PUBLIC TESTIMONIALS

National Center for Toxicological Research (NCTR)
Science Advisory Board (SAB) Meeting
May 18-19, 2022
Virtual Meeting

The following testimonials were submitted before the meeting:

Anonymous

I started taking Singulair many years ago when I had run through all of the otc and prescribed options for allergy meds. I tried doing shots but at the time, it was not easy for me to leave work 3 times a week. My PA started me on the name brand formulary and my insurance covered it. For the first few years i did not notice any side effects. I already have generalized anxiety disorder and did not notice an increase in anxiety symptoms. I am also quite bad at taking medication on a regular basis because I likely have adhd. So I was only taking it when I was having allergy symptoms. 4 years ago, my allergies were really bad and I was struggling with them. I started taking it again, but now I was given generic.

One night I had a massive panic attack. I was home alone with my son who was probably 10 at the time. I debated on calling 911. I was scared that they wouldn't have a place for him to go or that he would end up with a foster until my family members could be reached. I have never had a panic attack like this before and it was terrifying. I felt like if I fell asleep I wouldn't wake up. At this point I had no idea what caused it and my anxiety meds did not really calm me down. My body felt like it was vibrating, it was a warm sensation. I thought it could have been something I ate or was exposed to or maybe the one drink I had many hours before. I did wake up the next day. It made me extremely anxious for a few weeks.

Months later, I was driving my son to school, it was dark out. After dropping him off I went to go to work. I was driving down a street I had lived off of for 10+ years. I somehow forgot where I was. I pulled over for about 10 minutes. I was in a full on panic. So many thoughts were racing through my head. I was afraid I would get arrested or hit by a car that didn't see me. So many irrational thoughts. Again this isn't an experience I have ever had. I called into work and made it home about half an hour later. Since at that time, I was the sole carer for my child, I was scared to seek care in the event I was admitted to the hospital and I didn't have anyone to watch him.

The last episode was in November. I had been reminded by the doctor to take my allergy pills on a regular basis. Two days later I was driving to pick up my son from school and I started not being able to breathe. Panic set in in the middle of rush hour on the freeway. I had to focus really good on breathing to make it through to a safe place to pull over for a bit.

Later that night I was laying in my bed with my husband. And my heart started beating really fast. I felt that warm feeling all over and it felt like the core of my body was covered in vapor rub. I told my husband that he needed to watch me and if anything happened to call for ambulance. I took a double dose of my rescue meds and after about 2 hours it subsided.

That was the last time I took Singulair or its generic alternative. I started searching for side effects for my meds and I found the black box warning that none of my prior doctors told me about.

I was hesitant to write this because I have pre existing mental health issues, though they were never this extreme. Prior to the Singulair I had only had 1 or 2 mild panic attacks that I was able to talk myself through. I don't normally take meds for it, they are there for emergencies. It has been well managed for years through mindfulness and breathing techniques. This wasn't a case of me being over dramatic or exaggerating symptoms, these experiences have taken a toll on me mentally. I don't know if I'll have another one, or if this was it. I'm afraid to take other allergy meds because of what happened to me. I am very upset that doctors aren't informed about this or brush it off like it's not a thing. This medication is dangerous. I am lucky I did not have any of the suicidal idealations that others have had. I had some weird lasting effects after stopping. I was having a hard time regulating my body temperature. In the middle of winter I was unable to take a hot shower. It had to be about 80 degree water or I would feel faint. I would get hot flashes and cold flashes for no reason. My blood pressure is now not well controlled I had to start a new medication to keep it in the normal range. I had headaches for about a month after stopping.

Please consider removing this medication it's not safe for people. If you have questions about my experience, please let me know.

Anonymous

I urge the FDA to require further studies into the side effects of this medication.

I took this medication for a very short period of time & continue to experience side effects.

When on this medication, my prescribing doctor was convinced the mental anguish & sleeping issues were being caused by work stress. This was about 7 years ago. However, they did decrease me to a kid's dosage to try to convince me to stay on it.

After a couple more weeks, I continued to feel worse, & my asthma, for which it was prescribed, had not improved in any way.

Fast forward about two years & I begin seeing a new ENT who calls it Montelukast instead of Singulair so I didn't realize they were the same medication at first - not until I had been on it again for two weeks. I immediately stopped after feeling the same side effects before & confirming it was the same medication again.

I now have this in my allergies list with all of my doctors & pharmacy.

My side effects during the first two years included feeling the worst anger I had ever felt. I would scream on my way home from work for 45 minutes straight. I had no patience. I have always been a quiet, laid back, controlled person - this wasn't like me at all.

My continued side effects include sleeping issues &, worse than that, I had trouble feeling emotions. My mind knew how I would normally have reached & wanted to react, but my body would "feel" numb or depressed. I knew I had nothing to be depressed about, so it was very frustrating. For almost two years, every laugh was faked to hide the effects from family & friends who were struggling to understand & didn't know how to help me. I also struggle with concentration & remembering, at times.

I recently began a medication that has helped, finally, to balance my mind & body, allowing them to slowly become in sync again. I'm finally feeling a little relief, but I still have to force myself some days to leave the house or even shower & change clothes. It has had a negative impact on how I perceive myself because for years I couldn't trust my own emotions or thoughts, because I knew they weren't accurate.

I hope further testing to determine better who this drug is capable of helping, and to protect others from suffering it's side effects, like so many already have, is made a priority & soon.

I belong to an online Facebook group with 16,000+ members that is dedicated to the side effects of Montelukast. Some of the stories are heartbreaking for the patients & their families.

PLEASE DO MORE TO PROTECT US AGAINST MONTELUKAST.

My doctors didn't believe me at first. Many in the group had similar experiences. Doctors weren't aware of these side effects soon enough & blamed mental issues instead, while the patient continued taking it. This can be prevented if proper studies are completed.

Thank you for your time. It is appreciated.

Kathryn Box

Hi Donna,

My name is Kathryn Box & I am 42 years old.

Thank-you for the opportunity to share my experience with using Montelulast/Singular.

A little background information on myself. I am an asthmatic. It is primarily allergy related & can sometimes be exercise induced. I’ve had breathing issues my entire life & have been on & off of inhalers & over the counter doctor recommended allergy medications throughout my life. Currently the only medications I take are in relation to my allergies & asthma.

A few years ago shortly after moving to Arizona my breathing worsened. I was initially put through allergy testing & began the use of a neubulizer to provide daily doses of Albuterol. Between fall of 2018 & spring of 2020 I was prescribed Singular & was provided the generic alternative Montelukast.

I did not see any immediate changes or marked improvements to my breathing but was advised by my doctors to remain on it.

I felt a bit of brain fog & initially wrote it off as stress. I also began to feel depressed at times, becoming withdrawn from social situations and even my own family which was highly uncharacteristic of my normally outgoing persona. It was so marked at one point even clients of mine began asking in telephone conversations if I was alright because I just did not sound like my usual chipper self. I went off Singular for a few months & my mood began to improve. The fog lifted, my depression shrank away.

Then came spring of 2020. In the beginning of March i had gone back on Singular & within weeks began to withdraw again. Yet again I did not correlate those feelings with medications. I assumed it was due to having been laid off & the stress many of us were feeling due to the pandemic. In April the voice's started. I thought I was going insane. I would look around the room, knowing I heard a voice even when there was no one there. It began to tell me to close the windows. Or just single words calling me names (b*tch, asshole, loser). At that point I became even more withdrawn not knowing what to do. I would sleep for days at a time, just to avoid the voice. Sleeping was the only reprieve but it only came during the day & nights were long. No matter if I tried to stay up my entire sleep schedule was off. I stopped answering my phone, the door, talking to my family, friends. The day it told me to hurt myself with a knife I went off the Singular. I felt like there was a battle in my head, with my own consciousness & this other voice that was not at all my own only wanting to cause harm to myself. Within a few days I began to sleep again. Within a week I noticed the voice was gone. Within a few weeks my energy levels began to return & I started going outside again & engaging with friends and family once again. I began to share with my husband & friends my suspicions. After 2 months of not being on the meds I decided to try them once again, curious to see if anything happened. I decided to try going on it for 2 weeks. I think within 48hrs was when I knew it was the Singular. Within a week the voices came back & I stopped them again.

This time though, I told my husband & my friends of my plans to try the meds & to tell me if they noticed a difference I'd stop. They noticed the difference within the first week as well. I was more subdued, often my bright sunny disposition was at all times melancholy.

I have always been so embarrassed by this experience it is liberating to share knowing this may help others. Thank-you for allowing me to share my experience. I know I am not alone in these kinds of side effects & am thankful I was one of the lucky ones.

Please feel free to reach out if you have additional questions

Kathryn Box

Christine Barnes

Dear Donna Mendrick,

Thank you for this opportunity to share with the FDA advisory board the side effects my son experienced while taking Montelukast and subsequently after stopping this medication. He was prescribed montelukast following a hospitalization from a viral induced asthma attack in December 2018 at the age of 5. We were never warned about the potential side effects, nor asked about how he was doing with respect to potential side effects during the regular and frequent follow-up appointments. Overtime he began complaining of stomach pain and head-aches. The pain and head-aches worsened to a degree that they impacted his school attendance and he had no interest in doing all the things he previously loved. We made regular visits to his pediatrician with these concerns. Additionally, he was waking multiple times during the night with nightmares, bed-wetting, and he was afraid to go to school or have us leave his side. With continuing and increasing symptoms, his pediatrician referred him to a gastro specialist. While waiting to be seen by the pediatric specialist I began researching the medication, I learned about the side effects of singular/montelukast and realized it could be the cause . When I consulted with the prescribing pulmonary and allergy specialist, we were told to immediately stop the medication. This was in April of 2020.

When we stopped the medication, in addition to the other symptoms, he began experiencing increased anxiety, unusual bouts of rage and agitation, tears that he could not explain, self-loathing, he could not concentrate and was having difficulty with math and writing that was always easy for him. He was no longer interested in reading. He could no longer do a sheet of math facts that he would have completed in less than a minute. His writing became jumbled and there was no spatial awareness on the page. His letters were big and small and he was not able to write on or within the lines. Previously the teachers and family commented about his writing being so neat. He said he felt like his brain was on fire and was buzzing. He said he needed to keep busy in order to be distracted from how he felt. Additionally he started to complain of throat pain, lumps. His lab tests showed that he had low iron. He was experiencing nose bleeds, peeling feet, and started complaining of sticky hands and needed to wash his hands continually and bathe multiple times a day. He was having intrusive thoughts and fear of dying. He was miserable and asked us to help him feel better- every day . He has been referred to pediatric GIs, ENTs, neurologists, Neuro-psychologist and cognitive therapists.

We started seeing some improvements in the side effects about 9 months after stopping but when he was told to take cetirizine to address suspected cold/seasonal allergies in Jan 2021. It triggered all the symptoms we experienced with montelukast within 24 hours of taking the medication and heightened them. Again, we were told to stop this medication immediately. Upon probing the pulmonary specialist following this event - we were told that montelukast and cetirizine are not the preferred medications any longer due to the negative side effects. Both medications were prescribed by the same nationally recognized pediatric hospital. We were not given any recommendations on how to address the symptoms our son was experiencing other than being referred to multiple other specialists or dis-regarding that there was a relationship to montelukast. When examined by a pediatric neurologist in January 2021 at nationally recognized pediatric hospital - it was acknowledged in the visit summary that a brain injury may have occurred due the montelukast. Recovery from this event took about another 9 months. He is still affected by OCD, intrusive thoughts and cognitive struggles but are slowly improving. He is on a clean diet with no dyes or artificial sweeteners.

We would like the FDA to educate providers that the side-effects to montelukast are real and may increase upon suspension.

We would like the FDA to study what help can be provided to alleviate the side-effects and help in the recovery.

We would like to understand the long-term effects and how we can move forward to help our son in his recovery. How do we know the severity and what may trigger a relapse? What other medications should we avoid?

We are grateful that the FDA is listening and hopeful that information is received to educate the medical providers, community and will lead to help for those already impacted by this medication and prevent others from experiencing the same.

Thank you for your time .

Christine Barnes

Anonymous

To the Members of the Science Advisory Board to the National Center for Toxicological Research,

I am presenting my written public testimonial piece for your review and consideration for the May 18 and 19, 2022 US Food and Drug Administration virtual public advisory committee meeting. Thank you.

Bang, bang, bang...over and over. As we stood outside her bedroom...after a day of raging and confusion, the head banging on her wall was excruciating. When would it stop? Will it ever stop? Our bodies and souls were fragments of what use to be...we were worn down. Our daughter was worse off, however. She was the one experiencing the trauma that was eating away at her being. We were losing her....

We knew at this time that she had made three attempts to end her life. She had been prescribed Lexapro to offset her symptoms. She was participating in a Children's Hospital DBT therapy program. None seemed to be making any impact in her life. Her physician continued to "up" her dosage of Lexapro while continuing to prescribe Singulair and Montelukast. Our daughter was no longer the athlete she had been or was meant to be. All scholarship opportunities and decision making were gone. Our once social butterfly was no longer to be seen. No more laughter. No more joy. Teachers that use to rave about our daughter were now silent. The grades that supported this admiration were barely hanging on. No more honor roll. Just embarrassment and shame and anguish. Somehow....she had gone from "the world was hers" to a world wherein she felt she wasn't good enough.... anymore. She knew she was a mess. She wanted to be "committed." She wanted to die.

Our beautiful, little girl had turned into a raging and self-harming maniac. She lost boyfriends, friends, sports, jobs, opportunities and we had no idea what was causing this slow, but now rapid rate of demise of our daughter.

We do not remember the precise year...but my oldest adult daughter was a pharmaceutical rep for Merck. As my younger victim daughter began to experience a rash here and there, my older rep daughter told us about "her" drug. It was Singulair. "It is a great drug," she claimed! It could be given to adults and children; even babies. She later told us that reps actually called it a "placebo" drug as it was so tame. Yes...this was indeed a wonderful, little miracle drug. My younger daughter was around age seven at this time. She began to take this drug "as needed" and continued for several years, thereafter.

As she grew, her sports and activities increased. She also developed sports-induced asthma and she began using a rescue inhaler, while continuing her usage of Singulair...again as needed. We began to suspect she had more than sports-induced asthma, and her usage of treatment options increased. While in junior high, she began to take Singulair and Montelkast more routinely. Small symptoms began to emerge at this time, but we passed them off as something else; boyfriend issues, puberty, etc. These symptoms included anxiety and agitation.

By high school, her symptoms began to increase, including delusional thoughts and actions. She would often lash out at those she was closest to...including language only a sailor would use. Once she began to drive, she would often drive off in a fury. Many times she would do so, only wearing pajamas as this is when the "ugly" of this drug set in...night time and after a day of trying to hold it together. She would insist others had uttered words when they had not. She would insist events and situations had happened when they had not. The family walked on eggshells so as to not upset. To upset meant her life could be in danger. We could not leave the home with or without her. We were hostages in our own home; we were fearful each and every minute of the day; what would come next?

By the time we figured this all out, our daughter was barely attending school. Fortunately, covid was at its height and schools were shut down. This allowed my daughter to do her "crazy" from the comfort of our home. By her senior year, she was all but bed-bound. Her competitive sports program kept her going. I suppose she knew she had to keep swimming; otherwise, she knew she would have lost it all. She had to attend classes in order to compete. She failed to show up for certain practices and she could barely muster enough strength or will to qualify for state. (This young lady, at one point, could not get enough of pool time. She was also the swim state champion as a ten year old.) Again, covid was still affecting events, so she was able to "zoom in" for a few of her classes in order to pretend she was "normal."

One day, while on social media, I came across a mother's plea for help for her daughter. She was advising the group that her daughter had neuropsychiatric symptoms. A woman responded, asking if her daughter was taking Singulair or Montelukast. A light went off. But...how could this little drug be causing all of our horrifying chaos? I brought it up with my older rep daughter. She was just as stunned as I was. After all, she was taught that this drug did NOT cross the blood brain barrier. I had no choice but to believe, however. I am not sure how much longer she would have survived if we had not chosen to "believe." We began to wean her off this drug on October 11, 2020, as suggested by members of a Montelukast side effects FB page. And although her symptoms escalated in the beginning (adverse withdrawal symptoms), I saw for the first time in years...a twinkle in her eye. I knew then that indeed it may have been this drug that had been destroying my daughter.

It took months to see any real improvement that would deem her to be functional. Last year, this time, approximately seven months post taking of this medication, she continued to suffer so much...she attempted to jump out of a moving vehicle a few times. We also feared she would jump off of a condo patio while on her graduation trip. Her moments of raging and anger were ongoing. But...she had improved. She was healing.

This healing consisted of numerous rabbit holes taken in order to find her "fix." We have been using neurofeedback for over a year...none of which is covered by insurance. Our savings and retirement have been used up. We have used various supplements and have utilized lab work often. She is now in therapy to unlearn what may have been developed as "habit" in reacting to trauma and drug incited behavior. Again, none or most of this is not covered by insurance. Perhaps it was only time that has healed her. We desperately need answers.

Today, she just completed one year of college. (Despite not having any scholarship opportunities.) Although she was signed up for dorm life activity, she spent most of her time at home (her college is 45 miles down the road). But that's okay. We are thrilled she is thriving as best as she is able to do so. She has come so far from the wounded, young lady she was two years ago. She continues to suffer from bouts of anxiety, OCD and agitation. However, we hope she will continue to heal and that one day she can be the girl that is not clouded or harmed by this drug. We have NO doubt it was this drug that caused the turmoil she has suffered. (As a side note, her asthma, allergies and mystery rashes have subsided or improved after coming off this medication.)

I hope one day all those who have the power to do so...will help protect others from the tragedy that our family and so many others have suffered. Thank you for your time.

Ashley Bracken

Dear Donna,

Thank you so much for this opportunity to be able to share with the FDA advisory board. There are many families that have had horrible side effects from Montelukast. This is my family's story. It is still raw because of the death of my daughter in December 2021 from suicide because of Singulair/Montelukast.

Ashley (38) I was pregnant with my first child when I was prescribed Singulair for the first of many times at 21 years old. I noticed that I had very vivid dreams of hurting and killing people when I was on Singulair 10MG. My brain still struggles to recall. I never knew this was linked to my many problems until Dec 2021 when I saw the warning for the 1st time. I have attempted to take my life 3 times, all while I was on Singulair. I have been on antidepressants since 2007 because of the damage done to my brain from trying to help my lungs. I stopped taking Singulair in 2012 after my last attempt never knowing it was causing all of it. I am in counseling and working hard to stay healthy physically and mentaly now.

I experience- agitation, including aggressive behavior or hostility, attention problems, bad or vivid dreams, depression, feeling anxious, irritability, suicidal thoughts and actions, and trouble sleeping.

Our daughter Jerica (10) was only on Singulair 5MG for 12 weeks until our 14 year old took her life and we saw the black box warning for the first time. She was having very scary dreams and when we took her off she would go into screaming fits where she would hyperventilate and hide in her closet. She is dealing with major anxiety. She has had to leave school because of it and is homeschooled now.

Jerica experiences- agitation, including aggressive behavior or hostility, attention problems, feeling anxious, irritability, sleepwalking, and suicidal thoughts and actions.

Our daughter Genevieve (14) had asthma and started taking Singulair/Montelukast 5MG when she was 7 years old. While we were on hikes Genevieve would complain that her legs hurt, she was experiencing muscle pain. We noticed when she turned 10, she began to pull away from friends and stay inside all the time reading books. She was an obedient straight A student, who was setting records for the number of books read at her school and academically gifted. In April 2021 when she was 13 her dosage of Montelukast was doubled to 10MG. We put together a lot the puzzle pieces from reading her notes, messages, emails and scouring through her phone that she almost took her own life that summer of 2021 and ultimately completed suicide in December of 2021. Afterwards we found a screenshot on her phone of the symptoms of taking Montelukast and she had every single symptom. She became irritable and aggressive, but we figured those two were typical teenage pubescent changes. What wasn't normal was when she described dreams of hurting people and even her loved ones. We believe that because of those, she "needed to do something to stop it". We think she was worried that she would act out those dreams. She was hearing voices, "so many voices" that told her she wasn't worth saving or fixing and that she should take her own life. She had debilitating OCD which we had her in counseling for before Covid hit and canceled everything. She would wash her hands until they bled before Covid. She would not touch door knobs, and she would leave her hands balled up when she hugged people. She said the OCD was the reason she stopped reading books. She complained of a brain fog or cloudiness. She noticed signs of depression, but was hiding it from us and her friends. In reading others stories, we have noticed she had very similar symptoms to so many.

Genevieve experienced- agitation, including aggressive behavior or hostility, attention problems, bad or vivid dreams, depression, disorientation or confusion, feeling anxious, hallucinations (seeing or hearing things that are not really there), irritability, memory problems, obsessive-compulsive symptoms, restlessness, suicidal thoughts and actions, tremor or shakiness, and trouble sleeping.

We are forever broken because of the side effects of this drug.

My questions to you are as follows:

Why were we never notified of the black box warning in March 2020?

Why would they prescribe a drug to children knowing the possible psychiatric side effects?

How many more innocent children have to suffer these awful side effects of this poison???

Are you going to provide guidelines to help other families that wish to stop taking this drug?

Where are the studies of long term effects on these children?

Thank you for your time,

Ashley Bracken

Anonymous

It was about three years ago when I noticed my daughter having troubles with her neck. She was having these muscle spasms (tics) that I swore were from technology hand held devices. I would take away her iPad for weeks at a time convinced that she just needed breaks. After a while, it wasn't worth the argument and she just played as normal. She was in a very dark stage, always wanting to be alone, grandparents had noticed a major mood change in our happy, artsy, funny little girl. We chalked it up to The Covid Shutdown and assumed it would all subside when things got back to normal. She had gone from being an incredibly talented painting artist at 9-10 years old to a dark, sad, almost angry pre-teen. Seemed like she would just shut completely down when we tried to spend any kind of time with her. Finally, a little over a year ago, I had enough and interrupted her time to see what was on her ipad. She had been finding a work around to get online and chat on different platforms with random people. Everything was false identities. She had told me she was having trouble distinguishing what was reality and what wasn't. She told me that she was very sad and that she had thoughts of suicide. It was devastating. I immediately held her, and tried to calm her down and help her understand how much we love her. She just said that it's been going on for a while now that she's been having some of these challenges.

I immediately contacted the school counselor and found her a therapist where I have a trusted doctor for myself. School empathized with me and said unfortunately we are seeing a lot of this with the 7th graders since the shut down. They have missed so much socialization and growth during this very imperative time in their life.

Fast forward seven months when our world really began to turn upside down. Our beautiful little girl has now developed more tics, of which we had been to our primary, multiple times, gone to physical and occupational therapy to help with the muscle tightness, have seen a therapist every week for months, have joined a group at school for supporting kids. We had been told to seek evaluation from a pediatric neuro psychologist for possible Tourette's syndrome. They are so booked the appointment was an entire year away. That wasn't good enough for me. I'm physically watching my beautiful little girl who a year ago was reading 3-4 grade levels beyond her own and wanted to go to college in Boston and become a lawyer, drastically drown in whatever is happening. She was not sleeping at night and having nightmares. She was ticking so bad it looked like she was seizing. Her verbal tick, throat clearing and a click noise is so frequent it sometimes makes it hard to breathe.

One night after a horrible episode of tics that made it almost impossible to sit up and suddenly have her a stutter, I had enough. I finally looked up her medication that she had been taking for her asthma for almost 4 years and to say I was absolutely devastated would be an understatement. Every single symptom we have experienced since the beginning of when she started on the medication is a side effect of this poison they call Montelukast. I immediately sent multiple MyCharts to our doctors with links upon links of what I had found along with all the detail of what we had been going through. The on call doctor called me the next day and casually said to just stop taking the medication. Two days later, my doctor called and said to stop taking the medication and to call for a Neuro psych appointment immediately, of which they told me they would only evaluate her for learning disability. I called a family member who is a doctor and he had no idea about this drug. My prescribing doctor said she had no idea about the side effects. The pharmacist said he has been prescribing this for 20 years and has never had anyone bring this to his attention.

Today, we are 21 days off, cold Turkey. She has now missed weeks of school, we are trying to do half days but it is extremely stressful for her. She isn't sleeping. She is having hallucinations at night. Nightmares. She even experienced a couple frontal lobe seizures last weekend. We are absolutely terrified of what this drug has done to our baby girl. We just want her well again. I'm so grateful I randomly figured it out…. Though going through the withdrawals are absolutely awful, I cannot imagine keeping her on that poison. I am hopeful there is light at the end of this tunnel.

Our daughter is 13. She was prescribing this medication in December of 2018; we took her off the medication on April 25, 2022; no one had EVER said anything to us about any side effects.

Tania Bray

Thank you for providing the opportunity for this testimonial

"My daughter was a strong, vivacious child, brimming with passion and energy. Her life ground to a halt in September 2016 when at the age of twelve she was admitted to hospital with a bowel impaction. This was followed by ever worsening nausea, vomiting, diarrhoea and abdominal pain. Within the year she spent a large amount of time curled up in pain on the couch or in the toilet. After the onset of asthma like symptoms my daughter was prescribed 5mg Montelukast (Sept 2017) by her paediatrician for a suspected mast cell activation disorder (MCAD). The medication was not discussed with me and I didn't ask any questions, I was happy that she had been prescribed a key medication for MCAD's.

Montelukast was a miracle drug, it was the first drug that uncurled her and gave her some quality of life – I was in love with it. Response to Montelukast and antihistamines meant she was well on her way to a clinical diagnosed for Mast Cell Activation Syndrome (subsequently dx'd Hereditary Alpha Tryptasemia) .

As time passed my daughters illness became increasing complex and multi-systemic, her reactions to medications were frequently adverse, perverse or paradoxical, testing found little of significance. The early suspicions that she was lying or faking didn't go away and many health professionals thought her illness was psychosomatic. I was contacted in February 2018 by the school, my daughter had expressing suicidal thoughts. These thoughts were attributed to her being a teenager with a chronic illness, it was to be expected. The failure for medicine to make progress in diagnosing her "mystery illness" and her referral to the Clinical Physiologist for CBT training furthered this assumption that she was a head case.

From 2018 onwards her neuropsychic and physical symptoms slowly worsened. She spent increasing amounts of time in my bed due to nightmares, she became fearful that she would be murdered in her bed and she took to sleeping with a knife under her pillow. She wore swimming togs in the shower scared someone was going to break in and rape her.

At some time the OCD started, she refused to eat things perceived as dirty, or prepared by dirty people or placed on dirty plates etc… and developed aversion to previously loved foods. Some days she didn't eat or struggled to find something clean enough to drink out of. She fell below the 3 percentile for BMI for her age.

She became confused, she didn't know what day it was, what was coming up or what had occurred. She would ask the same questions over and over again. She would become upset because her world didn't make sense. She became sensitive to sound and agitated with visual stimulation. She also became aggressive towards her brother, smashing is head into a wall because her looked at her, she could not be trusted to be left alone with him. She had a nightly period of mania. She didn't sleep well. Then the Tic's began.

Towards the end she was so bad that the following was typical for her. We decided to see a sequel movie, she knew the story. The movie was loud and visual and within the first five minutes she was all but writhing in her chair and kept asking what was happening, she was confused by the storyline. She asked to leave, which I agreed to and 30 mins later she started texting me, asking where we were, she couldn't' find us and different people were sitting in our seats. It turned out that she had returned to the wrong theatre and she had been there some time, she was entirely incapable of reasoning that the movie she left was a musical and the one she returned to a cartoon and that she was in the wrong place, she was distressed because we had disappeared. It turned out the reason she had left was because she needed to buy a stress ball from a $2 shop. She gave the stress ball a pounding to for the rest of the movie. It didn't help and by the end of the movie she was hand clenching and flapping, she knew she was doing it but couldn't stop, even when her little brother made fun of her.

By July 2018 her paediatrician told us there was nothing she could do for her and she was to be dumped on CAMH's, we had reached a low point. I tried to make sense of what was happening- the only thing that vaguely made sense was Montelukast which frequently caused serious side effects in the MCAD community (some MCAD experts believe the failure rate is about 1/3). I took her off Montelukast on 25th July 2018, over the next few days I could see the side effects falling away. By the following week she was telling the paediatrician and clinical physiologist that the urges were gone, but the thoughts were still there. Coming off Montelukast was hard for all of us, two steps forward, one step back. I could see my strong, vivacious child, brimming with passion and energy coming back to me. I rejoiced. Over time many of her "MCAD" symptoms also disappeared e.g tachycardia and I suspect that many of her symptoms were Montelukast driven not MCAD.

This was not to last, my bombproof child started to experience social anxiety. Despite the best efforts of CAMHS she rapidly went downhill until it was imposable for her to attend classes. By the September 2018 she was unable to go more than 20m into the school grounds and by the Christmas summer holidays my social butterfly was close to agoraphobia. Once she started hydroxyzine and cromolyn, famotidine she started to cope with the anxiety and returned to school in February 2019. After coming off Montelukast for a year and her meds were no longer working well and she started to struggle again, previously tolerated meds were lost. It subsequently turned out her increased sensitivities to meds from Montelukast was causing heightened neuropsychic side effects from other meds, including the SRRI's they put her on to help her with the Montelukast damage. Her Drs missed the additional ADR's and the damage became compounded.

Between the side effects and the withdrawal symptoms she has lost most of her high school schooling. My bright child is smart but not academic, she is unable to catch up, her memory is not good, and she struggles with focusing– it is too hard. She dreamed of being a judge or a politician, however it is unlikely she will be able to work more than the part time, minimum wage she is currently doing.

When she was first seen by a psychiatrist for the Montelukast side effects he was bemused by my belief that she was effected by Montelukast, he believed it was probably functional, but indulged my request for her to be put on hydroxyzine which I was required to source and import. She remained under CAMHS for 4-5 years, the only treatment they offered was CBT (useless), psychiatric meds (caused ADR's) and support. They had nothing to offer by way of effective treatment and beyond support did nothing to help her with recovery. I was able to find a list of "things" people coming of Montelukast had found helpful. That was the only guidance that I could provide her Dr's , I don't think the list was particularly helpful and most defiantly had no scientific basis. I suspect it went straight into the rubbish bin.

There is an overwhelming need for research on what this med is doing to the brain, who is it likely to effect and effective treatments for those are affected. Will my daughter 's daughters brain ever be repaired, will I get her back ??? Is there anything I could do better ???

Information needs to be available to prevent suspectable individuals being prescribed Montelukast and to guide health professionals in the treatment of effected individuals. My daughter has been largely baby sat by health professionals, they simply didn't know how to treat her and in the few attempts they did make they compounded the symptoms. Please anything you can find out to fill this information void is helpful.

Tania Bray

Gillian Brittan

My name is Gillian Brittan and I wanted to share my son's experience and after-effects from Montelukast, generic for Singulair.

My then three year old son suffered from pneumonia then two bouts of bronchitis within four months --we were so scared of the damage to his lungs. The allergist recommended Montelukast. I had taken this medication myself for uncontrolled asthma a few times and didn't think anything of giving it to my son (I had never received warnings). The doctor did say to look out for the side effect of "something like the kid in the "Exorcist"" and that if we made it to six weeks we would be in the clear. His chuckle with the warning alarmed me, be he said it was very rare.

Eight weeks passed with no "Exorcist" moments so I put the warning out of my mind. I wasn't aware of the other more common side effects that were occuring: bruising, restless legs, night terrors, vivid nightmares, and anxiety/separation anxiety. I chalked these changes up to being a rough "three-nager." Around month four extreme aggression began--we thought it was because his sleep had become so poor. It spilled over into preschool where he attacked staff and went on rampages tearing apart the classroom.

Worried about our son, I was Googling psychosis in toddlers. As I tried to figure things out, he began to lose hope at home after big explosive episodes. If he wasn't in complete denial of an outburst (he literally didn't recall anything about them), he was so distraught he said he was so scared and didn't want to live. He would bang his head against the wall and I found kitchen knives under his pillow--thankfully only the butter knives he could access. All at only three years old.

During this time I came across a detailed list of side effects from Montelukast and saw that my son was suffering from many of them. I contacted our prescribing doctor and got an appointment for the next week. I described the issues at home and school --we were on the verge of getting kicked out of preschool. The doctor observed some of his anxiety and aggression at the appointment and agreed he needed to stop taking Montelukast and get a new asthma management plan. He had taken this medication for about nine months.

After a few weeks off, we had fewer outbursts, but when he did have them, they were still highly escalated. After about three months, overall behavior improved, but he continued to have sleep issues and anxiety. School remained a challenge because they couldn't manage the triggers & resulting rage like we could at home. We started the assessment process for an IEP where he eventually qualified as emotionally disturbed (ED). Through First Five California and our preschool we were referred to The Chadwick Center for trauma therapy, jumping to the head of the waitlist due to observed dangerous behaviour to himself and school staff. It was positive to have help and support, but devastating to know my then newly four year old experienced this because of medication side effects.

We went through therapy to rewire the learned behavioral responses created when on Montelukast that also supported us in developing parenting and school based support strategies to handle his rage and anxiety. We were able to enroll him into a preschool program with trauma-informed staff and safety measures to protect him those around him. Thankfully with all these resources and time, there was marked improvement after a year. Not everyone has those supports.

He is now seven and thriving in first grade. There are still sleep issues and some anxiety, but we continue to use learned strategies to manage it. He is no longer a danger to himself or others. He once again engages in hobbies and gets enjoyment from preferred activities. He laughs and jokes around --things that had quietly disappeared when medicated.

If you have made it this far, I want to say I appreciate all of your time. As a parent I thought I was protecting my child, but I unknowingly exposed him to the biggest danger he has had in his life this far. I also understand that I am very lucky in our situation because there are those who have lost their lives to suicide due to the side effects of this medication. There are those who have not made it all the way back from the side effects and still suffer a tremendously... needlessly. Having taken this medication myself without issues I know there are benefits to people. But seeing the effect on my son brings to mind the question: do the benefits outweigh the risks and dangers? This is an especially important question when we now successfully manage my son's asthma without this medication.

I appreciate your time and energy looking into the effects of this medication and I hope you understand that even though some may try to convince you our numbers are small, those numbers are very impactful because those numbers represent not only the lives of those taking Montelukast/Singulair, but their families and loved ones. Those numbers are also likely under reported. I may have never made the connection or gotten so involved as to do something. So please listen to our stories and please hear our voices as we try to bring attention to concerns for those who are unable to do so for themselves. The side effects of this medication do so much more than effect the person on the drug. Our whole family was frightened and terrified and suffering alongside my son. I hope a letter like this to a person like you can help others of avoid that same fate. I am just grateful that I still have my son.

Sincerely,

Gillian Brittan

Alicia Brown

Hello,

Thank you for the opportunity to share our family's experience with Montelukast. It has had devastating and long lasting side effects on my son.

Prior to being prescribed Montelukast, my son was outgoing, fun-loving, athletic, and gifted academically. He was full of life, joy and promise.

In 4th grade he was prescribed Montelukast for *mild* exercise induced asthma. Side effects were never shared with us and we never imagined something used to treat something so small could cause such serious issues.

He remained on Montelukast until the end of 7th grade. In 6th grade he began to pull away from his friends and quit football, and all other sports. In 7th grade he began having suicidal thoughts and attempted suicide twice. He received counseling support, but we were still unaware of the connection to Montelukast. Before 8th grade we moved across the country and we stopped the drug, because I learned of the possible side effects.

He continued to struggle with depression. In 9th grade he began struggling with suicidal thoughts every day. He also began to suffer from social anxiety. Being around other people, especially at school, became really difficult for him. He withdrew from almost everything and it's really a miracle that he didn't kill himself.

In December of 2021, he suffered a psychotic break and ended up in a mental health facility. He has continued to struggle daily with psychosis and has since been diagnosed with schizoaffective disorder and social anxiety. He will most likely suffer with this for the rest of his life. He is receiving intensive psychiatric care as well as Coordinated Specialty Care.

He is 16 and struggles with the following symptoms on a regular basis: social anxiety, fear of the dark, fear of being alone, delusions, hallucinations (auditory and visual), short term memory loss, and distorted thinking to name a few.

Our son is an otherwise healthy 16 year old, with a supportive, loving family. He had everything going for him. He loves science and wants to be a robotics engineer. Now he faces a life tainted by mental illness and he worries about whether or not he'll ever be able to live an independent life and achieve his goals.

More research needs to be done on the effects of Montelukast on the brain and if it can be corrected.

Thank you,

Alicia Brown

Kierie Brown

Dear Donna,

Thank you so much for this opportunity to be able to share with the FDA advisory board. There are many families that have had horrible side effects from Montelukast. My daughter is such a sweet, kind hearted, smart, loving kiddo. When she was about 4 years old she was diagnosed with mild asthma and allergies. She was hospitalized once at 5 years old then again at 7 years old for breathing issues. When she was about 11 years old her pediatrician recommended Montelukast. She was on 5mg to start. She had a hard time taking big pills so she took the chewable pill. It was only a few months after she started that she would wake up in the middle of the night screaming that there were bugs crawling all over here. My whole family would take turns going into her room to console her. We thought she was going crazy. It was awful and lasted several months. She went into counselling for about a year and a half. She then started with some OCD tendencies and extreme phobia of bugs and death. We never made the connection that this was linked to Montelukast until we saw Tammy Panny on the news on February 2021. It was like a lightbulb had gone off. I am an educator with over 30 years of experience and never had experienced anything like this before. She would always do this thing with her hands where she would blow on them back and forth since she started taking this medicine. She was always constantly washing her hands and this was pre-covid.

Fast forward a few years and the summer before 8th grade June 2020 her same pediatrician increased her dose from 5mg to 10mg. That is when things went from bad to worse. She had trouble sleeping, started not wanting to go to school. complained of headaches, stomach aches, etc. It was a struggle every single morning to get her out of bed and ready for school. It took a huge toll physically and mentally on my entire family. This was right when covid hit and the black box warning came out in March 2020. She was online for that time due to covid.

August 2020 she was starting HS. She was so excited to start high school. This is supposed to be a fun time in her life and it has been anything but that. She refused to go to school and it was always my stomach hurts, my head hurts, I'm tired. She barely finished her 1st semester of her freshman year of high school. This was so disheartening for my daughter who always excelled at school and was the teacher's pet. There were days we couldn't even get her up out of bed before noon. We took her to our pediatrician at least 8-9 times during this time and the doctors basically told us that there was nothing physically wrong with our daughter and referred us to a psychiatrist. NEVER once did they question that this was all caused from Montelukast.

It wasn't until we were watching a TV show on February 5, 2021 and saw Kammy on the news with her son Tyson. I almost starting crying when she shared her story on the news. "It was like a light bulb" went off. I will NEVER forget this day. We consulted the pharmacist first thing that Monday morning to find out what is the best way to taper off this drug. They really didn't know much about these side effects and told us to taper off. We did that slowly over the next few weeks. The withdrawal period took 6-8 weeks. WE had to withdraw her from school. It was like she was withdrawing from a narcotic. Sleeping 15-20 hours a day, withdrawn, barely would leave her room. We consulted with a psychologist and reached out to a naturopath as I was so concerned about putting her on anymore drugs.

Months and months went by and she still really wasn't getting any better. She started experiencing anxieties, depression, school refusal, sleep issues, OCD tendencies.

Fast forward to May 2022, 17 months after she went off this horrible drug, we chose neurofeedback therapy that was recommended by the support group I found and her anxieties and depression as lessened. She will have good days and bad days since going off this awful drug. The past 3 months we are slowly seeing more good days then bad. She's starting to want to hang out with her friends more. This awful drug has effected us mentally and financially and I hope you listen to every single family reaching out to you?

My questions to you are as follows:

Why were we never notified of the black box warning in March 2020?

Why would they prescribe a drug to children knowing the possible psychiatric

side effects?

How many more innocent children have to suffer these awful side effects of this poison???

Are you going to provide guidelines to help other families that wish to stop taking this drug?

Where are the studies of long term effects on these children?

Here is the interview I participated in November 2021.

https://www.azfamily.com/2021/11/03/maker-popular-allergy-drug-not-required-study-long-term-mental-health-impact/

Thank you for your time.

Kierie Brown

Tina Brown

Dear Members of the Science Advisory Board to the National Center for Toxicological Research and the Montelukast Working Group,

Please find below my family's testimonial submission regarding the side effects of Montelukast.

Our family has been devastated by the effects of Singulair (Montelukast). One of our children was on Montelukast for allergy-induced asthma and bedtime wheezing for 3 1/2 years, from February 2018 to August of 2021 (age 4 to age 8). Over that time, behavioral and psychiatric symptoms increased in severity. It was a gradual progression, giving us no obvious connection that the behavior and symptoms we were seeing were actually side effects from this medication. Additionally, the prescribing provider did not warn us about these possible side effects over three years ago when we started the medication. We had no knowledge of these possible effects, and therefore had no suspicion of this drug. Because some of our children have complicated medical histories and are adopted, we mistakenly attributed all of these changes over the years to prenatal trauma sustained by this child. We never suspected an asthma medication to have psychiatric effects.

We have been to many, many doctors over the years to try to determine how to help this child. Multiple pediatricians, neurologists, sleep doctors, behavioral health doctors, neuropsychological evaluations, and psychiatry waiting lists... We have done all of this with little relief of symptoms which became devastating, isolating, traumatic, and paralyzing. It is a terrible thing to watch your child suffer and have no answers that will help them. The disruption and trauma it has caused our entire family is deep and complex.

In January of 2020, I noticed these side effects buried deep in the notes of the prescription sheet. At the time, the symptoms we were seeing were not as severe, so I still didn't really make the connection. I did inquire about it with the doctor, mostly just because we were experiencing a lot of "irritability", and was told that it was "very rare" that this drug could cause irritability. So, we continued the med. I forgot about it until this February 2021 when during a neuropsychological evaluation, the consulting doctor brought up the possibility of these rare effects, said it was unlikely, but recommended a trial off of the medication if we could find something to replace it. We were between providers at the time, and we were still mostly seeing only "irritability", along with anxiety which I felt was typical given the child's trauma background. So, this recommendation slipped through the cracks, and we continued with the med.

Things got worse. Much, much worse. In August 2021, we suffered a very traumatic psychiatric event. Our child flew into a rage, broke the doorframe to her bedroom and tossed the contents of her bedroom down a flight of stairs. Her siblings watched in horror and hid in a nearby bedroom. This drove my husband desperately to a last-ditch Google search where he uncovered the Black Box Warning that had been placed on Singulair/Montelukast (unbeknownst to us) in March 2020 by the FDA. Things had come to the point that I now could now see in our child nearly every single side effect listed in the Black Box Warning. From the FDA black box warning, these side effects include:

-agitation, including aggressive behavior or hostility -attention problems -bad or vivid dreams -depression -disorientation or confusion -feeling anxious -hallucinations (seeing or hearing things that are not really there) -irritability -memory problems -obsessive-compulsive symptoms -restlessness -

sleepwalking -stuttering -suicidal thoughts and actions -tremor or shakiness -trouble sleeping -uncontrolled muscle movements

We immediately contacted the doctor and stopped Montelukast the next day after 3 1/2 years of use.

That was a Tuesday. By Thursday, we had a different child. We saw improvements in countless facets of life. There was a remarkable change in disposition. We saw smiles where there had been scowls. We heard laughter where there had been screams. We saw joy where there had been depression. We received hugs when our affection would have been refused. My children were able to play happily together. There were giggles in my home. This marked change left no doubt in my mind that this medication affected her brain in unspeakable ways.

Our road is not over. About 10 days later, we experienced a relapse in these effects. We have read that withdrawal can be a rollercoaster, and things can get worse before they get better. There will be setbacks mixed with the lasting trauma of living through these past years of a child in psychiatric distress. There are certainly still separate effects from the prenatal challenges I have mentioned. That will of course never change in this life.

Many of her previous psychiatric effects have returned in the now nine months since we stopped this medication. We have tried more psychotropic drugs with the help of a behavioral pediatrician and now a psychiatrist to help alleviate some of the instability our child experiences. Our whole family is still grieving and suffering the effects of montelukast. I wish we knew what it did to her brain and how we can help her heal. I know she is just one of so many other innocent children who have suffered from this drug. We feel that it has robbed her of her childhood and we hope and pray that she can recover in time to have happy memories where there once was so much grief and fear.

I urge you to investigate the effects of this medication, as well as safe recommendations for tapering and treatment plans for withdrawal. No one should suffer the way our daughter and our family has. Thank you.

Tina Brown

Anonymous

To whom it may concern,

Our daughter started taking Montelukast in May 2019 for exercise induced asthma, aged 13. In March 2022 we were alerted by her friend that she had taken an overdose of 60 tablets.

We have since found out that she has attempted to take her own life 6 times over a period of around 2-3 years, since starting this drug.

She has hid her depression from everyone, appearing happy and doing well at school.

On discovering the most recent overdose, we immediately stopped the Montelukast as I remembered that when it was prescribed the nurse practitioner said to ‘keep an eye on her’ but ‘not to be concerned’ about the side effects as they are extremely rare.

Since stopping the medication ‘cold turkey’ she has started to suffer with psychosis, her mental health has declined even further and she will probably not be mentally well enough to sit her GCSE exams.

This drug has been eating away at her mental health for over 2-3 years and we didn’t even know. We are lucky she is still alive, though at the moment, she does not want to be. Utterly heartbreaking. She should be a happy confident 16 year old going out with friends and having fun, instead we are on permanent suicide watch and praying that she recovers. Montelukast has destroyed her; I still cannot believe that we are going through this as a family.

We are UK based and have submitted a yellow card report, however, the side effects of this medication need to stop being played down; this medication is too easily prescribed in the UK. Medical professionals need to take the effects of this medication seriously and not instantly attribute other causes. I wonder how many others have lost loved ones and never pieced together the causes of this drug? How accurate are the ‘stats’ really? There are many many stories in the Montelukast support group which are identical to ours, so many young lives affected.

Anonymous

My encounter with this medication was through my l, now adult son who has just been released from drug rehab for the second time.

My son, Antonio, had asthma from a very young age; he was a client of the Breath Mobile. A government sponsored Medical RV, for the inner city schools, that was staffed with nurses and PAs that educated and monitored the students. The bus came to the school and the school nurse pulled the kids from class. My son was on this medication off and on for years. My son's demeanor changed so much and we were unsure, at the time, what was causing these changes. The tics, the twitching, the moodiness, the rolling of the eyes, and the rage. He had auditory hallucinations, felt "things" touching him, his thoughts told him he should kill people, kill himself, that he was not worthy and just put him down. Even years after my son not taking this medication he has never been the same. He has struggled with his mental health, has attempted suicide, cutting, wanting to live on the streets, and then drugs. He has been to numerous therapists and been on many medication to assist him with his mental health.

I urge you not to put anymore families through this nightmare.

Valencia Cole

Hi. My 6 rear old grandkid was put on this drug for seasonal allergies. She developed sudden onset of OCD tics night terrors stutter sadness for no reason anxiety high liver enzymes concentration issues and hallucinations (spiders). I told her docs who left her on the med but sent her to therapy. It wasnt until over 2 years later summer 2020 that I saw online the black boxed warning and that her symptoms could be from that drug. I told her doctor who looked it up and told us to stop med. She went through terrible withdrawals Fever sadness. She then developed a severe reaction to alternative antihistamines meds and dyes.She also had the sudden onset of urticaria and a positive ANA. She is now allergic to polyethylene glycol. A lot of her symptoms stopped with the stop of the med..but concentration issues sadness for no reason intrusive thoughts trouble sleeping remain. At one point after stopping med we tried zyrtec which retriggered her hallucinations. At one point age 9 she said she wished she wasnt a thing. Meaning she wanted to die. She is now being evaluated at UCDavis and UCSan Francisco for a lesion on the right side of her brain a spot on her pituitary gland PCOS cysts with mass and possible endometriosis. That drug has adversely altered the coarse of my grandkids life. I want the public to be made aware of the dangers of that drugs adverse side effects because I was never told nor did her doctors see that the symptoms could be from that drug. Im hurt and angry for my grandkid who has suffered deeply and continues to suffer from the adverse side effects that remain at the age of 10. How do I help her now? What is the protocol to fix this horrific damage done? Why do so many doctors not know about the adverse severity of this drug? I wish I could go back in time and she never took that drug..Every night she cant sleep because of the spider intrusive thoughts. Everyday she has concentration issues and emotional upset and physical challenges due to the adverse effects of that drug that was casually given to her for seasonally allergies. Please. How can I help her now and prevent thos from happening to others? Thank You Valencia Cole

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Anonymous

Izzy was on Montelukast for approximately 4 years. She has suffered with anxiety, screaming tantrums, aggression, pica, night sweats, night terrors, lack of interest in school, potential hallucinations, difficulty sitting still, and trouble concentrating. She is very sensitive with her emotions and can be triggered by seemingly small issues. It is hard for her to let go of some things as she dwells on them. She is also very overwhelmed by everyday tasks. After learning about the horrific side effects, she was taken off of this drug. After an appointment with a neuropsychcologist, she was diagnosed with ADHD and SPD with impairments in written expression and mathematics. She's had many appointments with a speech therapist for her impediments. Izzy has difficulty processing why she acts the way she does and says she doesn't mean to be a bad girl.

Matthew was on Montelukast for about 4 years. His side affects have included anxiety, aggression, night terrors, and potential hallucinations. He has a hard time controlling his emotions. Many times when getting in trouble he will laugh or smile uncontrollably and it can be taken out of context. He is also very emotional and easily upset. Matthew still suffers from side effects that haven't gone away.

Why did none of their doctors tell us about the potential side effects? I still see others being prescribed Montelukast without warning even though there is now a black box label. It is imperative to have further research conducted to better understand the withdrawal process, find answers for those already affected, and prevent this from happening to others.

Anonymous

Dear Donna,

Thank you for the opportunity to share my testimony. I have been an admin for many years on the Facebook Group https://www.facebook.com/groups/40378158644/.

I was unable to attend the meeting in Washington DC in 2019, but watched online through tears with my husband as our members shared their stories. I am so proud of the group for being an integral part of making the Black Box Label a reality.

Please note this was a very difficult task to write up our experience and I left out a lot of details of the chaos and crisis we went through. It may appear long, but this is the short version.

Due to my son's age (29) and being an adult who doesn't like to talk about this experience, and may not remember all of it as his memory was thwarted by the medication, I will need it to be kept anonymous. I value his privacy as he does not even have a Facebook account and rarely will discuss the past trauma. I wish he would, but he can't deal with it. It makes him feel "less than."

As I was apprehensive to take on this task due to PTSD and bringing up the past trauma, it is too important to not speak out.

Please know I appreciate any help you can to facilitate our ability to help our kids.

Email Attachment:

Prior to filling the prescription, my son was a happy, energetic, gregarious human. He excelled at anything he did. He won the National Northwest Competition in Ki Akido at the age of 5 years old. He was amazing at soccer and loved to draw. He read voraciously, and loved Calven and Hobbs comic books. He did not have anger issues and was always trying to be the helper. He was a funny, sweet kid. He had asthma from a young age on. He took albuteral and used a preventive inhaler. His allergies were controlled with those meds. But then I was told about this miracle med that could get him off of those meds and really works well. And it did, until it didn’t.

Then seven years later I found a blog on medications.com and read “our story.” I couldn’t stop crying. I realized I had been poisoning my son for 7 years. I was terrified and heartbroken. He started Singulair in 2002 at 9 years old. (10 mg, which is an adult dose as I know now). In 2004 they lowered the dose to 5 mg. Probably figured out they made a mistake. I took him off it in 2009. My son is currently 29 years. He moved out shortly after the pandemic started in 2020 at 27 years old.

Before 2009 when I discovered that Montelukast could cause side effects, I was taking him to doctors and counselors trying to figure out what was wrong. We were giving other meds to try and counter the side effects. We didn’t know. His side effects were and are still (just not as extreme), horrible nightmares like demons chasing him, he couldn’t sleep out of fear. Slept in our bed a lot of the time to feel safe. Said things like I don't feel of this earth or I feel like I don't belong here. He had leg twitches, flash rage, depression, adhd, ocd, odd, the list goes on.

His handwriting, that was beautiful, looked now as if he had palsy, barely legible. He sometimes had uneven pupil dilation. Life was horrible. He went to inpatient treatment at a childrens' psych facility, where they had increased his dose back to 10 mg. Then he started hearing things, scratching on the walls, visual and auditory hallucinations. This was all before we found out about the side effects.

He had to be "locked up" three more times to keep him safe at the same facility. Something I regret as we didn't know what was going on at the time.

He had been terrified of sleeping, and sleeping alone. Dreams were so horrifying. Self loathing, extreme anger over little frustrations, depression, extreme sadness, anxiety all simultaneously trying to take him out. His side effects creeped up over the first 7 years of starting Montelukast, after many counseling appts. and drs. appts, and his suicide attempt by running into rush hour traffic, we finally figured it out and quit the med (2009) and then the more extreme side effects came for years.

Off Montelukast (2009), 6 months later he had a manic episode and ended up in the Johnson Unit (psych ward) for a week. They put him on Depakote. That made him instant old. He lost his hair, gained weight, couldn't play music (guitar), wouldn't talk to his friends, isolated and cried every morning telling me he doesn't understand why he feels this way. He was very close to killing himself. They then started him on Wellbuterin which helped with the depression but he had to get off the Depakote. After arguing with his doctor at the time, they finally agreed to change to Lamictal.

Then he took Lamictal and Gabapenten. He went off the wellbuterin because we thought maybe it was causing the flash rage, which made him a danger to himself and those around him. The flash rage can still continue to this day if he doesn't make sure he is eating, sleeping, well and not under a lot of stress. In 2014, he is 21 years old and still suffers from serious social anxiety, flash rage, irritability, and regular anxiety. He can't handle any frustration. He goes to 1-100 in seconds. It is so sad. Half his life he's been dealing with this. He has held a job for a year but it was baby steps. Otherwise, he is self isolating due to not being able to remember words when talking and feeling extremely uncomfortable in his own skin.

In hindsight, if it weren't for our family sticking by him no matter what kind of behavior he had he may have gone through with suicide. I am grateful something in my gut told me there was something else wrong. I'm certain the symptoms he still suffers from are long term side effects from Montelukast

(Singulair). In 2009, his general practitioner took him off it with no argument. I handed him a two inch stack of information I had collected, but heard nothing back from them. No validation what so ever. He watched my child change and had nothing to say. Other than previously telling me to take parenting classes. He had known my son since he was 5 years old. He was 16 years old at this point.

2018, He went back to counseling, started back to school, lost 40 pounds in three weeks but he was manic (not good), and was eating really healthy (no sugar, low fats, etc. organic veggies every day) and was happy, then he started not being able to remember stuff, was dealing with confusion and got desperately depressed and anxious, like when he was on Depakote. Can't play his guitar didn't have any interest in anything. Doctor gave him Wellbutrin again and didn't help after 3.5 weeks and he said he started feeling hungry even after eating. His hair started shedding around 4 weeks after (we think from the stress of mania for three weeks, TE, and then hair went into resting phase now is shedding.)

We went to see a naturopath and he said when we get his blood work back to copy him. Tested hormone levels and testosterone is very low. Naturopath called me personally and said it's a smoking gun. Need to go see Primary Car physician. Now he had the blood work duplicated at 9 am to see if it would replicate results and it did. Referred us to endocrinologist. All tests came back good. Very confusing.

Visited our naturopath with various notes over the last 8 years and all his medical records. Also, he has a counseling appt. with a great Dr. in town that has had brain damage himself because lets be honest that is what has happened with this med, he offers Neurofeedback, also known as EEG biofeedback. He can get it once a week with his insurance. Less than optimal but it's something.

I put together all the notes on Excel spreadsheet regarding appts. etc. I went through all his records, the ones at psych appts and ER, even his primary care doc, how much they didn't even get right. They say he was in and out of jail. He was never in jail, he'd been picked up and taken to ER and such but they made him sound like a criminal or some out of control deviant teen who was lying and being deceptive. This is how my son, a victim of a pharmaceutical brain injury, was being treated.

Winter 2018, Anxiety, depression and obsessive thoughts, sleep issues are his lasting symptoms. Flash rage seems to be triggered by no sleep or dyes and preservatives in his diet. His "spark" of his personality is subdued which is probably the depression and anxiety. At this point, at a 5 on the scale of 1 to 10, 10 being can't answer the phone, leave the house, or play his guitar. So he's been basically treading water. Started the EEG Biofeedback. He also, of course, deals with PTSD from being an adolescent on Montelukast/Singulair without us to guilt and shame from things, behaviors presented. Mania if he doesn't take meds for it. Currently on Lithium.

Spring 2019, The prescribed Chinese herbs from the naturopath were working. Anxiety was at a new low and only is taking the tranquility when having anxiety. The Botanabol is working for his metabolism and labido, and the vital adapt is working. Now on two meds, albuteral as needed and the lithium. EEG neurofeedback has helped also with the social anxiety. He is currently transitioning back into society and the social anxiety has gone way down. Sleep issues are not as bad either. Still no flash rage. Went off lithium with no problems.

NOTE: My son never had a manic episode until quitting Montelukast (2009/16 yo) cold turkey. Stress and detoxing off the drug seemed to throw him into a barrage of worsening or new symptoms.

2022, He is currently working, living on his own (moved out in the middle of the pandemic) and in a relationship for a few years. I still freeze when he accidentally rolls over on his phone and pocket dials me at 2 a.m. I think oh no, what’s happened? He still can have flash rage, I’m not sure about the dreams, because he may not want to think about it to even share. He was diagnosed with high blood pressure. The depression and anxiety are dormant currently. He has had red flags of mania, but never to the height it had reached before.

I often wonder what my son’s life would have been like having not ever taken Montelukast. Would he have just graduated from college? (He never graduated high school.) What would my life look like? Would I have finished my degree, would I have excelled in my career? Where would we be right now? I am fortunate that I didn’t lose my partner as many did and that my son is still on the planet as many are not. But I can’t help but wonder what would our lives had been like if we never filled that prescription.

I hope that it will become a priority to figure out what can be done to help our people who are still suffering and figure out what it has done to their brain and mechanisms in their body. Is it reversible? Will they ever recover fully? Will I always worry about what other meds he can take if he needs them without a relapse of symptoms? Will I just ever stop waiting for the other shoe to drop?

Anonymous

Dear Donna Mendrick,

Thank you for the opportunity to share my family's experience with my little grandson.

My grandson took Singulair from age 4 yrs to age 5 yrs., having been prescribed for asthma.

From the first week there were some effects including nosebleeds, leg pain and a focus on bloody themes in his pretend play with misc. toy figures, which I thought was strange.

Within weeks the formerly happy, delightful, amiable little guy was having disturbed sleep, terrible sadness, 2 and 3 hour sobbing jags, violent rages, separation anxiety, paranoia, thoughts of death.

I did daily after-school care for him, so I spent a lot of time with him and we were very close. Like many of these kids do, he managed to keep his emotions together at school but let it all out when he got home with me.

It was real hell. I couldn't turn my back on him for fear of him socking me hard when he got a chance. I had to hide scissors and knives that I noticed him eyeing. Very stressful for me and his parents.

The prescribing M.D. told my daughter that this behavior was all normal for his age, that it wasn't the medication.

We finally got him off the drug over a 2 week period or so.

Thank God that within weeks we had our adorable boy back. Many people haven't been so fortunate, and some have lost their loved ones due to suicide.

Please do what you can to prevent other children and families from this.

Thank you.

Anonymous

My quiet, polite son was put on Montelukast for exercise induced asthma around his 5th birthday (April 2013). Four years later (2017) he began experiencing general and social anxiety as well as disordered eating, which was driven by the fact he thought he would be unpopular if fat, although he had always been lean. He attended a hospital outpatient program for disordered eating. Over the next few years he was easily startled by things such as seeing a bone on the ground on the walk to school and feared a decorative metal chicken in a neighbour's front yard. He was too scared to go and brush his teeth by himself because he worried "slender man" would come out of the bathroom fan. Because this was so long after he had started an asthma medication, we had no reason to connect it to his behaviour.

In 2019, he saw a psychologist for his anxiety and began wearing the same "uniform" out of school, a particular top and pants, which we needed to have two sets of so one was always available. Although the "uniform" changed about every 6 months, once established it could not even be worn alternatively with a previous "uniform". He also started self-harming, hitting himself with a stick leading to severe bruises on his thighs and scratching his arms, legs and chest because it made him feel better. He said things like "I should kill myself", that he was dumb and a bad person. Once when walking alone he followed two older boys who had made a comment to him and after they disappeared around a corner, he thought he heard them saying things about him from some bushes. He rang me crying and shouting hysterically and said he had followed the boys because he had been angry but he was later uncertain as to whether anyone had actually been in the bushes. He also started playing alone at school because he preferred to be alone although he had friends who wanted to spend time with him.

When I found he had been taking a pocket knife (which he had stolen as I had not allowed him to buy one) to his somewhat chaotic school because it made him feel safe when teachers were shouting (at the class, not him), I changed his school for Grade 6 (the last year of primary school in Australia). That year of schooling was disrupted by Covid lockdowns and he became more anxious, often getting heart palpitations when walking with me to school (he had extreme separation anxiety so I had to walk him there and pick him up). He had his school bag on ten minutes before we had to leave the house and became agitated if I we did not leave at the exact minute he felt we had to (which was very early). Even when schooling was online, I had to sit next to him all day and he would meltdown if we had not started working on a sheet at a particular time, to the point where I removed the clock from the wall.

He had extremely poor self-esteem and would ruminate on innocent things he had done as a young child and say what an idiot he was, and worry that people would use some of these things against him in the future and ruin his life. He said things like, "I should die". He would also say very mean things to members of the family, but it was extremely hard to parent him because he was either in the mean mode, or if I got through to him that what he had said had hurt someone's feelings, he would then become consumed by self-loathing for hours to the point where I thought he would self-harm. My whole family walked on eggshells and in situations where he felt bad, my husband or I sat with him so he wouldn't self-harm or run away (which he did do for several times for short periods).

Researching myself, the concept of Rejection Sensitive Dysphoria resonated deeply with me, and because of its association with ADD, I became convinced that is what his issue was. I did a symptom checker on the Additude website and he came up with about 9 diagnoses. As emotional dysregulation was his biggest issue, we took him to a psychiatrist who put him on Guanfacine. While this seemed to help a bit, he rapidly put on weight (which oddly he didn't seem to notice) and became very lethargic. Because of the heart palpitations as well, I took him off this.

Towards the end of Grade 6, his anxiety got so bad that he only attended school four days a week - those the wellbeing officer, who was great with him, worked. I was extremely fearful that he would drop out of schooling altogether. I am a trained social worker and around this time I told my husband I thought that he would always have mental health issues. He was hyper sensitive to criticism and easily embarrassed. His psychologist reported, "In my clinical opinion, he is a complex young man with an extensive history of assessments, the outcomes of which have been mixed and inconclusive. Although he has made gains with psychotherapy, these have been inconsistent and, overall, therapy was less helpful than would be expected given the investment." I just felt that they did not understand the extent of what was going on because we only saw them fortnightly and there was only so much you could explain about all the things that had happened. I began keeping a detailed calendar with short notes of all incidents.

We then sought a neuropsychiatric assessment for which myself and his teacher completed the Conners Comprehensive Behaviour Rating Scale. The scores I completed "were extremely elevated (i.e., T-score ≥ 84), indicating many more concerns than are typically reported: Emotional Distress (T = 90), Worrying (Emotional Distress subscale) (T = 90), Social Problems (Emotional Distress subscale) (T = 90), Separation Fears (Emotional Distress subscale) (T = 90) and Perfectionistic and Compulsive Behaviours (T = 84). The symptom-based criteria were met for a number of disorders including ADHD Inattentive Type, Obsessive Compulsive Disorder, Social Anxiety and Separation Anxiety." The Teacher scores "were extremely elevated (i.e., T-score = 90), indicating many more concerns than are typically reported: Emotional Distress (T = 90), Upsetting Thoughts/Physical Symptoms (Emotional Distress subscale) (T = 90), Social Anxiety (Emotional Distress subscale) (T = 90), Social Problems (T = 90), and Perfectionistic and Compulsive Behaviours (T = 90). The symptom-based criteria were met for various anxiety disorders, ASD, Obsessive Compulsive Disorder but not ADHD Inattentive Type (4/9 symptoms) or Hyperactive/Impulsive Type (3/9 symptoms)."

The neuropsych report concluded, "Although there is some complexity around the diagnosis, it is my opinion that he most likely meets criteria for ADHD Inattentive Type. The current assessment suggests that there is insufficient evidence to support a diagnosis of ASD. While he definitely presents with features of ASD, particularly in terms of his social communication and there are some subtle features suggestive of restrictive behaviours, there is not sufficient evidence to suggest that these difficulties were present during the early developmental period. Instead, it seems that he has grown into his social difficulties and poor emotional regulation in the context of significant anxiety. It is, however, noted that he has not responded particularly well to therapeutic intervention for social anxiety. Given these factors, it is possible that his increasing psychological difficulties may indicate the emergence of another (as yet unclear) mental health disorder. There is a sense from his detailed history that he ruminates and seeks perfection. I wonder if there may be an obsessional component to his anxiety, potentially indicating that he is preoccupied with his thoughts. These features may fit with his rigid and categorical thinking style evident on cognitive assessment. He will require careful monitoring of his mental health, particularly during his adolescence, which can be a turbulent time."

He was also assessed by an Occupational Therapist who diagnosed him with dysgraphia.

He then started seeing a ADHD specialist paediatrician.

In 2021, he started a new high school and by being very proactive with the well-being department and teachers around his difficulties and also him being back with some of his old school friends, he had a better year. On October 15 2021, I emailed his paediatrician about an upcoming appointment.

“The main concerns we have had since our last appointment have been around poor self-esteem (dumb - even when getting awards for most improved, ugly, hideous, hating popular kids), moodiness, chronic irritability and aggression (saying mean things to family members, often as a 'joke' or an attempt to engage). Three to four weeks ago I spoke to my husband and older son about how we should try and deal with this meanness (don't react to it, change subject etc) out of concerns that if he continued in this habit he would get his head punched in by someone one day. In between he is very loving, especially with me and is always quiet and polite at school. He also wears the same clothes literally 24/7. He has two sets. While this does not bother us, it is clearly unusual and the idea of wearing different clothes stresses him enormously.

On 30/9, I was shocked to read this article in The Age about the neuropsych side effects of Singulair, the asthma medication he has taken for 8.5 years. The FDA advice attached outlines them as (symptoms he has experienced highlighted): • agitation, including aggressive behavior or hostility • attention problems • bad or vivid dreams • depression • disorientation or confusion • feeling anxious • hallucinations (seeing or hearing things?? that are not really there) • irritability • memory problems • obsessive-compulsive symptoms • restlessness • sleepwalking • stuttering • suicidal thoughts and actions • tremor or shakiness • trouble sleeping • uncontrolled muscle movements.

Apparently these symptoms can emerge after chronic use rather than immediately (therefore making it hard to make the connection with the medication) and can also remain after discontinuation. For that reason, after talking to our GP, I have begun weaning him off it at the rate of 0.5mg a week. He is now taking 3.5mg, down from 5mg daily.

While this does not explain all of his issues, some of which were identified before he started taking it at 5 years old, it may explain some. I feel that his behaviour has improved since tapering the Singulair and my husband agrees. However it is obviously early days.”

I also had the neuropsych reassess him on 27/10/21 because I had concerns he may have dyscalculia. Her report states, “I repeated a few key assessment tasks that were difficult for him when he was seen 12 months ago. Objectively, he has made significant gains in his ability to take in new information. This had been a significant difficulty for him previously, as he was very easily overwhelmed by new information. He is now able to take in more information but he continues to be a little unreliable in how he uses this capacity, meaning that sometimes material sticks and sometimes it doesn’t. He continues to be slower than his peers in his ability to produce written output under timed conditions, and hasn’t made gains in this regard. Finally series of timed tasks that also require mental flexibility were re-administered. Last year he had specific difficulties with items that required him to shift between two components. This year the pattern was variable. He had made gains with the shifting aspect of the task but was slower on some of the easier conditions. The overall pattern isn’t one of specific difficulties with maths, but rather a degree of variability in his attention which leads to inconsistency in his task performance. Thus he is not considered to have dyscalculia (or a Specific Learning Disability involving Maths). A range of factors potentially impact on attention including fatigue, stress, general physical health and medications.”

My son has been completely off Singulair for almost 6 months and I am now convinced that the majority of his behavioural difficulties were caused by this medication. He is no longer super sensitive or solitary. I can tell him off without fearing he will self-harm or run away. He is more confident and independent. He has a positive view of his future and says things like, "I feel happy." He now wears a variety of clothes, does not need to leave home at a specific time and things nothing about incidents that occurred when he was younger which he previously saw as "embarrassing/ cringy" and as having the potential to be used against him and ruin his life. His bedroom, which was always meticulously tidy, is now messy. He himself says that when he was on the medication he was super sensitive and he doesn't feel that way anymore.

I feel very bad that the medication I gave him every day for 8 and a half years, the years in which his very personality was formed, had such a terrible impact on him, and on our entire family. The stress on me was unbelievable, and his behaviour caused tensions between myself and my husband. My oldest son also suffered because I had to put so much attention onto my youngest son. While the very worst effects have fallen away relatively quickly after tapering off very slowly, I wonder whether some behaviours, such as making critical "jokes" about people (although these are nowhere near as venomous as his previous comments about people), have just become habit and will also fall away over time.

Unbelievably, while I kept thinking Singulair was so effective because he never had asthma issues while on it, he seems to have outgrown his asthma at some point and is currently not taking any medication or suffering from asthma at all.

I am sad, appalled and angry that no doctor, hospital, psychologist, psychiatrist, OT, neuropsych or paediatrician who assessed my child or any pharmacist who dispensed this medication for so long ever raised the issue of Montelukast side effects with me. It took the bravery and effort of another parent who had suffered similar devastation at the hands of this drug to raise awareness of it in a public forum. As soon as I read the newspaper article, our whole devastating journey made sense. If it weren't for this parent, my family might still be living through hell. Please don't leave it up to exhausted and traumatised people like us to raise the alarm on this medication. As medical experts, it is your job and your duty to do so. In Australia, the warnings are weaker, the side effects warned of are different, and there is not even a patient information leaflet in the medication box. Please help us save some of the other families who still won't know why they are suffering.

I am happy to provide all reports and documents referred to in these pages if they would help.

Andrea S. White, Ph.D.

TO: US FDA Montelukast Working Group

FROM: Andrea S. White, Ph.D

DATE: May 16, 2022

RE: multiple diagnoses & side effects from montelukast

Please accept the following testimonial for the public advisory committee meeting of the Science Advisory Board to the National Center for Toxicological Research.

I am a 51-year-old female who took montelukast for ~5 years, from ages 31-35. I am now 16 years off montelukast. My primary diagnosis for taking montelukast was asthma, but I now know that the asthma was caused almost exclusively by a cat allergy.

Time on montelukast: ~5 years, ages 31-35

Side Effects: Initial extreme thirst presented after 18 months on Singulair. Blood tests revealed autoimmune activity (highly positive ANA); repeated quarterly blood tests eventually presented as a positive Anti-dsDNA after an 18 additional mos. During this time, I experienced the following: (bolded diagnoses were declared and treated by medical professionals, as indicated) -

- kidney pain, relieved with a course of steroids (urologist);
- costochondritis (primary care physician);
- moderate depression (MSW therapist);
- nocturnal polyuria (urologist);
- lichen sclerosus (GYN specialist);
- typical and atypical lupus syx: fatigue, joint pain; arthritis of cricoarytenoid joint (ENT specialist; this remains 16+ years off Singulair). I saw 3 rheumatologists during this time. My primary rheumatologist was Fatma Allam, MD, SUNY Upstate, Syracuse.
  - Plaquenil (hydroxychloroquine) was prescribed for the lupus, and it was successful in resolving most of the lupus-related pain
- Two miscarriages, diagnosed and managed by a variety of providers in NY and OH, as I moved during one of them. Post-singulair, I carried two pregnancies to term

Long-term effects & Impacts:

- permanent tinnitus (known side effect of hydroxychloroquine, but could also have been the montelukast) (ENT ;
- arthritis of the cricoarytenoid joint remains after 16 years off the drug;
- The depression and lupus impacted my career, as I took a health-related leave of absence from my tenure-track position and moved to Ohio to be closer to caregivers.

● Almost all other symptoms resolved with gradual removal of Singulair and 6 months of weekly acupuncture and weekly Chinese herbs

Duration & course:

- delayed onset of side effects (18 months)
- worsening symptoms for 4 years until I did 6 months of weekly acupuncture and Chinese herbs, at the end of which I stopped taking Singulair (because I moved away from my acupuncturist & the cat, to which I was allergic).
- After stopping Singulair & having acupuncture, all blood & urine testing was clear for lupus, according to rheumatologist. The lupus was cured. I was able to become pregnant a third time and successfully carry to term. A fourth pregnancy was also successful.

Health Care Professionals: None noted were aware or have been told. I had two rheumatologists follow me, diagnose the lupus, and then a third rheumatologist confirmed that the lupus was gone after I had it for 4 years.

Suzanne Effinger

I took montelukast for about 15 years. I experienced mood swings, anger, rage, and halucinations. the Halucinations consisted of seeing people screaming and hurting each other. It played like a movie in the back of my eyes. I also heard voices. It sounded like a tv was on in another room. I could not understand what they were saying but I heard them. I quit taking montelukast as soon as I found about the horrible symptoms. All of the symptoms have become less frequent but still occur occasionally. My allergy symptoms are slightly worse since quiting it but manageable.

Thanks,

Suzanne Effinger

Julia Fjeldsted

To whom it may concern,

I am writing to tell you about this horrible life-changing drug. My son was put on it at the end of 6th grade. For mild allergies. Six weeks later had an out of of character Strangstrange incident. Very out of character. He would go on and off the struggle based on symptoms. With medical records I was able to obtain strangely matched the good years and the weird incidents. We never had anything horrible, just enough that at one point I was asked if my son had a learning disability. This is what I do for a living, I treat learning disabilities. I said no. He must be experiencing anxiety but now I realize his anxiety was based on executive function disorder due to brain problems. Skip to freshman year of college I had to go pick him up. He had some sort of mental breakdown. chBut then he seemed fine then he'd be strange again then he seemed fine even better than mine What was happening is he was going on and off it based on his symptoms. He was top of his class in 6th grade a good musician you name it and had a good executive functioning skills in 6 th grade through 8th.I'm a diagnostician, speech language pathologist so I know these things. Although that may not count for much because as the years went by we attributed his sometimes very odd behavior to puberty or family stressors. He always would regain its equilibrium went off to college with music scholarship. He was back six months later after having some sort of breakdown. Things got much worse from there. my adult son now, doesn't work. Yet he worked in high school part time and kept up his grades and music.But here's the kicker. We didn't figure it out, the effects of this drug … his Psychiatrist didn't figure it out. This is how we found out. I started having allergies. Right before shelter in place in our state. So since I wasn't able to see a doctor I took his medication. What the heck. The stuff is harmless right? It's just an antihistamine. Well I had a personality change went from yes anxiety and depression due to things that been hard with our son to the first time in— my life threatening suicide. When I was finally able to see an allergist I asked him about the drug. He told me we don't put children on this. "They come back from summer camp after having psychosis." That was my son, except in college. I can't believe how he managed to symptoms and it was so hard. His junior year he transferred schools His advisor asked me if we had a learning disability. I evaluate learning disabilities for a living. You don't aqire Theseas a junior in high school. But he developed problems with memory and executive function. What have been easy became hard. By the time he went off to college he was exhausted from trying to get a music scholarship and having to work harder than ever. So April 2020. One month after the black box label goes on. My allergist tells me we don't prescribe this to children. Yet my son had been on it for eight years. I know realized that I waved goodbye to a great deal of him in seventh grade. It gets even more interesting. My husband went on it because he developed breathing problems due to construction at his teaching position. He was as on montelucast for a year.He was grumpy and clingy and lacked insight in a way he never had. He was on it until yes my allergist told us we don't prescribe this for children. We all went off at immediately. I continued to have night terrors for four months frequently. Then subsided and went away almost a year later. I'm very sensitive to medication's. It Was just a strange thing I ever tried it.My son I believe now had problems when he went off it. When he got his mental illness problems I kept on saying to all the professionals, it seems like he has a brain injury. I promise you it seems like as a brain injury and now I realize he does. Montelucast causes limbic system dysfunction which we definitely saw. We actually had professional say , After he left school,he had sensory processing disorder. I said he has something but that's not what he has because you don't get that unless, you're born with it or have a brain injury. My son has a brain injury. Here's what else is interesting to years later he has made good gains. He still has some memory problems but now chronic pain. he's not able to work. The kid that could work go to school etc. He's not able to work.He looks like someone recovering from a serious brain injury. About eight months later my night terrors started to go away. But they still happen on occasion. It absolutely amazes me that people can be on this for years yet it seems clear from what I'm finding out that people are on it for years and have depression, anxiety, even psychosis , physical health problems and they don’t know why. Because — how could this happen —but then you look at the mechanism of this drug and is clear, how could it not.

Sincerely ,

Julia Fjeldsted MA, CCC-SLP

Anonymous

Donna,

I’d like to share our story of my husbands experience with this medication. I say our story because I consider my whole family, including my parents, a survivor of this horrible “medication.”

My husband, now 40, was prescribed this drug a few years ago by his asthma and allergy doctor to be taken when ramping up to allergy season to help his allergy induced asthma. He was never warned by his Doctor or Pharmacist of the black box warning or major side effects. Looking back I now know it was causing side effects the whole time that are easily missed or written off as something else if you’re not warned to be on the look out. He was easily agitated, angry, showing obsessive behaviors, would drink heavily around this time every year, was anxious, and began having a strange throat clearing tic. Fast forward to the spring of 2021, I’m almost 7 months pregnant, and things began going downhill fast. He became withdrawn and increasingly quick to anger and began obsessively hoarding. He was always wearing head phones with music or something playing in an effort to drown out what was going on in his head. My husband, who I’ve been with since we were kids, is the most loving, intelligent, non violent, and passive person I know. But the person who emerged that spring was not him, and by summer he was almost unrecognizable. He was losing weight rapidly, he had stopped sleeping, was having memory issues, and bouts of angry outburst followed by fits of crying, became increasingly anxious/paranoid, withdrawn, and clearing his throat constantly. At the end of June, 8 months pregnant by now, we had a trip planned for a week in Utah followed by a week in Denver with my parents for our daughters softball tournaments. We loaded up our motorhomes and hit the road and the weeks following will forever be the most traumatic experience of all our lives. We spent the first night at a truck stop outside Utah and I noticed he didn’t sleep but I chalked it up to the extreme heat and our inability to cool the motorhome, nobody slept well that night. The following few days he was very reserved but I could tell he was anxious and he was crying constantly. (not a normal thing for him) and again that night he didn’t sleep and in fact woke me several times holding onto me and crying into my back. Day one at the fields he kept disappearing and when he would come back he would stare into the outfield like someone or something was watching us but at the time I didn’t realize that’s what was happening. Again that night he didn’t sleep and about 5 am left the motorhome for a drive in our rental car. That morning my daughter had to be at the fields at 8am, a 45 minute drive away, and he knew this but was no where to be found plus he had all her equipment with him. He was about 20 minutes from the fields at the time so my Dad took her and and I stayed behind with my mom and 2 sons to wait and he said he would meet them there. An hour later my Dad called and said he still wasn't there…I called again and he seemed off. He couldn't find the fields. Now my husband, the avid hiker and outdoors man can read a map, can work any electronic and never gets lost but this morning couldn't do any of those things. So my Dad had to track his location and give him turn by turn directions to the fields. He called me and said something is wrong with Mike. Now it was a 45 minute drive back to get us and 2 hours later he still wasn't back and once again I had to track him and lead him to us. When he arrived he said he was tired so I asked him to take a nap to see if maybe what was happening was just due to pure exhaustion. What happened next will leave you speechless. When he awoke from his nap I tried to get some answers but he had non. He couldn't explain where he had been or what had happened. I found him standing in the bedroom of our motorhome with his sunglasses on doing karate moves like he was fighting someone or something. I said, Mike what are you doing?! He stopped, removed his glasses and sat on the bed with a blank stare on his face. He shooshed me and then pointed around saying they're listening…I said who is listening? He kept whispering and then finally mouthed the words HELP ME! That's when I knew something serious was going on. He began crying again so I hugged him and said, ok I'll help you hang tight. I removed all my kids from the motorhome and went to get my Dad. When we entered the motorhome, he once again had his sunglasses on and was fighting something but this time it was more aggressive. My Dad tried to calmly talk him down but it was as if Mike had no idea who he was and he looked terrified of him. He began crying and my Dad embraced him while telling him it would be ok. Then it was like a switch was flipped and he became violent. He struggled to get away and was headed towards to the front when my Mom entered and he started screaming at her to get away but was actually looking beyond her and pointing. He ran back to our bed and began lifting it to retrieve the shot gun stored underneath when I screamed to my Dad warning him the gun was underneath. My Dad and I moved quickly to stop him and they began to struggle and fell to the ground. My Dad is 6'1", extremely fit and my husband is 5'8" and almost gaunt at this point but non of that mattered because suddenly my husband was like the hulk and overpowered my Dad taking him to the ground. My Dad hit his head on the side of our bed and was punching at Mike while he was biting my Dad on the chest then wrapped his hands around my Dads face. It appeared as if he was going to rip my Dads eyes out so I screamed Mike and began prying his fingers away from my father's face. He released stood up, his face, arms and shirt covered in blood and I don't mean just a little blood, he looked like Carrie when they dump the bucket of pigs blood on her head, and he ran from the motorhome screaming. I went out after him afraid of what might happen while my Dad followed behind me and my Mom was calling the police and ambulance. Now we had quite the crowd gathering by now and he was running around the little area outside our motorhomes shooting a non existent gun at non existent people and fighting the air then began running towards me saying get down and as I started to go towards the ground, 8 months pregnant, in an effort to shield myself from him, he laid himself over my body like he was the one shielding me from something. He quickly got up and ran towards the river fighting trees and shrubs along the way. He threw himself on the ground and began dunking his head in the river and frantically washing the blood off before once again jumping up to fight. He was shooting his fake gun and karate chopping the air when finally the police and ambulance arrived. Now let me remind you this was at the height of the defund the police movement and everyone was on edge so I was screaming at the officers that it was a mental health crisis, he's not armed, and to please help him. When the officers approached he just stopped, turned around and put his hands up and allowed them to put the cuffs on and sit him down. The EMTs were tending to my Dads head and my kids were screaming from the motorhome they're gonna kill him, please don't kill our Dad! Then it all started over again! He kicked out at the 5 officers standing over him got up and started running. I'm screaming to them he is hallucinating but that didn't matter they slammed him to the ground and the EMT quickly gave him a shot of something. They strapped him to the gurney and loaded him in the ambulance and he started to calm down. They informed me I couldn't ride with him because they would be arresting him for assaulting a police officer. They transported him to the Park City ER for examination and then would be taking him to jail! My Dad and I followed to the hospital but were not allowed to see him. While we waited in the lobby they sent a nurse out to speak with us so we could tell her what happened. She said he was handcuffed to the bed, calm, and clearly coming off meth! I said my Husband doesn't do drugs! She said well he is too old to suddenly be schizophrenic so there is no other explanation other than meth! I again told her my husband has a very important government job where he is tested regularly and he doesn't do drugs! She was unconvinced and said well we shall see when his drug test comes back. At that point they took my Dad back to put stitches in his head and the cops came to talk to us. They said Mike was telling them his name was George but other than that he was being calm and polite so they would he arresting him shortly for assault. I pleaded with them that he was having some sort of mental break, please don't release him and please don't take him to jail. I was told it was drugs, he is calm and they had no choice! Well it was drugs all right but little did we know it was prescribed, FDA approved drugs! Anyways they took him to jail and the next morning I called early to check on him and they said he was minutes from being released, no events during the night and he will need to appear before a judge in a couple months. I begged them not to release him until we got there and were about 30 minutes away. The officer said he would do his best. By the time we got there he had been let out and was no where to be found. We drove around looking frantically as he had no idea where he was, no ID, money, phone, or shoes and we didn't know his mental state. We went back to the jail and asked them to review cameras so we could at least see what direction he went. Then about 20 minutes later he popped up, the officer said he had been hiding….He looked like a shell of himself. Rambling, shaking and clearly his throat constantly. He began chugging water in the back seat and choking on it over and over as if he had forgotten how to swallow. He started nervously looking out the windows and behind us the whole drive back mumbling. That's when the paranoid ranting began and he told us we needed to get out of the car and we got scared. I whispered to my Dad to turn around and head back to Park city ER! I told Mike to wait while I went inside and pleaded with the staff to help us because I didn't think he would come inside willingly and they said they couldn't force him. So I went back outside and asked him if he would go in and see a doctor because I was worried. He must have realized it too because he went willingly. They gave him some more antipsychotic medicine, talked about the night prior, said he had NO drugs in his body according to the prior nights drug test and must he experiencing a psychosis brought on by an underline psychotic disorder. They released him and said to keep him on Zyprexa until we could get him home to a doctor…I was floored! When we got back he laid down and slept for about an hour. I was in the other motorhome with everyone and decided I should go check on him. I found him up, sunglasses on, and again doing karate trying to fend off something. I quietly backed away, removed anything he could use as a weapon and instructed my Dad to call 911 again. They told us not to engage, keep him calm and help was on the way. This time they sent a park ranger who was trained in mental health who arrived first. I asked Mike if he would come out and talk to him and assured him he was only there to help. He introduced himself and was able to get him out of the motorhome and keep him calm. He told the ranger he was hearing voices that were telling him to do awful things and shadow people following him. The police and ambulance arrived shortly after. The same officers and EMTs from the day prior.

This time they knew it wasn't meth and treated him completely different. They gave him another shot and strapped him to the gurney willingly this time. I asked them to please not take him to the same ER, we need somewhere with the ability to hold him for evaluation. I thought I'd never see my husband normal again, I thought he would miss the birth of our child, I thought my kids were gonna grow up without their Dad! They drove him almost an hour away to a hospital that had appropriate staff to care for him and kept him for a day and a half. I was able to visit him the next day in their secured portion of the ER meant for people having mental issues. They said he would get agitated but remained mostly calm with the help of certain medications. When I finally went in he was a shell of himself but seemed to be coming around. We met with a mental health professional that said Mike was experiencing an extreme psychosis episode most likely brought on by an underlying mental health condition, most likely bipolar/manic depression and his lack of sleep made him have a full blown episode. He said there is a mental health crisis and they have no beds available in their hospital outside the ER but would be willing to keep him another night for observation while they looked for an inpatient bed available locally. He begged the doctor to let him leave, said he was fine. When Mike left the room to use the restroom the doctor confided he was still extremely agitated off the medications and didn't think he should leave. Together we convinced Mike to stay. The next day they transferred him to a mental health facility where he would be held for at least 72 hours for observation. That night he had another bought of psychosis, attacked a nurse giving her a concussion, over powered 2 big male orderlies and managed to break down a steel door! They had no idea what was going on with him and advised more antipsychotic medicines such as haldol! By day 4 they were ready to release him and directed us to get him back to WA right away, keep giving him all these medicines and get him help right away as it was possible he was schizophrenic or bipolar at the very least. Well I was in Denver at this point and we had left our motorhome and continued on with my parents. I had no other choice. So my father in law and brother in law flew to Utah, picked up our motorhome and then picked up Mike. They said he was a little off but he was just sleeping the whole time. I hopped on a plane, left my kids with my parents, and met them at home. They brought me a zombie! He spent the next month sitting in a chair, unable to remember anything or even recall what happened 10 minutes prior. He was unable to find any mental health support as there was indeed a crisis across the country due to the pandemic lockdowns. He decided he wasn't going to take any medications and that he just wanted to see if he would be ok. By month 2 he was getting better and was able to resume working again. The Park city police dropped the charges because there was in fact no drugs in his system and it was clearly a mental health crisis and week after week, month after month my husband slowly began to return to "normal" but non of us came out unscathed. I began suffering from nightmares and would wake constantly crying for no reason. My youngest son was having terrible behavior problems and issues sleeping and my Dad was still suffering as well. It wasn't until about 7 months later though that we connected all the dots. Mike came home with his prescriptions and the side of the Mentelukast bottle just happened to catch my eye..it was a warning for mental health issues! That's when I began my search online and found 10 pages of testimony from victims of this horrific drug! Each story was as if we had wrote it ourselves. Then I found the black box warning followed by the possible to cause psychosis and neuropsychological side effects warnings! I couldn't believe my eyes! Finally an answer! My husband wasn't manic, he wasn't schizophrenic or psychotic! He was poisoned and not one doctor knew to even ask or suspect it was medication related! I was relieved and outraged at the same time. When I told Mike what I had found and read it was like a actual physical weight was lifted off his shoulders too. We flushed the medicine and began advocating to everyone we knew. 10k plus dollars later in medical bills and missed work we finally had answers but it will never heal us from the trauma. Last month my son took a baseball to the eye and his face was covered in blood. While I was cleaning him up I had a panic attack and fainted. I was fine one second and on the ground unconscious the next. The trauma of this whole experience came flooding back in an instant and I'll never be the same. I can't believe they give this to kids and I often wonder how many lives have been lost, either because they killed themselves or someone else. How many people are being affected and have no idea it's because of this FDA approved poison. 20 plus years of people being prescribed this and doctors still deny it has these effects, still telling people it's safe. Some still have no idea it even has a black box warning! No one should ever be given this medication again! We survived but will never be the same. Please take this medication off the market.

Carla Gaikis

My son began on singulair(montelukast) at 1yr old. It was prescribed for reactive airway and chronic bronchitis. We discontinued the medication when he was 5 when he began having multiple focal seizures. I found the Parentsforsafety.org web site. I found the answer to my son's medical issues: Montekulast. My son had excessive behavioral issues from the time he was 3. There were multliple other side effects as well: excessive urination, night terrors, ocd like behaviors, indescribable aggression, projectile vomiting, and attention and memory issues. Before finding Parents for safety, we had no idea what was going on with my son. We sought treatment from multiple medical professionals: Pediatrician, Play therapist, Counselors, Psychologist, and Psychologists. No one ever mentioned the possibilty that any of these behaviors could be related to Montelukast. Instead, he was dx with ADHD, ODD, and OCD. Which in turn brought on more medication. Some were even heavy psychotropic medications that no 3 or 4 yrs old should be on. Not to mention, these medications never changed behavior as he was still taking the Montelukast, and personally, never needed these other medications. When the seizures began at 5 and I began putting pieces together, the Montelukast was stopped cold turkery. We had a period where things were better. Some things stopped automatically. He never had projectile vomiting again and no further night terrors. The excessive urination began to decrease in frequency. The more research i did on the Montelukast the more things i discovered. I read that some of the side effects will take as long as the child was on the med to be off before they go away. For the most part, i found this to be true. But, in the mean time, hell on earth is what my son and my family went through. My son had to go to a special behavioral school for 2 yrs because the public school system could not handle his meltdowns. We went through multiple meltdowns daily! Have you every had to hold a child down to to protect him from himself? He has been integrated back into the public school but has struggled a great deal. He has been left with many lingering, life changing effects of the medication. He most recently suffers from ASD like behaviors. Last year he underwent Nuro psychological testing. ASD was not an official diagnosis. He was ultimately diagnosed with short-term memory deficit. He typically has ASD like behaviors and is very socially awkward. He is now 16 years old. Has been off Singulair for 11 years. He has been seizure free for approximately two years. Still on multiple seizure medication's.. We do notice a relapse when artificial sweeteners or dyes are added in to his diet. He still struggles with aggressive tendencies at times. He is now almost 16 yrs old and outweighs me by 80 + pounds. I can't really hold him down any more so now not only do I have to find ways to keep him safe but I have to keep myself safe as well. Per documented other research re: mice that were given Montelukast, it demonstrated changes to the hippocampal region of the mouse brain. My son's MRI has shown cortical dysplasia involving the hippocampal and the paraphippocampal regions on the left. Is this due to the Montelukast?? I would love to know? How has this drug impacted my son's brain? He may never be who God created him to be due to this medication. He may never drive due to montelukast. He may never be able to achieve his dreams of being a firefighter/paramedic as you need to drive to perform these jobs. So, NO, the benefits did not outweigh the risks! I would love to learn about the long-term side effects of this medication and would love to know if they are treatable.

My son is living proof of the walking talking side effects of this medication. Especially, as a child that started the medication at such a young age. Knowing now that it crosses the blood brain barrier, I think this medication has severely and permanently damaged his brain.
Thank you for your time.

Carla Gaikis

Anonymous

My husband starting taking this drug for asthma symptoms. He has always been the guy with great clarity, drive, and top dog status at any job he held. Within a month, he was complaining about the inability to concentrate and craft simple emails at work. He was confused and overwhelmed a lot. He was having vision problems and light sensitivity. He had major OCD symptoms and had started fixating on certain things. He had gone from solid rock to mush concerning his emotions. He was worried about himself and the sudden onset of intrusive thoughts. He had major tics that he could not control. He had excessive thirst and frequent urination.

Within the 2 month mark, me and other family members urged him to stop taking the drug. Things only intensified after that. His pride kept him from divulging the horrid truth that I now know was slowly taking over his body. Added to the above mentioned symptoms, he complained of really bad nightmares. He had trouble sleeping and/or was afraid to fall asleep. I caught him at least 3 times in the middle of the night in what I would call psychotic breaks combined with sleep walking events. He asked if I heard the voices and saw the faces in a mirror. I tracked his phone and found him by the freeway overpass at 3am one cold winter night. He seemed possessed but would have a moment of clarity afterwards. He would be in denial. He was paranoid that anyone would find out about what was going on and lose his job. He was paranoid that he was going to lose me. He was paranoid that “they” were going to lock him up. He was not getting any doctors I convinced him to see, to understand or admit that this drug had anything to do with it. This made him even more depressed because of his successful past and pride. He made comments under his breath that I now realize were about suicide. He could not handle going for walks anymore. He started to have hallucinations while driving.He was throwing up a lot. He had a red blotchy rash on his back and neck. He got bad nosebleeds daily. He paced the house with OCD. He complained that he could feel something twitchy inside his skull. He had freezing extremities and pins and needle sensations. I tried to take care of him everyday and hope that the withdrawal symptoms would go away. I lost my battle and so did he when 3-4 months after start of

Montelukast, I found him hanging in the basement. He was 42. Thank you for letting me share. I'm sure there are many things I have forgotten.

Anonymous

Hello Donna,

I am writing on behalf of my adult daughter aged 23. She took Singulair (Montelukast) from 2010 to 2017, prescribed by her allergist for seasonal allergies.

In June 2016, she graduated from High School. In September 2016, she began university. By second year university, after discontinuing the Singulair (Montelukast) she began to have serious side effects that interrupted her ability to do her coursework.

She began to have the following long term side effects:

- agitation, including aggressive behaviour or hostility
- attention problems, inability to focus
- bad dreams, nightmares
- depression
- anxiety
- disorientation and confusion, forgetfulness
- irritability
- suicidal thoughts
- self harm (cutting)
- feelings of physical and mental exhaustion (that required daily 2 - 3 hour naps)

Being on this drug has greatly affected my daughter's quality of life.

She continues to suffer with these symptoms and has shared with me that she wanted to end her life so she could "make it all stop."

She continues to see a psychologist weekly.

If I had known the side effects of Singulair (Montelukast) I would have never agreed to let her take the drug.

Vedan Hamid

Hi Donna, thank you so much for this important opportunity to share with the FDA advisory board my experience with Montelukast.

I am born severe asthmatic, I remember my childhood as having to get injections every week at the hospital of my birth city, or at home, and sometimes dealing with an anaphylactic reaction and having to be send to the ER.

As I was growing up, during my puberty, my asthma symptoms started easing, up to being practically symptoms free for a period of 10 years.

Unfortunately, in January 2021, a major unknown trigger at the time (cat dander allergy) woke my asthma back to full blown symptoms. Due to the severity of my symptoms, I was admitted in hospital for 2 weeks. This is when I started the treatment with Montelukast, along side with Symbicort 320/9.

During my hospitalization, I've had various tests done to understand the risks factors of my asthma and allergies in the future, but there were no evidence of a major risk, except for cats, mold, dust and pollen. A CT scan was done at the end of my hospitalization and my lungs were clear, nothing abnormal, my asthma symptoms were controlled and my new treatment with Montelukast seemed to work.

The day I came out of the hospital (after 2 weeks), the same night, I've experienced high fever with night terrors, confusion, hallucinations, headache, and just the feeling of severely suffering mentally. I found this very unusual and shared my experience in the -Asthma Support Group- of Facebook. Some members have commented that this might be caused by Montelukast and redirected me to the -Montelukast (Singulair) Support and Discussion Group-... there I read other members experiences and their side effects were very similar. But I was wondering how a medicine to treat asthma and allergies could have such neuropsychiatric side effects, so I have decided to see if it really was caused by Montelukast to clear my doubts.

The next day I did not take Montelukast and slept at night without any issues. Then the following day I took montelukast again, at night time as prescribed, and I have experienced the same horrible symptoms, if not worse than the previous time, with again fever.

Some members of the asthma group suggest I take it in the morning, that reportedly it resolved their issues with night terrors, but it didn't change a thing.

That night, I have had high fever, night terrors, hallucinations, all my body aching, but unfortunately this time my fever lasted much longer time, with severe difficulties breathing. I could not move from bed, and every little movements I was doing was causing me to severely hyperventilate and experience palpitations. I did think I was about to die and my blood oxygen level was low (82). An ambulance came the next day and I was admitted to the hospital for another 2 weeks, just few days after my previous hospitalization.

The diagnostic was : severe double pneumonia with edema, the CT scan result have completely changed from clear lungs to severe inflammation.

Doctors were very surprised as to how this was possible since my previous CT scan of my lungs, again just a few days ago, was clear and did not show any signs of Pneumonia. However as I explained how this happened, my symptoms, none of the doctors believed that these were caused by Montelukast, and they did not know about the Black Box Warning released by the FDA.

During this hospital stay, doctors tried to give me Montelukast several times, even though I systematically refused, they could not acknowledge the fact that my night terrors, hallucinations, fevers and pneumonia could be caused by Montelukast. (I have never taken Montelukast again)

I have also started developing heartburn (later diagnosed with GERD).

The following days, I have continued experiencing vivid nightmares, to the point when some nights I would wake up from a vivid nightmare and would not know whether I am still awake or asleep, taking me an hour to realize I am truly awake and that I am in fact in the reality.

As my health condition was getting better and controlled, I got discharged from the hospital and stayed at home for 1 month to recover, but in fact it took me 2-3 months to fully recover from this double pneumonia.

Back at home, my boyfriend would realize I am not quite like myself. I would get angry very easily for things that have never really mattered before. I would not have the patience I had before, and please believe me that I was someone with a lot of patience.

My withdrawals at that time were :

Anxiety, depression, loss of motivation and interest in all things, attention and memory issues, agitation and agression, confusion, dizziness, headache, hallucinations, bad vivid dreams (night terrors), trouble sleeping, drowsiness, tremor, restlessness, stuttering, heart palpitations, heartburn, severe nausea, joint pain, muscles aches and cramps, nose bleeds, deep coughing, diarrhea, numbness of arms and legs, intracranial hypertension, increase of weight.

More than a year has passed by and I am still experiencing some long term side effects symptoms (even though less intense) that are affecting my quality of life.

I experience nightmares almost every night, sometimes vivid, sometimes accompanied with hallucinations. Troubles having a full night sleep due to agitation. I have been diagnosed with language memory trouble by my neurologist, which can sometimes be very troublesome during important conversations. I have a constant noise (tinnitus like) in my head, but both my ENT and Neurologist cannot seem to find what could be the cause of it, so we are still in the process of searching.

I still have trouble getting my motivation back and socializing like I used to do, I am mostly staying in calm silent environments, avoiding social interactions.

When I am sick and get fever, all my Montelukast side effects symptoms would reappear intensely and take about 3-4 days to dissipate, except for the long term effects.

From time to time I am still experiencing nausea, headache or intracranial hypertension.

My most recent experience that stayed in my mind, due to the mental impact it can create, are hallucinations of choking at night. I have had a sleep study and the results are negative for breathing issues at night, however the study does show that I have gone through a phase of nightmare/hallucination.

I am currently still active in the -Montelukast (Singulair) Support and Discussion Group-, whether because I still need support or because I can offer support.

But I am, like many others, sad that the group is growing constantly, as many come to experience neuropsychiatric events due to this drug. Currently there are about 100 new members every week, and it is increasing as more media are talking about it.

Reportedly, in a vast majority of cases, the patient have not been warned of the Black Box Warning released by the FDA, just like I also wasn’t warned. And reportedly, in a vast majority of cases, the patient have been given Montelukast as a first resort medicine, as I came to experience it too.

My questions to the FDA advisory board would be the followings :

-Will there soon be an indication on how to stop Montelukast (Singulair)?

-Will there soon be an indication on how to treat long term side effects and withdrawals?

-Could you investigate furthermore on the impact of Montelukast on a human body and invest on further research concerning the long term effects and withdrawals?

-Will there soon be any measures on informing properly every medical professionals concerning the Black Box Warning?

-Will there soon be any measures to counter the prescription of Montelukast (Singulair) as a first resort medicine?

-Will there be any sanctions toward Merck for the lack of actions in the prevention for the safety of the patients being prescribed Montelukast ?

Thank you very much for giving us the opportunity to speak out and share our experience.

Respectfully,

Vedan Hamid

Valerie Harnish

I am writing to inform you of the adverse effects I have experienced from taking Montelukast/Singulair. I began taking Montelukast in May of 2015 and continued taking it for seven years until Monday March 7th 2022. Over the past seven years, while on Montelukast, I experienced many adverse effects. At the time I did not know that the struggles I was experiencing were due to Montelukast. I experienced severe brain fog and decline in cognitive function and memory. So much so, that I believe that my brain has been permanently damaged. I experienced mood swings that made my emotional reactions disproportionate, uncontrollable, and even irrational. A sharp and persistent increase in depression and anxiety. Self loathing, and at one point I even thought I wasn't a real person. Due to all of this, I have been unable to work for the past seven years. I went to my Doctor with my depression and anxiety issues, and they never considered Singulair as the cause of these issues. Instead, I was prescribed a variety of antidepressants and anti-anxiety medications. As many as three anti-depressants at a time. None of these medicines worked for long, and left me feeling like a Zombie. I put on 50 pounds of extra weight, and even at times contemplated suicide. I felt like I was unable to feel joy or happiness. In 2019, I started taking CBD for my debilitating depression and anxiety, and to ween myself off of the antidepressants, that I felt were harming me. And I did feel some relief. I made many lifestyle changes; began yoga and regular exercise. Changed my diet, stopped drinking alcohol altogether, but even these changes were no match for Montelukast. After a short remission I seemed to get even worse. To have put in all the years of hard work to lose weight, sleep and eat better, and try like hell to be happy, it felt hopeless. In March of 2020, when I first heard of the FDA Boxed Warning for Singulair, I first wondered if that was what was causing all of these issues. But with COVID pandemic being very scary for someone with lifelong asthma and allergies, the idea of stopping my medicine that was supposed to be helping me be able to breathe was too much to handle. Over the past two years, I've experience a Roller Coaster of Ups and Downs, where some periods of time I would feel normal, and some times felt like I was trapped in hell. Most recently, at a very low low, and dark place, I decided that if this medicine had anything to do with how I was feeling, that I had to stop taking it. I could no longer risk my mental health. That was ten weeks ago that I decided no more of this bad, dangerous, harmful drug. I quit cold turkey on 3/7/22 and immediately felt like my old self for the first few days. What followed was an even more extreme Roller Coaster of panic attacks, severe debilitating depression, and suicidal thoughts. I feared for my life and often needed 24 hour care and monitoring, because I thought I would hurt myself. I reported this to my Doctor, and they acted as if they were unaware of the Black Boxed Warning. They prescribed me Xanax for the panic attacks. After reading the warnings of side effects on those drugs, I couldn't risk taking them either. After ten weeks, I'm feeling some relief, but still struggling on a daily basis. I can only hope that I will continue to improve, instead of continuing the Roller Coaster of adverse effects. This outline of adverse effects is just the tip of the iceberg, and doesn't begin to explain all the damage done to my family and myself. How is there no system in place to warn people of the level of harm that can happen from taking this drug? There should be, and I hope that my story can help educate others of the dangers of taking Montelukast. Somehow, my Doctors office still to this day doesn't seem aware of the dangers.

-Valerie Harnish

Amanda Harrod

Hi Donna,

Thank you for the opportunity to share my family’s experience with the FDA advisory board.

My nephew - who was such a bright, happy, social, and extremely smart child - was prescribed Montelukast at age 7 and took the medication daily for 3 years, until our family began noticing changes in his behavior - anxiety, sadness, some anger, etc. These things were out of the norm for him but we thought it may just be a matter of getting older…nonetheless, my sister (his mother) had him meet with a therapist for safe measure.

Thank God.

After a few sessions, my sweet, gentle, happy, and INNOCENT 10-year-old nephew said that he felt like he wanted to kill himself.

Once his pediatrician was aware of these thoughts, she recommended he stop taking Montelukast immediately because of a black box label for suicidal ideation given to the drug 10 months earlier. Imagine the anger you'd have as a parent having no doctors, pharmacists, or any medical professional notify any parents with children on this POISON of these side effects immediately.

After finding a support group of parents with children who lived similar nightmares, we took my nephew off of the medication and braced for the withdrawal we'd heard so much about - let me tell you, we were not ready.

For an entire year, my family was on suicide watch for a 10-year-old boy who screamed daily in fits of anger, sadness, and depression "I want to DIE" "Just KILL ME" "I'm so stupid and I don't want to live anymore" "My brain is telling me I'm dumb and I don't deserve to live"

Kicking. Hitting. Screaming. Hiding under covers in fits of tears. Unconsolable. Unable to read (and we're talking about a kid who read the entire Harry Potter series before the age of 9) "My brain HURTS" Unable to get out of bed, go to school, or play with his friends. Constant, descriptive, horrible thoughts of all the ways he'd kill himself, if only we'd let him.

For an entire year. We lost an an entire year of our life to give him and his brain the space to heal. Doctors wanted to shove more poison down his throat. "Antidepressants are the only way"….they weren't. We know for a fact the symptoms that were brewing under the surface while taking the medication became full blown after stopping. The withdrawal was unbearable and nearly destroyed our life. Had we not had the means to quit jobs to take care of him, buy the cleanest foods, have the nicest teachers that passed him despite him missing 8 months of school, and the research of so many others that came before us….his brain would have never had the time or space to heal like it needed to after digesting Montelukast ever day for years.

We'll never get that time back, but we're thankful to have a LIVING boy with his entire life ahead of him. He still has struggles with anxiety and bad days, and the fear of losing him to his mind will likely never go away, but we're AWARE and that's what other parents deserve. They deserve to KNOW what this medicine can do to their children and how they can help them heal after. I hope that no other family has to experience the trauma, fear, or hurt this medicine has caused our family. Something needs to change.

Praying for change,

Amanda Harrod

Roseanne Hecht

Dear Donna,

My son was prescribed Singulair at the age of 4 for allergies and allergy induced asthma episodes. Several weeks after starting this medication he started to wake up screaming from nightmares 4 or 5 times per week. It would take ages to get him settled and back to sleep. I thought, "I guess this is just a phase." Around 5 1/2 I noticed that my once outgoing and super athletic boy had started to withdraw from his friends at school and on his soccer team. Only 6 months prior he was the first on the field and encouraging his teammates to play. All of sudden he just stood on the field in a fog. Again I thought, "I guess it's just a phase."

As time went on his apathetic attitude took over everything. He no longer found joy in any activities that he once enjoyed. He preferred to just sit alone and no longer wanted to play. This of course was also punctuated by bouts of extreme rage, frustration, OCD and anxiety. Anxiety so strong he couldn't bear to leave my side. For a child who used to barely look my way when I dropped him at school, it was a shock.

And then came the words. He would say "I'm not worth anything." "I'm so stupid." "Everything would be better if I wasn't here." He became consumed with death. Always asking me questions about dying. Telling me he didn't think he should be alive. **At age 7 he actually attempted to take his life. I had to tackle my 7 year old child as we fought over the knife he grabbed in the kitchen. I had to hold him while he screamed uncontrollably that he didn't want to be alive anymore. AT AGE 7.**

I had been searching for help and answers and stumbled upon a Facebook group dedicated to discussing side effects of singulair. It shocked me to my core to see my son had just about every side effect you could have from this poison. We took him off immediately and have spent thousands of dollars of treatments and therapies to repair what this drug took from my son. While many of his side effects have improved over the last 4 years off the medication, many still linger. He still suffers from anxiety and panic attacks, he can not eat anything with food dye or MSG as they set off every symptom he's ever had including suicidal ideation. Every time he gets sick with a cold or flu, we deal with weeks of side effects symptoms.

If I could go back in time and not give this to my child, I would in a heartbeat. It has most likely forever changed who he was at his core - thoughtful, easy going, energetic. I can't give him those things back. I can't really make it better for him but I can do everything in my power to make sure others don't suffer the way we have.

I'd like to see more research into the neuropsychiatric effects this has on children and adults.

I'd like to see Doctors be made aware of how harmful this drug can actually be. They still prescribe like it's the first line of defence for seasonal allergies. How? How are the drug reps allowed to continue to push this knowing of the dangers??

Thank you for your time.

Roseanne Hecht

Son was on Singulair from Age 4 - 7. He is 11 today and still experiences the horrors of this drug.

Elizabeth Hicklin

To Whom it May Concern,

I took my last pill of Singulair/Montelukast on June 10, 2019. I had been on it for over 20 years, since 1998, when I started at about 20 years old, while in college. I never had depression issues prior to using this drug. In these 20 years, I have dealt with severe depression, anxiety, sleep issues, and daily suicidal thoughts. I've been through years of psychological therapy and recently to a psychiatrist, who was the first to question the use of Singulair and its relation to my condition.

The effects of this drug for 20 years are terrible, but the withdrawal and its effects made it all worse. With the support of my PCP and psychiatrist, I decided to wean off of the medication. On Oct 21, 2018, I reduced my dose from 10mg to 7.5mg. The first day (Monday), I felt fine. The second day, I started to feel anxious and more depressed than normal. By October 24 (day 3), I was in what I would now compare to "detoxing" of a drug, I was shaking, sweaty, nauseas, body aches, had extreme anxiety and depression and could not sleep (Even with my prescription sleep medicine). I was ready to take myself to the hospital psychiatry ward, but fortunately I have a very supportive family who helped me through it. I called my psychiatrist who advised me to go back to the 10mg and come see her again. After consulting with her and my PCP, neither knew of any "way" to stop taking Montelukast slowly. My asthma doctor had passed away a few years ago and since the Singulair was controlling my asthma, I did not seek out another doctor. However, when this occurred, I called 3 doctors in the Orlando area to try to make appointments, but specifically about weaning off of Singulair. Every doctor said there was no reason to wean.

I went back on the 10mg until after the new year and then started (with my PCP, psychologist and Psychiatrists support) weaning off of the medication. There is NO documentation, so this was just a "shot in the dark". We decided to wean 1mg per month. Once I got to 6 mg, I started decreasing every 2 weeks. I am now off of Singulair, and am maintenanced using a Corticosteroid inhaler. My weaning process was slow and scary. There were times I thought it was getting worse, but I pushed through. I now do not have daily thoughts of suicide, but have not been able to come off of my depression, anxiety and sleep medications. I believe it will take more time for my body to heal.

This drug has had an enormous impact on my life. I honestly didn't believe my Psychiatrist when she first related those issues with Singulair. It had completely changed my life 20 years ago! (Being on oral steroids constantly and theophylline). Little did I know how much this drug really affected my adult life.

Since 2019, I continue to have issues with depression, anxiety and insomnia. I continue to meet doctors and pharmacist who have no clue that this drug has a Black Box warning. In fact, just this past Friday one of my son's pediatricians (One in a group we normally don't see) had no clue about the side effects. A pediatrician!!!! I know many PCP's who prescribe this that have no clue that there are neuropsychiatric side effects. My husband's PCP wanted to put him on it for a cough. When my husband said he didn't think it was a good idea and I (his wife) has had depression, anxiety, etc, the doctor told him "Those side effects are not proven". (Even though it was added to the Patient Education in 1998).

Please take this into consideration to help numerous children, parents, adults and doctors become more educated and aware of the potential side effects. In my case, the benefits did not outweigh the risks. Will I ever feel "normal" again? Will I ever stop having thoughts of taking my life? A blessed life with 2 beautiful boys (6 and 8) and a devoted husband who is just as passionate about this cause as I am. Thank you so much for your time and consideration.

Elizabeth Hicklin

Angela Holding

Dear Donna

My grandson was prescribed Montelukast at age 11 to treat an asthmatic night cough.

The doctor warned us with an eye roll that 'some parents think this made their kids hyperactive' Our pharmacist offered no warning.

The cough soon went but two weeks later our innocent, sweet natured boy began to change. He was hoarding old books and comics, developed tics , began symmetrically tapping, wanted certain phrases repeated and had to speak last in any conversation.

Then he started to constantly confess to having the most horrific thoughts such as raping his mother or eviscerating his little brother. It was so constant his Mum used to hold her hands over her ears and say ' Please stop- just for 10 minutes'

As you can imagine we were beside ourselves and finally realised that he had OCD with intrusive thoughts, this is now listed as a side effect but was not at the time.

Thank goodness my daughter realised that all the problems had arisen after he started taking Montelukast . We researched and found, through a FB support group, that many other children had similar side effects. We stopped Montelukast and within a couple of weeks the OCD was almost gone but he suffered outbursts of totally out of character rage over the next three months. He was seen by CAMHS who verified that he had suffered OCD as a side effect of Montelukast and they submitted an adverse effect report.

His relationship with his Mum was badly impacted and 3 years on he had another episode of intrusive thoughts needing therapy after a stressful experience. The whole episode and aftermath was horrible both for my grandson and the family.
Angela Holding

Shayna K

Hello there,

I am writing today to share my sons story with this awful drug. My son Carter before this drug was a happy boy, who loved his brothers, his family, school and life. He excelled in school, had many friends, and was always smiling and laughing. In March of 2019 my son had a reaction to a medication that caused him to struggle breathing and we called 911.

Fast forward a few weeks and we ended up at the allergist, who ultimately prescribed this medication to help Carter with some breathing and allergy issues. We didn't see the side effects immediately, although in hindsight they were there. We started to see some issues with schoolwork, and socially things seemed like they were slowly changing. He was smiling less and less joy came from him. Come early February 2020, right before Covid, my son tried running away briefly. This is NOT who my son was, what was happening!? We immediately met with the school, him, counselors all of it. Carter felt worthless, like nobody loved him, like he wasn't as good as his older brothers. It was devastating. Then we all know how Covid went, and that for sure didn't help our situation.

We then started researching and trying to figure out why the sudden change in him. Our family situation hadn't changed. I then researched this medication he was on, Montelukast. I couldn't believe what I was reading. How could this medication be doing this to my son? But it was, not only to mine, but hundreds of thousands of other families. We took Carter off this medication and started finding ways to help him naturally, as now I was afraid of medication.

Now fast forward to today, two years later. My son suffers severe anxiety, struggles to focus in school due to lack of concentration. He feels worthless, is depressed, has no friends now, and struggles socially. NONE of this present before Montelukast. My life and his life have changed forever. Due to his self esteem issues now, among many other issues now, he was severely bullied verbally. That sent him into a deeper depression. I now have to take him to therapy and a psychologist to help him work through the mental struggles he faces. And sadly, I'm too terrified to medicate with anything at all!! I mean, could you truly blame me? All of this could have been avoided if I had been given something different for my son originally, my happy life loving son, who is now sad and lost.

He also struggles to eat, we had to do bloodwork and that was normal, minus some vitamin D issues and high protein in the urine. All concluded as fine by his pediatrician.

Western medicine has failed my son, the FDA has failed my son and thousands of other kids. PLEASE remove this from the market. I pray every day that families don't have to go through what mine has. This drug is causing a mental health crisis in children, and people need to be aware.

Thank you for taking the time to read this, I hope you'll consider the many families and kids who have suffered from the side affects of this medication.

Shayna K

Anonymous

To whomever this may concern,

I was prescribed montelukast for exercise induced asthma and allergies. It gave me severe headaches/migraines for almost two weeks along with really vivid dreams. Over time these side effects subsided and it slowly began to change my behavior towards others and how well I could handle stress. I 'felt' different but didn't think it was the medication. It wasn't until after taking it for 98 days that I noticed myself that I was acting out more, my patience was short and if something was out of my control, I would act out in anger. I didn't recognize myself. I asked my pharmacist if it was safe to stop cold turkey because of the mental side effect and I got a definitive yes. Within 2 days of stopping, I felt different, I could process decisions better, I thought before I did something in anger, I was turning back to me. On day 3, I was shaking so bad from the withdrawal and my anxiety rose very fast and out of the blue. It's been 9 days, and my anxiety is out of control, I haven't kept food down for 3 weeks. My coworkers are seeing a change in me. I'm turning back slowly into my old self, with my decision making process a little slower.

Since stopping this medication, my breathing has improved! It's like I don't need my inhaler anymore. While on it, I could never get my breathing to a steady point of control. Now I'm getting dizzy because of my inhaler dose(too high).

I now suffer from anxiety because of this medication.

Alisha Lechner

Dear Donna,

Thank you for the opportunity to share with the FDA advisory board my daughters experience with Montelukast. Our daughter started taking Singulair (Montelukast) for allergies at 1.5 years old for 6 months and started showing signs of neuropsychiatric behavior symptoms and I didn’t link to the medicine. I just thought it was “terrible twos” as a first time mother. She would have manic episodes, rage, demonic like behavior, in a daze, dilated pupils, uncontrollably crying were just a few which would start immediately after I would give it to her at bath time 2 hours long until she would fall asleep from exhaustion there was no controlling or comforting her. I started to notice the behavior would occur after I would give her the Montelukast as they became more frequent so I looked up the side effects and sure enough I found there were adverse reactions and immediately stopped it! The episodes stopped immediately so I thought it would just end everything but here we are 4 years later and over the years she slowly started similar behavioral episodes that occur with certain triggers such as other medications OTC and Rx that would trigger the episodes along with sugar and foods with additives and artificial dyes and sweeteners what seem to be mostly toxin triggers. I was at a loss on how to prevent it. We tried to avoid the trigger foods, kept a journal so I could try to figure it out. I was doing everything in my power to avoid the episodes! It seemed over time the episodes were getting worse with new issues hallucinations, night terrors, complaining her body hurt at her joints, physically could not get up off the floor. Still to this day she is triggered by artificial dyes and sugars, tiredness, even infections and viruses seem to trigger her episodes. She has developed psoriasis rashes and psoriasis arthritis. We have been through rounds of detoxes. I had been tirelessly trying to find the reason for it all researching online and found a support group: Montelukast (Singulair) Side Effects Support and Discussion Group, where I finally found the exact same stories and my eyes were opened to so much more than I could ever get help from our pediatrician who was unaware of adverse neuropsychiatric side effects and much worse they don't seem to go away after discontinuing! I have no idea the extent of damage to my daughter's brain as clearly this asthma/allergy medicine affects severely in children and adults and the need for awareness with the medical professionals. While I am grateful the black box warning was added many providers and pharmacists still are unaware and down play the neuropsychiatric side effects as rare. We need answers as to why and how this drug affects the brain and is causing these adverse side effects and what treatment there is to fully recover from the damage. Because so much is unknown no one can get any treatment or help from medical professionals. Our only help right now is from each other's experiences from the support group. I encourage your committee to find ways to educate providers and research further into these adverse side effects. My hope one day is to know what this medicine has done exactly and there will be treatment for my daughter to continue her life not held back by these side effects.

Thank you for your time,

Alisha Lechner

Rachel Masterman

Dear Donna,

I am writing to tell you our story.

My extremely happy, beautiful boy suffered a few viral induced wheeze episodes and was put on Montelukast when he was 2 years old. Granules that had to be given once a day.

We were never warned of any side effects or anything to look out for so we trusted the doctor and I gave them to him every day.

For 2 and a half years I watched my son go from being this bubbly, happy little lad, full of energy go to an angry, destructive, extremely sad and pain riddled monster.

I took him to the doctor many times , terrified because of the awful hallucinations and nightmares that he would have every night. He would see huge spiders and shadows climbing down his walls and would scream the house down . He started bed wetting and complaining of awful pains in his legs and stomach. His behaviour was just awful. He would literally smash his toys to pieces in a frenzy then sit and cry uncontrollably. He said he felt so sad but couldn't explain why. He would tell me he wanted me to die ! It was just a horrific time. He was almost kicked out of nursery for his behaviour and that's when I broke down thinking something was serious mentally wrong with my beautiful son.

I just happened to Google Montelukast and there in black and white on my screen was the list of potential side effects of this drug. I cried for hours and just held my son and apologised to him for putting this poison in his little body every day.

I soon discovered the Facebook page of thousands of other parents who had also been through very similar experiences with Montelukast. I was horrified with what I read. The tragic stories of Cody Miller plus many others just broke my heart.

I took my son off cold turkey and then all hell broke loose. The night sweats and screaming like he was coming off heroin or something! It was awful. My doctor was completely unsympathetic and continued to say that there were no side effects of this drug and that it must be something else !!

I contacted our local newspaper and they highlighted our story, then a national newspaper also followed up our story and it allowed other parents to also discover the link between their kids and these awful side effects. Because you wouldn't think for one minute that a little tablet or some granules for asthma would cause such devastation. But it does. It needs to be highlighted. Still doctors are prescribing Montelukast and not warning parents of side effects. People are still taking their own lives. It has to stop.

My son has been free of this poison for 6 years now but he is damaged. He is riddled with anxiety, he doesn't go to school, he doesn't leave the house. I believe this drug has damaged my son and he will never heal. He no longer has nightmares but I believe he was robbed of his childhood. He is literally scared of everything.. it breaks my heart.

But.. he is just 1 of thousands of stories that you will probably read. He is just a number... but he is my son.. and he is broken.. all due to Montelukast .

I pray something will be done about this drug and we need answers. How can I help my son to heal from this ?

I need answers because I believe he has suffered long term side effects because of this drug. Is there any cure ? Can I heal him in any way ?

Thank you for taking the time to read my email.

Regards

Rachel Masterman

Katie Z.

Dear Dr. Donna L. Mendrick,

I am writing to share my family's experience with the drug Singular/montelukast with the FDA workgroup. Clearly more information about this drug and is neuropsychological effects is direly needed in the medical community and general public.

My son was diagnosed with mild allergic rhinitis when he was 6 months old. At the age of 4, he started having mild coughing when he was running around (which was often, as he was a very active kid). We were referred to an allergist who started him on Singulair and Zyrtec, the doctor stating that if we started him on this combination of medications and allowed him to take it for a year, it would likely prevent him from developing full blown asthma. We were not warned of any potential side effects. It was effective for clearing up his nasal congestion and the coughing did seem to subside over a number of months.

The emotional and behavioral side effects did not begin right away but were more of an accumulative effect over time that we didn't originally recognize could be due to the medication. We chalked it up to him struggling to adjustments in our family, etc. But over time, our sweet, always silly and happy, fun-loving little boy seemed to fade away and he became more and more agitated, irritated, and frustrated with the smallest provocations. This grew into full-on rages at home, screaming at the top of his lungs, tearing his room apart, yelling that he wanted to die or that we should kill him or that he should live alone. He seemed to have hallucinations at night before bed, would yell and cry and talk about himself in horrible ways to himself as he went to sleep. These issues started affecting his behaviors not only at home but at school and day camp (he was asked to leave one camp, we removed him from a different day care setting before they could remove him from another over two different summers).

1st grade ramped up the issues tenfold as he was starting to learn more difficult tasks like reading and math, which he was good at but would get frustrated with right away if he didn't get the right answer, ripping up the work, saying he was stupid, cursing, and these situations would trigger the big rages at home at night where he'd remain upset, winding back up into rage many times over the course of a couple of hours. We had to watch his every move every minute of the day, requiring the supervision typically necessary for a two year old but in the body of a 7 year old because he would get so easily angered and aggressive that he would hurt his sisters if they didn't play a game the way he wanted, if they looked at him wrong, or if they sat too close to him. At school, the teachers suspected he had autism because he was overwhelmed with recess time and refused to go out because he couldn't figure out how to choose who and what to play with or navigate social situations without getting into trouble. They had to have him seated away from his peers because everything they did bothered him and he'd frequently lash out and hit or kick them if they got close to him or he thought they were going to touch his things. He was losing friends and constantly feeling miserable and angry. He rarely smiled anymore. Every little change in routine would spin him out so much that several times that year he ripped up the daily schedule on the board in a rage when the schedule was modified. He had to know everything that happened in advance or he was wracked with anxiety. He couldn't even tolerate compliments as it would trigger fears that he'd let that person down later and a shame spiral would begin. I could go on and on with examples of rages, meltdowns, and comments about how he wanted to die or someone should kill him. And I could go on and on about how this affected the daily life of our family. It was miserable for everyone and jeopardized his ability to attend school and our ability to attend work. My husband and I were exhausted and constantly on edge. We took him to a mental health clinic and he was diagnosed with ADHD and anxiety, although he had unusual presentations of both and would meet criteria for other diagnoses (depression, ODD, DMDD) as well based on his behaviors.

On Valentine's Day, the classroom had a party, which was an off schedule day. The teacher reported nothing that triggered him other than this, but he had removed himself from the classroom for some reason. In the office, he told one of his old teachers "I wish I was dead and everyone in my class was dead." He said it matter-of-factly. The teacher emailed us with this concern and how seriously these threats will be taken in a couple of short years. The next day, my husband looked up all of his medications in a desperate search for answers and found the black box warning that is now on Singulair. Despite being a mental health therapist, I had no idea of the black box warning on this med, as did none of my coworkers, psychiatric ARNPs included. I was blown away. By that time, he had been on it for 3 increasingly hellish and heartbreaking years. We learned what little we could about how to pull him off of the medication (not provided by any official source, mind you, as there is no information like this to be had, but from other parents).

We decided to taper him off over the course of several weeks despite his pediatrician stating that he should be able to stop it abruptly without problem. Thankfully, he didn't have the type of withdrawal symptoms that many report other children have had, just occasional waves of increased behaviors and emotional intensity that he had at the height of the worst of it. But by and large, his emotional outbursts, behaviors, suicidal and homicidal thoughts gradually all got better. He started saying "I love you" to us again and we began to feel like the sweet son that we'd missed was coming back. His teacher, who had been tracking his behaviors all year and was on page 90 of behavioral reports for the year, reported great improvement in his ability to tolerate frustration, ability to work through his emotions, and not act so impulsively. His trend lines on his graphs went at a 45 degree incline in increase of positive behaviors and the opposite for negative behaviors. It felt like a miracle.

We now are only two months removed from totally having him off the Singulair and things are bumpy at times and certain situations or food combinations will still trigger big meltdowns or rages, but they are generally fewer, farther between, and less intense. We are still working on reversing some behavioral and interactional patterns/loops that were well worn pathways in his brain developed at that time. But I don't have to watch him like a hawk and he's getting more confident in himself again, not constantly calling himself an idiot or stupid and cursing at himself or others. His reading jumped to above grade level (he was slightly behind) because he wasn't giving up and raging about all of his mistakes. He is making new friends and as I write this he is at a sleepover with one of them (to me a very good sign that socially he may catch up as well with enough time).

Throughout all of this the reaction from the medical community when we shared that we believed this could be some of the cause of his issues was quite dismissive and disheartening. I first spoke to his mental health provider, who had never heard of this black box warning but said she's look into it. Then I messaged his pediatrician, his current prescriber, who basically said, "I'm sorry he's having those issues, you can taper him off of it over a week if you want but there are no guidelines." His mental health provider consulted with the allergist who prescribed it years prior, who told her that he had only known of one case in which he had prescribed this drug and there were these effects. And in that case, the effects were sudden, they were taken off of it, and it stopped. End of story. This reaction was very minimizing of any potential permanent or long-term damage that may have been done and the hell that this medication put our entire family (and his teachers) through.

In the meantime, when I spoke to other parents, I got story after story from parents about how their child was on it for a brief time and had significant behavioral issues and they took the child off. In the first 6 weeks, 5 different parents shared that type of a story with me. This just did not seem to match what the allergist's contention was. I started paying attention to my own patients and noticed that my youngest OCD patient had been taking Singulair for years, I had patients and coworkers who were parents that had their kids on this medication and were reporting behavioral concerns that were being labeled anxiety, ODD, and ADHD. It is alarming to me the number of children that continue to be put on this medication as a first choice to manage mild cases of asthma and allergies, especially when many of them have family histories of serious mental health problems that could make them already susceptible to developing depression, anxiety, or suicidal ideations.

The questions/concerns that I have for the workgroup are:

· Should this medication be banned for certain people that have significant family histories of serious mental illness?

· Should any ages have this medication eliminated as an option? We are certainly not the first family to chalk this up to other causes for our young children whose brains are so vulnerable in their development.

· What are the recommendations of discontinuing the medication (Taper? For how long? Does this depend on how long the person took it?).

· More research needs to be done about recovery timelines and whether some of the changes to brain functioning are permanent or can expected to be recovered from at some point. Many parents who had their kids on it for years report that six months or several years after discontinuing they finally felt like most of the effects were gone. Others report that they are never quite the same.

· **Please lobby for a great increase in literature, trainings, and dissemination of information to medical professionals and pharmacists so** that they are aware and give clear warnings to patients who are prescribed this medication and so that medical professions can believe parents like us when it is happening. The black box warning came out right when COVID-19 hit the U.S. so was easily overlooked by a medical field that had bigger issues to manage. However, the time is NOW to make sure no more at risk and very young children get prescribed this medication without heavy warning. Mental health professionals such as myself also need education in order to distinguish between typical mental health disorders and effects potentially caused by this drug, so that children all over America are not taking several medications to try to alleviate the mental health symptoms caused by their allergy/asthma medication.

Thank you for taking the time to review my family's experience and my questions.

If this letter is to be submitted to anything that will be found on the Internet or any other public source, I ask that my full name not be shown to protect my son's privacy. Perhaps you can use Katie Z only. Thank you for this consideration.

Sincerely,

Katie Z.

Paul (Pei-ming) Wu

Dear Donna,

Thanks for giving me the opportunity to testify to the horror of Montelukast. I hope our painful account can help shed some light on the toxicity research of this medicine, making the medical community more aware of its potent negative effects. I hope your study can uncover the root cause of so many inexplicable symptoms, as well as propose a better treatment method for those suffering from these horrifying side effects.

History

My son, Daniel Wu (11 year old then), started to show some psychotic effects in the middle of July, 2018 in Taiwan. He had been using Singulair for 4 years. We stopped the medicine at the end of July. He then took a long international flight back to the US, and in the following days had an acute psychotic episode around August 10th. He was admitted to Sheppard Pratt Hospital for over 10 days. He was discharged as the acute suicidal thoughts had subsided. However, he still underwent strong auditory hallucinations, angry outburst, etc. afterwards.

Around September, 2018, we then seek treatment from a psychiatrist, a pediatrician, etc. We tried four different SSRI, but these drugs not only failed to bring him any relief but also aggravated his side effects.

We also went through another round of blood tests, in an attempt to rule out rare disease. The outcome points out that he may have some autoimmune issue.

Since traditional SSRI is unable to help him, we turned to a holistic doctor's help. We run through a neurotransmitter test, and at least the outcome highlights many issues in his neurotransmitters. My son finally got some relief after taking the supplements (Calm PRT) recommended by the holistic doctors. The treatment starts from around Nov, 2018.

Fast forwarding to Mar, 2019, since his psychotic symptom improves a bit (but not back to himself), we seek help from a CBT therapist. After three sessions, we found out that his delusion level elevates. We were forced to stop the therapy.

Meanwhile, we sought opinion from the leading PANDAS doctor in Washington DC, Mrs.Latimer. Initially Dr. Latimer thought Daniel must have PANDAS. But the test results surprised her, because they are not like those from a typical PANDAS. She said Daniel has an overactive immune response, whereas typical PANDAS children exhibited weakened immune responses. Still, Daniel received treatment using antibiotics, and was even given a steroid shot. To our dismay, no appreciable improvement can be seen after these medications. Eventually he was given a diagnosis of autoimmune encephalitis, partially due to the elevated level from the Cunningham panel.

It was not until Nov, 2020 that we observed that Daniel could finally go outdoors and go biking without having panic attacks. Before this point, he basically had to stay indoors, because any outdoor trip may elevate his delusion level. We thought that maybe some more therapy can be a bit of help, so we signed him up for neurofeedback therapy (Neurogrow in Northern Virginia). The initial test revealed that Daniel has an overactive brain and could benefit from therapy. Our hope was soon shattered into pieces. After only three sessions, all the panic attack symptoms came back in full force. The next time that he can go bike outdoors is April 2022 in Florida.

Desperate for answers, I found another specialist in Maryland, Dr. Phyllis Heffner. She did re-examine Daniel's history in a different perspective, and believed his relapse is infectious based. After several tests, it turned out that Daniel had issues with mold, Lyme, mycoplasma, EBV, clostridium, etc. Just as we thought we have finally found a clue, the outcome of the treatment plan is a complete disappointment. Any medications or supplements prescribed by the doctor did not bring any relief to Daniel's well being, if not make him worse.

As of May 2022, Daniel can step outside now, but it is still not without struggles (details to be listed in the following section). We are now working with a therapist, and have made some progress.

Symptom

Other than the classical side effects, some of Daniel' symptom are extreme. I list them in the following.

Schizophrenia: Ever since the onset of the side effects, he had delusions that a gang of stalkers

tried to follow and harm him. His delusion was so severe in the beginning that even when he was playing an online game, he thought people could read his thoughts via the internet connection. And any player's nickname could become an encrypted message meant to send to him.

Panic attack: For the first 3 years, he was mostly isolated at home. He would suffer from panic attacks whenever he goes outdoors. This might be related to his delusion, because he would mistake a stranger talking on a phone as shouting at him and wanting to assault him.

Insomnia: He cannot sleep without taking Olly melatonin gummy. For 2 plus years, we have to sleep

by his side so that he can be calm enough to fall asleep.

Food sensitivity: MSG and artificial color is a big No to him. In addition, we found out that he

cannot have sugars, or any fermented food. His diet became very restrictive, or his anxiety elevated through the roof. In one instance, I found that he had a reaction after using Listerine kid oral rinse which contains sorbitol.

Supplement sensitivity: We learned a hard lesson that most of the supplements did not help him

but made him feel worse. There are just a very few of them that trigger no response.

Sound sensitivity: He became very sensitive to noises, especially to cars. We have to move to a

quieter place for the healing to begin. For 3+ years, he has to use white noise generator to blank the environmental sounds in his bed. He could be awakened full of anger if there is a very noisy car/truck.

Light sensitivity: The very first symptom surfaces. So bad that he had to shut down all the window

blinds and use clothes to tuck in the door gap. So bad that he had to sleep inside a walking closet for 3 months. It went away in 2 years.

Thirst: This surfaces in the middle of the recovery. For 2 years, he constantly felt thirsty, and had to drink a lot of water regardless of day or night. This symptom disappears.

Urination: In one instance, it was thought he had an UTI, and had to sleep on the toilet for 3 consecutive nights. It turned out that he had no UTI at all.

Rage: This happened at the beginning withdrawal phase, and lasted about 3 months. He had anger outbursts several times a day. At that time, he hitted a pillow with full force, threw things at the window, and blamed that all of these are our faults. He could easily do push-up 100 times at that time (Adrenaline problem?).

Religious hallucination: Just like a scene from the exorcist movie, during the hospital stay, he uttered something like " My (imaginative) friend John said that you are a fake Christian!"

My take

In retrospect, I suspect that Montelukast suppressed my son's immune system. Over the long run, the infection becomes too much to bear, and your immune system collapses. To make things worse, stopping the medicine abruptly at that point may send your immune system into further distress, inducing autoimmune response. The limbic system in the brain seems to be the main target, as it is the part that takes charge of flight and fight response. In one instance, I still vividly remember that while waiting in the ER, Daniel saw the nurses talking through the glass window, and he thought they were mocking him. He then became like Hulk, trying to roll up his sleeves, kick and scream against the window.

Final Words

Almost four years passed, and Daniel did get better gradually. Though he is still far from becoming his old self. The truth might be that he will never be. For numerous times, he wept that he had lost so much.He had dropout from school from 1 year, and had to be homeschooled afterwards. He lost most of the contacts to his friend. The pandemic only makes things worse. He lost the privilege of enjoying the food he liked. He was like a prisoner trapped inside a jail.

Please have some mercy. Take another look at the safety of Montelukast. I hope the tragedy won't repeat again and again.

Footnote

It is weird that during my own investigation in my previous company in Maryland. Two of my managers have sons and daughters that suffer from mental illness. One told me he had never had a family history of mental illness, yet his son and daughter both had issues (bipolar). The other told me when his son was in third grade, one day he exhibited extreme anxiety and he had to haul him back home from school. His son is now in high school, and has to drink a lot of water. Guess what is common in this story? The sons and daughters both had Montelukast when they were young. I wonder how many other hidden cases are like that in this society. The mental illness has brought so much pain and shame to someone's life that one of my managers ends up being divorced.

Sincerely

Paul (Pei-ming) Wu

Anonymous

Hello! First off, I would like to say I'd like to remain as anonymous as possible. This story is about my son, who is a minor, and it's his story to tell, if and when he's ready, but I want to help get this drug off the market, if possible.

I don't remember how old my son was when he started Montelukast...maybe 6 or 7 years old. His allergist prescribed it to help with his horrible allergies. Not long after starting it, he started to become very negative. He used phrases like "I wish I was never born" or "I don't want to be alive". There was nothing significant that changed in his life, outside of taking this medication. We couldn't figure it out for the longest time. I got a call from his 3rd grade teacher one day saying that he was trying to cut himself with scissors. Thankfully they were kids scissors and not very sharp, so it only left indentations on his legs. I had seen someone on Facebook post about how Montelukast was causing depression and other awful side effects in children. We decided to take him off the medication (not knowing that he should have been tapered off). It has taken years and a lot of therapy to get him to a better place. He finally has friends and a social life, but sometimes we still struggle with the negative thoughts. He still doesn't want to be out with his friends as much as other kids his age. I have hope that someday he will be fully rid of the side effects from Montelukast. And further, I hope that the FDA will do long term studies on this medication and see how horrible this drug is for so many people.

Lisa Weaver

I am writing this letter to share my experience with Montelukast.

My son, Brayden, has mild asthma. He had an inhaler and would need to go to urgent care for a breathing treatment a few times a year. In the summer of his 3rd-grade year, he had a terrifying attack. We went to the ER, where he was treated and, after several hours, able to get his breathing under control.

That attack led me to see a pediatric pulmonologist who prescribed the montelukast. I still have a vivid memory of the dr. explaining this drug and how wonderful it worked. Like an answer to my prayer, after coming off the scariest moment in my life.

Let me describe my son before the medicine - Brayden was happy, confident, and outgoing - all that a parent could hope for. Things began to change. Upon reflection, I can say his personality changed months after the medicine - at least that I noticed. He became increasingly withdrawn from his friends and next to his family. This once outgoing, full of energy boy only wanted to lay in his bed. Sometimes he would watch TV; other times, he would just lay there. He would cry often. I could see his self-worth crumbling. He took everything as a personal attack - innocent actions perceived by him to mean he wasn't loved. Example - If another family member changed the tv channel, he would retreat to his room and cry.

I was at a loss - what could be wrong? Are his friends being mean to him? Is something going on at school? Is this normal for a boy his age? What can I do to help him?

Fast Fw to his sixth-grade year - things were so bad we knew we had to get him help. It was to the point where he would go to school but little else. He would not get out of his bed. He would cry in his bed often. I would say, "What is wrong with you?" - He would answer, "I don't know" I would offer to take him and his friends to go-carts, golfing, Lazer tag - all things my old Brayden would have loved. But, of course, he didn't want to do any of it.

His anger started to get bad - before this, he was not an angry child. He would become furious at his older sister, which did worry me as he became stronger.

Also, during this time (which started about his 6th-grade year), he would have head twitches. He would move his head from side to side and then look down and whisper various words. At the time, I had no idea all of the things could be related.

My husband and I talked one day about Brayden - as we often did - and how to help him. There are some days when he is a lot better. One weekend out of town visiting family, we forgot the medicine, and he was so happy. There were other days when we forgot the medication, and he was happy. Could that have been it? Could it be the medicine? We decided we would call the Dr. The next day and let her know we needed to discontinue the medication.

As chance would have it, the next day, we stumbled upon the FDA black box warning for this medicine. I immediately called the dr. office and left a message explaining the black box warning and that I saw these symptoms. The nurse returned my phone call and told me that if I "felt" I needed to stop, I could. We stopped the medication, and we felt we had our child back. Brayden was so depressed, withdrawn, and angry while taking the meds that it seemed as if we had our Brayden back when we stopped the meds. Looking back, the improvement was drastic, but he wasn't quite back. We couldn't see it because we were so grateful to have most of him back. He went through months of lingering depression and anger. Still not as bad as when he was on the medication.

While it seems like my son is 100% back - He is confident, happy, and outgoing - I wonder what has this done to him? Someone, please help me help him.

Long story short - This medicine destroyed my son for over a year. Words can not express how this medicine harmed a 4th-grade boy. It caused depression, loss of self-worth, anger, and Tourette-like symptoms.

My story doesn't end there ….

I am a 4th-grade teacher. Fast Fw a year after Brayden, stopped this medication. I had a student struggling with asthma and left school early one day to see a pulmonologist.

Let me describe this student from a teacher's perspective - Very happy, friendly, overly talkative, but a joy to have in class.

A couple of weeks after his dr. Appointment, and I got a call from his mom. Mom wanted to know what I was doing to her son? Was I being mean to him? What was I doing? Her son was not himself. He was depressed, crying all the time, and not himself. Nothing at home had changed, so it must have been me. For the next few days, I watched this student closely. In my classroom, at lunch, and on the playground. I saw this student was just as his parents described him. He was struggling a lot. I was determined to help this student. Then it just hit me. I bet he is taking Montekulst.

I called the parent and asked if I could talk "parent to parent". I shared my son's story and encouraged them to look up the box warning and call their doctor.

The next day, the child came school back to himself. A couple of weeks later, the parents called and thanked me. Parents stopped the medication and their happy child was back.

I want to do whatever I can to spare any more children from the effects of this medication. Please reach out to me for any questions or anything else I can do to help.

Lisa Weaver

Anonymous

Recently, the school nurse called me to pick up my 5 y/o son due to a low pulse ox and complaining of chest pain. They did not have his inhaler as he only had mild intermittent asthma only brought on by illness , until today, so his dr said he didn't need it at school. I had to bring him to his peds office so they could sign an authorization for the nurse to give him his inhaler in the future, and get a note for him to return. We saw the other doctor , I guess his wasn't in, but after examining him and questioning us both she determined he has seasonal allergies and wanted to add a med, montelukast. I had no idea what it was until she called it singulair. "Oh! I took that as a kid. Great! Let's do it. " Now she says, I must warn you, there are some pretty scary side effects listed for this drug, emotional problems, vivid dreams, but don't let that scare you as I have never seen a patient exhibit any of that. I didn't think anything of it really. All drugs have a plethora of warnings on them. I did some research anyway when I got home , as I wanted to be proactive about this and I landed here.

All of a sudden it dawned on me. My brother , who had a more severe case of asthma, as mine I would say is moderate , was on several medications. Including … Singulair. Now, while his asthma was under control, when he began this drug, he turned into something else. First, it was the tics. He was diagnosed with Tourette's syndrome. Mostly he had involuntary hand and arm motions , and leg and foot as well. And he'd do this weird thing where he would blow on his arm. Possibly more I don't remember. Well eventually the tics lessened in number , and maybe at that point he was taken off the singulair, I don't remember exactly how long he was on it but it was years, where as I was only on it briefly. Well, he continued to change. He became extremely aggressive , and physical abusive toward me. My childhood was an absolute nightmare. In my late teens I escaped this hell and moved with the other parent, but the damage was done, I was extremely depressed , and had severe anxiety and still do today. I've had years in and out of treatment , medications , therapy etc. I don't know if my brief time on the drug can cause all of that or not, but the trauma I experienced via my brother absolutely didnt help. Unfortunately, I had already given my son a tablet when I made the connection. This resulted in a high fever , and a sedated state. He was confused & couldn't follow instructions. We discontinued use of this poison. Please stop giving this to kids.

Christina Trogdon

Thank you for the opportunity to submit my personal concerns.

Hi Donna,

I am a 46 year old mother of four. I was prescribed montelukast as a treatment for asthma and allergic disease by my allergist in June of 2019. I stopped taking montelukast in November of 2021. Montelukast was quite effective at helping to control the asthmatic symptoms and allergies I was dealing with due to mold and pollen sensitivity. While taking this drug though, I suffered from anxiety, depression, and severe sleep disturbances. These psychiatric symptoms improved after I stopped taking montelukast but came back worse than ever approximately two and a half months later in February 2022. In addition to the psychiatric symptoms I experienced while on this drug and the rebound post treatment, I also have had an uptick in bacterial sinus infections starting around the time I began montelukast. These have been next to impossible to treat unless I'm antibiotics for weeks at a time. These infections are still problematic and now are chronic in nature. I am currently under the care of a hematologist who is trying to understand why my white blood count has been chronically elevated since 2019. I recently discovered that there is clinical research speaking to a correlation between montelukast treatment and bacterial infections.

What do I need to do to heal from this drug? How do I stop experiencing side effects? Why haven't doctors been made aware of the dangers montelukast poses?

Christina Trogdon

Deborah Thomas

Ms Mendrick. I want to share with you the side effects of montelukast for me personally. My daughter is a compound pharmacy tech so I found out by accident about the black box warning. We were going shopping with her friend, also a pharmacy technician, when they brought it up. I sat in stunned silence.

Ticking off on my fingers all the things that pertained to me. I was in shock. Before taking this drug I was the happiest person I knew. For some unknown reason to me, and why would I question a doctor, this was part of a cocktail to help me with urticaria issues that were out of control. A few months passed by and I went into a very dark funk. I could never put my finger on what the problem was. Just a feeling of impending doom. I cried all the time. Every. Single. Day. I shied away from all my friends. My family had to drag me out into public. I was fine staying in pajamas with no showers. Not brushing my teeth. The teeth I spent thousands on to have a nice smile. Then came the hard part. Putting together a plan on how to end my life. I knew I couldn't make it bloody. So I stockpiled my anxiety meds. I had over 1000 pills saved up. I had all the letters written. Looking back at those letters now it would have broken the family members hearts. I was blaming them. Blaming them for this nightmare of a life. It took an amazing therapist, one I still see every week. Every week for a few years. I will probably never be free from therapy. There are still bad days. Very bad days. I have a tic now. That's an added plus, right? My marriage fell apart. I'm barely on speaking terms with my son. My daughter is the one who worries daily about me. Why should she have to shoulder this burden? She has a beautiful family and this should not be a subject in her life. Or mine. Or the thousands of others suffering. I deplore what this drug has done to my life. I have few friends now. I was the life of the party. Then I wasn't. I wasn't even invited to parties. I would not have gone. If I could be a hermit I swear to you that's the path I would travel. I have to talk myself out of buying a one way plane ticket every week. I'm aware enough not to renew my passport. It would be too tempting to disappear. I beg of you to do what you must to save others from being subjected to this so called drug. There must be a better drug out there. I'm praying you will believe me when I tell you everything I am saying is the truth. I pray that God continues to give me the strength to go on.

Truthfully

Deborah Thomas

Help us!

Traci T.

Hi. My name is Traci T. and I heard the FDA was accepting testimonials from people affected by Montelukast. I'd prefer my last name not be publicly posted since these aren't my stories to make public but 5 members of my family experienced adverse effects to Montelukast. One of my children was **severely** affected, so I'll save his story for last.

I will preface this by saying all but one of the family members did experience an improvement in their lung/allergy symptoms, but it was not worth the side effects and was discontinued in every case.

- My youngest son began having night terrors and began struggling with ADHD like symptoms to the point he nearly failed that year of elementary school. Prior to montelukast he was being considered for the gifted and talented program, scored in the exceptional area on his state exams, and had a great conduct record. Suddenly he couldn't sit still, was massively accident prone, and uncharacteristically forgetful. He also went from being very laid back to having a short fuse. All stopped a few months after discontinuing the montelukast and went back to being his awesome self.

- My sister's child developed anxiety and depression to the point she stopped taking it behind her mother's back (she was an extremely obedient rule-following child so this was really unusual).
- Her mother (my sister) was also struggling with odd health issues, sleep issues, depression, anxiety, and an extremely short fuse while on montelukast, to the point she was consulting her doctor about getting on an SSRI because her oldest and husband were concerned about her behavior, but when I mentioned how montelukast affected my kids she realized it started after she got on the montelukast so she discontinued and started to feel like herself again.
- My mother has lung issues and her doctors tried her on Montelukast even though we were hesitant about it, she didn't see any improvement and for the first time in her life she experienced severe depression to where she felt hopeless about everything and would just randomly cry (that is NOT like my mom at all). She discontinued after about a month and said she would never go back on it because she never wanted to feel that way again.

But the really awful one was my older son. It destroyed his life, damaged his body, and nearly took his life. He was a wonderfully sweet boy, even the whole extended family just adored him. After montelukast he was incredibly angry all the time, our whole house began living in fear of him and he did over a thousand dollars in damage to his room. We had to pull him out of school. He said he couldn't feel anything inside except anxiety and he genuinely thought he was insane. He developed fungus infections in his ears that we had to see a specialist every two weeks for because they couldn't stop them. They were baffled. Then he got what appeared to be a case of pinkeye. He ended up having to see a specialist 50 miles away every other day and was on 22 doses of medicine a day trying to save his eyes. The eye specialist finally figured out it was some sort of EBV attacking his eyes and said he'd never seen anything like it. He'd had mono as a child but hadn't been around anyone with it prior to the onset of the pinkeye symptoms. It all stopped when he quit taking montelukast. It took longer for the mental health effects to heal. He ended up taking a bunch of pills, not sure if it was a suicide attempt or he was just desperately trying to make himself feel better, but he nearly died and was in Texas Children's ICU from it. It took years to get him back to the sweet guy he used to be and he has terrible PTSD from it all and anxiety still. He's terrified of medications now and can't tolerate antihistamines because they give him a similar feeling.

Thank you so much for looking further into this medication. It turned our lives upside down for years and we're still healing from it. I wouldn't wish it on anyone else.

Traci T.

Jill Swierczewski

My son had been on the medication Singular (Montelukast) for 2 years for his severe allergies. We were prescribed this medicine thinking it would improve his quality of life from constant sinus infections. But what we got instead was a 10 year old who became distant/withdrawn, experienced increasing anxiety, sensory disorder and aggression. After some very difficult few months I began my research on Singular where I found thousands of similar cases. When my sons doctor prescribed this medication there was no talk of psychiatric side effects. BUT when you read past the normal side effects of nausea, headache they list POSSIBLE depression, aggression and suicidal tendencies.

On September 27th, the FDA met with the Pediatric Neuropathic to hear testimony regarding the horrific side effects and with-drawl symptoms that Montelukast has had on thousands of families. They were urging for more education on this drug to be known to doctors and pharmacists. Their overall goal is to put a “black box” on prescriptions. https://www.fda.gov/media/74382/download The majority of complaints of side effects have been confronted with denial from doctors who don’t have enough information or are possibly seeking monetary commission from the pharmaceutical companies.

All I have is what we personally been through. And that is a boy who before starting on Montelukast had a constant smile on his face to someone who thought life was out to get him. When you as a parent have to physically restrain your 11 year old on the floor so he will not go after his sister you feel like a failure and doubt everything. Leading up to that he had suffered from chronic stomachaches, OCD, nightmares that lead to constant bed wetting, unable to control his body movements and the biggest challenge of all not being able to comprehend reality. If he didn’t get want he thought was what he deserved it would lead to hours of screaming and tearing a room apart. An example is when he didn’t get the right kind of chips on a road trip that had my daughter and I stranded in the convenience store for over an hour while my husband tried to deescalate him.

Many professionals and peers may think that he was just acting out for attention and needs more discipline. I thought that every waking hour until the night that it all came to a head. My beautiful 11 year old boy told me he didn’t want to live anymore. As my husband and I were on watch all night I began to do some research on a drug that he was innocently on for 2 years for sinusitis. I was physically awake for 36 hours reading everything I could about this evil drug. He never took that drug again! The next 6 months were a rollercoaster but knowing that it was the withdrawal side effects and it will be temporary was priceless.

Now 2 years later my son is the center of my life! Finishing 8th grade in top of his class while taking classes at the high school, playing sports and most importantly has a smile on his face everyday. Yes he still deals with OCD tendencies and when he gets emotional it’s hard for him to see the truth but he recognizes and acknowledges it.

To those who still, after thousands and thousands of similar stories, think that this drug had nothing to do with my sons. I ask you, WHY has he never said the words “I don’t want to live” again after stopping Montelukast? It is surreal that I can say we were the lucky ones. So many caring families and innocent lives have been taken just because Merck wants a profit and manipulates the medical profession.

My goal, as is the wonderful Montelukast Side Effects Support and Discussion Group, is to be advocates to parents and individuals who trusted those to help and instead blamed us for their negligence. I send the black box information to as many school nurses I can. They are the ones who interact with our children everyday and the majority of them know NOTHING about the side effects of a drug that is advertised so innocently. WE are our children's best advocate and we will not stop!

Thank you for acknowledging this nightmare and hopefully one day, sooner than later, NO individual or family will know how this drug destroys lives.

Kindest Regards,

Jill Swierczewski

Jocelyn Suiter

Dear Donna,

I have been given your email address to provide a testimonial about our family's experience with Singulair (montelukast). I would like to make this submission to the public advisory committee meeting of the Science Advisory Board to the National Center for Toxicological Research, and in particular, bring it to the attention of the Montelukast Working Group.

My son was on Singulair for at least two years from age 9. There was no warning of side effects from his three prescribing doctors nor was there any warning labels on the medication.

His side effects included depression, anxiety, inability to sleep, and lack of motivation, he was over-sensitive, wanted to go to the toilet all the time, and had emotional outbursts, tantrums and leg pains. He also had OCD-type behaviour, including chewing his clothes obsessively.

The entire family was affected by his behaviour which included screaming, severe breakdowns in public, overreactions and stress, His marks were affected at school; he lost the ability to make friends. No one wanted to be near him, and sometimes he didn't want to be there. He often told us we would be better off without him.

The side effects began months after beginning Singulair. As such, we never made the link between behaviour and mental illness to an asthma medication. Most side effects stopped with discontinuation except for his anxiety and depression which continued to be an issue for several years.

It is apparent that little research has been done on how montelukast affects the brain, particularly children's brains. If we don't know how it affects the brain, then how can we heal those suffering from montelukast-induced side effects?

In my son's case, we stopped the medication cold turkey. Yet would his side effects have not been long term if he had tapered off the medication? Again, there is little research in this area, despite the fact most doctors recommend tapering of medications which affect the brain, including anti-depressants. The FDA, in fact, recommends to stop montelukast immediately if there are side effects. There needs to be research focused on this to see if this is the correct advice or whether stopping immediately causes withdrawal side effects and long-term issues.

Montelukast is one of the world's most popular drugs to treat asthma and allergies. It is increasingly being prescribed for COVID-19 symptoms, and may be used in the future for Alzheimer's patients. It is vital that research identifies the process by which montelukast affects the brain and if there are any indicators as to who may be likely to suffer damage, long or short term.

It may be that this medication needs to be banned for an entire cohort of patients.

Certainly, this research will be crucial to convince the many doctors who deny the existence of montelukast side effects.

I don't want any children to suffer like my son did. But they are.

thank you for your consideration.

Jocelyn Suiter

Anonymous

To Whom It May Concern:

In May 2017, my son was 11 years old. His new pediatric allergist prescribed Montelukast/Singulair to help with his environmental allergies and asthma. When we asked the doctor questions about the safety of Montelukast/Singulair, the doctor assured us it was safe and effective.

In the summer of 2017, we started noticing some changes in our son's behavior. The changes in his personality and mental health included anxiety, extreme mood swings, depression, aggression, nervousness, anger, defiance, nightmares, and impulsivity. These were not any personality characteristics he showed prior to taking the medication. During these first few months on the medicine, I can recall 2 significant events that were out of the ordinary. First, he left a sports camp in the middle of the day and walked home. Second, he got in a physical confrontation with another kid and hacked him over the head with a large Nerf gun. Both behaviors were out of the ordinary for our son. If I had been encouraged to look for negative side effects of the medication, these would have been “red flag” moments. Unfortunately, I did not connect these events to the medication. We thought it was due to his age and pre-pubescent angst.

In November 2017, just 6 months after being on a daily dose of Montelukast/Singulair, our son ran away from our house in the late evening hours. He rode his bike in the dark beside a 2-lane highway. He did not have a light on his bike and he was not wearing a helmet. He rode over 5 miles along this busy highway and was missing for over 2 hours. It’s a miracle he was not hit and killed.

Our son told us he had an overwhelming feeling of "being out of control". He said he was having thoughts that he did not want to have. He had no idea why he was having these negative thoughts and had no idea what to do about them.

After the running away in November, we started taking our son to a counselor. Assessments showed him to be clinically depressed and anxious.

In December 2019, a month after he stopped taking Montelukast/Singulair, our son was invited to attend an outpatient day-treatment program at our local Children's Hospital. However, while he was at the day program, he expressed both suicidal and homicidal thoughts. Because of this, he was transferred and admitted to a psychiatric inpatient unit. Our 11-year-old son spent 10 very long days and nights locked up in a psych ward.

As a result of taking Montelukast/Singulair, our son also developed nightmares and trouble sleeping. He started asking to sleep with all his lights on. Then, he started sleeping in our room for fear of being alone in his bed. He was afraid to fall asleep. His nightmares were terrifying, and he had extremely dark and disturbing dreams. He would not and could not tell me about the nightmares because they were so horrific. Up until he was 13-years-old, he had occasional relapses and would ask to sleep in our room.

There were also incidents of him hitting himself on the head, trying to put a bag over his head, hitting his head against the wall, and other acts of self-harm.

In addition, we noticed an increase in disturbing and violent thoughts. He was full of rage and anger and he started showing a fascination in violent video games and guns. He talked about wanting to kill people.

It's difficult to believe that this dangerous medicine that he took for 6 months impacted his life for more than 2 years. We will never forget the trauma and the mental health issues this drug caused. Our entire family was deeply impacted and nearly destroyed by Montelukast/Singulair. We can strongly and clearly state, the benefits of this drug did not outweigh the risk. In all honesty, he never needed to be on this drug. As parents, we will lament the decision to put him on this drug and hold a grudge against the allergist who prescribed it so casually.

Our experience was horrific while our son was on Singulair/Montelukast, but it decidedly got worse AFTER he stopped taking it. We took him off the drug cold turkey and the results were disastrous. In fact, his time in the psychiatric inpatient unit was approximately 4 weeks after his last dose of the medication.

The result of this medication included over $4,000 in out-of-pocket medical expenses, withdrawing him from public school, selling our dream home, and moving to a new community for a fresh start. As a family, this experience impacted every one of us, and we are still recovering. We all experience trauma but no one experienced it to the extent of our young son. It never should have happened, we will never forget, and we will fight to make sure no one else has to experience what our son and our family experiences.

We urge the FDA to do whatever is in their power to investigate and to prevent more harm from this medication. Please do what you can to protect the children, youth, and adults that are being prescribed Montelukast/Singulair.

Sincerely

____

Mary & Madison Shatto

Good day.

I wish I never had to be a part of any of this but here I am typing an email that is ever so painful once again. The main person hurt and lives with long term unexplained medical issues is my child. I was also on Singulair for a few months which left me with long term medical issues as well.

What would my child's life be if she was never prescribed what I was told was the safest children's asthma medication on the market with little to no side effects?

There was no warning by the asthma specialist, the pediatrician, the many trips to the ER, the counselors, Department of Children and Families or anyone over all the years she was prescribed Singulair. In fact most told me that I was crazy, and still after the black box day and many news stories, articles etc people do not believe me. My child deserves a correct diagnosis and stop getting guesses or incorrect diagnoses due to the fact that no doctor is able to explain what happened to her brain during the many years of usage from age 3/4 until 11 years old.

Singulair/Montelukast affected children and adults should have their own documented category of medical issues/diagnosis until they can figure out how to fix what they broke in us.

Below I will include my last submission to the FDA prior to the black box. It was written in haste and so condensed due to space allowed for the comments to get the point across.

My child was prescribed name brand Singulair for athletic asthma at approx 3/4 & until almost 12 years old. In those years Night terrors,extreme fears of heights,plants,flying insects,dying,people,unable to go into rooms alone & inability to rationalize that these fears that just appeared overnight but we never put a connection to Singulair.At 6 bladder issues began with no warning.She was subjected to punishments,embarrassments,low self esteem,swearing she never felt the loss of bladder.Years after stopping Montelukast a new ped stated that enuresis was always labeled & she should have been taken off at that time. Her asthma doctor did not take her off for almost 5 more years. She went from 1st grade winning the most Christian like character award for her kind, sweet loving, helpful spirit to having a counselor for her aggressive, violent behavior and labeled ODD. She would go through bouts of being non-verbal. She would cry,grunt, & lash out. We started a family counselor as well to try to help her deal with emotions. I asked to have her tested for schizophrenia, ocd, mental illnesses.Aggressive behavior,night terrors,hallucinations tics,grunting, sucking her shirt and needing to be held like a baby.At 7 talk about dying,no one cared about her,then fear of everyone else dying. When I addressed my concerns to the doctors I was always met with 'there are little known side effects and no withdrawal, Singulair is the safest asthma medicine on the market' there must be something else causing this.My bubbly, outgoing child that people had once encouraged me to get into acting was now a child living in sickness, mental anguish, introverted and would hardly leave the house.

Labeled no withdrawal. After my own adverse reaction to montelukast I am very leary of doctor. He tells us 'that she seems to be outgrowing asthma,she is one of the lucky ones' but we will monitor over the next few visits before we make changes. I tell him of my issues, the behavioral/mental & physical issues she has been having which he advised me again nothing. Singulair is not labeled for any of those issues as side effects, so it is not caused from the medicine. Next visit she does her breathing test all looks literally the same as 3 months prior because I watched her blow the leaves off the trees test. He says her asthma is worsening & we need to give her additional medicines. I refuse. I remind him she was growing out of asthma 3 months ago & then we change the discussion to stopping montelukast. I always wonder if he just wanted to get her off singulair without any backlash since I told him over & over of adverse reactions he denied but thats only speculation. So now she stops taking the montelukast, this nightmare should be over, not one I am typing a condensed version of 8 yrs on FDA comment & continue to live with years later. The withdrawal sickness started with cold like symptoms, crying, restlessness, but not like a regular cold so I phone Doctor with withdrawal concerns since she has taken nearly 8 years, Dr says 'it can't be from singulair as it is not labeled for withdrawals. If you feel she is sick we advise you to take her to ER but again it would not be stopping Montelukast as people stop & start it all the time with no ill affects'. Meanwhile my child is shaking & babbling. I attempt to sit her up to talk to me. Her eyes roll back in her head with no color when they partially open. She is talking words I cannot understand to the wall. I call urgent care & they say the only way to help is take her by ambulance but all the hospital will do is keep her hydrated & monitor her so they tell me how to care for her at home in the same manner as an addict coming off drugs. I give her liquids & ibuprofen with a dropper change her in a pull up & pray for the best for my not quite 12 year old child. She has no recollection of any of this and did not know what day of the week it was several days later when she became coherent. This is withdrawal!

Some side effects suffered: behavioral, aggressive, violent, non-verbal, enuresis uncontrollable, night terrors, hip pain daily, stomach pain, always tired but afraid to sleep in own room, runny nose, respiratory infections, eczema flare ups, acne, rashes, depression, anxiety, suicidal thoughts, nausea, asthma, tics, memory loss, weight gain/loss, stunted growth, vision changes, confusion, brain fog, head pain, headaches, ear infections, wheezing, extreme sadness, self loathing, heightened sensitivity, irrational fears of plants, heights, people, fear of the pictures on our wall at home saying the girl was always watching her and didn't like her yet they were pictures of her. Im sure there are many I missed due to her inability to verbalize at such a young age.Today she just turned 15, almost 4 years post montelukast, yet dealing with many of these adverse reactions.

No parent needs to unknowingly find out what the Singulair/Montelukast version of their child is like.

Please FDA keep our children safe!!

Now my child is 17. She has not recovered from Singulair. She has memory loss that no person should suffer. Thankfully she went to a high school that she did independent learning and graduated. She studied so much to ace her tests, yet two days later would have zero recollection of any of the materials. It was a very hard road for a brilliant child to have her brain stolen due to asthma medication. What could she have been in her adult life if this medication had never been prescribed to her? I can’t even imagine her with a job outside the home. She has fear of leaving our house and selective mutism when she gets overwhelmed or afraid which she has no control over when it happens. Staying home during covid was her saving grace to finish her pace work with less anxiety than being at the school physically. School had been very difficult. The school was involved with her due to suicidal ideations. She was on an on call suicide watch check in program for a very long time.

Over the course of the last two years she has seen, gastroenterologist, endocrinologist, cardiologist, pediatrician and no one has any answers. She doesn’t want to see doctors any more. They take her blood, they want to try out different medication, run tests but they don’t have any clue and she refuses to be their Guinea pig at this age which I can’t blame her. She has had stretch marks since she was around 8 years old and none of these doctors will look at the possibility of Cushings. She is unable to take any type of adult medication even though she is of size and weight. Even taking a half of a children’s medication dosage can have an adverse reaction. She had started to have allergy symptoms. I purchased children's allergy medications with utter fear of how she would react. Claritin non-drowsy 24 hour medication made her belligerent, unable to speak and as if she regressed to the days of Singulair. It was so scary. I was able to take the angry child up to her room to bed, where she slept until the next day from a non drowsy half dosage of medicine for up to age 11. Children's Benadryl made her scary hallucinations come back and itchy skin. Even Tylenol made her pupils dilate and I thought I was going to need to take her to the hospital she was anxious and crying and sucked her shirt like she was in pain the same as she did while on Singulair and again afterwards has no recollection of where the days went or what happened.

No parent should have to watch the demise of their own child and not have a clue it happened from their asthma medication while on it or years post usage.

Had I not been prescribed this medication and it made me think I was going to die, she might have.

For my own self I can’t even take an ibuprofen and know how it will affect me.

I’m taking children's medication myself if I absolutely have no other options but to take something. I can’t eat food I have eaten my entire life. I have irrational thoughts that are brutal. This is a daily life struggle to manage my own thoughts and function as a working single mother. Two lives turned upside down in one home and we are not alone. This is far more common than reported and it needs to stop.

I know you will have many other letters to read. I can’t summarize the daily life struggles to mean enough for you to feel the emotional and physical pain that we went through and continue to deal with daily due to Singulair/Montelukast.

My hope is that there is a diagnosis that comes from further research. My hope is that something will be found to open the pathways in the brain back up correctly that Singulair damaged to give us a normal brain function. The diagnosis should be listed as having a Traumatic Brain Injury caused from Singulair/Montelukast usage, as that is what it has caused.

Thank you for taking the time to read my condensed story. If it helps save one other person from this tragedy then it serves it’s purpose.

Mary & Madison Shatto

Vanessa Sellick

Dear Members of the Science Advisory Board to the National Center for Toxicological Research,

I am the mother of two Montelukast affected children and an Administrator of the Montelukast Singulair Side Effects Support and Discussion Group on Facebook. We currently have over 16,300 members.

My families Montelukast story is long and sad. Both of my children suffer with long term side effects and withdrawal from their time on Montelukast.

My oldest son:

- suffered a suicide attempt at five years old during Montelukast use
- has a diagnosis of OCD (Montelukast induced)
- has a diagnosis of depression
- has a diagnosis of social anxiety
- failure to develop normal handwriting
- after five negative autism assessments he has a diagnosis of Neurodiverse, as he does not fit the normal presentation for autism diagnosis. I believe he suffers from a montelukast induced syndrome. Psychologists and psychiatrists are constantly confused but his presentation.
- has been hospitalised with depression
- has been had multiple suicide attempts
- has self harmed
- suffers self loathing
- has suffered so much more but I will stop at this.

Our oldest son was on Montelukast from age 2 to 5 years old, his formative years. He is now 16 years old and still suffers significantly as a result of the damage Montelukast caused. The lives of those who suffer the neuropsychiatric side effects can be forever altered. They can become reliant on mental health services to function. They can withdraw from school or work. Their relationships can be destroyed for ever.

It is important to note that we stopped Montelukast use abruptly (cold turkey) for my oldest son. The side effects were terrible whilst using Montelukast, but during withdrawal in the weeks after stopping our son became exceptionally distressed. He would run away over nothing. He developed and overactive flight response to minor stress. It was during his withdrawal that he ran from our house in distress, stopped to look back at me and purposefully threw himself in front of a car. He was five years old at the time.

Since this time I have talked to thousands of other people who have experienced similar overwhelming emotions during withdrawal from Montelukast.

In contrast, we tapered my younger son off Montelukast once we linked our older sons struggles to his Montelukast use. Our youngest son suffered a far less intense withdrawal and has suffered significantly less long term mental health struggles after coming off. Within one week of coming off Montelukast our youngest sons personality totally changed. He became more social, more willing to try new foods and participated more in activities such as swimming lessons. He seemed happier and his core and his sense of humour appeared. The dramatic change was noticed by acquaintances and his child care team.

As you know, in 2020 the US FDA issued a Black Box Warning on Montelukast. To the horror of our group the FDA advised those suffering Montelukast side effects to abruptly stop using it. There was no advice to see your doctor first to organise an alternative medication to monitor asthma and there was no advice to consult with your doctor about whether you should taper off a drug that was just acknowledged as having a direct action on the brain and crossing the blood brain barrier in substantial levels.

The questions I have is:

- If medications that have a direct action on the brain are usually tapered off, why isn't the tapering off method the updated discontinuation advice for Montelukast?
- Is anyone exploring if Montelukast is causing microglia dysfunction in those who suffer an adverse reaction to Montelukast?
- how can we heal those who suffer the long term side effects?
- what damage has Montelukast done to the brain of those who suffer an adverse reaction?
- what happens when you abruptly stop a medication such as Montelukast that blocks GPR17 (which impacts myelination of the brain) and IL6 (the major cytokine in the central nervous system, linked to normal brain function)? Is the brain flooded at this point resulting is intense and life-threatening neuropsychiatric side effects?
- why isn't the 4 to 8 week intense withdrawal period experienced by many people discontinuing Montelukast, acknowledged by the FDA and the manufacturers?

Important research papers and articles that have been released recently include:

- *In vitro cytotoxicity of montelukast in HAPI and SH-SY5Y cells* published research by Griffith University in Australia regarding Montelukast and brain toxicity https://www.sciencedirect.com/.../pii/S0009279720300326...
- ***Adverse drug reactions of leukotriene receptor antagonists in children with asthma: a systematic review*** - a research paper I co-authored with the University of Liverpool and the Alder Hey Hospital in the UK - https://bmjpaedsopen.bmj.com/content/5/1/e001206
- **Neuropsychiatric reactions with the use of montelukast** - a peer reviewed article I co-authored with two pharmacovigilance experts and a paediatrician from the Netherlands - https://www.bmj.com/content/376/bmj-2021067554

Children and adults are suffering horrific side effects and some are even dying by Montelukast induced suicide. We need urgent research into the impact Montelukast has on oligodendrocytes, precursor cells and microglia.We need treatments for those carrying mental health and brain injuries from this medication.

Please reach out if you require any additional information. I am confident that the members of the Montelukast (Singulair) Side Effects Support and Discussion Group would be very happy to participate in any discussions you desire. We have a large pool of individuals that have suffered the neuropsychiatric side effects.

Thank you for your attention and consideration of my questions.

Kind regards,

Vanessa Sellick

Susan Selna

To:Dr. Donna Kendrick, Designated Federal Officer NCTR

From: Susan Selna

Subject:Written comments for May 18/19, 2022 public advisory committee meeting of the Science Advisory Board to the National Centers for Toxicological Research

Dear Dr. Mendrick:

In 2006, my son's allergist prescribed 5mg Singular to manage his allergies and mild asthma. In the spring of 2009, the allergist increased the dosage to 10mg.

During the 2008-2009 school year, my son started to have problems falling asleep and staying asleep. The symptoms started to cascade to night terrors, vivid dreams, sleepwalking and sleep talking, anxiety, hallucinations, depression, forgetfulness and repetitive behaviors. In the spring of 2010, he said to my husband and I, "I have no reason to live."

Upon hearing this, I started on the search for a psychiatrist for him. In the middle of the search, I read the "what to expect at your first appointment" post on our medical insurance site." At the first appointment, bring all your medications." So, I checked. The 2009 FDA update included all of my son's symptoms.

April 22, 2010 was the last dose of montelukast. Two weeks later, he slept through the night for the first time in 18 months. Three weeks later, I caught him smiling. When I asked why he was smiling, my 10 year old said, "I feel happy for the first time in a very long time."

While he experienced relatively quick improvement, Singular side effects are still part of his life. His recovery continues. As a 20 year old, he has anxiety and occasional trouble sleeping. At 17 years old, he was diagnosed with Crohn's disease. Singular changed the trajectory of this child's life, and not in a good way.

In my opinion, the scope of adverse events associated with montelukast can only be called anecdotal as the frequency of adverse events is not measured. As Dr. Ann Diehl, Pharmacist Safety Evaluator, FDA Office of Surveillance and Epidemiology Division of Pharmacovigilance said at the September 29, 2019, Joint Meeting of the Pediatric Advisory Committee (PAC) & Drug Safety and Risk Management Advisory Committee (DSaRM) said,"Incidence rates cannot be calculated using FAERS data because we do not know the total number of events occurring in the population or the total number of exposures." As a result of the lack of well designed and collected data, the incidence of adverse events seems to be an educated guess at best.

In 2020, Yilmaz, et al published the results of a pediatric data collection survey which demonstrates higher incidence of adverse events than currently believed. Based on their learnings, a broader data collection process can be designed to include a larger sample size and one which include adults as adults suffer from negative events as well as children.

I can envision a data collection system utilizing contemporary infrastructure of a health care system like Kaiser-Permanent, Harvard Health or perhaps on-line pharmacies. Establishing a data collection system in an established patient base enables longer term information gathering as well as access to wide patient demographics. It can also be the precursor of a patient-physician tool to appropriately monitor a patient's response to montelukast.

Please consider an investment in improving the lives of people who do not know why they feel the way they do through accurate data collection and analysis.

Best regards,

Susan Selna

If you can't measure it, you can't improve it. – Peter Drucker

"In God we trust, all others must bring data." - Edwards Demming

Yilmaz Bayer, O., Turktas, I., Ertoy Karagol, H., Soysal, S. and Yapar, D., 2020. Neuropsychiatric adverse drug reactions induced by montelukast impair the quality of life in children with asthma. *Journal of Asthma*, 59(3), pp.580-589.

https://pubmed.ncbi.nlm.nih.gov/33287615/

Anonymous

Good evening Ms. Medrick,

I am writing to you on behalf of my daughter. She started taking Montelukast in 2016 at the age of 5. She was given this medication to help with "seasonal allergies" Over the course of the next 2 years we would see her change before our eyes. She started having trouble sleeping, bad dreams, trouble focusing, and would start screaming and having tantrums. I will never forget the day she was screaming for no real reason (which was very unlike her) and I realized she was no longer the happy joyful child that she was for the first 5 years of her life. She was sad and angry. She had good days, but the sad days far outnumbered the happy ones. What was hard was when she told me "I don't know why I'm sad. I don't like feeling like this." This was my wake up call. So many doctors would tell us that it was just her age. But it wasn't. It was this medication. She stopped in 2018 at the age of 7. It took time for her to get over the side effects. She started having better sleep and slowly started to come out of the fog and sadness. Today at 11 she is living her best life. Doing well in school. Sleeping well again and no longer feeling sad for no reason. No one and I mean no one warned us of the side effects of this drug. I am so glad we did the right thing for our daughter before it was too late.

Due to privacy concerns, please have my name redacted and posted anonymously or with a first name to the public docket.)

Sincerely

T.L. Salazar

To whom it may concern,

I am sure I will leave some things out but I will try to cover the last 12 years on this medication in a nutshell. My now 16 1/2 year old daughter has been on this drug and its generic brand since she was 5 years old, I'll refer to her as APS. She was born with fluid in her lungs and from birth was susceptible to immune and lung infections, including phoenicia, bronchitis, asthma, and allergies. It wasn't until she started kindergarten that we experienced many illnesses due to increased exposure to germs and bacteria, guessing from being around other kids that she was put on Singular by the first of many pediatricians. Years went by with success, around the 3rd grade she started experiencing recurring and diagnosed IBS, and vomiting occasionally. After that mood changes, depression, anxiety, ticks, and nightmares set in and have continued to date. As she was prescribed many doses of antibiotics and steroids, inhalers, nebulizer treatments, and allergy testing for boights of asthma that always quickly turns into bronchitis she gained weight and experienced severe emotional distress. Eventually she was diagnosed with type 2 diabetes, acid reflux, severe allergies, psychological eposodes that involved the treatment nd following of counselors and psychologists after cutting, suicidal thought and idealation. The gastrological issues got worse and worse over the last three years and she has now developed something called gastroparesis, devastating. Today and for the majority of the last year we have seen many specialists, been to ER many times, and consulted with anyone that we could to find answers to the issues she has incurred over her life span. In Dec 2021 we tapered off the asthma and allergy meds and have seen a reduction in the blood sugar and psychotic episodes, but unfortunately with this new gastro diagnosis she is due to suffer the rest of her life. We were so desperate to stop the GI problems, get the diabetes under control, asthma and allergies and the worst of it the vomiting anytime, that we even tried Homeopathy, unfortunately as with anything natural it may take time, meanwhile the psychology of the effects of singular and its sister drugs continue to cause emotional and physical bodily harm to APS. Every medical professional that I have brought the side effects of this drug, is quick to dismiss and gaslight the insinuation of its lethalness. We have seen better days in mood and personality since we stopped the drug, but unfortunately the long term use we believe caused the onset of so many of her other medical issues. As a mother seeing and being apart of this group mortified me, and in the beginiing of my joining I had to digest alot of information and exoeriences, none the less I have had to deal with my own grief and terror having allowed my chid to use this drug for so long not even knwing the hazard and potentiaal riskd to her, to anyone using it. We have spent the majority of the last 12 years looking for answers to why she has suffered all these things and it is apparent reading the stories we are not alone. I hope someday my beautiful, smart, patient, and loving daughter will be able to experience some type of normalcy, and unfortunately it wasn't until her and took a stand against some of the medications and stopped them that only some of her symptoms and illnesses have slowed down, but others have progressed. Both my daughter and I suffer painfully because we trusted and used this drug for years, only to find out the dangers definitely outweigh the effectiveness. I am so angry and sad as I watch in horror everytime she has a psychotic episode or a GI flareup that sends us to the hospital. I know my daughter has had many diagnoses but I believe that all of them started with the use of this drug having started on 5mg and as she got older up to 10mg. I am devastated for her and what the future holds for her, it is mortifying and heartbreaking to hear your daughter/kid at any age tell you they want to end it all, constantly worrying about if she'll ever get past any or most of what it has caused her life to be.

Sincerely,

TLSalazar

Tracy

Dear Ms. Mendrick,

Thank you for considering my testimony about my son’s horrific neuropsychiatric side effects after taking montelukast for seasonal allergies for just 3 weeks in 2016.

My name is Tracy and my son is Christopher. We live in New Jersey. I would like only our first names used in any public materials. Chris was twelve years old when he was prescribed montelukast by an allergist due to his tree pollen allergies that led to cases of bronchitis in springtime.

After just three weeks on this medication, my terrified twelve-year-old son came to me and told me he was experiencing intense anxiety and suicidal ideation. He had no prior problems with anxiety and depression. He had previously been diagnosed with ADHD. I read the packet insert and realized montelukast was likely causing these sudden symptoms. I was relieved that we had an answer. Both the allergist and our pediatrician told us to stop the drug immediately. We expected he would improve immediately. This did not happen. Chris experienced severe withdrawal—he suffered with OCD (intrusive thoughts) and a motor tic. His life was unbearable for months, resulting in a one week inpatient psychiatric hospitalization. With medication and the care of both psychiatrist and therapist, as well as school staff, he slowly recovered over the period of one year. He missed much school and suffered socially. Our entire family suffered as a result of the trauma this drug caused. His treatment is still ongoing six years later, but thankfully he is no longer in crisis. He is 18 and going to college in September. I consider us lucky that montelukast didn’t end his life. I am very aware of the other lives lost.

Please continue to research the effects of this drug and warn the medical community about the very real risks.

Sincerely,

Tracy

Richard and Angela

Dear Donna,

Our once active, extremely intelligent and talented vibrant daughter, was prescribed Montelukast in the summer of 2019 (when she was 11 years old), by her allergist, for exercise-induced asthma. The weekend she started it she was at a 4H camp and became sick to her stomach, for which the camp nurse gave her an antacid. She also reported having a strange out-of-body experience, but nothing that sounded fearful or traumatic – she was able to stay at camp for the entire week.

While the medication did help her with asthma when exercising, she mysteriously developed rib pain (diagnosed then as costochondritis) and had two unexplained syncope episodes, during her first year on the medication. In addition, she became easily fatigued and complained of ongoing leg pain to the point she had difficulty standing while taking a shower, and decided to take baths instead. Fast forward one year to 2020, she began to develop changes in mood, and minor OCD symptoms, but nothing that elevated concern or that needed treatment, as she was in remote school and longed to get things back to normal.

Because she was no longer playing sports, in March – April 2021, we decided to stop the Montelukast, at which point things began to spiral out of control. Her mood and behavioral issues began to quickly intensify. She became increasingly short-tempered with all members of our family, and stopped taking care of the many pets she loved and adored. She started turning off the lights in the house, turning the TV off if someone was watching it, turning down the volume on the radio, and asking that no one speaks. At the time, we thought some of this was occurring because of remote learning, and being away from her cherished friendships for long periods of time during the pandemic.

In May 2021, she was eligible for the COVID vaccine (age 13), which opened the door for things to return to normal for her. She was vaccinated with the first dose of the Pfizer vaccine, and had a significant increase in her behaviors and neurological symptoms. She developed more significant mood swings / outburst, OCD, avoidant-restrictive food intake disorder, joint pain, and sleep inversion. She began twitching, hopping, and jerking her body. By now, we had learned about the side effects of montelukast, by researching what may have been going on with her. We reviewed the only medications she had recently been taking, and we found the black box warning for montelukast that had been issued one year prior. No one had warned us of these potential side effects, including her asthma doctor, primary care doctor, and pharmacist. Her PCP dismissed our concerns immediately, and diagnosed her with all of these severe mental health issues that developed within a few days (OCD, Tourette's, Major Depression, and eating disorder). We sought support from the Facebook support group and learned that many other children had experienced these symptoms of Montelukast withdrawal, only made worse by immune system triggers which most kids not taking Montelukast recover from quickly.

When she had the 2nd dose of Pfizer vaccine, she experienced another precipitous drop in functioning. She was no longer able to function in her life. She could only attend school for 1-2 hours per day, to finish her final exams. Her mood, motor tics, vocal tics, dystonia, sleep inversion, severe avoidant and restrictive food intake behaviors, urinary incontinence, and constant screeching made it impossible for her to leave our home, or sit with anyone of her family members for any length of time. We spent the summer in complete chaos and fear, bouncing around from one provider to the next, looking for answers. We missed work, lost pay, lost friends, and our family was in crisis. She was diagnosed with Pediatric Acute Neuropsychiatric Syndrome (PANS), and we planned for treatment at a specialty clinic in

Tucson, AZ. This was one of the worst cases they had ever seen. She received intravenous immunoglobulin therapy there one time per month, for 3 months. We had to come home in December, as we could no longer afford to be relocated there.

It was not until this month (May 2022) that we were able to find a provider to continue treatment (monthly intravenous immunoglobulin therapy or IVIG), while she steadily declined. At this point in time our daughter is mute, has impaired adaptive functioning, impaired cognitive functioning, food and chemical sensitivities, cannot walk, has migraines and whole-body joint and muscle pain with spasms and continues to be locked-in with obsessive thinking, agitation, and avoidant and restrictive food behaviors. She has not walked since February. Her family and friends have not heard her voice since January. She receives nursing care, physical therapy, and speech therapy in our home multiple days per week. She requires total, around the clock, personal care. She has missed all of 8th grade. We travel 3 hours one way, one time per month for treatment at a specialist clinic. It took us from December until now to find her care in New York State, because no doctor would treat her, because they do not know how to help her. She has been trialed on dozens of medications, and experienced a whirlwind of negative side-effects. Our only hope is that IVIG will regulate and retrain her immune system, promote brain and central nervous system healing, and lessen her symptoms over time.

While taking montelukast for the two years - the following diagnosis were given by her PCP at the time: **costochondritis, idiopathic syncope.**

After one month of stopping montelukast the following diagnoses have been provided by the many doctors who have treated her (in order): **Obsessive-compulsive disorder, Major Depressive Disorder, Tourette's syndrome, Eating Disorder, Movement Disorder, Pediatric Acute Neuropsychiatric Syndrome (post-infectious autoimmune encephalopathy), Acute Disseminated Encephalomyelitis vs. Metabolic Derangement vs. leukoencephalopathy, akinetic mutism, Lyme encephalitis, systemic Bartonellosis, systemic Mycoplasma Pneumonia, Major Neurocognitive Disorder, Autoimmune Encephalitis, post and peri-COVID neurological syndrome, and multiple autoimmune syndrome**.

Our questions:

1. What does montelukast do to the healthy developing child and adolescent blood-brain barrier?

2. What does montelukast do to child and adolescent microglia?

3. When stopping montelukast, how does the child and adolescent immune and autoimmune system respond?

4. What impact does active or prior montelukast use have on viral and bacterial growth and / or proliferation in a child and adolescent?

5. What interaction does montelukast have with mRNA vaccines?

6. How can we best help our child back to good health?

7. How can we help her doctors understand what is going on with her, and how to help her?

Thanks,

Richard and Angela

Shirley Reyes

Greetings my name is Shirley Reyes of Taos New Mexico. I am writing on the behalf of my son Alejandro Reyes who is now serving a one-year sentence at my nearest Youth Detention Center. The reason for my email is that I dad with the negative side effects that have caused my son many problems due to the intake of this nasty medicine. My son has been in and out of psychiatric treatment with many medications causing very detrimental pain to my son and to the family also to the community. Montelukast is great for asthma and allergies I will not argue that but its side effect mentally causing a child to become unstable and depressed anxious suicidal an eating disorder entitled pyka. I do have medical records my son has been seen by Top Doctors psychiatrist counselors therapist occupational therapy the whole works. I did everything possible to help my son so that he could live a normal life and Montelukast caused Great harm. During his intake of medication he had many many mental problems behavioral problems social problems sensory issues the list goes on. While doctors had no clue that this was a dangerous medication while all along singular knew about it and chose to keep quiet because the numbers were low the medication was spread around unbeknownst to many people who were then taken as behavioral and mental client and put on stabilizing medications that I feel my son never needed I do have a story that I could share with you however I feel that an email is not the proper way to express what my son my family and the community went through while my son took this monster of a medication. It is my opinion that this medication be removed off of the market immediately and that it be further investigated as it is prescribed too many young children who end up with many behavioral problems that this side effect is causing I'm begging you to please take a first-look a second look a certain look and then after that make a fourth look and that choice to do something about removing this medication that is causing harm to our children our society and not to mention our future

Once again I want to thank you from the bottom of my heart for taking this time to listen to my email. I am sitting in the middle of this wildfire in New Mexico with orders to evacuate at any time but I felt compelled to write this email at this late in this state I hope that it is not too late and that you will take consideration to read my email my phone number is.

Once again thank you for your time as it is greatly appreciated

Shirley Reyes

Anonymous

TO: US FDA Montelukast Working Group

FROM:

DATE: May 16, 2022

RE: side effects from Montelukast and extreme withdrawal symptoms

My daughter was placed on Montelukast for possible exercise induced asthma and seasonal allergies in March of 2022, when she was 13 years old. The prescribing pediatrician told us that the medication may cause nightmares and to let them know if any occurred.

Montelukast did help with allergy symptoms, but did not help with the asthma.

My daughter took this medication for a few months and then suddenly started having panic attacks and nightmares at night. She had never had trouble going to bed before. She was so terrified to go bed that I slept in her room for many nights trying to keep her calm. I called the doctor and they said to stop giving it to her and all would be well.

There was little improvement after stopping and in fact a few weeks later I did not recognize my own child. She was agitated all the time, her behavior was bizarre, she drew frightening pictures of monsters and death. She started getting obsessive about things. She thought she saw people in mirrors. She started hallucinating bugs. She had debilitating headaches and would not come out of her room. Her vision was distorted. She refused to leave the house. Her eating habits changed. She would not tolerate certain textures of foods and still will not eat eggs. Over the next few months the acute symptoms got better gradually. I would say I felt hopeful of possible full recovery after 6 months. At 9 months she was better but depressed, still hallucinating and withdrawn.

Now almost 2 years later, my daughter experiences anxiety significant enough that we finally put her on medication for it. The end of last year she stopped hallucinating the bugs thankfully. During that time she was evaluated for psychosis, but not found to be psychotic. She still has a phobia of bugs and does not like to be outside. She still has occasional nightmares, intermittent insomnia and refuses to sleep without a light on. She continues to have some headaches and has some difficulty in school.

She has seen headache specialists, allergy specialists, multiple counselors and two different primary care doctors. None of the doctors were aware of the black box warning. The doctors also do not know what has caused her difficulties, but have repeatedly told me that it could not be related to Montelukast. As soon as I started reading of other people's experiences, I truly came to believe that this all started with the medication. So far all tests have come back negative with the exception of low iron stores.

My daughter remembers very little from the time when she had severe symptoms. She barely attended school that first year. She barely got out of bed. I am so grateful that she has overcome most of these difficulties, but if I had known what this drug could do, I never would have given it to her.

Dr. Kanu Priya

Thank you for this opportunity to report our personal story. We hope this would be meaningful in raising awareness about the serious and debilitating side/ withdrawal effects of Montelukast medicine.

Our request:

1. FDA should insist on manufacturers to strongly recommend that Healthcare providers need to INFORM the patients and their families (e.g., parents of children) about the risks of prescribing Montelukast.
2. -It should not be given over the counter.
3. FDA should **initiate research-based investigation** into the side effects due to the usage of Montelukast- both short- and long-term side effects, withdrawal symptoms, and chances of recovery from stopping the medication.
4. Research needed to be done about the **prolonged side-effects** of the medicine even after the patient stops using it.
5. Investigate the monetary cost and the cost on Quality of life of the patients (& their families).

Brief overview of our story:

It's with a deep anguish that I wish to report the devastating **neuro psychiatric** and other **physiologica**l long term side effects that our son suffers from till now due to the medicine Montelukast. We live in Bangkok, Thailand. The doctors prescribed Singulair (and later its different brands) to control allergies and asthma of our son since he was 10 years old (in 2008). We were **never informed** about the side effects of this drug.

Our son is now 23 years old and just started working after completing his education which was disrupted as he had to take medical leave of absence from his university 1 year (2018-19) when he was diagnosed with Major Depressive Disorder. We believe this was most likely caused by this medication as he was a brilliant young boy before that, confident, highly motivated, high achiever and a deeply caring person- concerned about environment and sustainability.

Period of taking Montelukast:

Our son was prescribed Singulair/ Montelukast since 2008, where he took it intermittently for 5 years; and since 2013 he took it continuously for 5 years till October 2018. He stopped taking the medicine in October 2018- after which he had serious withdrawal symptoms, which lasted for many months. This included suicidal thoughts and even an attempt – that we did not know till recently.

Current status- long term side effects:

He continues to suffer from many debilitating side effects of taking the medicine **even now** including low moods/ depression, anxiety, insomnia, stomach issues, to name just a few.

Impact of Montelukast:

We were assured that this medicine is safe and we never found out about its possible adverse effects until last year (2018), when our son started struggling with problems like insomnia, anxiety, low motivation and low concentration, mood changes, irritability, etc. Though we observed the behavioral changes earlier too we never understood that these were linked to taking a medicine – that was "supposed" to help him! These problems became acute- he went to see several doctors, and finally he was diagnosed with Major Depressive Disorder in September 2018. At that time, after seeing several specialists, including psychiatrists and allergists, our son researched himself and discovered several journal articles detailing the adverse neuropsychiatric side effects of Montelukast. We could relate to a lot of the research and issues faced by other Montelukast users!

There have been other significant impacts on his physiological functions that were confirmed with the complete health checkups done in 2018 and 2019- there has been a negative impact on various other body functions- liver function, heart palpitations, increased eosinophil count, etc. The current check in March 2022, also shows these impacts.

He was a brilliant student, (just to mention that he got a full scholarship to study at an engineering program at a prestigious university, ranked amongst Top 10 in the world), independent, confident, wise and caring. As parents it's been truly heartbreaking to see him struggle with severe impacts of this medicine including being compelled to take "medical leave of absence" from university. He still struggles to find his old self.

We have been consulting several doctors (allergy specialists, psychiatrists and psychotherapists) and was on anti-depressants and therapy in 2018-19; the cost is not covered in any healthcare insurance. We can afford it (there is nothing more precious than his life for us!), but the cost on his overall quality of life and basic functioning- doing things that an average 23-year-old should be enjoying, has been tremendous!

Our entire extended family has also suffered deeply.

Research and Support

We have been doing research and trying to find out more about the medicine's side effects. Through this process we also discovered the **Facebook group-** **Montelukast (Singulair) Side Effects Support and Discussion Group** (over 16,300 members now) that supports patients and their families suffering from Montelukast adverse effects – so we know, sadly enough, that our son is not the only one. In sharing our story- we would like to spread awareness about this to prevent other children and adults suffering the extreme side effects.

We urge the FDA to please look into this matter and highlight the severe debilitating impacts of Montelukast and its variants – PLEASE put the black box warning on the labels and also EDUCATE doctors who are giving this medicine. Please note that in some countries (Thailand and India) we can still buy this medicine over the counter too!

Hoping that our report will be strongly considered for action,

Best Regards,

Dr. (Mrs.) Kanu Priya

Lauren Prince

Hi Ms. Mendrick,

I'd like to share my 7-year-old son's experience with Montelukast over the last 9 months: a confusing, slow unraveling of a reasonably well-adjusted gifted student. My son was started on Singulair for seasonal Asthma and chronic stuffy nose with no mention of box warnings or dangerous side effects. He is smart and athletic and understood his responsibility to take his singulair tablet to help him breathe. My observations are in hindsight:

In the first three months, he became quick to shut down verbally when things did not go his way with friends and family or simply out of no where. Often becoming so hopeless all he could do was roll around on the ground yelling what would become a go-to, "THERE'S NOTHING TO DO IN LIIIFE!" Soon this anger/grunting bled into his after school activities. He was quite a good gymnast and did not want to quit but had to because he could not control his strong emotions that erupted from non-problems. Ultimately, these "light-switch" blow ups crept into school where transitions became a nightmare. Basic instructions and tasks became overwhelming to a child who used to be a role model to the other, more wild boys in class. In April during one of his classroom blow ups, he threatened a kid and held scissors up at him and got in-school-suspension. Two days later, he received another referral for similar anger as his teacher was quicker to respond not knowing what his next move would be. His emotional outbursts at this point are almost cartoonish anger, clenching fists, total loss of control. A diffent person suddenly takes over over the slightest inconvenience.

That weekend at my wit's end I finally thought about the timeline of his medication. I started to read out the singulair side effects to my husband and I hear my son chime in, "oh, Singulair.... I haven't taken that in like a week!" WITHDRAWAL. Who can say which other blow ups came from a missed dose here and there?

My son hasn't been able to start any new activities despite his willingness because he emotionally cannot handle new environments, unfamiliar directions. I am counting down the days left in the school year hoping we make it without getting kicked out of the Gifted program for behavioral reasons. He's less ready NOW for 3rd grade than he was at the beginning of the school year!

3-4 weeks off the medicine there are glimmers of old personality but still lots of struggles and outbursts. Our pediatrician saw him when I raised concerns but did not ask a single question about his emotional well-being. They just jumped to the next drug they should prescribe. I'm so disheartened.

The Facebook group is the only place where people care about this because our stories are so similar, but it is sad to see how many are going through the same pain and struggle. I don't want to be a crazy

Facebook lady who believes in pseudoscience. Please give this drug the attention it needs to be prescribed safely and disseminate this information to our providers, ESPECIALLY PEDIATRIC. We cannot be complacent in mental health these days and I believe Montelukast is most likely causing harm to vulnerable children. I'm so thankful there will be a professional forum for these horror stories to be shared with.

Sincerely,

Lauren Prince

Judy Pope

Hi Donna

Thank you so much for the opportunity to share our family's experience with Montelukast and the long lasting effect it has had on my son.

My son was an academically gifted, outgoing boy who loved amateur dramatics when he was given Montelukast at the age of 12. Initially, he started with disturbing nightmares & a low mood which was out of character for him & concerning enough for our doctor to fast track him to youth mental health services. Sadly, neither they nor the doctor connected his behaviour changes to Montelukast even though he'd only been taking it for a couple of months.

His symptoms became increasingly worse & included horrible, violent rages several times a day followed by feelings of worthlessness & suicidal ideation, he talked daily about killing himself. He hated the way he behaved but said he had no control over it & also little memory of what he'd done or said during his rages, even moments after.

His nightmares had also worsened & now included night terrors & hallucinations which left him so scared to go to bed that he had to sleep in my room. He developed such bad anxiety that we had to take him out of school & homeschool.

Mental health services could not understand why he wasn't responding to therapy but, of course, he could not whilst he was still taking this drug. It took nearly 2 years for me to discover that Montelukast could be responsible for his problems. He stopped cold turkey & although some issues (most noticeably the aggression) improved quite quickly he was left with severe anxiety, depression & sensory issues which he hadn't suffered prior to taking Montelukast. These issues still remain over 5 years after stopping.

He is now 19 & still has a fear of sleep & the dark when he hadn't needed even a night light previously.

It has had a devastating effect on our family, his father & I separated & his younger sister has resentment issues due to how he treated her. Worst though is my son, from a younger life full of promise, I'm not sure he will ever be able to function as an independent adult. More than anything, I would be forever grateful for research into what Montelukast does to the brain & if it can be healed.

Thank you for your time.

Judy Pope

Kammy Pany

Dear Donna:

Thank you so much for this opportunity to be able to share with the FDA advisory board our families experience with montelukast. Our son was always the sweetest little boy, kind, caring for others and had the hugest little dimple that would melt anyones heart. In February 2016, our son was 5 years old and diagnosed with asthma and severe outdoor allergies. He also was an asthmatic baby, and required the nebulizer every 4 hours many months of the year. He had recently been extremely ill that past Christmas with very high fever, pneumonia and a close to ruptured ear drum. Being outdoors for a prolonged period was difficult for him, he would get very congested, have a horrible cough all night, his eyes would swell and I would wake up every hour to check on him. When the allergist suggested montelukast, we were desperate and would do anything to help him at this point. It seemed like a great solution. After a few weeks it was amazing, he was able to run and play outside and we weren't constantly worried about the pollen and his allergies. As time went on, we picked up the prescription, there were no warnings from the pharmacist or his doctor. So if we didn't know what to ask, there were no questions.

As time went on subtle changes occurred in my son (about 18 months after starting). He started having facial tics, scrunching his nose and shrugging his shoulders. His behavior seemed to also go backwards. I remember asking myself, aren't things supposed to get easier at 6 years old than at 2? He started to tantrum for hours over absolutely nothing. Examples were bedtime, showering, going to school, getting in the car. Basically anything and everything could be a trigger. It was impossible to console him. We got to a point where one of us adults had to be one on one with him 24/7 and the other had to be with his two younger sisters. Being together in a room got to be too damaging for his sisters, he would yell at them that they were ruining the game he was playing, or that he just didn't want them there. We stopped eating meals together as a family as he would scream about what color cup I gave him or that his sisters weren't eating properly. We had to split who would drive him to school, one would take his sisters the other would take him. He was unable to be in the car with them or he would unbuckle his seat and roam around the car angry if they were reading a book or even speaking. As you can imagine it got very stressful to manage - I ended up having to quit my job as I never knew when I had to pick him up at the drop of a hat at school. My husband luckily had a very accommodating boss that understood what we were going through and he ended up having to leave work many times due to this ongoing crisis. My son who was once a star student started having behavior issues at school. The teachers would e-mail me daily about his behavior. He would lose it in the middle of class, one day he even tried to leave the building. I had no idea what happened to my son. He had urinary frequency, almost every half hour and barely ate. Sometimes he'd randomly throw up and no one in the house was sick. I cried daily and researched and researched to try to find answers. I remember looking him in the eyes and seeing just an empty stare - like the kid I once knew had disappeared. We even took him for a neuropsych exam and they gave him a slew of dx, one being ADHD - but this happening so suddenly was haunting me. When medications were suggested for ADHD I then started researching more as I was concerned with him taking meds on top of his asthma meds when I found a thread in an asthma group about the side effects of montelukast. The light bulb went off- and my husband and I agreed, yes this is it! This is our answer!!!!

His doctors agreed these were side effects he was experiencing and to stop immediately. Little did I know the rollercoaster ride we were about to endure. A few days after stopping, his little dimple returned! He also was able to compromise which was unheard of days before. But then he started getting horrible vivid nightmares, he had high fevers, crazy thirst and flash rage that seemed even worse than when he was on the medication. For example he tried to get out of the car at a red light because he was mad at what restaurant we were going to. The school was confused as they asked why he was worse after stopping the medicine? The facebook support group helped guide us through those tough weeks after stopping. We got to a point I wasn't sure if I needed to bring him to the ER has his whole body was flailing. We ended up having to strap him into the car seat just so he wouldn't hurt himself. It was one of the scariest points of my life. Every dr we saw said the medicine was out of his body, this wasn't the montelukast. But why were thousands in the support group saying the same thing happened to them?

Things were still tough those first few months after stopping, but definitely nothing like while he was on the drug. The severity and frequency of the episodes started dwindling as time went on. He still was not entirely himself a year after stopping. Each month he continued to improve. We threw everything at it for him to recover, neurofeedback therapy, CBT therapy, you name it we did it. Healing him became my full time job along with being an administrator for the support group. It wasn't until about 3 years after stopping that he seemed to be back to himself. Time definitely healed. He also became sensitive to artificial dyes, sweeteners, msg, preservatives and gluten. If he had one of those things a singulair type relapse would occur. I will say the long term use of this drug I believe caused him to have MCAS- many other members report this as well. When you react to many different foods and chemicals. He didn't have this before. And what is so crazy is that montelukast is a main treatment for MCAS, more research needs to be done on this. Although controversial he also was diagnosed with PANDAS as well. While he was on the drug he had strep around 6 or 7 times, we removed his tonsils but the strep titers remained extremely elevated. His behavior is back to baseline on antibiotics. If we stop the antibiotics his behavior comes back. This study is interesting how montelukast increased the bacteria levels in mice. https://pubmed.ncbi.nlm.nih.gov/17042138/ I'm not sure if the repeated episodes of strep are linked to the montelukast or not- but I wish I knew then to stop to see if it helped at all. Difficult to know now. Other members report PANS/PANDAS in some children after stopping this medication.

Anyways, this is our condensed story. This medication took years out of my sons and his sisters childhood. I am so glad the FDA recently upgraded the labeling to a black box but we are finding that some providers and pharmacists still do not know of this. They also are still downplaying the neuropsychiatric side effects. We also need more guidance on how to safely discontinue. Members join the group in crisis and we do not have tools to help them. The guidance says to stop immediately but would a slow taper be less shock on the system? Would it have helped my son? What is the permanent damage to a childs brain from long term use of this drug? Did the toxicity cause my sons MCAS and PANDAS? There are so many unanswered questions. We urge you to please find ways to communicate to providers the dangers of this medication, and to continue research on the mechanisms of these side effects.

Here is the two news articles my son and I were in last year:

https://www.azfamily.com/2021/02/06/singulairs-dangerous-side-effects-allergy-medicine-can-cause-depression-suicides/

https://www.abc15.com/news/state/valley-mother-shares-warning-of-singulair-side-effects-on-son

Thank you for your time,

Kammy Pany

Rachel Palilonis

My son took Montelukast since he was around 3 years old for cough variant asthma. He is now 8. We took him off the medicine this year.

He had many tantrums as a young child, but I figured it was what 3 year olds do. But he was also overly aggressive at times and had poor coping skills. He has had night terrors where he would run around the house hallucinating and screaming. His anxiety developed around 4 where he had fears of many different things. Currently he is afraid of his room and won't go in there unless someone is present. This year he started throwing raging fits- where he would be violent, throw things, kick and punch his sister and parents. He also expressed suicide ideations and negative self talk. When we took him off the medicine that is when we saw the most aggression and depression during withdrawal- which his doctors said shouldn't happen (but it got worse before it got better). He's been off the medicine for 4 months. He has not had one night terror. He's been less anxious but still has fears. He still has aggressive tendencies and poor coping skills. He hasn't had as many negative talks.

I'm sad that I wasn't aware what this medicine could do to my son. I wonder if he would have been a different child if I did not have him on this medicine for so long. I pray he learns some coping skills with his therapist.

I hope to continue to spread the word how harmful this medicine is.

Thank you for letting me express my concerns.

Rachel Palilonis

Julie Noyola

Dear Donna,

Here is our story of my daughter being on this dreadful medicine! My daughter's doctor prescribed Montelukast because of allergies and slight asthma when she was 3.5 years old. My daughter before the medication was sweet and social! We didn't go through the " terrible 2" phase. When she was on Montelukast, she became a terrible 2 almost overnight. She had these huge meltdowns over nothing, she started to have nightmares that felt so real to her. At school she started hitting her classmates, throwing her shoes and tipping over chairs, hiding under tables, when standing in line, hit a student if they looked at her. She developed OCD, anxiety, depression, and auditory processing problems. School had most of the behavior problems because she took Montelukast at night so when she got home the medication was wearing off. When she was at the end of kindergarten, her IEP team wanted us to see if her doctor could do blood work or something to see what was happening to her. At 7.5 years old her doctor did bloodwork and sent us to an Allergist because her asthma was getting worst. Her doctor also sent the school concerns to the Allergist. He right away told us to stop Montelukast and put her on an inhaler. 2 days being off Montelukast, my daughter told me"mommy I am happy". I cried but I didn't realize yet how Montelukast robbed me of my sweet child yet. I found the group of Facebook and other parents had stories of their child having the same behaviors as mine. My daughter has been off of it for almost 3 years and she struggles almost daily with anxiety, OCD, depression, and at times nightmares. If it had a black label when she was prescribed Montelukast, I never would have given it to her.

Thank you for your time reading my daughter's story.

Sincerely,

Julie Noyola

Anonymous

Dear Donna,

I am a parent of adult child who was placed on Singular (5mg) from the age of 5 to about 11 years old. She had asthma and her pediatrician had prescribed this medication.

At the time she was taking it she would have vivid dreams of spiders, which terrified her. She suffered from digestive issues as well as anxiety. She also suffered from fatigue as well as lack of concentration.

She missed quite a bit of school her sophmore year due to digestive issues. She was tested for celiac which came back negative.

She stopped taking it because she no longer needed it as her asthma was under control and only seasonal.

When she was in high school she started having more anxiety, feelings of hopelessness and loneliness even in a room full of her friends. It progressively worstened as she got older.

Fast forward to college. She is under a psychiatrists care for depression, anxiety and fatigue.

I firmly believe this all stems from the use of singular. The black box warning was not in place when she was taking it.

Had I known then what I know now about Montelukast I would have never aloud her to take this medication.

I really hope and pray that more will be done and that Doctors will take us seriously about questioning this medication and that the FDA will not allow this medication for children.

Thank you for taking the time to hear me out.

Please do not use my name and respect my right to privacy.

Sincerely

Kimberly Morales

Our daughter's STORY…

ALEXIA MORALES was a sweet, Confident, caring, calm, relaxed, witty, extremely intelligent, endlessly talented, over-achieving, popular, well-adjusted, well-spoken, well-behaved, beautiful 11 yr old little girl...exceptionally smart since she was 9 months old! Placed in Advanced classes since Kindergarten, highly excelled in absolutely everything she attempted. Alexia won dance competitions, performed solo Piano recitals, achieved Straight A's, awarded Student of the Month many times, chosen as Star Student in Spanish, Won prestigious Writing Award, etc.

THEN ONE DAY, IT ALL CHANGED. SHE TOOK A PRESCRIBED TINY CHEWABLE PILL NAMED "MONTELUKAST" (Generic Singular). AND IT DESTROYED HER COMPLETELY. IT WAS A NEAR DEATH TRAGEDY & HER LIFE BECAME UNMANAGEABLE OVER NIGHT!!!

Stage 1 With her sudden onset of illness which came out of nowhere on 10/13/20.....Alexia experienced horrific side effects! (Dizziness, Nausea, Clammy, Confusion, Disorientation, lightheaded, Slurred Speech, Headaches, Tingling in hands/feet, Stomach Pain, Heart Palpitations, Shortness of Breath, Joint Pain/Muscles aches, Vision disturbances, Fatigue, Severe weakness of limbs, swollen face, weight gain, irritability, acting silly (not like herself) & a general feeling of Malaise all day long). She could barely get out of bed for 3 weeks straight! *IT WAS AS IF HER BODY & BRAIN HAD BEEN POISONED.

By 11/3/20, Alexia ended up in the Emergency Room with her very first ever episode of what appeared to be Temporary Paralysis/Seizure of some kind. She continued to have these episodes every day until her Pulmonologist advised to ***STOP TAKING HER PRESCRIBED MEDICATION, NAMED MONTELUKAST (GENERIC SINGULAIR)!

[WE DISCOVERED THAT THERE WAS A "BLACK BOX WARNING LABEL ISSUED BY THE FDA" THAT IT HAS THE POTENTIAL TO CAUSE NEUROPSYCHIATRIC SYMPTOMS (NEUROLOGICAL & PSYCHIATRIC FEATURES).]***

After stopping the Montelukast on 11/18, the episodes of what appeared to be seizures/paralysis & all the above mentioned symptoms immediately began to subside. After 3 weeks, they stopped completely!!! Life was returning to normal and we saw our baby girl getting better and returning to her normal self!

STAGE 2 And then the UGLY aftermath began!!! Alexia started to experience "WITHDRAWAL" symptoms which were BRAND NEW & traumatic to her life.

They were as follows: Severe Brain Fog, abnormal body movements/Seizures, Sensory issues, Cognitive disturbances, onset of a Learning Disability, Unable to Focus/Concentrate, Personality changes, Stuttering, difficulty Reading/Writing, difficulty Comprehending what people were saying, Loss of Balance/Coordination (Falls), Loss of Muscle Control, weak arms/legs, mood swings, agitation, hopelessness, sleep issues, eating disorder, weight loss, etc etc etc

(Note: All of these symptoms have gotten much better today. Most have gone away with time (after months & months of rest, intense hydration, eating clean & healthy, Professional Grade Doctor prescribed Supplements & lots of LOVE, PATIENCE & COMPASSION)

STAGE 3 Long term Damage? - Now, after a year of being off of the Montelukast, other new symptoms have submerged. These may be the lasting long-term damage from the severe reaction (Brain Inflammation) from stopping the medication. The latest symptoms are : Chronic Fatigue, Memory loss, muscle weakness, small panic attacks, anxiety, depression, zoning out, fidgeting, problems with attention/focus, OCD, TICS, tense Neck, changes in mood/personality, etc.

AND THE MOST DEBILITATING SYMPTOM OF ALL!!!...THE ONE THAT HAS RESURFACED AND IS STILL OCCURING TODAY IS...

HER BODY IS BECOMING PARALYZED! SHE LOSES THE ABILITY TO USE HER LEGS, FEET, ARMS, HANDS, HEAD & SPEECH FOR 15 TO 20 MINUTES WITH MOST EPISODES.

We have been to dozens of Doctors. No one has definitively diagnosed her condition of what appears to be Seizures/Temporary Paralysis. And, no one knows exactly what happened to her Brain, Immune System and Nervous System by the damage caused by taking......then stopping Montelukast.

Thank you for listening!

-Kimberly Morales-

Anonymous

I began taking Singulair around the age of 7. I was easily agitated, throwing tantrums over seemingly small issues. I didn’t understand why but I wanted to hurt myself. I was hurting inside, feeling worthless, like the world would be a better place without me. During the tantrums I would scream and cry uncontrollably for hours until I exhausted myself and couldn’t any longer. It was almost as though I was watching myself through an out-of-body experience and had no control. My family always felt like they were walking on eggshells trying not to “set me off”. At the age of twelve there was a suicide attempt. The behavioral issues had never been attributed to the drug. Every major event from that point on has deeply affected me. Many therapists and psychiatrists diagnosed me with anxiety, depression, OCD, and ADHD. I was on different medications to regulate my mood swings for a few years. Nothing really helped.

My insurance provider finally refused to cover Singulair brand. I spent months fighting it with doctors notes and phone calls all while suffering heightened withdrawal symptoms. It was shocking to learn after all these years we were not alone. Although Singulair has been discontinued for a few years, I am still left trying to cope with side effects. My mom and I are both saddened and angry for not realizing sooner the influence this drug has made. We are still left with unanswered questions. What kind of alterations has this drug permanently left? Why were none of my doctors able to make the correlation?

Kimberly Miller

Thank you for the opportunity to share

Due to asthma I was prescribed Singular in my early 40’s. Immediately, it seemed, I could breath so much easier. At first this felt like such a wonderful medication. Other than a rescue inhaler I was not on any other medications. I was very fit and ran races, including ultra marathon distances.

Several weeks later I started experiencing extreme sadness, lack of motivation, and was crying all the time for no reason. My husband kept asking me what was wrong, I would cry and tell him I do not know. I would look at just a couple dishes in the sink and feel so overwhelmed at having to put them in the dishwasher. I also would fixate on things (OCD?). I had never, ever dealt with any mental health issues prior. My husband and I were talking as he helped me try to figure out what I was dealing with. He asked if I thought it may have started at the same time as the new medication I was on. It felt like an aha moment. I looked on the warnings (this was a decade ago) and it mentioned mood change but nothing in detail. I decided to quit the medication 6 weeks to 8 weeks after I had started it. Thankfully after a few days joy came back to. Motivation came back to me. I felt as if I was healing. Several weeks later I felt back to normal for the most part. Occasionally I get triggered and have to remind myself not to fixate. Occasionally I get triggered and have a moment of losing control of my emotions.

My grandchildren were also both on this medication. There stories are not mine to tell but they had issues with it as well.

Thank you again for the opportunity to share. I sincerely hope that going forward this medication is only used as a last choice when nothing else is working and that people are carefully monitored for side effects.

Kimberly Miller

Melanie Meyers

Dear Donna,

Thank you for taking the time to listen and share my family's experience with Montelukast.

My son, Aidan, had been prescribed Singulair and later Montelukast since he was about age three. He had allergy induced asthma and he was allergic to everything (grasses, molds, dust mites, pollen, animals). Aidan was taking nebulizers year round, zyrtec during allergy season and oral steroids frequently. Despite these medications, his constant cough continued. The doctor prescribed singulair and it did lessen his allergy/asthma symptoms. So, we kept him on it for many years without any noticeable side effects. Looking back, Aidan did begin having a tic at that same time, but I never connected it to his allergy medication.

Then, Aidan's senior year of high school, during Covid, he began to express that he was feeling very depressed. Aidan also stated during this time that voices were telling him to drive his car off the road and his mood was volatile. He started doing outpatient telehealth. During this same time, he had run out of his prescription of Montelukast and we were working on getting a doctor's appointment to get a refill. I was never warned of withdrawal from stopping Montelukast, but I now believe that Aidan was suffering withdrawal at this time.

Aidan went to the Asthma and Allergy doctor and his dose was doubled to 10 mg in February 2021, which is the standard dose for his age. Within two weeks, Aidan was having neuropsychiatric side effects, including: vivid nightmares (so scary that he was afraid to sleep), intrusive thoughts, suicidal ideation with self harm, depression, episodes of agitation and aggression, and he ended up hospitalized two times in March 2021.

After the second hospitalization, I found information on Montelukast and the black box warning. I immediately stopped the medication, but our family's nightmare continued. Aidan has had one suicide attempt and eight inpatient psychiatric stays in the past year with many new diagnoses and medications. The neuropsychiatric side effects return with some medications and artificial sweeteners.

The most frustrating part is the lack of validation from the medical community. In the ER and in the inpatient psychiatric hospital, no doctors were aware of the potential connection between Montelukast and Aidan's neuropsychiatric side effects. They all said, "it would be out of his system by now" and were unaware of the black box warning.

Please research long term effects of this medication and effective treatment options for persons who have been adversely affected. Please educate medical professionals about the dangers of Montelukast/ Singulair.

Melanie Meyers