IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
BALTIMORE DIVISION

JOYANI GHOSH and RUTH ANNE CLARKE, Plaintiffs, vs. REGENERON PHARMACEUTICALS, INC., SANOFI-AVENTIS U.S. LLC, GENZYME CORPORATION, Defendants.	CASE NO.: COMPLAINT FOR DAMAGES DEMAND FOR JURY TRIAL

I. INTRODUCTION

1. Plaintiffs Ruth Anne Clarke and Joyani Ghosh (collectively, "Plaintiffs") bring this action on behalf of themselves and all others in the United States who consumed the dangerous pharmaceutical product Dupixent. Plaintiffs bring claims for damages, injunctive relief, and for the costs of funding a medical monitoring program for all patients who have used Dupixent but have not yet developed cutaneous T-cell lymphoma ("CTCL").

2. Defendants Regeneron Pharmaceuticals, Inc., Sanofi-Aventis U.S. LLC, and Genzyme Corporation (collectively, "Defendants") developed, manufactured, promoted and sold Dupixent as a biologic medication for the treatment of multiple inflammatory diseases and conditions of the skin and respiratory tract in adults and patients as young as six months old.

3. Defendants misrepresented that Dupixent was a safe and effective treatment when in fact the drug causes CTCL, a rare form of non-Hodgkin's lymphoma, and/or triggers a

reaction leading to severe and rapid clinical progression of otherwise subclinical and undiagnosed CTCL.

4. CTCL is a T-cell lymphoma that starts in the skin. It affects white blood cells called T-cells, or T lymphocytes, which begin to attack the skin. CTCL primarily presents as persistent, itchy skin rashes, but can result in hair loss and tumors, sores, and ulcers. In advanced stages, the disease can metastasize to lymph nodes, blood, or internal organs, and can be fatal. Mycosis fungoides and Sézary syndrome are the two most common subtypes of CTCL.

5. Post-marketing case reports and scientific studies began to flag an unexpected cluster of CTCL cases in Dupixent patients as early as 2018. Database studies published in 2024 and 2025 report a 2- to 4-fold higher incidence of mature CTCL after only 16 weeks of continuous exposure to Dupixent.

6. Defendants knew or should have known that Dupixent, when taken as prescribed and intended, is linked to the development and/or rapid clinical progression of CTCL.

7. Yet Defendants failed to warn physicians and the public about this causal relationship and the risks attendant to the use of Dupixent.

8. As a result, patients and physicians alike have been misled about the safety and efficacy of Dupixent.

9. Each of the Plaintiffs used Dupixent and were thus exposed to a substance that is highly dangerous and linked to a rare and potentially fatal disease. As a result, of their consumption of Dupixent, they have suffered subcellular damage and/or are at an increased risk of developing CTCL.

10. As a result of Defendants' conduct, Plaintiffs and the Class require medical monitoring and assert claims here for negligence, defective manufacture, failure to warn, a

violation of the Magnuson-Moss Warranty Act, breach of implied warranty of merchantability, fraudulent concealment, and other legal violations as set forth herein.

11. Medical monitoring is appropriate here because exposure to Dupixent is known to cause or lead to the development of CTCL, a serious and potentially fatal disease. The odds of survival are much higher if the disease is diagnosed and treated early—5-year survival rates for early-stage CTCL are between 90 and 100%, while 5-year survival rates for tumor-stage CTCL drop to around 50%.

12. CTCL can be difficult to diagnose and even clinical CTCL is often misdiagnosed as another skin condition. Furthermore, Dupixent can suppress symptoms of emergent CTCL, meaning that symptoms may become evident after a long course of treatment or after treatment ceases.

13. Here, the proposed monitoring program would first call for regular appointments with a dermatologist to perform and document a full skin examination. Subsequently, the patient would undergo regular visits for careful skin surveillance and biopsy of suspicious lesions as well as monitoring for CTCL-related symptoms, including blood testing, lymph-node assessment, and imaging. Finally, should CTCL develop, treatment would expand to include skin-directed treatment, for CTCL confined to the skin, or systemic treatment for CTCL that does not respond to skin-directed treatment or has metastasized.

14. Plaintiffs seek injunctive and monetary relief, including creation of a fund to finance independent medical monitoring and treatment services, including but not limited to notification to all people exposed to Dupixent, as well as examinations, testing, preventative screening, and care and treatment of cancer resulting from the exposure to Dupixent.

II. PARTIES

A. Plaintiffs

15. Plaintiffs are individuals who used Dupixent and have suffered injuries therefrom.

1. Joyani Ghosh

16. Plaintiff Joyani Ghosh currently lives in Chicago, Illinois, but resided in Boston, Massachusetts when she was first prescribed Dupixent and began taking the drug. Ms. Ghosh is 29 years old.

17. She was first prescribed Dupixent in 2017 to treat severe eczema.

18. Ms. Ghosh moved to Chicago in August 2022, after taking Dupixent for approximately 5 years while residing in Massachusetts.

19. She used Dupixent in a manner consistent with and as intended by Defendants.

20. She continued taking the drug until 2023, when she was diagnosed with b-cell lymphoma. Ms. Ghosh paused her use of Dupixent while undergoing treatment for b-cell lymphoma. She resumed use of Dupixent in 2025 at the advice of her dermatologist to address hair loss resulting from her lymphoma treatment but ceased using it in March of 2026 because it was not effective.

21. Prior to beginning to take Dupixent, she was warned only about eye irritation as a potential side effect. She was not warned of the risk of CTCL.

22. Had she known Dupixent was dangerous, Plaintiff would not have used or purchased Dupixent. As a result of Defendants' deception, and Plaintiff's use of Dupixent, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop cancer and other diseases.

2. Ruth Anne Clarke

23. Plaintiff Ruth Anne Clarke lives in Chesapeake, Maryland. Ms. Clarke is 73 years old.

24. She was first prescribed Dupixent in April 2026 to treat prurigo nodularis.

25. She used Dupixent in a manner consistent with and as intended by Defendants.

26. As per her prescribing doctor's instructions, Ms. Clarke took the first dose of Dupixent (which was a double dose) and four weeks later took a second dose. Within hours of the second dose she developed severe pain and swelling in her left leg. Two months later, pain and swelling persisted and she was still unable to walk normally. Recently, she has begun to experience joint pain in her right leg as well and she worries that she may have rheumatoid arthritis as a result of Dupixent.

27. She was not warned that this was a potential side effect of taking Dupixent, nor was she warned about the risk of CTCL.

28. Had she known Dupixent was dangerous, Plaintiff would not have used or purchased Dupixent. As a result of Defendants' deception, and Plaintiff's use of Dupixent, Plaintiff suffered subcellular injury that creates and/or increases the risk that Plaintiff will develop CTCL.

B. Defendants

29. 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.

1. Regeneron Pharmaceuticals, Inc.

30. Defendant Regeneron Pharmaceuticals, Inc. ("Regeneron") is a corporation organized under the laws of the state of New York with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

31. Regeneron is the official sponsor of the Biologics License Application ("BLA") for Dupixent in the United States (BLA 761055), which BLA 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

32. Regeneron subsequently submitted and obtained approval of multiple supplemental BLAs to expand the indications for Dupixent to various conditions in adult and pediatric patients.

33. As the official sponsor of the BLAs for Dupixent, Regeneron holds significant responsibility and control over the drug and all activities and materials relating thereto. Regeneron has been substantively involved in the development and sale of Dupixent and the design, funding, conduct, authorship, publication and dissemination of scientific research and promotional messaging related to Dupixent and the indications for which Dupixent has received approval to treat.

2. Sanofi-Aventis U.S. LLC

34. Defendant Sanofi-Aventis U.S. LLC ("Sanofi-Aventis"), a wholly-owned subsidiary of Sanofi S.A., a French multinational pharmaceutical company ("Sanofi"), is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

35. Sanofi-Aventis has been substantively involved in, inter alia, the development and sale of Dupixent and the design, funding, conduct, authorship, publication and dissemination of scientific research and promotional messaging related to Dupixent and the indications for which Dupixent has received approval to treat.

3. Genzyme Corporation

36. Defendant Genzyme Corporation ("Genzyme"), a wholly-owned subsidiary of Sanofi, is a corporation organized and existing under the laws of the State of Massachusetts, having its principal place of business at 450 Water Street, Cambridge, Massachusetts 02142. Genzyme has done business under various names and/or aliases, including "Sanofi Genzyme" and "Sanofi-Genzyme," at certain times relevant to this action.

37. Genzyme has been substantively involved in, inter alia, the coordination and funding of third parties to design, conduct, author, publish and disseminate scientific research and promotional messaging related to Dupixent and the indications for which Dupixent has received approval to treat. Prior to Dupixent's launch, Genzyme worked hand in hand with Defendants Regeneron and Sanofi-Aventis in commercializing Dupixent.[1]

4. Dupixent was Jointly Developed and Marketed By Defendants

38. Defendants, directly and/or through third parties, were both independently and collaboratively engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Dupixent throughout the

[1] *Regeneron Pharm., Inc. & Sanofi, Regeneron and Sanofi Announce Marketing Authorization Application for Dupixent® (dupilumab) Accepted for Review by the EMA* (Dec. 8, 2016), https://investor.regeneron.com/news-releases/news-release-details/regeneron-and-sanofi-announce-marketing-authorization

United States and controlling the BLA for Dupixent and other intellectual property associated with Dupixent.

39. In September 2003, Regeneron entered into a Collaboration Agreement with a predecessor-in-interest of Sanofi-Aventis regarding the co-development of an oncology medicine.

40. In November 2007, Regeneron entered into a new License and Collaboration Agreement with Sanofi, via its subsidiaries and/or affiliate entities. Under this License and Collaboration Agreement, Sanofi agreed to provide research funding in exchange for exclusive rights to co-develop and co-commercialize certain biopharmaceuticals discovered by Regeneron.

41. Defendants contemporaneously entered into a Discovery and Preclinical Development Agreement under which Regeneron would discover and create products for joint development and commercialization with Sanofi and its subsidiaries and/or affiliates. Such products would be considered a "Licensed Product" under the terms of the License and Collaboration Agreement.

42. In November 2009, Defendants Regeneron and Sanofi, via its subsidiaries and/or affiliate entities, expanded the scope and terms of their collaboration in an Amended and Restated License and Collaboration Agreement and Amended and Restated Discovery and Preclinical Development Agreement. The Amended and Restated License and Collaboration Agreement currently remains in effect, with subsequent amendments in May 2013, July 2015, April 2020 and September 2021, while the Amended Discovery Agreement expired in 2017.

43. Dupixent was one of the drugs Defendants agreed to co-commercialize under the Amended and Restated License and Collaboration Agreement.

44. Sanofi, individually and/or through its subsidiary, Sanofi-Aventis, continues to supply funding for ongoing Dupixent development research being conducted by Regeneron

45. Under the terms of the Amended and Restated License and Collaboration Agreement, Defendants have a reciprocal duty to regularly share information relating to the commercialization of Dupixent, to include anticipated launch dates, key market metrics, market research and sales, as well as to promptly notify the other party of any major market developments.

46. Sanofi, the parent company of Defendants Sanofi-Aventis and Genzyme, recognizes all sales of Dupixent. Profits and losses arising from commercial operations in the United States, including those associated with Dupixent, are split equally between Sanofi and its subsidiaries and Regeneron.

47. Sanofi serves as the "Lead Regulatory Party," as defined in the Amended and Restated License and Collaboration Agreement, responsible for managing pharmacovigilance and product complaints and for formulating and implementing any related strategies for Dupixent in the United States. Further, Sanofi-Aventis handles all processing and submissions of adverse event reports and product complaints for Dupixent in the United States on behalf of Sanofi. Despite this, Defendants have joint responsibility under the terms of the Amended and Restated License and Collaboration Agreement to collaborate in fulfilling all regulatory requirements concerning pharmacovigilance and risk management plans and product complaint reporting associated with Dupixent in the United States. Further to this joint responsibility, Defendants executed a Safety Data Exchange Agreement setting forth the specific procedures to be used to coordinate the investigation and exchange of reports of adverse events and complaints associated with Dupixent to ensure timely communication to regulatory authorities and

compliance with applicable laws as prescribed in the Amended and Restated License and Collaboration Agreement.

48. Defendants directed and continue to direct advertising and informational materials to physicians and potential users of Dupixent for the specific purpose of selling Dupixent across the United States, including in the states where Plaintiffs reside.

49. Defendants manufactured, marketed, and distributed Dupixent injected into Plaintiffs.

50. Profits and losses associated with the sale of Dupixent in the United States are split between Sanofi-Aventis (individually and/or through its parent and/or subsidiaries) and Regeneron.

III. JURISDICTION AND VENUE

51. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of Defendants, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action.

52. This Court has personal jurisdiction over Defendants because Defendants have sufficient minimum contacts in Maryland, and because Defendants have otherwise intentionally availed themselves of the markets within Maryland through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

53. Venue is proper in this District because "a substantial part of the events or omissions giving rise to the claim occurred" in this District, 28 U.S.C. § 1391(b)(2), and Defendants are subject to the personal jurisdiction of this Court, 28 U.S.C. § 1391(b)(3).

IV. FACTUAL ALLEGATIONS

A. Dupixent Is Prescribed to Treat Inflammatory Health Conditions

54. Dupixent (dupilumab) is a blockbuster drug and a flagship product of both Sanofi-Aventis and Regeneron. Sales of Dupixent were $11.6 billion in 2023, $14.1 billion in 2024 and $18.3 billion in 2025.

55. Dupixent is a therapeutic biologic used in the treatment of infants, children and adults with inflammatory health conditions in the United States and worldwide.

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

57. Dupixent is a human monoclonal immunoglobulin G4 antibody that binds to the interleukin (IL)-4 receptor alpha subunit shared by IL-4 and IL-13 to prevent their signaling. IL-4 and IL-13 signaling produces an inflammatory cascade that has been implicated in a number of immune-mediated inflammatory conditions. The mechanism of action through which Dupixent exerts a therapeutic effect in patients has not been definitively established.

58. Dupixent is supplied by Defendants in 200 mg and 300 mg single-dose prefilled syringes and single-dose prefilled pens. Dupixent is self-administered by patients or by caregivers through a subcutaneous injection in 1-, 2- or 4-week intervals depending on age, weight and therapeutic indication.

59. The active ingredient in Dupixent, dupilumab, was originally discovered by Regeneron during the mid- to late-2000s.

60. Regeneron submitted Investigational New Drug Application number 107969 to the United States Food and Drug Administration ("FDA") on July 12, 2010, requesting permission to study Dupixent in human subjects. The FDA deemed the first Phase I clinical

study to assess the safety and tolerability of Dupixent in adult patients with atopic dermatitis "Safe to Proceed" on August 21, 2010.

61. Regeneron completed its submission of BLA number 761055 for Dupixent to the FDA on July 28, 2016. Defendants officially received FDA approval to market Dupixent in the United States on March 28, 2017, for the 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.

62. Following its approval in March 2017, Defendants proceeded to submit several supplemental BLAs to the FDA seeking to market Dupixent for the treatment of additional health conditions and expand the patient population to include nearly all age groups, as shown in the table below.

Date	Condition	Patient Age Group
October 2018	Asthma	12 years and older
March 2019	Atopic dermatitis	12 years and older
June 2019	Chronic rhinosinusitis with nasal polyps	Adults
May 2020	Atopic dermatitis	6 years and older
October 2021	Asthma	6 years and older
May 2022	Eosinophilic esophagitis	12 years and older
June 2022	Atopic dermatitis	6 months and older
September 2022	Prurigo nodularis	Adults
January 2024	Eosinophilic esophagitis	1 year and older
September 2024	Chronic rhinosinusitis with nasal polyps	12 years and older
September 2024	Chronic obstructive pulmonary disease	Adults
April 2025	Chronic spontaneous urticaria	12 years and older
June 2025	Bullous pemphigoid	Adults

63. As a result of Defendants' ubiquitous advertising efforts to broaden Dupixent's patient population, more than 750,000 patients in the United States have received at least one dose as of 2026.

B. CTCL Poses a Serious Health Risk

64. Unbeknownst to consumers, the use of Dupixent is associated with the development of CTCL, a serious health condition.

65. CTCL is a form of non-Hodgkin lymphoma that is initiated by the malignant proliferation of T-cell lymphocytes contained in the skin. CTCL is an extremely rare condition estimated to affect fewer than 10 out of every 1 million people in the United States annually. The disease typically presents with patches, plaques, or rashes on the skin and may evolve over years.

66. 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. Many patients will require several different types of treatments throughout their lifetime. As lesions become more resistant to treatment, or in patients initially presenting with more severe forms of CTCL, more aggressive treatment approaches are usually necessary.

67. Early detection of CTCL is of critical importance because a delay in diagnosis contributes to disease progression and high risk of mortality.

68. CTCL can cause severe itching, pain and physical disfigurement which can significantly impair health-related quality of life, especially in later stages of the disease. CTCL can also metastasize to affect tissues and organs other than the skin. Survival rates vary depending on stage at the time of diagnosis, and patients with moderate to advanced CTCL experience markedly reduced survival.

69. Diagnosis of CTCL is typically made through repeated skin biopsies and blood tests. Imaging and biopsies of lymph nodes and bone marrow may also be performed in certain circumstances. CTCL is graded or staged according to the TNMB (Tumor, Node, Metastasis, Blood) criteria developed by the International Society for Cutaneous Lymphomas and the European Organization for Research and Treatment of Cancer based the proportion of skin affected by lesions, the type and size of lesions, metastasis to lymph nodes or other organs and the number of Sézary cells in the blood. CTCL stages range from I to IV, and include substages indicated by letters A or B, with higher numbers and letters indicating greater severity

70. The most common subtypes of CTCL are Mycosis fungoides and Sézary syndrome. Other forms of CTCL include peripheral T-cell lymphoma, subcutaneous panniculitis-like T-cell lymphoma, primary cutaneous anaplastic large cell lymphoma and extranodal natural killer/T-cell lymphoma. CTCL and its subtypes fall within a broader category of malignant disease processes referred to as mature T-cell and NK-cell lymphomas.

71. CTCL is typically a non-aggressive and slowly progressing disease, taking an average of 3 to 5 years, and up to 70 years, from initial presentation of symptoms until becoming diagnosable through clinical and histopathological evaluation. 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.

72. Certain environmental triggers can prompt rapid progression of CTCL. Indeed, when undiagnosed or misdiagnosed as another dermatosis, treatment-emergent “unmasking” of CTCL has long been a known risk with the use of certain medications.

73. Early studies observed no association between atopic dermatitis and CTCL, alternatively finding that rates of atopic dermatitis were very low in CTCL patients and not significantly different from the general population. The sequential observation of atopic dermatitis followed by Mycosis fungoides or Sézary syndrome was also extremely rare. However, as the use of powerful immunomodulating therapies in the treatment of dermatological conditions became commonplace, reports of CTCL in patients with atopic dermatitis—including both new-onset cases and unmasking or progression of pre-malignant cases—began to appear more frequently in the literature. Unsurprisingly, the ensuing expanded utilization of biological therapeutics in the management of dermatologic conditions was accorded by a parallel rise in CTCL diagnoses in treated patients. At the same time, studies reporting an increased risk of CTCL attributable to atopic dermatitis—as opposed to atopic dermatitis medications—have almost exclusively been funded and conducted by manufacturers of atopic dermatitis medications and their associates.

74. Although CTCL and b-cell lymphoma are both lymphomas arising from lymphocytes, they are distinct diseases with different pathology markers, clinical behavior, staging, and treatments. The two diseases arise from different lymphocyte lineages and are usually genetically distinct malignancies. There is no known causal link between Dupixent and b-cell lymphoma.

C. Use of Dupixent Causes CTCL

75. Despite being a relatively rare disease, CTCL has been widely reported among patients taking Dupixent. These cases 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. Evidence

supporting a causal relationship between use of Dupixent and CTCL is derived from both experimental and observational studies in humans.

76. Years before being approved for marketing by FDA, the first report of Dupixent-linked CTCL occurred in a patient treated with Dupixent in a Phase II clinical trial in adults with atopic dermatitis. In this study, Mycosis fungoides stage IV was reported in 1 of 97 (1.03%) subjects treated with dupilumab and 0 of 97 subjects assigned to placebo.[2] According to the FDA Medical Review for Dupixent, this subject presented on day 35 of treatment with apparent worsening of his atopic dermatitis after receiving 7 doses of Dupixent 300 mg and, on day 48, this subject was formally diagnosed with Mycosis fungoides stage IV and Dupixent was discontinued. Mycosis fungoides stage IV was noted to be ongoing at the end of the study.

77. Following this and another CTCL clinical trial case, Defendants amended the study protocol for the ongoing Phase III open-label trial on January 12, 2015, to designate "mycosis fungoides and cutaneous T-cell dyscrasias" as adverse events of special interest. However, Defendants did not likewise amend protocols for all ongoing or subsequent clinical trials in Dupixent development programs.

78. The results of the Phase III open-label extension trial were eventually posted to ClinicalTrials.gov in October 2023 and published in JAMA Dermatology in July 2024 and indicated CTCL was reported in a total of 3 patients who continued their Dupixent treatment from prior clinical trials. One additional subject treated with Dupixent developed T-cell lymphoma.[3] In addition to a tripling in the number of CTCL cases reported in Dupixent-treated

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[2] Center for Drug Evaluation and Research. Medical Review: Dupixent (dupilumab). Application Number 761055. U.S. Food and Drug Administration. March 2017.

[3] U.S. National Library of Medicine. NCT01949311. Open-label Study of Dupilumab in Patients With Atopic Dermatitis, *available at* https://clinicaltrials.gov/study/NCT01949311 (last accessed Jul. 1, 2026)

patients in this trial since November 2014, Mycosis fungoides was also noted to be one of the 5 most common treatment-emergent adverse events leading to discontinuation in this study.[4]

79. Defendants downplayed the risk of CTCL in communications with the FDA prior to receiving approval.

80. The link between Dupixent and CTCL became even more apparent after the drug was approved in light of the long-term use among hundreds of thousands of patients.

81. Indeed, following its approval for marketing in the United States in March 2017, independent clinicians and researchers began investigating and reporting a concerning association between Dupixent use and the development of CTCL. This large and growing body of research has been published in the form of cohort studies, cross-sectional studies, analyses of postmarketing adverse events, case series and individual case reports.

D. Defendants Failed to Adequately Test Dupixent

82. Defendants knew or should have known that Dupixent has a propensity to exacerbate preexisting CTCL or cause its development.

83. Although numerous studies, articles, and case reports provided evidence of Dupixent's link to CTCL, Defendants failed to adequately test Dupixent to investigate these risks.

84. Defendants failed to conduct carcinogenicity studies of Dupixent in any animal species prior to its approval by the FDA. Since receiving approval, Defendant still has not conducted any formal testing to evaluate the carcinogenic properties of Dupixent, nor have they

[4] Beck LA, Bissonnette R, Deleuran M, et al., *Dupilumab in Adults With Moderate to Severe Atopic Dermatitis: A 5-Year Open-Label Extension Study*, JAMA Dermatol. 2024;160(8):805-812. doi:10.1001/jamadermatol.2024.1536

conducted any formal testing to identify potential mechanisms through which Dupixent exposure causes "unmasking" or exacerbation of subclinical CTCL.

E. Defendants Marketed Dupixent as Safe and Effective

85. Defendants have aggressively promoted Dupixent as a necessary, life-changing therapy for patients suffering from inflammatory health conditions. Much of Defendants' approach has involved expanding the market for its use by convincing individuals with subtle symptoms, or even no symptoms, that they actually have a serious, undiagnosed inflammatory health condition, and penetrating the existing market by convincing patients that their current treatment regimen is inadequate to control their disease and/or has an unacceptable safety profile.

86. In the face of the studies and evidence linking Dupixent to CTCL, Defendants' marketing repeatedly assured physicians and patients that Dupixent is safe and effective.[5]

87. Defendants poured billions of dollars into direct-to-consumer advertising depicting Dupixent as being highly safe and effective and capable of greatly improving the quality of patients' lives. Between 2018 and 2024, Defendants spent an estimated $2.7 billion dollars to advertise Dupixent across all media types, including approximately $1.2 billion on direct-to-consumer television advertisements for atopic dermatitis, asthma, and gastrointestinal conditions. From 2019 on, Defendants' annual advertising expenditures for Dupixent were the highest or among the top three highest of all marketed drugs.[6]

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[5] *See, e.g.*, Dupixent Patient Brochure, 2025, *available at* https://www.dupixent.com/dam/jcr:fe8b9ba2-e8c0-4768-a483-89d1b1e6997c/DIGITAL_Dupixent%20AD%206th%20Gen%20Feel%20the%20Heal%20Patient%20Brochure.2026-05-19-19-38-25.pdf (last accessed Jul. 1, 2026)

[6] *See, e.g.*, Andrea Park, *AbbVie Pulls Off a Hat Trick with 3rd Straight Year as Top TV Drug Ad Spender, Buoyed by Skyrizi and Rinvoq Spots*, Fierce Pharma (Jan. 22, 2025), https://www.fiercepharma.com/marketing/abbvie-pulls-hat-trick-3rd-straight-year-top-tv-drug-ad-spender-buoyed-skyrizi-and-rinvoq (last accessed Jul. 1, 2026); Andrea Park, Nick Paul Taylor & Zoey Becker, *The Top 10 Pharma Drug Ad Spenders of 2024*, Fierce Pharma (June 30,

88. In conjunction with branded advertising, Defendants' marketing seeks to raise awareness of the conditions Dupixent treats to increase consumer anxiety and diagnosis rates and thereby increase prescriptions of Dupixent. To this end, Defendants conducted large-scale unbranded disease awareness campaigns. With these unbranded campaigns, Defendants began seeding the market for Dupixent well before it received FDA approval for marketing in the United States.

89. Defendants' marketing efforts also involved using published scientific literature to promote perceptions that atopic dermatitis is underdiagnosed or, if patients have already received a diagnosis of atopic dermatitis, that they are not being sufficiently treated.

90. Defendants also funded and promoted hundreds of continuing medical education programs as a vehicle to disseminate seemingly unbiased unbranded disease awareness marketing materials directly to healthcare providers. These programs were designed to increase screening and diagnoses of atopic dermatitis, asthma and other indicated health conditions and corresponding prescriptions of Dupixent, boosting Defendants' profits in the process. For instance, Defendants established ADVENT, a global medical education platform disseminating "non-promotional" information to healthcare providers worldwide regarding Type 2

2025), https://www.fiercepharma.com/marketing/top-10-pharma-drug-ad-spenders-2024 (last accessed Jul. 1, 2026); Ben Adams, Andrea Park & Nick Paul Taylor, *AbbVie Makes Clean Sweep—Skyrizi and Rinvoq Top TV Drug-Ad Spender for 2023*, Fierce Pharma (Jan. 9, 2024), https://www.fiercepharma.com/marketing/abbvie-makes-clean-sweep-skyrizi-and-rinvoq-top-tv-drug-ad-spender-2023 (last accessed Jul. 1, 2026); Ben Adams, Andrea Park & Nick Paul Taylor, *The Top 10 Pharma Drug Ad Spenders for 2023*, Fierce Pharma (June 3, 2024), https://www.fiercepharma.com/marketing/top-10-pharma-drug-ad-spenders-2023 (last accessed Dec. 9, 2025); U.S. Gov't Accountability Off., GAO-21-380, *Prescription Drugs: Medicare Spending on Drugs with Direct-to-Consumer Advertising: Report to the Committee on the Judiciary*, U.S. Senate (May 2021), https://www.gao.gov/assets/gao-21-380.pdf (last accessed Jul. 1, 2026).

inflammatory diseases that Dupixent has been approved to treat or in which Dupixent is currently being investigated.

91. Finally, in addition to extensive branded and unbranded disease awareness marketing, Defendants used influential third parties to (i) promote the use of Dupixent in an unrestricted manner, (ii) inappropriately characterize the safety and effectiveness of the drug, and (iii) further drive awareness of inflammatory health conditions. To this end, Defendant engaged and funded major academic societies, patient advocacy organizations, trade groups and leading subject matter experts who are charged with shaping clinical treatment guidelines.

F. Defendant Failed to Warn Physicians and Patients

92. Even though numerous studies, articles, and case reports indicated that Dupixent was linked to the development of CTCL or the exacerbation of subclinical CTCL, Defendants failed to warn doctors and consumers that Dupixent should not be prescribed or administered to patients with T-cell lymphoma and that these diagnoses should be ruled out by testing (including biopsies) prior to administering Dupixent.

93. Researchers and clinicians strongly recommended that atopic dermatitis patients undergo skin biopsies and other tests to rule out subclinical T-cell lymphoma prior to beginning the use of Dupixent, as well as ongoing monitoring and screening during the use of Dupixent to detect the development of CTCL during the use of Dupixent.

94. Additionally, researchers and clinicians counseled physicians to vigilantly monitor for signs of CTCL when an atopic dermatitis patient shows signs of non-responsiveness or a brief period of initial responsiveness followed by resurgence of symptoms.

95. Defendants failed to heed these warnings by, for example, recommending appropriate screening and monitoring of patients to reduce the risk of CTCL in patients taking the drug.

96. Defendants took the opposite approach, advocating for increased dosage of Dupixent when the approved dosing regimen did not result in relief of atopic dermatitis symptoms.

97. Defendants wholly failed to warn physicians and patients that Dupixent was contraindicated for persons with confirmed or suspected T-cell lymphoma, and that the presence of the disease must be excluded by testing prior to use of Dupixent.

98. Defendants wholly failed to warn physicians and patients that following the use of Dupixent, a patient must undergo regular testing and monitoring to rule out the development of CTCL.

99. Defendants wholly failed to warn physicians and patients of the signs and symptoms of the development of CTCL during the course of treatment with Dupixent, including eczematous plaques in new locations, worsening itching, and other warning flags.

100. Since the drug was first approved in 2017, the prescribing information for Dupixent has been deficient in that it has failed to provide adequate instructions for its safe prescription and use. This information lacks, for example, no warning to patients and physicians of the risk of CTCL or any other form of cancer due to Dupixent use or contraindication for patients with a history of CTCL. Nor does this information direct physicians to screen patients prior to beginning treatment, to monitor patients during the course of treatment, or to discontinue use if the patient exhibits signs of non-responsiveness or worsening of symptoms or otherwise develops indicators of CTCL.

101. These failures to warn are inexcusable in light of the clinical evidence and research findings indicating a causal link between Dupixent use and CTCL. Such information was known to Defendants at all times relevant hereto.

102. On the contrary, Defendants have spent billions of dollars aggressively marketing Dupixent as a necessary and life-changing therapy for patients suffering from various inflammatory conditions in order to ramp up prescriptions for Dupixent.

G. Plaintiffs and Class Members Have Suffered Present Injury in That They Have Suffered Bodily Harm and also Need to Incur the Cost of Medically Necessary Diagnostic Testing Due To Their Increased Risk Of Disease Caused By Exposure To Dupixent

103. Use of Dupixent has resulted in consumers suffering from cancer, namely CTCL.

104. Plaintiffs and Class Members have been significantly exposed to Dupixent, which causes and/or exacerbates subclinical CTCL. Plaintiffs and Class Members have injected or otherwise taken Dupixent, where it was absorbed into tissue and into Plaintiffs' and Class Members' bloodstream, producing subcellular or other physiological changes in Plaintiffs and Class Members. As a result, Plaintiffs and Class Members are presently at an increased risk of developing CTCL.

105. Data exists to indicate that the presence, accumulation, and/or persistence of Dupixent in human blood and/or tissue, including that of Plaintiffs and the other Class Members, is injurious and physically harmful and results in unwanted, unconsented-to, and deleterious alterations, changes, and/or other presently-existing physical injury and/or adverse impacts to the blood and/or bodies of Plaintiffs and the other class members, including but not limited to subcellular injuries.

106. Moreover, based on available scientific literature, exposure to Dupixent places Plaintiffs at risk of developing CTCL. Dupixent's therapeutic mechanism changes the gene

expression of immune and tissue cells and, although the exact causal pathway is unknown,[7] a large body of research has established that Dupixent's effect on immune and tissue cells leads to new, primary cases of CTCL as well as the rapid progression of preexisting occult CTCL.

107. Defendants did not seek or obtain permission or consent from Plaintiffs or the other class members before engaging in such acts and/or omissions that caused, allowed, and/or otherwise resulted in the contamination of Plaintiff's and the other Class Members' blood and/or bodies with Dupixent.

108. Plaintiffs and the other Class Members are reasonably concerned and fearful of the effects of having been exposed to Dupixent, including what such exposure will and/or will likely do to them, including reasonable fear of CTCL and/or other serious disease that may have long latency periods after such exposures.

109. Plaintiffs and the other Class Members should not have to wait until actual diseases, death, or other adverse effects occur as a result of Dupixent in their blood and/or bodies before adequate monitoring, testing, and/or research is funded.

110. Plaintiffs and the other Class Members should not have to bear the burden of funding and/or performing such monitoring, testing, and/or research, which is likely to cost more than millions of dollars, when Plaintiffs and the other Class Members did not consent or provide permission to Defendants to put a hazardous compound in their blood and/or bodies, and Defendants have reaped many millions of dollars in profits from the acts and/or omissions that

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[7] Whether Dupixent is directly carcinogenic or mutagenic has not been established, as "[a]nimal studies have not been conducted to evaluate the carcinogenic or mutagenic potential of dupilumab." *FDA-Approved Prescribing Information for Dupixent® (dupilumab), revised April 2026*, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761055s082lbl.pdf (*last visited* Jul. 16, 2026).

caused, permitted, allowed, and/or otherwise resulted in Plaintiffs' and the other class members' exposure to Dupixent.

111. As a result of Defendants' tortious conduct in the manufacture, development, marketing, and sale of Dupixent, Plaintiffs and Class Members have been significantly exposed to a hazardous compound. Plaintiffs and Class Members have injected Dupixent into their blood and/or tissue, where it produced subcellular or other physiological changes in Plaintiffs and Class Members.

112. As a proximate result of Defendants' tortious conduct, Plaintiffs and Class Members have been and are presently at an increased risk of CTCL, which risk requires them to incur, both now and in the future, the cost of medically necessary diagnostic testing for the early detection of illness, disease process or disease arising from their exposure to Dupixent.

113. Plaintiffs and Class Members have suffered a present injury proximately caused by Defendants' tortious conduct. Plaintiffs have a legally protected interest in not being exposed to harmful compounds—like Dupixent—that can result in an increased risk of illness, disease, or disease process. Plaintiffs and Class Members also have a legally protected interest in avoiding the present and ongoing medical need for expensive diagnostic testing.

114. The exposure to Defendants' Dupixent, the consequent subcellular or other physiological changes in Plaintiffs and Class Members, and the resulting increased risk of illness, disease, and disease process, has caused Plaintiffs and Class Members a present and ongoing injury. This injury consists of the need to incur the cost of medically necessary diagnostic testing for the early detection of illness, disease, and disease process arising from Defendants' tortious development, marketing, and sale of Dupixent.

115. Defendant's tortious conduct constitutes an invasion of the legally protected interests of Plaintiffs and Class Members and has injured Plaintiffs and Class Members. Plaintiffs and Class Members would not have the present and ongoing need to incur the cost of medically necessary diagnostic testing to monitor the presence of illness, disease, or disease process arising from their exposure to Dupixent, and the consequent subcellular or other physiological changes arising therefrom, but for the past and ongoing exposure they suffered owing to the tortious conduct of Defendants.

116. Diagnostic and monitoring procedures exist that make possible the early detection of CTCL caused by Dupixent. These monitoring procedures will benefit Plaintiffs and Class Members because they will allow for the early detection of latent disease associated with exposure to Dupixent. Catching CTCL early often allows for more treatment options. Overall outlook depends on early diagnosis; the sooner a person is checked, the better the outcome will be.

117. These monitoring procedures are different from what would normally be recommended in the absence of exposure to Dupixent. The general unexposed population does not receive these procedures as a routine matter of course because, e.g., these tests are designed to detect the specific diseases known to be associated with exposure to Dupixent.

118. Such monitoring procedures in the form of periodic diagnostic testing conform to the standard of care and are reasonably necessary to ensure that disease processes can be identified early and aggressively treated. Effective medical tests exist for reliable early detection, and early detection combined with effective treatment will significantly decrease the severity of the illness, disease, disease process, or injury. The present value of the costs of such tests is calculable and Plaintiffs and Class Members will prove such costs at trial.

119. Such monitoring procedures include testing and screening necessary to detect the existence of CTCL caused by exposure to Dupixent as described herein, including but not limited to blood tests, physical examinations, imaging, biopsies, and other similar methods for examination, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations. Additionally, medical monitoring includes medical and surgical procedures necessary for diagnosis and treatment.

120. Medical monitoring is recognized as beneficial for early detection where there is an increased risk of disease from exposure to hazardous substances.[8] The purpose of medical monitoring in the form of diagnostic testing is early identification of latent or unrecognized illness, disease, or disease process so that early treatment can be given to reduce the impacts of the toxic exposure.[9] Medical monitoring is widely accepted as a prudent response to exposure to substances that cause cancer, like Dupixent.[10]

121. Plaintiffs and Class Members have suffered an injury consisting of the present and future need of medically necessary diagnostic testing to diagnose the warning signs of the illness, diseases, and/or disease processes resulting from exposure to Dupixent. Early detection of illness, diseases and disease processes allows for more treatment options, reduces the cost of treatment, and increases the chances of an improved outcome. If the illness, disease, or disease

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[8] *ATSDR's Final Criteria for Determining the Appropriateness of a Medical Monitoring Program Under CERCLA*, 60 FR 38841, July 28, 1995.

[9] *Id.*

[10] *See* http://www.c-8medicalmonitoringprogram.com/docs/med_panel_education_doc.pdf (last accessed Jul. 1, 2026); Department of Environmental Health, *Fernald Medical Monitoring Program*, UNIVERSITY OF CINCINNATI COLLEGE OF MEDICINE, https://med.uc.edu/eh/research/projects/fcc/fmmp-history (last accessed Jul. 1, 2026); Environmental Health & Safety, *Pesticide Users Medical Monitoring Program*, UNIVERSITY OF FLORIDA (revised Jan. 21, 2014), http://www.ehs.ufl.edu/programs/ih/pesticide/ (last accessed Jul. 1, 2026); World Trade Center Health Program, *About the Program*, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/wtc/about.html (last updated Dec. 15, 2017).

process is permitted to develop until it becomes obvious, Plaintiffs and Class Members will have lost valuable treatment time and will likely require a more costly medical intervention.

122. The alternative to medical monitoring is to wait to see if and when Plaintiffs or any Class Member dies, develops CTCL, or suffers other adverse health effects necessitating diagnostic testing.

123. Plaintiffs' and Class Members' present need to incur the cost of diagnostic testing is reasonably medically necessary as a direct and proximate result of Defendants' conduct due to the Plaintiffs' and Class Members' exposure to Dupixent, and the subcellular or other physiological changes that have resulted therefrom.

124. Plaintiffs and the Class are currently in need of costly diagnostic testing. Specifically, they now need monitoring procedures that are reasonably medically necessary to enable Plaintiffs and Class Members to obtain early detection and diagnosis of illness, disease and disease process, including abnormalities indicative of CTCL, as the proximate result of Defendants' tortious conduct described herein.

125. Plaintiffs and Class Members seek as damages the costs of such diagnostic testing for the early detection of illness, disease, and disease process to allow for early treatment beneficial to Plaintiffs and Class Members, or in the alternative, the award of the reasonable and necessary costs for the establishment of a court-supervised program of diagnostic testing through equitable and/or injunctive relief.

126. Plaintiffs and Class Members also seek all other available and necessary relief in connection herewith, including the establishment of a panel of scientists to study the effects on the human body of exposure to Dupixent and for medical monitoring for those individuals who were significantly exposed to such compounds.

V. EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

127. The running of any statute of limitations has been equitably tolled by Defendants' fraudulent concealment and/or omissions of critical safety information. Through its affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiffs and their physicians the true risks associated with Dupixent.

128. As a result of Defendants' actions, Plaintiffs were unaware, and could not have reasonably known or learned through reasonable diligence, that they had been exposed to the risks and harms set forth here and that those risks and harms were the direct and proximate result of Defendants' acts and omissions.

VI. CLASS ACTION ALLEGATIONS

129. Plaintiffs bring this action on behalf of themselves and, under Federal Rule of Civil Procedure 23(a), (b)(2), (b)(3), and (c)(4), as representatives of the classes defined as follows:

> All individuals who consumed Dupixent while residing in Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming and the territories and possessions of the

United States of America since January 1, 2012, with no prior diagnosis of T-cell lymphoma (the "Multistate Class").

130. Excluded from the Multistate Class, and from the other additional and alternative classes defined below, are Defendants and their subsidiaries and affiliates; all persons who make a timely election to be excluded from the Class or classes to the extent any class is an opt-out class or a hybrid opt-out class; governmental entities; and any judicial officers who preside over this case and their immediate family members.

131. Plaintiffs allege additional subclasses for Multistate Class Members who consumed Dupixent while residing in Maryland and Massachusetts.

132. Plaintiffs further allege additional subclasses in combinations of the above States, territories, and possessions to the extent class members from jurisdictions can be grouped together for purposes of class treatment given that Rule 23 and choice of law principles permit certification of subgroups of states and provide that relatively minor differences in state law that can be overcome by grouping similar laws together.

a. Plaintiff Ghosh seek to represent a Massachusetts class or class(es) of states with similar applicable laws to Massachusetts, where medical monitoring is or likely would be recognized as an independent claim, as defined below:

All individuals who consumed Dupixent while residing in Alaska, Arizona, Arkansas, California, Colorado, Delaware, District of Columbia, Florida, Guam, Hawaii, Idaho, Indiana, Kansas, Maine, Massachusetts, Minnesota, Montana, New Mexico, Pennsylvania, Puerto Rico, South Carolina, South Dakota, Utah, Virgin Islands, West Virginia, and Wyoming since January

1, 2012, with no prior diagnosis of T-cell lymphoma (the "Independent Claim Class").

b. Plaintiff Clarke seeks to represent a Maryland class and/or class(es) of states with similar applicable laws to Maryland, where medical monitoring is or likely would be recognized as a remedy for other claims asserted herein, as defined below:

All individuals who consumed Dupixent while residing in Alabama, Alaska, California, Connecticut, Delaware, District of Columbia, Georgia, Guam, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, Ohio, Oklahoma, Oregon, Puerto Rico, South Carolina, Tennessee, Texas, Virgin Islands, Virginia, Rhode Island, South Dakota, Vermont, Washington, Wisconsin, and Wyoming since January 1, 2012, with no prior diagnosis of T-cell lymphoma (the "Remedy Class").

133. Collectively, the foregoing Multistate Class and its subclasses are referred to as the "Class."

134. As alleged throughout this Complaint, the Defendants engaged in uniform and standardized conduct towards the Classes. The Defendants did not differentiate, in their degree of care or candor, their actions or inactions, or in the content of their statements or omissions, among individual Class Members. The objective facts on these subjects are the same for all Class members. Within each Claim for Relief asserted by the respective Classes, the same legal standards govern. Additionally, many states share the same legal standards and elements of proof, facilitating the certification of multi-state classes for some or all of the claims.

135. No actual conflict of laws exists between the laws of Plaintiffs' home states, and the laws of other class members' states. Or alternatively, any potential conflict is a false one. The lack of conflict, or the false conflict, between the laws of Plaintiffs' home states and the laws of other class members' states means it is appropriate to certify the Multistate Class under the laws of the abovementioned states.

136. Plaintiffs reserve the right to narrow or expand the foregoing class definition, or create subclasses, in light of future fact discovery, and including as the Court deems necessary. These may include, by way of example, bellwether classes or state or other sub-classes.

A. The Classes Meet the Rule 23 Requirements

137. Plaintiffs meet the prerequisites of Rule 23(a), (b), and (c) to bring this action on behalf of the Class and Classes.

138. **Numerosity (Rule 23 (a)(1))**: While the exact number of Class Members cannot be determined without discovery, the proposed multistate class potentially reaches the millions, and there is no proposed class with fewer than thousands or more of members. The Class Members are therefore so numerous that joinder of all members is impracticable as to the multistate class and/or as to the subclasses.

139. **Commonality (Rule 23(a)(2))**: Even a single common question can drive a litigation and warrant certification. Here, material common questions of law and fact exist as to all Class Members, including but not limited to:

a. Whether Dupixent causes users to develop CTCL;

b. Whether Defendants negligently or defectively manufactured Dupixent consumed by Plaintiffs and other Class Members;

c. Whether Defendants misrepresented facts or failed to warn as to the hazard posed by Dupixent;

d. Whether each Defendant made and breached implied warranties to Plaintiff and other Class Members regarding the safety of Dupixent;

e. Whether Plaintiffs and other Class Members have suffered subcellular injury and are at increased risk of developing cancer as a result of each Defendant's unlawful conduct;

f. Whether testing is available for the cancer to which Plaintiffs and the Class Members are at increased risk;

g. The nature and extent of medical monitoring, testing, examinations, and treatment necessary to address the risks created by Plaintiffs and other Class Members' consumption of Dupixent;

h. When Plaintiffs' and other Class Members' claims for relief accrued;

i. Whether Defendants fraudulently concealed Plaintiff's and other Class Members' causes of action.

140. **Typicality (Rule 23(a)(3))**: Plaintiff's claims are typical of Class Members' claims. Plaintiff and other Class Members all suffered the same type of harm, including exposure to Dupixent and consequent subcellular injury and increased risk of developing CTCL, but have not yet been diagnosed with cancer. Plaintiffs bring claims under the same legal and remedial theories as the class. Plaintiffs' claims arise out of the same set of facts and conduct as all other Class Members.

141. **Adequacy of Representation (Rule 23(a)(4) and Rule(g))**: Plaintiffs are committed to pursuing this action and have retained competent counsel experienced in

pharmaceutical and products liability litigation, medical monitoring, consumer litigation, and class actions. Accordingly, Plaintiffs and their counsel will fairly and adequately protect the interests of Class Members. Plaintiffs' claims are coincident with, and not antagonistic to, those of the other Class Members and Plaintiffs will fairly and adequately represent the interests of Class Members

142. **Rule 23(b)(2):** Defendants have acted on grounds that apply generally to Class Members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Classes as a whole.

143. **Rule 23(b)(3) Predominance and Superiority:** Here, the common questions of law and fact enumerated above predominate over the questions affecting only individual Class Members, and a class action is the superior method for fair and efficient adjudication of the controversy. The likelihood that individual Class Members will prosecute separate actions for medical monitoring is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues is furthermore not efficient, timely or proper. Judicial resources will be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated plaintiffs. Plaintiffs' counsel, highly experienced in pharmaceutical and product liability litigation, consumer litigation, class actions, and federal court litigation, foresee the efficient management of this case as a class action.

144. **Rule 23(c)(4) Issues Class:** To the extent the Court determines there are material differences in the relevant laws and that such differences present class manageability issues precluding multistate class certification for all purposes, Plaintiffs submit that a multistate issue

class is appropriate for determination of common material fact issues in the case, and are predicates for the entitlement to medical monitoring (such as exposure, misconduct, increased risk, existence of testing and benefit of testing, among others).

VII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

NEGLIGENCE
(Individually and on Behalf of the Class)

145. Plaintiffs repeat and re-allege the preceding paragraphs as if fully set forth herein.

146. Each Defendant owed a duty to Plaintiffs and the Classes to use and exercise reasonable and due care in the manufacturing, testing, distribution, labeling, marketing, warnings, disclosures, and sale of Dupixent.

147. Each Defendant owed a duty to Plaintiffs and the Classes to assess, manage, and communicate the risks, dangers, and adverse effects of Dupixent, and to warn patients—including Plaintiffs and the Class—and their physicians and healthcare providers of such risks, dangers, and adverse effects.

148. Defendants' duties included properly advertising, analyzing, designing, developing, distributing, formulating, labeling, manufacturing, marketing, promoting, researching, selling, and testing Dupixent, and providing adequate information regarding the risks and dangers of use of Dupixent.

149. Each Defendant owed a duty of care to Plaintiffs and the Classes because they were the foreseeable, reasonable, and probable users of Dupixent. Each Defendant knew, or should have known, of the hazards posed by Dupixent, and each was in the best position to uncover and disclose these facts.

150. Each Defendant breached these duties by failing 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.

151. Although Defendants knew or should have known that use of Dupixent posed a serious risk of bodily harm to consumers, Defendants continued to market the drug without including appropriate warning language.

152. Each Defendant negligently failed to promptly and immediately warn and disclose to Plaintiffs and other Class Members, and the medical and regulatory communities, of the hazard posed by Dupixent as soon as it was discovered, delaying notice of this harmful and potentially fatal toxic exposure to a substance that causes CTCL and thus causing continued exposure to the substance, and delaying necessary testing, examinations, surveillance, and treatment.

153. Defendants' negligent conduct created and then exacerbated an unreasonable, dangerous condition for Plaintiffs and other Class Members.

154. A reasonably prudent drug manufacturer, distributor, promoter, or seller under the same or similar circumstances would not have engaged in the aforementioned conduct.

155. Defendants acted with recklessness and willful and wanton disregard for the health of Plaintiffs and other Class Members.

156. Each Defendant's own unreasonable, negligent actions and inactions were taken or not taken with willful and wanton disregard for the health of Plaintiffs and other Class Members and created a foreseeable risk of harm to Plaintiff and other Class Members.

157. As a direct and proximate result of each Defendant's negligent conduct, Plaintiffs and other Class Members have suffered subcellular injury that creates and/or increases the risk

that Plaintiffs will develop CTCL, necessitating notice to all Class Members, sufficient funding for the tests and evaluations of each Class Member, and sufficient funding for necessary ongoing tests, evaluations, and treatment.

158. Plaintiffs and Class Members seek compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to Dupixent as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

SECOND CLAIM FOR RELIEF

NEGLIGENCE PER SE
(Individually and on Behalf of the Class)

159. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

160. Each Defendant owed a duty to Plaintiffs and the Classes to use and exercise reasonable and due care in the manufacturing, testing, distribution, labeling, marketing, warnings, disclosures, and sale of Dupixent.

161. Each Defendant owed a duty to Plaintiffs and the Classes to assess, manage, and communicate the risks, dangers, and adverse effects of Dupixent, and to warn patients—including Plaintiffs and the Class—and their physicians and healthcare providers of such risks, dangers, and adverse effects.

162. Each Defendant owed a duty to Plaintiffs and the Class because each state, territory, and possession has adopted /or adheres to federal labeling standards.

163. Each Defendant failed to comply with federal labeling standards.

164. Each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class.

165. As a direct and proximate result of each Defendant's negligent conduct, Plaintiffs and other Class Members have suffered subcellular injury which creates and/or increases the risk that Plaintiffs will develop CTCL, necessitating notice to all Class Members, sufficient funding for the tests and evaluations of each Class Member, and sufficient funding for necessary ongoing tests, evaluations, and treatment.

166. Plaintiffs and Class Members seek compensatory damages for, and the creation of a fund to adequately finance the costs of, the creation of a fund to adequately finance the costs of medical monitoring procedures (1) to notify and alert all people exposed to Dupixent as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

THIRD CLAIM FOR RELIEF

MEDICAL MONITORING
(Individually and on Behalf of the Independent Claim Class)

167. Plaintiffs repeat and re-allege the preceding paragraphs as if fully set forth herein.

168. As a proximate result of Defendants' acts and omissions, the Class is at an increased risk of developing cancer above the normal base-level risk.

169. As alleged above, Dupixent causes life-threatening cancer in humans.

170. The Class Members may not develop cancer for many years.

171. The Class Members are at an increased risk as they injected Defendants' Dupixent for extended periods of time, some as many as several years, and as a result were exposed to a substance that causes CTCL.

172. Based upon the findings of numerous cohort studies, cross-sectional studies, and analyses of postmarketing adverse events, case series and individual case reports, the Class is at an increased risk of cancer as users of Dupixent.

173. The Class Members are at an increased risk of CTCL as they were injected Defendants' Dupixent in quantities, and over periods of time sufficient to establish an exposure level that is considered to be hazardous to health, and that is considered to be sufficient to cause cancer or increase the risk of developing cancer.

174. The exposure was caused solely and proximately by Defendants' failure to adequately test, study, and/or research Dupixent both before and after the drug was approved, and also by Defendants' failure to promptly warn and disclose to Plaintiffs and other Class Members, and the medical and regulatory communities, the hazard posed by Dupixent.

175. Defendants had duties to the Class Members to: adequately and thoroughly test Dupixent to ensure and warrant that Dupixent was both therapeutically effective and safe, as claimed and advertised to the Class Members; to disclose to the Class Members any significant health hazard known or discoverable by Defendants; and to ensure that Dupixent was safe, reliable, and non-hazardous for human consumption—its intended purpose.

176. As alleged above, Defendants' own negligent acts and omissions resulted in an increased risk of developing CTCL for all members of the Class. CTCL is a serious disease-causing life-threatening illness and debilitating subcellular injury. Technology, analytical tools, test and/or monitoring procedures exist and are readily available to provide for the testing and early detection of CTCL in patients. These technologies, tools tests and/or monitoring procedures are accepted and widely used by the scientific and medical community. These existing scientific methods include, but are not limited to, blood tests, physical examinations, imaging, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations.

177. Early detection of cancer in patients is one of the best, and sometimes the only means to treat cancer such that it does not cause lasting, permanent injury, illness, or death.

178. Early detection of cancer in patients necessarily allows patients to avail themselves of myriad forms of treatment, each of which is capable of altering the course of the illness, such as bringing the cancer into remission, removal of any malignant tumors, and other treatment to alleviate injury.

179. The tests and treatments for the early detection and treatment of cancer must be prescribed by a qualified physician, and are conducted according to the latest, contemporary, and widely accepted scientific principles. Because CTCL is a rare cancer (and one that can be difficult to identify), cancer screenings may not be conducted with the frequency necessary to identify CTCL in the absence of exposure to Dupixent. In other words, the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Plaintiff and Class Members require more frequent screenings not within the purview of routine medical exams.

180. The facts alleged above are sufficient or more than sufficient to plead a claim for medical monitoring as a cause of action.[11]

181. Plaintiffs seek, on behalf of themselves and the Class Members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to Dupixent as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

FOURTH CLAIM FOR RELIEF

STRICT LIABILITY - FAILURE TO WARN
(Individually and on Behalf of the Class)

182. Plaintiffs repeat and re-allege the preceding paragraphs as is fully set forth herein.

183. Defendants failed to warn Plaintiffs and the Class Members, and the medical and regulatory communities, of the potential or actual hazard posed by Dupixent as soon as this was suspected or known.

184. Defendants' failure to warn was intentional, reckless, and in wanton and willful disregard for the rights and health of Plaintiffs and other Class Members, causing exposure to a substance that causes CTCL and delay of diagnosis and treatment.

[11] Alternatively, in states where medical monitoring is not available as an independent cause of action, Plaintiffs seek medical monitoring as a remedy for the other causes of action asserted herein.

185. Defendants are strictly liable for their failure to warn or adequately disclose information.

186. As a direct and proximate result of each Defendant's failure to warn or disclose information, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' Dupixent they consumed created and/or increased the risk that Plaintiffs and other Class members will develop cancer.

187. Plaintiffs seek, on behalf of themselves and the Class Members, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to Dupixent as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

FIFTH CLAIM FOR RELIEF

VIOLATION OF THE MAGNUSON-MOSS WARRANTY ACT
15 U.S.C. § 2301 et seq.
(Individually and on Behalf of the Class)

188. Plaintiffs repeat and re-allege the preceding paragraphs as is fully set forth herein.

189. This Court has jurisdiction to decide claims brought under 15 U.S.C. § 2301 by virtue of 28 U.S.C. § 1332 (a)-(d).

190. Doses of Dupixent are "consumer products" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(1).

191. Plaintiffs are "consumers" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(3). They are consumers because they are persons entitled under applicable state law to enforce against the warrantor the obligations of its implied warranties.

192. Defendants were "supplier[s]" and "warrantor[s]" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(4)-(5).

193. 15 U.S.C. § 2310(d)(1) provides a cause of action for any consumer who is damaged by the failure of a warrantor to comply with a written or implied warranty.

194. Defendants provided Plaintiffs and the other Class members with an implied warranty of merchantability in connection with the purchase of Dupixent that is an "implied warranty" within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(7). As a part of the implied warranty of merchantability, Defendants warranted that Dupixent was fit for its ordinary purpose as a safe pharmaceutical medication, would pass without objection in the trade as designed, manufactured, and marketed, and were adequately contained, packaged, and labeled. N.J. Stat. Ann. § 12A:2-314(2)(a), (c), and (e); U.C.C. § 2-314.

195. Defendants breached these implied warranties, as described in more detail above, and are therefore liable to Plaintiffs and the Class pursuant to 15 U.S.C. § 2310(d)(1). Without limitation, doses and/or batches of Dupixent share common design defects in that they have caused subcellular injury and an increased risk of developing CTCL.

196. In their capacity as warrantors, Defendants had knowledge of the defects in the batches of Dupixent they manufactured, distributed, and sold, any efforts to limit the implied warranties in a manner that would exclude coverage of Dupixent is unconscionable, and any such effort to disclaim, or otherwise limit, liability for Dupixent is null and void.

197. Privity is not required here because Plaintiffs and each of the other Class members are intended third-party beneficiaries of any contracts between Defendants and their distributors, and specifically, of the implied warranties. The distributors were not intended to be the ultimate consumers of Dupixent and have no rights under the warranty agreements provided with each container of Dupixent; the warranty agreements were designed for and intended to benefit consumers. Finally, privity is also not required because the batches and/or doses of Dupixent are dangerous instrumentalities due to the aforementioned defects and nonconformities. In the alternative, to the extent it is required, it is satisfied.

198. Pursuant to 15 U.S.C. § 2310(e), Plaintiffs are entitled to bring this class action and are not required to give Defendants notice and an opportunity to cure until such time as the Court determines the representative capacity of Plaintiffs pursuant to Rule 23 of the Federal Rules of Civil Procedure.

199. Furthermore, affording Defendants an opportunity to cure their breach of written warranties would be unnecessary and futile here. At the time of sale of each batch and/or dose of Dupixent, Defendants knew, should have known, or were reckless in not knowing of their misrepresentations concerning Dupixent's hazardous nature and failure to perform as warranted, but nonetheless failed to rectify the situation and/or disclose the Dupixent's hazardous nature.

200. Plaintiffs seek injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to Dupixent as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations,

(3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

SIXTH CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY (Individually and on Behalf of the Class)

201. Plaintiffs repeat and re-allege the preceding paragraphs as if fully set forth herein.

202. Defendants are merchants with respect to Dupixent within the laws of each jurisdiction.

203. At all times relevant all of the Multistate Class States have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. §

47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; and Wyo. Stat. § 34.1-2-314.

204. Each Defendant was a merchant within the meaning of the above statutes.

205. Each Defendant's Dupixent product constituted "goods" or the equivalent within the meaning of the above statutes.

206. Each Defendant was obligated to provide Plaintiffs and other Class Members Dupixent reasonably fit for the purpose for which the products were sold, and to conform to the standards of the trade in which Defendants are involved such that the product did not cause cancer and was of fit and merchantable quality.

207. Each Defendant knew or should have known that Dupixent was being manufactured and sold for the intended purpose of human consumption (or is strictly liable in the event of lack of actual or constructive knowledge) and impliedly warranted that their Dupixent was of merchantable quality and fit for that purpose.

208. Each Defendant breached its implied warranty because Dupixent causes or exacerbates cancer and is not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

209. Defendants were provided notice of these issues by numerous studies, case reports, and other clinical and research-based evidence revealing a causal link between Dupixent and CTCL.

210. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants'

Dupixent they consumed created and/or increased the risk that Plaintiff and other Class members will develop CTCL.

211. Plaintiffs seek injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to Dupixent as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

SEVENTH CLAIM FOR RELIEF

FRAUD/FRAUDULENT CONCEALMENT
(Individually and on Behalf of the Class)

212. Plaintiffs repeat and re-allege the preceding paragraphs as is fully set forth herein.

213. This claim is brought on behalf of the Multistate Class or, alternatively, under the laws of all of the Multistate Class States, as there is no material difference in the law of fraud and fraudulent concealment as applied to the claims and questions in this case.

214. As shown above, the Defendants knew, or should have known that use of Dupixent they produced, marketed, posed health hazards to users, namely the increased risk of CTCL.

215. Despite this, Defendants each misrepresented, concealed and suppressed material facts concerning the hazards posed by Dupixent they manufactured, distributed, and sold.

216. Defendants made fraudulent, intentional and material misrepresentations and omissions regarding the safety and efficacy of Dupixent and of Dupixent's side effects, including that concerning an increased risk of CTCL, to Plaintiffs and the Class directly through promotional materials, advertising, package inserts, journal publications, and the product monograph.

217. The safety and efficacy of Dupixent was also fraudulently and intentionally misrepresented to Plaintiff's healthcare providers with the intent that such misrepresentations would result in Dupixent being prescribed and administered to Plaintiff.

218. Defendants each knew, or reasonably should have known, that these representations regarding the safety, efficacy and side effects of Dupixent were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

219. Defendants fraudulently and intentionally made misrepresentations and/or actively concealed, suppressed, or omitted this material information with the intention and specific desire to induce consumers and the medical community, including Plaintiffs and Plaintiffs' healthcare providers, to use, prescribe and purchase Dupixent.

220. Defendants fraudulently and intentionally knew that Plaintiffs and/or Plaintiffs' healthcare providers would rely upon such material misrepresentations and/or omissions in selecting Dupixent for the treatment of Plaintiff.

221. Plaintiffs and Plaintiffs' healthcare providers detrimentally relied on the fraudulent misrepresentations outlined below.

222. The Defendants each had a duty to disclose that Dupixent they manufactured, distributed, and sold, was potentially hazardous to the Class Members' health and was unsafe for

human consumption or ingestion. Plaintiffs relied on Defendants' representations that Dupixent they were purchasing and ingesting was safe.

223. To the extent applicable, Plaintiffs and other Class Members were justified in relying on Defendants' misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated to each Class member, including through product labeling and other above-discussed statements by Defendants. No reasonable consumer would have purchased Dupixent but for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

224. The aforementioned concealment was material, because if it had been disclosed Plaintiffs would not have purchased or otherwise obtained Dupixent from Defendants.

225. The aforementioned representations were also material because they were facts that would typically be relied on by a person purchasing or obtaining Dupixent. The Defendants each knew or recklessly disregarded that their representations were false because they knew that Dupixent they were manufacturing, distributing, and selling was a substance that causes cancer and/or increase the risk of cancer. The Defendants each intentionally made the false statements in order to sell Dupixent and avoid the expense and public relations nightmare of a recall.

226. Plaintiffs relied on the Defendants' reputation, along with their failure to disclose the hazards of Dupixent, and the Defendants' affirmative assurances that Dupixent was safe for human consumption and/or injection.

227. However, Defendants each concealed and suppressed material facts concerning obligations to monitor and test their products.

228. Further, Defendants each had a duty to disclose the true facts about Dupixent because they were known and/or accessible only to Defendants who had superior knowledge and

access to the facts, and the facts were not known to or reasonably discoverable by Plaintiffs and the Classes.

229. As a direct and proximate result of each Defendant's fraud, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' Dupixent created and/or increased the risk that Plaintiff and other Class members will develop cancer.

230. As a result of the fraud, Plaintiffs have suffered direct and consequential damages, and they seek recovery of those damages, and the creation of a fund to adequately finance the costs of medical monitoring procedures (1) to notify and alert all people exposed to Dupixent as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following judgment:

1. Certifying this Action as a class action;

2. Appointing Plaintiff(s) as Class Representative(s), and appointing undersigned counsel as Class Counsel to represent the Class;

3. A finding that Defendants are liable pursuant to each and every one of the above-enumerated causes of action;

4. Awarding appropriate preliminary and/or final injunctive relief;

5. Directing the Defendants to fund medical monitoring in an amount sufficient to fund a science panel as well as necessary notice and medical care, including but not limited to examinations, tests, pathology, blood tests, evaluations, treatment, as necessary and appropriate;

6. Payment to Plaintiff and other Class Members of compensatory damages necessary for their monitoring and care;

7. An award of attorneys' fees and costs;

8. Interest as provided by law, including but not limited to pre-judgment and post-judgment interest; and

9. Such other and further relief as this Court may deem equitable and just.

JURY DEMAND

Plaintiffs respectfully request a trial by jury on all causes of action so triable.

Dated: July 17, 2026

Respectfully Submitted,

/s/ Jason S. Rathod
Jason S. Rathod
Nicholas A. Migliaccio
Bryan G. Faubus*
MIGLIACCIO & RATHOD LLP
412 H St., NE
Washington, DC 20002
(202) 470-3520 (Tel.)
(202) 800-2730 (Fax)
E-mail: nmigliaccio@classlawdc.com
jrathod@classlawdc.com
bfaubus@classlawdc.com

** Pro hac vice admission anticipated*

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

Joyani Ghosh and Ruth Anne Clarke

(b) County of Residence of First Listed Plaintiff Cook County, IL and Cecil County, MD
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Migliaccio & Rathod LLP
412 H St NE, Ste 302, Washington, DC 20002
(202) 470-3520

DEFENDANTS

Regeneron Pharmaceuticals, Inc., Sanofi-Aventis U.S. LLC,Genzyme Corporation

County of Residence of First Listed Defendant Westchester County, NY, Somerset County, NJ, Middlesex County, MA
(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 U.S.C. § 1332(d)

Brief description of cause:
Product liability re Dupixent

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ exceeds jurisdictional minimum

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Zahid N. Quraishi DOCKET NUMBER 3:26md3180

DATE 7/17/2026

SIGNATURE OF ATTORNEY OF RECORD /s/ Jason S. Rathod

FOR OFFICE USE ONLY

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

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

UNITED STATES DISTRICT COURT

for the
District of Maryland

Joyani Ghoshi and Ruth Anne Clarke

Plaintiff(s)

v.

Regeneron Pharmaceuticals, Inc., Sanofi-Aventis U.S. LLC, Genzyme Corporation

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591

A lawsuit has been filed against you.

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

Migliaccio & Rathod LLP
412 H St NE, Ste 302
Washington, DC 20002

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

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

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

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

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

UNITED STATES DISTRICT COURT

for the
District of Maryland

Joyani Ghoshi and Ruth Anne Clarke

Plaintiff(s)

v.

Regeneron Pharmaceuticals, Inc., Sanofi-Aventis U.S. LLC, Genzyme Corporation

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Sanofi-Aventis U.S. LLC
55 Corporate Drive
Bridgewater, NJ 08807

A lawsuit has been filed against you.

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

Migliaccio & Rathod LLP
412 H St NE, Ste 302
Washington, DC 20002

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

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

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

UNITED STATES DISTRICT COURT

for the
District of Maryland

Joyani Ghoshi and Ruth Anne Clarke

Plaintiff(s)

v.

Regeneron Pharmaceuticals, Inc., Sanofi-Aventis U.S. LLC, Genzyme Corporation

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Genzyme Corporation
450 Water Street
Cambridge, MA 02142

A lawsuit has been filed against you.

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

Migliaccio & Rathod LLP
412 H St NE, Ste 302
Washington, DC 20002

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

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

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

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: