

SB 7 Request: Change the language of "COVID-19 Vaccine" to "Pandemic or Regional Disease treatment", since language specific to COVID-19 will make any legislative protections obsolete for the "next pandemic," like Marburg.

Much of the legislative health protections we rely on, i.e. FDA product safety requirements, labeling requirements, informed consent approvals, etc., become null **under the declaration of a "Public Health Emergency of International Concern"** as outlined on pg. 9 of <u>The American Domestic Bioterrorism Program</u> (ADBP) by Katherine Watt. This ADBP report is a forensic review of decades of public health federal laws and outlines the following changes in Federal statute and makes **actions that we have known to be "illegal" become "legal" under emergency declarations**. These statute changes below are under an emergency declaration and were applied during the COVID-19 pandemic and would apply to any current or future declared pandemic disease.

- The use of the EUA products marketed as Covid-19 vaccines "shall not be considered to constitute a clinical investigation," and the products are exempt from laws regulating use of investigational, experimental drugs or devices on human beings. Federal Food Drug and Cosmetics Act, 21 USC 360bbb3(k). 1997, 2004, 2005, 2013. (See Excerpts from Pfizer's Motion to Dismiss on pg. 2)
- There are no required standards for product safety, and <u>only one standard for efficacy</u>: <u>a declaration by</u> <u>the HHS Secretary that a product "may be effective."</u> Federal Food Drug and Cosmetics Act, 21 USC 360bbb-3(c)(2)(A). 1997, 2004.
- 3. There are no informed consent duties for those who administer the products (to provide risk and benefit information and obtain consent) or rights for those who receive the products (to receive risk and benefit information and give consent). 21 USC 355(i)(4), for drugs, and 21 USC 360j(g)(3), for devices. 2016.
- 4. There are **no labeling requirements** regarding the contents or ingredients in the products marketed as Covid-19 vaccines.
- There is no consumer fraud because the only legal party to the financial transactions is the government's Department of Defense as buyer of the COVID-19 vaccine as a medical countermeasure or "prototype" for \$19.50 / dose.

**REQUEST:** As seen in the Public Health Emergency Preparedness and Management bill and in <u>Text 21 USC 360bbb-</u> <u>3 – Authorization for Medical Products for Use in Emergencies</u> language contained in these statutes refers to "medical products for use in Emergencies" rather than the specific term of vaccines. And since COVID-19 disease is just one of potentially many other declared emergencies i.e. Monkey Pox, Marburg, Ebola etc., and a vaccine is just one of potentially many more Emergency Use Authorization (EUA) products we could be subjected to such as a microchip or implant medical procedure.

## NOTES:

1. 04/06/2023: Lab Advisory: CDC Issues Health Alert for Marburg Disease Outbreaks

2. Pfizer documented in the February 28, 2021, <u>CUMULATIVE ANALYSIS OF POST-AUTHORIZATION</u> <u>ADVERSE EVENT</u> pgs 30-38: **1,291 adverse events of "special interest."- 1P36 gene deletion.** 



I. WHAT WE NOW KNOW ABOUT THE PFIZER "VACCINE" agreement with the Department of Defense: Screenshots from the <u>Pfizer's 04-22-2022 Motion to Dismiss</u> (MtD) in the whistleblower case of Brook Jackson vs Ventavia clearly show that under the Other Transaction Authority (OTA) agreement framework with the Department of Defense, the agreements are "not subject to Federal Acquisition Regulation", nor subject to Good Clinical Practices or FDA regulations. The deployment of the COVID-19 "vaccine" was as a "military medical countermeasure" and NOT a normal new drug delivery as believed and as the evidence shows.

Ex. 10 at 1079.) Such agreements are executed under DoD's Other Transaction Authority

("OTA") and, as a statutory matter, are not subject to the Federal Acquisition Regulation ("FAR"),

which is the primary regulation otherwise used by Government agencies in their acquisition of

1. Pg 12 supplies and services with appropriated funds. See 10 U.S.C. § 4022(f)(2); see also NSTI, LLC v.

Compl. ¶ 135.) The SOW describes a "large scale vaccine manufacturing demonstration" that

imposes no requirements relating to Good Clinical Practices ("GCP") or related FDA regulations.

(Am. Compl., Ex. 10 at 1080.) It states explicitly that Pfizer's "clinical trials" are "out-of-scope,"

- "not related" to the agreement, and that the relevant studies were undertaken at Pfizer's expense
- 2. Pg 13

<sup>24</sup> Again, the "agreement" at issue, Pfizer's OTA agreement with DoD, specifies the number of doses the Government would buy and the price the Government would pay, but does not impose any requirements relating to Pfizer's clinical development activities, FDA regulations, or FAR. And, regardless, the Government paid the resulting invoices with actual knowledge of Relator's

3. Pg 22 allegations concerning regulatory noncompliance.

Update: March 31, 2023 – Jackson v Pfizer dismissed "if the Government pays a <u>particular</u> claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." USDC ED Texas - Beaumont / Judge Truncale

**II.** THE <u>FEDERAL LAWS</u> WHICH PROHIBIT OVERSIGHT OF HHS SECRETARY UNILATERAL PANDEMIC DECISIONS:

1. 42 USC 247d-6d(b)(7): "No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection."

2. 42 USC 247d-6d(b)(8): **Authority of state**, local and tribal governments, and individuals to manage public health emergency and medical countermeasures classification and regulation outside of **HHS/DOD control is preempted**.

3. 42 USC 247d-6d(b)(9): There is an extremely limited obligation for HHS to report to Congress on public health emergency status and medical countermeasures classifications, and **no authorization for Congress to override HHS declarations, determination, and decisions**.

## APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

**1p36** deletion syndrome; 2-Hydroxyglutaric aciduria; 5'nucleotidase increased; Acoustic neuritis; Acquired C1 inhibitor deficiency; Acquired epidermolysis bullosa; Acquired epileptic aphasia; Acute cutaneous lupus erythematosus; Acute disseminated encephalomyelitis; Acute encephalitis with refractory, repetitive partial seizures; Acute febrile neutrophilic dermatosis; Acute flaccid myelitis; Acute haemorrhagic leukoencephalitis; Acute haemorrhagic oedema of infancy; Acute kidney injury; Acute macular outer retinopathy; Acute motor axonal neuropathy; Acute motor-sensory axonal neuropathy; Acute myocardial infarction; Acute respiratory distress syndrome; Acute respiratory failure; Addison's disease; Administration site thrombosis; Administration site vasculitis; Adrenal thrombosis; Adverse event following immunisation; Ageusia; Agranulocytosis; Air embolism; Alanine aminotransferase abnormal; Alanine aminotransferase increased; Alcoholic seizure; Allergic bronchopulmonary mycosis; Allergic oedema; Alloimmune hepatitis; Alopecia areata; Alpers disease; Alveolar proteinosis; Ammonia abnormal; Ammonia increased; Amniotic cavity infection; Amygdalohippocampectomy; Amyloid arthropathy; Amyloidosis; Amyloidosis senile; Anaphylactic reaction; Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock; Anaphylactoid syndrome of pregnancy; Angioedema; Angiopathic neuropathy; Ankylosing spondylitis; Anosmia; Antiacetylcholine receptor antibody positive; Anti-actin antibody positive; Anti-aquaporin-4 antibody positive; Anti-basal ganglia antibody positive; Anti-cyclic citrullinated peptide antibody positive; Anti-epithelial antibody positive; Anti-erythrocyte antibody positive; Anti-exosome complex antibody positive; Anti-GAD antibody negative; Anti-GAD antibody positive; Anti-ganglioside antibody positive; Antigliadin antibody positive; Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive; Anti-HLA antibody test positive; Anti-IA2 antibody positive; Anti-insulin antibody increased; Anti-insulin antibody positive; Anti-insulin receptor antibody increased; Antiinsulin receptor antibody positive; Anti-interferon antibody negative; Anti-interferon antibody positive; Anti-islet cell antibody positive; Antimitochondrial antibody positive; Anti-muscle specific kinase antibody positive; Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive; Anti-neuronal antibody positive; Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis; Anti-NMDA antibody positive; Antinuclear antibody increased; Antinuclear antibody positive; Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive; Antiribosomal P antibody positive; Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive; Anti-vimentin antibody positive; Antiviral prophylaxis; Antiviral treatment; Anti-zinc transporter 8 antibody positive; Aortic embolus; Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis; Application site vasculitis; Arrhythmia; Arterial bypass occlusion; Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

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5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy; Atypical pneumonia; Aura; Autoantibody positive; Autoimmune anaemia; Autoimmune aplastic anaemia; Autoimmune arthritis; Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder; Autoimmune haemolytic anaemia; Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism; Autoimmune inner ear disease; Autoimmune lung disease; Autoimmune lymphoproliferative syndrome; Autoimmune myocarditis; Autoimmune myositis; Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis; Autoimmune pancytopenia; Autoimmune pericarditis; Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis; Autoinflammation with infantile enterocolitis; Autoinflammatory disease; Automatism epileptic; Autonomic nervous system imbalance; Autonomic seizure; Axial spondyloarthritis; Axillary vein thrombosis; Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation; Basedow's disease; Basilar artery thrombosis; Basophilopenia; B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions; Benign familial pemphigus; Benign rolandic epilepsy; Beta-2 glycoprotein antibody positive; Bickerstaff's encephalitis; Bile output abnormal; Bile output decreased; Biliary ascites; Bilirubin conjugated abnormal; Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism; Cerebral artery thrombosis; Cerebral gas embolism; Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic