

# **Respondent's Exhibit C**



**Centre universitaire de santé McGill  
McGill University Health Centre**

*Les meilleurs soins pour la vie  
The Best Care for Life*

September 14, 2007

Lynn Ricciardella  
Trial Attorney  
United States Department of Justice  
Torts Branch, Civil Division  
1425 New York Avenue, NW, Rm. 3140  
Washington, DC 20005

RE: William Yates Hazelhurst  
DOB: 2000-11-02  
DK No 03-0654V

Dear Ms. Ricciardella,

I have reviewed the extensive medical records of William Yates Hazelhurst and the expert opinion of Dr Corbier filed by the petitioners.

**Clinical History**

William Yates Hazelhurst was born on February 11, 2000 to a G<sub>1</sub>A<sub>0</sub>P<sub>0</sub> 28 year old female following 41 weeks gestation. His birth weight was 9lbs 2oz and Apgars of 8 and 9. Birth history was largely unremarkable although a note was made of mild ABO incompatibility following a positive direct Coombs test (Pet Ex 1 at 11).

At 24 days of life on 03-07-2000 he presented to his pediatricians office with a complaint of fussiness that was diagnosed as consistent with infantile colic. He was noted at that time to have possible oral thrush and was treated with Nystatin (Pet Ex 2 at 9-11). On 04-07-2000, at the 2 month visit, a note was made of improvement of symptoms while using Tagamet and that mother had discontinued breast feeding. He received his first vaccines. His well baby check-ups at 4 and 6 months showed no significant concerns raised by parent or physician. From this point forward I will summarize in point form for clarity.

- 09-05-2000 Age -7 months diagnosed with upper respiratory tract infection followed by otitis media on 09-27-2000 (Pet Ex 2 at 22-23).
- 10-26-2000 Age 8 1/2 months diagnosed with upper respiratory tract infection followed by otitis media on 10-31-2000 (Pet Ex 2 at 24-25).



- 11-22-2000 Age 9½ months report of transient shaking episodes over past 2-3 months which were apparently decreasing in frequency on history. Diagnosed with thrush (Pet Ex 2 at 29).
- 01-17-2001 Age 11 months. Rash on thumb consistent with thumb sucking dermatitis. Decision taken to treat with Diflucan in case of candidal superinfection (Pet Ex 2 at 33).
- 02-08-2001 Age - 12 months. Upper respiratory tract infection with otitis media. Treated with antibiotics. 12 month vaccines given (pet Ex 2 at 35-37).
- 02-27-2001 Episode of bronchospasm (Pet Ex at 38).
- 05-01-2001 Age - 15 months seen by pediatrician for fussiness. Nothing found (Pet Ex 2 at 41).
- 09-20-2001 Age 19 months seen by pediatrician for irritability. Nothing found (Pet Ex 2 at 49).
- 10-23-2001 Age 20 months diagnosed with otitis media (Pet Ex 2 at 50).
- 01-07-2002 Age 23 months diagnosed with gastroenteritis followed by otitis media and oral thrush (Pet Ex 2 at 53).
- 02-14-2002 Age 2 years diagnosed with croup followed by otitis media on 02-21-02 (Pet Ex 2 at 55-56).
- 05-04-2002 Age - 27 months diagnosed with otitis media (Pet Ex 2 at 74).
- 05-13-2002 Age 27 months episodes of unresponsiveness followed by screaming. CT and EEG normal.

Subsequently, he had a viral illness at age - 3 on 02-02-2003 and fever without focus at age 6 ½ years on 08-26-2006. Following placement of PE tubes, the episodes of otitis media resolved (Pet Ex 8 at 1).

In summary, his first 2 years of life William Yates had four physician diagnosed upper respiratory tract infections and a total of 7 episodes of otitis media, five of which followed clear viral infections. He had gastroenteritis once.

He was diagnosed with Autistic Spectrum Disorder at age 27 months (Pet Ex 6 at 1) after concern regarding speech delay raised by his parents at 25 months of age (Pet Ex 2 at 58).

Subsequent to his diagnosis William Yates was diagnosed on 04-17-2003 at age 3 years with gastroesophageal reflux disease with eosinophilic colitis on pathology (Pet Ex 20 at 2, 9-10).

**Immune Status and Laboratory Investigations.**

On 08-12-2002 at age 2 ½ William Yates was seen by Dr Blaiss and an evaluation of his immune function was performed. Dr Blaiss evaluation included total immunoglobulin levels, humoral response to vaccines, complement levels and function and T and B cell enumeration. When all results were available Dr Blaiss concluded that *the immune system of William Yates was normal.*

Other investigations were performed to evaluate the level of heavy metals in William Yates. Pet Ex 21 at 10 is a report of heavy metal assays showing no mercury levels

detected in 2004 and Pet Ex 23 @14 shows that hair analysis also failed to detect mercury in this child.

### **Petitioner's Claim**

I have reviewed the expert report of Dr J Corbier in which he supposes that “*Yates represents a group of children with regressive autism with evidence of a weakened immune system ...*” and suggests that “*Yates immunological impairment, the presence of infection during his 12 month vaccination and the subsequent onset of regressive symptoms, it is very likely that thimerisol played a significant role in the development of Yates autism.*” (Pet Ex 26 at16). Earlier in this report Dr Corbier states the following in Pet Ex 26 at 12 ; “*In Yates case, one manifestation of a genetic-based problem leading to potential harm from environmental triggers is his innate immune weakness...When you add to the immune problem the various potential susceptibilities...cause by a genetic defect, then we can understand why children like Yates with autism are complex and vulnerable at the same time.*” To sum up, Dr Corbier suggests that Yates has an inherent weakness in his immune system which predisposes him to vaccine or toxin-induced autism. **There is however no evidence that Yates' immune system is/was abnormal.**

As mentioned previously William Yates had physician diagnosed upper respiratory tract infections, otitis media and episodic thrush. The suggestion made by Dr Corbier is that the frequency of these infections is evidence of an impaired immune system (Pet Ex 26 at 6). In addition, Dr Corbier makes reference to other events in Yates' history that I am unable to find reference to in the submitted record. In particular, he states that Yates had a prolonged episode of screaming within 24 hours of the 6 month vaccine and within 7 days there were episodes of shaking and blank staring (Pet Ex 2 at 5). In Pet Ex 2 at 29 , during the 9 month routine visit, there is mention of shaking episodes which are resolving, I am however unable to find mention of the temporal association to the 6 month vaccination or the screaming episode. Interestingly I find a clinic visit on 09-27-2000 at age 71/2 months because of “crying all night” which was diagnosed as otitis media (Pet Ex at 23). Dr Corbier also notes development of chronic lymphadenopathy and low grade fever (Pet Ex 26 at 5). I find no note of this in any of the submitted records. There are several well child visits where the physician noted absence of lymphadenopathy (see Pet Ex 2).

### **Literature Review and Analysis**

One important question arises; what is a normal frequency of infection in the first 2 years of life? According to the pediatric textbook Primary Pediatric Care 4th edition. Chapter 167, pg 1235 under the heading "Normal Patterns of Infections in Childhood" it is expected for children to have up to 6-10 infections per year during the first 2 years of life.<sup>1</sup> During the first years of life our immune systems are frequently stimulated by exposure to novel organisms. Over time, the memory component of the system prevents the development of signs and symptoms of infection upon subsequent exposures. Thus the natural history of infections in childhood is for a young child to have symptomatic infections in the range of 6-10/year, or approximately 1 per month during the school year. Summer months have less virus circulation and thus the infection frequency decreases

somewhat. With this in mind, it is clear that Yates had as many infections as his peer group. In addition, when examining the types of infections, Yates' otitis media often followed acute viral illnesses such as upper respiratory tract infections (URTI). It has been shown in large epidemiological studies that otitis media follows URTI in 1/3 children and that otitis media in infancy more commonly occurs in males.<sup>2-6</sup> Finally, if one follows the medical record, it appears that the frequency of these infections decreased as Yates' became older. Thus not only did Yates have an infection frequency well within the expected range for age but he also followed the patterns predicted for his age and sex.

Yates also had several episodes of oral candidiasis. In the first year of life approximately 5-10% of children will develop oral candidiasis. Risk factors include frequent antibiotic courses, poor oral hygiene and use of oral pacifiers and thumb sucking. The treatment of choice is to insure that all potential reservoirs of the fungus are removed and replaced. This includes toothbrushes, pacifiers and toys that have been placed in the mouth. It is important to realize however that 60% of healthy children harbor candida in their mouths and thus are at risk for development of symptoms.<sup>7,8</sup> Of note, children with oral thrush do not develop antibodies to the fungus unless the infection becomes invasive. This child did not experience invasive candidiasis.

### Summary and Conclusions

1. I find no evidence of abnormality in William Yates' infection history or in the immune assessment done at age 21/2 years and *there is absolutely no clinical evidence therefore of the innate immune weakness* supposed by Dr Corbier.
2. The hypothesis put forth by Dr Corbier is that Yates innate immune weakness predisposed him to the cascade of events leading to the development of his regressive autism. *The objective evidence however shows that this child's immune system was normal upon laboratory evaluation* and thus would not have played the role in the development of his autism hypothesized by Dr Corbier.
3. It is my opinion that William Yates Hazelhurst has autism and I find no association between his disorder and his immune system's ability to respond to routine childhood vaccination.

Sincerely



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## References

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