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

STEPHANIE HAMMAR,
On behalf of her son
R.S.B., a minor

Civil Case No._____

Judge:_____

Plaintiff,

v.

MERCK & CO., INC.

Defendant.

COMPLAINT FOR DAMAGES AND
JURY DEMAND

Stephanie Hammar, on behalf of R.S.B., a minor, ("Ms. Hammar" "Minor Plaintiff"/"Plaintiff" respectively) by and through counsel, submits the following Complaint and Jury Demand against Defendant MERCK & CO., INC. ("Merck" or "Defendant") and allege and aver as follows:

I. INTRODUCTION

1. Minor Plaintiff has developed neuropsychiatric injuries as a result of ingesting Merck's prescription pharmaceutical product, Singulair®, indicated for: a) prophylactic and chronic treatment of asthma; b) acute prevention of exercise-induced bronchoconstriction (EIB); and c) relief of symptoms of allergic rhinitis.

2. Defendant knew or should have known of the risks of neuropsychiatric injuries prior to the time it began selling Singulair® in 1998. In 1996, Defendant filed a patent application for montelukast, the active ingredient in Singulair®, acknowledging montelukast's possible effects on cerebral spasm. Further, montelukast has been tested extensively starting prior to 1998, and continuing through today. Many of these studies have demonstrated a correlation—and some

show causation—between Singulair® usage and the development of neuropsychiatric events. Defendant has ignored these studies.

3. Originally, the Singulair® label contained no warnings regarding neuropsychiatric events. Over the past 22 years Defendant has slowly and belatedly added grossly insufficient warnings regarding neuropsychiatric events to the product label. Finally, on March 4, 2020, the Food & Drug Administration (FDA) required Defendant to add a Black Box Warning, the strongest type of warning, to Singulair®'s label, regarding neuropsychiatric events. FDA also required a new Medication Guide.

4. The new proposed Black Box warning provides "serious neuropsychiatric events have been reported in patients taking Singulair®." As finally admitted by Defendant in its April 2020 proposed label revisions, neuropsychiatric events reported by patients using Singulair® include:

> agitation, aggressive behavior or hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, dysphagia (stuttering), hallucinations, insomnia, irritability, memory impairment, obsessive-compulsive symptoms, restlessness, somnambulism, suicidal thoughts and behavior (including suicide), tic, and tremor…
>
> Psychiatric disorders: agitation including aggressive behavior or hostility, anxiousness, depression, disorientation, dream abnormalities, hallucinations, insomnia, irritability, restlessness, somnambulism, suicidal thinking and behavior (including suicide), tremor *[see Warnings and Precautions (5.4)]*. [1]

The new warning goes on to state that "the benefits of Singulair® may not outweigh the risks…".

5. Defendant also modified the drug labeling Section 5.1 to disclose some neuropsychiatric events were reported after Singulair® discontinuation as well as

[1] Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., "Full Prescribing Information: Singulair® (montelukast sodium) Tablets, Chewable Tablets, and Oral Granules [US Patent No. 5,565,473]," Reference ID: 3106826 (Whitehouse Station, NJ: Merck & Co., Inc., 1998, revised Mar. 2012): 3-4, § 5.4: Neuropsychiatric Events; 6-7, § 6.2: Post-Marketing Experience. Accessed at https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021409s036lbl.pdf.

acknowledge that montelukast distribution into the brain in rats. In addition, the Defendant modified Section 12.3 to remove the word 'minimal' from the description of its distribution into the brain.

6. In its March 4, 2020 press release FDA noted that "many patients and health care professionals are not fully aware of these risks." Further, by requiring the addition of the Black Box warning, the FDA "aims to make sure patients and medical providers have the information available to make informed treatment decisions."

II. PARTIES

A. Plaintiff

7. Ms. Hammar and Minor Plaintiff are residents of Manitowoc, Wisconsin. With the consent of his parent Stephanie Hammar, Minor Plaintiff was prescribed Singulair® from approximately December 2010 to August 2012 for the purpose of treating Minor Plaintiff's asthma and hay fever symptoms. Stephanie Hammar filled the prescriptions and purchased Singulair®. Minor Plaintiff ingested Singulair® as prescribed. As a direct and proximate result of ingesting Singulair®, Minor Plaintiff was admitted to Bellin Psychiatric Center's inpatient facility for suicidal and homicidal thoughts, and was ultimately diagnosed with Major Depressive Disorder, Anxiety Disorder, Obsessive-Compulsive Disorder, Ego-Dystonic and Intrusive thoughts about Homicidal, Suicidal, and Sexual Thoughts, and Poor Coping – all of which are neuropsychiatric events identical or akin to those now included on the Singulair® label. Had the Minor Plaintiff, Minor Plaintiff's prescriber, or Minor Plaintiff's parent known that Singulair® could cause Minor Plaintiff to suffer neuropsychiatric events, the prescriber would not have prescribed Singulair®, the Minor Plaintiff's parent would not have purchased Singulair®, and the Minor Plaintiff would not have ingested Singulair®. Minor Plaintiff has incurred medical expenses and will continue to

incur expenses in connection with medical treatment as a result of these injuries, which were caused by Defendant's conduct with respect to Singulair®'s design, labeling, manufacture, marketing and sale. Minor Plaintiff has endured and will continue to endure pain, suffering, mental anguish, trauma, and loss of enjoyment of life as a result of his injuries, has suffered lost earnings and/or a loss of earning capacity, and other injuries and damages to be proven at trial.

B. Defendant

8. Defendant Merck is a corporation organized under the laws of Delaware, with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, N.J. 07033. From 1998 through 2012, Defendant had exclusivity with respect to Singulair®, and was the sole manufacturer and seller Singulair®. In 2012, Defendant's patent expired, and generic manufacturers entered the market; however, Defendant has maintained control of brand name Singulair®.

9. Defendant is a multinational pharmaceutical corporation. As of December 2017, lifetime sales of Singulair® 2343 $47.9 billion, constituting the fifteenth best-selling prescription drug in history..[2] Annual revenue from Singulair® peaked in the 2011—2012 fiscal year, with $4.9 billion in sales.[3] As of 2018, Merck held the fourth largest market share of the pharmaceuticals industry at 4.44% and $42.3 billion in revenues, with $708 million in revenues coming from Singulair® sales.

III. JURISDICTION & VENUE

[2] Brumley, James, "The 15 All-Time Best-Selling Prescription Drugs," Investing, *Kiplinger.com* (Washington, DC: Kiplinger, Dec. 5, 2017). Accessed at https://www.kiplinger.com/slideshow/investing/t027-s001-the-15-all-time-best-selling-prescription-drugs/index.html.

[3] "Top asthma drugs in the United States based on revenue in 2011—2012 (in million U.S. dollars)," *Statista.com* (Statista, 2020, released Aug. 2012).

10. Plaintiff is domiciled in and a citizen of WISCONSIN.

11. Merck is a multinational pharmaceuticals corporation that is organized under the laws of Delaware with its principal place of business in Kenilworth, New Jersey.

12. This Court has diversity jurisdiction over the claims in this Complaint because the aggregate amount in controversy exceeds the sum of $75,000.00, and the case is between citizens of different states. 28 U.S.C. § 1332(a)(1).

13. Venue is proper within this District under 28 U.S.C. § 1391 because the injuries sustained by Plaintiff, as described herein, occurred within WISCONSIN

IV. STATEMENT OF THE FACTS

A. The Discovery of Montelukast and Development of Singulair®

14. Defendant discovered the anti-asthmatic properties of montelukast, the active ingredient in Singulair® and was granted U.S. Patent No. 5,565,473 on October 15, 1996, which expired on August 3, 2012. FDA first approved Singulair® for clinical use in 1998.[4]

15. Singulair® has become a ubiquitous monotherapy treatment as an alternative to, and as an add-on therapy to, inhaled corticosteroids (ICS) such as fluticasone. Approximately 9.3 million patients received a dispensed montelukast prescription from U.S. outpatient pharmacies in 2018, with 2.3 million of these being children younger than 17 years.[5]

[4] U.S. Food & Drug Administration, *Singulair® (montelukast sodium) US FDA Label 2019 [*uspi-mk0476-mf-2004r041], (Merck, 1998-2020).

[5] U.S. Food and Drug Administration, Drug Safety Communications, *FDA requires Boxed Warning about serious mental health side effects for asthma and allergy drug montelukast (Singulair®); advises restricting use for allergic rhinitis: Risks may include suicidal thoughts or actions*," 3-4-2020 FDA Drug Safety Communication (Mar. 4, 2020) (citing IQVIA Total Patient Tracker™. Year 2018. Data extracted June 2019). Accessed at https://www.fda.gov/media/135840/download.

16. Singulair® (montelukast) is a leukotriene receptor antagonist that binds with high affinity and selectivity to the cysteinyl leukotriene receptor-1 (CysLTR1) in order to prevent this receptor from interacting with leukotrienes, which are inflammatory mediators. Such binding consequently assists in inhibiting many of the physiological actions elicited by CysLTs at the receptor which could have facilitated asthma or allergic rhinitis. As an example, montelukast modulates expression of CysLTR1 and CysLTR2 in airway eosinophilic (i.e., high count of white blood cells) inflammation of OVA-induced asthmatic mice because the drug functions in bodies as a CysLT1 receptor antagonist.[6]

17. Cysteinyl leukotrienes (CysLT) are eicosanoids (i.e., signaling molecules) that are released by various types of cells, including mast cells and eosinophils, both of which are implicated in allergy and anaphylaxis as well as the immune system. When these CysLT bind to their corresponding CysLT receptors (e.g., CysLT binding to CysLT1R), they may act to up- or down-regulate the receptor and its coordinating effect. For example, CysLT1 binding to CysLT1 receptors found on smooth muscle cells in respiratory airways simulates specific cell activities that then facilitate the underlying pathophysiology of asthma and allergic rhinitis.

18. Facilitating conditions for asthma include CysLT-mediated airway bronchoconstriction, vascular permeability, occluding mucous secretion, and eosinophil recruitment. In allergic rhinitis, nasal mucosa release CysLTs when exposed to allergens like pollen during both early- and late-phase reactions and then participate in eliciting the prototypical symptoms of allergic rhinitis like a congested nose and congested airway. Simply put, if allergens

[6] Zhang YJ, Zhang L, Wang SB, Shen HH, Wei EQ. Montelukast modulates lung CysLT(1) receptor expression and eosinophilic inflammation in asthmatic mice. *Acta Pharmacol Sin*. 2004;25(10):1341-1346 (Finding that montelukast inhibited the up-regulation of the CysLT1 receptor in airway eosinophilic inflammation of ovalbumin-induced (i.e., egg whites) asthmatic mice.

(e.g., dust and pollen) are the gasoline and CysLTs are the gas pedal that drive the asthma and allergies engine, Singulair® hits the brakes.

B. Singulair® (Montelukast) Crosses the Blood-Brain-Barrier and Causes Neuropsychiatric Events.

1. Introduction to the Blood-Brain Barrier

19. Montelukast crosses the blood-brain barrier (BBB), which is a semi-permeable (i.e., partial porous) membrane of endothelial cells (blood and lymphatic vessel lining) that is highly selective in preventing solutes in circulating blood from non-selectively entering the extracellular fluid (e.g., cerebrospinal fluid) and thereby interacting with neurons in the central nervous system (CNS). The CNS influences activity within all of the parts of the body and is constituted primarily by the brain and spinal cord. Neurons function to communicate with other cells via connections called synapses. Neurons are like telephones in that they receive signals and synapses are similar to telephone lines that carry signals.

20. The function of the BBB is to protect the brain from circulating pathogens and thereby render bloodborne brain infections rare. No antibodies, only certain antibiotics, and exceedingly few drugs in general may pass the BBB and thereby have an impact on the CNS.

21. The clinical significance of the BBB is due to its difficulty as a drug target to overcome. Difficulty may be attributed to its 100% exclusion of large-molecule neurotherapeutics and 98% exclusion of all small-molecule drugs (e.g., anti-depressants like Prozac, anxiolytics like Xanax) .[7] In terms of size and rough complexity, if a small-molecule drug like aspirin (21 Daltons) were a bicycle (~ 20 lbs), a large-molecule drug or small biologic like human growth hormone (~

[7] See, e.g., Pardridge, William M. "The Blood-Brain Barrier and Neurotherapeutics." *NeuroRx*. 2005 Jan; 2(1): 1—2. Doi: 10.1602/neurorx.2.1.1; Pardridge. "The Blood-Brain Barrier: Bottleneck in Brain Drug Development." *NeuroRx*. 2005 Jan; 2(1): 3—14. Doi: 10.1602/neurorx.2..3

3,000 Daltons) would be a Toyota Prius (~ 3,000 lbs), and a large biologic like immunoglobulin G antibody (~ 25,000 Daltons) would be an F-16 fighter jet (~ 25,000 lbs without fuel).[8]

22. Small molecules are considered anything less than 900 Daltons. A molecular weight of 400 Daltons or less increases a drug's chances of penetrating the CNS.[9] Montelukast weighs 608.18 Daltons.

23. Additionally, molecules with less than 8 hydrogen bonds have an increased likelihood of penetrating the BBB. These are weak intermolecular (i.e., between molecules) bonds between a lone pair electron "donor" and an electron "acceptor." If the "acceptor" is the team, the lone pair "donor" is the person who is getting picked last. Montelukast has 4 hydrogen bond acceptors and 2 hydrogen bond donors. Rendering the drug capable of having only 6 hydrogen bonds. Because of this, montelukast has an inherent increased likelihood of penetrating the BBB.

24. In order to deliver neurotherapeutic drugs to the brain to treat illnesses such as depression, schizophrenia, and obsessive-compulsive disorder, they must be able to cross the BBB. More lipid soluble or lipophilicity molecules are better able to penetrate the CNS. Montelukast has been proven more lipid soluble than its sister class drug, Zafirlukast. In other words, because montelukast "likes" dissolving in fats or oils more than zafirlukast, montelukast is better able to cross the BBB.[10]

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[8] Deepak Gupta et al. "A CMO Perspective on Quality Challenges for Biopharmaceuticals," *BioProcess Int'l* (Oct. 1, 2013, 9:00 AM), accessed at http://www.bioprocessintl.com/manufacturing/antibody-non-antibody/a-cmo-perspective-on-quality-challenges-for-biopharmaceuticals-347335; *See also*, McNally, Eugene J., and Jayne E. Hastedt. "Development of Drug Products: Similarities and Differences Between Protein Biologics and Small Synthetic Molecules." In *Protein Formulation and Delivery*, 2nd ed. Edited by Eugene J. McNally and Jayne E. Hastedt. Drugs and the Pharmaceutical Sciences, Vol. 175 (Boca Raton, FL: CRC PressTaylor & Francis Group, 2008): 327—333, 328—329.

[9] E.g., Pardridge, William M., "Drug transport across the blood-brain barrier," J Cereb Blood Flow Metab. 2012 Nov; 32(11): 1959–1972. Published online 2012 Aug 29. doi: 10.1038/jcbfm.2012.126

[10] See Mougey, Edward B.; Hua Feng; Mario Castro, Charles G. Irvin, and John J. Lima, "Absorption of Montelukast is Transporter Mediated: a Common Varient of OATP2B1 is Associated with Reduced Plasma concentrations and Poor Response," [Author manuscript; available in *PMC* 2010 Feb 1] *Pharmacogenet Genomics*, 2009 Feb; 19(2): 129–138. doi: 10.1097/FPC.0b013e32831bd98c.

25. Because montelukast crosses the BBB, it exerts a systemic effect upon the CNS that results in, among other things, adverse neuropsychiatric events.

2. Singulair® (Montelukast) Crosses the Blood-Brain-Barrier.

26. Montelukast crosses the blood-brain barrier and thereby accumulates in the central nervous system (CNS), which is constituted by the brain and spinal cord. This drug accumulation occurs with both oral and intravenous doses, and in both humans and animals:

> Most importantly, **in a human subject taking 10 mg per day montelukast, that is, the approved dose to treat asthma, we detected [oral] montelukast in the serum and in the CSF** in a similar concentration as in the rats (Supplementary Fig. 1a), suggesting that the standard 10 mg per day dose in humans is sufficient to reach a therapeutic dose in the CSF. In addition, a re-analysis of the original CNS pharmacology data of montelukast27indicates a significant BBB penetrance of the drug (Supplementary Fig. 1b). **These data clearly demonstrate that orally administered montelukast does cross the BBB in a therapeutic dose**, and that age-dependent differential BBB integrity does not affect the capacity of montelukast to enter the brain…
>
> Remarkably, montelukast serum levels [following intravenous drug administrations in rats] were almost identical to the maximum plasma concentrations in humans after oral administration of the clinical dose of 10 mg montelukast daily… illustrating that the animals were treated with montelukast in a dose that pharmacologically resembles the one that is approved for its use in humans. [11]

27. Studies show that expression of the CysLTR1 (including that bound with montelukast) is not limited to the lungs. Instead, it occurs in different cells in the brain, including microvascular endothelial cells—components of the blood brain barrier. Pre-clinical studies of human and animal model tissue implicate CysLTR1 antagonists (e.g., Singulair®/montelukast,

[11] Marschallinger, J., Schäffner, I., Klein, B. *et al.* Structural and functional rejuvenation of the aged brain by an approved anti-asthmatic drug. *Nat Commun* 6, 8466 (2015), 4, 10. https://doi.org/10.1038/ncomms9466. (Emphases added).

Onon/pranlukast, and Accolate/zafirlukast) as exerting effects upon traumatic brain injuries (TBI), ischemic brain injuries (e.g., stroke, TIA), cold-induced brain injuries, multiple sclerosis, auto-immune encephalomyelitis, Alzheimer's disease, and Parkinson's disease.[12] Activation of CysLTR1 is associated in animals with facilitating pathogen entry into the brain by disrupting the Blood Brain Barrier (BBB).[13] Among these pathogens are HIV-1 and *Escherichia coli*-mediated meningitis.[14] Furthermore, "[i]t has been demonstrated that [Singulair®] could increase the proliferation of neuronal precursor cells in vitro through the receptors CysLT1R and GPR17 [(G protein-coupled receptor 17)]."[15] Accordingly, although "expression of the CysLT1R in the normal human brain is very low/non-existent," montelukast blockades GPR17 and thereby "strongly elevate[s] neural stem and progenitor proliferation."[16] In other words, montelukast promotes nerve cell growth by expressing the activity of receptors

28. Singulair® accumulates in the brain at a rate that is higher than its accumulation in the lungs:

> Although montelukast was so far always considered as a drug with only limited CNS penetration, careful re-analysis of the original pharmacokinetic report on montelukast reveals that one hour after i.v. drug administration, a substantial amount of radioactive equivalents of [C14] montelukast (~1/10 of the plasma levels) had

[12] Ghosh A, Chen F, Thakur A, Hong H (2016). "Cysteinyl Leukotrienes and Their Receptors: Emerging Therapeutic Targets in Central Nervous System Disorders". CNS Neuroscience & Therapeutics. 22 (12): 943-951. doi: 10.1111/cns.12596. PMC 6492851. PMID 27542570.

[13] Bertin J, Jalaguier P, Barat C, et al. Exposure of human astrocytes to leukotriene C4 promotes a CX3CL1/fractalkine-mediated transmigration of HIV-1-infected CD4 + T cells across an in vitro blood–brain barrier model. Virology 2014;454–455:128–138.

[14] Zhu L, Maruvada R, Sapirstein A, et al. Arachidonic acid metabolism regulates Escherichia coli penetration of the blood-brain barrier. Infect Immun 2010;78:4302–4310.

[15] Yohanna Eriksson, Martina Boström, Asa Sandelius Kaj Blennow, Henrik Zetterberg, Georg Kuhn, and Marie Kalm, The anti-asthmatic drug, montelukast, modifies the neurogenic potential in the young healthy and irradiated brain, *Cell Death and Disease* 9:775 (2018), 5. Doi 10.1038/s41419-018-0783-7. (citing Huber, C. et al. Inhibition of leukotriene receptors boosts neural progenitor proliferation. *Cell. Physiol. Biochem.* 28, 793-804 (2011). doi: 10.1159/000335793.).

[16] Sansing-Foster, Veronica V., Ivone E. Kim, Dipti Kalra, Efe Eworuke, Lockwood G. Taylor, Lisa M. Harinstein, and Monica Munoz, "Neuropsychiatric Events with Use of Montelukast in Pediatric Patients," *FDA Briefing Document: Pediatric Advisory Committee Meeting*, (Sept. 27, 2019), p. 14, § 1.4.4. Accessed at https://www.fda.gov/media/131035/download.

> reached the brain (Supplementary Fig. 1b). Most remarkably, while in plasma (and most other organs, for example, lung and muscle) montelukast levels strongly decreased within 24 h, the amount of montelukast in the brain increased. As a consequence, **24 h after drug injection, montelukast levels in the brain were even higher than in plasma** (Supplementary Fig. 1b), suggesting the existence of an active transport mechanism for montelukast through the BBB.

29. Singulair® accumulates in the brain because of its binding affinity to a BBB transporter:

> Indeed, montelukast is taken up from the intestine into the blood stream by the organic anion-transporting polypeptide (OATP)2B1, a transporter that is expressed also by endothelial cells of brain capillaries. Also, **the majority (99%) of montelukast in plasma is bound to proteins, mainly albumin, providing a BBB transport mechanism as albumin has been shown to act as a carrier through the BBB. The potential of montelukast to enter the CNS is further strongly supported by our present pharmacokinetic results obtained from rats** (Supplementary Fig. 1a).

30. Pre-clinical data also provide ample evidence of how montelukast enters into the brain:

> Strikingly, montelukast was also detected in the CSF in a human asthma patient, who was on the approved 10 mg per day dose of montelukast, and levels in serum and CSF were almost identical to the concentrations found in rats treated with 10 mg kg^{-1} montelukast (Supplementary Fig. 1a). **Entry of montelukast into the CNS is further supported by the plethora of preclinical data on the effects of systemic montelukast treatment on brain structure and function.** In various animal models of neurodegenerative diseases, including a model of kainic acid-induced loss of memory function, an acute Huntington's disease model of quinolinic acid and malonic acid injection-induced degeneration of striatal neurons, and a β-amyloid injection model of Alzheimer's disease, treatment with montelukast attenuated behavioural deficits, which was accompanied by structural brain changes such as inhibition of neuroinflammation and reduced neuronal cell death.[17]

[17] Marschallinger (2015), 10 (Emphases added); see also, Zhang WP, Hu H, Zhang L, et al. Expression of cysteinyl leukotriene receptor 1 in human traumatic brain injury and brain tumors. *Neurosci Lett.* 2004;363(3):247-251; Lenz QF, et al., *Neuroscience*, 2014). Doi: 10.1016/j.neulet.2004.03.088.

31. Animal studies demonstrate that Singulair® administered orally can be found in the brain and cerebrospinal fluid (CSF) found in the subarachnoid space between the two innermost (arachnoid mater and pia mater) of three protective membranes covering the brain and spinal cord:

> The biologic mechanisms underlying the neuropsychiatric events associated with montelukast treatment are currently not well understood. However, evidence from animal studies suggests that montelukast could act directly on cells in the brain. Orally administered montelukast (10 mg/kg/day, 7 days) was **detectable in brain tissue and cerebrospinal fluid (CSF)** in rats, providing evidence for its **ability to cross the blood-brain barrier**.[18]

These studies' findings were cited within the FDA's Briefing Document re: Singulair®.[19] Thus, taking Singulair® results in the accumulation of its active ingredient, montelukast, in brain tissue and cerebrospinal fluid.

3. Because Singulair® (Montelukast) Crosses the Blood-Brain-Barrier, It Can and Does Cause Neuropsychiatric Events.

32. The risk of new neuropsychiatric events is greater in pediatric patients who take Singulair®. "Children with asthma who experienced suicidality (i.e., suicidal thoughts),

[18] Zhao R, Shi WZ, Zhang YM, et al. Montelukast, a cysteinyl leukotriene receptor-1 antagonist, attenuates chronic brain injury after focal cerebral ischaemia in mice and rats. *J Pharm Pharmacol.* 2011;63(4):550-557; Zhang CT, Lin JR, Wu F, et al. Montelukast ameliorates streptozotocin-induced cognitive impairment and neurotoxicity in mice. *Neurotoxicology.* 2016;57:214-222 (Emphasis added). This study was also cited during the FDA hearings regarding Singulair®. Aladdin, Meena M., Ph.D., Health Researcher, Public Citizen's Health Research Group, "Testimony Before the FDA's Pediatric Advisory Committee and Drug Safety and Risk Management Advisory Committee – Neuropsychiatric Events with Use of Montelukast in Pediatric Patients," FDA.gov (Sept. 27, 2019). Accessed at https://www.fda.gov/media/131487/download. (quoting Food and Drug Administration. Guidance for industry: Warnings and precautions, contraindications, and boxed warning sections of labeling for human prescription drug and biological products — content and format. October 2011. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075096.p df. Accessed September 26, 2019).

[19] FDA Briefing Document, p. 14, § 1.4.4 (citing Volpe C, Kalra D, A. N. *Pharmacovigilance Review of Neuropsychiatric and Churg-Strauss Syndrome* (Feb. 21, 2014); Kalra D, Gatti J, T P. *Pediatric Postmarketing Pharmacovigilance and Drug Utilization Review of Montelukast* (September 2, 2014)).

depression, tics, tremors, stuttering, agitation, and night terrors. a new-onset neuropsychiatric event [have] nearly twice the odds of having been prescribed montelukast in the year before their event."[20] Furthermore, "children prescribed montelukast for asthma management had nearly twice the odds of neuropsychiatric events, compared with those on other asthma maintenance medications.[21]

33. Additionally, a 2016 retrospective analysis of Individual Case Safety Reports (ICSRs) recorded up to January 1, 2015, in the World Health Organization's (WHO) database (VigiBase®), pulling from over 20 million reports of global suspected adverse effects of medicines. Their findings were as follows:

> Neuropsychiatric disorders as side effects of montelukast were more frequently reported for children than for adults. Infants and children seem to be more prone to sleep disturbances, whereas adolescents present symptoms of depression/anxiety and psychotic reactions more often. Suicidal behavior and completed suicide appear to be more frequently reported than previously thought in practice…Practitioners should be aware of the risk of neuropsychiatric events associated with montelukast use, and should advise the patient and report new cases.[22]

Thus, the neuropsychiatric dangers posed by Singulair® are much greater for children than for adults. Children with new onset neuropsychiatric events are twice as likely to have taken Singulair®, and children who are taking Singulair® are twice as likely to have neuropsychiatric events when compared with those taking other drugs (e.g., inhaled corticosteroids). This is significant because inhaled corticosteroids are known to have "**severe adverse psychological**

[20] Glockler-Lauf SD, Finkelstein Y, Zhu JQ, Feldman LY, To T. "Montelukast and Neuropsychiatric Events in Children with Asthma: A Nested Case-Control Study. *Journal of Pediatrics*. 2019;209:176-182.e4. doi: 10.1016/j.jpeds.2019.02.009. (n = 898 NAE, 3,497 matched controls, p = 0.01).
[21] *Id.*
[22] Ana Aldea Perona, Mar García-Sâiz, Emilio Sanz-Álvarez. Psychiatric Disorders and Montelukast in Children: A Disproportionality Analysis of the VigiBase®. *Drug Safe.* (Springer, 2016: New York, NY) 39:69-78, 69; see 76. Doi: 10.1007/s40264-015-0360-2. (n = 14,670 ICSRs, 2,630 neuropsychiatric events in people aged <18 years).

effects including psychosis"[23] which can also "manifest in cognitive disorders, behavioral changes, and frank psychiatric disease."[24]

34. The risk of neuropsychiatric events associated with taking Singulair® are greater than those associated with taking ICS (e.g., albuterol). "In the real-life setting, children initiated on montelukast experience **a notable risk of neuropsychiatric ADRs leading to drug cessation**, that is significantly higher than that associated with [inhaled corticosteroids] ICS."[25]

35. Suicidality (i.e., suicidal thoughts) and suicide are a very real risk of taking Singulair®. "Suicidal behavior and completed suicide appear to be more frequently reported than previously thought in practice…Practitioners should be aware of the risk of neuropsychiatric events associate with montelukast use and should advise the patient and report new cases." (n = 14,670 Individual Case Safety Reports for montelukast).[26] Additional studies have found, "[M]ontelukast is associated with neuropsychiatric adverse drug reactions such as depression and aggression [and nightmares in children]."[27] Additionally, "[adverse drug reactions in published case reports] included agitation, anxiety, depression, sleep disturbance, hallucinations, **suicidal thinking and suicidality, tremor**, drowsiness, neuropathies, and seizures." Further, immune

[23] F. A. Stuart, T. Y. Segal, S. Keady, "[Review:] Adverse psychological effects of corticosteroids in children and adolescents," *Arch Dis Child* 25 Apr. 2005: 500—506. Doi: 10.1136/adc.2003.041541 (emphasis added).
[24] Linda B. Drozdowicz and J. Michael Bostwick, "[Review:] Psychiatric Adverse Effects of Pediatric Corticosteroid Use," *Mayo Clin Proc.* June 2014: 817—834. Doi: http://dx.doi.org/10.1016/j.mayocp.2014.01.010.
[25] Benard B, Bastien V, Vinet B, Yang R, Krajinovic M, Ducharma FM. "Neuropsychiatric adverse drug reactions in children initiated on montelukast in real-life practice." *Eur Respir J*. 2017 Aug 17;50(2). Doi: 10.1183/13993003.00148-2017. Print 2017 Aug. (n = 12; ci = 95%) (Cited by 5 other articles) (Emphasis added).
[26] Aldea Perona A, García-Sáiz M, Sanz Álvarez E. "Psychiatric Disorders and Montelukast in Children: A Disproportionality Analysis of the VigiBase (®)." *Drug Saf*. 2016 Jan;39(1):69-78. Doi: 10.1007/s40264-015-0360-2. (Cited by 8 other articles) (Emphasis added); *See* Aladdin, Menna M. "Testimony Before the FDA's Pediatric Advisory Committee and Drug Safety and Risk Management Advisory Committee – Neuropsychiatric Events with Use of Montelukast in Pediatric Patients." Sept 27, 2019. Accessed at https://www.fda.gov/media/131487/download.
[27] Haarman MG, van Hunsel F, de Vries TW. "Adverse drug reactions. Of montelukast in children and adults." *Pharmacol Res Perspect*. 2017 Oct;5(5). Doi: 10.1002/prp2.341 (Cited by 2 other articles).

system, induction of hypersensitivity reactions, and hepatobiliary/pancreatic/uropoietic disorders "**are characterized by severe prognosis (i.e., neurological deficit and fatal hepatotoxicity**."[28]

36. Singulair® causes a decrease in neuronal proliferation (nerve growth) in the hippocampal neurogenic zone (part of the brain largely involved in things from short-term memory to long-term memory, and spatial memory). Montelukast can cause "**negative effects both acutely and after 2 weeks of daily administration of montelukast."** [29] In short, giving Singulair® to healthy children can delay their nerve growth in the part of the brain that is most important to short-term memory, long-term memory, and spatial memory. Furthermore, alterations in the hippocampus have been linked to a variety of cognitive pathologies such as anxiety, depression, addiction and neurodegenerative diseases such as Parkinson's.[30]

C. Defendant knew the risks of neuropsychiatric events but failed to warn prescribers, parents, or patients of the risk.

1. Defendant Misled the FDA in Its New Drug Application

37. Defendant misled the FDA with purpose and intent in its original New Drug Application (NDA) 20.829 and 20.830 which were used to obtain FDA approval for Singulair® 5mg intravenous dosing. The footnotes to Table 4 of said NDAs state "only trace amounts were detected in the brain" and "radioactivity in all tissues declined with time, and the remaining radioactive equivalents in tissues were very low at 24 hour post dose". However, Table 4 in fact

[28] Calapai G, Casciaro M, Miroddi M, Calapai F, Navarra M, Gangemi S. "Montelukast-induced adverse drug reactions: a review of case reports in the literature." *Pharmacology*. 2014;94(1-2):60-70. Doi: 10.1159/000366164. (Emphasis added).
[29] *Id* at 6.
[30] See 5. Sapolsky R. M., "Glucocorticoids and hippocampal atrophy in neuropsychiatric disorders," *Arch Gen Psychiatry*. 2000;57:925–935. Doi: 10.1001/archpsyc.57.10.925.

demonstrates the amount of radiolabeled drug in the brain increased over time and when looked at as a ratio of brain:plasma, 0.041:0.142, **the 24 hour interval the level in the brain is 3.46 times or 346% greater than in the plasma.** Furthermore, from 1 hour post administration to the 24 hour interval the radioactive level of drug in the **plasma decreased by 96.64**%, whereas the radioactive level of drug in the **brain increased by 21.36% if you are just looking at volume in each specific tissue and not a ratio of brain:plasma**. Despite this data being statistically significant, Merck neglected to study the effects on the brain in clinical trials and misled the FDA in the way they reported their data.[31]

38. Two years before it was permitted to sell Singulair® in the United States, Defendant obtained a patent for montelukast. In the patent application, ***Defendant claimed that montelukast is "useful in treating …cerebral spasm,"***[32] admitting that at least by 1996, Defendant knew montelukast could affect the brain. Nonetheless, the Singulair® label from the day Defendant began sales in 1998 contained no warning of Singulair®'s possible effect on the brain, let alone of neuropsychiatric events.

2. Defendant Did Not Satisfy Its Ongoing Duty of Pharmacovigilance

39. Even if Defendant could somehow explain away this explicit admission, it failed to add warnings of neuropsychiatric events in connection with its ongoing duty of pharmacovigilance. Every year since Singulair®'s launch in 1998, neuropsychiatric adverse event reports involving children two months to 17 years of age have been filed with the FDA in connection with Singulair®. In 1998 alone, 10 neuropsychiatric adverse events involving children

[31] Merck, "Table 4: Radioactive Equivalents (¨ug/g or ug/ml) of 1 ^{14}C|Montelukast in the Tissues of Rats Receiving 5 mg/kg i.v. (Mean ± SD; n=3) [Sponsors Table 17 Ref. G-1 Vol. 29 pp. G-65]" [brackets original], *NDA 20.829 and 20.830*, 13.
[32] U.S. Patent No. 5,565,473

were reported. In 1999, an additional 83 adverse events were reported. Sixty-six more children using Singulair® suffered neuropsychiatric adverse events in 2000. By 2020, a total of 3,135 children suffered such events, as reported to the FDA, including 242 children under 24 months of age. Furthermore, the United States General Accounting Office has testified before Congress that, "Experts believe that FDA's [Adverse Event Reporting System (AERS) system [only] includes an estimated 1 to 10 percent of adverse reactions."[33]

40. Once FDA reviewed this Adverse Event data, after prompting by a consumer rights group, FDA was induced to question whether neuropsychiatric events warnings needed to be added or strengthened. The FDA addressed mental health side effects associated with montelukast in March 2008 and January 2009 with regard to its ongoing safety reviews, and in June 2009 and August 2009 with regard to its subsequent labeling updates to the *Precautions* prescribing information.

D. FDA Required Merck to Add the Black Box Warning to the Singulair® Label.

41. The FDA met jointly in 2019 to discuss its safety review of neuropsychiatric events in pediatric patients, with special concern given for the use of Singulair® for "minimal indications" such as cough and the "disconnect" between existing label warnings and proper communications to families of the risk of using the asthma and allergy medication. This updated evaluation included review of the Adverse Event Database data on hyperkinesia, excoriation, and numerous neuropsychiatric events which occurred during post-discontinuation and withdrawal from Singulair®. The FDA recommended that health professionals should "[a]dvise all patients of

[33] Janet Heinrich (Assoc. Dir. Health Fin. And Pub. Health Issues, Health and Human Serv. Div.), "Adverse Drug Events: Substantial Problem but Magnitude Uncertain [GAO/T-HEHS-00-53]," *Testimony: Before the Committee on Health, Education, Labor, and Pensions, U.S. Senate* (United States General Accounting Office: Tues Feb. 1, 2000), 6. Accessed at https://www.gao.gov/new.items/he00053t.pdf.

the risk of neuropsychiatric events when prescribing montelukast…[because] many health care professionals and patients/caregivers are not aware of this risk, and **suicides and other adverse events continue to be reported….**"[34] The FDA further recommended that health professionals should "[m]onitor all patients treated with montelukast for neuropsychiatric symptoms. Events have occurred in patients with and without pre-existing psychiatric disease."[35]

42. On March 4, 2020, an FDA press release announced the requirement of a Black Box warning because the FDA "decided a stronger warning is needed after conducting an extensive review of available information and convening a panel of outside experts, and therefore determined that a *Boxed Warning* was appropriate."[36] The FDA further stated that because the risk of mental health side effects may not outweigh the risks in some patients, "montelukast should be reserved for those who are not treated effectively with or cannot tolerate other allergy medicine."[37]

V. TOLLING OF THE STATUTE OF LIMITATIONS AND ESTOPPEL

A. Discovery-Rule Tolling

43. Within the period of any applicable statute of limitations, Plaintiff could not have discovered through the exercise of reasonable diligence that Singulair® caused a significantly increased risk of adverse neuropsychiatric events.

44. Plaintiff did not discover, and did not know of, facts that would have caused a reasonable person to suspect that his injuries were caused by Defendant's concealment and

[34] FDA, "Singulair® (montelukast and All Montelukast Generics: Strengthened Boxed Warning – Due to Restricting Use for Allergic Rhinitis," FDA.gov (Mar. 4, 2020), accessed at https://www.fda.gov/safety/medical-product-safety-information/Singulair®-montelukast-and-all-montelukast-generics-strengthened-boxed-warning-due-restricting-use. (Emphasis added).
[35] *Id.*
[36] *Id.*
[37] *Id.*

suppression of the fact that individuals who ingested Singulair® were at significantly increased risk of developing neuropsychiatric events.

45. Plaintiff could not have reasonably discovered the true extent of Defendant's deception or suppression about Singulair®'s safety until the FDA required the Boxed Warning about the serious mental health side effects for Singulair® and the advisement on the restriction of use of Singulair®.

46. For these reasons, all applicable statutes of limitations have been tolled by operation of the discovery rule.

B. Fraudulent-Concealment Tolling

47. All applicable statutes of limitations have also been tolled by Defendant's fraudulent concealment throughout the period relevant to this action of Singulair®'s significantly increased risk of causing neuropsychiatric events in those individuals who ingest Singulair®.

48. Instead of disclosing to consumers the significant link between Singulair® and neuropsychiatric events, Defendant continued to manufacture and sell Singulair® without prominently disclosing this information on the drug's label or elsewhere. Further, Defendant misled the public into believing Singulair® was safe by repeatedly touting the safety of Singulair® and failing to adequate warn of the significant relationship between Singulair® and neuropsychiatric events.

49. Defendant's fraudulent and/or deceptive statements include those made in television advertisements that only warn patients to call their doctor if their "asthma symptoms get worse" and emphasize mildness of symptoms.

C. Estoppel

50. Defendant was under a continuous duty to adequately disclose to and inform Plaintiff of the risk of developing neuropsychiatric events with Singulair®.

51. Defendant knowingly, affirmatively, and actively concealed, suppressed, ignored, or recklessly disregarded the true risks of developing neuropsychiatric events associated with Singulair® and never updated the drug's label to adequately disclose this risk.

52. Based on the foregoing, Defendant is estopped from relying on any statutes of limitations in defense of this action.

D. Continuing Tort

53. The continuing tort doctrine applies when there is a repeated or continuous injury and the tort is not completed until the last injury is inflicted or the wrongdoing ceases. In cases of continuing torts, the statutes of limitations do not begin to run until the date of the last tortious act.

54. Plaintiff used Singulair® over extended periods. Each time Plaintiff ingested Singulair®, it constituted a continuing tort.

55. The time period associated with Plaintiff's statute of limitations did not begin to run until, at the earliest, Plaintiff's last use of Singulair®.

VI. CLAIMS FOR RELIEF

COUNT I
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

56. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

57. At all times relevant, Defendant tested, developed, designed, labeled, manufactured, marketed, sold, distributed, advertised, and promoted Singulair®.

58. Singulair® is and at all times was defective, unreasonably dangerous, and unsafe for its intended purpose because, when ingested, it causes an increased risk of adverse neuropsychiatric events in patients who ingest Singulair®.

59. The risk of neuropsychiatric events from Singulair® ingestion, including but not limited to (a) agitation, aggressive behavior, or hostility; (b) attention problems; (c) bad or vivid dreams; (d) depression; (e) disorientation or confusion; (f) feeling anxious; (g) hallucinations (seeing or hearing things that are not really there); (h) irritability; (i) memory problems; (j) obsessive-compulsive symptoms; (k) restlessness; (l) somnambulance (sleepwalking); (m) stuttering; (n) suicidal thoughts (suicidality) and actions; (o) tremor or shakiness; (p) trouble sleeping; and (q) uncontrolled muscle movements (tics) were actually known to and foreseeable to Defendant at all times during the period which it manufactured and sold Singulair®. As further described above, the scientific community expressed concern about the propensity of montelukast to cause an increased risk of neuropsychiatric events when ingested. From the time of Singulair®'s launch until the present day, various scientific literature, as further discussed above, has expressed concerns about an increased risk of adverse neuropsychiatric events in patients who ingest Singulair® (montelukast). Plaintiff was unaware of this scientific literature, but Defendant was aware of it.

60. The increased risk of neuropsychiatric events was actually or should have been known to Defendant at all times during the period that it manufactured and sold Singulair®.

61. The dangers posed by Singulair® go beyond that which would be contemplated by the ordinary consumer with ordinary knowledge common to the community as to its characteristics.

62. The design defects rendered Singulair® unreasonably dangerous.

63. The benefits of Singulair®'s design are outweighed by the design's inherent risk of danger in causing neuropsychiatric events.

64. At the time Singulair® left Defendant's control, there was a practical and technically feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Singulair®.

65. Singulair®'s design defect existed at the time Singulair® left Defendant's possession and control.

66. Singulair® reached the intended consumers, handlers, and users throughout the United States, including Plaintiff, without substantial change in its condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendant.

67. Defendant knowingly designed Singulair® with the design defect that causes Singulair® to cause an increased risk of neuropsychiatric events when ingested to maximize profits.

68. Singulair® is not unavoidably unsafe and the harm was not caused by an unavoidably unsafe aspect of Singulair®.

69. At all times relevant, Defendant knew or had reason to know that Singulair® was defective and was inherently dangerous and unsafe when used in the manner instructed and provided by Defendant to patients and healthcare providers.

70. Singulair® was first approved by the FDA in 1998 pursuant to New Drug Application 020829 (Tablet; Oral). Following the filing of NDA 020829, there were other NDAs filed by Defendant, including NDA Nos. 020830 (Tablet, Chewable; Oral) and 021409 (Granule; Oral). In filing each of these NDAs, Defendant could have submitted an alternative or different formulation for Singulair®, one in which Singulair® would not cause an increased risk of

neuropsychiatric events. Defendant instead continued to utilize the defective design of Singulair®, which caused an increased risk of neuropsychiatric events upon ingestion.

71. Singulair® was and is more dangerous than alternative products such as inhaled corticosteroids (ICS), and Defendant could have designed Singulair® to make it less dangerous. At the time Defendant designed Singulair®, the state of the industry's scientific knowledge was such that a less risky design or formulation was attainable. This state of extant scientific knowledge regarding leukotrienes in general, and Singulair® in particular, has continued to grow over time. Thus, at the time Singulair® left Defendant's control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendant's medications for asthma and allergic rhinitis

72. Plaintiff ingested Singulair® for an approved purpose and experienced Suicidal and Homicidal thoughts, Major Depression, Obsessive-Compulsive Disorder, Anxiety, Ego-Dystonic and Intrusive Thoughts about Homicidal, Suicidal and Sexual Thoughts, and Poor Coping as a result of his Singulair® use.

73. Plaintiff ingested Singulair® without adequate knowledge of Singulair®'s dangerous characteristics.

74. At all times relevant, Plaintiff used Singulair® in an intended or reasonably foreseeable manner without knowledge of Singulair®'s dangerous characteristics.

75. Plaintiff could not have reasonably discovered the defects and risks associated with Singulair® or montelukast-containing products before or at the time of ingestion and use as a result of Defendant's suppression of, failure to obtain, or failure to provide scientific information linking montelukast to neuropsychiatric events.

76. The defects in Singulair® were substantial and contributing factors in causing Plaintiff's injuries, and, but for Defendant's misconduct and omissions, Plaintiff would not have sustained his injuries.

77. Had Plaintiff known of the defects in Singulair®, he would not have taken Singulair®. Instead, he would have taken a safer alternative to Singulair® that would not have exposed him to neuropsychiatric events.

78. Plaintiff's injuries, harms, losses, and damages were directly and proximately caused by Singulair® and Singulair®'s defect while Plaintiff's parent purchased and Plaintiff used Singulair® in a reasonably foreseeable manner for which recovery is sought.

79. Defendant's defective design of Singulair® was willful, wanton, fraudulent, malicious, and conducted with reckless disregard for the health and safety of users of Singulair®, including Plaintiff.

COUNT II
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

80. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

81. Defendant tested, developed, designed, labeled, manufactured, marketed, sold, distributed, advertised, and promoted Singulair® during the periods set forth above.

82. At all times relevant, Defendant had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure Singulair® did not cause users and consumers to suffer from unreasonable and dangerous risks.

83. At all times relevant, Defendant had a continuing duty to warn Plaintiff, Plaintiff's parent, and Plaintiff's prescribers of the dangers associated with Singulair® use.

84. At all times relevant, Defendant could have provided adequate warnings or instructions regarding the full and complete risks of Singulair® and its active ingredient montelukast because Defendant knew or should have known of the unreasonable risks of harm associated with the use of Singulair® and montelukast. Such warnings could have been adequately disclosed in circumstances not limited to Singulair®'s labeling.

85. At all times relevant, Defendant failed to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of Singulair® and to those who would foreseeably prescribe, use, or be harmed by Singulair®, including Plaintiff.

86. Despite the fact that Defendant knew or should have known that Singulair® posed a grave risk of harm, it failed to exercise reasonable care to warn of the dangerous risks associated with its use. The dangerous propensities of Singulair® and its active ingredient, montelukast, as described above were either known to Defendant or scientifically knowable to Defendant through appropriate research and testing by known methods at the time Defendant distributed, supplied, or sold Singulair® and not adequately known to prescribing healthcare providers and end users and consumers, such as Plaintiff.

87. Defendant knew or should have known that Singulair® created significant risks of serious bodily harm to consumers, as alleged herein, and Defendant failed to adequately warn prescribing healthcare providers and consumers, i.e., the reasonably foreseeable users, of the risks of ingesting Singulair®. Upon information and belief, Defendant wrongfully concealed or suppressed information concerning the dangerous nature of Singulair® and its active ingredient, montelukast, and further made false and/or misleading statements concerning the safety of Singulair® and montelukast.

88. Singulair® is and at all times was defective and not reasonably fit, suitable, or safe for its intended purpose because Defendant designed Singulair® in a defective manner and failed to give adequate warnings or instructions at the time Singulair® left Defendant's control and after.

89. Defendant failed to provide adequate warnings of the dangers regarding the fact that Singulair® caused an increased risk of adverse neuropsychiatric events in individuals who ingested Singulair®.

90. Defendant failed to provide adequate warnings of the dangers regarding the fact that Singulair® ingestion increased the risk suffering from neuropsychiatric events, including but not limited to (a) agitation, aggressive behavior, or hostility; (b) attention problems; (c) bad or vivid dreams; (d) depression; (e) disorientation or confusion; (f) feeling anxious; (g) hallucinations (seeing or hearing things that are not really there); (h) irritability; (i) memory problems; (j) obsessive-compulsive symptoms; (k) restlessness; (l) somnambulance (sleepwalking); (m) stuttering; (n) suicidal thoughts (suicidality) and actions; (o) tremor or shakiness; (p) trouble sleeping; and (q) uncontrolled muscle movements (tics).

91. Singulair®'s failure-to-warn defects existed at the time Singulair® left Defendant's control.

92. Defendant distributed Singulair® without sufficient warnings to notify Plaintiff's prescriber, Plaintiff's parent, or Plaintiff of the dangers inherent in ingesting Singulair®.

93. Defendant knew or should have known that most physicians who prescribed Singulair® did not know or fully appreciate the seriousness of the risks associated with Singulair® or montelukast.

94. Plaintiff ingested Singulair® for an approved purpose and experienced neuropsychological events as a result of his Singulair® use.

95. Defendant knew or should have known that the minimal warnings disseminated with Singulair® were inadequate, failed to communicate adequate information on the dangers and safe use of Singulair®, and failed to communicate warnings and instructions that were appropriate and adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses.

96. Had Plaintiff, Plaintiff's parent, or Plaintiff's physician known of the defects in Singulair®, Minor Plaintiff would have been prescribed and would have ingested a safer alternative to Singulair® that would not have exposed him to increased risks of suffering neuropsychiatric events.

97. Plaintiff ingested Singulair® without knowledge of its dangerous characteristics.

98. Plaintiff's injuries, harms, losses, and damages were directly and proximately caused by Singulair®, including the lack, insufficiency, or adequacy of warning of Singulair®'s unreasonable dangers as set forth above while Plaintiff used Singulair® in a reasonably foreseeable manner for which recovery is sought.

99. Defendant's failure to adequately warn of the dangerous effects of Singulair® including the increased risk of suffering neuropsychiatric events from Singulair® use was willful, wanton, fraudulent, malicious, and conducted with reckless disregard for the health and safety of users of Singulair®, including Plaintiff.

COUNT III
NEGLIGENCE

100. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

101. At all times relevant, Defendant had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and distribution of Singulair®, including the duty to take all reasonable steps necessary to manufacture,

promote, advertise, and/or sell a medication that was not unreasonably dangerous to consumers and users of the medication.

102. At all times relevant, Defendant had a duty to exercise reasonable care in the marketing, advertisement, and sale of Singulair®. Defendant's duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using Singulair® and appropriate, complete, adequate, and accurate warnings concerning the potential adverse effects of ingestion of Singulair® and its active ingredient, montelukast.

103. At all times relevant, Defendant knew or, in the exercise of reasonable care, should have known of the hazards and dangers of Singulair® and specifically its increased risk of neuropsychiatric events when ingested.

104. Accordingly, at all times relevant, Defendant knew or, in the exercise of reasonable care, should have known that use of Singulair® could cause or be associated with Plaintiff's injuries, and thus, created a dangerous and unreasonable risk of injury to the users of Singulair®, including Plaintiff.

105. Defendant also knew or, in the exercise of reasonable care, should have known that users and consumers of Singulair® and their prescribing physicians and healthcare providers were unaware of or did not know or fully appreciate the seriousness and magnitude of the risks associated with use of Singulair® and montelukast.

106. Defendant breached its duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, marketing, supply, promotion, advertisement, packaging, sale, and distribution of Singulair® in that Defendant manufactured and produced a medication containing montelukast, knew or had reason to know of the defects inherent in Singulair® or had reason to know that a user's or consumer's ingestion of Singulair® created a

significant risk of harm and unreasonably dangerous side effects, and failed to prevent or adequately warn of these risks and injuries.

107. Defendant was negligent in its promotion of Singulair® by failing to adequately disclose material risk information as part of its promotion and marketing of Singulair®, including the internet, television, and print advertisements. Nothing prevented Defendant from being honest in its promotional activities, and in fact, Defendant had a duty to disclose the truth about the risks associated with Singulair® in its promotional efforts outside of the of the context of labeling.

108. Defendant had and has the ability and means to investigate, study, and test its products and to provide adequate warnings, and Defendant failed to do so. Upon information and belief, Defendant has wrongfully concealed information and has further made false and/or misleading statements concerning the safety of Singulair® and montelukast.

109. Defendant's negligence included:

a) Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, advertising, and/or distributing Singulair® without thorough and adequate pre- and post-market testing;

b) Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, advertising, and/or distributing Singulair® while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of ingesting Singulair® and specifically its active ingredient, montelukast, and, consequently, the risk of serious harm associated with ingestion of Singulair®;

c) Failing to undertake sufficient studies and conduct necessary tests to determine whether Singulair® was safe for its intended use;

d) Failing to use reasonable and prudent care in the design, research, manufacture, and development of Singulair® so as to avoid the risk of serious harm associated with the ingestion of Singulair®;

e) Failing to design and manufacture Singulair® so as to ensure it was at least as safe and effective as other medications on the market treating the same and/or similar conditions;

f) Failing to provide adequate instructions, guidelines, and safety precautions to those persons Defendant could reasonably foresee would prescribe and use Singulair®;

g) Failing to adequately disclose to Plaintiff, physicians, users/consumers, and the general public that use and ingestion of Singulair® presented severe risks of developing neuropsychiatric events;

h) Failing to adequately warn Plaintiff's parent, Plaintiff, physicians, users/consumers, and the general public that Singulair®'s risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiff, prescribing physicians, and other consumers;

i) Systematically suppressing or ignoring contrary evidence about the risks, incidence, and prevalence of the side effects of Singulair® and montelukast-containing medications;

j) Representing that Singulair® was safe for its intended use when, in fact, Defendant knew or should have known that Singulair® was not safe or presented serious risks when used for its intended purpose;

k) Declining to make or propose any changes to Singulair®'s labeling or other promotional materials that would alert consumers, physicians, and the general public of the seriousness and magnitude of the risks of ingesting Singulair® and its active ingredient, montelukast;

l) Advertising, marketing, and recommending the use of Singulair® while concealing or failing to adequately disclose or warn of the dangers known by Defendant to be associated with or caused by the use of Singulair® and montelukast;

m) Continuing to disseminate information to consumers and physicians that indicates or implies that Singulair® is safe for use; and

n) Continuing the manufacture and sale of Singulair® with the knowledge that it was unreasonably unsafe and dangerous.

110. Defendant knew and/or should have known that it was foreseeable that individuals such as Plaintiff would suffer injuries as a result of Defendant's failure to exercise ordinary and reasonable care in the manufacturing, marketing, labeling, distribution, and sale of Singulair®.

111. Minor Plaintiff, Plaintiff's parent, and Plaintiff's prescriber did not know the nature and extent of the injuries that could result from the intended use of Singulair® or its active ingredient, montelukast. Absent Defendant's negligence, Plaintiff would not have developed neuropsychological events.

112. Defendant's conduct, as described above, was not only negligent but it was also reckless. Defendant regularly risked the health and lives of consumers and users of Singulair®, including Plaintiff, with knowledge of Singulair®'s dangers. Defendant has made conscious decisions not to voluntarily re-design, re-label, adequately warn, or adequately inform physicians

and the public, including Plaintiff, of the increased risk of developing neuropsychiatric events when ingesting Singulair®. Defendant's reckless conduct therefore warrants an award of punitive damages.

113. As a direct and proximate result of Defendant placing Singulair® into the stream of commerce, Plaintiff suffered injuries, harms, losses, and damages.

COUNT IV
BREACH OF EXPRESS WARRANTY

114. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

115. At all relevant times, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Singulair®, which is defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Singulair® into the stream of commerce.

116. Defendant had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of Singulair®, including a duty to:

a) ensure that its products did not cause the user unreasonably dangerous side effects;

b) adequately warn of dangerous and potentially fatal side effects; and

c) adequately disclose adverse material facts, such as the true risks associated with the use of Singulair®, when making representations to consumers and the general public, including Plaintiff.

117. The ability of Defendant to properly disclose those risks associated with Singulair® is not limited to representations made on the labeling.

118. At all relevant times, Defendant expressly represented and warranted to the purchasers of its products, by and through statements made by Defendant in labels, publications, package inserts, and other written materials intended for consumers and the general public, that Singulair® was safe to human health, effective, fit, and proper for its intended use. Defendant advertised, labeled, marketed, and promoted Singulair® representing the quality to consumers and the public in such a way as to induce their purchase or use, thereby making an express warranty that Singulair® would conform to the representations.

119. These express representations include incomplete or inadequate warnings and instructions that purport, but fail, to adequately include the complete array of risks associated with use of Singulair®. Defendant knew and/or should have known that the risks expressly included in Singulair® warnings and labels did not accurately or adequately set forth the risks of developing the serious injuries complained of herein. Nevertheless, Defendant expressly represented that Singulair® products were safe and effective, that they were safe and effective for use by individuals such as Plaintiff, and/or that they were safe and effective as a medication.

120. The representations about Singulair®, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

121. Defendant placed Singulair® into the stream of commerce for sale and recommended its use to consumers and the public without adequately warning of the true risks of developing the injuries associated with the use of Singulair®.

122. Defendant breached these warranties because, among other things, Singulair® was defective, dangerous, and unfit for use, did not contain labels representing the true and adequate

nature of the risks associated with its use, and were not merchantable or safe for its intended, ordinary, and foreseeable use and purpose. Specifically, Defendant breached the warranties in the following ways:

a) Defendant represented through its labeling, advertising, and marketing materials that Singulair® was safe, and intentionally or negligently withheld and concealed information about the risks of serious injury associated with use of Singulair® and by expressly limiting or ignoring the risks associated with use within its warnings and labels; and

b) Defendant represented that Singulair® was safe for use and intentionally or negligently concealed information that demonstrated that use of Singulair® created an increased risk of developing and causing NSEs, and that Singulair®, therefore, was not safer than alternatives available on the market.

123. Plaintiff detrimentally relied on the express warranties and representations of Defendant concerning the safety and/or risk profile of Singulair® in deciding to purchase and obtain the product. Plaintiff reasonably relied upon Defendant to accurately and adequately disclose known defects, risks, dangers, and side effects of Singulair®. Plaintiff would not have purchased or used Singulair® had Defendant properly disclosed the risks associated with the product, either through advertising, labeling, or any other form of disclosure.

124. Defendant had sole access to material facts concerning the nature of the risks associated with Singulair®, as expressly stated within its warnings and labels, and knew that consumers and users such as Plaintiff could not have reasonably discovered that the risks expressly included in Singulair® warnings and labels were inadequate and inaccurate.

125. Plaintiff had no knowledge of the falsity, incompleteness, or inadequacy of Defendant's statements and representations concerning Singulair®.

126. Plaintiff used Singulair® as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by Defendant.

127. Had the warnings, labels, advertisements, or promotional material for Singulair® accurately and adequately set forth the true risks associated with the use of Singulair®, including Plaintiff's injuries, rather than expressly excluding such information and warranting that the product was safe for its intended use, Plaintiff could have avoided the injuries complained of herein.

128. As a direct and proximate result of Defendant's breach of express warranty, Plaintiff has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

129. As a proximate result of Defendant's breach of express warranty, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish and other personal injury and damages.

130. As a proximate result of Defendant's breach of express warranty, as alleged herein, Plaintiff sustained a loss of income and/or loss of earning capacity.

COUNT V
BREACH OF IMPLIED WARRANTIES

131. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

132. At all relevant times, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Singulair®, which was

and is defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Singulair® into the stream of commerce.

133. Before the time Plaintiff used Singulair®, Defendant impliedly warranted to its consumers, including Plaintiff, that Singulair® was of merchantable quality and safe and fit for the use for which it was intended; specifically, as a medication.

134. Defendant failed to adequately disclose that Singulair® has dangerous propensities when used as intended and that use of Singulair® carries an increased risk of developing severe injuries, including Plaintiff's injuries.

135. Plaintiff was an intended beneficiary of the implied warranties made by Defendant to purchasers of Singulair®.

136. Defendant expected Singulair® to reach, and Singulair® did in fact reach, consumers and users, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

137. At all relevant times, Defendant was aware that consumers and users of its products, including Plaintiff, would use Singulair® as marketed by Defendant, which is to say that Plaintiff was a foreseeable user of Singulair®.

138. Defendant intended that Singulair® be used in the manner in which Plaintiff, in fact, used it and which Defendant impliedly warranted to be of merchantable quality, safe, and fit for this use, even though Singulair® was not adequately tested or researched.

139. In reliance upon Defendant's implied warranty, Plaintiff used Singulair® as instructed and labeled and in the foreseeable manner intended, recommended, promoted, and marketed by Defendant.

140. Neither Plaintiff nor his parent could not have reasonably or adequately discovered or known of the risks of serious injury associated with Singulair®.

141. Defendant breached its implied warranty to Plaintiff and his parent in that Singulair® was not of merchantable quality, safe, or fit for its intended use, or adequately tested. Singulair® has dangerous propensities when used as intended and can cause serious injuries, including those injuries complained of herein.

142. The harm caused by Singulair® far outweighed its benefit, rendering the product more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

143. As a direct and proximate result of Defendant's breach of implied warranty, Plaintiff has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

144. As a proximate result of the Defendant's breach of implied warranty, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish and other personal injury and damages.

145. As a proximate result of Defendant's breach of implied warranty, as alleged herein, Plaintiff sustained a loss of income and/or loss of earning capacity.

VII. JURY TRIAL DEMAND

Plaintiff demands a trial by jury on all of the triable issues within this pleading.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff through his mother Stephanie Hammar requests that the Court enter judgment in his favor and against Defendant and award Plaintiff:

a) actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;

b) consequential damages and ascertainable losses in such amount to be determined at trial and as provided by applicable law;

c) exemplary and punitive damages sufficient to punish and deter Defendant and others from future wrongful practices;

d) pre-judgment and post-judgment interest;

e) costs including court costs, expert fees, deposition costs, and other litigation costs and expenses;

f) attorneys' fees as permitted under applicable law; and

g) any other relief the Court may deem just and proper.

Dated: 9/9/2020

By: s/ Kimberly Beck

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Dated: 9/9/2020

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