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BILL SB 911: Food Drugs and Cosmetics-Gene Structure-and Function-Modifying Products-Labeling

Premise of testimony for labeling: Genetic Vaccine Platform Used in Animals for Meat and Dairy Consumption Pose an Unreasonable Risk to Consumers, Workers and the Environment, Must at Least Have Labeling While Health Risk Studies and Shedding Studies are Being Done

Testimony by Janci C. Lindsay, PhD., Director of Toxicology and Molecular Biology, Toxicology Support. Services, LLC.

1. There are a number of new generation genetic vaccines which have been approved by USDA for use in various animals meant for human consumption. Several of these use plasmid DNA as the direct vaccine or in the process of making the vaccine.
2. Manufactures and proponents assert that safety studies for the use of this technology in our food supply such as—genotoxicity, carcinogenicity, shedding and secondary transfection, have been done but when pressed for these studies come up empty handed.
3. These genetic vaccines are in fact “Gene Therapies” or “Genetic Biologics”, as acknowledged by SEC filings and patent related to the technologies and as such carry the long known risks of insertional mutagenesis leading to cancers like leukemias and lymphomas and also lethal auto immune reactions from the action of having “self-cells” express foreign proteins which are the target of the immune system.
4. USDA has ruled that you cannot introduce meat into the stream of commerce which has cancer. These shots increase the cancer risk to the animals who receive them and their vectors increase the risk of adverse health effects to humans who could be secondarily transfected.
5. Interspecies variation in bio-distribution and degradation must be taken into consideration and not swept off as bio-identical. Example: mice inoculated with a plasmid DNA vaccine supposedly had no more detectable plasmid after 90 minutes while the plasmids used in another DNA vaccine for salmon were present for one year post shot!

6. Genetic vaccines have the potential to shed to livestock handlers and those who work in the meat slaughter and packing industries posing a risk of non-consensual transfection and possible increased risk for adverse effects including increased cancer risk. This can occur:
 - a. During inoculation with the genetic vaccines
 - b. Working with meat products during slaughter and packaging
 - c. Working with animal waste during cleaning and housing work.
7. Genetic vaccines in LNPs can cross gut barrier of consumer and transfect host cells and potentially gut bacteria causing secondary transfection and expression of vaccine antigen.
8. Genetic vaccine present in milk from inoculation of Mother can transfect consumer of milk products. Heat does not always kill these elements especially DNA.
9. Genetic vaccines can enter the environment in soil bacteria and can be consumed by other animals besides target animals leading to antibiotic resistance risk (plasmids) and risk to animals and environment through off-target transfection.
10. These technologies are still experimental and extensive toxicology, genotoxicity, carcinogenicity and reproductive toxicology studies on these products have not been done—
11. The Genetic biologics/vaccines can shed to other people and the environment and cause unintended transfection of other organisms. This must be studied before their large scale use in the food we eat!

References

- Collins C, Lorenzen N, Collet B. DNA vaccination for finfish aquaculture. *Fish Shellfish Immunol.* 2019 Feb;85:106-125. doi: 10.1016/j.fsi.2018.07.012. Epub 2018 Jul 11. PMID: 30017931.
- Guidance for Industry Considerations for Plasmid DNA Vaccines for Infectious Disease Indications. U.S. Department of Health and Human Services Food and Drug Administration Center for Biologics Evaluation and Research November 2007. [Guidance-for-Industry--Considerations-for-Plasmid-DNA-Vaccines-for-Infectious-Disease-Indications.pdf](#)
- Gore, M. Adverse effects of gene therapy: Gene therapy can cause leukaemia: no shock, mild horror but a probe. *Gene Ther* 10, 4 (2003). <https://doi.org/10.1038/sj.gt.3301946>
- High KA. The risks of germline gene transfer. *Hastings Cent Rep.* 2003 Mar-Apr;33(2):3. PMID: 12760106. [The risks of germline gene transfer - PubMed \(nih.gov\)](#)
- Kaplan JM, Roy I. Accidental germ-line modifications through somatic cell gene therapies: some ethical considerations. *Am J Bioeth.* 2001 Fall;1(4):W13. PMID: 12862004. [Accidental germ-line modifications through somatic cell gene therapies: some ethical considerations - PubMed \(nih.gov\)](#)

- Nancy M. P. King. "Accident & Desire: Inadvertent Germline Effects in Clinical Research." *The Hastings Center Report*, vol. 33, no. 2, 2003, pp. 23–30. *JSTOR*, <https://doi.org/10.2307/3528151>.
- Romano G, Marino IR, Pentimalli F, Adamo V, Giordano A. Insertional mutagenesis and development of malignancies induced by integrating gene delivery systems: implications for the design of safer gene-based interventions in patients. *Drug News Perspect*. 2009 May;22(4):185-96. doi: 10.1358/dnp.2009.22.4.1367704. PMID: 19536363.
- Mulrone, T.E., Pöyry, T., Yam-Puc, J.C. *et al.* *N*¹-methylpseudouridylation of mRNA causes +1 ribosomal frameshifting. *Nature* (2023). <https://doi.org/10.1038/s41586-023-06800-3>