AFLDS WHITE PAPER: CIVIL LIBERTIES SURROUNDING MEDICAL EXPERIMENTATION

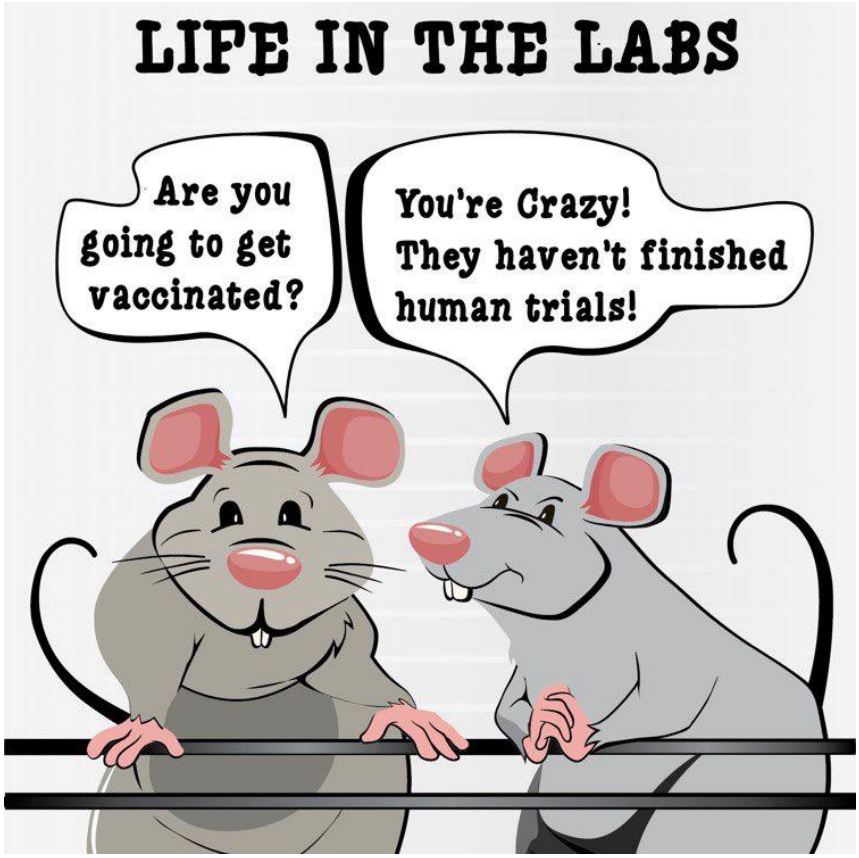
THE CIVIL LIBERTIES & HUMAN RIGHTS IMPLICATIONS OF MANDATING COVID-19 VACCINE CANDIDATES

Civil Liberties & Human Rights Issues Surrounding the COVID-19 Vaccine Candidates

For many decades it has been illegal and unethical to mandate or coerce any medical treatment. Virtually all countries, NGOs, organizations, policy leaders, and physicians adhere to this principle, including the USA, the European Union, United Nations and the World Health Organization.

Quite simply, by international law, no person can ever be coerced to take an experimental treatment.

Unfortunately, AFLDS is aware of many people who have already been fired for refusing to take what is currently an experimental medication. This paper addresses this issue.



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The Experimental COVID-19 Vaccines

The Pfizer, Moderna, AstraZeneca and Johnson & Johnson products are not approved by the FDA. Because they are only months old, with extremely limited safety and efficacy testing, the FDA has properly classified them as experimental. The soonest the Moderna and Pfizer/BioNTech experimental vaccines could be considered by FDA for full licensure (in adults only) is when the trials are expected to conclude, on October 27, 2022[1] and January 31, 2023[2], respectively.

Emergency Use Authorization vs. FDA Approval

An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. Under an EUA, FDA may allow the use of unapproved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives.[3] Current use of any of these four agents is authorized under an Emergency Use Authorization (EUA).[4] Being approved under an Emergency Use Authorization means "the products are investigational and experimental" only,[5] their investigational studies have not been completed, and they are only permitted to be approved because there is no FDA approved alternative.

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[1] https://clinicaltrials.gov/ct2/show/NCT04470427

[2] https://clinicaltrials.gov/ct2/show/NCT04368728

[3] https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained

[4] https://www.fda.gov/media/144414/download (and my two pdfs)

[5]https://ca.childrenshealthdefense.org/home-page/childrens-health-defense-california-chapter-sends-letter-to-all-california-superintendents-regarding-medical-ethics-emergency-use-products-voluntary-testing-vaccine-safety/

Informed Consent of Emergency Use Authorization Products

Since an Emergency Use Authorization (EUA) means the products are investigational and experimental only, products approved for emergency use are prohibited from being mandated by federal law, and an individual must consent to the use of the experimental product. An EUA is very specific: "…individuals to whom the product is administered are informed … of the option to accept or refuse the product …"[6]

21 U.S.C. §360bbb-3 "Authorization for medical products for use in emergencies"

- (e) (conditions of authorization)
- (1) unapproved product
- (A) required conditions
- (ii) appropriate conditions designed to ensure that individuals to whom the product is administered are informed
- (III) of the option to accept or refuse administration of the product

1. "The FDA has an obligation to ensure that recipients of the vaccine under an EUA are informed, to the extent practicable under the applicable circumstances, that FDA has authorized the emergency use of the vaccine, of the known and potential benefits and risks, the extent to which such benefits and risks are unknown, that they have the option to accept or refuse the vaccine, and of any available alternatives to the product."[7]

At the regular August 2020 CDC Advisory Committee on Immunization Practices (ACIP) weekly meeting held at the CDC in Atlanta Georgia, the CDC-ACIP Executive Secretary Amanda Cohn, MD stated:[8]

> "I just wanted to add that, just wanted to remind everybody, that under an Emergency Use Authorization, an EUA, *vaccines are not allowed to be mandatory*. So, early in this vaccination phase, individuals will have to be consented and they won't be able to be mandated." (Emphasis added)

[6] https://www.law.cornell.edu/uscode/text/21/360bbb-3

[7] https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws

[8] https://www.youtube.com/watch?v=p0zCEiGohJs&list=PLvrp9iOILTQb6D9e1YZWpbUvzfptNMKx2&index=43. Minute 1:14:40

Pharmaceutical Companies are Shielded from Liability

For more than 30 years, pharmaceutical companies have been shielded from liability for virtually all vaccine inoculations. In that time the number of vaccines has risen dramatically - to include 72 dosages of vaccines. In contrast, in the 1980's, children took two types of shots: dtp - combination tetanus and mmr - combination measles. The pharmaceutical companies faced expensive liability for injuries to children caused by their vaccines, and unfortunately instead of creating safer vaccines, Congress passed the National Childhood Vaccine Injury Act that just eliminated pharmaceutical liability for vaccines.[9] This Act means vaccine manufacturers effectively have complete immunity when a person is injured or killed by a vaccine. Over $4 billion has been paid out for vaccine injuries and deaths even though HHS estimates less than 1% of adverse events are even reported. Mandating any such procedure involving a company that is shielded from liability is unethical.

Businesses are Not Shielded from Liability with Experimental Agents

Employers are not shielded from liability like pharmaceutical companies when it comes to an experimental agent. In 2005, Congress enacted the PREP Act. The PREP Act authorizes the Secretary of the U.S. Department of Health and Human Services to issue a PREP Act declaration in response to a public health emergency. "On March 10, 2020 the Secretary of HHS made a public health emergency declaration for COVID-19, which makes the PREP Act's protections applicable to the COVID-19 pandemic."[10] A PREP Act declaration provides immunity from tort liability claims (except willful misconduct) to individuals or organizations involved in the manufacture, distribution, or dispensing of medical countermeasures. Although pharmaceutical companies are not liable (unless willful misconduct), the PREP Act does not shield ***employers or businesses*** as "covered persons" and ***should they attempt to mandate vaccination, they may be liable for resulting harm.***" The Covid-19 vaccines are emergency use products, and as such, as not fully licensed, the law is clear: States may not mandate the vaccines, and private entities may do so only at the peril of violating federal law.[11]

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[9] https://www.nap.edu/read/2138/chapter2

[10] The Public Readiness and Preparedness Act (PREP): What you need to know - Minnesota Dept. of Health (state.mn.us)

[11] https://childrenshealthdefense.org/defender/under-federal-law-can-your-employer-make-you-get-covid-vaccine/

Informed Consent: History

It has been universally accepted for decades that fully-informed consent of the individual in medical treatments and experimentation is absolutely inviolate. The roots of informed consent and medical ethics arose from the Nuremberg Code in the 1940's and the World Medical Association Declaration of Helsinki in 1964. It grew out of the Nuremberg Germany Trials after WWII, led by the United States, Great Britain, France and the USSR. In the "Doctors' Trial," some of the > 38,000 German physicians who carried out unethical medical programs in which human beings were forced or coerced to comply with medical experiments, were tried. The Nuremberg Code became the basis for all modern medical ethics laws and global human rights, including informed consent laws. It is considered the most important document in the history of medical ethics. It was reprinted in its entirety in the New England Journal of Medicine on its 50th Anniversary and included on the last page herein.[12]

Nuremberg and Helsinki principles became widely accepted throughout the entire world, including by the World Health Organization (WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO). These principles are stated in Article 7 of the United Nations International Covenant on Civil and Political Rights (1966)[13] and in the Council for International Organizations of Medical Sciences - an international consortium has the CIOMS Ethical Guidelines for Biomedical Research.[14] In addition to Nuremberg and Helsinki, the United States created a National Commission which published the "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" which became known as the Belmont Report and which was ultimately codified into federal law by the Department of Health and Human Services Title 45 CFR part 46. Fourteen other federal agencies joined HHS in this Code and it is used in all Institutional Review Boards by hospitals, clinics and medical journals.[15] Virtually all states have similar regulations, referenced here one example is California.[16]

In short, it is universally established by all reputable governments, NGOs, organizations, policy leaders, and physicians for many decades, that it is absolutely forbidden to coerce or influence, let alone force, any human being to take any experimental medical treatment and that fully informed consent is absolutely mandatory.

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[12] https://www.nejm.org/doi/full/10.1056/nejm199711133372006

[13] http://hrlibrary.umn.edu/instree/b3ccpr.htm

[14] https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

[15] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/45-cfr-46/index.html

[16] http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=24172.&lawCode=HSC

The Nuremberg Code Rule 1: Failure to Obtain Informed Consent

The foundational premise of medical ethics is found in the beginning of the Nuremberg Code which defines informed consent in great detail. The Nuremberg Code spends so much time on informed consent because scientists well know that it is far too easy for a scientist or physician to lead or mislead, inform or misinform, educate or obfuscate, most laypersons into consenting, per the doctor's preference. This can be for a malevolent reason or just a matter of limited time, information, resources. But it is precisely because the temptation to not inform patients is universal across all times and places, that The Nuremberg Code places an enormous emphasis on obtaining it and requires that there is:

- no element of force/fraud/deceit/duress/overreaching/coercion/constraint
- sufficient knowledge and comprehension … to make an understanding and enlightened decision

Informed consent is very obviously not happening in relation to these COVID-19 vaccine candidates. For example, people assume a vaccine reduces: transmission of the virus, reduction in hospitalizations, reduction in death, but the COVID-19 experimental vaccines are not known to do that. Informed consent means people must be told that:[17]

1. They are not receiving an FDA-approved vaccine but rather are being given an experimental agent on conditional approval through an EUA.
2. The pharmaceutical companies do not claim that the vaccine candidates prevents transmission of the virus. *Newsweek,* asking Dr. Anthony Fauci, head of the U.S. National Institute of Allergy and Infectious Diseases, whether people who get a Covid-19 vaccine could still pass on SARS-CoV-2 to others: "That's a good question. We don't know that yet. We do not know if the vaccines that prevent clinical disease also prevent infection."[18] The WHO: "I don't believe we have the evidence on any of the vaccines to be confident that it's going to prevent people from actually getting the infection and therefore being able to pass it on.[19] The FDA website regarding Pfizer: "the scientific community does not yet know if the Pfizer-BioNTech COVID-19 Vaccine will reduce such transmission."[20]
3. The pharmaceutical companies do not claim that the vaccine candidates reduce hospitalization or death rates. In fact the vaccine protocols did not measure if the vaccine prevented serious disease or death. The definition of success was whether

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[17] https://www.forbes.com/sites/williamhaseltine/2020/09/23/covid-19-vaccine-protocols-reveal-that-trials-are-designed-to-succeed/?sh=758ed57b5247

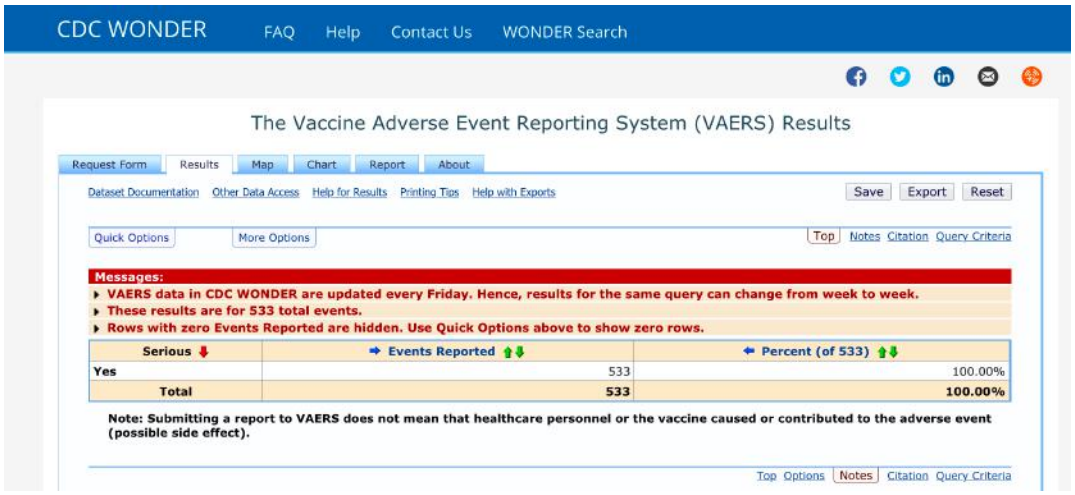
[18] https://www.newsweek.com/coronavirus-anthony-fauci-covid-vaccine-passport-mandatory-vaccinations-travel-1558303

[19] https://www.who.int/multi-media/details/who-daily-press-conference-on-novel-coronavirus---28-december-2020

[20] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/pfizer-biontech-covid-19-vaccine-frequently-asked-questions#60062795cadfd

they prevented mild-moderate disease (e.g. cough, headache)![21] The data on whether or not they reduce hospitalization or death is still going to have to be gathered and that will take months to years.

4. These experimental vaccine candidates were called effective based upon extraordinarily tiny numbers of persons who got mildly symptomatic in the placebo vs. treatment group. Moderna: 53 people, Pfizer 32 people, Johnson & Johnson 77 people.[22] The vaccine trials are not comparing the rates of transmission of the virus or rates of hospitalization or death. The vaccines were approved for emergency use based only upon less symptoms.
5. The VAERS (Vaccine Adverse Events Reporting System database maintained by the government shows 533 deaths temporally related to receiving the experimental COVID shot out of ~35 million vs. 23 deaths temporally related to receiving the influenza shot out of ~150 million. This is a 100x death rate.[23] The CDC also set up a *non-public* database to report COVID-19 injuries and death and it is unknown what that number is. Reporting to a non-public database violates the purpose of VAERS and the public has a right to know the true adverse events numbers.



[21] https://www.forbes.com/sites/williamhaseltine/2020/09/23/covid-19-vaccine-protocols-reveal-that-trials-are-designed-to-succeed/amp/

[22] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/pfizer-biontech-covid-19-vaccine-frequently-asked-questions#60062795cacfe To date, only a small number of severe cases have occurred during the study, which makes it difficult to evaluate whether the vaccine reduces the severity of COVID-19.

[23] VAERS Database search "COVID" February 14, 2021 by author.

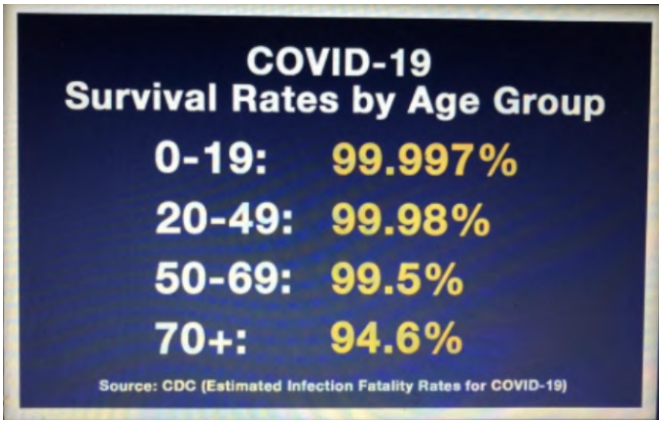
The Nuremberg Code Rule 1: The Doctor/Nurse Is Failing to Prove Informed Consent

> "The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity."

Even the most cursory conversation with physicians and nurses who are tasked with doing the inoculations reveals almost universal ignorance of the facts delineated above. The professional and fiduciary obligation to be informed, so as to be able to adequately obtain informed consent by sharing one's superior knowledge, cannot be delegated to anyone else. This degree of willful ignorance exceeds ordinary negligence and is gross negligence. In other words, it goes beyond malpractice and into the criminal category. The facts delineated above must be conveyed by the doctor or the nurse, and when they are not, the doctor or nurse is grossly negligent.

The Nuremberg Code Rule 6: Unacceptable Risk of Death

"The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment."



The most enduring myth regarding COVID-19 is that this is a highly lethal infection. It is not. The data is unequivocal. COVID-19 kills very rarely and almost all deaths are in the medically fragile. Nearly 80% of all coronavirus-related deaths in the US through November 28, 2020 have occurred in adults 65 years of age and older and only 6% of the deaths had COVID-19 as the only cause mentioned. On average, there were 2.6 additional conditions or causes per death.[24]

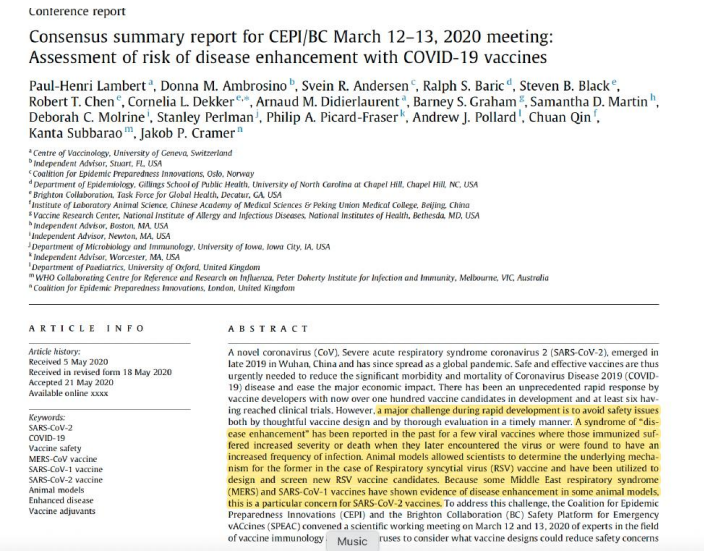
Under age 50 the chance of surviving COVID-19 approaches 100% even without treatment and age 50-70, the chance of surviving even without treatment is 99.5%. In comparison, per VAERS, the government run vaccine reporting system, which is well documented to capture less than 1% of actual adverse events,[25] within six weeks of the trials of the experimental vaccines, there have been >500 deaths and >11,000 adverse events.[26] This is out of ~30 million doses. In comparison, the influenza death

[24] https://www.cdc.gov/nchs/nvss/vsrr/COVID_weekly/index.htm#Comorbidities

[25] https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

[26] https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=CAT&EVENTS=ON&VAX=COVID19

rate in VAERS, has had 19 deaths out of ~150 million doses.[27] In other words, receiving the COVID-19 vaccine is associated with an 80x death rate than receiving the influenza vaccine! While VAERS is not proof of the cause of death, the VAERS numbers are highly alarming, especially because preliminary reports show that many of the deaths sound exactly like what scientists have warned about.



Conference report

Consensus summary report for CEPI/BC March 12–13, 2020 meeting: Assessment of risk of disease enhancement with COVID-19 vaccines

Paul-Henri Lambert [a], Donna M. Ambrosino [b], Svein R. Andersen [c], Ralph S. Baric [d], Steven B. Black [e], Robert T. Chen [c], Cornelia L. Dekker [e,*], Arnaud M. Didierlaurent [a], Barney S. Graham [g], Samantha D. Martin [h], Deborah C. Molrine [i], Stanley Perlman [j], Philip A. Picard-Fraser [k], Andrew J. Pollard [l], Chuan Qin [f], Kanta Subbarao [m], Jakob P. Cramer [n]

[a] Centre of Vaccinology, University of Geneva, Switzerland
[b] Independent Advisor, Stuart, FL, USA
[c] Coalition for Epidemic Preparedness Innovations, Oslo, Norway
[d] Department of Epidemiology, Gillings School of Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA
[e] Brighton Collaboration, Task Force for Global Health, Decatur, GA, USA
[f] Institute of Laboratory Animal Science, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China
[g] Vaccine Research Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD, USA
[h] Independent Advisor, Boston, MA, USA
[i] Independent Advisor, Newton, MA, USA
[j] Department of Microbiology and Immunology, University of Iowa, Iowa City, IA, USA
[k] Independent Advisor, Worcester, MA, USA
[l] Department of Paediatrics, University of Oxford, United Kingdom
[m] WHO Collaborating Centre for Reference and Research on Influenza, Peter Doherty Institute for Infection and Immunity, Melbourne, VIC, Australia
[n] Coalition for Epidemic Preparedness Innovations, London, United Kingdom

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ABSTRACT

A novel coronavirus (CoV), Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), emerged in late 2019 in Wuhan, China and has since spread as a global pandemic. Safe and effective vaccines are thus urgently needed to reduce the significant morbidity and mortality of Coronavirus Disease 2019 (COVID-19) disease and ease the major economic impact. There has been an unprecedented rapid response by vaccine developers with now over one hundred vaccine candidates in development and at least six having reached clinical trials. However, a major challenge during rapid development is to avoid safety issues both by thoughtful vaccine design and by thorough evaluation in a timely manner. A syndrome of "disease enhancement" has been reported in the past for a few viral vaccines where those immunized suffered increased severity or death when they later encountered the virus or were found to have an increased frequency of infection. Animal models allowed scientists to determine the underlying mechanism for the former in the case of Respiratory syncytial virus (RSV) vaccine and have been utilized to design and screen new RSV vaccine candidates. Because some Middle East respiratory syndrome (MERS) and SARS-CoV-1 vaccines have shown evidence of disease enhancement in some animal models, this is a particular concern for SARS-CoV-2 vaccines. To address this challenge, the Coalition for Epidemic Preparedness Innovations (CEPI) and the Brighton Collaboration (BC) Safety Platform for Emergency vACcines (SPEAC) convened a scientific working meeting on March 12 and 13, 2020 of experts in the field of vaccine immunology [illegible] ruses to consider what vaccine designs could reduce safety concerns

Music

The known complications of prior coronavirus vaccine attempts include the highly lethal Antibody Dependent Enhancement (ADE) which results in the recipient's death. This paradoxical reaction has been seen repeatedly with prior coronavirus and similar virus vaccine trials.[28] [29] ADE has its own Wikipedia page which says:[30] "It has been observed mainly with positive-strand RNA viruses. Among them are … Dengue Virus, Yellow Fever Virus, Zika Virus, Coronaviruses." This is not "fringe" but is a well-known, serious concern raised early by scientists in the pandemic.[31]

The possibility of these experimental vaccines causing ADE is so concerning, that many scientists already agree the risk is much too high to release these experimental vaccines to the public at large. The known and potential benefits of the experimental vaccines, do not "outweigh the known and potential risks of the experimental vaccines."[32] This is in direct opposition to the criteria for issuance of authorization for EUA.

On December 1, 2020, the ex-Pfizer head of respiratory research Dr. Michael Yeadon and the lung specialist and former head of the public health department Dr. Wolfgang Wodarg filed an application with the European Medicine Agency responsible for approving drugs in the European Union, for the immediate suspension of all SARS CoV 2 vaccine studies, in particular the BioNtech/Pfizer study on BNT162b.[33] [34] One of the

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[27] https://www.medalerts.org/vaersdb/findfield.php

[28] https://www.sciencemag.org/news/2019/04/dengue-vaccine-fiasco-leads-criminal-charges-researcher-philippines

[29] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3335060/

[30] https://en.wikipedia.org/wiki/Antibody-dependent_enhancement

[31] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7247514/pdf/main.pdf

[32] 21 U.S. Code 360bbb-3(C)(2)(B)

[33] https://2020news.de/en/dr-wodarg-and-dr-yeadon-request-a-stop-of-all-corona-vaccination-studies-and-call-for-co-signing-the-petition/?fbclid=IwAR3yoj0SCIK8WaaS0-w1vIoi-g4qNYydTxT3aK01NJDwHut3jWpygtnnbNY

[34] https://2020news.de/wp-content/uploads/2020/12/Wodarg_Yeadon_EMA_Petition_Pfizer_Trial_FINAL_01DEC2020_EN_unsigned_with_Exhibits.pdf

biggest reasons they cited was the formation of so-called “non-neutralizing antibodies” can lead to an exaggerated immune reaction, especially when the test person is confronted with the real, “wild” virus after vaccination.

This so-called antibody-dependent enhancement, ADE, has long been known from experiments with corona vaccines in cats, for example. In the course of these studies all cats that initially tolerated the vaccination well, died after catching the wild virus. Often the deadly problems are not seen until the (late stage) animal studies. Because the SARS-CoV-2 vaccine attempts are so new, there are no published, peer-reviewed animal studies on their long term safety.[35]

The first two Covid-19 experimental vaccines are based on new technology, messenger RNA, which has never been approved for any vaccine, or even entered final-stage trials until now, so there’s no peer-reviewed published human data to compare how mRNA vaccine technology compares to older technologies. In addition, just by the mere fact that these trials were launched within the past several months, we cannot know of any long-term effects or interactions with other viruses such as influenza or the seasonal cold.

Considering that the two frontrunners take an entirely novel approach with mRNA, and considering that the problem of Antibody Dependent Enhancement has not been excluded and that it is a well-established reason why there has never been an FDA-approved coronavirus vaccine, it violates Precept 6 of the Nuremberg Code, and all universally accepted codes of medical ethics, to offer the experimental COVID-19 vaccine to persons at exceedingly low risk of death.

[35] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-data-preclinical-studies-mrna We learn about these studies only from the company itself.

The Nuremberg Code Rule 6: Unacceptable Risk of Infertility

There is preliminary evidence that the concern of infertility should be taken much more seriously. There have been at least 15 mid-pregnancy reported miscarriages following taking the experimental vaccine in the first seven weeks.[36] It is unknown how many pregnant women took the experimental vaccine but 15 mid-pregnancy failures is alarming because it was not known to be taken by many pregnant women.

The mechanism of action of the experimental mRNA vaccines includes a possible auto-immune rejection of the placenta. In layman's terms, the vaccine may permanently interfere with a woman's ability to maintain a pregnancy. The vaccine companies themselves acknowledge the possibility of ill effects on a pregnancy on the vaccine bottle, which says the following: "it is unknown whether COVID-19 mRNA VaccineBNT162b2 has an impact on fertility. And women of childbearing age are advised to avoid pregnancy for at least two months after their second dose."[37]

We already have suggestions of where serious problems will arise, based upon early data and mechanism of action. There is evidence to support that the vaccine could cause permanent auto-immune rejection of the placenta.[38][39]

Placental inflammation resulting in stillbirths mid-pregnancy (second trimester) is seen with COVID-19 and with other similar coronaviruses. The way the experimental vaccines work, it is concerning that that deleterious effect on the placenta, which in the wild only lasts as long as the acute illness, would instead be lifelong. It is pure arrogance to assume we know all we need to know about something as unique and multi-factorial as becoming, and staying, pregnant. Consider: "The syncytiotrophoblast is the outermost layer of the placenta, the part that is pressed against the uterus. It's literally a layer of cells that have fused together, forming a wall….This wall of cells keeps mom and baby working in harmony and not killing each other. There's no other structure like this anywhere else in the body."[40]

There is a case report of a woman with a normally developing pregnancy who lost the otherwise healthy baby at five months during acute COVID-19. The mother's side of the placenta, the synctiotrophoblast, was very inflamed. This "infection of the maternal side of the placenta inducing acute or chronic placental insufficiency resulting in miscarriage or fetal growth restriction was observed in 40% of pregnant women with

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[36] https://twitter.com/drsimonegold/status/1358902079595577344?s=10. Author VAERS database search February 10, 2021

[37] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/941452/Information_for_healthcare_professionals.pdf

[38] https://2020news.de/en/dr-wodarg-and-dr-yeadon-request-a-stop-of-all-corona-vaccination-studies-and-call-for-co-signing-the-petition/?fbclid=IwAR3yoj0SCIK8WaaS0-w1vIoi-g4qNYydTxT3aK01NJDwHut3jWpygtnnbNY

[39] https://2020news.de/wp-content/uploads/2020/12/Wodarg_Yeadon_EMA_Petition_Pfizer_Trial_FINAL_01DEC2020_EN_unsigned_with_Exhibits.pdf

[40] https://whyy.org/segments/the-placenta-went-viral-and-protomammals-were-born/

similar coronaviruses"[41] Thus far SARS-Co-V-2 appears to be similar.[42] This issue has not been studied despite saying that "Additional studies of pregnant women with COVID-19 is warranted to determine if SARS-CoV-2 can cause similar adverse outcomes."

The mRNA vaccines may instigate a similar reaction as the virus. There is a component in the vaccine that could cause this same auto-immune rejection of the placenta but indefinitely. In layman's terms: getting COVID-19 has been associated with a high risk of mid-pregnancy miscarriage because the placenta fails – but the vaccine may do the exact same thing – but not for just the few weeks of being sick – but forever. Meaning repeated pregnancies would keep failing ~ mid-pregnancy. It is completely reckless to give this vaccine to millions of people who would otherwise all be expected to recover, until we know the answer to that question. It must be absolutely ruled out that a vaccine against SARS-CoV-2 could trigger an immune reaction against syncytin-1, as otherwise infertility of indefinite duration could result in vaccinated women.[43] [44]

Because the effects on fertility (specifically syncytin-1 and the syncytiotrophoblast) are unknown while the odds of surviving SARS-CoV-2 in this age group are well known to be nearly 100%, it is unethical to offer an experimental vaccine to persons who want to have children.

XI. Several vaccine candidates are expected to induce the formation of humoral antibodies against spike proteins of SARS-CoV-2. Syncytin-1 (see Gallaher, B., "Response to nCoV2019 Against Backdrop of Endogenous Retroviruses" - http://virological.org/t/response-to-ncov2019-against-backdrop-of-endogenous-retroviruses/396), which is derived from human endogenous retroviruses (HERV) and is responsible for the development of a placenta in mammals and humans and is therefore an essential prerequisite for a successful pregnancy, is also found in homologous form in the spike proteins of SARS viruses. There is no indication whether antibodies against spike proteins of SARS viruses would also act like anti-Syncytin-1 antibodies. However, if this were to be the case this would then also prevent the formation of a placenta which would result in vaccinated women essentially becoming infertile. To my knowledge, Pfizer/BioNTech has yet to release any samples of written materials provided to patients, so it is unclear what, if any, information regarding (potential) fertility-specific risks caused by antibodies is included.

According to section 10.4.2 of the Pfizer/BioNTech trial protocol, a woman of childbearing potential (WOCBP) is eligible to participate if she is not pregnant or breastfeeding, and is using an acceptable contraceptive method as described in the trial protocol during the intervention period (for a minimum of 28 days after the last dose of study intervention).

This means that it could take a relatively long time before a noticeable number of cases of post-vaccination infertility could be observed.

[41] https://jamanetwork.com/journals/jama/fullarticle/2765616

[42] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30311-1/fulltext

[43] https://2020news.de/en/dr-wodarg-and-dr-yeadon-request-a-stop-of-all-corona-vaccination-studies-and-call-for-co-signing-the-petition/?fbclid=IwAR3yoj0SCIK8WaaS0-w1vIoi-g4qNYydTxT3aK01NJDwHut3jWpygtnnbNY

[44] https://2020news.de/wp-content/uploads/2020/12/Wodarg_Yeadon_EMA_Petition_Pfizer_Trial_FINAL_01DEC2020_EN_unsigned_with_Exhibits.pdf

The Nuremberg Code in its Entirety:[45]

Innumerable Laws, Codes, Regulations all across the world, including the United States and Europe and South America, rely on the following ten principles.

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

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[45] https://www.nejm.org/doi/full/10.1056/nejm199711133372006

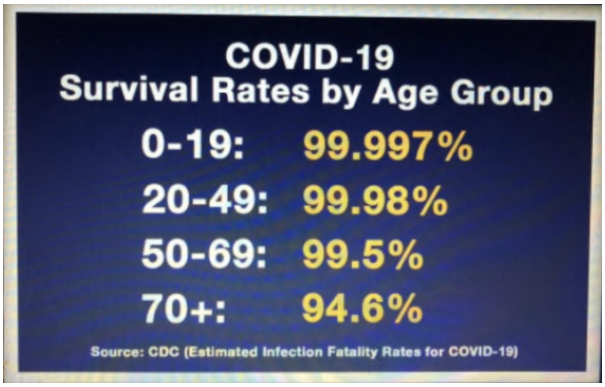
[Significant portions of the following are taken from: Am J Public Health. 2005 April; 95(4): 581–59, *Jacobson v Massachusetts*: It's Not Your Great-Great-Grandfather's Public Health Law Wendy K. Mariner, JD, LLM, MPH, George J. Annas, JD, MPH, and Leonard H. Glantz, JD]

Introduction to SCOTUS Law Regarding Mandatory Vaccinations

The landmark SCOTUS decision on the police power to force vaccinations was decided in Jacobson concerning the deadly smallpox virus. The board of health ordered all adults to be vaccinated or pay a $5 fine. In 1905 the SCOTUS held that the vaccination law applied when it was necessary for the public health, if the Board of Health did not act arbitrarily, and the vaccination was reasonable. The SCOTUS found two possible justifications in restricting individual liberty to mandate vaccination:

- under the pressure of great dangers to the safety of the general public
- state should use means that have a real or substantial relation to their goal

Jacobson is relevant but not determinative on the COVID-19 vaccine situation for four reasons.



1. Jacobson ruled on a deadly threat. Smallpox is a deadly, contagious virus with no treatment, that killed the young and old, healthy and infirm. SARS-CoV-2 has a vanishingly low rate of death, mainly in the untreated frail elderly.

2. Jacobson mandated an approved medication, not an experimental treatment. The smallpox vaccine had been developed more than 100 years earlier for a virus that had been killing millions for centuries.[46]

3. Since Jacobson, protection of individual liberty has drastically broadened.

4. Jacobson held that if a person did not comply they must forfeit $5 (~$150 today).

The overarching and foundational reason Jacobson is not determinative in the current pandemic, is that SARS-CoV-2 is not lethal nor contagious nor untreatable like smallpox. The CDC numbers listed are for untreated persons. There are now hundreds of studies and thousands of physicians who have attested in scientific papers and under oath in Congress that there is extremely effective early treatment that saves nearly 100%. There is simply no government interest, no public policy, that outweighs a person's right to bodily integrity when there is no public threat.

In addition, Jacobson is non dispositive because the vaccine candidates are still in investigational stages only. Jacobson is predicated upon vaccines being FDA approved, which they are not. Currently the vaccine candidates are in investigational stages only. The trials are expected to conclude on October 27, 2022 for Moderna[47] and January 31, 2023 for Pfizer.[48]

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[46] https://www.historyofvaccines.org/timeline#EVT_1

[47] https://clinicaltrials.gov/ct2/show/NCT04470427

[48] https://clinicaltrials.gov/ct2/show/NCT04368728

21 U.S.C. §360bbb-3 codifies[49] the absolute right for all people to refuse experimental treatments and this right was affirmed by the CDC in August 2020.[50] Federal Law HHS Title 45 CFR part 46 and fourteen other federal agencies and virtually all Institutional Review Boards prohibit mandating experimental treatments.[51] Virtually all states have similar regulations. All of this jurisprudence protecting individual liberty against mandated experimental therapies has arisen long after Jacobson but has now been established USA law for decades.

For this reason, experimental vaccines can never be mandated, but this paper continues with a fuller explanation of all the reasons experimental or fully licensed vaccines for SARS-CoV-2 can never be mandated: scientific, Constitutional, legislative, international law.

Summary of the Law Since Jacobson

Both the law and medicine have changed since Jacobson, including: infectious diseases were the leading cause of death, there was no FDA, antibiotics were forty (40) years into the future, and there was no universally accepted doctrine of Informed Consent. People with mental illness were shut away in institutions, contraception was a crime, interracial marriage was a crime, women did not vote, and Jim Crow laws were still in effect.[52] For comparison's sake, consider that more than twenty years *after* Jacobson, the SCOTUS upheld a Virginia law that authorized the involuntary sterilization of "feeble-minded" persons who were institutionalized.[53] "The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes." This type of reasoning is no longer accepted. Over many decades the SCOTUS has been steadily moving away from this type of reasoning.

The Bill of Rights exists as a bulwark to forbid majority tyranny on matters of fundamental importance. Many social changes have led the SCOTUS to broaden the protection of individual liberty. WWII and Naziism led to the Nuremberg Code and informed consent, the civil rights movement of the 1950's struck down state-imposed school segregation, and Roe vs. Wade found a right to bodily privacy that was so important it overruled developing human life. The Court created an explicit hierarchy of rights and tests for determining whether laws can restrict constitutionally protected rights. The most important rights, deemed "fundamental" were subjected to "strict scrutiny" and include: freedom of speech and association, voting, but also decisions about marriage[54][55], contraception[56][57], procreation[58], family relationships[59], child rearing and education. (This is in contrast to the "rational basis" test which is applied to laws that only restrict non fundamental rights, which need only be "rationally related" to any "legitimate state interest.")

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[49] https://www.law.cornell.edu/uscode/text/21/360bbb-3

[50] https://www.youtube.com/watch?v=p0zCEiGohJs&list=PLvrp9iOILTQb6D9e1YZWpbUvzfptNMKx2&index=43. Minute 1:14:40

[51] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/45-cfr-46/index.html

[52] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1449224/

[53] *Buck v Bell*, 274 US 200 (1927)

[54] *Zablocki v Redhail*, 434 US 374 (1978)

[55] Loving v Virginia, 388 US 1 (1967)

[56] Carey v Population Services Intl, 431 US 678 (1977)

[57] Griswold v Connecticut, 381 US 479 (1965)

[58] *Roe v Wade*, 410 US 113 (1973)

[59] *Lawrence v Texas*, 539 US 558 (2003)

If a right is fundamental and adjudicated under strict scrutiny, the law must be as narrowly tailored as possible. These mandated vaccines clearly abridge a fundamental right to bodily integrity and reproduction, so the question is if mass inoculation is the most narrowly tailored solution? The answer is clearly no as the experimental vaccines are approved on the basis of symptom reduction *only,* meaning they benefit the *recipient*, not definitely reduce the risk to *others.* The stated public policy reason to abridge the fundamental right to bodily integrity (via forced vaccination) is is the greater social welfare, not the individual's own welfare. It is well settled in American jurisprudence that individuals can never be mandated to take any medical treatment to save their own life. Because the current COVID-19 vaccine candidates only purport to reduce symptoms, not definitely reduce transmission, they fail the strict scrutiny test.

Since Jacobson, the Court has recognized the rights of individuals to make decisions about medical treatment, including the right to refuse life-saving treatment.[60][61][62][63] Decisions to participate in research or to use experimental and investigational drugs also require the individual's informed consent, even in the most highly regulated situation of persons serving in the military.[64] Personal liberty has been consistently upheld even if the right is not explicitly called fundamental.[65][66][67] Other examples of the SCOTUS broadening protections for individual liberty, even when the right is not called fundamental, include the right to a public education[68] and the right to same-sex marriage.[69]

In terms of forcing people to comply with medications against their will, the SCOTUS has steadily moved toward protecting individual liberty. A state statute that actually forced people to be vaccinated over their refusal would be unconstitutional as people have a right to refuse treatment.[70][71][72] And since Griswold v CT, there can be no state laws that interfere with personal reproductive decisions. All competent adults have the right to refuse sterilization.[73]

Thus the legitimacy of compulsory vaccination programs depends upon both scientific factors and the law. People would be less likely to voluntarily accept a suspect program.[74]

- scientific: prevalence, incidence, severity of the contagious disease, the mode of transmission, the safety and effectiveness of any vaccine in preventing transmission, and the nature of any available treatment

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[60] Washington v Harper, 494 US 210 (1990)

[61] *Vacco v Quill*, 521 US 793, 807 (1997)

[62] Cruzan v Director, Missouri Dept of Health, 497 US 261, 279 (1990)

[63] Washington v Glucksberg, 521 US 702 (1997)

[64] United States v Stanley, 483 US 669 (1987)

[65] San Antonio Independent School District v Rodriguez, 411 US 1, 102–3 (1973)

[66] Planned Parenthood of Southeastern Pa v Casey, 505 US 833 (1992)

[67] Stenberg v Carhart, 530 US 914 (2000)

[68] Plyler v. Doe, 457 U.S. 202 (1982)

[69] Obergefell v. Hodges, 576 U.S. 644 (2015)

[70] Cruzan v Director, Missouri Dept of Health, 497 US 261, 279 (1990)

[71] *Vacco v Quill*, 521 US 793, 807 (1997)

[72] Physician assisted suicide and the Supreme Court: putting the constitutional claim to rest. Mariner WK, Am J Public Health. 1997 Dec; 87(12):2058-62

[73] Griswold v Connecticut, 381 US 479 (1965)

[74] The federal smallpox vaccination program: where do we go from here? Kuhles DJ, Ackman DM. Health Aff (Millwood). 2003 Jul-Dec; Suppl Web Exclusives():W3-503-10.

• law: protection against unjustified bodily intrusions and unreasonable penalties for refusal

Even in an emergency, when there is a rapidly spreading contagious disease and an effective vaccine, the state is not permitted to forcibly vaccinate or medicate anyone. The constitutional alternative is to segregate infected and exposed people separately to prevent them from transmitting the disease to others.

> [And even with quarantine, modern constitutional law demands a high level of justification. The Supreme Court has long recognized that "involuntary confinement of an individual for any reason, is a deprivation of liberty which the State cannot accomplish without due process of law,"[75] and some justices have called freedom from such confinement fundamental in nature.[76] Historically large-scale quarantines have had little positive effect on epidemics.[77] And even in prior SARS epidemic, quarantine was almost always done in the person's home, and it was almost never necessary to compel isolation.[78] [79]]

As a practical matter, major new epidemics (like terrorist attacks, like wartime) are likely to be considered national emergencies and lead to overreactions which threaten to trample constitutional rights. This is what happened when the military forced Americans of Japanese descent into internment camps during World War II, in a decision that we have regretted ever since.[80] Sixty years later noting the following, we made a better decision:

> *History teaches that, in time of war, we have often sacrificed fundamental freedoms unnecessarily. The Executive and Legislative Branches, reflecting public opinion formed in the heat of the moment, frequently have overestimated the need to restrict civil liberties and failed to consider alternative ways to protect the national security.*[81] [82]

Special mention must be made of cases of involuntary commitment for mental illness, which is analogous to today's pandemic fears. SCOTUS requires states to prove that a person is not just mentally ill but that the illness also renders the person dangerous to others, before it can hold someone involuntarily.[83][84][85][86][87]

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[75] *O'Connor v Donaldson*, 422 US 563, 580 (1975)

[76] Foucha v Louisiana, 504 US 71 (1992)

[77] Large-scale quarantine following biological terrorism in the United States: scientific examination, logistic and legal limits, and possible consequences. Barbera J, Macintyre A, Gostin L, Inglesby T, O'Toole T, DeAtley C, Tonat K, Layton M. JAMA. 2001 Dec 5; 286(21):2711-7

[78] http://www.louisville.edu/medschool/ibhpl/publications/SARS%20REPORT.pdf.

[79] Public health measures to control the spread of the severe acute respiratory syndrome during the outbreak in Toronto. Svoboda T, Henry B, Shulman L, Kennedy E, Rea E, Ng W, Wallington T, Yaffe B, Gournis E, Vicencio E, Basrur S, Glazier RH. N Engl J Med. 2004 Jun 3; 350(23):2352-61

[80] Korematu v United States, 323 US 214 (1944)

[81] *Hamdi v Rumsfeld*, 124 S Ct 2633 (2004)

[82] Rasul v United States; Al Odah v United States, 124 S Ct. 2686 (2004)

[83] Foucha v Louisiana, 504 US 71 (1992)

[84] Carey v Population Services Intl, 431 US 678 (1977)

[85] *O'Connor v Donaldson*, 422 US 563, 580 (1975)

[86] *Addington v Texas*, 441 US 418, 425 (1979)

[87] *Vitek v Jones*, 445 US 480, 494 (1980)

One hundred years after Jacobson, both public health and constitutional law has evolved. Public health has better science, more treatment options, better communications, all which favor individual liberty, in concordance with jurisprudence since the 1940's. On the other hand, during a time of fear and panic, people may be easily convinced that their security depends upon giving up their liberty. And it is cheaper for the legislatures to create laws that restrict personal liberty than develop programs that actually prevent disease and improve health.

Ultimately the Bill of Rights was designed to protect individuals against abuses by the State, even when the abuses have the support of the majority. If people do not trust public officials to protect their personal liberty, government will not be able to persuade the public to take even reasonable precautions. Public health programs that are based on force must be relegated to the 19th century. In the 21st century, public health requires the public's trust, which requires the robust preservation of personal liberty guaranteed by the Constitution.

Conclusion: Experimental Vaccine Candidates Cannot be Mandated

The robust jurisprudence protecting individual liberty against mandated experimental therapies, which arose long after the SCOTUS ruled in Jacobson, has now been established USA law for decades. It seems likely that a mandate with a similar fact pattern to Jacobson, specifically a law that authorized mandatory vaccination, during an epidemic of a lethal disease like smallpox, with refusal punishable by a monetary fine, would still be considered constitutional. The facts in Jacobson are similar to passing the rational basis test of modern times.

Jacobson required, at a minimum, that the proposed vaccine had been approved, was found to be safe and effective and prevented the transmission to others, and that the disease still existed in the population where it can cause serious injury to others. With the current fact pattern of the investigational stages of the COVID-19 vaccine candidates, none of those conditions exist. Thus any mandates for the COVID-19 vaccine candidates would fail both the 100-year old Jacobson threshold and the rational basis test. In addition there has been no policy discussion of instituting a mere monetary fine for failure to comply. Rather the punishment for noncompliance has been suggested to be much more sweeping and draconian, including calls for persons to be unable to work, to travel, to go to school, to participate in interstate travel or public life. There are even examples of young women being fired for not wanting to take the vaccine due to concerns over pregnancy.[88]

Requiring a "vaccine passport" to participate in daily American life was not a suggestion in Jacobson - even though smallpox is a deadly, contagious virus with no treatment that killed the young and old, healthy and infirm, in complete contrast to SARS-CoV-2 which has a vanishingly low rate of mortality almost exclusively in the frail and elderly, and >250 scientific studies demonstrating various other effective treatments. In addition, the smallpox vaccine had been developed more than 100 years earlier for a virus that had been killing millions for centuries in contrast to SARS-CoV-2 vaccine candidates which were just launched in 2020.[89]

In addition, since Jacobson, the SCOTUS has developed jurisprudence with a much deeper and broader understanding and respect for individual liberty. In regards to bodily integrity and medical freedom specifically, The Nuremberg Code and Declaration of Helsinki led to universal acceptance that no person can ever be coerced or mandated to taking an experimental treatment. This is codified in federal and international law.

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[88] https://www.dailymail.co.uk/news/article-9272291/NYC-waitress-fired-job-saying-wanted-wait-COVID-19-vaccine.html

[89] https://www.historyofvaccines.org/timeline#EVT_1

The fact pattern in today's potential mandates for COVID-19 experimental vaccines violates four levels of the law: Constitution -rational basis, Constitution -strict scrutiny, legislative and international law, and is therefore illegal.

1. Rational Basis: By CDC data, COVID-19 is not a deadly threat (comparable to smallpox) to the general population. The vaccine candidates are not FDA-approved. They have not yet been demonstrated to be safe (too early in the investigational phase) nor effective (not shown to reduce transmission of the virus, reduce hospitalization, reduce death). Thus there is no rational basis that supersedes individual liberty.
2. Strict Scrutiny: Over the past 100 years, the Constitutional doctrine of strict scrutiny applies to any law that interferes with a person's fundamental rights of individual liberty, including: bodily integrity, reproductive rights, and procreation. All three of these rights are implicated by the experimental vaccines.
3. Legislative: COVID-19 agents are currently investigational only, with the earliest possible date of full approval being late 2022 or early 2023. Investigational agents can never be mandated as there is an absolute right of refusal regarding experimental treatment codified in 21 U.S.C. §360bbb-3[90]. This is codified into federal law Title 45 CFR part 46 and by fourteen federal agencies and is used in all Institutional Review Boards by hospitals, clinics and medical journals.[91] In August 2020, the CDC specifically affirmed that the experimental vaccine candidates for COVID-19 can never be mandated.[92]
4. International Law: The World Health Organization (WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO) prohibit mandated experimental treatment and require informed consent. These principles are stated in Article 7 of the United Nations International Covenant on Civil and Political Rights (1966)[93] and by the Council for International Organizations of Medical Sciences, an international consortium with the CIOMS Ethical Guidelines for Biomedical Research.[94]

[90] https://www.law.cornell.edu/uscode/text/21/360bbb-3

[91] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/45-cfr-46/index.html

[92] https://www.youtube.com/watch?v=p0zCEiGohJs&list=PLvrp9iOILTQb6D9e1YZWpbUvzfptNMKx2&index=43. Minute 1:14:40

[93] http://hrlibrary.umn.edu/instree/b3ccpr.htm

[94] https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf