness includes the following acts and omissions:

a. Failing in their obligation to provide consumers and the medical community, including Plaintiff and Plaintiff's Prescribing Healthcare Providers, with accurate, adequate and clinically relevant information, data and warnings regarding the risk of T-cell lymphoma, including PTCL and CTCL, associated with use of Dupixent, and/or that there existed safer alternative pharmaceutical drugs to treat Plaintiff's condition(s);

b. Failing to properly and adequately test Dupixent before releasing the drug to market;

c. Failing to continually monitor, test, and analyze data regarding safety, efficacy, and the prescribing practices for Dupixent;

d. failing to conduct adequate post-marketing studies, non-clinical and clinical testing, and post-marketing surveillance and analyses to determine and subsequently communicate the safety profile and side effects associated with the use of Dupixent;

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

f. 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;

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

h. Failing to notify and warn the public and the medical community, including Plaintiff and Plaintiff's prescribing and treating physicians, of reported adverse drug events involving T-cell lymphoma, including CTCL and PTCL;

i. 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 T-cell lymphoma;

j. Failing to conduct adequate pharmacovigilance and prepare a pharmacovigilance assessment and plan to mitigate the risks of the development or exacerbation of T-cell lymphoma, including CTCL and PTCL;

k. Misrepresenting the safety of Dupixent in labeling, advertising, package inserts, promotional materials and other marketing resources and materials including but not limited to making claims of safety which misleadingly implied that Dupixent had been adequately evaluated for its carcinogenic potential;

l. Failing to provide warnings, instructions or other safety information that accurately reflected the risks of Dupixent and how to avoid same, including but not limited to the following:

i. failure to include a BOXED WARNING advising patients and their healthcare providers of the risk of T-cell lymphoma, including CTCL and PTCL, with Dupixent treatment;
ii. failure to include warnings in section 5, WARNINGS AND PRECAUTIONS, advising patients and their healthcare providers of the risk of T-cell lymphoma, including CTCL and PTCL, with Dupixent treatment;
iii. failure to reference to T-cell lymphoma, including CTCL and PTCL, in section 6, ADVERSE REACTIONS, advising patients and their healthcare providers that clinically significant T-cell lymphoma adverse reactions have been reported with the use of Dupixent;
iv. failure to include a contraindication for use in patients with a history of T-cell lymphoma, including CTCL and PTCL, or active T-cell lymphoma, including CTCL and PTCL;
v. failure to include 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 T-cell lymphoma before commencing treatment with Dupixent;
vi. failure to include instructions directing healthcare providers to perform regular and continuous monitoring during treatment with Dupixent for the development of signs and symptoms of T-cell lymphoma and repeat biopsies to detect changes in pathologies during treatment with Dupixent consistent with T-cell lymphoma development; and
vii. failure to include 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 T-cell lymphoma, including CTCL and PTCL.

m. Failing to provide adequate post-marketing warnings and instructions after Defendants knew or should have known of the significant risks of serious adverse events and/or reactions, including, but not limited to an increased risk of T-cell lymphoma, including CTCL and PTCL, associated with use of Dupixent;

n. Failing to exercise ordinary care in the advertisement and promotion of Dupixent;

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

p. Failing to adequately warn Plaintiff's Prescribing Healthcare Providers regarding the increased risks of the development or acceleration of T-cell lymphoma, including CTCL and PTCL, through various communication vehicles, including Dupixent's labeling, patient medication guides, Dear Healthcare Provider letters, press releases, and other risk communication options;

q. 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;

r. Downplaying, diminishing or hiding the risks associated with Dupixent, even after Defendants knew or should have known of the significant risks of Dupixent use; and

s. Violating applicable state and federal laws and regulations.

166. A reasonably prudent drug manufacturer, distributor, promoter, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

167. Defendants had a post-sale duty to warn physicians, including Plaintiff's Prescribing Healthcare Providers, and consumers, including Plaintiff, about the potential risks and complications associated with use of Dupixent.

168. Plaintiff and Plaintiff's Prescribing Healthcare Providers reasonably relied upon the

skill, superior knowledge, and judgment of Defendants. 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.

169. Defendants knew and/or should have known that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the testing, labeling, supplying, marketing, distributing, selling, advertising, and warning of the risks and dangers of Dupixent, as described herein.

170. As a direct and proximate result of one or more of the above-stated acts, omissions, and conduct committed by the Defendants, Plaintiff sustained serious bodily injuries 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.

THIRD CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION
Against All Defendants

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

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

173. Defendants owed a duty to prescribing physicians, other healthcare providers and to consumers of Dupixent, including Plaintiff, to accurately and truthfully represent the risks of the drug. Defendants breached their duty by misrepresenting the safety and known risks of Dupixent

and/or by failing to adequately warn Plaintiff's prescribing physicians, the medical community, Plaintiff, and the public about the risks of Dupixent, including that use of Dupixent results in increased risk of the development or exacerbation of T-cell lymphoma in individuals with presentations similar to Plaintiff, which Defendants knew or in the exercise of diligence should have known.

174. The Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of Dupixent knew, or reasonably should have known, that health care professionals and consumers of Dupixent would rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of prescribing and using the drug.

175. The Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of Dupixent knew, or reasonably should have known, that patients using Dupixent would suffer from the development or exacerbation of T-cell lymphoma including CTCL and PTCL because the information disseminated by Defendants and relied upon by health care professionals and consumers, including Plaintiff and Plaintiff's Prescribing Healthcare Providers, was materially inaccurate, misleading, or otherwise false.

176. The Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the risks of Dupixent was accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers, including via advertising campaigns, labeling materials, print advertisements, social media and commercial media, that was materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

177. Among Defendants' numerous misrepresentations and misleading omissions were

Defendants' assurances that Dupixent was safe and effective, that it would "heal your skin from within," that it would allow patients to "du [sic] more," and that it woud provide "benefits with every breath."

178. Despite their knowledge of serious problems with Dupixent, Defendants continued to market Dupixent, present at conferences, and distribute medical literature, studies, and other communications to the medical community in an effort to mislead them and the general public about the risks associated with Dupixent and instead create the image and impression that Dupixent was safe for all patients.

179. Defendants made such statements even after they became aware of serious complications with Dupixent. Defendants did not reveal (and instead concealed) their knowledge of serious complications and other bad data.

180. Defendants made these representations with the intent to induce reliance thereon, and to encourage prescribing and using Dupixent.

181. Defendants knew or should have known that Plaintiff, Plaintiff's Prescribing Healthcare Providers, and the general medical community did not have the ability to determine the true facts which were intentionally and/or negligently concealed and misrepresented by the Defendants.

182. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiff's Prescribing Healthcare Providers were induced to, and did, prescribe and use Dupixent, thereby causing Plaintiff to suffer severe personal injuries.

183. Plaintiff and Plaintiff's Prescribing Healthcare Providers would not have used or prescribed Dupixent had the true facts not been concealed by the Defendants.

184. Defendants had sole access to many of the material facts concerning the defective

nature of Dupixent and its propensity to cause serious and dangerous side effects.

185. During the time frame that Plaintiff was prescribed and took Dupixent, Plaintiff and Plaintiff's Prescribing Healthcare Providers were unaware of Defendants' negligent misrepresentations and omissions.

186. The misrepresentations made by Defendants, in fact, were false and known by Defendants to be false at the time the misrepresentations were made.

187. Defendants failed to exercise ordinary care in making their representations concerning Dupixent.

188. Plaintiff and Plaintiff's Prescribing Healthcare Providers reasonably relied upon the misrepresentations and omissions made by the Defendants.

189. Plaintiff's and Plaintiff's Prescribing Healthcare Providers' reliance on the above-described misrepresentations and omissions was the direct and proximate cause of Plaintiff's injuries.

190. As a direct and proximate result of reliance upon Defendants' negligent misrepresentations and omissions, Plaintiff sustained serious bodily injuries 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 either permanent or continuing, and Plaintiff will suffer the losses in the future. Plaintiff's injuries are permanent and he will continue to suffer these losses in the future.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
Against All Defendants

191. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint

as if fully set forth herein and further allege as follows:

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

193. Defendants expressly warranted to Plaintiff, Plaintiff's healthcare providers, and the general public, by and through Defendants and/or their authorized agents or sales representatives, in publications, labeling, the internet, advertisements, social media, brochures and other communications intended for physicians, patients, Plaintiff, and the general public, that Dupixent was safe, effective, fit and proper for its intended use.

194. As set forth above, Defendants warranted that Dupixent would "heal your skin from within," that it "helps you feel the heal and see the difference with less itch and clearer skin," that it would allow patients to "du [sic] more," and that it would provide "benefits with every breath."

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

196. At the time of the making of the express warranties, Defendants had knowledge of the purpose for which Dupixent was to be used and warrantied the same to be in all respects safe, effective and proper for such purpose.

197. Dupixent materially failed to conform to those representations made by Defendants, in package inserts, advertisements, and otherwise, concerning the properties and effects of Dupixent, which Plaintiff purchased and injected in direct or indirect reliance upon these express representations. Such failures by Defendants constituted a material breach of express warranties

made, directly or indirectly, to Plaintiff and Plaintiff's healthcare providers concerning the Dupixent sold to Plaintiff.

198. Defendants expressly warranted that Dupixent was safe and effective. However, Defendants did not have adequate proof upon which to base such representations, and, in fact, knew or should have known that Dupixent was dangerous to the well-being of Plaintiff and others.

199. Dupixent does not conform to those express representations because it is defective, is not safe, and has serious adverse side effects.

200. Plaintiff and Plaintiff's physicians justifiably relied on Defendants' representations regarding the safety and effectiveness of Dupixent, and Defendants' representations became part of the basis of the bargain.

201. Plaintiff and Plaintiff's healthcare providers justifiably relied on Defendants' representations that Dupixent was safe and effective in their decision to ultimately prescribe, purchase and use the drug.

202. Plaintiff's Prescribing Healthcare Providers justifiably relied on Defendants' representations through Defendants' marketing and sales representatives in deciding to prescribe Dupixent over other alternative treatments on the market, and Plaintiff justifiably relied on Defendants' representations in deciding to purchase and use the drug.

203. Plaintiff's Prescribing Healthcare Providers prescribed, and Plaintiff used, Dupixent for its intended purpose, and in a reasonable, foreseeable manner.

204. Plaintiff purchased and injected Dupixent without knowing that the drug is not safe or effective, but that Dupixent instead causes the development, exacerbation or acceleration of T-cell lymphoma.

205. The Dupixent manufactured and sold by Defendants did not conform to Defendants'

express representations because the Dupixent caused serious injury to Plaintiff when used as recommended and directed.

206. As a direct and proximate result of Defendants' breaches of express warranties, Plaintiff sustained serious bodily injuries 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.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY
Against All Defendants

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

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

209. Defendants were the sellers of Dupixent and sold Dupixent to be injected for treatment of atopic dermatitis. Plaintiff was prescribed and purchased Dupixent for this intended purpose.

210. When the Dupixent was prescribed by Plaintiff's Prescribing Healthcare Providers and taken by Plaintiff, the product was being prescribed and used for the ordinary purpose for which it was intended.

211. Defendants impliedly warranted, through their marketing, advertising, distributors and sales representatives, that Dupixent was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

212. In fact, Dupixent was not of merchantable quality nor fit for the ordinary purposes and uses for which it was sold and did not meet the expectations of consumers.

213. The Dupixent manufactured and supplied by Defendants was not of merchantable quality and was not fit for the ordinary and/or particular purpose for which it was intended as physicians and patients would expect the drug to not cause the development or accelerated progression of T-cell lymphoma.

214. Plaintiff and Plaintiff's Prescribing Healthcare Providers reasonably and justifiably relied upon the skill and judgment of Defendants as to whether Dupixent was of merchantable quality and safe for its intended and particular use and purpose.

215. Contrary to such implied warranties, Dupixent was not of merchantable quality or safe for its intended and particular use and purpose, because the drug causes the development and/or accelerated progression of T-cell lymphoma.

216. Defendants' breach of their implied warranties resulted in Plaintiff being prescribed and using Dupixent, which placed Plaintiff's health and safety at risk and resulted in the damages alleged herein.

217. As a direct and proximate result of Defendants' acts and omissions, including breach of implied warranties, Plaintiff was prescribed and injected with Dupixent and sustained serious bodily injuries 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.

SIXTH CAUSE OF ACTION
LOSS OF CONSORTIUM
Against All Defendants

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

219. At all relevant times, Plaintiff Jeanette Baum was and is the lawfully wedded wife of Plaintiff Anthony Baum, and as such, was and is entitled to the services, consortium, and society of Plaintiff Anthony Baum.

220. As a result of the defective nature of Dupixent and the tortious conduct of Defendants, Plaintiff Jeanette Baum was deprived of the services, consortium, and society of Plaintiff Anthony Baum.

221. As a direct and proximate result of Defendants' wrongful conduct as described herein, whether through strict liability or negligence, Plaintiff Jeanette Baum has suffered and will continue to suffer the loss of support, companionship, service, love, affection, society, intimate relations, and other elements of consortium all to the detriment of their marital relationship for which Plaintiff Jeanette Baum is entitled to compensatory damages in an amount to be proven at trial

PRAYER FOR RELIEF

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

a. Judgment in favor of Plaintiffs and against each Defendant, for damages in such amounts as may be proven at trial as determined by the jury in its discretion after hearing the evidence;

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 and emotional distress, and loss of consortium, in an amount in excess of the jurisdictional limits of this court and as determined by the jury in its discretion after hearing the evidence at trial;

c. Attorneys' fees and costs;

d. Interest; and

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

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury on all counts and as to all issues.

Dated: April 2, 2026 Respectfully Submitted,

/s/ Robin Greenwald
Robin Greenwald, Esq. (Ill Bar # 6183798)
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