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Maryland BILL HB1422: Human Relations-Protections Against Discrimination-Genetic Procedures

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There are many reasons why individuals may wish to decline evolving genetic biologics. These must be protected in Maryland as an individual's right to have a choice as to what goes in their bodies.

1. **Many of these genetic biologics technologies are still experimental and extensive toxicology, genotoxicity, carcinogenicity and reproductive toxicology studies on these products have not been done—AND ARE NOT REQUIRED for FDA Emergency Use Authorization EUA licensure in a Public Health Emergency.**

2. **"Genetic Biologics", 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 proteins which are the target of the immune system.**

3. **Religious reasons for refusal. These genetic technologies often utilize cell lines obtained from aborted human fetuses in order to either make or test the genetic biologics. This goes against the fundamental doctrines of many religions.**

4. **These technologies can integrate into and alter human DNA which also goes against many religious doctrines.**

5. **Current genetic biologics are plagued by plasmid DNA contamination as well as bacterial endotoxin. This contamination will increase the risk of the DNA integrating into the genome in an oncogenic manner.**

6. **Integration of genetic biologic DNA into the genomic DNA of an ovarian cell line was just shown last week by genomist Kevin McKernan.**

7. **DNA plasmids which contaminate the genetic biologics have human compatible sequences allowing them to replicate inside human cells. This was not intended and means there is no "OFF" switch to antigen production.**

8. **The Lipid nanoparticle technologies (LNPs) used to cloak and transport the genetic payload in these technologies goes to every cell in the body and even crosses the blood brain barrier. They preferentially go to fatty tissues such as the liver, pancreas, endocrine glands, brain and the ovaries and testes but also target to the heart.**

9. **It has been a long known risk to pass gene therapies/genetic biologics on to progeny if the gene therapy makes it to the testes or is given to a pregnant mother. The child has no informed consent.**

10. **These genetic biologics are showing evidence of inducing immune tolerance rather than an immune reaction against the target antigen. This will create epidemics of disease is highly inoculated individuals. We must pause the use of these until this is resolved.**

11. **The Genetic biologics may shed to other people and the environment and cause unintended transfection which can lead to dire health consequences and sidelines informed consent.**

Selected References

- **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)
- **21 USC 360bbb-4b: Medical countermeasure master files (house.gov)**
- **Banoun H. mRNA: Vaccine or Gene Therapy? The Safety Regulatory Issues. Int J Mol Sci. 2023 Jun 22;24(13):10514. doi: 10.3390/ijms241310514. PMID: 37445690; PMCID: PMC10342157.**
- **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.**
- **Section 564 FD&C Act. Note that the EUA pathway should not be confused with the "Expanded Access Use" regulatory pathway which is often colloquially referred to as an "emergency use". The expanded access is an investigational pathway and is regulated in the same manner as all normal drug approvals. (21 CFR 312.310-320)**
- **21 USC 360bbb-3(k): If a product is the subject of an authorization under this section, the use of such product within the scope of the authorization shall not be considered to constitute a clinical**

investigation for purposes of section 355(i), 360b(j), or 360j(g) of this title or any other provision of this chapter or section 351 of the Public Health Service Act [42 U.S.C. 262].