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Attorneys for Plaintiff ANDREW ZAIKIS

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ANDREW ZAIKIS

Plaintiff,

v.

REGENERON PHARMACEUTICALS, INC.,
AND SANOFI-AVENTIS U.S. LLC

Defendants.

Civil Action No. 3:26-cv-8509

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Andrew Zaikis, by and through the undersigned attorneys, brings this action against REGENERON PHARMACEUTICALS, INC., and SANOFI-AVENTIS U.S. LLC (collectively, “Defendants”), for personal injuries suffered as a proximate result of injection of Defendants’ prescription drug Dupixent (dupilumab), and alleges 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-name prescription drug Dupixent® (“Dupixent”).

2. Defendants manufactured, promoted, and sold Dupixent as a biologic medication for the treatment of multiple conditions, including atopic dermatitis (“AD”), asthma, nasal polyps, and other inflammatory diseases of the skin and respiratory tract in adult and pediatric patients. Dupixent is 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 the patient’s age and body weight.

3. Dupixent caused the development, acceleration, and/or aggravation of cutaneous T-cell lymphoma (“CTCL”) in Andrew Zaikis. CTCL is a rare type of cancer that affects white blood cells called T cells, or T lymphocytes. T cells help the body’s immune system to fight germs. T-cell lymphomas are a subtype of non-Hodgkin lymphoma (“NHL”).

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

5. Defendants knew or should have known that Dupixent, when taken as prescribed

and intended, causes and/or exacerbates T-cell lymphoma, including CTCL.

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

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

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

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

PARTIES

10. Plaintiff Andrew Zaikis was injected with and physically harmed by the Defendants' product Dupixent.

11. At all relevant times since Mr. Zaikis's initial injection of Dupixent, Plaintiff was and is a resident and citizen of Vineyard Haven, Massachusetts.

12. Plaintiff was injected with Defendants' Dupixent product. As a direct and proximate result of use of Defendants' Dupixent product, Plaintiff incurred and continues to incur medical expenses, and suffered and continues to suffer severe pain and physical and emotional injuries, including the development and/or acceleration and exacerbation of CTCL and loss of enjoyment of life.

13. Defendant Regeneron Pharmaceuticals, Inc. (“Regeneron”) is and was at all times relevant hereto a corporation organized under the laws of the state of New York with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

14. Defendant Sanofi-Aventis U.S. LLC (“Sanofi-Aventis”) is and was at all times relevant hereto a limited liability company organized 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 S.A., a French multinational corporation (“Sanofi”).

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

16. Regeneron subsequently submitted and obtained approval of multiple supplemental BLAs to expand the indications for Dupixent to AD in pediatric patients; to asthma, chronic rhinosinusitis with nasal polyps (“CRSwNP”), and eosinophilic esophagitis (“EoE”) in adult and pediatric patients; and to prurigo nodularis (“PN”) and chronic obstructive pulmonary disease (“COPD”) in adult patients.

17. Regeneron is the current official sponsor of the BLA for Dupixent in the United States, and thus maintains significant responsibility and control over the drug and all activities and materials relating thereto. Regeneron has been substantively involved in the development and sale of Dupixent and the design, funding, conduct, authorship, publication, and dissemination of scientific research and promotional messaging related to Dupixent and the indications for which Dupixent has received approval to treat.

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

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

JURISDICTION AND VENUE

20. This court has diversity jurisdiction over this action pursuant to 28 U.S.C. § 1332, as the amount in controversy exceeds \$75,000 and the Parties are citizens of different states.

21. 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, Sanofi-Aventis had and has its principal place of business in this District, and both Defendants conducted substantial business in this District related to Dupixent.

22. Each Defendant purposefully availed itself of the privilege of conducting activities in New Jersey, such as marketing, promoting, distributing, and selling its products (including Dupixent) in New Jersey.

23. Regeneron is registered to do business in New Jersey and established an agent to receive service of process in New Jersey, and is therefore amenable to suit on any claim in New Jersey.

24. Regeneron can be served at its registered agent for service of process, CT Corporation System, at 820 Bear Tavern Road, West Trenton, NJ 08628.

25. Sanofi-Aventis can be served at its registered agent for service of process, Corporation Service Company, at Princeton South Corporate Center, Suite 160, 100 Charles Ewing Blvd., Ewing, NJ 08628.

FACTUAL BACKGROUND

A. Chronic Rhinosinusitis with Nasal Polyps

26. Dupixent was initially developed and approved to treat moderate to severe AD when topical treatments are not sufficient or appropriate. Since then, it has been approved to treat multiple additional conditions, such as CRSwNP in patients whose disease is not controlled.

27. Like AD, CRSwNP is a chronic inflammatory disease characterized by upregulation of the type 2 immune response.

B. Dupixent

28. Dupixent is a top-selling, blockbuster drug and a flagship product of both Sanofi-Aventis and Regeneron.¹ Sales of Dupixent were \$14.1 billion in 2021 and at or above \$4 billion per quarter for the first two quarters of 2025.²

29. Dupixent (dupilumab) is a biologic medication – i.e., a specialty medication made inside living cells and designed to target specific parts of the immune system involved in a particular disease. It 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

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-sanofigrowth-165640339.html>; <https://www.fiercepharma.com/pharma/sanofi-and-regenerons-dupixent-course-inflection-year-copd>.

complexes.³

30. Dupixent is now indicated for the treatment of multiple conditions, including AD, asthma, CRSwNP, and EoE in adult and pediatric patients, and for the treatment of PN and COPD in adult patients.

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

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

C. Dangers of Dupixent: CTCL

33. Shortly after Dupixent was released to the market, concerned clinical and academic physicians began publishing case reports and case series linking dupilumab use with T-cell lymphoma such as CTCL (including mycosis fungoides and Sezary syndrome).⁴ At least 29

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

⁴ See, e.g., 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; Choo, et al., Angioimmunoblastic T-cell lymphoma unmasked by treatment with dupilumab. *JAAD Case Reports.* 2023;33:87-90; Hamp, et. al., Dupilumab-Associated

studies regarding 124 patients who developed lymphoproliferative disorders after dupilumab use have been published.⁵

34. Following temporary, minimal, or no benefit from Dupixent, doctors have observed, *inter alia*, worsening dermatitis, lymphadenopathy (swollen lymph nodes), and disease progression with rapid tumor growth.⁶ Irreversible and aggressive cutaneous lymphoma disease acceleration in previously undiagnosed patients has also been reported.⁷

35. The published medical literature contains multiple documented cases of AD transforming into CTCL in response to dupilumab therapy.⁸ Performance of serial histopathologic evaluation of lymphoid infiltrates before and during dupilumab treatment in seven patients demonstrated that dupilumab causes progressive transformation of AD to CTCL.⁹

36. 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 observations of and concerns about patients developing CTCL after

Sezary Syndrome, *Indian Journal of Dermatology*. 2023;68(4):459-462; Park, et al., Cutaneous T-cell lymphoma following dupilumab use: a systematic review. *International Journal of Dermatology*. 2023; 62:862-876 (collecting and analyzing case studies).

⁵ Li, et al., Dupilumab-associated lymphoproliferative disorders: a comprehensive review on clinicohistopathologic features and underlying mechanisms. *Current Opinion in Immunology*. 2025; 94:102563.

⁶ See, 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; 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.

⁷ See, 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.

⁸ 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.

⁹ Sokumbi, et al., Evolution of dupilumab-associated cutaneous atypical lymphoid infiltrates. *Am J Dermatopathol*. 2021;43(10):714-20.

Dupixent use.

37. A recent retrospective cohort study from Memorial Sloan Kettering Cancer Center identified 30 patients with dupilumab exposure for AD or eczema followed by 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.”¹⁰

38. Several recent studies investigated the association between dupilumab and the exacerbation of pre-existing CTCL or its development by using a large database (TriNetX) to compare the incidence of CTCL in patients who have used dupilumab with those who have never used it. One study extracted data from 60 health care organizations that encompassed 22,888 AD patients who were prescribed dupilumab and over one million patients who did not use dupilumab. A second analysis was performed that 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 AD who were prescribed dupilumab had a four-fold higher risk of developing CTCL (OR 4.1003, 95% confidence interval 2.055-8.192), and a high increased risk remained statistically significant after exclusion of prior disease-modifying antirheumatic drug use (OR 3.202, 95% confidence interval 1.573-6.514).¹¹

39. A second study by a different group of scientists using the TriNetX database compared patients with AD 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

¹⁰ 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.

¹¹ 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.

statistically significant increased relative risk (“RR”) of developing CTCL compared to those who were never treated with dupilumab (RR = 4.59, 95% confidence interval 2.459-8.657, $P < 0.0001$).¹² The investigators found that the risk of developing CTCL is highest in the first year of therapy with dupilumab and in adult patients.¹³

40. 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.¹⁴ 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.¹⁵

41. Another recent population-based cohort study using the TriNetX database compared patients with asthma treated with dupilumab with those treated with the combination of inhaled corticosteroids and long acting β -agonists. Dupilumab-treated patients were found to have a statistically significant higher risk of lymphoma, including CTCL (HR 5.63, 95% confidence interval 1.16-27.37).¹⁶

42. Several published analyses of the FDA Adverse Event Reporting System (“FAERS”) database of dupilumab-related adverse events reported between 2017 and 2023

¹² Mandel, et al., Increased risk of cutaneous T-cell lymphoma development after dupilumab use for atopic dermatitis. *Dermatol Ther.* 2024;1-8.

¹³ *Id.*

¹⁴ 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.

¹⁵ Beck, et 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>.

¹⁶ Ma, et al., Dupilumab and lymphoma risk among patients with asthma: a population-based cohort study. *Eur Resp J.* 2025; 66:2500139.

found a strong safety signal for CTCL with dupilumab.¹⁷ “Compared to other therapies used in AD, dupilumab had the most case reports and the highest RORs [reporting odds ratios] for CTCL.”¹⁸

43. 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.¹⁹

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

45. Physicians who have prescribed Dupixent to patients who were then diagnosed with CTCL after Dupixent use have reported their concerns to sales representatives of Defendants.

46. Researchers have identified a biologically plausible causal link between dupilumab and CTCL. Specifically, dupilumab may cause initiation and/or progression of CTCL via the same mechanism through which it improved AD and CRSwNP: the IL-13 receptor blockade leads to increased IL-13 in the local milieu, driving CTCL stimulation and

¹⁷ 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. 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).

¹⁸ 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.

¹⁹ Mota, et al, Real-world evidence on the risk of cancer with anti-IL-5 and anti-IL-4Ra biologicals. *Allergy.*2022:1375-1377.

progression.²⁰ Dupilumab may also disrupt the equilibrium phase maintained by IL-4, leading to the progression of CTCL by triggering an “escape phase” of tumor cells.²¹

47. Upon information and belief, Defendants have not informed the FDA of all of the newly-acquired, mounting evidence that use of Dupixent results in the development, accelerated progression, and/or exacerbation of T-cell lymphoma, including CTCL.

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

D. Defendants’ Failure to Test Dupixent

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

50. Despite the fact that peer-reviewed case reports, case series, epidemiologic articles, and studies emerged providing evidence of the carcinogenic dangers of Dupixent,²² 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

²⁰ 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.

²¹ 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.

²² See, 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.

susceptibility to its development.

E. Defendants' Failure to Warn

51. 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.

52. Defendants failed to warn physicians and patients that Dupixent should not be prescribed to or administered to patients with confirmed or suspected T-cell lymphoma, including CTCL, and that these diagnoses should be ruled out by skin biopsy, testing for T-cell receptor gene arrangement, flow cytometry of the blood, or otherwise, prior to Dupixent administration—especially for patients with atypical presentations such as adult-onset AD, patients without personal or familial atopic medical history, and/or erythrodermic and other uncharacteristic presentations like plaques, nodules, or sparing flexural sites.²³

53. 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 immunohistorical evaluation should be performed before and during treatment with dupilumab.²⁴ Early detection of CTCL is critical because a delay in diagnosis contributes to disease progression and a high risk of mortality.²⁵

²³ See Mandel, et al., Increased risk of cutaneous T-cell lymphoma development after dupilumab use for atopic dermatitis. *Dermatol Ther.* 2024;1-8; Guitart J, Dupilumab, Atopic Dermatitis, and Mycosis Fungoides—New Insights on an Evolving Story, *JAMA Dermatology.* 2023; 159(11):1177-1178; Guglielmo, et al., Mycosis fungoides and IL-4/13 inhibitors: what is known and unmet needs. *Expert Review of Clinical Immunology.* 2025; 21(6):723-729.

²⁴ See Sokumbi, et al., Evolution of dupilumab-associated cutaneous atypical lymphoid infiltrates. *Am J Dermatopathol.* 2021;43(10):714-20.

²⁵ Park, et al., Cutaneous T-cell lymphoma following dupilumab use: a systematic review. *International*

54. Defendants failed to warn physicians and patients that use of Dupixent in patients with adult-onset AD and no history of atopy may result in development, acceleration, and/or exacerbation of CTCL.²⁶ Defendants failed to warn physicians that these patients should be closely monitored and that a biopsy of skin lesions should be performed when clinical improvement is minimal or absent.²⁷

55. 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.²⁸ Providers and patients should have been warned to be on the lookout for inadequate treatment response (including following initial improvement) and/or signs and symptoms of CTCL to promptly evaluate for T-cell lymphoma following detection of the same. Defendants should have warned that signs and symptoms that merit prompt evaluation for T-cell lymphoma in patients on Dupixent with presumed AD 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.²⁹

56. Defendants have heavily marketed Dupixent in television advertisements, social media, the internet, and print brochures as providing clearer skin, fast itch relief, and better

Journal of Dermatology. 2023; 62:862-876.

²⁶ See Hollins, et al., Long-Standing dermatitis treated with dupilumab with subsequent progression to cutaneous T-cell lymphoma. *Cutis*. 2020; 106(2):E8-E11.

²⁷ Li., et al., Dupilumab-associated lymphoproliferative disorders: a comprehensive review on clinicohistopathologic features and underlying mechanisms. *Current Opinion in Immunology*. 2025: 94:102563.

²⁸ 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 cutaneous 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.

²⁹ 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.

breathing. For patients with eczema, Defendant claims that Dupixent “help[s] heal your skin from within”³⁰ and “helps you feel the heal and see the difference with less itch and clearer skin.”³¹ They encouraged patients to “show off your skin.”³² For patients with asthma, Defendants claim that Dupixent “helps people with asthma breathe easier” and will allow them to “get more out of [their] lungs,” to “Du [sic] more with less asthma,” and “achieve better breathing that lasts.”³³ Defendants promote Dupixent as providing “[b]enefits with every breath.”³⁴ For patients with COPD, Defendants claim that Dupixent is “proven to help reduce flareups so you can do more with less COPD” and that it “helps adults breathe easier starting in as little as two weeks. That could mean more places visited, more dogs walked, more gardens tended, more to look forward to. It’s amazing what can happen when you can do more.”³⁵ And for patients with CRSwNP, Defendants claim that “Dupixent goes beyond your nasal polyps by helping block a key source of underlying inflammation that can cause them”³⁶ and that “Dupixent helps you du [sic] more with less nasal polyps.”³⁷

57. In their 2024 “Welcome to Dupixent” guide, Defendants claim that “Dupixent

³⁰ 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>.

³¹ See, 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/>.

³² See, e.g., Dupixent “Show Off: Pool and Party” TV spot, <https://www.ispot.tv/ad/6Jz9/dupixent-show-offpool-and-party>.

³³ 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-betterroller-disco>. See also <https://www.dupixent.com/asthma/>.

³⁴ <https://www.dupixent.com/asthma/>.

³⁵ Dupixent TV Spot, “More”, https://www.ispot.tv/ad/Tj_6/dupixent-more. See also <https://www.dupixent.com/copd/>.

³⁶ Dupixent TV Spot, <https://www.ispot.tv/ad/BeOp/dupixent-holidays-nasal-polyps-go-beyond>.

³⁷ Dupixent TV Spot, <https://www.youtube.com/watch?v=EmGi1IKFI4k>.

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.”

58. Defendants made repeated representations that Dupixent is safe and effective, including references to “safety results” from clinical trials.³⁸ 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.

59. According to the Drugs@FDA website, the label for Dupixent has been updated 32 times, but Defendants’ U.S. labels have not contained any warning or any information whatsoever on the propensity of Dupixent to cause the development, accelerated progression, or exacerbation of T-cell lymphoma, including CTCL.

60. 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.

61. Defendants could have filed a CBE supplement under Section 314.70(c) of the FDCA to make “moderate changes” to Dupixent’s label without any prior FDA approval.

MR. ZAIKIS’S USE OF DUPIXENT

62. Mr. Zaikis was prescribed Dupixent in or around October of 2022. Mr. Zaikis received regular injections with Dupixent every two weeks for a period of approximately three years before discontinuing treatment with Dupixent in January of 2026.

³⁸ See, e.g., Dupixent Patient Brochure, 2025, Sanofi and Regeneron Pharmaceuticals, Inc., “Dupixent helps you feel the heal and see the difference.”

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

64. Mr. Zaikis had not been diagnosed with lymphoma of any kind (including CTCL) prior to initiation of Dupixent.

65. In or around November of 2025, at age 73, Mr. Zaikis developed an itchy rash. He had no history of AD.

66. Mr. Zaikis's skin condition continued to worsen with use of Dupixent.

67. In January of 2026, Mr. Zaikis discontinued treatment with Dupixent. His dermatologist conducted a punch biopsy, the results of which were consistent with mycosis fungoides.

68. In February of 2026, Mr. Zaikis was diagnosed with Stage B1 mycosis fungoides.

69. Defendants failed to timely and adequately warn Mr. Zaikis and his medical providers of the propensity of Dupixent to cause the development or accelerate the progression of CTCL and of the need to perform appropriate diagnostic tests before initiating Dupixent treatment, despite Defendants' knowledge of the same. Defendants also failed to warn Mr. Zaikis and his medical providers to cease use of Dupixent and/or to obtain appropriate diagnostic tests if Dupixent did not improve his condition.

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

71. Mr. Zaikis and Mr. Zaikis'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.

72. Through their affirmative misrepresentations and omissions, Defendants actively

concealed from Mr. Zaikis and Mr. Zaikis's physicians the true and significant risks associated with Dupixent injections.

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

74. As a direct and proximate result of the Defendants' wrongful actions and inactions, Mr. Zaikis sustained and continues to sustain severe physical and emotional injuries, including loss of capacity for enjoyment of life, aggravation and exacerbation of pre-existing conditions, mental and physical pain and suffering, and cost of medical, hospital, and other care and treatment.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

Mass. Gen. Laws ch. 106, §§ 2-314, *et seq.*

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

76. 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.

77. Defendants knew or should have known that the warnings and other clinically relevant information and data which they distributed regarding the risks associated with

Dupixent use were inadequate.

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

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

80. 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.

81. 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.

82. The warnings that accompanied Dupixent and the corresponding label, full prescribing information, instructions for use, and patient information were inadequate such that the product was unreasonably dangerous for its expected, intended, and/or foreseeable uses, functions, and purposes.

83. Dupixent and its corresponding label, full prescribing information, instructions for use, and patient information were unreasonably dangerous as distributed, marketed, delivered, and/or sold by Defendants.

84. Defendants marketed, promoted, distributed, and sold an unreasonably dangerous 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.

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

86. 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.

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

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

89. 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, of which Plaintiff was a part.

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

91. Plaintiff's prescribing physicians, nurse practitioners, and physician assistants (collectively, "Plaintiff's Prescribing Providers") would not have prescribed Dupixent to Plaintiff or would have ceased injecting it had they been apprised by Defendants of the increased risk of development, exacerbation, or acceleration of CTCL in patients similar to Plaintiff.

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

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

94. Similarly, if Defendants had warned of the increased risk of development, acceleration, and/or exacerbation of CTCL associated with the usage of Dupixent in individuals with Plaintiff's presentation in the patient information handout, brochures, marketing and promotional materials and advertisements directed to users like Plaintiff, Plaintiff as an objectively prudent person would not have chosen to inject Dupixent, notwithstanding Plaintiff's

Prescribing Providers' recommendation.

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

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

97. Defendants continued to aggressively promote and sell Dupixent without adequate warnings, even after they knew or should have known of the unreasonable risks of serious injury including the development or exacerbation of CTCL, which can lead to accelerated disease progression and death from the drug.

98. Defendants had an obligation to provide Plaintiff and Plaintiff's Prescribing Providers with adequate clinically relevant information and 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.

99. 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 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.

100. The Dupixent designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed by Defendants was unreasonably dangerous due to inadequate post-marketing surveillance and/or warnings because, even after Defendants knew or should have known of the risk 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.

101. As a direct and proximate result of Defendants' conduct, including the inadequate warnings, lack of adequate testing and research, and the unreasonably 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 either permanent or continuing, and Plaintiff will suffer losses in the future.

102. 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, and sell Dupixent.

SECOND CAUSE OF ACTION

VIOLATION OF NEW JERSEY PRODUCT LIABILITY ACT

N.J. STAT. §§ 2A:58C-1, *et seq.*

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

104. New Jersey law imposes a duty on producers, manufacturers, distributors, lessors,

and sellers of a product to exercise all reasonable care when producing, manufacturing, distributing, leasing, and selling their products.

105. At all times mentioned herein, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the Dupixent that was used by Plaintiff.

106. Dupixent was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by Defendants.

107. At all relevant times, and at the times Dupixent left Defendants' control, Defendants knew or should have known that Dupixent was unreasonably dangerous because it did not adequately warn of the increased risk of development, exacerbation, or acceleration of CTCL, especially when used in the form and manner as provided by Defendants.

108. Despite the fact that Defendants knew or should have known that Dupixent caused unreasonably dangerous injuries, Defendants continued to market, distribute, and/or sell Dupixent to consumers, including Plaintiff, without adequate warnings.

109. Despite the fact that Defendants knew or should have known that Dupixent caused unreasonably dangerous injuries, Defendants continued to market Dupixent to prescribing physicians, including Plaintiff's Prescribing Providers, without adequate warnings.

110. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of its failure to provide adequate warnings, as set forth herein.

111. At all relevant times, given its increased safety risks, Dupixent was not fit for the ordinary purpose for which it was intended.

112. At all relevant times, given its increased safety risks, Dupixent did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff.

113. Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Dupixent into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous injuries, such as the increased risk of development, exacerbation, or acceleration of CTCL.

114. At all relevant times, Plaintiff was using Dupixent for the purposes and in a manner normally intended.

115. The Dupixent designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate warnings or instructions, as Defendants knew or should have known that the product created a risk of serious and dangerous injuries, including an increased risk of development, exacerbation, or acceleration of CTCL, as well as other severe and personal injuries which are permanent and lasting in nature, and Defendants failed to adequately warn of said risk.

116. The Dupixent designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects, including the increased risk of development, exacerbation, or acceleration of CTCL, as well as other severe and permanent health consequences from Dupixent, they failed to provide adequate warnings to users and/or prescribers of the product, and continued to improperly advertise, market and/or promote their product, Dupixent.

117. The label for Dupixent was inadequate because it did not warn and/or adequately

warn of all possible adverse side effects causally associated with the use of Dupixent, including the increased risk of development, exacerbation, or acceleration of CTCL.

118. The label for Dupixent was inadequate because it did not warn and/or adequately warn that Dupixent had not been sufficiently and/or adequately tested for safety risks, including the increased risk of development, exacerbation, or acceleration of CTCL.

119. The label for Dupixent was inadequate because it did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Dupixent.

120. The label for Dupixent was inadequate because it did not warn and/or adequately warn of the severity and duration of adverse effects, as the warnings given did not accurately reflect the symptoms or severity of the side effects.

121. Communications made by Defendants to Plaintiff and Plaintiff's Prescribing Providers were inadequate because Defendants failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Dupixent, including the increased risk of development, exacerbation, or acceleration of CTCL.

122. Communications made by Defendants to Plaintiff and Plaintiff's Prescribing Providers were inadequate because Defendants failed to warn and/or adequately warn that Dupixent had not been sufficiently and/or adequately tested for safety risks, including the increased risk of development, exacerbation, or acceleration of CTCL.

123. Plaintiff had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and Plaintiff's reliance upon Defendants' warnings was reasonable.

124. Plaintiff's Prescribing Providers had no way to determine the truth behind the inadequacies of Defendants' warnings as identified herein, and his/her/their reliance upon

Defendants' warnings was reasonable.

125. Upon information and belief, had Plaintiff's Prescribing Providers been warned of the increased risk of development, exacerbation, or acceleration of CTCL, which is causally associated with Dupixent, then the Prescribing Providers would not have prescribed Dupixent and/or would have provided Plaintiff with adequate warnings regarding the dangers of Dupixent, so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Dupixent.

126. Upon information and belief, had Plaintiff's Prescribing Providers been warned that Dupixent had not been sufficiently and/or adequately tested for safety risks, including the increased risk of development, exacerbation, or acceleration of CTCL, the Prescribing Providers would not have prescribed Dupixent and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Dupixent, so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Dupixent.

127. If Plaintiff had been warned of the increased risk of development, exacerbation, or acceleration of CTCL, which are causally associated with Dupixent, then Plaintiff would not have used Dupixent and/or suffered from the development, exacerbation, or acceleration of Plaintiff's CTCL.

128. If Plaintiff had been warned that Dupixent had not been sufficiently and/or adequately tested for safety risks, including the increased risk of development, exacerbation, or acceleration of CTCL, then Plaintiff would not have used Dupixent and/or suffered from development, exacerbation, or acceleration of Plaintiff's CTCL.

129. If Plaintiff had been warned of the increased risk of development, exacerbation, or acceleration of CTCL, which is causally associated with Dupixent, then Plaintiff would have informed Plaintiff's Prescribing Providers that Plaintiff did not want to take Dupixent.

130. Upon information and belief, if Plaintiff had informed Plaintiff's Prescribing Providers that Plaintiff did not want to take Dupixent due to the risks of development, exacerbation, or acceleration of CTCL, or the lack of adequate testing for safety risks, then Plaintiff's Prescribing Providers would not have prescribed Dupixent.

131. By reason of the foregoing, Defendants have become liable to Plaintiff for the designing, marketing, promoting, distribution and/or selling of unreasonably dangerous product, Dupixent.

132. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product which created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendants are therefore liable for the injuries sustained by Plaintiff.

133. Defendants' inadequate warnings for Dupixent were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

134. Said inadequate warnings for Defendants' drug Dupixent were a substantial factor in causing Plaintiff's injuries.

135. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries, including development, exacerbation, or acceleration of Plaintiff's CTCL, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

136. As a result of the foregoing acts and omissions Plaintiff did incur medical, health, incidental, and related expenses, and requires and/or will require more health care and services.

Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

THIRD CAUSE OF ACTION

NEGLIGENCE

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

138. 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.

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

140. Prior to and during the time frame of Plaintiff's use of Dupixent, Defendants breached this duty, failed to exercise reasonable care, and were negligent and careless in the testing, study, research, manufacture, inspection, labeling, promotion, advertisement, marketing, distribution, and sale of Dupixent.

141. 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.

142. 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, and/or acceleration of CTCL.

143. 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 the warning language to disclose these harms.

144. Defendants failed to exercise due care under the circumstances, including through the following acts and omissions:

- a. Negligently failing to properly and adequately test Dupixent before releasing the drug to the market;
- b. Negligently failing to conduct sufficient post-marketing testing and surveillance of the drug;
- c. Negligently manufacturing, marketing, advertising, distributing, and selling the drug;
- d. Continuing to negligently manufacture and distribute the drug without adequate warnings and instructions after Defendants knew or should have known of Dupixent's adverse effects;
- e. Negligently manufacturing, marketing, advertising, distributing, and selling the drug to consumers, including Plaintiff, without an adequate warning of the unreasonable danger of the drug;
- f. Negligently failing to notify and warn the public, including Plaintiff and physicians, of reported incidents involving injury and the negative health effects attendant to the use of the drug;
- g. Negligently failing to conduct sufficient clinical analysis of Dupixent, which if properly performed would have shown that Dupixent had serious side effects, including but not limited to the increased risks of the development or acceleration of CTCL;
- h. Negligently failing to conduct adequate pharmacovigilance and prepare a

pharmacovigilance assessment and plan to mitigate the risks of the development or exacerbation of CTCL;

- i. Negligently misrepresenting the safety of Dupixent;
- j. Negligently failing to provide warnings, instructions, or other information that accurately reflects the risks of Dupixent;
- k. Negligently failing to exercise due care in the advertisement and promotion of Dupixent;
- l. Negligently disseminating information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the serious risks of Dupixent;
- m. Negligently failing to adequately warn Plaintiff's prescribing physicians regarding the increased risks of the development or acceleration of CTCL through various communication vehicles, including Dupixent's labeling, patient medication guides, Dear Healthcare Provider letters, press releases, and other risk communication options;
- n. Aggressively promoting Dupixent without adequate warnings and instructions even after Defendants knew or should have known of the unreasonable risks from the drug;
- o. Negligently diminishing or hiding the risks associated with Dupixent; and
- p. Negligently violating applicable state and federal laws and regulations.

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

146. Plaintiff and Plaintiff's prescribing physicians reasonably relied upon the skill, superior knowledge, and judgment of Defendants. Defendants had a continuing duty to warn

Plaintiff and his prescribing physicians of the dangers associated with Dupixent. Had Plaintiff and his physicians received adequate warnings regarding the risks of Dupixent, Plaintiff would not have been prescribed and used the product.

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

148. 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. The losses are either permanent or continuing, and Plaintiff will suffer losses in the future.

FOURTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

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

150. 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.

151. 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.

152. 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.”

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

154. 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.

155. 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 failure by Defendants constituted a material breach of express warranties made, directly or indirectly, to Plaintiff concerning the Dupixent sold to Plaintiff.

156. 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.

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

158. 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.

159. 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.

160. Plaintiff's Prescribing 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.

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

162. 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 CTCL.

163. 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.

164. 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. The losses are either permanent or continuing, and Plaintiff will suffer losses in the future.

FIFTH CAUSE OF ACTION

PUNITIVE DAMAGES

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

166. Defendants have engaged in aggressive and reckless marketing efforts, including highlighting the lack of a requirement for initial laboratory testing and ongoing laboratory monitoring as a favorable attribute of Dupixent in promotional materials to physicians and patients despite the fact that such testing was necessary to avoid serious adverse health outcomes, such as Plaintiff's CTCL, and this was known or knowable to Defendants.

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

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

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

170. Defendants have intentionally misled healthcare providers and the general public in making superiority claims for Dupixent as compared to other medications despite possessing

the knowledge that these claims are false.

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

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

173. As a direct and proximate result of the defective and dangerous nature of Dupixent, Plaintiff suffered injury, and resulting severe pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are permanent, and Plaintiff will continue to suffer the losses in the future.

PRAYER FOR RELIEF

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

a. Judgment in favor of Plaintiff and against each Defendant, for damages in such amounts as may be proven at trial 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 earning and ability to earn money, mental anguish and emotional distress, 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. Exemplary and punitive damages in an amount to be proven at trial, and sufficient to punish Defendants or to deter Defendants and others from repeating the injurious conduct alleged herein;

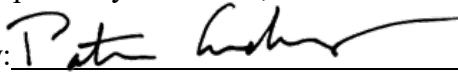
d. Attorneys' fees and costs;

e. Interest; and

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

Dated: July 10, 2026

Respectfully submitted,

By: 
Patrick Andrews

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CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

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

(c) Attorneys (Firm Name, Address, and Telephone Number)
See attachment.

DEFENDANTS

Regeneron Pharmaceuticals, Inc., and Sanofi-Aventis U.S. LLC

County of Residence of First Listed Defendant Westchester County, New York
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys (If Known)

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

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

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

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

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

Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 151 Medicare Act ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans) ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholders' Suits ☐ 190 Other Contract ☐ 195 Contract Product Liability ☐ 196 Franchise	PERSONAL INJURY ☐ 310 Airplane ☐ 315 Airplane Product Liability ☐ 320 Assault, Libel & Slander ☐ 330 Federal Employers' Liability ☐ 340 Marine ☐ 345 Marine Product Liability ☐ 350 Motor Vehicle ☐ 355 Motor Vehicle Product Liability ☐ 360 Other Personal Injury ☐ 362 Personal Injury - Medical Malpractice PERSONAL INJURY ☐ 365 Personal Injury - Product Liability ☒ 367 Health Care/Pharmaceutical Personal Injury Product Liability ☐ 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY ☐ 370 Other Fraud ☐ 371 Truth in Lending ☐ 380 Other Personal Property Damage ☐ 385 Property Damage Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881 ☐ 690 Other LABOR ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Management Relations ☐ 740 Railway Labor Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Employee Retirement Income Security Act IMMIGRATION ☐ 462 Naturalization Application ☐ 465 Other Immigration Actions	☐ 422 Appeal 28 USC 158 ☐ 423 Withdrawal 28 USC 157 INTELLECTUAL PROPERTY RIGHTS ☐ 820 Copyrights ☐ 830 Patent ☐ 835 Patent - Abbreviated New Drug Application ☐ 840 Trademark ☐ 880 Defend Trade Secrets Act of 2016 SOCIAL SECURITY ☐ 861 HIA (1395ff) ☐ 862 Black Lung (923) ☐ 863 DIWC/DIWW (405(g)) ☐ 864 SSID Title XVI ☐ 865 RSI (405(g)) FEDERAL TAX SUITS ☐ 870 Taxes (U.S. Plaintiff or Defendant) ☐ 871 IRS—Third Party 26 USC 7609	☐ 375 False Claims Act ☐ 376 Qui Tam (31 USC 3729(a)) ☐ 400 State Reapportionment ☐ 410 Antitrust ☐ 430 Banks and Banking ☐ 450 Commerce ☐ 460 Deportation ☐ 470 Racketeer Influenced and Corrupt Organizations ☐ 480 Consumer Credit (15 USC 1681 or 1692) ☐ 485 Telephone Consumer Protection Act ☐ 490 Cable/Sat TV ☐ 850 Securities/Commodities/Exchange ☐ 890 Other Statutory Actions ☐ 891 Agricultural Acts ☐ 893 Environmental Matters ☐ 895 Freedom of Information Act ☐ 896 Arbitration ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision ☐ 950 Constitutionality of State Statutes
REAL PROPERTY ☐ 210 Land Condemnation ☐ 220 Foreclosure ☐ 230 Rent Lease & Ejectment ☐ 240 Torts to Land ☐ 245 Tort Product Liability ☐ 290 All Other Real Property	CIVIL RIGHTS ☐ 440 Other Civil Rights ☐ 441 Voting ☐ 442 Employment ☐ 443 Housing/Accommodations ☐ 445 Amer. w/Disabilities - Employment ☐ 446 Amer. w/Disabilities - Other ☐ 448 Education PRISONER PETITIONS Habeas Corpus: ☐ 463 Alien Detainee ☐ 510 Motions to Vacate Sentence ☐ 530 General ☐ 535 Death Penalty Other: ☐ 540 Mandamus & Other ☐ 550 Civil Rights ☐ 555 Prison Condition ☐ 560 Civil Detainee - Conditions of Confinement			

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:

State law products liability and warranty claims based on pharmaceutical injury.

VII. REQUESTED IN COMPLAINT:

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

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Hon. Zahid N. Quraishi

DOCKET NUMBER MDL No. 3180

DATE

07/10/2026

SIGNATURE OF ATTORNEY OF RECORD

/s/ Patrick I. Andrews

FOR OFFICE USE ONLY

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

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
 - (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
 - (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
- United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
- Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
- Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.
- Original Proceedings. (1) Cases which originate in the United States district courts.
- Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
- Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
- Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
- Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
- Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
- Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket. **PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
- Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
- Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related cases, if any. If there are related cases, insert the docket numbers and the corresponding judge names for such cases.

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

CIVIL COVER SHEET – ATTACHMENT

Attorneys for plaintiff:

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