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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

WILLIAM HINTON JR. AND LABARBARA CAROLYN HINTON, Plaintiffs, vs. **REGENERON PHARMACEUTICALS, INC.; and SANOFI-AVENTIS U.S. LLC,** Defendants.	**Case No.: _____** **COMPLAINT FOR DAMAGES** **DEMAND FOR JURY TRIAL**

COMPLAINT

NOW COME Plaintiffs WILLIAM HINTON JR. ("Plaintiff") and LABARBARA CAROLYN HINTON (hereinafter collectively referred to as "Plaintiffs"), by and through the undersigned attorneys, and 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.

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 cutaneous T-cell lymphoma (CTCL), a form of non-Hodgkin lymphoma (NHL), and/or triggers a reaction leading to severe and rapid clinical progression of otherwise subclinical and undiagnosed CTCL.

4. Defendants failed to warn physicians and the public about Dupixent's propensity to cause CTCL or rapidly exacerbate subclinical CTCL.

5. Dupixent caused the development and/or aggravation and accelerated progression of cutaneous T-cell lymphoma (CTCL) in Plaintiff William Hinton Jr.

6. CTCL is a rare type of cancer that affects white blood cells called T cells, or T lymphocytes. 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 William Hinton Jr. has been diagnosed with Mycosis fungoides.

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 CTCL.

8. Numerous case reports and scientific studies have established that Dupixent causes T-cell lymphoma, including CTCL, 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 rapid exacerbation of T-cell lymphoma, including CTCL. 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 seek compensatory damages, punitive 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 William Hinton Jr. was repeatedly injected with and physically harmed by the Defendants' product Dupixent.

13. At all relevant times since William Hinton Jr.'s initial injection of Dupixent, Plaintiffs were and are residents and citizens of Philadelphia, Pennsylvania located in Philadelphia County.

14. Plaintiff William Hinton Jr. was injected with Defendants' Dupixent (dupilumab)

product from approximately April 2025 until October 2025. As a direct and proximate result of use of Defendants' Dupixent product, Plaintiff incurred and continues to incur medical expenses and has 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.

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 Pennsylvania. Upon information and belief, Sanofi employs sales representatives throughout Pennsylvania 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 in the state of Pennsylvania.

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

[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.

to Pennsylvania physicians and potential users of Dupixent for the specific purpose of selling Dupixent in Pennsylvania 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, marketed, distributed, and/or sold Dupixent worldwide and throughout the United States, including in and throughout the state of Pennsylvania, 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 $150,000.00 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 the claims asserted herein 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 Pennsylvania, such as marketing, promoting, distributing, and selling its products (including Dupixent) in Pennsylvania including in this District.

FACTUAL BACKGROUND

A. Atopic Dermatitis

31. 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.

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

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

B. Dupixent

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

35. 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.

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

37. 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

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

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.

38. 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: CTCL

39. CTCL is a form of non-Hodgkin lymphoma that is initiated by the malignant proliferation of T-cell lymphocytes contained in the skin.

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

41. CTCL is typically a non-aggressive and slowly progressing disease. Accordingly, patients who have unidentified, subclinical CTCL that goes undiagnosed or is potentially diagnosed as some other dermatosis in the interim are likely to remain asymptomatic and live without clinical or pathological signs of CTCL for long periods of time, or even indefinitely.

42. 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 (including mycosis fungoides and Sezary syndrome).[4] The reports have increased over time and have included diagnoses of new, primary CTCL as well as an unexpected "unmasking" or severe and rapid clinical progression of otherwise subclinical and undiagnosed CTCL occurring weeks to years following initiation of Dupixent use. This large and growing body of research has expanded to cohort studies, cross-sectional studies and analyses of postmarketing adverse events.

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

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

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

44. 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]

45. 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]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

51. 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 significant after exclusion of prior disease-modifying antirheumatic drug use (OR 3.202, 95% confidence interval 1.573-6.514).[14]

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

53. 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

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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.*

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."

54. 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.

55. 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-

[17] Ahmed, et al., Risk of Cutaneous T-cell lymphoma in atopic dermatitis patients treated with dupilumab and JAK inhibitors: a TriNetX cohort study." *Archives of Dermatological Research*. 2026; 318:37.
[18] Hasan, et al., Response to Flynn et al., "Dupilumab therapy for atopic dermatitis is associated with increased risk of cutaneous T cell lymphoma: A retrospective cohort study." *J Am Acad Dermatol*. 2025; e7-e8.
[19] Beck, at al., Dupilumab in adults with moderate to severe atopic dermatitis: a 5-year open-label extension study. *JAMA Dermatol*. 2024; 160:805-812; https://clinicaltrials.gov/study/NCT01949311.

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]

56. 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 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.

57. 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

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

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

2021, at least 64 reports of cutaneous lymphoma, of which 59 were specified as T-cell lymphoma, had been reported.

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

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

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

61. 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

[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.

extent to which the reporting of a given adverse event is observed to be disproportionately reported with a given drug.

62. 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.

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

64. 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."

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

[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.

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

67. The causal link between dupilumab and CTCL has been found to be biologically plausible. Specifically, dupilumab may cause initiation and/or progression of CTCL via the same mechanism through which it improves atopic dermatitis: the IL-13 receptor blockade which leads to increased IL-13 in the local milieu, driving CTCL stimulation and progression.[25] 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.[26]

68. The data, analyses and information described in this Complaint that was received prior to Plaintiff's use of Dupixent constitutes newly acquired information pursuant to C.F.R. § 601.12(f)(6), which supported a label change to Dupixent in order to properly warn about CTCL with Dupixent use.

69. Upon information and belief, Defendants have not informed the FDA of all of the newly-acquired, mounting evidence that use of Dupixent results in the development, accelerated progression and/or exacerbation of T-cell lymphoma, including CTCL. Defendants had such newly acquired information at least as early as 2018 upon receipt of multiple adverse event reports of CTCL

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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] 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.

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]

70. 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 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

71. 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.

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

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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.").

[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.

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

E. Defendants' Failure to Warn

74. As case reports, case series, observational studies, and analytical cohort studies evidencing a strong risk of CTCL with Dupixent use accumulated, researchers expressed concern, advised caution and strongly recommended that atopic dermatitis patients undergo multiple skin biopsies to rule out underlying cutaneous malignancy prior to prescribing Dupixent. Furthermore, these clinicians recommended ongoing monitoring and repeat screening through serial biopsies and other means to detect changes in pathology during the course of Dupixent treatment that may be indicative of disease transformation. Additionally, researchers advised healthcare providers to maintain a high degree of clinical suspicion for CTCL when a patient shows signs of non-responsiveness or brief, initial responsiveness to Dupixent treatment followed by exacerbation of symptoms. Despite calls from these researchers year after year, Defendants provided no such recommendation to aid in the appropriate screening and monitoring of patients to reduce or eliminate their risk of Dupixent-induced CTCL or Dupixent-induced progression of CTCL.

75. 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]

76. Defendants failed to warn physicians and patients that Dupixent should not be prescribed or administered to patients with confirmed or suspected T-cell lymphoma, including CTCL, and that these diagnoses should be ruled out, by skin biopsies, testing for T-cell receptor gene arrangement, flow cytometry of the blood, or otherwise, prior to Dupixent administration, especially with atypical presentations such as adult-onset atopic dermatitis, patients without personal or familial atopic medical history, and/or erythrodermic and other uncharacteristic presentations like plaques, nodules or sparing flexural sites.[30]

77. 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 CTCL is of critical importance because a delay in diagnosis contributes to disease progression and high risk of mortality.[32]

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

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[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 Immunology*. 2025; 21(6):723-729.

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

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

and/or exacerbation of CTCL.[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]

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

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

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[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.

[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.

[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.

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

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

82. Defendants' failure to appropriately revise the United States prescribing information for Dupixent to reflect the clinically important risk of T-cell lymphoma, including CTCL, with Dupixent treatment continued in the face of mounting evidence from postmarketing adverse

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

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

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

85. 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)).

86. 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)).

87. 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)).

88. 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.

89. 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, 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)).

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

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

92. 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 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, with Dupixent use through prudent and reasonable means within their capacity.

93. Instead of warning physicians to monitor and test for T-cell lymphoma, including CTCL, before and during use of Dupixent, Defendants' marketing materials and websites for Dupixent expressly advertised: "NO INITIAL LAB TESTING OR ONGOING LAB MONITORING" is required for prescription and treatment with Dupixent.[37]

94. 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.

95. Defendants marketed Dupixent in television advertisements, social media, the internet, and print brochures as providing clearer skin, fast itch relief, and better breathing. For patients with eczema, Defendants claim that Dupixent "help[s] heal your skin from within"[38] and "helps you feel the heal and see the difference with less itch and clearer skin."[39] They encouraged

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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 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/.

patients to "show off your skin."[40] 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."[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 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."[43]

96. 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."

97. 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.

98. 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

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[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/.

[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."

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.

99. 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

100. Plaintiff has chronic obstructive pulmonary disease (COPD) and severe asthma. Plaintiff was prescribed Dupixent by his pulmonologist.

101. Plaintiff was injected with Dupixent from April 2025 until October 2025. Thus, Plaintiff received multiple injections of Dupixent over a period of approximately seven months and was repeatedly exposed to the drug.

102. Plaintiff developed a worsening of a preexisting small rash and the development of a new rash while taking Dupixent.

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

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

105. Plaintiff was diagnosed with CTCL in late October 2025.

106. Defendants failed to timely and adequately warn Plaintiff and his medical providers of the propensity of Dupixent to cause the development or accelerate the progression of CTCL and the need to get appropriate diagnostic tests before initiating Dupixent treatment, despite

Defendants' knowledge of same. Defendants also failed to warn Plaintiff and his medical providers to cease use of Dupixent and/or to get appropriate diagnostic tests to diagnose or rule out CTCL if Dupixent did not improve his condition or if he developed a rash or his skin became worse while on Dupixent.

107. Defendants' failure to warn resulted in Plaintiff developing CTCL.

108. Defendants' Dupixent was at all times utilized and prescribed by Plaintiff and his medical providers in a manner foreseeable to Defendants.

109. Plaintiff and Plaintiff's medical providers 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.

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

111. 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.

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

113. As a direct and proximate result of the dangerous and defective nature of Dupixent as described herein, Plaintiff suffered and continues to suffer CTCL and resulting severe pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical

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

CAUSES OF ACTION

FIRST CAUSE OF ACTION
NEGLIGENCE
Against All Defendants

114. Plaintiffs hereby incorporate by reference paragraphs 1-113 of this Complaint as if fully set forth herein and further allege as follows:

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

116. 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.

117. 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 physicians, nurse practitioners, and physician assistants (hereinafter collectively referred to as "Plaintiff's Prescribing Healthcare Providers"), of those risks, dangers, and adverse effects.

118. 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.

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

120. 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.

121. 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 including CTCL.

122. 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 including or revising any warning language.

123. 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 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;

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 CTCL;

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;

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, 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, with Dupixent treatment;

iii. failure to reference to T-cell lymphoma, including CTCL, 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, or active T-cell lymphoma, including CTCL;

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 CTCL 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 CTCL and repeat biopsies to detect changes in pathologies during treatment with Dupixent consistent with CTCL 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.

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, 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, 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.

124. 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.

125. 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.

126. 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.

127. 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.

128. As a direct and proximate result of one or more of the above-stated acts, omissions, and conduct committed by the Defendants, Plaintiff suffered injury, and resulting severe pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. Plaintiff's injuries are permanent and he

will continue to suffer these losses in the future.

SECOND CAUSE OF ACTION
PUNITIVE DAMAGES
Against All Defendants

129. Plaintiffs hereby incorporate by reference paragraphs 1-128 of this Complaint as if fully set forth herein and further allege as follows:

130. 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.

131. 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.

132. 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.

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

134. 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.

135. Defendants have intentionally failed to properly warn healthcare providers about the

true risk of T-cell lymphoma, including CTCL, related to Dupixent use despite possessing knowledge that Dupixent causes these serious adverse events.

136. Defendants' actions were willful and malicious in that Defendants' conduct was carried on with a conscious disregard for the safety and rights of others, including Plaintiff. Defendants' conscious disregard is evident from, *inter alia*, the adverse event reports discussed herein and Defendants' failure to test despite their safety claims. 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.

137. 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.

THIRD CAUSE OF ACTION
LOSS OF CONSORTIUM AND SERVICES
Against All Defendants

138. Plaintiffs hereby incorporate by reference paragraphs 1-137 of this Complaint as if fully set forth herein and further allege as follows:

139. At all relevant times, Plaintiff LaBarbara Carolyn Hinton was and is the lawfully wedded wife of Plaintiff William Hinton Jr., and as such, was and is entitled to the services, consortium, and society of Plaintiff William Hinton Jr.

140. As a result of the defective nature of Dupixent and the tortious conduct of Defendants, Plaintiff LaBarbara Carolyn Hinton was deprived of the services, consortium, and

society of Plaintiff William Hinton Jr.

141. As a direct and proximate result of Defendants' wrongful conduct as described herein, whether through strict liability or negligence, Plaintiff LaBarbara Carolyn Hinton 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 LaBarbara Carolyn Hinton is entitled to compensatory damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment in their favor and 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;

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

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

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

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

DEMAND FOR JURY TRIAL

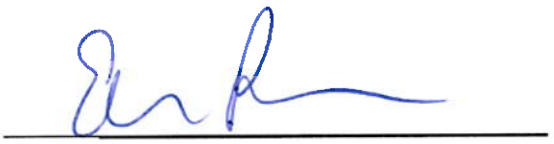
Plaintiffs demand a trial by jury on all issues.

CERTIFICATION PURSUANT TO LOCAL RULE 53.2

Pursuant to Local Rule 53.2 I hereby certify that the damages sought herein exceed $150,000.

Dated: March 25, 2026

Respectfully Submitted,



Ellen Relkin, PA Bar No. 314992
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Fax: 212-344-5461

Attorneys for Plaintiffs

JS 44 (Rev. 04/21)

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

WILLIAM HINTON JR. and LABARBARA CAROLYN HINTON

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

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

Weitz & Luxenberg, P.C., 220 Lake Drive East, Suite 210
Cherry Hill, New Jersey 08002; (856) 755-1115

DEFENDANTS

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

County of Residence of First Listed Defendant Westchester County, NY
(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)*

(For Diversity Cases Only)

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

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

Click here for: Nature of Suit Code Descriptions.

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

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

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

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

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

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

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

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

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (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

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 USC §1332 - Diversity

Brief description of cause:
Product Liability; Personal 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 Honorable John F. Murphy DOCKET NUMBER 2:26-cv-00763-JFM

DATE 3/25/2025

SIGNATURE OF ATTORNEY OF RECORD /s/Ellen Relkin

FOR OFFICE USE ONLY

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

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DESIGNATION FORM

Place of Accident, Incident, or Transaction:_____

RELATED CASE IF ANY: Case Number:_____ Judge:_____

1. Does this case involve property included in an earlier numbered suit? Yes ☐
2. Does this case involve a transaction or occurrence which was the subject of an earlier numbered suit? Yes ☐
3. Does this case involve the validity or infringement of a patent which was the subject of an earlier numbered suit? Yes ☐
4. Is this case a second or successive habeas corpus petition, social security appeal, or pro se case filed by the same individual? Yes ☐
5. Is this case related to an earlier numbered suit even though none of the above categories apply? If yes, attach an explanation. Yes ☐

I certify that, to the best of my knowledge and belief, the within case ☐ **is** / ☐ **is not** related to any pending or previously terminated action in this court.

Civil Litigation Categories

A. Federal Question Cases:

☐ 1. Indemnity Contract, Marine Contract, and All Other Contracts)
☐ 2. FELA
☐ 3. Jones Act-Personal Injury
☐ 4. Antitrust
☐ 5. Wage and Hour Class Action/Collective Action
☐ 6. Patent
☐ 7. Copyright/Trademark
☐ 8. Employment
☐ 9. Labor-Management Relations
☐ 10. Civil Rights
☐ 11. Habeas Corpus
☐ 12. Securities Cases
☐ 13. Social Security Review Cases
☐ 14. Qui Tam Cases
☐ 15. Cases Seeking Systemic Relief ***see certification below***
☐ 16. All Other Federal Question Cases. *(Please specify)*:_____

B. Diversity Jurisdiction Cases:

☐ 1. Insurance Contract and Other Contracts
☐ 2. Airplane Personal Injury
☐ 3. Assault, Defamation
☐ 4. Marine Personal Injury
☐ 5. Motor Vehicle Personal Injury
☐ 6. Other Personal Injury (*Please specify*):_____
☐ 7. Products Liability
☐ 8. All Other Diversity Cases: *(Please specify)*_____

I certify that, to the best of my knowledge and belief, that the remedy sought in this case ☐ **does** / ☐ **does not** have implications beyond the parties before the court and ☐ **does** / ☐ **does not** seek to bar or mandate statewide or nationwide enforcement of a state or federal law including a rule, regulation, policy, or order of the executive branch or a state or federal agency, whether by declaratory judgment and/or any form of injunctive relief.

ARBITRATION CERTIFICATION (CHECK ONLY ONE BOX BELOW)

I certify that, to the best of my knowledge and belief:

☐ Pursuant to Local Civil Rule 53.2(3), this case is not eligible for arbitration either because (1) it seeks relief other than money damages; (2) the money damages sought are in excess of $150,000 exclusive of interest and costs; (3) it is a social security case, includes a prisoner as a party, or alleges a violation of a right secured by the U.S. Constitution, or (4) jurisdiction is based in whole or in part on 28 U.S.C. § 1343.

☐ None of the restrictions in Local Civil Rule 53.2 apply and this case is eligible for arbitration.

NOTE: A trial de novo will be by jury only if there has been compliance with F.R.C.P. 38.