NATIONAL INFORMED CONSENT EXEMPTION

Scientific Citations for National Informed Consent Exemption (NICE) Act

SECTION 2. Legislative Findings.

1. The Constitution does not permit a vaccine mandate, including a mandate by the Executive Branch imposed on federal employees as a condition to maintain the employment they need to feed themselves or their families.[i]

2. It is unconscionable for any entity to use force or coercion to compel individuals to take a vaccine without their informed consent, and even more egregiously unconscionable for a vaccine to be administered under emergency use authorization (EUA) without adequate warnings of known potential risks to that specific employee or patient.[ii] The rights of the American people to free exercise of religion, due process of law, and protection from religious discrimination, includes the fundamental right to decline vaccination and testing for infectious disease without penalty.

3. Mandating vaccines, including experimental vaccines, does not fall within any of the Executive authorities, according to article II, section 2 of the United States Constitution.[iii]

4. According to the American Heritage Medical Dictionary, informed consent is the consent by a person to undergo a medical procedure after receiving all material information regarding risks, benefits, and alternatives.[iv]

5. Vaccines in America are licensed and regulated federally.[v]

6. Product inserts for vaccines approved by the United States Food and Drug Administration (FDA) evidence that:[vi]

    a. Each vaccine on the routine vaccination schedules published by the US Centers for Disease Control and Prevention (CDC) has never been clinically evaluated in humans for its long-term potential to cause cancer, impair fertility, and mutate genes.

    b. The pivotal clinical trial relied upon by the Food and Drug Administration (FDA) for approval of each vaccine on the CDC schedule did not evaluate the safety of the vaccine (1) for at least one year after the vaccine is administered, and (2) against a control group that received (A) a truly inert placebo, or (B) another vaccine approved based on a pivotal clinical trial that included a control group that received a truly inert placebo.

7. In 2018, the United States Department of Health and Human Services (HHS) published that it has no evidence that its Secretary completed any of the 16 required vaccine safety reports, bi-annually pursuant to U.S. Code § 300aa–27(c) ("Report Within 2 years after December 22, 1987, and periodically thereafter . . .").[vii]

8. In 2018, the FDA published, "Until a vaccine is given to the general population, all potential adverse events cannot be anticipated."[viii]

9. In 2020, the National Institutes of Health (NIH) published, "The 'gold standard' for testing interventions in people is the 'randomized, placebo-controlled' clinical trial, in which volunteers are randomly assigned to a test group receiving the experimental intervention or a control group receiving a placebo (an inactive substance that looks like the drug or treatment being tested). Comparing results from the two groups suggests whether changes in the test group result from the treatment or occur by chance."[ix]

10. The field of medicine and science is advancing at a rapid pace. The IOM has reported that it can take up to 17 years for a new best practice to reach the average physician and surgeon. It is prudent to recognize doctors' discretion when applying all of their knowledge, training, expertise, and new developments in the care of their patients.[x]

11. Vaccine ingredients are commonly sourced from foreign nations.[xi]

12. America's national security is directly impacted by mandatory vaccination.[xii]

And for additional context, see also:

1. In 2016, the CDC published, "Finally, because the childhood immunization schedule is essentially a long-term exposure, occurring over 18 to 24 months, long-term adverse events may be more biologically plausible than short-term events."[xiii]

2. In 2013, The National Academy of Sciences (NAS) published, "… studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted." [xiv]

3. In 2011, the Institute of Medicine (IOM) published that it "found a paucity of information, scientific or otherwise, that addressed the risk of adverse events in association with the complete recommended immunization schedule…." [xv]

4. In 1994, the IOM evaluated vaccines for Diphtheria, Tetanus, Measles, Mumps, Polio, Hepatitis B, and Hib, and located sufficient evidence to support a causal connection between a vaccine and 12 serious injuries, including death, thrombocytopenia, and Guillain-Barré Syndrome, finding "The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meetings indicated that many parents and physicians share this concern." [xvi]

5. In 2011, the IOM evaluated vaccines for Varicella, Hepatitis B, Tetanus, Measles, Mumps, and Rubella, and located sufficient evidence to support a causal connection between a vaccine and 18 injuries, including pneumonia, meningitis, MIBE, and febrile seizures. The Institute of Medicine found the scientific literature insufficient to conclude whether or not those vaccines caused 135 other serious injuries commonly reported after their administration, including: Acute Disseminated Encephalomyelitis, Afebrile Seizures, Amyotrophic Lateral Sclerosis, Arthralgia, Autoimmune Hepatitis, Brachial Neuritis, Cerebellar Ataxia, Chronic Headache, Chronic Inflammatory Demyelinating Poly-neuropathy, Chronic Urticaria, Encephalitis, Encephalopathy, Erythema Nodosum, Fibromyalgia, Guillain-Barré Syndrome, Hearing Loss, Immune Thrombocytopenic Purpura, Infantile Spasms, Juvenile Idiopathic Arthritis, Multiple Sclerosis, Neuromyelitis Optica, Optic Neuritis, Polyarteritis Nodosa, Psoriatic Arthritis, Reactive Arthritis, Rheumatoid Arthritis, Seizures, Small Fiber Neuropathy, Stroke, Sudden Infant Death Syndrome, Systemic Lupus Erythematosus, Thrombocytopenia, and Transverse Myelitis.[xvii]

6. In 2017, the CDC published, "Inability to determine causation. VAERS reports are usually not helpful in assessing whether a vaccine actually caused the reported AEs because they lack either unique laboratory findings or other information necessary to draw such conclusions. Often multiple vaccines are administered at the same visit, making attribution of causation to a single vaccine or antigen difficult. Additionally, there is lack of an unvaccinated group for comparison in VAERS."[xviii]

7. In addition to inadequate data on short-term effects, the long-term effects of vaccination are numerically undefined because vaccines have never been studied or evaluated by the United States in comparison to a large group of fully unvaccinated persons who have never received a vaccine.[xix]

8. In 2013, the IOM acknowledged that various health comparisons of unvaccinated children to vaccinated children are scientifically possible from a large database, including data within the Vaccine Safety Datalink (VSD). The IOM published, "It is possible to make this comparison through analyses of patient information contained in large databases such as VSD…" [xx]

9. In 2021, the CDC published, "6 in 10 adults in the US have a chronic disease [and] 4 in 10 adults in the US

have two or more. [Chronic diseases are the] leading causes of death and disability and leading drivers of the Nation's $3.8 Trillion in annual healthcare costs." [xxi]

10. In 2011, a study published in Academic Pediatrics found "An estimated 43% of US children (32 million) currently have at least 1 of 20 chronic health conditions assessed, increasing to 54.1% when overweight, obesity, or being at risk for developmental delays are included; 19.2% (14.2 million) have conditions resulting in a special health care need, a 1.6 point increase since 2003."[xxii]

11. In 2014, the Pentagon confirmed that the majority of Americans aged 17 to 24 are no longer fit for military service, as approximately 71% of the 34 million 17-to-24-year-olds in the U.S. would not qualify for military service because of reasons related to health, physical appearance and educational background.[xxiii]

12. Vaccines are medical products designed to alter the natural immune system.[xxiv]

13. There are over 250 new vaccines currently in research and development according to the biopharmaceutical industry publication PhRMA.[xxv]

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i. Shen, Wen W. (April 2, 2021). State and Federal Authority to Mandate COVID-19 Vaccination. Congressional Research Service. https://crsreports.congress.gov/product/pdf/R/R46745 ("[A] direct federal mandate on individuals to receive a vaccine may be susceptible to challenge because such mandates could be construed as compelling individuals who are 'doing nothing' to engage in the commercial activity of receiving a specified health care service…. Even if a vaccine mandate falls within Congress's enumerated powers, other constitutional provisions may constrain governmental action. In the context of public health regulations, the key constraints are those grounded in federalism and the protection of individual rights.")

ii. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I-III) recognizes the patient has "the option to accept or refuse administration of the [EUA] product"; United States Food and Drug Administration (2017). Emergency Use Authorization of Medical Products and Related Authorities. Guidance Document, Docket Number FDA-2016-D-1025. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#preemption ("FDA believes that the terms and conditions of an EUA issued under section 564 preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564."); United States Food and Drug Administration (2021). Information Fact Sheet for Recipients and Caregivers About Comirnaty (COVID-19 Vaccine, mRNA) and Pfizer-Biontech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19). https://www.fda.gov/media/144414/download ("WHAT IF I DECIDE NOT TO GET COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE? Under the EUA, it is your choice to receive or not receive the vaccine. Should you decide not to receive it, it will not change your standard medical care."); Doe #1 v. Rumsfeld, 2005 U.S. Dist. LEXIS 5573 (D.D.C. Apr. 6, 2005) ("this Court issued an order permanently enjoining the military's anthrax vaccine program… This injunction, however, shall not preclude defendants from administering AVA, on a voluntary basis, pursuant to the terms of a lawful emergency use authorization ("EUA")"); United States Food and Drug Administration (2017). Emergency Use Authorization of Medical Products and Related Authorities. Guidance for Industry and Other Stakeholders. https://www.fda.gov/media/97321/download ("In an emergency, it is critical that the conditions that are part of the EUA … be strictly followed, and that no additional conditions be imposed.")

[iii] Shen, Wen W. (April 2, 2021). State and Federal Authority to Mandate COVID-19 Vaccination. Congressional Research Service. https://crsreports.congress.gov/product/pdf/R/R46745 ("Except in certain limited circumstances, including in the immigration and military contexts, no existing federal law expressly imposes vaccination requirements on the general population.")

[iv] informed consent. (n.d.) The American Heritage® Medical Dictionary. (2007). Retrieved September 3 2021 from https://medical-dictionary.thefreedictionary.com/informed+consent

[v] United States Centers for Disease Control and Prevention (2020). Vaccine Safety – Overview, History, and How the Safety Process Works. Retrieved September 3 2021 from https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html; United States Food and Drug Administration. (2018). Science and the Regulation of Biological Products. Retrieved September 3 2021 from https://www.fda.gov/about-fda/histories-product-regulation/science-and-regulation-biological-products; Baylor NW. (2016). The Regulatory Evaluation of Vaccines for Human Use. Methods Mol Biol. 2016;1404:773-787. https://pubmed.ncbi.nlm.nih.gov/27076337/

[vi] United States Food and Drug Administration (2021). Vaccines Licensed For Use In the United States. https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states. See representative example: United States Food and Drug Administration. Package Insert: Infanrix. Retrieved on September 3 2021 from https://www.fda.gov/media/75157/download (e.g., "INFANRIX has not been evaluated for carcinogenic or mutagenic potential or for impairment of fertility…. Selected adverse reactions reported [pre-licensing] from a double-blind, randomized Italian clinical efficacy trial involving 4,696 children administered INFANRIX or 4,678 children administered whole-cell DTP vaccine (DTwP) (manufactured by Connaught Laboratories, Inc.) as a 3-dose primary series are shown in Table 4…. Because these [post-licensing] reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccination.")

[vii] United States District Court, Southern District of New York. Informed Consent Action Network v. United States Department of Health and Human Services. Case 1:18-cv-03215-JMF Document 18 Filed 07/09/18.

[viii] United States Food and Drug Administration. (2018). Vaccine Product Approval Process. https://web.archive.org/web/20201112021055/http://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-product-approval-process (accessed November 2021) ("Until a vaccine is given to the general population, all potential adverse events cannot be anticipated.") See also, World Health Organization (2019). Global Vaccine Safety Summit. Marion Gruber, PhD – Director, FDA Office of Vaccines Research and Review (OVRR) and the FDA Center for Biologics Evaluation and Research (CBER). https://www.who.int/news-room/events/detail/2019/12/02/default-calendar/global-vaccine-safety-summit ("One of the additional issues that complicates safety evaluation is that if you look at, and you struggle with the length of follow-up that should be adequate in a, let's say a pre-licensure or even post-marketing study if that's even possible. And again, as you mentioned pre-licensure clinical trials may not be powered enough.")

[ix] National Institutes of Health (2020). Health Info: Placebo effect. https://www.nccih.nih.gov/health/placebo-effect.

[x] California Bus. & Prof. Code §2234.1 ("the National Institute of Medicine has reported that it can take up to 17 years for a new best practice to reach the average physician and surgeon, it is prudent to give attention to new developments not only in general medical care but in the actual treatment of specific diseases").

[xi] United States Food and Drug Administration (2018). Importing CBER-Regulated Products Into the United States. Vaccines, Blood & Biologics. https://www.fda.gov/vaccines-blood-biologics/exporting-cber-regulated-products/importing-cber-regulated-products-united-states. See also, Council of Foreign Relations (August 14, 2019). U.S. Dependence on Pharmaceutical Products From China. https://www.cfr.org/blog/us-dependence-pharmaceutical-products-china. See also, Human Vaccines (2010), China's Emerging Vaccine Industry, 2010 Jul;6(7):602-7. Epub 2010 Jul 1. https://pubmed.ncbi.nlm.nih.gov/20523120/. See also, Merck Press Release (April 16, 2013). Merck Opens New Manufacturing Facility in Hangzhou, China. https://www.merck.com/news/merck-opens-new-manufacturing-facility-in-hangzhou-china/. See also, The U.S. Government Accountability Office (2016). Report, Drug Safety: FDA Has Improved Its Foreign Drug Inspection Program, but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices. https://www.gao.gov/assets/690/681689.pdf. See also, NBC News (May 10, 2019). Tainted drugs: Ex-FDA inspector warns of dangers in U.S. meds made in China, India, May 10, 2019, https://www.nbcnews.com/health/health-news/tainted-drugs-ex-fda-inspector-warns-dangers-u-s-meds-n1002971. See also, World Health Organization (2010). Presentation by World Health Organization's Senior Adviser, Health Economist Miloud Kadder, "Global Vaccine Market Features and Trends". https://www.who.int/influenza_vaccines_plan/resources/session_10_kaddar.pdf.

[xii] United States Centers for Disease Control and Prevention. (2017). Why Global Health Security Is Essential to U.S. National Security. https://www.cdc.gov/media/releases/2017/p0921-global-health-security.html.

[xiii] Glanz, J, et al (2016) White Paper on the Study of the Safety of the Childhood. Immunization Schedule. Vaccine Safety Datalink. United States Centers for Disease Control and Prevention. https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf.

[xiv] The National Academy of Sciences (2013). The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies. Washington, DC: The National Academies Press. doi: 10.17226/13563. https://download.nap.edu/cart/download.cgi?record_id=13563&file=1-16.

[xv] The National Academy of Sciences (2013). The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies. Washington, DC: The National Academies Press. doi: 10.17226/13563. https://download.nap.edu/cart/download.cgi?record_id=13563&file=59-74.

[xvi] Institute of Medicine (1994). Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality. Washington, DC: The National Academies Press. https://doi.org/10.17226/2138.

[xvii] Institute of Medicine (2012). Adverse effects of vaccines: Evidence and causality. Washington, DC: The National Academies Press. https://www.nap.edu/read/13164/chapter/2#3.

[xviii] Miller E, et al. (2017). Chapter 21: Surveillance for Adverse Events Following Immunization Using the Vaccine Adverse Event Reporting System. CDC: Manual for the Surveillance of Vaccine-Preventable Diseases. https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html.

[xix] See notes xiii, xiv, and xv above.

[xx] See note xiv above.

[xxi] United States Centers for Disease Control and Prevention (2021). Chronic Diseases in America. National Center for Chronic Disease Prevention and Health Promotion. https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm.

[xxii] Bethell et al. (2011). A national and state profile of leading health problems and health care quality for US children: key insurance disparities and across-state variations. Academic Pediatrics 11(3 Suppl):S22-S33.

https://doi.org/10.1016/j.acap.2010.08.011.

[xxiii] Feeny, N. (2014). Pentagon: 7 in 10 Youths Would Fail to Qualify for Military Service. Time Magazine. https://time.com/2938158/youth-fail-to-qualify-military-service/.

[xxiv] National Institute of Allergy and Infectious Diseases. (2019). Vaccine Types. https://www.niaid.nih.gov/research/vaccine-types.

[xxv] PhRMA (July 21, 2020). Report: Medicines in Development for Infectious Diseases 2020 Report. https://phrma.org/resource-center/Topics/Report/Medicines-in-Development-for-Infectious-Diseases-2020-Report; PhRMA. (2016). New report highlights more than 250 vaccines in development. https://catalyst.phrma.org/new-report-highlights-more-than-250-vaccines-in-development.