

## 6 BATCH NO. A81CA149A

*January 16, 2010*

"I felt a sharp pain in my hip; then it was over. What they were injecting and why, I did not know, yet for twenty of us those injections were to change our whole lives."

—Robert C. O'Brien  
*Mrs Frisby and the Rats of Nimh*

It was anticipated that the swine flu virus of 2009 would tip pandemic scales and claim the lives of hundreds of thousands of people worldwide as it had done throughout the previous century. Fearing a repeat of the Spanish Flu of 1918 where H1N1 thrived in the trenches and killed more soldiers than on the battlefields (with estimates ranging from eight to fifty-million deaths total), the World Health Organization (WHO) officially declared the existing H1N1 infection a global pandemic. Within weeks, European governments responded by contracting with major multinational pharmaceutical companies, including GlaxoSmithKline (GSK), to formulate an effective vaccine. A prototype was developed,

resulting in the vaccine, Pandemrix. By December 2009, we received a letter from our local doctor requesting that Mathilda be brought in for the free vaccination program on January 16. Every other family in the UK with a child under five years of age also received such a request. The WHO, together with governments across the globe, supported scientific concerns that this H1N1 virus would target the young and medically vulnerable, potentially resulting in serious complications and high rates of admissions to critical care units.

Our letter also stated that Pandemrix was a “safe and effective licensed vaccine approved by the European Commission” and would result in “non-serious complications, which were in line with expectations.” What the letter did not mention, however, was that the vaccine Pandemrix had not been tested or authorized on children. Parents like us were unaware of this crucial detail, a fact that I have since tried very hard to come to terms with. Moreover, the vaccine was “adjuvanted” and contained not only the H1N1 antigen but also a chemical compound called Squalene. Adjuvants are advantageous since they intensify the effectiveness of a vaccine by turbo-boosting the body’s immune system, resulting in a “hyper-activation.” “They are used to elicit an early, high, and long-lasting immune response,,” according to

the Vaccine Risk Awareness Network. From a pharmacological point of view, the fact that Pandemrix elicited a very strong immune response meant efficacy was high.

The antigen itself was in short supply in 2009 and 2010, resulting in the production of a vaccine in which a minimal amount of antigen was used to attain the required response—a process known as “antigen sparing.” Using an adjuvanted vaccine further increased supply by as much as fourfold, and consequently, greater numbers of people could receive the vaccine before H1N1’s sweep through the country.

In a climate of socialized healthcare where the government foots the bill with tax-payers’ money, a more affordable and timely vaccine for a large proportion of the population was then a very attractive option. Later, debate about the use of Squalene and the strength of the vaccine given to young children that year would preoccupy scientists and doctors. They had rarely seen young children present in their offices with symptoms of narcolepsy—a profoundly disabling neurological condition. The original vaccine called for two doses, one shot followed by another several weeks later. Soon it was obvious that the immune response was so robust that by the time the vaccine was given out to the UK, only one jab was required.

What was the link between the H1N1 vaccine and the surge in numbers of these children? Some researchers

believe it was the H1N1 virus itself that was involved, devastating the immune system, which fought the virus as it was supposed to, but also killed the hypocretin cells in the hypothalamus—the loss of which resulted in narcolepsy. Others think the vaccine was just too strong while some maintain the adjuvant theory. To date, the precise mechanism that triggered the destruction of hypocretin cells is still being debated. Yet, no doubt is cast over the reality: the 2010 H1N1 vaccine brought about hundreds of cases of narcolepsy in both children and adults.

At the same time, as more cases emerged in Europe, it became evident that some children were developing symptoms of the devastating sleep disorder although they had received a different vaccine—one without an adjuvant. Different children had merely been exposed to the flu from family members, and others had no knowledge or recollection of either exposure or the vaccine.

In our opinion, Mathilda had already spent enough time in the company of doctors at Bristol Children's Hospital. Although she had outgrown her laryngomalacia, reflux and failure to thrive, she was still slight for her age and had only turned the corner in the past year. None of us had ever had a flu shot before. Because of Mathilda's potential vulnerability and the anticipated impact of the H1N1 virus on children her age, Oliver

and I thought this might be the one time we should consider a flu vaccine for one of our kids. Having discussed this at home, together, we made the decision to go ahead. In reality, it was I who drove her there.

It happened on Saturday, January 16, 2010. I ploughed through a rainstorm with the window wipers going full blast, driving through the water-logged streets to our newly remodeled family health center. All three children were huddled in the back, and we talked of what they might do indoors that day once we returned home. We found the waiting room teeming with rambunctious toddlers and parents waiting their turn. They had come solely for the same reason we had—the vaccine. I was struck by the scale of it all. The children sat on the floor beside me as I handed them each a book to try to read through the chaos.

“Crisp, Mathilda?” One of the doctors, a spritely young woman, eventually called us in from the large doors that separated the seating area from the rest of the health center.

“Yes! That’s us, kids. Let’s go.” I sprang up, stuffed our things into my bag and grabbed Mathilda’s hand. Anxious not to lose the doctor as she bounced down the long corridor at a pace closer to a light jog than a walk, I

urged Elliot and Liberty to hurry. The health center had turned the large front office into a makeshift clinic. All the over-sized desks, top heavy with phones and files, were pressed to the walls while temporary vaccinating stations were erected in their place. With her typical jolliness, Dr. Larsen motioned for us to sit in one of the large black office chairs in the corner. As Mathilda climbed up on my lap, I fixed my feet firmly on the floor to avoid the two of us twirling round when the needle went in.

“You have a busy day ahead,” I commented, now facing a large circle of other parents trying to keep siblings from wheeling the chairs around the room. The already vaccinated children were crying. Others were trying to physically avoid the needle poised before them. Usually we saw a doctor within the privacy of a single medical room. This morning’s clinic resembled some bizarre mass-herding project. A burly nurse in every-day clothes approached us, and without introducing herself, picked up the vaccine on the mobile tray unit and double-checked the batch number in unison with the doctor. Together they intoned, “H1N1, A81CA149A, Right arm, expiry August, 10.”

“This is just a little scratch and is very quick,” Dr. Larsen said encouragingly over the rising levels of distress.

“You’ll be fine Mathilda. Look at me sweetheart,” I said, pulling her in tight and turning away from the tray of needles and band aids.

“Can you hold her arm still? You’re such a brave little girl.” Dr. Larsen drew up the syringe of Pandemrix and prepared the cotton ball and records. I motioned for Libby to pull the lid off the treat box we had brought as a distraction should Mathilda cry as the needle went in. Inside was a packet of Cadbury’s chocolate buttons. Saturdays were candy days in our house, and most weeks, with 50 pence in their pockets, the children walked down to the corner shop and picked out a treat. On this occasion, I had brought the sweets with us.

Elliot was looking nervous. “What’s the injection for? Do I have to come back for one?” He was staring at the ring of children across the office.

“This is just for little kids, and we give it to them to protect them from getting really sick.” Dr. Larsen was speaking whilst finishing up with Mathilda’s arm that I was still gripping tightly.

“Tonight you should give her Calpol [Tylenol] in case she has a fever. Otherwise, you are all done. What a good girl. You were so brave,” she said, wiping the blood and applying pressure to the small mark below her shoulder. I rubbed the circular band-aid in place, took Mathilda off my lap and whispered to Elliot that it was

rude to stare at the other children who were about to be subjected to the same shot in either one of their arms.

It took three seconds for Mathilda to receive the H1N1 vaccine that was supposed to prevent serious illness. Just a moment for 24% of British parents to unknowingly subject their children to a vaccine that had only been tested on a small portion of adults; even these clinical trials had not been completed to an adequate level of safety. Across Europe, 37% of children between the ages of 2 and 15 were similarly vaccinated with Pandemrix by March of 2010.

Sweden and Finland were the first countries to alert the rest of the world of the unprecedented rise in childhood narcolepsy, a serious and incurable autoimmune illness rarely seen below the age of fifteen. Only after did this same realization hit Britain. As around 1,500 children across Europe became neurologically sick, what emerged over the following months was the possibility that the H1N1 vaccine had backfired. For the British government and GSK, it was another pharmacological headache. For hundreds of children and families, it became a personal tragedy.



The weather took a darker turn as the four of us left the health center and headed home. I called Oliver to hold off on the lunch he was preparing since the appointment went much quicker than I expected. I looked up at Mathilda in the rear view mirror and praised her for not crying when she had the injection. Passing the box of candy back to where all three were laughing, the four of us drove back towards home, and an uneventful weekend.

And that was it. How easy it was to unknowingly flip all our lives over in one short ride. Since then I have gone back to what should have been an unremarkable hour, grappling with guilt and painful regret through endless nights of sleep deprivation and days of watching Mathilda sleep her childhood away. All the symptoms of narcolepsy and suffering crystallized in the seconds it took for her to have the H1N1 vaccine. Many times I have imagined myself ripping the kitchen clock off the wall and turning back the hands of time, taking her to the candy store, the park, anywhere but to the clinic that would ruin her life. I wish she had cried, protested, screamed and refused the needle. I wished she had begged me to take her home. But she was three years old. She trusted me, and I in turn foolishly trusted in a system that was supposed to keep her safe.

We don't talk about it often. The last time Mathilda asked me why she can't sleep like other kids was several years ago. We were in the bathroom drawing up her nighttime medication and preparing a small tray of food that would stop her from vomiting in the morning. I explained how she was one of hundreds of children to develop narcolepsy as a result of the swine flu vaccine.

"Did it hurt me when the needle went in?" she asked.

"Not at the time. You didn't even flinch."

"So if it didn't hurt, why did I get narcolepsy?"

"It doesn't work like that darling. Just because the vaccine didn't hurt you on the outside, doesn't mean it didn't damage you on the inside."

"Did you want me to have the vaccine?" She said starting to brush her teeth.

"Yes and no. I didn't want you to get sick with the flu. But if I'd have known you would get narcolepsy, I wouldn't have taken you that day. It's hard being a Mom sometimes, because we always want the best for our children but we can't always control what happens. And that means difficult things come along, things that we want to take away but we can't."

"I like it when you say you wish you could take away my narcolepsy, but I don't want *you* to have it."

"That's kind. It's true sweetheart, if I could take it away, I would." I set the timer on the safe that would protect her from taking the second dose before 3 a.m.

Mathilda rinsed out her mouth, and before wiping her face dry, looked at me and said:

“I’m tired.”

‘It’s okay. Let’s get to bed. Dad is on first dose. Do you want to go say goodnight to him?’

“I’m too sleepy. Can he come in to me?”

“Of course.”

We walked just a few feet to Mathilda’s bed. I lifted the two cats off the pillows and turned them out for the night through the farmhouse door in her room. As I covered her with a Disney-style blanket and removed books, pens and various scribbled notes strewn across the bed, she rolled towards the wall. Drowsy, and a few moments away from another night of fractured sleep and medication, Mathilda lifted her hand and reached for me. I took her slender fingers and placed Cocoa, her love-worn bear, under her arm. Even now, her final words still resonate, as if to absolve me from a day and a decision that would leave her brain damaged.

“You’re a great mom for me.”

“And you are my favorite seven-year-old in the whole world.”

“Can you rub my feet? They hurt.”

“Sure. Where’s the pain?” Oliver appeared in the doorway to say goodnight and saw me rubbing Mathilda’s ankles. I thought by then she was already gone—succumbing to the inevitable hallucinations that

would torment her for the next several hours. Oliver began clearing the floor from the bed to the doorway, picking up American Girl doll accessories and other soft toys, more books and a wet towel. Turning off the nightstand, I walked towards the hallway and heard a final faint murmur—words that would do much to connect us but little to assuage my remorse.

“Mom, you did what you thought was best for me,” she whispered.