From: Scott and Sheri Hunter
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Date: April 3, 2003

To: Honourable John T. Nilson, Q.C.
Minister of Health

Re: **Dr. Findlater Memorandum dated March 5, 2003**
Ministers Referral Number 6783 - June 2002

I must first extend my gratitude for your both taking the time to review my families and son's vaccine concerns. I feel compelled however, to ensure a couple points are made clear and are part of the public record if only through a letter to your offices.

1> Dr. Findlater makes reference to Kirk's relative health prior to December 1999 referring to "developmental milestones" having been met. Just so there's no room for misinterpretation, Dr. Kotagol of the MAYO clinic - after reviewing our photos and videos - and in consultation with a team of pediatric neurologists in May 2000, saw no evidence of a related precondition that has been referred to on line 2.8 of the ACCA Case Review Form. (Those pictures and video were made available to the neurologists here and were never reviewed.)

I also wish to record that Kirk's pediatrician from birth to 6 months, Dr. Ducasse, made it also clear to us that he was satisfied Kirk had demonstrated no developmental problems of any sort prior to December 1999.

2> In order to better manage our son's intensive condition, we decided to transfer Kirk into the care of his neurologist's wife and pediatrician, for no other reason than to consolidate Kirk's chain of command. Her testimony should never have been used to replace the first hand clinical observations of Kirk's primary pediatrician, Dr. Ducasse.

I submit the pediatric professional that was in the best position to assess Kirk's developmental progress prior to December 1999 was not consulted and further, in a private conversation, led me to believe he was not completely convinced this was not a vaccine insult.

3> On items 2.3a, 2.3b and 2.4 we would appreciate some clarification as Dr. Findlater was not in a position to comment on the ACCA's intent. The product monograph refers to events related to the vaccine that this form suggests are not known to be related to Pentacel. Although the monograph clearly states:

"Neurological complications such as peripheral neuropathies and demyelinating diseases of the central nervous system (CNS) following some tetanus toxoids or diphtheria toxoids have been documented but are rare"

...2

"The following neurologic illnesses have been reported as temporally associated with some vaccines containing tetanus toxoid: ..... EEG disturbances with encephalopathy (with or without permanent intellectual and/or motor function impairment)."

"As with any vaccine, there is the possibility that broad use of the vaccine could reveal rare adverse reactions not observed in clinical trials. A temporal association of neurological disorders (including encephelopathy, with or without permanent brain damage and/or intellectual impairment) has been reported following the parenteral injection of other biological products and should always be carefully considered when an immunization is indicated."

4> I want to make a few points regarding VAAEs (Vaccine Adverse Event Surveillance System) and Kirk's suspected injury. Health Canada's "Guidelines for Reporting Adverse Events Associated with Vaccine Products" published by The Document Disseminating Division at the Laboratory Centre for Disease Control, states a suspect injury such as my son's should have been reported within 15-30 days after injury:

"Priority (15-day) Reports
All reports of serious VAAEs must be forwarded to LCDC within 15 calendar days of the receipt of the report by the Canadian manufacturer.
Although they are not explicitly covered under regulations, the Division of Immunization also considers as serious cases those that would fall under ACCA review criteria (see Appendix 2 for definition). These should also be forwarded under the 15-day criteria."

"**Serious** is defined as any reaction that results in death, or is life-threatening requires in vaccine recipient hospitalization, or prolongation of existing hospitalization, results in persistent or significant disability, or incapacity is a congenital anomaly/birth defect.
In addition, LCDC defines serious for the purpose of database extraction for review by the ACCA as meeting the following diagnoses or criteria...

- anaphylaxis: all cases
- convulsion: afebrile and hospitalized
- febrile seizure with hospitalization for 3 days or more
- encephalopathy and encephalitis/meningitis: all cases
- anesthesia/paresthesia and paralysis: all cases
- Guillain Barré syndrome: all cases
- thrombocytopenia: all cases
- other severe or unusual events with hospitalization"

5> VAAEs requires that physicians and health professionals NOT make causal assessments prior to reporting. Kirk's neurologist refused to entertain vaccine injury to such an extent, he informed us after 6 months of intensive investigation which confirmed a diagnosis of idiopathic seizures, he would "never" reconsider vaccine as a possible trigger. As a matter of fact, it took us over a year of constant shoving to get this "possible" injury recorded and still Kirk's only official documenting of the parent's suspicions was recorded at the MAYO Clinic in Rochester, despite repeated attempts with several health professionals here. The following is taken from Health Canada's "Guidelines for Reporting Adverse Events Associated with Vaccine Products"

" Reporters are not required to have made any formal causality assessment in their reports."

"...the cornerstone of vaccine surveillance activities is a **voluntary** system in which health care providers...report to local, provincial/territorial public health authorities events **they feel** are temporally associated with an immunization."

Allowing various health care providers to report based on their "feeling" should be unacceptable

6> If the following 2001 CCDR (Canada Communicable Disease Report for Disease Report) excerpt is true regarding VAAEs then the frequency of this event as quoted on the ACCA's Case Review Form 2.1 of 1-4% suggests to me there already exists statistically significant events we could generate profiles from that might help identify children at risk.

"The objectives of post-marketing surveillance of VAAEs are:

- identify infrequent events
- estimate rates of occurrence of VAAEs
- carry out lot-by-lot monitoring in case there are unusually high rates of VAAEs
- identify risk factors for VAAEs
- raise the awareness of health care providers
- identify areas for further research
- identify problems requiring quick epidemiologic investigation
- reassure the public."

7> As for the mechanism behind Kirk's injury, it is my opinion this injury could have been triggered by the vaccine. If Kirk had an underlying sensitivity to any of the vaccine ingredients, a reaction might manifest in any number of dysfunctional autoimmune responses. The VAERS database records several thousand reactions yearly that result in skin eruptions, rashes, or redness at the site of injection, some up to 14 days post immunization. Based on this casual observation, this suggests an immune reaction could conceivably manifest in children such as mine many days after the vaccination. The question becomes - Why wouldn't we demand the maker research a connection to allergic predisposition in some children and develop a test to identify them prior to vaccination?

The CDC's website (Centre for Disease Control) contains a table of injury that allows compensation for injuries presenting within 72 hours that I've read was established based on US litigation won and lost. I believe the table Health Canada uses to determine causality was derived from the US version and does not mean injury can't and doesn't happen outside that window of time, rather that it likely wasn't worth the financial investment challenging it in court.

8> Pentacel- According to Dr. Sheifele's report attached, the acellular component seems to have been added in 1997 post-licensure and the clinical trials in Sweden using the exact ingredients only involved completely healthy children. Two points that may have been reason enough for the FDA to request new trial data. Most other clinical trials referenced in the monograph utilize component trials not the DTaPP - ActHib all in one combination with the one mention of Quadracel trials in Canada not dated. It goes without saying, any change in the product ingredients should have constituted a reason for retrial given the potential immunologic sensitivities to the new elements.

The maker's website indicates they are currently trialing Pentacel now for US approval in 2004. If indeed we are running trials in Canada, (see attached and below) Kirk's potential injury and others like him are not being included in trial data. (We have met other parents, John and Linda Kozole, that haven't reported there child's (Matthew) injury even though their story is, by all accounts, identical to Kirk's. NOTE: They were also patients of Kirk's neurologist) If the newly introduced acellular component is indeed less reactive, which studies below suggest, how would we know if the incidence of latent immunologic injury isn't possible and doesn't present an even greater risk, if our current system of reporting discounts injury beyond 72 hours. If that weren't bad enough, Health Professionals were "encouraged" (below) to vaccinated immune compromised children.

"Infectious disease Society of America 37th Annual Meeting November 20 1999 -
Dr. David Scheifele of the **Alberta Children's Hospital** in Canada and co-workers presented a comparison of adverse events from ***acellular versus whole-cell pertussis vaccine as used in a combination vaccine product.*** These studies were conducted in Canada..."

"In Canada in **1997**, the routine combination vaccine DTP-IPV-Hib was **changed to DTaP**-IPV-Hib."

"Records were evaluated for hospitalization ... that occurred-within **0-72 hours** after immunization with DTP or DTaP."

"Prelicensure studies suggested that the rate of each of these complications was reduced by a factor of 10 with acellular pertussis vaccine. However, **only completely healthy children were immunized** and studied in preclinical testing. The question these investigators hoped to answer is whether this reduction in adverse events would hold true in clinical practice, when **vaccination of** children with a history of seizures and stable neurologic conditions as well as **those with mild under lying infections was encouraged.**"

9> As incomplete and under-investigated as it appears the ACCA's final report was, it has taken over three years to complete the vaccine injury report process. I'm told it can take as little as 16 months to license a vaccine. The only report the vaccine maker got of Kirk's possible injury was recorded by myself some 2 years after his injury. Since there is no legal requirement for either the Health professional to report to Health Canada or Health Canada to report to the vaccine maker, how can the Canadian public be comforted with "the benefits outweigh the risks". No one can tell any individual what their true risk of injury is, and on this point I suggest the various division and departments of Health should reconsider their approach.

Since our dysfunctional reporting mechanism stands legally in the way of manufacturers access to information, I might suggest VAAEs is one of the reasons Canada is finding favour with multinational companies wishing to research their products. I have written Barbara Loe Fischer of the NVIC (National Vaccine Information Centre), Senator Burton of the US Congress and the FDA Biologics Department to make them aware of the potential concern.

So while I am satisfied with Dr. Findlater's handling of this matter in regard to the charge of his office. It would be my desire to still meet with the Minister regarding department policy issues specifically where they pertain to the tracking and reporting of vaccine injury. We would also like to see a revised more complete report from the ACCA and discuss possible financial remuneration through Medicare for reasons we've indicated that follow.

10> Kirk's quality of life has improved immeasurably through the divine care of Dr. L. Nieslen in Winnipeg. With her 24/7 care and treatment of Kirk we have eliminated the need for the ineffective, expensive anti-epileptic drug therapy and have unwittingly adopted the financial and physical obligation of care from Sask Health. Sheri was forced to leave her job to work full time with Kirk, which has eased the tax-payer burden of the many programs and professionals assigned to Kirk's ongoing rehabilitation. Not to take away from the exceptional job various OT, speech pathologists, nutritional and dietary staff have contributed and continue to. However, the fact remains Kirk's care comes with a price not currently covered by Medicare or insurance. We'd like an opportunity to present you with a cost approximation of Kirk's ongoing maintenance which we would argue should be covered by Medicare. I challenge anyone to refute Kirk's obvious progress under homeopathic care.

Indeed I cannot be satisfied until I see measures put in place to ensure the true benefit versus risk picture is presently accurately and made available to parents making an informed decision regarding the new multiple and combination vaccines. It is my opinion Kirk's immune system and many others are buckling under the immense weight of too much preventative care.

Thank you for your attention.

Scott and Sheri Hunter
Constituents Saskatoon Eastview

Cc: Dr. Findlater, Chief Medical Health Officer
Judy Junor, MLA Saskatoon Eastview

Enclosed: Attachment