UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE

CHANDRA RICHARDSON, individually, and on behalf of the ESTATE OF CYNTHIA MARIE HYDE, Plaintiff, vs. **REGENERON PHARMACEUTICALS, INC.; and SANOFI-AVENTIS U.S. LLC,** Defendants.	**COMPLAINT AND DEMAND FOR JURY TRIAL** **Civil Action No.: _____**

Plaintiff Chandra Richardson, individually and on behalf of the Estate of Cynthia Marie Hyde ("Decedent"), by and through the undersigned attorneys, and brings this action against REGENERON PHARMACEUTICALS, INC. and SANOFI-AVENTIS U.S. LLC (hereinafter, collectively, "Defendants"), for personal injuries and wrongful death suffered as a proximate result of injection into Cynthia Marie Hyde of Defendants' prescription drug Dupixent® (dupilumab) (hereinafter "Dupixent" or "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 prescription drug Dupixent® (hereinafter "Dupixent").

2. Defendants manufactured, promoted and sold Dupixent as a biologic medication for the treatment of multiple conditions, including atopic dermatitis (AD), asthma, and other

inflammatory diseases of the skin and respiratory tract in adult and pediatric patients. Dupixent is a biologic medication administered by subcutaneous injection with an initial dose administered at two different injection sites and subsequent doses administered every two to four weeks, depending on age and body weight.

3. Dupixent caused the development and/or aggravation of T-cell lymphoma in Cynthia Marie Hyde (hereinafter "Decedent"). T-cell lymphoma 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. There are several types of T-cell lymphoma, including cutaneous T-cell lymphoma (CTCL) and peripheral T-cell lymphoma (PTCL). CTCL is a T-cell lymphoma that starts in the skin, whereas PTCL refers to systemic T-cell lymphomas that are found in the lymph nodes, other organs, the blood and some types also involve the skin. Mycosis fungoides and Sezary syndrome are the two most common subtypes of CTCL.

5. Defendants knew or should have known that Dupixent, when taken as prescribed and intended, causes and/or exacerbates T-cell lymphoma, including CTCL and PTCL.

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

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

8. As a proximate result of Defendants' wrongful actions and inactions, Decedent was injured and suffered serious personal injuries, including severe pain, loss of enjoyment of life,

economic loss, out-of-pocket costs of medical tests and treatment, and death from use of Dupixent.

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

THE PARTIES

10. Plaintiff Chandra Richardson brings this action on her own behalf and in her capacity as the Administrator of the Estate of Cynthia Marie Hyde, her deceased mother. Decedent Cynthia Marie Hyde died on October 28, 2024 in Nashville, Davidson County, Tennessee. Plaintiff is pursuing this action due to the personal injury and resultant death suffered by Cynthia Marie Hyde in her capacity as Decedent's court-appointed legal representative (Administrator). Decedent Cynthia Marie Hyde's injury and death were the direct and proximate result of her injection of Dupixent.

11. Plaintiff Chandra Richardson is a citizen of the State of Tennessee, and resides at 144 Sophie Drive, Antioch, Tennessee, which is located in Davidson County.

12. Decedent was injected with Defendants' Dupixent (dupilumab) product in June and July 2024. As a direct and proximate result of use of Defendants' Dupixent product, Decedent incurred medical expenses, and suffered severe pain and physical and emotional injuries, including development and/or acceleration and exacerbation of T-cell lymphoma, loss of enjoyment of life and death.

13. 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.

14. Defendant SANOFI-AVENTIS U.S. LLC (hereinafter "sanofi-aventis"), a wholly-owned subsidiary of Sanofi, 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.

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

16. Regeneron subsequently submitted and obtained approval of multiple supplemental biologics license applications (sBLAs) to expand the indications for Dupixent to atopic dermatitis in pediatric patients; to asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), and eosinophilic esophagitis (EoE) in adult and pediatric patients; and to the treatment of prurigo nodularis (PN) and chronic obstructive pulmonary disease (COPD) in adult patients.

17. Defendants jointly developed, manufactured, marketed and distributed Dupixent throughout the nation including the state of Tennessee.

18. More than 800,000 people are being treated with Dupixent globally.[1]

19. Dupixent is a top-selling, blockbuster drug and a flagship product of both Sanofi-Aventis and Regeneron.[2] Sales of Dupixent were $14.1 billion in 2024 and at or above $4 billion per quarter for the first two quarters of 2025.[3]

20. Defendants manufactured, marketed and distributed the Dupixent injected into

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[1] *Id*.
[2] https://www.accio.com/business/sanofi-top-selling-drugs; https://synapse.patsnap.com/article/what-are-the-top-selling-drugs-of-regeneron.
[3] 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.

Decedent.

21. 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 throughout the United States, including in and throughout the State of Tennessee, and generated substantial revenue as a result.

JURISDICTION & VENUE

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

23. Each Defendant regularly conducts business in Tennessee, including directly or indirectly marketing, promoting, distributing, and selling its products in Tennessee, including Dupixent.

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

25. The harm suffered by Plaintiff and Decedent in Tennessee arises from and/or is related to each Defendant's contacts with Tennessee, including marketing, promoting, distributing, and selling its products in Tennessee, including Dupixent, and other conduct purposefully directed at Tennessee.

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

27. Defendant Regeneron's activities in Tennessee include a 5-year, $5 million investment to bolster science, technology, engineering and mathematics (STEM) in Nashville,

which was announced in 2023.[4] Regeneron also collaborates with the University of Tennessee Health Science Center to sequence DNA.[5]

28. Defendants perform clinical trials in Tennessee.

29. Defendant Sanofi-Aventis does business related to consumer healthcare and medication in Tennessee through its wholly owned subsidiary Chattem, Inc., which is headquartered in Chattanooga.[6]

30. Each Defendant's contacts with Tennessee were not random, isolated, or fortuitous.

31. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim, including the distribution, sale, and administration of Dupixent to Decedent and Decedent's development, diagnosis, and treatment of T-cell lymphoma, all occurred in the Middle District of Tennessee.

32. Defendant Regeneron Pharmaceuticals, Inc. is registered to do business in the State of Tennessee and can be served at its registered agent for service of process, CT Corporation System, at 300 Montvue Rd., Knoxville, TN 37919-5546.

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

FACTUAL BACKGROUND

A. Atopic Dermatitis

34. Dupixent was initially developed and approved to treat moderate to severe atopic

[4] https://investor.regeneron.com/news-releases/news-release-details/regeneron-builds-together-changetm-initiative-five-year-5

[5] https://news.uthsc.edu/uthsc-collaborates-with-the-regeneron-genetics-center-to-advance-precision-medicine-in-the-mid-south/#:~:text=the%20Mid%2DSouth,UTHSC%20Collaborates%20with%20the%20Regeneron%20Genetics%20Center%20To%20Advance%20Precision,as%20part%20of%20the%20collaboration.

[6] https://www.news.sanofi.us/press-releases?item=118517

dermatitis when topical treatments (treatments applied to the skin) are not sufficient or appropriate.

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

36. 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

37. Dupixent (dupilumab) is a biologic medication – a human monoclonal antibody – that inhibits the signaling of interleukin-4 (IL-4) and interleukin-13 (IL-13) by specifically binding to the IL-4 receptor alpha subunit that is shared by the IL-4 and IL-13 complexes.[7]

38. Dupixent is 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.

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

40. Upon information and belief, at no time after receiving approval did Defendants take initiative to update their package insert or request permission from the FDA to warn about the development or exacerbation of T-cell lymphoma including CTCL and PTCL. 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

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

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

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

C. Dangers of Dupixent: CTCL

42. Shortly after Dupixent was released to the market, concerned clinical and academic physicians began publishing case reports linking dupilumab use with T-cell lymphoma, including CTCL (including mycosis fungoides and Sezary syndrome) and PTCL.[8] 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.[9] Irreversible and aggressive cutaneous lymphoma disease acceleration in previously undiagnosed patients has also been reported.[10]

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[8] *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 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).

[9] *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; 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.

[10] *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.

43. A recent retrospective cohort study from Memorial Sloan Kettering Cancer Center identified 30 patients with dupilumab exposure for atopic dermatitis or eczema followed by confirmed CTCL, 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."[11]

44. 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 atopic dermatitis patients who were prescribed dupilumab and over one million patiens who did not use dupilumab. A second analysis was performed which 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).[12]

45. A second study by a different group of scientists using the TriNetX database compared patients with atopic dermatitis who were treated with dupilumab with those who were treated with alternative therapies and found that patients treated with dupilumab had an almost five-fold statistically significant increased relative risk (RR) of developing CTCL compared to those

[11] 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.
[12] 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.

who never treated with dupilumab (RR = 4.59, 95% confidence interval 2.459-8.657, P < 0.0001).[13] These investigators found that the risk of developing CTCL is highest in the first year of therapy with dupilumab and in adult patients.[14]

46. 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.[15] 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.[16]

47. Several published analyses of the FDA Adverse Event Reporting System (FAERS) database of dupilumab-related adverse events reported between 2017 and 2023 found a strong safety signal for CTCL with dupilumab.[17] "Compared to other therapies used in AD [atopic dermatitis], dupilumab had the most case reports and the highest RORs [reporting odds ratio] for CTCL."[18]

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

[14] *Id*.

[15] 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.

[16] Beck, at al., Dupilumab in adults with moderate to severe atopic dermatitis: a 5-year open-label extension study. *JAMA Dermatol*. 2024; 160:805-812; https://clinicaltrials.gov/study/NCT01949311. In addition, two patients developed Hodgkin's disease and one patient developed Hodgkin's disease lymphocyte predominance type state III. https://clinicaltrials.gov/study/NCT01949311.

[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.

[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.

48. Analysis of the World Health Organization global database of individual case safety reports (VigiBase) found an eleven fold statistically significant odds ratio of 11.11 (95% confidence interval 6.77-18.23) of CTCL with dupilumab use.[19]

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

50. 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.

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

52. 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 and/or exacerbation of T-cell lymphoma, including CTCL and PTCL.

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[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.

[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.

53. Upon information and belief, at no time did Defendants request permission from the FDA to warn physicans and patients about the newly acquired information related to the development or acceleration of T-cell lymphoma, CTCL and/or PTCL 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

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

55. 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 pre-existing T-cell lymphoma or increasing susceptibility to its development.

E. Defendants' Failure to Warn

56. 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 and PTCL, from use of Dupixent.

57. Defendants failed to warn physicians and patients that Dupixent should not be prescribed or administered to patients with confirmed or suspected T-cell lymphoma, including CTCL and PTCL, and that these diagnoses should be ruled out, by skin biopsy, testing for T-cell receptor gene arrangement, flow cytometry of the blood, or otherwise, prior to Dupixent

[22] *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.

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.[23]

58. Defendants failed to warn physicians and patients that due to the risk of development and exacerbation of T-cell lymphoma with dupilumab, careful clinical, histopathologic and immunohistochemical evaluation should be performed before and during treatment with dupilumab.[24] Early detection of CTCL and PTCL is of critical importance because a delay in diagnosis contributes to disease progression and high risk of mortality.[25]

59. 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 and/or acceleration of CTCL and PTCL.[26] Defendants failed to warn 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]

60. 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

[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., Evidence 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 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.

nonresponders.[28] 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 PTCL and to promptly evaluate for T-cell lymphoma following detection of same. Defendants should have warned that signs and symptoms that merit prompt evaluation for T-cell lymphoma in patients on Dupixent with presumed atopic dermatitis include new eczematous plaques in locations different than original sites, worsening pruritus (itching), lymphadenopathy, and new-onset moderate to severe "atopic dermatitis" in the elderly.[29]

61. Defendants have heavily marketed Dupixent in television advertisements, social media, the internet, and print brochures as providing clearer skin, fast itch relief, and better breathing. For patients with eczema, Defendants claim that Dupixent "help[s] heal your skin from within"[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 breath easier" and will allow them to "get more out of

[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 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.

[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.

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

[their] lungs," to "Du [sic] more with less asthma" and "achieve better breathing that lasts."[33] Defendants promote Dupixent as providing "Benefits 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 breath 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]

62. 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."

63. Defendants made repeated representations that Dupixent is safe and effective, including references to "safety results" from clinical trials.[36] 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 or progression of T-cell lymphoma, including CTCL and PTCL.

64. According to the Drugs@FDA website, the label for Dupixent has been updated thirty-two times, but Defendants' U.S. labels have not contained any warning or any information whatsoever on the propensity of Dupixent to cause the development or exacerbation of T-cell lymphoma including CTCL and PTCL.

65. Defendants should have warned patients and prescribers, including Decedent and

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

Decedent's treating physicians, that 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.

66. Defendants could have filed a "Changes Being Effected" ("CBE") supplement under Section 314.70(c) of the FDCA to make "moderate changes" to Dupixent's label without any prior FDA approval.

DECEDENT'S SPECIFIC FACTS

67. Decedent Cynthia Marie Hyde, a native of Denmark, Tennessee, moved to Nashville to attend Tennessee State University. In Nashville she met her husband, John B. Hyde, Jr., who preceded her in death. They had one daughter, Plaintiff Chandra Richardson.

68. Decedent dedicated 25 years to Bank of America (formerly Commerce Union), serving as a Research & Adjustments Analyst and Supervisor.

69. Decedent was a lifelong member of Faith United Missionary Baptist Church. She was known for her love of cooking, often catering church events and after-school programs.

70. Beginning in June 2023, Decedent lived with Plaintiff and her grandson Aiden (13), with whom she shared an inseparable bond. Decedent remained independent until June 2024, managing her own care, attending appointments, and actively helping raise her grandson.

71. Prior to June 2024, Decedent was instrumental in caring for her grandson, which among other things allowed Plaintiff to travel for work.

72. In 2019, at the age of 69, Decedent was diagnosed with adult-onset atopic dermatitis via skin biopsy.

73. Decedent was prescribed Dupixent for treatment of atopic dermatitis in May 2024.

At this time Decedent had an erythrodermic presentation (intense and widespread reddening of the skin), with hyperpigmented lichenified edematous patches on 80% of her body, including her face, arms, legs and torso.

74. Dupixent brochures were provided to Decedent by her prescriber prior to her first injection.

75. Decedent was injected with Dupixent in June and July 2024 at Decedent's physician's office by health care providers at that office.

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

77. Decedent had not been diagnosed with lymphoma of any kind (including CTCL and PTCL) prior to initiation of Dupixent.

78. By the end of July 2024 Decedent had developed hypertrophic (raised and thickened) scars on her forehead and right arm. She continued to have an erythrodermic presentation, with hyperpigmented lichenified edematous patches on 75% of her body, including her face, arms, legs and torso.

79. Dupixent did not improve Decedent's atopic dermatitis and was stopped for this reason.

80. Two months later, Decedent was hospitalized on September 30, 2024 for facial swelling and was treated for cellulitis, which resolved. During her admission, she was found to have a fairly diffuse skin rash and underwent biopsy, "which signed out as PTCL" with "clinical picture most consistent with cutaneous involvement of a high-grade, biologically aggressive T cell lymphoma."[37] This was the first biopsy performed on Decedent since her initiation of Dupixent.

[37] Progress Note, Dr. Michael T. Byrne, Oct. 24, 2024, Ascension St. Thomas Hospital Midtown.

Ms. Hyde was first informed of her lymphoma diagnosis on October 4, 2024.

81. Decedent's physicians informed her on October 24 and 25, 2024 that they recommended against treatment of her lymphoma because it was a high-grade, aggressive T-cell lymphoma and treatment would be associated with increased morbidity/mortality.

82. Based on her October 2024 biopsy result (which references mycosis fungoides within the differential), her erythrodermic presentation, and her failure to respond to Dupixent, Decedent most likely had CTCL which was dormant and quiescent until Dupixent transformed it into a fatal malignancy.

83. During the months of September and October, Cynthia Marie Hyde endured pain, suffering and mental anguish. She died on October 28, 2024.

84. Plaintiff cared for her mother during the painful and devastating month of October, 2024.

85. Defendants failed to timely and adequately warn Decedent and her medical providers of the propensity of Dupixent to cause the development or accelerate the progression of T-cell lymphoma, despite Defendants' knowledge of same.

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

87. Decedent and Decedent'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.

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

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

90. As a direct and proximate result of the Defendants' wrongful actions and inactions, Decedent sustained severe physical and emotional injuries, including loss of capacity for enjoyment of life, aggravation and exacerbation of preexisting conditions, mental and physical pain and suffering, cost of medical and hospital and other care and treatment, and death.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN

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

92. 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.

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

94. Decedent and Decedent's treating and prescribing physicians did not have the same

knowledge as Defendants and no adequate warning was communicated to Decedent or to her physicians.

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

96. 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 Decedent.

97. Defendants had a continuing duty to provide consumers, including Decedent and Decedent'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.

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

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

100. Defendants marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, Dupixent, to health care providers empowered to prescribe and dispense Dupixent, and to consumers, including Decedent, 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 Decedent.

101. 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 and PTCL, which can lead to accelerated disease progression and death.

102. 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.

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

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

105. 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.

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

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

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

109. Upon information and belief, had they been provided adequate warnings and instructions by Defendants, Decedent's Prescribing Healthcare Providers would have performed a biopsy when her clinical improvement with Dupixent was minimal, which would have resulted in earlier detection of Decedent's T-cell lymphoma and allowed time for treatment to occur.

110. Alternatively, even if Defendants had apprised Decedent's Prescribing Healthcare Providers of the increased risk of development or exacerbation of CTCL and PTCL in individuals with Decedent's presentation with usage of Dupixent and these Prescribing Healthcare Providers had still recommended usage of Dupixent to Decedent, the Prescribing Healthcare Providers would have relayed the information concerning the increased risk to Decedent, and Decedent as an objectively prudent person would not have chosen to inject Dupixent, notwithstanding Decedent's Prescribing Healthcare Providers' recommendation.

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

112. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Decedent and Decedent's Prescribing Healthcare Providers to the dangerous risks of Dupixent including, among other things, increased risk of the development or exacerbation of CTCL and PTCL, 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.

113. 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 and PTCL, which can lead to accelerated disease progression and death.

114. 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 and PTCL, which can lead to accelerated disease progression and death from the drug.

115. Defendants had an obligation to provide Decedent and Decedent's Prescribing Healthcare 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.

116. 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 Decedent's Prescribing Healthcare Providers, were inadequately informed about the true risk-benefit profile of Dupixent and were not sufficiently aware that serious injury and death might be associated with use of Dupixent.

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

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

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

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

121. The foreseeable risk of serious injury and death caused by Dupixent could have been reduced or avoided by Decedent and/or Decedent's prescribers had Defendants provided reasonable instructions or warnings of these foreseeable risks of harm.

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

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

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

125. As a direct and proximate result of Defendants' conduct, including the inadequate warnings, dilution or lack of information, lack of adequate testing and research, and the defective and dangerous nature of Dupixent, Decedent sustained serious bodily injury, severe pain and suffering, mental anguish, emotional distress, loss of enjoyment of life, medical expenses and other economic losses, aggravation of previously existing conditions and death.

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

SECOND CAUSE OF ACTION
NEGLIGENCE

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

128. 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 Decedent.

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

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

131. 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.

132. 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 or acceleration of CTCL and PTCL.

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

134. Defendants failed to exercise due care under the circumstances, and their gross negligence and recklessness includes the following acts and omissions:

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

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

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

d. 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;

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

f. Negligently failing to notify and warn the public, including Decedent, 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 and PTCL;

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 and PTCL;

i. Negligently misrepresenting the safety of Dupixent;

j. Negligently failing to provide warnings, instructions or other information that accurately reflected 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 Decedent's prescribing physicians regarding the increased risks of the development or acceleration of CTCL and PTCL through various communication vehicles, including Dupixent's labeling, patient medication guides, Dear Healthcare Provider letters, press releases, and other risk communication options;

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.

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

136. Decedent and Decedent's prescribing physicians reasonably relied upon the skill, superior knowledge, and judgment of Defendants. Defendants had a continuing duty to warn Decedent and her prescribing physicians of the dangers associated with Dupixent. Had Decedent and her physicians received adequate warnings regarding the risks of Dupixent, Decedent would not have been prescribed and used the product.

137. Defendants knew and/or should have known that it was foreseeable that consumers such as Decedent 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 dangers of Dupixent, and otherwise distributing the drug.

138. As a direct and proximate result of one or more of the above-stated acts, omissions, and conduct committed by the Defendants, Decedent sustained serious bodily injury, severe pain and suffering, mental anguish, emotional distress, loss of enjoyment of life, medical expenses and other economic losses, aggravation of previously existing conditions and death.

THIRD CAUSE OF ACTION
NEGLIGENCT MISREPRESENTATION

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

140. 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 Decedent.

141. Defendants owed a duty to prescribing physicians, other healthcare providers and to

consumers of Dupixent, including Decedent, to accurately and truthfully represent the risks of the drug. Defendants breached their duty by misrepresenting the safety and known risks of Dupixent and/or by failing to adequately warn Decedent's prescribing physicians, the medical community, Decedent, and the public about the risks of Dupixent, including that use of Dupixent results in increased risk of the development or exacerbation of CTCL and PTCL in individuals with presentations similar to Decedent, which Defendants knew or in the exercise of diligence should have known.

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

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

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

false, and unreasonably dangerous to consumers such as Decedent.

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

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

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

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

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

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

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

152. Defendants had sole access to many of the material facts concerning the defective nature of Dupixent and its propensity to cause serious and dangerous side effects.

153. At the time Decedent was prescribed and took Dupixent, Decedent and Decedent's Prescribing Healthcare Providers were unaware of Defendants' negligent misrepresentations and omissions.

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

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

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

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

158. As a direct and proximate result of reliance upon Defendants' negligent misrepresentations and omissions, Decedent sustained serious bodily injury, severe pain and suffering, mental anguish, emotional distress, loss of enjoyment of life, medical expenses and other economic losses, aggravation of previously existing conditions and death.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

159. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint

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

160. 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.

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

162. As set forth above, Defendants warranted that Dupixent would "heal your skin from within," that it would allow patients to "du [sic] more," and that it would provide "benefits with every breath."

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

164. 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.

165. Dupixent materially failed to conform to those representations made by Defendants, in package inserts and otherwise, concerning the properties and effects of Dupixent, which Decedent purchased and injected in direct or indirect reliance upon these express representations.

Such failures by Defendants constituted a material breach of express warranties made, directly or indirectly, to Decedent concerning the Dupixent sold to Decedent.

166. 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 Decedent and others.

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

168. Decedent and Decedent'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.

169. Decedent and Decedent'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.

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

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

172. Decedent purchased and injected Dupixent without knowing that the drug is not safe or effective, but that Dupixent instead causes the development or acceleration of CTCL and PTCL.

173. The Dupixent manufactured and sold by Defendants did not conform to Defendants' express representations because the Dupixent caused serious injury and death to Decedent when

used as recommended and directed.

174. As a direct and proximate result of Defendants' breaches of express warranties, Decedent sustained serious bodily injury, severe pain and suffering, mental anguish, emotional distress, loss of enjoyment of life, medical expenses and other economic losses, aggravation of previously existing conditions and death.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

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

176. 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.

177. Defendants were the sellers of Dupixent and sold Dupixent to be taken for treatment of atopic dermatitis. Decedent was prescribed and purchased Dupixent for this intended purpose.

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

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

180. In fact, Dupixent was not of merchantable quality nor fit for the ordinary purposes

and uses for which it was sold and did not meet the expectations of consumers.

181. The Dupixent manufactured and supplied by Defendants was not of merchantable quality and was not fit for the ordinary and/or particular purpose for which it was intended as physicians and patients would expect the drug to not cause the development or acceleration of CTCL and PTCL.

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

183. Contrary to such implied warranties, Dupixent was not of merchantable quality or safe for its intended and particular use and purpose, because the drug causes the development or acceleration of CTCL and PTCL

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

185. As a direct and proximate result of Defendants' acts and omissions, including breach of implied warranties, Decedent was prescribed and injected with Dupixent and sustained serious bodily injury, severe pain and suffering, mental anguish, emotional distress, loss of enjoyment of life, medical expenses and other economic losses, aggravation of previously existing conditions and death.

SIXTH CAUSE OF ACTION
WRONGFUL DEATH

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

187. When Decedent passed away, she left surviving family members, including her daughter Chandra Richardson and grandson Aiden John Richardson.

188. Plaintiff brings this action on behalf of the Decedent's Estate and surviving heirs under the Wrongful Death Act, Tennessee Code Annotated § 20-5-106 et seq., and other applicable laws.

189. As a result of Defendants' aforementioned wrongful conduct regarding Dupixent, Decedent suffered her wrongful and untimely death on October 28, 2024.

190. As a direct and proximate result of Decedent's wrongful death, Decedent's surviving heirs have been injured and have suffered, and will continue to suffer, inter alia: loss of consortium; loss of companionship; loss of care and affection; loss of advice, guidance, and counsel; loss of financial contributions; and loss of service.

191. As a direct and proximate result of Decedent's wrongful death, Decedent's surviving heirs have also been injured by incurring expenses for Decedent, including but not limited to hospital, medical, funeral, and burial expenses.

192. Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor against all Defendants for compensatory damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

SEVENTH CAUSE OF ACTION
SURVIVAL ACTION

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

194. When Decedent passed away, she left surviving her family members including her daughter Chandra Richardson and grandson Aiden John Richardson.

195. Plaintiff brings this action on behalf of Decedent's Estate and her surviving heirs

under the Survival Act, Tennessee Code Annotated § 20-5-103 et seq., and other applicable laws.

196. Plaintiff seeks all damages recoverable under the Survival Act, including but not limited to all damages arising out of Defendants' conduct that would have been recoverable by Decedent had she survived as described herein, including and without limitation, damages for pain and suffering, and loss of life's pleasure up to and including the time of her death, as well as lost income, lost future income, medical expenses, and other expenses incurred as a result of Defendants' conduct up to and including the time of her life expectancy.

197. Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor against all Defendants for compensatory damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

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, but because Tennessee law requires Plaintiff to set forth a specific amount in its initial complaint, Plaintiff hereby requests that damages be found in the amount of $2 million;

b. Compensation for past economic and non-economic losses, including but not limited to medical expenses, pain and suffering, loss of consortium, mental anguish and emotional distress, in such appropriate amounts as determined by the jury in its discretion after hearing the evidence at trial, but because Tennessee law requires Plaintiff to set forth a specific amount in its initial complaint, Plaintiff hereby requests that damages be found in the amount of $2 million;

c. Attorneys' fees and costs;

d. Interest; and

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

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury on all counts and as to all issues.

Dated: October 1, 2025 Respectfully Submitted,

s/ Mark P. Chalos
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JS 44 (Rev. 03/24)

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

CHANDRA RICHARDSON, individually, and on behalf of the ESTATE OF CYNTHIA MARIE HYDE

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Mark P. Chalos, Esq.
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
222 Second Avenue South, Suite 1640

DEFENDANTS

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

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

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

Attorneys *(If Known)*

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

- ☐ 1 U.S. Government Plaintiff
- ☐ 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

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

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

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:
Personal Injury and wrongful death as a result of prescription drug

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
10/01/2025

SIGNATURE OF ATTORNEY OF RECORD
s/Mark P. Chalos

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.