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VIA REGISTERED MAIL AND E-MAIL

A fully referenced version can be viewed online at http://deadlyallergy.com/2016/12/penta

December 12, 2016

The Honorable Jane Philpott Minister of Health House of Commons Ottawa, Ontario K1A 0A6 Jane.Philpott@parl.gc.ca The Honorable Eric Hoskins
Minister of Health & Long-Term Care
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Dear Ministers Dr. Philpott and Dr. Hoskins,

Re: <u>PENTA 5 in 1 vaccine injected into babies in Canada (except Manitoba)</u> from 1994 to 1997 and its relationship to the epidemic of anaphylaxis in children and young adults

I could not let another New Year go by without writing heads of government to ensure that the sordid history of the PENTA vaccine is recorded in your correspondence archives.

According to the SickKids Foundation, anaphylaxis to foods is affecting approximately 300,000 children and their families in Canada. It is unsure whether this estimate includes the first wave of the epidemic that included my son, who is now an adult at 23. What was the difference between his vaccination schedule and his mildly allergic sister 6 years older? While our daughter received the polysaccharide Hib – on its own - at the age of 18 months, our son was in the first wave of children to receive various conjugate Hib vaccines (adjuvanted) concurrent or combined (PENTA 5 in 1) with the DPT-IPV in infancy. The scientific literature is clear Vaccines can cause anaphylaxis.

Since the introduction of concurrent administration of DPT-P + haemophilus influenza B conjugate in infancy in 1993 there has been a dramatic increase in life threatening chronic children's health conditions <u>including anaphylaxis</u>. In 2008, then Prime Minister Stephen Harper announced additional funding (for a total of \$5 Million) for the MedicAlert Foundation's No Child Without program including free medical bracelets for children. Stunningly, the <u>press</u> release states:

"In Canada, the number of children suffering from afflictions such as allergies, asthma, or childhood diabetes, is ever increasing. Critical conditions (e.g. asthma, various

allergies) sometime require urgent medical attention by paramedics and/or doctors. It's estimated that one in 10 Canadian children have severe allergies, asthma, diabetes, epilepsy and other conditions that can be life-threatening if emergencies are not treated properly and promptly."

That was in 2008. I would hope that you and every other doctor, government and public health official in this country would find it unacceptable that 1 in 10 children in Canada live with life threatening conditions, and would leave no stone unturned to find out WHY. While a single measles case can cause pandemonium, the numbers of these affected children continue to rise without any alarm bells. What is being done by government and health officials, other than throwing money at MedicAlert bracelets, to address the epidemic of life threatening conditions in children?

Parents of children affected by food anaphylaxis and/or autism have spent numerous years and countless hours investigating why our children are affected with such severe immune system and brain malfunctions. The PENTA Project investigations have revealed that the PENTA 5 in 1 combination (1994 - 1997) did not have a DIN # or a Notice of Compliance rendering it illegal according to Health Canada. 11,000+ adverse events, including deaths, were reported to PHAC for the PENTA combination over the three years that PENTA was in use. You may request PHAC ATIP reports A-2013-00096 and A-2013-00097 to view all of this data, which is too large to upload to a website. All subsequent 5 in 1 vaccines including Pentacel and Pediacel are based on this illegal combination, putting into question all vaccine schedules since 1994.

Access to Information requests over many years to all levels of government including requesting PENTA licensing information provided scant information, and <u>Ontario</u>, <u>Canada</u>, and <u>local health unit</u> ATIP responses **did not acknowledge that the PENTA combination existed at all!**

Parents like me have scoured the medical literature to find scientific proof of a vaccine connection to anaphylaxis. The website http://www.deadlyallergy.com resource and science sections outline some of that literature. The book The Peanut Allergy Epidemic, What's Causing It and How to Stop It by Canadian Historian Heather Fraser MA, BA, B.Ed. details the history of the whole sordid mess. Mrs. Fraser's book is fully referenced, and should be read by every doctor, nurse, politician, health official and parent.

Heather Fraser contacted her Member of Parliament, Nathaniel Erskine-Smith, on June 27, 2016 with a "Request for an investigation into the unlicensed PENTA vaccine & its long term consequences" that was sent to you, Health Minister Philpott, on Heather's behalf. The extensive binder of evidence, memory stick with the full file of PENTA adverse events, along with a copy of the book, *The Peanut Allergy Epidemic*, never received a response or even the courtesy of an acknowledgement. Minister Philpott, what happened to this material, and when are you going to respond to Heather Fraser?

I will send any recipient of this e-mail a copy of Heather Fraser's book upon request in hopes of **SOMEONE** finally addressing the long term health effects experienced by the recipients of the PENTA vaccines and children continuing to be affected by the <u>epidemic of anaphylaxis</u>.

Surprisingly, the Canadian Medical Association Journal published my letter in 2004: http://www.cmaj.ca/content/170/4/437/reply#cmaj el 942 which includes some information on the PENTA saga prior to our knowledge of this vaccine combination being illegal:

"After retrieving the lot numbers of the vaccines given to my anaphylactic child I sent in an Access to Information request to Health Canada for 1) the 100% composition of the vaccines my child received and 2) a list of vaccine adverse events reported for the 8 lots he received. Health Canada can't provide me with a 100% composition because it's proprietary information. For the adverse event information I was asked to pay \$600 down and \$1200 in fees. This information, from 1993-95, was not on a computerized database - why wasn't it?

After waiting a year and paying only for photocopying, I received the data from Health Canada. I had to manually count the 975 reactions: death, seizure/convulsion, dysopnoae, speech disorder, allergic reaction, adenopathy, hypotonic-hyporesponsive episode, severe pain and/or swelling, screaming episode, hypokinesia, persistent crying, severe vomiting and/or diarrhea, lethargy, fever, cyanosis, rashes, eczema, pneumonia, lymphocytosis, sterile abcess/nodule/necrosis, infective abscess, tachycardia, gait abnormal, ataxia, bulging fontanelle, sepsis, vaso-vagal reaction, tremor, arthritis, cellulitis, bradyapnoea, delirium, reduced consciousness, shaking, somnolence, anaphylaxis, apnoae, encephalopathy, asthma, injection site reaction, shortness of breath, and confusion.

Repeated attempts to get an explanation as to why one particular lot was able to rack up 664 reactions (including 34 seizures/convulsions) without being pulled from the market have gone unanswered by local and Ontario health officials, officials with Health Canada and participants of IMPACT. Also unanswered: The National Report on Immunization, 1996 states: "If the number and type of reports for a particular vaccine lot suggested that it was associated with more serious adverse events or deaths than are expected by chance, the federal government has the responsibility and will, as well as the legal authority, to immediately recall that lot." The U.S. Centers for Disease Control considers a vaccine "hot lot" one that generates reports of more than two deaths or two convulsions or a total of 10 adverse reports. Health Canada officials reported an investigation should be initiated after a "cluster of reports" and that means "3 or more." This being the case the majority of vaccines my child received should have been recalled? Why weren't they?

Another of the many unanswered questions is "How do you determine whether the adverse event is attributed to the DPT-P or the Hib when they were both given at the same time, and now in the same syringe? Could anyone provide me with safety studies

relating to the DPT-P and Hib being given concurrently, and whether IgE levels were tested pre and post vaccination?"

To make matters worse, my recent Access to Information request for a product monograph, including studies that the licensure was based on, for the 5 in 1 "PENTA" (whole cell pertussis, DTPolio combined with Hib) vaccine that Health Canada supposedly licensed in 1994 and my child received in 1995 was answered with "After a thorough search for the requested information, no records were located which respond to your request." The "PENTA" vaccine is not even listed in the Compendium of Pharmaceutical Specialties for 1993, 1994 or 1995.

Frightening.....and unacceptable."

The United States FDA never approved the 5 in 1 PENTA, and the FDA waited until 2008 to license the acellular pertussis version of PENTA called Pentacel. The <u>FDA approval document</u> for Pentacel lists "several items of concern" ... **this with a vaccine that had been injected in Canadian children since Pentacel was rushed in to take the place of PENTA on July 1, 1997.**

As stated above, the Toronto's SickKids Foundation reports that there are 300,000 children in Canada living with life threatening food anaphylaxis. Are they including the children who received the PENTA vaccine who are now adults? We don't know. <u>Clearly, anaphylaxis</u> continues to affect children at epidemic proportions in this country.

To not mention the vaccine connection to allergy (<u>as shown in the medical literature</u>) prior to vaccination means that parents do not have fully informed consent to vaccination. Now that Ontario is intent on <u>changing the legislation</u> of the Immunization of School Pupils Act to require an "education session" prior to a parent filing an exemption, the province must ensure that fully informed consent is given. I would suggest that until such time that concrete causes of anaphylaxis are found that "vaccines are not tested for their potential to cause allergic disease" must be included in any informed consent discussions with Ontario parents and children prior to vaccination. For that matter, until such time that the cause of cancer is found, a statement such as "vaccines are not tested for their potential to be carcinogenic or mutagenic" (see Section 13) must also be included.

Informed consent, according to the Health Care Consent Act in Ontario:

Elements of consent

- 11. (1) The following are the elements required for consent to treatment:
- 1. The consent must relate to the treatment.
- 2. The consent must be informed.
- 3. The consent must be given voluntarily.
- 4. The consent must not be obtained through misrepresentation or fraud.

and must include:

- 1. The nature of the treatment.
- 2. The expected benefits of the treatment.
- 3. The material risks of the treatment.
- 4. The material side effects of the treatment.
- 5. Alternative courses of action.
- 6. The likely consequences of not having the treatment.

Members of the National Advisory Committee on Immunization (NACI) and vaccine decision makers in upper levels of provincial and federal governments **should not be allowed to have any Conflict of Interest with any pharmaceutical company.** Of the current NACI Chair and Vice Chair (voting) and the 10 voting members 11 out of 12 have indirect or direct conflict of interest. This is unacceptable. According to this Conflict of Interest report **the IMPACT network, which is supposed to monitor vaccine injury in this country, is conflicted!** (See Wendy Vaudry) "YES ...Co Primary Investigator of the IMPACT Network - which is partially supported by grants from Industry (Novartis, GlaxoSmithKline, Sanofi)" This is an outrage!

No wonder I never heard from any of the IMPACT participants after pleading for them to look into anaphylaxis in 2002!

I request a reply with your suggestions on how to put a halt to this epidemic of anaphylaxis. At the very least, children exhibiting any form of rash or other allergy symptoms should have their vaccinations delayed or offered in individual (one at a time) vaccinations in fractioned doses to prevent the development of severe allergic disease (this was done in the past, see History section of deadlyallergy.com). Sadly individual doses of infant/toddler vaccine are no longer available. 5 or 6 in 1 and 3 in 1 combination vaccines are the only choices for parents now. Is there any wonder parents are worried when the vaccination schedule begins at 2 months with 7 or 8 different vaccines in 5 or 6 in 1 combinations (depending on the province) at one "well baby visit"?

Respectfully yours,

Rita Hoffman

Dedicated to Pierre Morin, Penta Project parent, who died in October of 2010

CC:

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Vaccine Choice Canada

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The Penta Project