SHINGRIX vaccine is unsafe and its approval must be revoked

Vinu Arumugham
Oct 2017
vinucubeacc@gmail.com

To:
Vaccines and Related Biological Products Advisory Committee
FDA

Background

My son was diagnosed with multiple life-threatening food allergies and asthma at ~1 year old.

At ~5, he received four vaccine shots in one sitting, developed anaphylaxis and spent the night in the ICU.

Our doctors did not know what caused it nor did they have a cure. I had no option but to research the matter myself. It became quickly obvious that food protein contaminated vaccines cause the food allergy epidemic.[1–4]

Controversies in Vaccine Safety
A Critical Review
I wrote the chapter on Vaccine Induced Allergies**.**
https://www.elsevier.com/books/controversies-in-vaccine-safety/shaw/978-0-12-803254-1

Continuing the investigation, it does not take long to realize that ALL injected proteins can be dangerous and need to be carefully studied and effects understood before use.

SHINGRIX

I reviewed the following SHINGRIX document:
https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/UCM575190.pdf

Immunization with animal protein contaminated vaccines cause autoimmune diseases

Chinese Hamster Ovary (CHO) host cell protein contamination of vaccines is a fundamental safety problem. SHINGRIX vaccine antigens are produced on CHO cells. Cancer research has demonstrated that immunization with homologous xenogeneic proteins (such as vaccines contaminated with animal proteins that resemble human proteins) results in autoimmunity.[5–7]

As previously described for Type 1 diabetes (T1D), low affinity self reactive (LASR) T cells that barely qualify to be positively selected in the thymus, can have high enough affinity to self peptides to be functional and cause autoimmune disease upon activation.[7] T cells with T cell receptors (TCR) that

recognize peptides that differ by as little as one amino acid from a self peptide, can be positively selected and migrate to the periphery.[8]
If homology is 100%, animal derived peptides being identical to self peptides, have a low probability of causing autoimmune disease. This is because T cells that bind self peptides with high affinity would be negatively selected in the thymus. There are many regions where animal protein sequence is identical except for one to two amino acid difference compared to homologous human proteins. Peptides from such near-identical regions can be expected to activate LASR T cells, resulting in autoimmune disease. The $AS01_B$ adjuvant in the SHINGRIX vaccine provides the necessary innate immune system derived costimulation (as described in the SHINGRIX document), required for LASR T cell activation.[9]

For decades, vaccinologists have been reluctant to understand the immunological mechanism of how vaccines work, fail or hurt the body. Pulendran et al.[10] write:

“Despite their success, one of the great iro-nies of vaccinology is that the vast majority of vaccines have been developed empirically, with little or no understanding of the immunological mechanisms by which they induce protective immunity. However, the failure to develop vaccines against global pandemics such as infection with human immunodeficiency virus (HIV) despite decades of effort has underscored the need to understand the immunological mechanisms by which vaccines confer protective immunity.”

Like the vaccinologists, pharmaceutical companies also fail to understand the immunological mechanisms of other products. Monoclonal antibody products produced on CHO cells began to fail due to the induction of anti-drug antibodies (ADA) against the animal peptides. The pharmaceutical companies and regulators have ignored immune responses to injected animal proteins for decades. Now with ADA, they have been forced to look at the issue.[11]

Dr. Vibha Jawa, a director with Merck commented on the article below (see comments section):
“We are beginning to look at residual proteins and contaminant with vaccines
Depending on animal protein a degree of homology with human self can be evaluated using algorithm to understand the extent of tolerance.
Additionally in vitro human immune cell assays can be run to understand thersholds of these proteins and their adjuvant effects”
https://www.researchgate.net/publication/305628626_Evaluating_Immunogenicity_Risk_Due_to_Host_Cell_Protein_Impurities_in_Antibody-Based_Biotherapeutics

So, immunotoxic effects of non-target proteins in general and animal proteins in particular, that contaminate vaccines, have not been studied or understood thus far. Such poorly designed, poorly understood vaccines have been administered for decades and continue to be administered. Unfortunately, these immunotoxic vaccines have therefore caused the epidemic of allergy[1–3], asthma[3], autism[12,13], autoimmune diseases[4,6,14–23] and require a complete re-design[4].

<u>Autoimmunity due to molecular mimicry to other proteins in SHINGRIX</u>

Wraith et al.[24] have suggested bioinformatics analysis of vaccine antigens to determine autoimmunity risk. The SHINGRIX document provides no such analysis. Bioinformatics analysis of VZV glycoprotein E for molecular mimicry to self antigens and autoimmunity risk is required.

Likewise, *Salmonella minnesota* and *Quillaja saponaria* Molina proteins need bioinformatics analysis for molecular mimicry to self antigens.

Autoimmune disease manifestation can take years. It is unacceptable to sicken people for years waiting for pharmacovigilance signals that usually get lost in the noise. We need immediate pre/post vaccination autoimmune serology as suggested by Wraith et al.[24] to detect these problems right away.

Dismissal of serious adverse events (SAE) and potential immune-mediated inflammatory diseases (pIMDs) without root cause analysis, is unacceptable.

Possible autoimmune etiology of adverse events (AEs) such as optic ischemic neuropathy, supraventricular tachyarrhythmias[18], supraventricular tachycardia, must be immediately investigated and root cause understood before approval.

Root cause must be established for all serious and non-serious pIMDs before approval.

Looking at the big picture

Natural varicella infection prevents some types of cancer. So a varicella vaccine increases the rate of those cancers. Lee et al.[25] wrote:

"In a comprehensive analysis of familial and personal medical histories in adults with glioma, we previously showed that history of chickenpox and=or shingles was inversely correlated with case status.36"

Has this been accounted in the risk vs. benefits analysis? The risk vs. benefits analysis must be published.

Conclusion

The safety evaluation of SHINGRIX is inadequate and the approval must be revoked.

References

1. Arumugham V. Evidence that Food Proteins in Vaccines Cause the Development of Food Allergies and Its Implications for Vaccine Policy. J Dev Drugs. 2015;4(137):2.
2. Arumugham V. Professional Misconduct by NAM Committee on Food Allergy [Internet]. 2016. Available from: https://www.zenodo.org/record/1034559
3. Arumugham V. Medical muddles that maim our children with allergies, asthma and autism [Internet]. Unpublished; 2017. Available from: https://www.zenodo.org/record/1034595
4. Shaw CA, Dwoskin C. Controversies in Vaccine Safety: A Critical Review. Elsevier Science & Technology Books; 2017.
5. Naftzger C, Takechi Y, Kohda H, Hara I, Vijayasaradhi S, Houghton AN. Immune response to a differentiation antigen induced by altered antigen: A study of tumor rejection and autoimmunity. Proceedings of the National Academy of Sciences of the United States of America. 1996. p. 14809–14.

6. Arumugham V. Cancer immunology, bioinformatics and chemokine evidence link vaccines contaminated with animal proteins to autoimmune disease: a detailed look at Crohn’s disease and Vitiligo [Internet]. 2017. Available from: https://www.zenodo.org/record/1034777

7. Arumugham V. Bioinformatics analysis links type 1 diabetes to vaccines contaminated with animal proteins and autoreactive T cells express skin homing receptors consistent with injected vaccines as causal agent [Internet]. 2017. Available from: https://www.zenodo.org/record/1034775

8. LOH DY. 8 - Transgenic Mouse Model of Lymphocyte Development BT - Molecular Mechanisms of Immunological Self-Recognition. In Academic Press; 1993. p. 99–104.

9. Malhotra D, Linehan JL, Dileepan T, Lee YJ, Purtha WE, Lu J V, et al. Tolerance is established in polyclonal CD4(+) T cells by distinct mechanisms, according to self-peptide expression patterns. Nat Immunol. United States; 2016 Feb;17(2):187–95.

10. Pulendran B, Ahmed R. Immunological mechanisms of vaccination. Nat Immunol. United States; 2011 Jun;12(6):509–17.

11. Jawa V, Joubert MK, Zhang Q, Deshpande M, Hapuarachchi S, Hall MP, et al. Evaluating Immunogenicity Risk Due to Host Cell Protein Impurities in Antibody-Based Biotherapeutics. AAPS J. United States; 2016 Nov;18(6):1439–52.

12. Arumugham V. Autism Spectrum Disorders: A special case of vaccine-induced cow’s milk allergy? [Internet]. 2017. Available from: https://www.zenodo.org/record/1034557

13. Arumugham V. Strong protein sequence alignment between autoantigens involved in maternal autoantibody related autism and vaccine antigens [Internet]. 2017. Available from: https://www.zenodo.org/record/1034571

14. Arumugham V. Role of vaccine contamination with aquaporin-4 containing chick embryo cell culture in the etiology of neuromyelitis optica spectrum disorders [Internet]. 2017. Available from: https://www.zenodo.org/record/1034773

15. Arumugham V. Role of MMR II vaccine contamination with GAD65 containing chick embryo cell culture in the etiology of type 1 diabetes [Internet]. 2017. Available from: https://www.zenodo.org/record/1034771

16. Arumugham V. Protein sequence identity between human thyroperoxidase region recognized by human autoantibodies and multiple vaccine antigens [Internet]. Available from: https://www.zenodo.org/record/1034769

17. Arumugham V. Strong protein sequence alignment between vaccine antigens and adiponectin: an autoantigen involved in atherosclerosis-related coronary artery disease, cerebral infarction, diabetes mellitus and obesity [Internet]. 2017. Available from: https://www.zenodo.org/record/1034756

18. Arumugham V. Strong protein sequence alignment between autoantigens involved in cardiac arrhythmias and vaccine antigens [Internet]. 2017. Available from: https://www.zenodo.org/record/1034758

19. Wang B, Shao X, Wang D, Xu D, Zhang J-A. Vaccinations and risk of systemic lupus erythematosus and rheumatoid arthritis: A systematic review and meta-analysis. Autoimmun Rev. Netherlands; 2017 Jul;16(7):756–65.

20. Rinaldi M, Perricone R, Blank M, Perricone C, Shoenfeld Y. Anti-saccharomyces cerevisiae autoantibodies in autoimmune diseases: From bread baking to autoimmunity. Clinical Reviews in Allergy and Immunology. 2013. p. 152–61.

21. Arumugham V. Significant protein sequence alignment between Saccharomyces cerevisiae proteins (a vaccine contaminant) and Systemic Lupus Erythematosus associated autoepitopes [Internet]. 2017. Available from: https://www.zenodo.org/record/1034585

22. Arumugham V. Flawed assumptions fuel autoimmune disease: The sorry state of vaccine safety science [Internet]. 2017. Available from: https://www.zenodo.org/record/1034760

23. Arumugham V. Vaccine induced autoimmunity: The price we pay for a flawed vaccine design and safety process [Internet]. 2017. Available from: https://www.zenodo.org/record/1034593

24. Wraith DC, Goldman M, Lambert P-H. Vaccination and autoimmune disease: what is the evidence? Lancet (London, England). England; 2003 Nov;362(9396):1659–66.

25. Lee ST, Bracci P, Zhou M, Rice T, Wiencke J, Wrensch M, et al. Interaction of allergy history and antibodies to specific varicella-zoster virus proteins on glioma risk. Int J Cancer. 2014;134(9):2199–210.