

OPEN LETTER TO LEGISLATORS REGARDING FETAL CELL DNA IN VACCINES

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My name is Dr. Theresa Deisher. I am Founder and Lead Scientist at Sound Choice Pharmaceutical Institute, whose mission is to educate the public about vaccine safety, as well as to pressure manufacturers to provide better and safer vaccines for the public. I obtained my doctorate from Stanford University in Molecular and Cellular Physiology in 1990 and completed my post-doctoral work at the University of Washington. My career has been spent in the commercial biotechnology industry, and I have done work from basic biological and drug discovery through clinical development.

I am writing regarding unrefuted scientific facts about fetal DNA contaminants in the Measles-Mumps-Rubella vaccine, which must be made known to lawmakers and the public.

Merck's MMR II vaccine (as well as the chickenpox, Pentacel, and all Hep-A containing vaccines) is manufactured using human fetal cell lines and is heavily contaminated with human fetal DNA from the production process. Levels in our children can reach up to 5 ng/ml after vaccination, depending on the age, weight and blood volume of the child. That level is known to activate Toll-like receptor 9 (TLR9), which can cause autoimmune attacks.

To illustrate the autoimmune capability of very small amounts of fetal DNA, consider this: labor is triggered by fetal DNA from the baby that builds up in the mother's bloodstream, triggering a massive immune rejection of the baby. This is labor.

It works like this: fetal DNA fragments¹ from a baby with about 300 base pairs in length are found in a pregnant mother's serum. When they reach between 0.46–5.08 ng/mL in serum, they trigger labor via the TLR9 mechanism¹¹. The corresponding blood levels are 0.22 ng/ml and 3.12 ng/ml. The fetal DNA levels in a child after being injected with fetal-manufactured vaccines reach the same level that triggers autoimmune rejection of baby by mother.

Anyone who says that the fetal DNA contaminating our vaccines is harmless either does not know anything about immunity and Toll- like receptors or they are not telling the truth.

If fetal DNA can trigger labor (a naturally desired autoimmune reaction), then those same levels in vaccines can trigger autoimmunity in a child. Fragmented fetal DNA contained in vaccines is of similar size, ~215 base pairs.^{III}

This is direct biological evidence that fetal DNA contaminants in vaccines are not in low innocuous amounts. They are a very strong proinflammatory trigger.



Administration of fragments of human fetal (primitive) non-self DNA to a child could generate an immune response that would also cross-react with the child's own DNA, since the contaminating DNA could have sections of overlap very similar to the child's own DNA.

Children with autistic disorder have antibodies against human DNA in their circulation that nonautistic children do not have. These antibodies may be involved in autoimmune attacks in autistic children.^{iv}

Duke University demonstrated in a recently conducted study that significant improvements in behavior were observed when children with autism spectrum disorder were treated with their own banked autologous cord blood^v. This treatment clearly shows that most children with autism are not born with it since genetic diseases like Down syndrome or muscular fibrosis cannot be treated with autologous stem cells. Therefore, an environmental trigger, or triggers, introduced to the world around 1980 when autism first began to rise, must be identified and eliminated or reduced in the environment.

- Strong change-point correlation exists between rising autism rates and the US vaccine. manufacturing switch from animal-derived cell lines for rubella vaccine to human aborted cell lines in the late 70s^{vi}.
- The earliest change point for Autistic Disorder (AD) birth year was identified for 1981 for California and U.S. data, preceded by a switch in the manufacturing process:
 - In January 1979, the FDA approved the manufacturing switch for the rubella virus from animal based (high passage virus, HPV-77, grown e.g. in duck embryo cells) to the human fetal cell line WI-38 using the RA27/3 virus strain^{vii}. Both the newly approved monovalent rubella vaccine and a trivalent mumps, measles and rubella vaccine utilize the WI-38 fetal cell line for manufacturing of the rubella vaccine portion.
- Prior to 1980, autism spectrum disorder was a very rare, almost unknown disease. According to the figures of the CDC, the rate of autism in 2014 was 1 in 59 children, a very steep increase since just 2000, when it was 1 in 150. CDC: "The total costs per year for children with ASD in the United States were estimated to be between \$11.5 billion – \$60.9 billion (2011 US dollars)^{vill}."
- Recently, duplications and de novo deletions have been recognized in up to 10% of simplex autism spectrum disorders, corroborating environmental triggers on the genetics of autism spectrum disorders^{ix}.
- The rubella portion of the MMR vaccine contains human derived fetal DNA contaminants of about 175 ngs, more than 10x over the recommended WHO threshold of 10 ng per vaccine dose^x.
- No other drug on the market would receive FDA approval without thorough toxicity profiling (FDA follows international ICH guidelines) -> this was never conducted by the pharmaceutical industry for the DNA contamination in the MMR vaccine.
- Vaccines produced with human fetal cell lines contain cell debris and contaminating
 residual human DNA, which cannot be fully eliminated during the downstream purification
 process of the virus^{xi}. Moreover, DNA is not only characterized by its sequence (ATCG), but also
 by its epigenetic modification (e.g. DNA methylation pattern etc.). This decoration is highly
 species specific, which is why non-human DNA will be eliminated, while this is not necessarily
 the case with fetal human DNA.



Injecting our children with human fetal DNA contaminants bears the risk of causing two wellestablished pathologies:

 <u>Insertional mutagenesis</u>: fetal human DNA incorporates into the child's DNA causing mutations. Gene therapy using small fragment homologous recombination has demonstrated that as low as 1.9 ng/ml of DNA fragments results in insertion into the genome of stem cells in 100% of mice injected^{xii}. The levels of human fetal DNA fragments in our children after vaccination with MMR, Varivax (chickenpox) or Hepatitis A containing vaccines reach levels beyond 1.9 ng/ml.
 <u>Autoimmune disease</u>: fetal human DNA triggers a child's immune system to attack his/her own body.

An additional concern: retrovirus contamination.

Human endogenous retrovirus K (HERVK) is a contaminant in the measles/mumps/rubella vaccine^{xill}.

- HERVK can be reactivated in humans^{xiv}. It codes for a protein (integrase) specialized in integrating DNA into the human genome.
- Several autoimmune diseases have been associated with HERVK activity^{xv}.
- It is also in the same family of retroviruses as the MMLV virus used in a gene therapy trial, in which inappropriate gene insertion (insertional mutagenesis) led to subsequent additional somatic mutations and cancer in 4 of 9 young boys^{xvi}.
- It is therefore possible that the HERVK gene fragment present in the MMR vaccine is active, codes for the integrase or the envelope protein, and thus has the potential to induce gene insertion, fostering insertional mutagenesis and autoimmunity.

The presence of both the high level contaminating fetal DNA as well as the HERVK contamination in the MMR vaccine is an unstudied risk with huge implications and dangers for individual and public health.

Solution: Pressure manufacturers to switch back to animal cell line derived rubella vaccines as was successfully done in Japan:

- Based on Takahashi strains of live attenuated rubella virus, produced on rabbit kidney cells. A single dose of this vaccine has been recently proven to retain immunity for at least 10 years when rubella was under regional control^{xvii}.
- Split MMR vaccine into three individually offered options as done in Japan.

The MMR vaccine manufacturing process needs to be changed to address and eliminate the above risks for the public.

Thank you for your consideration. I will be happy to address any questions you may have concerning the above.

Sincerely,

Theresa A. Deisher, Ph.D.



END NOTES

¹ Lo et al. Am J Hum Genet. 1998 Apr;62(4):768-75 ^{II} Enninga et al. Front Immunol. 2015 Aug 26;6:424 iii Deisher et al. Issues Law Med. 2015 Spring;30(1):47-70 Nostafa et al. 2014, J Neuroimmunol, Vol. 272, pp. 94-98; Mostafa et al. 2015, J Neuroimmunol, Vol. 280, pp. 16–20 ^v Dawson et al. Stem Cells Transl Med. 2017 May;6(5):1332-1339 vi Deisher et al. Issues Law Med, 2015 Vol. 30, pp. 25-46 vii https://www.cdc.gov/vaccines/pubs/pinkbook/rubella.html; Plotkin, SA. 2006, Clinical Infectious Diseases, Vol. 43, pp. S164-168; viii https://www.cdc.gov/ncbddd/autism/data.html ^{ix} Sebat et al. 2007, Science., Vol. 316, pp. 445-449; Sanders et al. 2011, Neuron, Vol. 70, pp. 863-885 * Series, WHO Technical Report. WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION 941; Deisher et al. Issues Law Med. 2015 Spring;30(1):47-70 xi Kramberger et al. Hum Vaccin Immunother. 2015;11(4):1010-21. xii McNeer, N A et al. "Systemic delivery of triplex-forming PNA and donor DNA by nanoparticles mediates site-specific genome editing of human hematopoietic cells in vivo." Gene therapy vol. 20,6 (2012): 658-69. doi:10.1038/gt.2012.82 xiii Victoria et al. J Virol. 2010, Vol. 84, pp. 6033-6040

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^{xvi} Hacein-Bey-Abina et al. J Clin Invest. 2008 Sep;118(9):3132-42

^{xvii} Jpn J Infect Dis. 2016 May 20;69(3):221-3