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June 2009 Newsletter

Editorial Contents:

1) **The National Vaccine Advisory Committee Vaccine Safety Working Subgroup has recommended that new studies be done to evaluate vaccine safety, including additional study of the potential vaccine–autism link.**

Introduction:

Just when the pharmaceutical industry thought the vaccine – autism controversy had been resolved, the National Vaccine Advisory Committee has recommended further study of vaccine safety. A perceived fear of the safety of the US vaccination schedule has lead increasing numbers of parents to opt out of full compliance. The numbers of children who are not fully vaccinated has now reached a point where 'herd' immunity may be compromised, compelling the CDC to hold town hall meetings and convene a Vaccine Safety Working Subgroup. Despite research ruling out mercury (Thimerosal) or the measles portion of one specific vaccine, autism continues to rise to a level of 1 in every 64 children in the UK. The NVAC draft report recommends further study of the potential for vaccines to contribute to autism in children who have underlying mitochondrial disease, a worthwhile study given the clinical history of such children developing autism after vaccinations (see the Poling case). What the NVAC has overlooked, however, in their recommendations, is that epidemic regressive autism is associated with the switch from using animal cells to produce vaccines to the use of aborted human fetal cells for vaccine production. Now when we vaccinate our children, some vaccines also deliver contaminating aborted human fetal DNA. The safety of this has never been tested.

Dr. Theresa Deisher, President, Sound Choice Pharmaceutical Institute

The National Vaccine Advisory Committee Vaccine Safety Working Subgroup has recommended that new studies be done to evaluate vaccine safety, including additional study of the potential vaccine–autism link.

We have learned a great deal about autism in the past decade or so. There is a genetic component to autism, yet it is not from a single gene. Autism and autism spectrum disorder are polygenic diseases, meaning that multiple genes have been shown to be associated with these diseases. Studies have also clearly shown that there is an environmental component, a trigger, that is required. What this means is that some children have a genetic predisposition such that when they experience some other stress or damage they develop autism, while children without this genetic predisposition who are exposed to the same stress or damage do not develop autism. Vaccines are an obvious potential environmental trigger for autism. Childhood vaccination programs were introduced to the US in about 1970.

Before this we did not vaccinate our children widely, largely because vaccines, other than smallpox, were not available.

Between 1970 and 1985 about 60% of US children were vaccinated for mumps, measles and rubella. Nationwide vaccination compliance campaigns brought that rate up to over 90% by the mid-1990s. In 1979 a new version of the MMR vaccine was introduced to the US, and by 1983 only the new version was available.

Autism began rising in the US after 1979 and spiked up dramatically between 1983 and 1990 from 1 in 10,000 children to 1 in 500. A decade later, in 1988, this new version of the MMR vaccine was introduced to the UK. Autism rates spiked up dramatically afterwards.

The temporal association between the introduction of the new MMR vaccine and autism rates, separated by a decade in the US and the UK, was what lead scientists to first suspect that vaccines, particularly the new MMR vaccine, might be associated with autism.

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Studies done to examine potential links between vaccines and autism have focused on the measles virus in this new MMR vaccine and on the presence of mercury (Thimerosal) in vaccines. However, in some countries mercury was completely removed from vaccines as early as 1993, yet autism rates have continued to increase in those countries. Furthermore, the scientific community has done careful, detailed studies that indicate that mercury in vaccines is not a trigger for autism. While the pharmaceutical industry would like to conclude, therefore, that vaccines are not the environmental trigger for autism, the temporal association between the new vaccine versions and autism is too compelling for parents and grandparents to ignore, and real-life experience continues to implicate vaccines as a trigger for autism in some way. The National Vaccine Advisory Committee agrees.

Imagine your 12 to 15 month old baby; learning to talk, learning to walk, laughing and interacting with you, giving you kisses. You take your child into the pediatrician for their regular check-up and vaccinations. Children at this age now receive up to four shots at a single visit. Within four to six weeks after their check-up your child has stopped talking, stopped interacting with you – your child has developed regressive autism. Regressive autism describes children who were developing normally and then cease to develop further language and social skills. Not only do they cease to continue to develop, they lose the language and social skills they had gained in their young lives. How devastating!

Recent evaluation of autism and autism spectrum disorder demonstrates that the number of children with 'regressive' autism is much higher than previously published; as high as 41% of autism or autism spectrum diagnoses. *(Hansen RL; "Regression in Autism: Prevalence and Associated Factors in the CHARGE Study", Ambulatory Pediatrics 2008, v8: 25-31).*

In addition to the emotional and financial burdens of autism that are so devastating to families, we cannot survive as a society with rates as high as 1 in 64, as they are now reported for the UK *(Baron-Cohen S; "Prevalence of autism-spectrum conditions: UK school-based population study. "Br J Psychiatry 2009 v194:500-509).*

The Vaccine Safety Working Group of the National Vaccine Advisory Committee (NVAC) to the CDC has acknowledged that the potential for vaccines to trigger autism in specific subsets of children warrants more detailed examination *(http://www.hhs.gov/nvpo/nvac/documents/NVACVaccineSafetyWGReport041409.pdf; http://www.hhs.gov/nvpo/nvac/documents/NVACVaccineSafetyWGReport041409.pdf).*

The focus of the NVAC draft report is on children who have underlying mitochondrial diseases, which may make them susceptible to adverse events following vaccinations. However, the NVAC has missed one critical and unavoidable component of vaccines in their recommended study, the presence of contaminating residual aborted human fetal DNA (See the vaccine package inserts for the presence of MRC5 residual DNA : http://www.merck.com/product/usa/pi_circulars/v/varivax/varivax_pi.pdf)

The new MMR vaccine introduced to the US in 1979 and then to the UK in 1988 was unique in more than just the measles component. The new MMR, MMR II, is produced using aborted fetal cells. Previous vaccines were made using animal cells. The early vaccines produced using aborted fetal cells, such as MMR II, don't even inform consumers that residual aborted fetal DNA is injected with each vaccine.*(http://www.merck.com/product/usa/pi_circulars/m/mmr_ii/mmr_ii_pi.pdf)*

More recently introduced aborted fetal cell vaccines do inform consumers that the vaccine contains contaminating residual DNA from the 'human diploid cell' used to produce the vaccine. *(http://www.merck.com/product/usa/pi_circulars/v/varivax/varivax_pi.pdf)*

However they don't inform the consumer that a 'human diploid cell' is a cell from an aborted fetus.

There are numerous issues of concern here. First and foremost is the moral aspect of what has been done. Electively aborted human fetuses were specifically selected and processed in order to create cell lines for vaccine production, as documented in publicly available FDA meeting minutes. *(http://www.fda.gov/ohrms/dockets/ac/01/transcripts/3750t1_01.pdf page 77 on)*

This was not just a one time occurrence, as many would like to believe. The use of fresh electively aborted fetal material and aborted fetal cell lines is pervasive in the biotechnology and pharmaceutical industry. The public needs to be concerned with the morals and ethics of scientists. History has taught us all too well what happens when we are not mindful of the morals and ethics within specialty professions.

Another issue of concern to us all, regardless of one's own personal opinion about the morals of abortion, is the issue of informed consent. As a society we are mindful of this in our food packaging, and we have the Nutrition Labeling and Education Act of 1992 that guarantees consumers can easily discover what is in the food they purchase. I may not be vegetarian, but I have no problem with vegetarians having the RIGHT TO KNOW whether meat products are contained in foods or were used in the preparation of the food they are purchasing. Yet, there is no law guaranteeing full disclosure about the use of aborted fetal cell lines to produce our vaccines and other medicines. Perhaps even more egregious, there is no law requiring full disclosure about the presence of contaminating aborted fetal DNA in those drugs and vaccines. Don't you want to know exactly what you are injecting into your children? Into yourself?

We have moral issues, informed consent issues, and we also have public safety issues with what has been done. The safety of injecting our children with aborted human fetal DNA has been debated for over 40 years, but has never been studied. Safety concerns about injecting residual aborted fetal DNA into our children include 1) the potential for subsequent autoimmune disease triggered by our children's immune system recognizing the contaminating DNA and generating antibodies that will also recognize their own similar DNA, and 2) the potential for insertion of the DNA into our children's own genome. The FDA's concerns about the potential for insertion of the contaminating human DNA have focused on oncogenesis, or tumor formation.

Concerns about the potential for residual contaminating DNA to insert into our own genome and thus disrupt the function of tumor suppressor genes have been demonstrated in the laboratory and also in humans. A 2008 FDA co-authored study demonstrated that genomic insertion of residual DNA lead to tumor formation in mice, with newborn mice being the most susceptible. *(Sheng L ; "Oncogenicity of DNA in vivo: tumor induction with expression plasmids for activated H-ras and c-myc " Biologicals 2008 v36:184-197)*

Not only has the potential danger been demonstrated in mice, but gene therapy clinical trials in human children have also shown us the dangers of DNA insertion into our genome. In gene (DNA) therapy clinical trials for X linked SCID disease (bubble boys), 4 out of 9 patients had unanticipated, inappropriate DNA insertion that disrupted a tumor suppressor gene, leading to acute lymphocytic leukemia in these boys. *(http://www.jci.org/articles/view/35700/pdf)*.

Random DNA insertion into a recipient's genes occurs by a process called homologous recombination. Laboratory studies have shown that this process occurs spontaneously only within a species.

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What that means is that naked, unaltered chicken DNA does not insert into a human genome and vice versa. However, naked, unaltered same species DNA rapidly crosses a cell's membranes to enter the nucleus and insert into the genome. The insertion is not a random process, but has been shown to occur at sites in our genes called 'hot spots'.

If extraneous DNA inserted into a skin cell that rapidly sloughs off to be replaced by new skin cells, it would probably not be a problem. However, insertion of extraneous DNA into a long-lived human cell such as a heart or a brain cell could have life-long consequences.

In 1979 a new MMR vaccine was introduced into the US and completely replaced the older version by 1983. Autism rates began to rise in the US after 1979 and rose dramatically after 1983. In 1988 this same new MMR vaccine was introduced into the UK and autism rose dramatically. We have studied Thimerosal (mercury) and found no link, we have studied the measles portion of this vaccine and found no link.

However, the compelling temporal association between this new MMR vaccine and autism cannot be ignored or explained away. What has been ignored is the fact that this new MMR vaccine introduced the use of aborted fetal cells for vaccine production. At one point as many as 94% of US children and 98% of UK children were given this vaccine. It is unconscionable that the public health risk of injecting our children with residual contaminating human aborted fetal DNA has been ignored.

Why has this risk been ignored? I don't know. I can only suggest that the refusal to carefully investigate the consequences of contaminating human fetal DNA may be related to a resistance, particularly prevalent amongst highly secular professions such as biomedical science, to anything that might question abortion.

Preliminary bioinformatics research conducted at Sound Choice Pharmaceutical Institute indicates that 'hot spots' for DNA insertion are found in eight autism-associated genes present on the X chromosome. These eight genes are involved in nerve cell synapse formation, central nervous system development and mitochondrial function. Could genomic insertion of the aborted fetal DNA, found in some of our childhood vaccines since 1979, be an environmental trigger for autism?

Could the fact that genes critical for nerve synapse formation and nervous system development are found on the X chromosome provide some explanation of why autism is predominantly a disease of boys? Could the 'hot spots' identified in these autism-associated genes be sites for insertion of contaminating aborted fetal DNA? These questions must be answered. With over 1 out of every 100 children now diagnosed with autism or autism spectrum disorder, it is unconscionable that we would not investigate this.

Please support Sound Choice Pharmaceutical Institute as we conduct the first bioinformatics and laboratory studies to determine the risk of genomic insertion of contaminating aborted fetal DNA into our children's genes.

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