

200 Park Avenue, 17th Floor, New York, NY 10166  
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

November 4, 2021

**VIA EMAIL**

U.S Representative, Chip Roy  
1005 Longworth HOB  
Washington, DC 20515

U.S. Representative, Thomas Massie  
2453 Rayburn HOB  
Washington, D.C. 20515

U.S Representative, A. Donald McEachin  
314 Cannon HOB  
Washington, DC 20515

U.S Representative, Ralph Norman  
569 Cannon HOB  
Washington, DC 20515

U.S. Representative, Bill Posey  
2150 Rayburn HOB  
Washington, DC 20515

U.S. Representative, Madison Cawthorn  
102 Cannon House Office Building  
Washington, DC 20515

U.S Representative, Dan Bishop  
1207 Longworth House Office Building  
Washington, DC 20515

U.S. Representative, Ronny Jackson  
118 Cannon HOB  
Washington, DC 20515

U.S. Representative, Kat Cammack  
1626 Longworth House Office Building  
Washington, DC 20515

U.S. Representative, Lisa McClain  
218 Cannon House Office Building  
Washington, DC 20515

U.S. Representative, Nicole Malliotakis  
417 Cannon House Office Building  
Washington, DC 20515

U.S. Representative, Claudia Tenney  
1410 Longworth House Office Building  
Washington, DC 20515

U.S Representative, Darrell Issa  
2300 Rayburn House Office Building  
Washington, DC 20515

U.S. Representative, Marjorie Taylor Greene  
1023 Longworth House Office Building  
Washington, DC 20515

U.S Representative, Andrew Clyde  
521 Cannon House Office Building  
Washington, DC 20515

Re: *Emergency Use Authorization of Pfizer's Vaccine for Children Illegal & Unethical*

Dear Representatives:

On behalf of the Informed Consent Action Network (“ICAN”), we write to you because of your stance defending individual and civil rights. If individual and civil rights do not include being

able to choose, without government coercion, what is put on or in our bodies, then they are illusory. It means these rights can evaporate at the whim of any public health official's opinion or agenda driven study.

In that vein, no child should be mandated to receive a COVID-19 vaccine, especially where there were serious legal and ethical breaches which occurred as part of the emergency use authorization (“**EUA**”) of Pfizer’s COVID-19 vaccine (the “**Pfizer vaccine**” or “**product**”) for children ages 5 through 11 (“**children**”).

The legal authority for the Food and Drug Administration (“**FDA**”) to issue an EUA for children for this product is lacking, including because there is no medical emergency for children and the vaccinated still become infected with and transmit the virus. (*Infra* § I.) It is also improper to issue an EUA for children when the data does not demonstrate that the known benefits outweigh the known risks, the trial was underpowered, and there are serious concerns regarding how they were conducted. (*Infra* § II.) The foregoing issues are compounded by the fact that federal health authorities have given financial immunity to Pfizer for injuries caused by this product, including if it engages in willful misconduct, despite a history of such conduct by Pfizer. (*Infra* § III.)

The FDA makes mistakes in authorizing and licensing products. It happens. But typically, the public is not coerced to receive the product. With this product, however, schools across the country are mandating this product based on the issuance of this EUA. **This brings into sharp focus precisely why civil and individual rights should never be contingent upon a medical procedure.** This right is the last and final backstop to the dangerous authoritarianism that results when we permit the government to decide what must be injected or placed into or onto our bodies.

Whatever your views are on the COVID-19 vaccine itself, we trust you will stand with Americans that reject letting the government decide what medical procedures they must engage in to participate in civil society.

## **I. EUA for Pfizer’s Vaccine is Illegal Because There is No Emergency**

Congress passed the law granting the FDA the authority to issue EUAs after the United States experienced September 11, 2001, and subsequent acts of terror, including envelopes with anthrax that were sent through the U.S. Postal Service.<sup>1</sup> To create a legal route to distribute an unlicensed and therefore, experimental, medical product in the event of bioterrorism, or a similar emergency, Congress enacted Section 564 of the Food, Drug, and Cosmetic Act (“**FDCA**”), codified at 21 U.S.C. § 360bbb-3 (“**Section 564**”).

Section 564 is supposed to be used in emergencies. There is no emergency necessitating an EUA for Pfizer’s vaccine for children. From March through October of 2020, children ages 5-14 had a one-in-a-million chance of dying *with* COVID-19,<sup>2</sup> and Johns Hopkins researchers

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<sup>1</sup> See [https://wwwnc.cdc.gov/eid/article/13/7/06-1188\\_article](https://wwwnc.cdc.gov/eid/article/13/7/06-1188_article) (detailing “the need for and genesis of the EUA, its requirements, its broad application to civilian and military populations, and its features of particular importance to physicians and public health officials.”).

<sup>2</sup> Woolf, MD, MPH, et al., *COVID-19 as the Leading Cause of Death in the United States*, JAMMA Network (December 17, 2020) <https://jama-network.com/journals/jama/fullarticle/2774465>.

analyzing 48,000 children diagnosed with COVID-19 found a mortality rate of **zero** among those who did not have a pre-existing medical condition such as leukemia.<sup>3</sup> The rate of hospitalization for COVID-19 according to the CDC is similarly clinically insignificant, ranging from zero to a peak of 1.3 per 100,000 for children.<sup>4</sup> And this metric does not necessarily correlate with severe cases of pediatric COVID-19 because it “may be inflated by the detection of mild or asymptomatic infection via universal screening.”<sup>5</sup>

Michael Kurilla, director of the division of clinical innovation at the National Institutes of Health’s National Center for Advancing Translational Sciences and a voting member of the Vaccines and Related Biological Products Advisory Committee, abstained from voting on whether or not to grant emergency use authorization to Pfizer’s vaccine for 5-11-year-olds stating: “**I don’t see the need for ‘emergency use’ of this vaccine across the entire age group.**”<sup>6</sup>

Not only is there no emergency with regard to children and COVID-19, but children receiving Pfizer’s vaccine can also become infected with and transmit the virus. As the Director of the CDC explained on national television, “what [the COVID-19 vaccines] can’t do anymore is prevent transmission.”<sup>7</sup> And numerous science-driven, not policy driven, studies have found that the same rate of infection among the vaccinated and unvaccinated, with each having the same viral load in their nasal cavity.<sup>8</sup>

Reflecting that the Pfizer vaccine does not prevent spread is a paper out of the Harvard Center for Population and Development Studies titled *Increase in COVID-19 are unrelated to level of vaccination across 68 countries and 2,497 counties in the United States.*<sup>9</sup> It found that, “the trend line suggests a marginally positive association such that countries with higher percentages of population fully vaccinated have higher COVID-19 cases per 1 million people. Notably, Israel with over 60% of their population fully vaccinated had the highest COVID-19 cases per 1 million

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<sup>3</sup> <https://collections.nlm.nih.gov/master/borndig/101774952/Risk%20Factors%20for%20COVID-19%20Mortality%20among%20Privately%20Insured%20Patients%20-%20A%20Claims%20Data%20Analysis%20-%20A%20FAIR%20Health%20White%20Paper.pdf>.

<sup>4</sup> [https://gis.cdc.gov/grasp/COVIDNet/COVID19\\_3.html](https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html).

<sup>5</sup> <https://hosppeds.aapublications.org/content/11/8/e151.long>.

<sup>6</sup> <https://www.c-span.org/video/?c4983670/fda-meeting-covid-vaccine-children>.

<sup>7</sup> <https://twitter.com/CNNSitRoom/status/1423422301882748929>.

<sup>8</sup> Riemersma, et al., *Shedding of Infectious SARS-CoV-2 Despite Vaccination*, medRxiv (August 24, 2021) <https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v4.full.pdf>; Brown, et al., *Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings-Barnstable County, Massachusetts, July 2021*, MMWR Morb Mortal Wkly Rep. (August 6, 2021); <https://pubmed.ncbi.nlm.nih.gov/34351882/>; Shitrit, et al., *Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population*, Israel, July 2021, Euro Surveill (September 2021); <https://pubmed.ncbi.nlm.nih.gov/34596015/>.

<sup>9</sup> Subramanian, et al., *Increases in COVID-19 are unrelated to the levels of vaccination across 68 countries and 2947 counties in the United States*, European Journal of Epidemiology (September 9, 2021) [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8481107/pdf/10654\\_2021\\_Article\\_808.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8481107/pdf/10654_2021_Article_808.pdf)

people in the last 7 days.”<sup>10</sup> The paper had a similar finding for U.S. counties, wherein higher vaccination did not equate to fewer cases.<sup>11</sup>

Hence, an EUA for Pfizer’s vaccine for children is without legal foundation because COVID-19 does not present an emergency for children.

## II. EUA for Pfizer’s Vaccine is Illegal Because Known Benefits Do Not Outweigh Risks

An EUA was also legally improper for yet another reason. The clinical trial relied upon to authorize the Pfizer vaccine for children had around 2,500 children with a safety review period from a couple weeks to two months. Since the rate at which COVID-19 injures children is well above one in 2,500, FDA cannot know whether the vaccine will cause less harm than COVID-19 in children. This is why the need for an adequately powered trial has been recognized by international scientists who have declared that “inadequately powered studies should themselves be considered a breach of ethical standards.”<sup>12</sup> However, based on what is known, the risks from the vaccine outweigh any determined benefits from this product.<sup>13</sup>

As one voting member of the FDA’s advisory committee, Michael Kurilla, M.D., Ph.D., explained, “The fact of the matter is you’re basing a decision for millions of children on a study of 2,400, really ... and that’s uncomfortable. So you want caveats.”<sup>14</sup> Another voting committee member, Eric Rubin, M.D., Ph.D., editor of the *New England Journal of Medicine* (“**NEJM**”), made clear why it could be uncomfortable: “**We’re never going to learn about how safe the vaccine is unless we start giving it, and that’s just the way it goes.** That’s how we found out about rare complications of the other vaccines.”<sup>15</sup>

The honesty is commendable. And every parent should, with this information, be able to decide whether or not to give this vaccine to their child. But many parents will not have this choice

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<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> Klassen, et al, *Children Are Not Just Small Adults: The Urgent Need for High-Quality Trial Evidence in Children*, Plos Medicine (August 2008) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2504487/>.

<sup>13</sup> The FDA made a presentation regarding the risk/benefit analysis for COVID-19 vaccination in pediatric populations, acknowledging the risk of excess myocarditis cases, hospitalizations, and ICU stays in children, available at <https://www.fda.gov/media/153507/download>. See also Mevorach, et al., *Myocarditis after BNT162b2 mRNA Vaccine against COVID-19 in Israel*, *The New England Journal of Medicine* (October 6, 2021) <https://pubmed.ncbi.nlm.nih.gov/34614328/> (“The incidence of myocarditis...increased after the receipt of the BNT162b2 vaccine, particularly after the second dose among young male recipients.”); Tano et al., *Perimyocarditis in Adolescents After Pfizer-BioNTech COVID-19 Vaccine*, *Journal of Pediatric Infectious Diseases Society* (July 28, 2021) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8344528/>; Marshall et al., *Symptomatic Acute Myocarditis in Seven Adolescents Following Pfizer-BioNTech COVID-19 Vaccination*, *Pediatrics* (June 4, 2021) <https://pubmed.ncbi.nlm.nih.gov/34088762/>; Schauer, et al., *Myopericarditis After the Pfizer Messenger Ribonucleic Acid Coronavirus Disease Vaccine in Adolescents*, *The Journal of Pediatrics* (July 2, 2021) <https://www.sciencedirect.com/science/article/pii/S002234762100665X>.

<sup>14</sup> <https://www.statnews.com/2021/10/26/pfizer-covid19-vaccine-kids-vrbpac-fda/>.

<sup>15</sup> [https://www.youtube.com/watch?v=laaL0\\_xKmmA&t=20971s](https://www.youtube.com/watch?v=laaL0_xKmmA&t=20971s).

if they want to keep their child in school. Hence, the FDA's EUA is not merely illegal, but insidious and destructive to basic civil and individual rights.

The above statement by Dr. Rubin is particularly perplexing because, as a NEJM editor, he just weeks prior accepted for publication a large-scale study consisting of 5.1 million Israelis revealing that around 14 per 100,000 boys aged 16 to 19 develop clinical myocarditis<sup>9</sup>. This is close to double the expected incidence rate of myocarditis in the United States.<sup>16</sup> Data from the CDC's V-safe monitoring system among adolescents ages 12-15 reveal that 40 per 100,000 children were hospitalized after the second dose of the Pfizer/BioNTech COVID-19 vaccine, which is numerous times the expected rate.<sup>17</sup> When we compare this with the CDC reported weekly hospitalization rate of <2 per 100,000 children, we quickly realize our regulators are failing to account for safety signals before mass vaccinating 28 million children aged 5-11 since **our government's own data suggests the benefits of mass vaccination do not outweigh the risks**.<sup>18</sup>

One peer reviewed paper, Kostoff *et al*, even calculated a conservative, 5-fold increase in deaths from the vaccine compared to COVID-19 alone.<sup>19</sup>

But the reality may be more pernicious. In Pfizer's clinical trial for 12- to 15-year-old children, which only had around 1,100 children, one child had a serious adverse reaction that resulted in, among other things, her being in a wheelchair with a feeding tube through her nose.<sup>20</sup> Pfizer reported this serious injury as abdominal pain. And despite informing the FDA of this misconduct, and the clear medical records and documentation supporting this misconduct, it has not acted.

But even if we put aside the glaring safety signals<sup>21</sup>, the vaccine efficacy is waning and the immunity it provides against Delta is questionable.<sup>22</sup>

Taken together, the EUA was not only illegal because there was no emergency for children, it is also illegal because it was not based on data which reflects that the known risks of the vaccine outweigh the known harms from COVID-19.

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<sup>16</sup> Gubernot et al., *U.S. population-based background incidence rates of medical conditions for use and safety assessment of COVID-19 Vaccines*, Vaccine (July 23, 2021). <https://pubmed.ncbi.nlm.nih.gov/34088506/>.

<sup>17</sup> Hause, et al., *COVID-19 Vaccine Safety in Adolescents Aged 12-17 Years – United States, December 14, 2020 – July 16, 2021*. MMWR CDC. (August 6, 2021). <https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e1.htm>.

<sup>18</sup> Delahoy, et al., *Hospitalizations Associated with COVID-19 Among Children and Adolescents – COVID-NET, 14 States, March 1, 2020-August 14, 2021*. MMWR CDC (September 10, 2021). <https://www.cdc.gov/mmwr/volumes/70/wr/mm7036e2.htm>.

<sup>19</sup> Kostoff, R. N. et al., *Why are we vaccinating children against COVID-19?* Toxicol Rep (September 14, 2021). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8437699/>.

<sup>20</sup> <https://aaronisiri.substack.com/p/fda-buries-data-on-seriously-injured>

<sup>21</sup> See discussion *supra* as well as <https://www.sirillp.com/wp-content/uploads/2021/11/ACIP-Pre-Letter-2021-11-01-9ced835baeddc18966a84e81d6c20cf6.pdf>.

<sup>22</sup> Wall et al., *Neutralizing antibody activity against SARS-CoV-2 VOCs B.1.617.2 and B.1.351 by BNT162b2 vaccination*. Lancet (June 3, 2021) [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)01290-3/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01290-3/fulltext).

### III. EUA of Pfizer's Vaccine is Destructive to Liberty

These same public health officials that say the Pfizer vaccine is safe enough to inject into children have also given **complete immunity to Pfizer for any injury caused by their Covid-19 vaccines.**<sup>23</sup>

Incredibly, Pfizer is even effectively immune for **willful misconduct** regarding its COVID-19 vaccine. That is because an injured individual can only sue Pfizer for willful misconduct regarding its Covid-19 vaccine if the federal government first sues Pfizer for such conduct.<sup>24</sup> And what are the odds the federal government will do so after wildly promoting the vaccine? About as likely as the FDA ever admitting they promoted a vaccine that caused widespread harm.

So, despite Pfizer's history of willful misconduct,<sup>25</sup> and that it is expected to exceed \$33.5 billion revenues in 2021,<sup>26</sup> it cannot be sued for injuries following its vaccination. It is incredible that our public health officials are apparently concerned about Pfizer's profits, but yet show no regard for the devastating financial situation their policies will put to Americans that do not want to take this liability free product when they lose their jobs or are kicked out of school. Nor concern for the devastating financial situation if they are injured by this vaccine and are effectively on their own without any real recourse for financial compensation.

What is most incredible is that, as noted above, the vaccinated can still transmit the virus. This product is therefore one for personal, not communal, protection. Nonetheless, you cannot say "no" to the product, cannot sue if you are injured,<sup>27</sup> cannot see the data underlying its licensure,<sup>28</sup> all while it will only potentially protect the individual required to receive the product.

It is indeed dystopian to expel a child from school or fire someone from their job for refusing to receive an injection that is only for that person's "benefit." Meaning, the government cares about its citizens so much it will make sure they can't go to school or hold a job if they don't take their medicine.

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<sup>23</sup> Pursuant to 42 U.S.C. § 247d-6d the federal government "*Declaration pursuant to section 319F-3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures against COVID-19*" provides that "manufacturers" of "any vaccine, used to treat, ... prevent or mitigate COVID-19" shall enjoy "[l]iability immunity," including, "from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a [COVID-19 vaccine]."

<sup>24</sup> Pursuant to 42 U.S.C. § 247d-6d(c)(5) "If an act or omission by a manufacturer or distributor with respect to a covered countermeasure, which act or omission is alleged under subsection (e)(3)(A) to constitute willful misconduct, ... such act or omission shall not constitute 'willful misconduct' ... if—(i)neither the Secretary nor the Attorney General has initiated an enforcement action with respect to such act or omission; or (ii)such an enforcement action has been initiated and the action has been terminated or finally resolved without a covered remedy."

<sup>25</sup> <https://www.citizen.org/article/twenty-seven-years-of-pharmaceutical-industry-criminal-and-civil-penalties-1991-through-2017/>.

<sup>26</sup>See <https://investors.pfizer.com/investor-news/press-release-details/2021/PFIZER-REPORTS-SECOND-QUARTER-2021-RESULTS/default.aspx> at *Update to Assumptions Related to BNT162b2 Within Guidance*.

<sup>27</sup> <https://aaronisiri.substack.com/p/covid-19-vaccine-manufacturers-can>.

<sup>28</sup> <https://aaronisiri.substack.com/p/scientists-sue-the-fda-for-data-it>.

If this form of authoritarianism is permitted to stand, there is no limit to what the government can mandate citizens to do in the name of public health. If a Covid-19 vaccine can be mandated for a child, then there is no reason the government cannot mandate every drug a doctor believes individuals should receive for their own good. Why not?

Nothing could be more dangerous. Science is about improving upon prior knowledge but when public health officials use the “science” to justify policy that results in mandates, then they become entrenched in defending their position. That results in a corruption of science and a dangerous descent into authoritarianism. Public health officials will get things wrong – that is fine. They are human. They will make what they presumably believe are the best recommendations they can at any given time.

But when those policies and recommendations and that science becomes the basis of taking away civil and individual rights it is not simply public health anymore. It is governance. And that is not to be done by a bunch of unelected public health officials at the CDC and FDA. That is to be done at most by the elected officials of this country with safeguards and boundaries attended with the legislative process.

No such safeguards exist for public health officials. It is plain they do not consider the cost/benefit to society as a whole. Their sole focus is on reduction of disease. Plainly, at all costs. Dr. Fauci said it best when asked at a congressional hearing about the economic, social, etc., impacts of his proposed public health policies and he responded that it’s not his job to consider those, that is the job of other agencies.

The solution to all the ills detailed above and the erosion of our rights is simple. The solution is **a clear line that no government should ever coerce anyone to receive any medical product or intervention.** That one clear line will avoid all the ills, illiberalism, and deprivation of rights occurring in large pockets of this country.

Liberty should never be contingent upon the opinion and whims of public health officials. Parents should not be coerced to give their child any medical product, let alone an unlicensed COVID-19 vaccine for a disease that rarely effects children. Every parent should be free to do so, but to coerce any parent to do so cuts as deeply as one can cut into our body of liberty rights.

On behalf of ICAN, we write to ask that you take all possible steps to unwind this dangerous precedent and resulting deprivation of civil and individual rights.

Sincerely Yours,



Aaron Siri, Esq.  
Elizabeth A. Brehm, Esq.