Questions to stimulate curiosity, study and responses to EUA countermeasures.

1. Do you think something weird is going on with FDA oversight of the "safety" and "efficacy" of the biological products known as Covid-19 vaccines that have entered interstate commerce and human recipients in the United States?

2. Are you interested in understanding how the legal classification of the biological products known as Covid-19 vaccines relates to the FDA's regulatory functions during the "public health emergency" that was declared in January 2020?

3. Are you familiar with the difference between the "expanded access to unapproved products" program established by Congressional act in 1997, and the "Emergency Use Authorization" (EUA) program established by Congressional act in 2004?

4. Are you familiar with the legal mechanisms through which products classified as EUA "countermeasures," under the EUA program during a declared public health emergency, are subject to abrogation of and/or exemption from standard FDA legal/regulatory definitions, product classifications and consumer safety duties pertaining to most other pharmaceutical drugs, devices and biological products?

5. Are you familiar with the PREP Act [Public Readiness and Emergency Preparedness Act] "targeted liability protections for pandemic and epidemic products and security countermeasures" program established by Congressional act in 2005?

6. Are you familiar with the legal mechanisms through which products classified as EUA countermeasures and used during a declared public health emergency, and manufacturers and administrators of EUA countermeasures, are subject to abrogation and/or exemption from standard civil liability and criminal prosecution for injuries and deaths caused by use of such products?

7. Are you aware of the Vaccine Injury Compensation Program established by Congressional act in 1986, alongside the National Vaccine Program, which removed vaccine injury and death claims from civil courts to a judicial forum in which due process and evidentiary standards differ significantly from standard civil tort claims? Are you aware of the Countermeasures Injury Compensation Program modeled on the VICP, established by Congressional act in 2005?

8. Are you aware that EUA countermeasures under current PREP Act declarations can be legally adulterated, contaminated and misbranded, and that cGMP (current Good Manufacturing Practice) compliance is not enforceable for these products?

9. Are you aware that the informed consent requirements in human clinical research are not applicable (are moot) for use of EUA countermeasures?

10. Are you aware that most Covid-19 EUA countermeasure products, including injections marketed as "Covid-19 vaccines," were ordered and paid for by the Department of

Defense (DoD), via non-transparent Other Transaction Authority procurement mechanisms?

11. Are you aware that all “Covid-19 vaccines” were ordered by the DoD as “prototypes and demonstrations,” and not as medical products?

12. Are you aware of a 2018 stipulation through which the US Department of Health and Human Services (HHS) acknowledged that no public records of safety assessments exist for the biological products classified as "vaccines" and listed on the childhood immunization schedule; that HHS cannot produce safety assessments for individual products and cannot produce safety assessments for the additive and cumulative harms caused by multiple products administered simultaneously or over time?

13. Are you aware of a 2019 regulatory amendment through which HHS suspended all previously enforceable rules pertaining to independent testing, site inspections and regulatory compliance for *all* biological products and *all* biological product manufacturing facilities, including but not limited to products classified as "vaccines," and products classified as "EUA countermeasures"?