

**IN THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF ALABAMA**

AMERICA'S FRONTLINE)
DOCTORS, ETC.; and)

DR. SCOTT JENSEN, MD,)
Individually; and)

ELLEN MILLER,)
Individually and as Guardian of)
3 Minor Siblings; and)

JODY SOBCZAK,)
Individually and as Father of)
2 Minor Children; and)

DEBORAH SOBCZAK,)
Individually and as Mother of)
2 Minor Children; and)

LYLE BLOOM,)
Individually and as Father of)
2 Minor Children; and,)

JULIE BLOOM,)
Individually and as Mother of)
2 Minor Children; and)

ANDREA MCFARLANE, RN)
Individually and as Mother of)
4 Minor Children; and)

JENNIFER GREENSLADE,)
Individually and as Mother of)
2 Minor Children; and)

Case No. _____

**PETITION FOR TEMPORARY
RESTRAINING ORDER**

STEVEN M. ROTH, MD,
Individually; and

MATT SCHWEDER,
Individually and as Father of
a Minor Child.

Plaintiffs,

vs.

XAVIER BECERRA, Secretary of
the U.S. Department of Health
and Human Services, and U.S.
DEPARTMENT OF HEALTH
AND HUMAN SERVICES, AND
John & Jane Does I-V; Black &
White Partnerships; and ABC
Corporations I-V,

Defendants.

“The Constitution of this Republic should make special provision for medical freedom. To restrict the art of healing to one class will constitute the Bastille of medical science. All such laws are un-American and despotic. ... Unless we put medical freedom into the constitution the time will come when medicine will organize into an undercover dictatorship and force people who wish doctors and treatment of their own choice to submit to only what the dictating outfit offers.” Attributed to Dr. Benjamin Rush – Founding Father, signer of the Declaration of Independence and personal physician to George Washington.

“The more it (vaccination) is supported by public authorities, the more will its dangers and disadvantages be concealed or denied.” M. Beddow Bayly – Physician.

**“Kids are one third of our population and all of our future.
Kids are never the experiment. Protect the Children.” AFLDS.**

PETITION FOR TEMPORARY RESTRAINING ORDER

I. SUMMARY

Plaintiffs bring before the Court today a request for a Temporary Restraining Order (“TRO”) against the U.S. Department of Health and Human Services (DHHS), and the relevant subagencies and personnel including but not limited to the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), the DHHS Secretary, the DHHS Assistant Secretary for Preparedness and Response, and the DHHS Vaccines and Related Biological Products Advisory Committee, seeking temporary injunctive relief against any existing or further authorization for use in children under the age of 16, of any of the COVID-19 “vaccines”¹ that have been approved under the Emergency Use Authorization (“EUA”) provided in 21 U.S. Code § 360bbb–3. In this Motion, Plaintiffs ask only that the *status quo* be maintained - that the EUAs not permit the use of COVID-19 vaccines in children under the age

¹ Plaintiffs explicitly reject the term “vaccine” as a description of the injections approved under EUA for use in reducing the symptoms of COVID-19. The traditional definition of a vaccine as given by Cambridge Dictionary is “a substance containing a virus or bacterium in a form that is not harmful, given to a person or animal to prevent them from getting the disease that the virus or bacterium causes.” This definition is the one relied upon by health care professionals and the lay public since vaccines first emerged, but recently has been altered in a number of places to allow for the synthetic and experimental material colloquially referred to as the “COVID-19 vaccines” to be included. Plaintiffs will refer to the injections of this material as the “vaccine” or “injection” for purposes of this filing but reject the categorization.

of 16, and that no further expansion of the EUAs to children under the age of 16 be granted prior to the resolution of these issues at trial. Such relief would protect the lives and safety of millions of children in the American public for whom serious illness and mortality from COVID-19 represent a zero percent (0%) risk statistically, but who face substantial risks from these experimental injections.

Plaintiffs not only face the imminent threat of irreparable injury of various types absent a TRO, but they also represent a diverse cross-section of the American public. They are doctors and other medical professionals. They are parents and children. They are coaches and mentors. They are healthy, and they suffer from underlying conditions. They are from various states. They are from various walks of life. They are individuals and organizations. They are experts and they are lay people. Most or all have been fully vaccinated in the past. **And they all have one thing in common.** Absent the requested relief, each of their lives stands to be inexorably and irreparably altered forever.

Plaintiffs will bring suit in the near future. The case will challenge the EUAs for the injections on several counts. It will be made clear to the Court in that case, based on the law and well-founded scientific evidence, that: the EUAs should never have been granted, the EUAs should be revoked immediately, the injections are dangerous biological agents that have the

potential to cause substantially greater harm than the COVID-19 disease itself, and numerous laws have been broken in the process of granting these EUAs and pushing these injections on the American people.

In the specific instance of minor Plaintiffs under 16, the Court must consider that an “EUA requires that an intervention address a serious or life-threatening condition², and for known and potential benefits of the intervention to be balanced against the known and potential harms.” There is not even a pretense of a factual basis that COVID-19 represents a serious or life-threatening condition for children under 16, since the CDC acknowledges they face 0% risk of mortality from COVID-19 statistically.

The Complaint will include claims for, *inter alia* (1) a declaration that the extension of the EUAs for the COVID-19 vaccines making them available for use in children under the age of 16 violates 45 CFR § 46.401, *et seq.*, which applies to "all research involving children as subjects, conducted or supported by [DHHS]"; (2) an order enjoining the use of COVID-19 vaccines in children under the age of 16, until such time as the DHHS Secretary has complied with 45 CFR § 46.401, *et seq.*; and (3) claims for civil money damages against individual government officials within DHHS, in their personal capacities, for violations of the Constitution, under 42 U.S.C. § 1983.

² <https://blogs.bmj.com/bmj/2021/05/07/covid-vaccines-for-children-should-not-get-emergency-use-authorization/>

On May 11, 2021, without any prior notice, the FDA extended the EUA issued for the Pfizer-BioNTech COVID-19 Vaccine for use in 12 to 15 year-old children. Given the extreme exigencies, Plaintiffs are seeking the temporary relief set forth herein even before filing their Complaint. Studebaker Corp. v. Griffin, 360 F.2d 692, 694 (2d Cir. 1966); United States v. Lynd, 301 F. 2d 818, 823 (5th Cir. 1962) ("The grant of a temporary restraining injunction need not await any procedural steps perfecting the pleadings"); National Organization for Reform of Marijuana Laws v. Mullen, 608 F.Supp. 945, 950 n. 5 (N.D. Cal. 1985) ("[o]wing to the peculiar function of the preliminary injunction, it is not necessary that the pleadings be perfected, or even that a complaint be filed, before the order issues").

II. PLAINTIFFS

1. **America's Frontline Doctors** ("AFLDS") is a non-partisan, not-for-profit organization of hundreds of member physicians that come from across the country, representing a range of medical disciplines and practical experience on the front lines of medicine. AFLDS' programs focus on a number of critical issues, including:

- Providing Americans with science-based facts about COVID-19;
- Protecting physician independence from government overreach;
- Combating the "pandemic" using evidence-based approaches without compromising Constitutional freedoms;
- Fighting medical "cancel culture" and media censorship;
- Advancing healthcare policies that protect the physician-patient relationship;

- Expanding COVID-19 treatment options for all Americans who need them; and
- Strengthening the voices of front-line doctors in the national healthcare conversation.

AFLDS' core beliefs, shared by each of its member health care professionals, include the following:

- That the American people have the right to accurate information using trusted data derived from decades of practical experience, not politicized science and Big Tech-filtered public health information.
- That critical public health decision-making should take place away from Washington and closer to local communities and the physicians that serve them. They are steadfastly committed to protecting the physician-patient relationship.
- That front-line and actively practicing physicians should be incorporated into the nation's healthcare policy conversation.
- That safe and effective, over-the-counter COVID preventative and early treatment options should be made available to all Americans who need them. They reject mandatory government lockdowns and restrictions not supported by scientific evidence. They support focused care for the nation's at-risk population, including seniors and the immune-compromised.

AFLDS, through its member physicians, is deeply committed to maintaining the physician-patient relationship in the face of government encroachment.

Each of AFLDS' member physicians is also deeply committed to the guiding principle of medicine, "FIRST, DO NO HARM". They take gravely their ethical obligations to their patients. It is axiomatic that a physician's duty is to his or her patient.

AFLDS has recommended that the experimental Covid-19 vaccines be prohibited for use in the under-20 age category, and strongly discouraged for use in the healthy population above the age of 20 through the age of 69. These recommendations have two sound and broadly scientific foundations upon which they are based. First, there is the undeniable fact that the Covid-19 vaccines are experimental and either lack clinical testing or have presented serious risks for young people in the 12 to 15 age group. The risks and safety evidence based upon such trials as there are, cannot justify the use of these vaccines in younger persons. Because AFLDS has taken the science-based position that it is unethical even to advocate for Covid-19 vaccine administration to persons under the age of 50, its and its membership cannot administer it or support any agency that attempted to do so for juvenile persons in the 12 to 15 age category.

It should be noted here that AFLDS is NOT against vaccines generally as a class of medical interventions. It has praised the speedy progress of the vaccine development program. It has taken care to ensure clarity in its position regarding support of the proper use of approved vaccines and the proper application of emergency use authorizations. It holds sacrosanct the relationship between doctor and patient where truly informed decisions are to be made, taking into consideration all of the factors relating to the patients' health, risks, co-morbidities and circumstances.

Given these considerations it would be grossly unethical and therefore impossible for AFLDS members to stand idly by while their patients and their patients' families are subjected to the imminent risk of experimental COVID-19 vaccine injections being administered to minor children. If the EUAs are allowed to stand unrestrained and extended to young children in the 12-15 year age group, AFLDS member physicians will be forced into further untenable positions of unresolvable conflict between their ethical and moral duties to their patients, and the demands of many of the hospitals in which they work.

Many of AFLDS member physician's employers subscribe to and follow the recommendations of the American Medical Association ("AMA"). In a special meeting in November of 2020, the AMA's Council on Ethical and Judicial Affairs, updated a previously published Ethics Opinion in the AMA Code of Medical Ethics as opinion 8.7, "Routine Universal Immunization of Physicians."

In this updated opinion, the astonishing position was taken that *not only* do physicians have an ethical and moral obligation to inject themselves with the experimental COVID-19 vaccination, *but they also* have an ethical duty to encourage their patients to get injected with the experimental COVID-19 vaccination. The ethics opinion repeatedly uses the phrase "safe and effective" as a descriptor for the experimental COVID-19 vaccination.

The AMA's ethics opinion goes on to state that institutions may have a responsibility to require immunization of all staff!

“Physicians and other health care workers who decline to be immunized with a safe and effective vaccine, without a compelling medical reason, can pose an unnecessary medical risk to vulnerable patients or colleagues,” said AMA Board Member Michael Suk, MD, JD, MPH, MBA. “Physicians must strike an ethical balance between their personal commitments as moral individuals and their obligations as medical professionals.”

The ethical opinion adopted by the AMA House of Delegates says that doctors “have an ethical responsibility to encourage patients to accept immunization when the patient can do so safely, and to take appropriate measures in their own practice to prevent the spread of infectious disease in health care settings.

[. . .]

“Physician practices and health care institutions have a responsibility to proactively develop policies and procedures for responding to epidemic or pandemic disease with input from practicing physicians, institutional leadership, and appropriate specialists,” says the updated opinion. “Such policies and procedures should include robust infection-control practices, provision and required use of appropriate protective equipment, and a process for making appropriate immunization readily available to staff. During outbreaks of vaccine-preventable disease for which there is a safe, effective vaccine, institutions’ responsibility may extend to requiring immunization of staff.”³ (emphasis added)

It is clear from this ethics opinion that AFLDS member physicians would be considered by their employers to be both morally and ethically bound by a duty to encourage 12-15 year old minors to receive the experimental COVID-19 vaccination injection.

³ <https://www.ama-assn.org/delivering-care/public-health/are-physicians-obliged-get-vaccinated-against-covid-19>

The AMA even offers a “COVID-19 VACCINE SCRIPT FOR PATIENT INQUIRIES”.⁴ Despite being styled as a script for *inquiries*, the script clearly intends for phone messages and office websites to lead with the following message for *every* caller, not simply those who wish to inquire about vaccines.

The proposed script reads: “*We are encouraging our patients to receive the COVID-19 vaccine when it is available and offered to them.*”⁵

To the extent that the AFLDS member physicians either lack control of their office website or telephone system, or are simply unaware of the message that has been placed there absent their knowledge and consent, the member physicians will have been forced unwittingly into an utterly untenable position. Such would create an unresolvable conflict for the member physicians, and deep confusion for their patients, who would thereby be receiving irreconcilable and contradictory messages from the same office.

To illustrate just how unresolvable these conflicts are, it is necessary to consider the massive power of big pharmaceutical companies over the institutions who employ the physicians and the ease with which a physician’s career can be destroyed through widely unregulated reporting which opens an investigation that can and often does render the physician virtually

⁴ <https://www.ama-assn.org/system/files/2021-01/covid-19-vaccine-patient-inquiry-script.pdf>

⁵ <https://www.ama-assn.org/system/files/2021-01/covid-19-vaccine-patient-inquiry-script.pdf>

unemployable. Not only do physicians have to choose between their ethical obligations to their patient to do no harm and their current job; the reality is that many of them will be choosing between their patients and their medical career.

It is critical to point out that for AFLDS member physicians, the practice of medicine is not simply a job. Neither is it merely a career. Rather, it is a sacred trust. It is a true high calling that often requires a decade or more of highly focused sacrificial dedication to achieve. The depth and the horror of the bind that this ethics opinion places the member physicians of AFLDS in, simply cannot be overstated.

To grasp the irreparable nature of the harm they face, one must consider the ease with which even an anonymous report can be made that may injure or haunt a physician's career.⁶ The National Physicians Database ("NPDB") was created by Congress with the intent of providing a central location to obtain information about practitioners. However, as Darryl S. Weiman, M.D., J.D. pointed out, the "black mark of a listing in the NPDB may not accomplish what the law was meant to do; identify the poor practitioner."⁷ Weiman goes on to point out that "It is the threat of a NPDB

⁶ <https://aapsonline.org/doctors-sue-texas-medical-board-for-misconduct-cites-institutional-culture-of-retaliation-intimidation/> (*Doctors were retaliated against and disciplined based on anonymous reports*).

⁷ https://www.huffpost.com/entry/the-national-practitioner_b_13173046

report which prevents the open discussion, fact-finding, and broad based analysis and problem solving which was the intent of the meaningful peer-review of the HCQIA.”⁸

The gross imbalance of equities between an individual physician and the various large institutions and pharmaceutical companies which exert tremendous sway over his or her professional calling has many physicians fearful of pushing back against such ethical binds as have been described above.⁹ Many physicians have a family and medical school debts to consider and should never be forced into such a bitter double bind.

The types of harm the AFLDS member physicians are inevitably subjected to by this extension of the EUAs to inject 12-15 year old minors with the experimental COVID-19 vaccine is truly irreparable. Such harm strikes at the moral and ethical underpinnings of their calling as a physician and drives irreparable wedges into the sacred doctor-patient relationship that cannot be healed and certainly cannot be addressed with monetary damages.

2. Dr. Scott Jensen, MD is a board-certified family medicine physician of 40 years. Dr. Jensen resides and practices in the state of Minnesota, where he was honored as the “Minnesota Family Physician of the Year” in 2016. Dr. Jensen is well aware the children in the 0-16 year old age

⁸ Id.

⁹ <https://aapsonline.org/doctors-sue-texas-medical-board-for-misconduct-cites-institutional-culture-of-retaliation-intimidation/> (*Doctors were retaliated against and disciplined based on anonymous reports*).

group have a 0% chance statistically of dying from COVID. As to the EUAs for the experimental COVID-19 vaccines, Dr. Jensen is keenly aware of the risks and benefits of these investigational agents as well as the current vaccine schedule for other diseases. Given that the statistical chance of death for children ages 0 to 16 is 0%, Dr. Jensen believes it would be reckless to subject anyone in that age group to the experimental COVID-19 vaccine. To recommend something that he considers reckless would violate his oath as a doctor and place him in an untenable position. It would place his young patients in that age group at risk and create similar conflicts to those described in the preceding paragraphs relating to the AFLDS member physicians. In addition, and based on the facts and statistics set forth in Dr. Jensen's Declaration attached hereto and incorporated herein by reference as Exhibit A, Dr. Jensen believes the use of coercion in the 0-16 year old age group that is not at risk of harm from COVID-19 would irreparably undermine public trust in all vaccines. He therefore requests an immediate temporary restraining order to halt the extension of the EUAs of the experimental COVID-19 vaccine for any and all ages under 16.

3. Ellen Millen (Ellen) is a resident of Huntsville, Alabama. Ellen is the Guardian of three siblings ages 5, 4 and 4. These children have been entrusted to her by Child Protective Services and she is responsible for making medical decisions for them. Ellen has obtained a medical exemption for vaccines and neither she nor their biological parents wish the children to receive the experimental COVID-19 vaccination. Ellen stands not only for the children currently in her care but for those who may be placed in her care in the future. She stands for her 22-year-old son and four other children who are unable to stand for themselves in opposing the application of the experimental COVID-19 vaccination to children of all ages who are at NO

statistical risk of death from COVID-19. Without a temporary restraining order as requested in this motion Ellen knows that the children in her care will face overwhelming pressure to receive the experimental COVID-19 vaccination injection from friends, parents of friends, sports organizations, summer camps, schools and colleges. The fear and pressure that this fragile at-risk population of children will be subjected to if the temporary restraining order is not granted is greater than that which is often faced by children from intact nuclear families. The nature of their placement outside of their home and away from their biological family leaves them particularly susceptible to the pressures and the fear mongering that they will receive from peers and authority figures. The harm that they will undergo emotionally, mentally, and/or physiologically is precisely the type of harm considered irreparable by the law in this case. The trauma that is created in this type of a situation will quite likely be carried for life, and no amount of damages can possibly erase the effects. Ellen's Declaration is attached hereto and incorporated here by reference as Exhibit B. Ellen seeks an immediate temporary restraining order to halt the extension of the EUAs for the experimental COVID-19 vaccines for any and all children 15 years old and younger.

4. **Jody Sobczak** (Jody), of Huntsville Alabama, is the father of two minor children ages 15 and 17. Jody has researched the experimental COVID-19 vaccines and fiercely opposes their use in healthy children of any age. He knows that his own children are placed at immediate and irreparable risk of harm by extending the EUAs for the experimental COVID-19 vaccines to adolescents. Jody is well aware that there are safe and effective alternative treatments readily available, and he adamantly opposes the suppression of those treatments in favor of experimental and potentially life-threatening agents. Jody's Declaration is attached hereto and incorporated herein as

Exhibit C. Jody seeks an immediate temporary restraining order to halt the extension order of EUAs for the experimental COVID-19 vaccines for any and all children 15 years old and younger.

5. **Deborah Sobczak** (Deborah), of Huntsville Alabama, is the mother of two minor children ages 15 and 17. Deborah has researched the experimental COVID-19 vaccines and also fiercely opposes their use in healthy children of any age. She knows that her own beloved children are placed at immediate and irreparable risk of harm by extending the EUAs of the experimental COVID-19 vaccine to adolescents. Deborah is well aware that there are safe and effective alternative treatments readily available and she adamantly opposes the suppression of those treatments in favor of experimental and potentially life-threatening agents. Deborah's Declaration is attached hereto and incorporated herein by reference as Exhibit D. Deborah seeks an immediate temporary restraining order to halt the extension of the EUAs for the experimental COVID-19 vaccines for any and all children 15 years old and younger.

6. **Lyle Bloom** (Lyle), of Huntsville, Alabama, is the father of two children ages 10 and 16, and the father of one young adult age 21. Lyle has researched the experimental COVID-19 vaccines and fiercely opposes their use in healthy children of any age. He knows that his own children are placed at immediate and irreparable risk of harm by extending the emergency use authorizations of the experimental COVID-19 vaccine to adolescents. Lyle is well aware that there are safe and effective alternative treatments readily available and he adamantly opposes the suppression of those treatments in favor of experimental and potentially life-threatening agents. Lyle's duly executed Declaration is attached hereto and incorporated herein as Exhibit E. Lyle seeks an immediate temporary restraining order to halt the extension

of EUAs of the experimental COVID-19 vaccines for any and all children 15 years old and younger.

7. **Julie Bloom** (Julie), of Huntsville Alabama, is the mother of two children ages 10 and 16, and the mother of one young adult age 21. Julie has researched the experimental COVID-19 vaccines and also fiercely opposes their use in healthy children of any age. She knows that her own beloved children are placed at immediate and irreparable risk of harm by extending the EUAs for the experimental COVID-19 vaccines to adolescents. Julie is well aware that there are safe and effective alternative treatments readily available and she adamantly opposes the suppression of those treatments in favor of experimental and potentially life-threatening agents. Julie's duly executed Declaration is attached hereto and incorporated herein as Exhibit F. Julie seeks an immediate temporary restraining order to halt the extension of EUAs for the experimental COVID-19 vaccines for any and all children 17 years old and younger.

8. **Andrea McFarlane, RN** (Andrea) of Huntsville, Alabama currently works as a trauma/ICU nurse at Vanderbilt. She is the mother of 4 children, 10, 12, 14 and 16. As a nurse, Andrea has seen tremendous pressure placed on staff to get the experimental COVID-19 vaccines. Even medical staff that have had COVID-19 are pressured relentlessly to take the experimental COVID-19 vaccines. It is well known among the staff that taking the experimental COVID-19 vaccines will leave you sick for days, and they accommodate for the expected sick reactions in their staffing plans. Andrea is also in school and as a student she is pressured and incentivized to get "vaccinated". As a mother, Andrea knows only too well the tremendous pressure her boys will be under to get "vaccinated". They will be under social and school pressure and Andrea deeply fears for their safety. She has studied

the vaccine. She knows that it is experimental and that it has proven harmful in many cases. She knows that her children are not at risk from COVID-19 and believes it should be illegal and that it is immoral to give an experimental and untested vaccine to children who are not at risk. She believes that if the TRO is not granted, not only will her children be at grave risk of irreparable harm, but she will be subjected to pressure in her profession to comply with an immoral policy. We know that the AMA through their ethics opinion set forth above in this Motion has already opined that institutions will likely have an obligation to require that their staff get injected with the experimental COVID-19 vaccinations. Should this happen, Andrea will be unable to work because she will not follow a policy that she believes is immoral. Andrea's duly executed Declaration is attached hereto and incorporated herein by reference as Exhibit G. Andrea is asking that this Court immediately impose the requested TRO in order to protect her children as well as herself from the grave risk of immediate and irreparable harm.

9. **Jennifer Greenslade** (Jennifer), of Remlap, Alabama, has an autoimmune disorder for which she takes medicine on a daily basis. She has researched the experimental COVID-19 vaccines and is aware that to take it would be to inject herself with an unknown agent that is largely unstudied but which carries risk to anyone with an autoimmune disease. She fears deeply for her own health and the health of her children, ages 9 and 12. The type of disease she has can be hereditary and nobody knows how it might interact with her children's health, whereas COVID-19 itself poses no risk of death to her children whatsoever. Jennifer has two cousins who did allow themselves to be injected with the experimental COVID-19 vaccines. They were both healthy prior to the injection. They became extremely ill after

being injected and spent weeks on the brink of death in the ICU. They are now out of the ICU but neither of them can walk and they require care from their children. This type of vaccine related injury constitutes irreparable harm. Her cousins were in good health and now they are unable to walk even though they survived the initial onslaught of the vaccine related sickness. Jennifer's health is not strong and her children may have inherited her autoimmune disorder. If they are pressured or mandated to take the vaccine and experience reactions similar to Jennifer's cousins' reactions, she and her children might not survive. For a mother of two small children it is a stark and terrifying concern to think that they may be killed or paralyzed or that she may be rendered unable to care for them or worse. Jennifer's duly executed Declaration is attached hereto and incorporated herein by reference as Exhibit H. She is seeking an immediate temporary injunction on behalf of herself, her children, and other similarly situated parents against the extension of the EUAs for children 15 and younger, who are at no risk from COVID-19.

10. Steven M. Roth, MD (Dr. Roth), of Alabama, has been a practicing emergency medicine physician for 13 years. As part of his practice, Dr. Roth sees patients of all ages. He is aware of the risks and benefits of these investigational agents as well as the current vaccine schedule for other diseases. Based on the most recent numbers from the CDC from May 5, 2021, anyone under the age of 16 has statistically NO risk of dying of Covid-19.

Dr. Roth has not seen a COVID-19 patient in many months, but he is currently seeing many patients who come to the emergency department as post-COVID-19 injection patients. All of these patients came in with COVID-19 like symptoms that occurred within 48 hours of the injection. All these

patients required hospital admission. Several of these patients progressed to death, caused by the vaccine.

Dr. Roth's concern is that based upon what he is seeing in the community, and because of the schools asking that students take the experimental COVID-19 injections and putting obstacles around those who do not take it, young people are being pressured to take an experimental injection, and many are succumbing to that pressure. This is deeply disturbing to Dr. Roth, because it is universally known that children virtually never die from COVID-19 and given that children have a very strong immune system, they are more likely than adults to have an over-reaction to the shot. This means that there is not only no benefit, but also an increased risk for children who receive the experimental COVID-19 injections. Also, with all prior viruses and vaccines, it has been accepted in the medical community that natural immunity is superior to vaccination, and there is no basis to believe that would be different with SARS-CoV-2. Because of these factors, it is actually not preferable to give the vaccine *even if it was definitely safe*, which these are not.

In addition, Dr. Roth is extraordinarily concerned that there have been no animal studies, nor long-term studies, of the COVID-19 vaccines, especially since prior coronavirus vaccines all caused death in the animals subjected to them.

Dr. Roth is aware of many thousands of physicians who agree with him, but who are under great pressure to say nothing. Dr. Roth has chosen to speak out now, at great personal cost to himself, because the alternative is unbearable. Dr. Roth could not live with himself if he stood by and allowed these experimental COVID-19 injections to be inflicted upon children universally, resulting in death and destruction over the

years. He considers it immoral and unconscionable that this experimental therapy will be given to children. Not only are children NOT at risk of death from COVID-19, but they are also NOT mini-adults. Their organs are still forming, and they are even more vulnerable than adults to developing auto-immune disease in this situation.

Dr. Roth would be deeply and directly affected by a change in FDA guidelines regarding vaccines for young people, and as a result he is imploring this Court to grant an immediate TRO to halt the approval of the infliction of the experimental COVID-19 injections upon children. In addition to the direct threat of irreparable harm posed to Dr. Roth's young patients, an additional unwelcome consequence of using coercion to mandate or pressure the participation of healthy young people who are statistically at NO risk is the risk of sharply reducing the public trust in all vaccines. This would also create what can only be described as irreparable harm to the public generally. Dr. Roth's duly executed Declaration is attached hereto and incorporated herein by reference as Exhibit I.

11. **Matt Schweder** (Matt) of Lexington, Kentucky, is the father of one minor daughter, age 15, and an adult son, age 25. Matt's son is in the Advanced Nurse Practitioner Program at Vanderbilt University. Matt's daughter is an active student and plays soccer for her high school. Matt has, until recently, coached girls select soccer for a number of years and he is very aware of the extraordinary power of peer pressure in the life of young adolescents. Matt's daughter is subjected to a barrage of peer pressure regarding vaccinating, which is a constant source of conversation for her friends, who have been taught to fear that which should hold no fear. In addition, her school system bombards her with weekly emails, pressuring and shaming her and her family into allowing themselves to be experimented on

with the experimental COVID-19 injections. The pressure is so intense that one of Matt's daughter's friends was forced to take the injection by his own mother, against his will, at the age of 16, and Matt's daughter had to undergo the trauma of knowing that her friend had become part of this dangerous human experiment even though he was adamantly opposed to doing so. Matt has conducted his own research into COVID-19, and he is well aware that children under the age of 16 have a 0% chance statistically of dying from COVID-19. Matt knows that safe and effective treatments for COVID-19 are available and he fiercely opposes the suppression of these treatments in favor of using untested and potentially life-threatening agents against children who are not at risk. As a father, Matt has witnessed the growing concern his son has, that his school or potential employer might decide to make the experimental agents mandatory, which would put his education to waste. The damages that Matt and his family face are irreparable if this EUA is permitted to be inflicted upon minor children, whose only risk of death comes from the vaccine itself. Therefore, Matt urgently moves this Court to find for his children and the children of America and immediately grant the TRO sought by this Motion. Matt's Declaration is attached hereto and incorporated herein by reference as Exhibit J.

III. REGULATORY AND FACTUAL CONTEXT

The EUAs for COVID-19 vaccines have been illegal from the start. There is and has been no *bona fide*, underlying, epidemiological emergency from COVID-19. Instead, an artificial emergency that is nothing more than a legal construct has been imposed on the population, based on a false COVID-19 death count (the result of illegal rule changes obliterating the

distinction between "dying with" and "dying from" COVID-19 and changing procedures and definitions for COVID-19 death certificates) and a false COVID-19 case count (the result of extensive PCR testing deployed at amplification cycles universally agreed, even by the WHO, the CDC and Dr. Fauci, to produce false positive test results).

The false emergency and attendant psychological manipulation through incessant, prolonged, fear-based reporting of the inflated death and case counts, have culminated in a campaign to coerce the American people to accept the COVID-19 vaccines, which are untested and unproven biological agents.

The American public are being misled as to the COVID-19 vaccines on multiple levels, including *inter alia*: to believe that they are FDA-approved; to believe that they are actually and in fact "safe and effective," as opposed to federal bureaucrats with apparent undisclosed conflicts-of-interest having determined merely that there is a "reasonable basis to conclude" that they are safe and effective; that there are no risks and many benefits, whereas in fact there are many risks and few benefits, particularly for children 15 and younger; that they are standard vaccines that involve the injection of dead or attenuated virus, versus gene therapy; that they prevent infection with COVID-19, and the transmission of COVID-19 to others; and that there are

no other effective alternative treatments.¹⁰ At the same time, the American public are being presented with countless incentives to induce their acceptance of the COVID-19 vaccines, and threats of negative consequences if they refuse them. All of this vitiates informed consent.

A. Regulatory Context.

The central legal issues arise from 21 U.S.C. § 360bbb–3 (which provides the legal framework for EUAs), as informed by 21 CFR § 202.1 (which relates to the advertising of prescription drugs and which requires a true statement of information relating to side effects, contraindications and effectiveness (§ 202.1(e)), customary international law, 21 CFR Parts 50 and 312, and 45 CFR Part 46 (which describes the requirements for human experimentation).

(1) 21 CFR § 202.1.

21 CFR § 202.1(e)(3) states specifically that “**If any part or theme of the advertisement would make the advertisement false or misleading by reason of the omission of appropriate qualification or pertinent information, that part or theme shall include the appropriate qualification or pertinent information**”. Advertising is categorically prohibited for an experimental

¹⁰ Plaintiffs contend that there are a number of safe and effective alternative treatments available that have been suppressed for what appears to be financial reasons, and are prepared to present scientific and medical evidence thereof.

vaccine that is not yet approved, which is a more stringent standard than for prescription drugs.

In addition, as Dr. Peter McCullough, the most cited and studied medical scholar on Covid-19 recently pointed out, there is a formal and overt collusion between Government stakeholders with a financial interest in the experimental vaccines, and the media, to actually suppress negative information about the experimental vaccines, rather than disclose the information, as any law relating to informed consent would mandate. Dr. McCullough describes a “whitewash of historic proportions”:

*“So I think this was effectively a scrubbing, like we’ve seen elsewhere. There is a **Trusted News Initiative**,¹¹ which is very important for Americans to understand, this was announced Dec. 10, and this is a coalition of all the major media and government stakeholders in vaccination, where they are not going to allow any negative information about vaccines to get into the popular media because they’re concerned about vaccine hesitancy, that if Americans got any type of fair, balanced coverage on safety events then they simply would not come forward and get the vaccine”¹² (emphasis added).*

The very concept of a consortium of Government stakeholders and major news outlets suppressing information is a gross violation of the legal principles further set forth in 21 CFR § 202.1(e)(5), which states in relevant part:

¹¹ <https://www.bbc.com/news/entertainment-arts-55257814>

¹² https://www.lewrockwell.com/2021/05/no_author/highly-cited-covid-doctor-comes-to-stunning-conclusion-govt-scrubbing-unprecedented-numbers-of-injection-related-deaths/

(5) “True statement” of information. An advertisement does not satisfy the requirement that it present a “true statement” of information in brief summary relating to side effects, contraindications, and effectiveness if:

(i) It is false or misleading with respect to side effects, contraindications, or effectiveness; or

(ii) It fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug...(emphasis added).

Dr. McCullough identifies financial stakeholders as including: “...the stakeholders – the CDC, NIH, FDA, Big Pharma, World Health Organization, Gates Foundation – they have made a commitment to mass vaccination”.¹³

Dr. McCullough further identifies the colluding news outlets as including:

“The partners signed onto the Trusted News Initiative to date are: Associated Press, AFP; BBC, CBC/Radio-Canada, European Broadcasting Union (EBU), Facebook, Financial Times, First Draft, Google/YouTube, The Hindu, Microsoft, Reuters, Reuters Institute for the Study of Journalism, Twitter, The Washington Post. The New York Times has also participated in the past.”¹⁴

This type of formal collusion in order to suppress information necessary for basic informed consent is antithetical to the protective purposes of 21 U.S.C. § 360bbb–3, 45 CFR Part 46 and 21 CFR § 202.1. The very agencies and officials responsible for protecting the American public from these experimental COVID-19 vaccines are deeply conflicted by substantial

¹³ Id.

¹⁴ Id.

financial incentives,¹⁵ and are they are pushing to provide what amounts to costly retail units of experimental agents to children who have no statistical risk to COVID-19, and do not need these interventions. Dr. McCullough suggests there is an incestuous relationship between these agencies and the pharmaceutical industry which causes the regulators to ignore safety issues:

“A lot of Americans don’t understand how tight these stakeholders are. Keep in mind the NIH [National Institutes of Health] is a co-owner of the Moderna patent, so they have a vested financial interest in keeping these vaccines going,” he said.

More than 15 months into the COVID nightmare, the evidence is beginning to suggest the U.S. government colluded from the outset with the Gates Foundation, CDC, FDA, the United Nations World Health Organization and Big Pharma to make the vaccines the central focus of the global COVID response effort. They started promoting the vaccines before they were even out of clinical trials, McCullough said, which is against U.S. regulatory law”¹⁶ (emphasis added).

(2) Customary International Law; 21 CFR Chapter 1, Part 50, Protection of Human Subjects, § 50.1 et seq., 21 CFR Part 312, Investigational New Drug Application, 45 CFR Part 46, Protection of Human Subjects

Customary international law applies directly to the United States and its agencies and instrumentalities. It is well established that customary international law includes a norm that prohibits non-consensual human

¹⁵ See attached Exhibit K “VAX ADVISORY CONFLICTS” for a detailed preliminary overview of the profound conflicts under the section entitled **FDA Vaccines and Related Biological Products Advisory Committee Roster: Content current as of 4/9/21.**

¹⁶ https://www.lewrockwell.com/2021/05/no_author/highly-cited-covid-doctor-comes-to-stunning-conclusion-govt-scrubbing-unprecedented-numbers-of-injection-related-deaths/

medical experimentation. Abdullahi v. Pfizer, 562 F.3d 163, 174-188 (2nd Cir. 2009). In August 1947, an International Military Tribunal ("IMT") sitting in Nuremberg, Germany convicted 15 Nazi doctors for crimes against humanity for conducting medical experiments without the consent of their subjects. "Among the nonconsensual experiments that the tribunal cited as a basis for their convictions were **the testing of drugs for immunization against malaria, epidemic jaundice, typhus, smallpox and cholera.**" Id. at 178 (quoting United States v. Brandt, 2 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, 181-182 (1949) (emphasis added). The Nuremberg Code was created as part of the IMT's judgment, and its first principle is that "[t]he **voluntary consent of the human subject is absolutely essential.**" Id. at 179. It contains other principles relevant here, for example that "[t]he 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 or unnecessary" (Principle 2), and "[t]he experiment should be [] designed and based on the results of animal experimentation" (Principle 3), and "[t]he degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem" (Principle 6).

The Nuremberg Code has been adopted and amplified by numerous international declarations and agreements, including the World Medical

Association's Declaration of Helsinki, the guidelines authored by the Council for International Organizations of Medical Services, Art. 7 of the International Covenant on Civil and Political Rights, International Covenants on Human Rights, the Universal Declaration on Bioethics and Human Rights, and others.

"The history of the norm in United States law demonstrates it has been firmly embedded for more than 45 years and [] its validity has never been seriously questioned by any court." *Id.* at 182. Federal Regulations relating to the protection and informed consent of human subjects implement this norm, and are binding legal obligations.

45 CFR § 46.401, *et seq.*, applies to "all research involving children as subjects, conducted or supported by [DHHS]." § 46.405 states:

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

- (a) The risk is justified by the anticipated benefit to the subjects;*
- (b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and*
- (c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in § 46.408.*

It is entirely reasonable to posit that the U.S. public health establishment would in fact design, fund, supervise and implement a non-consensual human medical experiment, in conjunction with private sector

actors. It has done so in the past. On October 1, 2010, President Obama apologized to the Guatemalan government and people for a program of non-consensual human experimentation that had been funded and approved by the U.S. Public Health Service ("PHS") and implemented on the ground by a PHS doctor employed for this purpose by private institutions but reporting to supervisors including PHS doctors. The evidence was suppressed and remained buried until discovered by a private researcher in 2010. A presidential commission investigated and found that in fact thousands of Guatemalans, including orphans, insane asylum patients, prisoners and military conscripts, had been intentionally exposed to syphilis, gonorrhea and other pathogens in furtherance of experiments on the use of penicillin as a prophylaxis.¹⁷

On May 16, 1997, President Clinton apologized to the African-American community for the "Tuskegee Study of Untreated Syphilis in the Negro Male", a non-consensual human medical experiment funded, organized and implemented by the PHS, again with important private sector participation. This was the longest non-therapeutic, non-consensual experiment on human beings in the history of public health, run by the PHS, spanning 40 years from 1932 until its exposure by a whistleblower in 1972. The purpose of the study was to observe the effects of untreated syphilis in black men and their

¹⁷ <https://bioethicsarchive.georgetown.edu/pcsbi/taxonomy/term/179.html>

family members. There are numerous other examples, too many for inclusion in this Motion.

That children are going to be used as experimental test subjects (guinea pigs) in medical experimentation using the COVID-19 vaccines is undeniable. The Texas State Senate heard sworn testimony on May 6, 2021 from Dr. Angelina Farella, a pediatrician who has given tens of thousands of vaccinations in her office. She testified:

"I have given tens of thousands of vaccinations in my career. I am very pro-vax actually except when it comes to this covid vaccine ... We are currently allowing children 16, 17 years old to get this vaccine, and they were never studied in this trial... Never before in history have we given medications that were not FDA approved to people who were not initially studied in the trial. There were no trial patients under the age of 18... They're extrapolating the data from adults down to children and adolescents. This is not acceptable. Children are not little adults. ... Children have 99.997% survivability from the covid. Let me repeat that for you all to understand: 99.997%."¹⁸

Senator Hall: "Has there been another vaccine that had the high incidents of serious hospitalizations and deaths that this vaccine is now showing?"

Dr. Farella: "Not to this extent. Not even close."

Sen. Hall: "Any other vaccine would have been pulled from the market?"

Dr. Farella: "Absolutely."

Sen. Hall: "Have you seen any other vaccine that was put out for the public that skipped the animal tests?"

¹⁸ <https://www.globalresearch.ca/no-vaccine-passports-texas-medical-doctors-testify-before-state-senate-oppose-mandatory-covid-shots/5744748>

Dr. Farella: "Never before. Especially for children."

Sen. Hall: "...Folks I think that's important to understand here, that what we're talking about is the American people ... **this is the test program.**"

(3) 21 U.S. Code § 360bbb–3(b), (c) and (e).

21 U.S. Code § 360bbb–3 governs the authorization of the use of medical products in emergencies. Plaintiffs contend that the DHHS Secretary violated § 360bbb–3(b) when he declared an emergency, and therefore the EUAs are invalid. Further, Plaintiffs contend that the Secretary violated § 360bbb–3(c), when he issued the EUAs for the COVID-19 vaccines, and therefore, on that basis additionally, the EUAs are invalid. In this Motion, Plaintiffs ask only that the *status quo* be maintained - that the EUAs not permit the use of the COVID-19 vaccines in the children under the age of 16, and that no further expansion of the EUAs to children under the age of 16 be granted until after trial.

§ 360bbb–3(b) authorizes the DHHS Secretary to declare an emergency after making one or more of certain findings, which declaration is the necessary predicate for the issuance of any EUA, as follows:

(b) Declaration of emergency or threat justifying emergency authorized use

(1) In general The Secretary may make a declaration that the circumstances exist justifying the authorization under this subsection for a product on the basis of—

(A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a

significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents;

(B) *a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with—*

(i) a biological, chemical, radiological, or nuclear agent or agents; or

(ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces;

(C) *a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or*

(D) *the identification of a material threat pursuant to section 319F–2 of the Public Health Service Act [42 U.S.C. 247d–6b] sufficient to affect national security or the health and security of United States citizens living abroad.*

The DHHS Secretary declared an emergency pursuant to § 360bbb–3(b)(I)(C), after making the relevant finding. Plaintiffs aver and the facts set forth below demonstrate that the finding was made in error, without any real justification, and as such the EUAs for the COVID-19 vaccines are invalid.

§ 360bbb–3(c) sets forth the standards applicable to the issuance of any EUA, as follows:

*(c) **Criteria for issuance of authorization.** The Secretary may issue an authorization under this section with respect to the emergency use of a product only if, after consultation with the Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances described in subsection (b)(1)), the Secretary concludes—*

- (1) that an agent referred to in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;*
- (2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is **reasonable to believe that—***

*(A) **the product may be effective in diagnosing, treating, or preventing—***

(i) such disease or condition; or

(ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this chapter, or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262], for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

*(B) **the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable;***

- (3) **that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition;***
- (4) in the case of a determination described in subsection (b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and*
- (5) that such other criteria as the Secretary may by regulation prescribe are satisfied.*

The balancing test required by § 360bbb–3(c)(2)(B) cannot be satisfied. Since the risk from COVID-19 to 12-15 year old children is statistically 0%, there is no real or material benefit to this age category of using these experimental vaccines. At the same time, the risks of using any untested drug are always substantial, and, in this case, the injections are already proving to be dangerous, even on the basis of the false and/or misleading statistics promulgated by DHHS.

Further, the Secretary cannot meet the requirement in § 360bbb–3(c)(3) of demonstrating that there is no adequate, approved alternative treatment. Below is a discussion of a number of treatments that are adequate and that are approved by a number of doctors. Plaintiffs contend that the word “approved,” which is not otherwise defined in the statute, should be interpreted to refer to approval by the medical community in the medical malpractice sense of “meeting the standard of care” applicable among similarly situated medical professionals. Further, Plaintiffs contend that FDA approval for alternative COVID-19 treatments have been wrongfully withheld despite strong scientific evidence that many of these “alternative” treatments are safer and more effective than the current EUA products.

Part (e) of 21 U.S.C. § 360bbb–3(e) requires, as a condition of the EUAs, that the DHHS Secretary ensure that *both* health care professionals administering EUA products and those who are treated with the EUA

products are furnished with the following information, which is a minimum threshold disclosure necessary in order to ensure the informed consent of vaccine subjects:

(II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

(III) of the alternatives to the product that are available, and of their benefits and risks.

As discussed *infra*, the Secretary is not ensuring that these minimum statutory disclosures are made. In fact, the DHHS and its sub-agencies appear to be working actively to suppress information regarding the potential dangers of these injections and alternative treatments, as opposed to ensuring that health care professionals and vaccine subjects have the information. At the same time, state and federal government officials are threatening the American public with a range of penalties should they decline the vaccine, and incentives should they accept it. All of this vitiates informed consent, especially as to children under 16 years of age. Expanding the EUAs will only compound the harm.

B. Factual Context.

(1) No Real Emergency.

In approximately January of 2020, the media began creating and circulating news stories that seemed designed to generate panic, regarding a new and deadly disease that could kill us all. This was odd given that the

estimated fatality rate at the time was between 2-4%. By contrast, tuberculosis has a fatality rate of approximately 10%, the original SARS virus had a fatality rate of approximately 9%, and the MERS virus had a fatality rate of approximately 30% - all had similar rates of spread.

The actual COVID-19 statistics present a very different picture than the one painted by the media - a fatality rate of 0.2% globally, which drops to 0.03% for persons under age 70, which is comparable to the yearly flu. Further, statistically, the fatality risk is limited to the elderly population.

Data from defendants confirm that there is no outsized nor unmanageable situation regarding COVID-19. The defendants admit the following through their public government portal: [HealthData](https://healthdata.gov)¹⁹ and the [COVID-19 Community Profile Report](https://healthdata.gov/Health/COVID-19-Community-Profile-Report/gqxm-d9w9)²⁰:

USA Total:

- ER visits – 1.2% due to COVID (26 states <1%, highest is 3.1%)
- inpatients -- 4% due to COVID (Light Green -- Low)
- ICU patients -- 9% due to COVID (Yellow -- Moderate)
- total hospitalizations -- 46 states ≤ 15 per 100,000 and 49 states ≤ 20
- “cases” – 9 per 100,000 per day

¹⁹ <https://healthdata.gov>

²⁰ <https://healthdata.gov/Health/COVID-19-Community-Profile-Report/gqxm-d9w9>

The actual COVID-19 fatality numbers are vastly lower than those reported. On March 24, 2020, the DHHS changed the rules applicable to coroners and others responsible for producing death certificates and making "cause of death" determinations - **exclusively for COVID-19**. The rule change states that "COVID-19 should be reported on the death certificate for all decedents where the disease caused *or is assumed to have caused or contributed* to death." Many doctors have attested that permitting such imprecision on a legal document (death certificate) has never happened before in modern medicine. This results in reporting of deaths as caused by COVID-19, even when in fact deaths were imminent and inevitable for other pre-existing reasons and caused by comorbidities. In other words, people dying **with** COVID-19 are being reported as dying **from** COVID-19. DHHS statistics are now showing that 95% of deaths classed as "COVID-19 deaths" involve an average of four additional comorbidities. This misattribution of the cause of death undoubtably stems from the substantial government subsidies paid to incentivize such misreporting of COVID-19 deaths.

Similarly, the actual number of COVID-19 "cases" is far lower than the reported number. The signs, symptoms and other diagnostic criteria for COVID-19 are laughably broad. Applying the criteria, countless ailments can be classed as COVID-19, especially the common cold or ordinary seasonal flu. Compounding the problem, the DHHS authorized the use of the polymerase

chain reaction ("PCR") test as a diagnostic tool for COVID-19, with disastrous consequences. The PCR tests are themselves experimental products, authorized by the FDA under separate EUAs.

A PCR test can only test for the presence of a fragment of the RNA of the SARS-CoV-2 virus, and literally, by itself, cannot be used to diagnose the COVID-19 disease. The RNA fragment detected may not be intact and may be dead, in which case it cannot cause COVID-19. This is analogous to finding a car part, but not a whole car that can drive. Manufacturer inserts furnished with the PCR test products include disclaimers stating that the PCR tests should NOT be used to diagnose COVID-19. This is consistent with the warning issued by the Nobel Prize winning inventor of the PCR test that such tests are not appropriate for diagnosing disease.

Further, the way in which the PCR tests are administered guarantees an unacceptably high number of false positive results. Cycle Threshold Value ("CT value") is essentially the number of times that a sample (usually from a nasal swab) is magnified or amplified before a fragment of viral RNA is detected. The CT Value is exponential, and so a 40-cycle threshold means that the sample is magnified around a trillion times. The higher the CT Value, the less likely the detected fragment of viral RNA is intact, alive and infectious.

Virtually all scientists, including Dr. Fauci, agree that any PCR test run at a CT value of 35-cycles or greater is useless. A study funded by the French government showed that even at 35-cycles, the false positivity rate is as high as 97%. Despite this, a majority of the PCR tests for COVID-19 deployed under EUAs in the United States are run at 35-45 cycles in accordance with manufacturer instructions. Under the EUAs issued by the FDA, there is no flexibility to depart from the manufacturer's instructions and change the way in which the test is administered or interpreted.

There is, however, one GLARING exception to this standard. THE CDC HAS STATED THAT ONCE A PERSON HAS BEEN VACCINATED, AND THEN AFTER VACCINATION THAT PERSON TESTS POSITIVE FOR COVID-19 USING A PCR TEST, THE CDC WILL ONLY "COUNT" THE POSITIVE RESULT AT 28 CYCLES OR LESS! Why the difference? More recently, the CDC has announced it will no longer compile and report data showing the total number of vaccinated who subsequently contract COVID-19: "[We are] transitioning to reporting only patients with COVID-19 vaccine breakthrough infection that were hospitalized or died to help maximize the quality of the data collected."²¹ There appears to be an agenda to protect the myths about the vaccine, rather than the public.

²¹ <https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html>

Ultimately, there is simply no objective evidence showing a public health emergency exists. On a national level, Plaintiffs are unaware of any intercounty requests for aid, or legitimately overwhelmed community health resources/hospitals. Plaintiffs also point out that the Cambridge dictionary defines the word emergency to mean, “something dangerous or serious, such as an accident, that happens suddenly or unexpectedly and needs fast action in order to avoid harmful results.” COVID-19 has been with us for well over a year, and we know far more about the disease than we did at the outset. Most importantly, we can identify with precision the age segment of the population that is at risk, and it decidedly is NOT children under 16 who have a statistically zero percent chance of death from COVID-19. If there is no emergency, then the EUAs should be invalidated entirely though, for purposes of this Motion, Plaintiffs only seek injunctive relief against the expansion of the EUAs to children under 16.

(2) Dangers of COVID-19 for Children Under 16 vs. Benefits/Dangers of Experimental Injection.

COVID-19 presents no threat to children under 16 statistically. The United States census counted more than 72 million people age 0-17.²² As of 5/5/2021, according to the CDC, there have been only 282 deaths WITH (not

²² <https://www.census.gov/quickfacts/fact/table/US/PST045219> or <https://datacenter.kidscount.org/data/tables/101-child-population-by-age-group#detailed/1/any/false/1729,37,871,870,573,869,36,868,867,133/62,63,64,6,4693/419,420>

from) COVID-19 in children 0-17, representing 0.000392% of that age demographic. 179 of those deaths appear to have involved influenza, and likely would be characterized as influenza deaths rather than COVID-19 deaths under standard "cause of death" reporting rules. These statistics alone make it impossible for the DHHS Secretary to satisfy the balancing test required by § 360bbb-3(c)(2)(B), as a condition to issuing EUAs for these experimental vaccines. Since the risk from COVID-19 to 12- to 15-year-old children is statistically 0%, there is no real or material benefit to this age category of using these experimental vaccines. There is NO public interest in subjecting children to experimental vaccination programs, in order to protect them from a disease that simply does not threaten them. Children are inherently incapable of providing informed consent. Neither the children, nor their parents, can possibly give informed consent to these experimental vaccines, since the DHHS Secretary has failed to make the even the minimum statutory disclosures regarding risks and alternative treatments, and at the same time they are targeted and pressured with incentives and penalties.

Given that there is no risk to children from the COVID-19 disease, *any* risk from the COVID-19 vaccines is too much under the law. What risks do these experimental vaccines carry? Scientists and healthcare professionals all over the world are sounding the alarm and frantically appealing to the

FDA to halt the vaccines. They have made innumerable public statements, but for the purposes of this pleading we attach one recent, illustrative and dramatic statement. 57 top scientists and doctors are calling for an immediate end to all vaccine COVID-19 programs²³. Other physician-scientist groups have made similar calls, among them: Canadian Physicians²⁴, Israeli People's Committee²⁵, Frontline COVID-19 Critical Care Alliance²⁶, World Doctors Alliance²⁷, Doctors 4 Covid Ethics²⁸, and America's Frontline Doctors²⁹. These are healthcare professionals in the field who are seeing the catastrophic and deadly results of the rushed vaccines, and reputed Professors of Science and Medicine, including the physician with the greatest number of COVID-19 scientific citations worldwide. We attach the authors, institutions and abstract here for the Court to understand the severity and urgency of the situation. They accuse the government of deviating from long-standing policy to protect the public. In the past, government has halted vaccine trials based on a tiny fraction – far less than 1% - of the number of unexplained deaths already recorded in these ongoing COVID-19 vaccine

²³ <https://newsvoice.se/2021/05/57-scientists-study-covid-vaccinations/>

²⁴ <https://canadianphysicians.org/>

²⁵ <https://doctors4covidethics.medium.com/the-israeli-peoples-committee-report-of-adverse-events-related-to-the-corona-vaccine-april-2021-47891f17d452>

²⁶ <https://covid19criticalcare.com/>

²⁷ <https://worlddoctorsalliance.com/>

²⁸ <https://doctors4covidethics.medium.com/>

²⁹ <http://www.americasfrontlinedoctors.org/>

trials!³⁰ The scientists all agree that the spike protein (produced by the vaccines) *causes disease even without the virus*, which has motivated them to lend their imprimatur to, and risk their reputation and standing on, the following statement:

57 Top Scientists and Doctors: Stop All Covid Vaccinations.

*Roxana Bruno¹, Peter McCullough², Teresa Forcades i Vila³, Alexandra Henrion-Caude⁴, Teresa García-Gasca⁵, Galina P. Zaitzeva⁶, Sally Priester⁷, María J. Martínez Albarracín⁸, Alejandro Sousa-Escandon⁹, Fernando López Mirones¹⁰, Bartomeu Payeras Cifre¹¹, Almudena Zaragoza Velilla¹⁰, Leopoldo M. Borini¹, Mario Mas¹, Ramiro Salazar¹, Edgardo Schinder¹, Eduardo A Yahbes¹, Marcela Witt¹, Mariana Salmeron¹, Patricia Fernández¹, Miriam M. Marchesini¹, Alberto J. Kajihara¹, Marisol V. de la Riva¹, Patricia J. Chimenó¹, Paola A. Grellet¹, Matelda Lisdero¹, Pamela Mas¹, Abelardo J. Gatica Baudo¹², Elisabeth Retamoza¹², Oscar Botta¹³, Chinda C. Brandolino¹³, Javier Sciuto¹⁴, Mario Cabrera Avivar¹⁴, Mauricio Castillo¹⁵, Patricio Villarroel¹⁵, Emilia P. Poblete Rojas¹⁵, Bárbara Aguayo¹⁵, Dan I. Macías Flores¹⁵, Jose V. Rossell¹⁶, Julio C. Sarmiento¹⁷, Victor Andrade-Sotomayor¹⁷, Wilfredo R. Stokes Baltazar¹⁸, Virna Cedeño Escobar¹⁹, Ulises Arrúa²⁰, Atilio Farina del Río²¹, Tatiana Campos Esquivel²², Patricia Callisperis²³, María Eugenia Barrientos²⁴, Karina Acevedo-Whitehouse⁵, **

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⁵School of Natural Sciences. Autonomous University of Querétaro, Querétaro, Mexico.

³⁰ https://www.lewrockwell.com/2021/05/no_author/highly-cited-covid-doctor-comes-to-stunning-conclusion-govt-scrubbing-unprecedented-numbers-of-injection-related-deaths/

⁶*Retired Professor of Medical Immunology. Universidad de Guadalajara, Jalisco, Mexico.*

⁷*Médicos por la Verdad Puerto Rico. Ashford Medical Center. San Juan, Puerto Rico.*

⁸*Retired Professor of Clinical Diagnostic Processes. University of Murcia, Murcia, Spain*

⁹*Urologist Hospital Comarcal de Monforte, University of Santiago de Compostela, Spain.*

¹⁰*Biólogos por la Verdad, Spain.*

¹¹*Retired Biologist. University of Barcelona. Specialized in Microbiology. Barcelona, Spain.*

¹²*Center for Integrative Medicine MICAEL (Medicina Integrativa Centro Antroposófico Educando en Libertad). Mendoza, República Argentina.*

¹³*Médicos por la Verdad Argentina. República Argentina.*

¹⁴*Médicos por la Verdad Uruguay. República Oriental del Uruguay.*

¹⁵*Médicos por la Libertad Chile. República de Chile.*

¹⁶*Physician, orthopedic specialist. República de Chile.*

¹⁷*Médicos por la Verdad Perú. República del Perú.*

¹⁸*Médicos por la Verdad Guatemala. República de Guatemala.*

¹⁹*Concepto Azul S.A. Ecuador.*

²⁰*Médicos por la Verdad Brasil. Brasil.*

²¹*Médicos por la Verdad Paraguay.*

²²*Médicos por la Costa Rica.*

²³*Médicos por la Verdad Bolivia.*

²⁴*Médicos por la Verdad El Salvador.*

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1. Abstract.

Since the start of the COVID-19 outbreak, the race for testing new platforms designed to confer immunity against SARS-CoV-2, has been rampant and unprecedented, leading to emergency authorization of various vaccines. Despite progress on early multidrug therapy for COVID-19 patients, the current mandate is to immunize the world population as quickly as possible. The lack of thorough testing in animals prior to clinical trials, and authorization based on safety data generated during

trials that lasted less than 3.5 months, raise questions regarding the safety of these vaccines. The recently identified role of SARS-CoV-2 glycoprotein Spike for inducing endothelial damage characteristic of COVID-19, even in absence of infection, is extremely relevant given that most of the authorized vaccines induce the production of Spike glycoprotein in the recipients. Given the high rate of occurrence of adverse effects, and the wide range of types of adverse effects that have been reported to date, as well as the potential for vaccine-driven disease enhancement, Th2-immunopathology, autoimmunity, and immune evasion, there is a need for a better understanding of the benefits and risks of mass vaccination, particularly in the groups that were excluded in the clinical trials. Despite calls for caution, the risks of SARS-CoV-2 vaccination have been minimized or ignored by health organizations and government authorities. We appeal to the need for a pluralistic dialogue in the context of health policies, emphasizing critical questions that require urgent answers if we wish to avoid a global erosion of public confidence in science and public health.

AFLDS medico-legal researchers have analyzed the accumulated COVID-19 data in terms of the balancing test required by § 360bbb–3(c)(2)(B), and report as follows:

- 1. Government Database (Defendant) Vaccine Adverse Event Reporting System (VAERS):*
 - a. 99% of all vaccine deaths this year are from COVID-19 injections (1% are from the other 100 vaccines)*
 - b. The current reported number of vaccine deaths for Q1 2021 constitutes a 12,000% -25,000% increase in vaccine deaths vs. prior years*
 - c. These statistics are based on the VAERS system*
 - i. VAERS only captures 1-10% reactions for all vaccines³¹*

³¹ <https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

- ii. *In **ten years** (2009-2019) there were 1529 vaccine deaths. In the first **four months** of 2021 there have been over 4,000.*
 - iii. *Reporting of many adverse events from COVID-19 vaccines are siphoned away from public VAERS into a non-public database called V-Safe which contradicts Congressional intent in creating VAERS in 1986 which was to make vaccine adverse events easily known to the public.*
2. *The Spike Proteins created by the COVID-19 vaccines are risky:*
- a. *Reproductive Health: Spike proteins are in the same family as the naturally occurring syncytin-1 and syncytin-2 reproductive proteins in sperm, ova, placenta.³² Antibodies raised against spike protein might interact with the naturally occurring syncytin proteins, adversely affecting multiple steps in human reproduction. The manufacturers did not provide data on this subject despite knowing about this spike protein similarity on syncytin proteins for more than one year; there are now a very high number of pregnancy losses in VAERS³³ and worldwide reports of irregular vaginal bleeding without clear explanation.*
 - b. *Vascular Disease: Salk researchers in collaboration with the University of San Diego, published in Circulation Research that the spike proteins themselves damage vascular cells, causing strokes or many other vascular problems.³⁴ All the vaccines are causing clotting disorders (coagulopathy) in all ages.³⁵ The spike proteins are known to cause clotting that the body cannot fix. Brain thrombosis, thrombocytopenia.³⁶*
 - c. *Autoimmune disease: The vaccines induce our cells to manufacture (virus-free) spike proteins. These spike proteins are then perceived to be foreign by the human immune system, initiating an immune response to fight them. While that is the intended therapeutic principle, it is also the case that any cell expressing spike proteins becomes a target for destruction by our own immune system. This is an auto-immune disorder and can*

³² <https://www.jennifermargulis.net/halt-covid-vaccine-research-scientist-urges-cdc/>

³³ VAERS database 2900 miscarriages! Queried by author on April 23, 2021

³⁴ <https://www.salk.edu/news-release/the-novel-coronavirus-spike-protein-plays-additional-key-role-in-illness/>

³⁵ <https://www.medrxiv.org/content/10.1101/2021.03.05.21252960v1.full>

³⁶ <https://b-s-h.org.uk/about-us/news/guidance-produced-by-the-expert-haematology-panel-ehp-focussed-on-vaccine-induced-thrombosis-and-thrombocytopenia-vitt/>

affect virtually any organ in the body. It is likely that some proportion of spike protein will become permanently fused to long-lived human proteins and this will prime the body for prolonged autoimmune diseases. Autoimmune diseases can take years to show symptoms and many scientists are alarmed at giving young people such a trigger for possible autoimmune disease.

d. Spike proteins directly cause disease: It is clear that spike proteins are not simple, passive structures which the virus uses to attach itself to cells. The spike protein is itself biologically active, even without the virus and these bind to our cells even more tightly causing harm to endothelial cells³⁷ which are throughout the entire human body, in blood tissue³⁸, in lung tissue.³⁹ The spike protein, being “fusogenic”, promotes cells to adhere to one another, initiating blood coagulation – including in the brain. Spike proteins also cross the blood-brain-barrier, a sacrosanct space in medicine. This has never been done before in a vaccine and the neurological effects are unknown.⁴⁰

e. Effect on the young: The vaccines are more deadly or harmful to the young than the virus, and that is excluding the unknown future effects on fertility, clotting, and autoimmune disease. There is a statistically zero chance of death from SARS-CoV-2 under age 18 according to the CDC but there are reports of heart inflammation in young men⁴¹ and at least one documented fatal heart attack of a healthy 15-year old boy in Colorado two days after his Pfizer shot.⁴² The vaccines induce the cells of the recipient to manufacture trillions of spike proteins with the pathology described above. Because immune responses in the young and healthy are more vigorous than those in the old, paradoxically, the vaccines may thereby induce, in the very people least in need of assistance, a very strong immune

³⁷ <https://www.biorxiv.org/content/biorxiv/early/2020/12/04/2020.12.04.409144.full.pdf>

³⁸ <https://www.salk.edu/news-release/the-novel-coronavirus-spike-protein-plays-additional-key-role-in-illness/>

³⁹ <https://medicalxpress.com/news/2021-04-sars-cov-spike-protein-lung.html>

⁴⁰ <https://scivisionpub.com/pdfs/covid19-rna-based-vaccines-and-the-risk-of-prion-disease-1503.pdf>

⁴¹ <https://www.timesofisrael.com/israel-said-probing-link-between-pfizer-shot-and-heart-problem-in-men-under-30/>

⁴² VAERS database 1242573-1

response, including those which can damage their own cells and tissues as well as by stimulating blood coagulation.

f. Chronic Disease: Healthy children whose birthright is decades of healthy life will instead face premature death or decades of chronic disease⁴³. We cannot say what percentage will be affected with antibody dependent enhancement⁴⁴, neurological disorders⁴⁵, autoimmune disease⁴⁶ and reproductive problems⁴⁷, but it is a virtual certainty that this will occur.

g. Unknown Effects: worldwide there are unexpectedly higher rates of death after receiving the vaccine.⁴⁸ Additionally, prior coronavirus and similar vaccines caused a phenomenon known as Antibody Dependent Enhancement (ADE) which is a paradoxically worse disease typically causing death or critical illness when the child or animal later encountered the virus in the wild. ADE is discovered during long term animal studies, and thus it is still an unknown risk.

h. Effect on society: scientists are concerned that universal inoculation may create more virulent strains. This has been observed with Marek's Disease in chickens.⁴⁹ Due to vaccinating a large number of chickens who were not at risk of death, now all chickens must be vaccinated or they will die from a virus that was nonlethal prior to widespread vaccination. It is a serious concern that our current vaccination policy, vaccinating everyone instead of those at risk, will over time, exert the same evolutionary pressure toward more highly virulent strains.

3. Differences Between COVID Injections and Prior Vaccine Programs:

a. Extreme Danger: Based only upon the numbers reported to VAERS, these vaccines should have been pulled off the market almost immediately. "A typical new drug at about five deaths, unexplained death, we get a black-box warning, your listeners would see it on TV, saying it may cause death. And then at about

⁴³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3335060/pdf/pone.0035421.pdf>

⁴⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3335060/>

⁴⁵ <https://pubmed.ncbi.nlm.nih.gov/22470453/>

⁴⁶ <https://pubmed.ncbi.nlm.nih.gov/25427992/>

⁴⁷ https://www.pure.ed.ac.uk/ws/portalfiles/portal/28839692/The_risks_of_using_allogeneic_cell_lines_for_vaccine_production_the_example_of_Bovine_Neonatal_Pancytopenia.pdf

⁴⁸ AuthorAFLDS data

⁴⁹ <https://www.jennifermargulis.net/halt-covid-vaccine-research-scientist-urges-cdc/>

50 deaths it's pulled off the market.”⁵⁰ In 1976 during the Swine Flu pandemic, the USA attempted to vaccinate 55 million Americans but when the shot caused 25 deaths, the program was pulled. The flu shot causes 20-30 deaths a year out of 195 million and there are now over 4,000 deaths out of about 100 million COVID-19 shots.⁵¹

b. Collusion to Censor: The Associated Press, AFP; BBC, CBC/Radio-Canada, European Broadcasting Union (EBU), Facebook, Financial Times, First Draft, Google/YouTube, The Hindu, Microsoft, Reuters, Reuters Institute for the Study of Journalism, Twitter, The Washington Post, The New York Times all participate in the “Trusted News Initiative” which has agreed to not allow any news critical of the shots.⁵² A Judge would not have to agree with one side or the other to recognize that s/he is likely not hearing the whole story when such an overwhelming majority of media/tech agree with their competitors on what is newsworthy.

c. Whistle Blowers: There are innumerable reports on social media of individuals and groups of physicians and nurses coming forward reporting what they are directly observing. We must take such reports extremely seriously given the enormous personal cost to persons reporting.

- i. Dr. Charles Hoffe who defied a gag order on Moderna⁵³*
- ii. Dr. Shucharit Bhakdi who predicted the blood clotting problems⁵⁴*
- iii. Dr. James Todaro & The Lancet retraction⁵⁵*
- iv. Dr. David Brownstein who was cited by the FTC for using vitamins⁵⁶*

⁵⁰ <https://leohohmann.com/2021/04/30/highly-cited-covid-doctor-comes-to-stunning-conclusion-govt-scrubbing-unprecedented-numbers-of-injection-related-deaths/>

⁵¹ <https://leohohmann.com/2021/04/30/highly-cited-covid-doctor-comes-to-stunning-conclusion-govt-scrubbing-unprecedented-numbers-of-injection-related-deaths/>

⁵² <https://www.bbc.com/news/entertainment-arts-55257814>

⁵³ <https://healthimpactnews.com/2021/canadian-doctor-defies-gag-order-and-tells-the-public-how-the-moderna-covid-injections-killed-and-permanently-disabled-indigenous-people-in-his-community/>

⁵⁴ <https://evidencenotfear.com/covid-vaccine-blood-clot-risk-was-known-ignored-buried-dr-sucharit-bhakdi/>

⁵⁵ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31324-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31324-6/fulltext)

⁵⁶ <https://www.youtube.com/watch?v=a-79BFjzhj8&t=472s>

- v. *Dr. Eric Nepute who was cited by the FTC for using Vitamin D*⁵⁷
- vi. *Dr. Pierre Kory who was ridiculed for using ivermectin*⁵⁸
- vii. *Dr. Joseph Mercola a victim of aggressive threats and cyberwarfare*⁵⁹
- viii. *Frontline COVID-19 Critical Care Alliance*⁶⁰
- ix. *America's Frontline Doctors*⁶¹
- x. *World Doctor Alliance*⁶²
- xi. *The Great Barrington Declaration*⁶³
- xii. *Pandemics Data and Analysis*⁶⁴
- xiii. *Doctors 4 Covid Ethics*⁶⁵
- d. *Conflict of interest: Consider that the J&J vaccine was paused for six clots but more than 4000 deaths due to Pfizer and Moderna has not resulted in a government pause. Note that the NIH is a co-owner of the Moderna patent. Note that Moderna and Pfizer (unlike J&J) plan to require an "update" once or twice annually.*⁶⁶

There are several factors that reduce any purported benefit of the COVID-19 vaccines. First, it is important to note that the Pfizer and Moderna EUA COVID-19 experimental injections were only shown to reduce symptoms – not block transmission. For over a year now, these Defendants and state-level public health authorities have told the American public that

⁵⁷ https://www.ftc.gov/system/files/warning-letters/covid-19-letter_to_dap_eric_nepute.pdf

⁵⁸ <https://www.newswise.com/coronavirus/dr-pierre-kory-president-of-the-flccc-alliance-testifies-before-senate-committee-on-homeland-security-and-governmental-affairs-looking-into-early-outpatient-covid-19-treatment>

⁵⁹ <https://articles.mercola.com/sites/articles/archive/2021/05/04/removing-articles-related-to-vitamin-d-c-and-zinc.aspx>

⁶⁰ <https://covid19criticalcare.com>

⁶¹ <https://www.americasfrontlinedoctors.org>

⁶² <https://worlddoctorsalliance.com>

⁶³ <https://gbdeclaration.org>

⁶⁴ <https://www.pandata.org>

⁶⁵ <https://doctors4covidethics.medium.com>

⁶⁶ <https://leohohmann.com/2021/04/13/cdc-pauses-johnson-johnson-injection-citing-rare-blood-clots-but-heres-what-youre-not-being-told/>

SARS-CoV-2 can be spread by people who have none of the symptoms of COVID-19, therefore Americans must mask themselves, and submit to innumerable lockdowns and restrictions, even though they are not manifestly sick. If that is the case, and these officials were not lying to the public, and asymptomatic spread is real, then what is the benefit of a vaccine that merely reduces symptoms? There isn't any.

Secondly, it appears that these Defendants either did lie about asymptomatic spread, or were simply wrong about the science. The theory of asymptomatic transmission - used as the justification for the lockdown and masking of the healthy - was based *solely* upon mathematical modeling. This theory had no actual study participants, and no peer review.⁶⁷ The authors made the unfounded assumption that asymptomatic persons were “75% as infectious” as symptomatic persons. But in the real world, healthy false positives turned out to be merely healthy, and were never shown to be “asymptomatic” carriers of anything.⁶⁸ Studies have shown that PCR test-positive asymptomatic individuals do not induce clinical COVID-19 disease, not even in a family member with whom they share a home and extended proximity. An enormous study of nearly ten million people in Wuhan, China showed that asymptomatic individuals testing positive for COVID-19 **never**

⁶⁷ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774707>

⁶⁸ <https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html>

infected others.⁶⁹ Since asymptomatic individuals do not spread COVID-19, they do not need to be vaccinated.

(3) Lack of Informed Consent

Around the nation it appears that the requirements for informed consent are being completely ignored by our public health system and particularly by self-interested DHHS officials. Throughout the DHHS, we see the use of the “safe and effective” moniker to describe these unapproved injections. The fact of the matter is that if the manufacturers of the injections were saying these things they would very likely be breaking the law.

As noted above, 21 U.S.C. § 360bbb–3 requires truly informed consent be given to anyone that is being administered these injections. Because these biological agents are still being studied it is only proper to call them experimental, and so 45 CFR Part 46 also applies, and requires even more in the way of informed consent. The studies on these injections **ABSOLUTELY DO NOT SCIENTIFICALLY CONCLUDE THAT THEY ARE "SAFE AND EFFECTIVE"**. Rather, the EUAs themselves talk extensively about demographics that have not had any real testing and where administration of the injections would thus be completely experimental. Children under 16 are amongst these demographics.

⁶⁹ <https://www.nature.com/articles/s41467-020-19802-w>

In addition, comments made by pharmaceutical executives are misleading to the public. In promoting their efforts to expand the EUA to kids, they cite the reason that the vaccine has already been given safely to hundreds of millions of people. This is false and misleading in two ways. First, medically speaking, children are not simply short adults. Their organs are still developing, and in addition those organs must function perfectly for many decades ahead of them. Secondly, the scientific harms are long term (autoimmune, reproductive, neurologic) and thus it is wholly irrelevant how *many* persons have received the vaccine, rather the *duration* of the research is what is determinative.

Pursuant to 45 CFR Part 46, experimentation on children gives rise to a heightened duty of protection. Rather than ethically ensuring that they are providing truly informed consent before experimenting on children, the Defendants are doubling down on the safe and effective moniker and want to expand experimenting on children without them or their parents even realizing that it is happening!

Despite the fact that non-consensual medical experimentation on children constitutes crimes against humanity under international law, the DHHS seems to be intent on both hiding the fact that these injections are literally experimental on children, and actually supporting state and private

sector actors in their efforts to coerce individuals into unknowingly participating.

Further exacerbating this already concerning lack of informed consent for those receiving the COVID injections is the potential exposure of those who did not consent at all to receiving the vaccine. Page 67 of the Pfizer EUA application⁷⁰ describes the possibility of exposure of unvaccinated, by the vaccinated, through inhalation or skin contact. Pursuant to the referenced document, each person getting the experimental shot had to consent to the possibility of exposing pregnant women through inhalation or skin contact (pharmaceutical companies can only disclose actual, not purely speculative, risks). According to the document, a reportable safety event occurred if:

A female is found to be pregnant while being exposed or having been exposed to study intervention due to environmental exposure. Below are examples of environmental exposure during pregnancy:

A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inhalation or skin contact.

As the vaccines have been rolled out, there are worldwide reports of irregular and often very heavy vaginal bleeding in the unvaccinated who are near the vaccinated, even in post-menopausal women. These public reports

⁷⁰ https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf

are [scrubbed from the internet rapidly](#)⁷¹, however plaintiff AFLDS has also received innumerable emails from around the world with the same reports. It is well documented that the vaccinated have excessive bleeding and clotting disorders including vaginal bleeding, miscarriages, gastrointestinal bleeding and ITP. Given that there is now the [real-world observation](#)⁷² of what appears to be transmission of something from vaccinated to unvaccinated adults, we simply do not know what will happen to unvaccinated children sitting next to vaccinated children for eight hours every day.

“[Self-disseminating vaccines](#)⁷³” is not a science fiction concept, rather it has been a research subject for [years](#)⁷⁴ if not decades.⁷⁵ The reportable safety event from the Pfizer application suggests that this type of vaccine is now a reality. Self-disseminating vaccines are the most literal of violation of informed consent imaginable, and any expansion of the EUA to children under the age of 16 puts unvaccinated children at risk without meeting the informed consent requirements of either 21 U.S.C. § 360bbb–3 or 45 C.F.R. Part 46.

⁷¹ <https://www.lifesitenews.com/news/thousands-of-women-report-hemorrhaging-reproductive-dysfunction-miscarriage-after-corona-shots>

⁷² <https://fromthetrenchesworldreport.com/bizarre-phenomenon-unvaccinated-getting-sick-being-around-the-covid-vaxxed/285650>

⁷³ <https://thebulletin.org/2020/09/scientists-are-working-on-vaccines-that-spread-like-a-disease-what-could-possibly-go-wrong/>

⁷⁴ <https://www.preemptproject.org/news/a-vaccine-that-could-spread-like-a-virus>

⁷⁵ <https://www.newscientist.com/article/mg24732960-100-we-now-have-the-technology-to-develop-vaccines-that-spread-themselves/>

The legally required heightened levels of informed consent are not being obtained, and the necessary precautions for studies on children are simply not being considered. The requested TRO is necessary to ensure the Plaintiffs are not subjected to further public coercion to partake in this illegal experiment.

(4) Suppression of Alternative Treatments & Conflicts of Interest.

Despite the misinformation being disseminated in the press – and, at times, by the Defendants – there are numerous alternative safe and effective treatments for COVID-19. Globally and in the United States, treatments such as Ivermectin, Budesonide & Dexamethasone, convalescent plasma and monoclonal antibodies, Vitamin D, Zinc, and Azithromycin are being used to great effect. While Dr. Anthony Fauci’s NIH, which happens to have a financial stake in Moderna’s COVID-19 vaccine⁷⁶, and others may downplay these treatments, the fact is that they have been used to great effect and have even resulted in a Nobel Prize nomination.⁷⁷

The following alternative treatments are available for COVID-19:

⁷⁶ <https://www.axios.com/moderna-nih-coronavirus-vaccine-ownership-agreements-22051c42-2dee-4b19-938d-099afd71f6a0.html>, See also: <https://assets.documentcloud.org/documents/6935295/NIH-Moderna-Confidential-Agreements.pdf>

⁷⁷ Dr. Vladimir ‘Zev’ Zelenko was nominated for the development of the “Zelenko COVID-19 Protocols” which include Hydroxychloroquine and zinc. Dr. Simone Gold, Founder of America’s Frontline Doctors was also nominated.

1. [Ivermectin: NY judicial order](#)⁷⁸, [Yale University](#)⁷⁹, [South Africa](#)⁸⁰, and [forty](#)⁸¹ [studies](#)⁸² and [India](#)⁸³
2. [HCQ effective in 238 studies](#)⁸⁴ [worldwide](#) including many peer reviewed in [USA Detroit](#)⁸⁵ [multicountry](#)⁸⁶ and doctor surveys [show a majority](#)⁸⁷ would use
3. [Budesonide](#)⁸⁸
4. [Dexamethasone](#)⁸⁹
5. [Vitamin D](#)⁹⁰,
6. [Zinc](#)⁹¹
7. [Azithromycin](#)⁹²
8. [Convalescent plasma](#)/monoclonal antibodies⁹³
9. [Colchicine](#)⁹⁴

⁷⁸ <https://www.wkbw.com/news/coronavirus/judge-orders-hospital-to-treat-covid-patient-with-experimental-drug>

⁷⁹ <https://trialsitenews.com/top-yale-doctor-researcher-ivermectin-works-including-for-long-haul-covid/>

⁸⁰ <https://www.biznews.com/thought-leaders/2021/03/16/ivermectin-in-sa>

⁸¹ <https://c19ivermectin.com>

⁸² https://journals.lww.com/americantherapeutics/fulltext/2021/00000/review_of_the_emerging_evidence_demonstrating_the.4.aspx

⁸³ <https://www.lifesitenews.com/opinion/change-away-from-successful-treatments-due-to-big-pharma-pressure-likely-cause-of-covid-death-catastrophe-in-india>

⁸⁴ <https://c19hcq.com>

⁸⁵ <https://www.ijidonline.com/action/showPdf?pii=S1201-9712%2820%2930534-8>

⁸⁶ <https://www.sciencedirect.com/science/article/abs/pii/S0300289620305354>

⁸⁷ 85% of global physicians recognized HCQ as at least partially effective in treating COVID-19, and more than half of the surveyed US physicians would take the drug or give it to family members early or even before onset of symptoms.

⁸⁸ [https://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(21\)00160-0/fulltext](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(21)00160-0/fulltext)

⁸⁹ <https://www.nejm.org/doi/full/10.1056/NEJMoa2021436>

⁹⁰ <https://pubmed.ncbi.nlm.nih.gov/33487035/>

⁹¹ <https://www.medicalnewstoday.com/articles/can-zinc-levels-predict-covid-19-severity>

⁹² <https://www.medrxiv.org/content/10.1101/2020.12.29.20248975v1.full>

⁹³ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19>

10. [Remdesivir](#)⁹⁵
11. [Nitazoxanide/azithromycin](#)⁹⁶

While many of these treatments have been publicly maligned, they are all working in various capacities around the world and are all safer than the COVID-19 injections.⁹⁷ The highly publicized attacks on early treatments seem to be done in bad faith in many instances. For example, one study on HCQ overdosed study participants with 2.5x lethal amounts of the drug and then reported the deaths as though they were not a result of the 2.5x lethal overdose.⁹⁸ The 27 physician-scientist authors of the study were civilly indicted and criminally investigated and still JAMA did not retract the article.⁹⁹

While plaintiffs make no allegations regarding legality or illegality of any of these conflicts of interest, they are numerous, now well publicized, and may create an incentive to suppress treatments while promoting

⁹⁴ <https://www.icm-mhi.org/en/pressroom/news/colchicine-reduces-risk-covid-19-related-complications>

⁹⁵ <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19>

⁹⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7192107/>

⁹⁷ Most of the drugs listed here are part of the FDA Adverse Events Reporting System – FAERS – and have shown to be safe for many years.

⁹⁸ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2765499>

⁹⁹ <https://www.sciencemag.org/news/2020/06/it-s-nightmare-how-brazilian-scientists-became-ensnared-chloroquine-politics>

experimental COVID-19 injections. Those conflicts are shown in a document attached hereto and incorporated herein with reference as Exhibit K.

Dr. Anthony Fauci is personally responsible for approving and granting NIAID and NIH monies for research responsible for the coronavirus spike proteins, as well as patents for coronavirus spike proteins. Dr. Fauci could have focused on treatments, including treatments he previously advised were beneficial (in SARS-CoV-1). Instead, Dr. Fauci directed the NIAID, NIH, Congress and the White House to develop vaccines, including Pfizer and Moderna vaccines where he has financial and professional ties.

The NIH Director stated the following in May, 2020: “We do have some particular stake in the intellectual property behind Moderna’s coronavirus vaccine.” In fact, NIH and Moderna signed a contract in December, 2019 that states “mRNA coronavirus vaccine candidates are developed and jointly owned by the two parties.”^{100, 101} And now Moderna is currently valued at \$25 billion despite having no federally approved drugs on the market.

Further, on May 11, 2021, Senator Rand Paul asked Dr. Anthony Fauci under oath about the origins of SARS CoV-2 and the NIH and NIAID funding for Gain-of-Function research, and Dr. Fauci stated to the Senator and to all of Congress and to the American people stating that the NIH and NIAID did

¹⁰⁰ <https://www.axios.com/moderna-nih-coronavirus-vaccine-ownership-agreements-22051c42-2dee-4b19-938d-099afd71f6a0.html>

¹⁰¹ <https://www.economicclub.org/events/dr-francis-collins-chris-nassetta-and-mary-brady>

not fund Gain-of-Function (making viruses more lethal) research when in fact, Plaintiffs' ongoing investigation and experts providing sworn declarations have revealed that he appears to have provided at least \$60 million in funding.

(5) Suppression of the Fact that Alabama Has Reached Herd Immunity.

The organization Physicians for Alabamans has concluded that Alabama has reached herd immunity, based upon evidence compiled by epidemiologist Dr. Suzanne Judd of the University of Alabama. Herd immunity is reached when a percentage of people have immunity to an infectious disease, thus reducing the wide-spread reach of the illness in the community.

An estimated 48% of Alabamans having contracted Covid-19, another 1.2 million Alabamans who are fully vaccinated, and another 400,000 Alabamans with partial immunity. These numbers establish the state's population has reached herd immunity. This assessment isn't based on these facts alone. The practical evidence is self-evident. We have averaged fewer than ten deaths a day over the past two to three months, we have had fewer than 50 hospitalizations a day over the past few weeks, and we have proven treatments going forward if others contract the virus. Based upon several

assessments last fall, we needed 50-72% herd immunity before protection could be expected.

(6) Preserving the Status Quo.

In this Motion, Plaintiffs seek relief only to the extent necessary to preserve the status quo by requesting immediate injunctive relief against any further expansion of the EUAs that would allow the administration of experimental COVID-19 injections to children under 16 years of age.

IV. LAW AND ANALYSIS

"The basis for injunctive relief in the federal courts has always been irreparable harm and the inadequacy of legal remedies." Beacon Theatres, Inc. v. Westover, 359 U.S. 500, 506–07 (1959), quoted in Sampson v. Murray, 415 U.S. 61, 88 (1974); Grasso Enterprises, LLC v. Express Scripts, Inc., 809 F.3d 1033, 1039 (8th Cir. 2016); Odebrecht Const., Inc. v. Sec'y, Florida Dep't of Transp., 715 F.3d 1268, 1288 (11th Cir. 2013). However, the "decision to grant or deny ... injunctive relief is an act of equitable discretion by the district court." eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006).

Under Winter v. Natural Resources Defense Council, Inc., 555 U.S. 7 (2008) and FRCP 65, the standard for preliminary injunction is showing: 1) a strong likelihood of success on the merits; 2) the possibility of irreparable injury; 3) the balance of hardships in its favor; 4) the advancement of public interest. The Supreme Court also noted that as an "alternative" approach to

weighing these four factors: "a court may grant the injunction if the plaintiff demonstrates either a combination of probable success on the merits and the possibility of irreparable injury or that serious questions are raised and the balance of hardships tips sharply in his favor," citing Freecycle Network, Inc. v. Oey, 505 F.3d 898, 902 (9th Cir.2007). *See also* Earth Island II, 442 F.3d at 1158; *Id.* at 677.

The 11th Circuit test has been distinguished to require the movant show: 1) substantial likelihood of success on the merits; 2) irreparable injury; 3) the threatened injury to the movant outweighs the damage the injunction may cause to the opposing party; and 4) the injunction would not be adverse to the public interest. Siegel v. LePore, 234 F.3d 1163, 1176 (11th Cir. 2000) (en banc); and Jysk Bed'N Linen v. Dutta-Roy, 810 F.3d 767, 774 (11th Cir. 2015).

While the burden of persuasion remains with the Plaintiffs, O'Connor v. Kelley, 2016 U.S. App. LEXIS 3683, at *10 (11th Cir. Feb. 29, 2016); Jordan v. Fisher, 2016 U.S. App. LEXIS 11734, at *4 (5th Cir. Feb. 10, 2016); Ferring Pharm., Inc. v. Watson Pharm., Inc., 765 F.3d 205, 210 (3d Cir. 2014), the "burdens at the preliminary injunction stage track the burdens at trial." Gonzales v. O Centro Espírita Beneficente União do Vegetal, 546 U.S. 418, 428–30 (2006); LSSi Data Corp. v. Comcast Phone, LLC, 696 F.3d 1114, 1123 n.11 (11th Cir. 2012). For purposes of a preliminary

injunction, this burden of proof can be shifted to the party opposing the injunctive relief after a *prima facie* showing and the movant should be deemed likely to prevail if the non-movant fails to make an adequate showing. Id.

In this case, the Plaintiffs have demonstrated, through their declarations and stated traumas and experiences, that they are facing a profound variety of irreparable harms. Each of them stands at great risk of profound loss and almost all of them stand at great risk of multiple and varied profound losses, *should the EUA experiment be further extended to younger children*. However, for each and every Plaintiff, and everyone that they represent in their person or profession, nothing whatsoever changes for the worse if the status quo is preserved.

In the following section, the Court will see clearly what has already been demonstrated beyond reasonable argument, that each prong of the four-part test tilts heavily in favor of the Plaintiffs. In this difficult moment, it is incumbent upon this Honorable Court to courageously protect and safely preserve the status quo, by granting the Temporary Restraining Order and keeping the Defendants from inflicting any more of their unsafe experiments upon the children of America. As Chief Justice Roberts has said:

[T]he Constitution principally entrusts the safety and the health of the people to the politically accountable officials of the States. But the Constitution also entrusts the protection of the people's rights to the

Judiciary—not despite judges being shielded by life tenure, but because they are. Deference, though broad, has its limits.

S. Bay United Pentecostal Church v. Newsom, 2021 U.S. LEXIS 758 * 4

(internal quotation marks omitted).

A. Four Part Test.

(1) Likelihood of Success on the Merits:

Parties “are not required to prove their claim, but only to show that they [are] likely to succeed on the merits.” Glossip v. Gross, 135 S. Ct. 2726, 2792 (2015); Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 22 (2008).

The Parties and the Claim are properly before this Court. This Court exercises subject matter jurisdiction in accordance with the provisions of 28 U.S.C. § 1331, as this litigation involves multiple claims and issues arising under federal law. Subject matter jurisdiction also arises under 42 U.S.C. § 1983, as this litigation involves the deprivation of rights, protections, privileges and immunities secured by the U.S. Constitution. Venue lies in this Court under 28 U.S.C. § 1391(e), since this is a civil action in which at least one Defendant is an officer or employee of the United States or an agency thereof acting in his official capacity, or an agency of the United States, no real property is involved, and one or more of the Plaintiffs reside in this judicial district.

Plaintiffs have standing to bring this litigation, as they are "adversely affected or aggrieved by agency action within the meaning of a relevant

statute." 5 U.S.C. § 702. Plaintiffs (1) have suffered some actual or threatened injury, (2) the injury can fairly be traced to the challenged actions of the Defendants, and (3) the injury is likely to be redressed by a favorable decision of this Court. N.H. Lottery Comm'n v. Rosen, 2021 U.S. App. LEXIS 1526 *15-17, quoting Lujan v. Defs. of Wildlife, 504 U.S. 555, 560 (1992).

Plaintiffs have demonstrated that the Defendants are in continuing, clear violation of the plain language of the federal law pursuant to which these claims are brought. 21 U.S.C. § 360bbb-3(c)(2)(B) requires the Secretary to satisfy a balancing test by demonstrating that "the known and potential benefits of [the COVID-19 vaccines], when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of [the COVID-9 vaccines]." As discussed above, the risk from COVID-19 to 12-15 year old children is statistically zero. The risks of the untested experimental COVID-19 vaccines are substantial, and, in this case, as established by credible and expert medical testimony, the injections are already proving to be dangerous. DHHS' own statistics substantiate its failure to meet the balancing test.

Further, § 360bbb-3(c)(3) requires that "there is no adequate, approved, and available alternative to the [COVID-19 vaccines]." Defendants cannot satisfy this requirement. A number of such alternatives are in fact adequate, approved and available, as discussed *supra*. They are "approved"

in the sense that medical practitioners accept them as standard of care, and some of them have been "approved" by the FDA. To the extent the FDA has withheld approval, it has done so wrongfully, against the backdrop of Defendants' conflicts of interest, despite strong scientific evidence that many of the alternatives are safer and more effective than the COVID-19 vaccines.

The truth is that several of the most successful treatments for COVID-19 have been studied more than almost any other drugs in the World, they have been demonstrated for many decades to be entirely safe and effective, prescribed safely to millions of patients, and their creators have been honored and lauded at the highest levels for their contribution to medicine. In short, these treatments are SO adequate and SO approved the World over, that they stand as the very antithesis to the pre-condition set forth in 21 U.S.C. § 360bbb-3(c)(3), which the Defendants are violating on an ongoing, formalized and more or less continuous basis.

§ 360bbb-3(e) requires, as a condition to the EUAs for the COVID-19 vaccines, that the DHHS Secretary ensure that both health care professionals and vaccine subjects have certain minimum information required in order to enable subjects to give their informed consent. The Secretary has not satisfied this requirement. Plaintiffs' Declarations attest to their lack of information and informed consent.

At the same time, public and private sector actors are deploying incentives and penalties designed to induce acceptance of the vaccine, further vitiating their voluntary, informed consent. The Governor of Ohio has just taken the shocking and unprecedented step of incentivizing Ohio residents to be injected with the experimental COVID-19 agents by offering entry into what amounts to a \$1 million prize lottery. In addition, he offers one “lucky” youngster the chance to win a “free” four-year college scholarship.¹⁰² Never mind that the winner may lack the life or health to enjoy their new fortune. In so doing, Ohio’s Governor has crudely departed from the realm of voluntary, informed consent and has struck a grating blow against medical autonomy. It is no secret that many lack *or have yet to develop* the discipline to resist the lure of “easy money” and by turning the EUA into a high stakes lottery game, he has introduced a subtle, insidious form of coercion and duress. It is hard to imagine that he will be the last to erode voluntary, informed consent in such a way.

Plaintiffs further contend and have substantiated the fact that DHHS and its sub-agencies appear to be working with elements of major media and big tech to actively suppress the potential dangers of these injections in direct defiance of their statutory duty to ensure that people are fully informed about the potential dangers. Plaintiffs contend, with a solid evidentiary basis for

¹⁰² <https://news.yahoo.com/vaccinated-ohio-shot-1-million-221700404.html>

doing so, that expanding the EUA to an even younger set of children who are at no risk of harm from Covid-19, will only further exacerbate this situation.

(2) Possibility of Irreparable Injury:

The Plaintiffs, as the moving party, must "demonstrate that irreparable injury is likely in the absence of an injunction." Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 22 (2008)_(emphasis added). Irreparable injury can be shown through the lens of 4 questions:

- 1) Is the type of injury actually irreparable;
- 2) Is it likely the movant will suffer this injury before a trial on the merits;
- 3) Are the defendant's actions the cause of the injury; and
- 4) is there an adequate alternative remedy for damages as opposed to the injunctive remedy at law?

Damage to an individual's or organization's reputation as a result of discharge may constitute "irreparable injury". Sampson v. Murray, 415 U.S. 61, fn. 68 (1974) ("We recognize that cases may arise in which the circumstances surrounding an employee's discharge, together with the resultant effect on the employee, may so far depart from the normal situation that irreparable injury might be found."). AFLDS medical professionals are being coerced into providing a medical intervention using an EUA product that is untested, and neither safe nor effective. They are under immediate threat of concrete irreparable harm. Injuring their patients by knowingly subjecting them to these dangerous COVID-19 vaccines, in violation of their sacred oaths, would lead to litigation, threaten their employment and medical

licenses, and irreparably damage their reputations. Refusing to harm their patients with the COVID-19 vaccines, and attempting to educate them about the risks of the vaccines, and the availability of alternatives, will lead to accusations of ethical violations, disciplinary actions by their licensing bodies, and highly publicized attacks, all of which would threaten their employment and medical licenses, and irreparably damage their reputations. They are in an untenable, unsustainable bind. "[T]he right to practice is [] a very precious part of the liberty of an individual physician or surgeon. It may mean more than any property. Such a right is protected from arbitrary infringement by our Constitution, which forbids any state to deprive a person of liberty or property without due process of law." Barsky v. Board of Regents, 347 U.S. 442, 459 (1954) (Douglas J., dissenting).

ALFDS relies on the integrity of its collective reputation to engage in its critical mission as an entity. Any perceived loss of that professional standing through the erosion of its member physicians' reputations would harm its own reputation as a body, and cause irreparable harm of the type discussed in Sampson v. Murray, supra. AFLDS as an organization faces a higher degree of exposure to imminent irreparable injury because it has the cumulative exposure of its members. The younger the population to which additional EUA's apply, the more clear and present becomes its exposure for this type of irreparable harm. The bitter irony of the situation is, AFLDS

could well suffer irreparable damage to its reputation and be hamstrung in its critical mission when its only “crime” would have been to remain steadfastly true to its high calling, protecting its members' sacred oaths as physicians, and to the interests of its members' patients. There is a very real sense in which an injury to an honest reputation through the gaslighting and dishonesty of an organized and financially conflicted consortium comprised of pharmaceutical manufacturers who enjoy immunity from liability and are reaping astronomical profits and regulators with conflicts of interest failing to protect the American public, truly exacerbates that which is already irreparable.

Clearly, AFLDS is not the only Plaintiff subject to the imminent risk of irreparable harm suffered through loss of reputation. Dr. Roth spoke of the great personal cost that he suffers by simply entering this litigation as a named Plaintiff. To the extent that administrators where he practices medicine see things differently than he does, he has effectively targeted himself. His sense of duty and moral integrity left him no choice, but he faces a number of grave risks in the choices he will have to make should this extension of the EUA be permitted against the young children of his practice.

Plaintiffs ask this Court to recognize that for the Doctors and medical professionals in this matter, as well as many hundreds and thousands across our land, simply being forced into this untenable position by the unlawful

extension of an experiment that was never lawful in the first place, creates emotional, mental and psychological duress from which some may never recover, and which certainly therefore must be considered a form of life-changing, irreparable harm.

Dr. Jensen is in a similar situation. A few years ago he was honored as the physician of the year in his state. Now, remaining true to that which brought him the highest honors in his profession could cost him his reputation and potentially his livelihood. Clearly he will suffer irreparable harm, should the COVID-19 vaccine EUAs be extended to children.

Ellen Miller will suffer irreparable harm should the state remove her from her position as a trusted placement for at-risk children. Hers, too, is a high calling. Her sense of moral obligation to the young souls entrusted to her care requires her to protect them from dangerous, experimental COVID-19 vaccines that they do not need. Protecting the children she is bound to protect, might result in her removal. The lives of the children she nurtures will be destabilized, and they will endure the trauma of losing parents for at least a second time. Our cities are filled with parentless children who need mothers like Ellen Miller, who are willing to sacrifice their own comfort to extend their love and their home and their resources. If Mrs. Miller loses her ability to stand in the gap for America's at-risk children, the irreparable harm will spread to other families and children with effects into the future.

Matt Schweder and his minor daughter live in a jurisdiction that has been subjected to an aggressive COVID-19 lockdown that regularly involves police enforcement. Matt's daughter is already under pressure to accept the experimental COVID-19 vaccines and will face overwhelming pressure should the EUAs be extended to the 12-15 years of age group.

Jennifer Greenslade has an auto-immune disease which her minor child may well have inherited. This places her child at risk from the experimental COVID-19 vaccines. As Dr. Roth testified in his Sworn Declaration, even if her child is not auto-immune, she is still at greater risk of harm from the experimental injections because children's healthy immune systems have a stronger reaction to the experimental agents. Dr. Roth speaks as a medical expert and practicing physician who has watched COVID-19 vaccine-injured patients in his practice proceed to death, where he could do nothing to save them. Thus Ms. Greenslade's child may be too immune compromised to survive the COVID-19 injections or may be too robust to survive them. In either case, the COVID-19 vaccines expose her child to a significant risk of injury or death. Ms. Greenslade has witnessed the devastating impacts that the COVID-19 vaccines had on her auto-immune cousins, and fears the same consequences for her child. For a mother like Jennifer, simply extending the EUA to her child's age category creates irreparable mental and emotional harm.

Andrea McFarlane is a trauma/ICU nurse. Her boys are 10, 12 14 and 16. As a family, they are in the very center of the firestorm of imminent and irreparable harm. Andrea could lose her job, her reputation, or even her life. She could lose her boys. They could lose their health, suffering lifelong injury or trauma from the experimental injections if choice is removed. The boys will suffer the loss of friends, along with the good will of their teachers, coaches and friends for their conscientious stand against human experimentation that they are taking as a family. All of this harm can be averted entirely by simply preserving the status quo.

Plaintiffs have summarized *supra* the horrific adverse events, including both injury and death, caused by the COVID-19 vaccines as reported to VAERS. They have also presented evidence, extracted from Pfizer's EUA application, that at least that particular COVID-19 vaccine is self-disseminating, and may be spread by the vaccinated to the unvaccinated, including children, without their knowledge or informed consent. Individuals coerced into taking an experimental COVID-19 vaccine, without complete information as to risks and alternatives, and under the duress of incentives, penalties and extreme social pressure, and individuals effectively vaccinated without their knowledge and consent by a self-disseminating technology, and injured or killed as a result, have suffered irreparable injury. Garcia v. Google, Inc., 766 F.3d 929, 939 (9th Cir. 2014) (aff'd on rehearing en

banc, 786 F.3d 733 (9th Cir. 2015)("Death is an 'irremediable and unfathomable harm' ... and bodily injury is not far behind.").

Dr. Roth has witnessed the death of patients caused by the COVID-19 vaccines. No vaccine in history has ever caused even a fraction of the deaths that are reported to have been caused by the COVID-19 vaccines. Extending the EUA will increase those numbers, whereas preserving the *status quo* will have the effect of protecting the children within the target age group from a real and concrete risk of injury and death. Every Plaintiff with children or patients in the target age group stands to be immediately and irreparably harmed by the extension, and conversely protected by the preservation of the *status quo*.

Plaintiffs also note that withholding safe and effective alternative treatments constitutes an irreparable harm. Henderson v. Bodine Aluminum, Inc., 70 F.3d 958, 961 (8th Cir. 1995).

(3) Balance of Hardships:

The balance of hardships test tilts decidedly in favor of the Plaintiffs. The Defendants can make no science-based argument that preserving the *status quo* will create any hardship for them or for the public. It is possible that they can show a future monetary loss connected with the financial conflicts that are revealed and mentioned in this TRO, but those are precisely

the kind of hardships they may not rely upon to balance this prong of the test in their favor.

On the other hand, the Plaintiffs have established by credible and expert testimony and reference to CDC official numbers that the target age group faces no exposure to harm from COVID-19. Granting the TRO will preserve that status quo. The 12-15 year olds who are not being harmed by COVID-19 will continue to suffer no harm from COVID-19. If the EUA is extended, then the children in the target age group who are currently safe from the injury and death being visited upon the already vaccinated to a degree that departs dramatically from recorded experience with all other vaccines, will immediately begin to suffer that injury and death within their own population.

Further, the logic for the COVID-19 vaccines breaks down when one considers the Defendants' theory of asymptomatic spread. For over a year now, these Defendants and state-level public health authorities have told the American public that SARS-CoV-2 can be spread by people who have none of the symptoms of COVID-19. If that is the case, then a vaccine that merely reduces symptoms yields no benefits - the virus spreads anyway. If that is not the case, and asymptomatic spread is not real, then asymptomatic individuals do not need to be vaccinated with a vaccine that neither prevents infection with SARS-CoV-2 nor prevents its transmission.

(4) Advancement of the Public Interest:

The Supreme Court has stated that a motion for pretrial injunctive relief must show "that an injunction is in the public interest." Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 20 (2008). "[T]he court should weigh the public interest in light of the likely consequences of the injunction. Such consequences must not be too remote, insubstantial, or speculative and must be supported by evidence." Id.; *see also* Courthouse News Service v. Brown, 908 F.3d 1063, 1068 (7th Cir. 2018) ("court must ask whether the preliminary injunction is in the public interest, which entails taking into account any effects on non-parties").

Plaintiffs have demonstrated, using the Defendants, own data, that COVID-19 presents no statistically significant mortality risk to children under the age of 16. Thus these children do not benefit from the COVID-19 vaccines, and the public has no interest in extending the EUAs to this age category.

However, the American public does have an immediate and overwhelming interest in ensuring that its public health establishment, laboring under financial conflicts of interest, subject to extreme political pressure, and insulated from scrutiny by unprecedented censorship, does not repeat the errors of Tuskegee and Guatemala, and commit new human rights crimes. The public has an overwhelming interest in ensuring that children

under the age of 16 are not subjected to non-consensual human medical experimentation in the COVID-19 vaccine rollout.

WHEREFORE, for all of the foregoing reasons, Plaintiffs respectfully request that the Court grant the relief requested herein, preserving the *status quo* by enjoining the very recent without notice extension of the EUA for the Pfizer-BioNTech COVID-19 Vaccine to the 12-15 year-old age group, and enjoining further extensions of the EUAs to children under the age of 16 until such time as these issues have been litigated and resolved at trial.

Respectfully submitted this 19th day of May, 2021.

/s/ Lowell H. Becraft, Jr.

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I, Dr. Scott Jensen, MD, have been a practicing family medicine physician for forty years. I was honored to be the recipient of the “Minnesota Family Physician of the Year” Award in 2016. I am board-certified in family medicine. As part of my practice, I see patients of all ages. Approximately half are over the age of 70. Of those patients, approximately 75% have elected to receive one of the Emergency Use Authorized COVID vaccines. I am aware of the risks and benefits of these investigational agents as well as the current vaccine schedule for other diseases. Based on the most recent numbers from the CDC from May 5, 2021, anyone under the age of 17 is at statistically zero risk of dying of Covid 19 infection.

As per the CDC there have been 42,429 deaths from all causes in Americans ages 0-17. Of those deaths 248 tested positive for Covid 19. It is well known that a positive test is not a certain measure of COVID infection (in acknowledging the testing inaccuracies, on April 27, 2021 the CDC changed its guidelines to no longer accept test results in vaccinated patients with cycles > 28), thus the more accurate number is likely the 54 who had a positive COVID test *and* pneumonia listed as the cause of death. Using either number gives a statistically zero chance of death (0.0058 or 0.0012) being due to COVID 19 infection or complications from COVID-19 in this age group; thus it is reckless to advance vaccine trials in children ages 0-17.

As a board-certified family practitioner, I would be directly affected by a change in FDA guidelines regarding vaccines for young people, and as a result I am requesting an immediate TRO to halt this request. In addition to the direct threat posed to my young patients, an additional unwelcome consequence of using coercion to mandate the participation of healthy young people who are at a statistical zero risk, relates to a possible reduction in the public trust in all vaccines.

Scott Jensen, MD
Scott Jensen, MD (May 7, 2021 15:24 CDT)

Scott Jensen, MD






Dr. Scott Jensen Letter

Final Audit Report

2021-05-07

Created:	2021-05-07
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DECLARATION OF ELLEN MILLEN

Ellen Millen of Huntsville, Alabama, hereby declares:

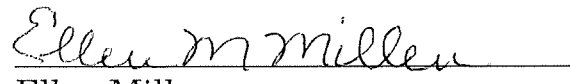
I am Guardian of three siblings, ages 5, 4 and 4, that have been placed under my care through Child Protective Services. I am responsible for making medical decisions related to the children in my care. I have obtained a vaccine exemption for the children in my care through the Madison County Health Department. I do not want the children in my care to receive experimental vaccines, and neither do the childrens' biological parents. I stand for all children and adolescents in opposing the emergency use authorization for children of any ages. I also have a 22-year-old son. I strongly feel the children currently in my care, as well as any future children in my care, face substantial risk if emergency use of the COVID-19 experimental vaccine is granted to adolescents. Without a Temporary Restraining Order, the children in my care face harm due to overwhelming pressure to take the vaccine from friends, parents of friends, sports organizations, summer camps, schools, and colleges.

I know there is essentially zero percent risk for young people dying of COVID-19 and fiercely opposes the use of an experimental, untested product in healthy children with no risk for a number of reasons. Furthermore, I know there are effective and safe treatments available to treat COVID-19

and oppose suppression of those treatments in favor of using untested and potentially life-threatening agents.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on May 12, 2021.


Ellen Millen

DECLARATION OF JODY SOBCZAK

Jody Sobczak of Huntsville, Alabama, hereby declares:

I am the father of two children, ages 15 and 17. I oppose the emergency use authorization for children of any age. I feel my children face substantial risk if emergency use of the COVID-19 experimental vaccine is granted to adolescents.

I know from my own research that there is essentially zero percent risk for young people dying of COVID-19 and fiercely oppose the use of an experimental, untested product in healthy children with no risk for a number of reasons. Furthermore, I know there are effective and safe treatments available to treat COVID-19 and oppose suppression of those treatments in favor of using untested and potentially life-threatening agents.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on May 12, 2021.



Jody Sobczak

DECLARATION OF DEBORAH SOBCZAK

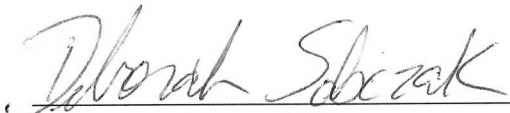
Deborah Sobczak of Huntsville, Alabama, hereby declares:

I am the mother of two children, ages 15 and 17. I oppose the emergency use authorization for children of any age. I feel my children face substantial risk if emergency use of the COVID-19 experimental vaccine is granted to adolescents.

I know from my own research that there is essentially zero percent risk for young people dying of COVID-19 and fiercely oppose the use of an experimental, untested product in healthy children with no risk for a number of reasons. Furthermore, I know there are effective and safe treatments available to treat COVID-19 and oppose suppression of those treatments in favor of using untested and potentially life-threatening agents.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on May 12, 2021.


Deborah Sobczak

DECLARATION OF LYLE BLOOM

Lyle Bloom of Huntsville, Alabama, hereby declares:

I am the father of two minor children, ages 10 and 16, and one adult child, age 21. I oppose the emergency use authorization for adolescents ages 12-15 and older. I feel my children face substantial risk if emergency use of the COVID-19 experimental vaccine is granted to adolescents.

I have done my research and know that there is essentially zero percent risk for young people dying of COVID-19 and fiercely oppose the use of an experimental, untested product in healthy children with no risk for a number of reasons. Furthermore, I know there are effective and safe treatments available to treat COVID-19 and oppose suppression of those treatments in favor of using untested and potentially life-threatening agents. I am very concerned about the way the emergency use authorizations have been rolled out and feel strongly that everyone has the right to choose medical treatment, especially potentially risky experimental treatment.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on May 12, 2021.

Lyle S Bloom

Lyle S Bloom (May 12, 2021 15:23 CDT)

Lyle Bloom






Declaration of Lyle Bloom

Final Audit Report

2021-05-12

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-  Document created by Nancy Vazquez (nancy@joeygilbertlaw.com)
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Signature Date: 2021-05-12 - 8:23:56 PM GMT - Time Source: server- IP address: 204.154.192.252
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DECLARATION OF JULIE BLOOM


Julie Bloom of Huntsville, Alabama, hereby declares:

I am the mother of two minor children, ages 10 and 16, and one adult child, age 21. I oppose the emergency use authorization for adolescents ages 12-15 and older. I feel my children face substantial risk if emergency use of the COVID-19 experimental vaccine is granted to adolescents.

I have done my research and know that there is essentially zero percent risk for young people dying of COVID-19 and fiercely oppose the use of an experimental, untested product in healthy children with no risk for a number of reasons. Furthermore, I know there are effective and safe treatments available to treat COVID-19 and oppose suppression of those treatments in favor of using untested and potentially life-threatening agents. I am very concerned about the way the emergency use authorizations have been rolled out and feel strongly that everyone has the right to choose medical treatment, especially potentially risky experimental treatment.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on May 12, 2021.


Julie A. Bloom (May 12, 2021 15:25 CDT)

Julie Bloom






Declaration of Julie Bloom

Final Audit Report

2021-05-12

Created:	2021-05-12
By:	Nancy Vazquez (nancy@joeygilbertlaw.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAH9uSYAlp9JlI8phChNcmjgHNDEWsDRB4

"Declaration of Julie Bloom" History

-  Document created by Nancy Vazquez (nancy@joeygilbertlaw.com)
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-  Document emailed to Julie A. Bloom (bloomerang5@outlook.com) for signature
2021-05-12 - 5:54:28 PM GMT
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2021-05-12 - 8:20:27 PM GMT- IP address: 24.96.250.120
-  Document e-signed by Julie A. Bloom (bloomerang5@outlook.com)
Signature Date: 2021-05-12 - 8:25:42 PM GMT - Time Source: server- IP address: 24.96.250.120
-  Agreement completed.
2021-05-12 - 8:25:42 PM GMT

DECLARATION OF ANDREA McFARLANE, RN

Andrea McFarlane, hereby declares:

I am currently working as a trauma/ICU nurse at Vanderbilt. I have been working within the Huntsville Alabama hospital system for more than five years and continue to do my NP precepting in Huntsville, Alabama.

At Huntsville hospital and Vanderbilt, we COVID test trauma patients and anyone else who presents with COVID like symptoms through the ER.

I was working as an ER nurse in Alabama when COVID first started, and it was very difficult because it was a new, scary situation.

We are not seeing many patients come into the trauma unit with COVID-19 currently nor have we over the winter months.

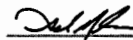
I have seen a tremendous amount of pressure placed on medical personnel to get the shot, even doctors and nurses who have had COVID-19! We are being pressured to get the shot and we're sick, really sick for days. This is well known – staffing takes this into account. My co-workers and fellow students have all recovered, but some did not get a second shot out of fear for what damage could have been caused from the first.

I am also currently in school and I am being pressured to get the vaccine. People who get the vaccine are given incentives, class time without a mask and so on.

I am a mom of four boys, ages 10, 12, 14 and 16 and I am extremely worried because I know my children will be pressured to take the vaccine. My 16-year-old son has many friends who have taken the vaccine. It's become the thing to do because kids are pressuring each other to take the vaccine and I am extremely worried for my children's health. No one loves kids more than their parents, plus I am a nurse and I read a lot on the subject. Based upon the trials being experimental and no published animal studies and no long-term safety data possible, this should not be able to even be offered to children! It should be illegal to pressure kids to take something new for a virus that doesn't hurt them, and I fear that if this TRO isn't granted my children will suffer harm. I also will be unable to work because I will be required to comply with a policy that I know is immoral.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on May 12, 2021.



Andrea McFarlane (May 12, 2021 21:55 CDT)

Andrea McFarlane

DECLARATION OF ANDREA McFARLANE






copy

Final Audit Report

2021-05-13

Created:	2021-05-13
By:	Nancy Vazquez (nancy@joeygilbertlaw.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAR0ijwzNEGcgRxxroe0iRSo_IHgFAgtNM

"DECLARATION OF ANDREA McFARLANE copy" History

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-  Agreement completed.
2021-05-13 - 2:55:51 AM GMT

DECLARATION OF JENNIFER GREENSLADE

Jennifer Greenslade, of Remlap, Alabama, hereby declares:


I have an autoimmune disorder for which I take daily medication, so I am very concerned that the experimental COVID vaccine could harm my health. I have seen reactions to the vaccine that appear to be random in others, and I am unwilling to take a chance. I have also read that the vaccines can be linked to autoimmune disease.

I have two children ages 12 and 9. I am unwilling to allow my children to be injected with the experimental COVID vaccine. This is because it is experimental and my own health issues which they may have inherited. It is also because we have two cousins who had very bad reactions from the COVID vaccine. They both spent several weeks in ICU. They were on the brink of death. They still cannot walk. Their daughter must care for them now. They were both healthy before the covid vaccine.

I have seen first-hand evidence that the vaccines are not always safe. It is not possible to know that my own health or my children's health will not worsen, especially because they are at increased risk from both sides of the family. In addition, I know that children don't get very sick or die from COVID. It should not be allowed for children.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on May ____, 2021.


Jennifer Greenslade (May 12, 2021 16:47 CDT)

Jennifer Greenslade






Declaration of Jennifer Greenslade

Final Audit Report

2021-05-12

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By:	Nancy Vazquez (nancy@joeygilbertlaw.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAZ_y6ExGSi2Oq1PReuYTt2h4A-oN2HJva

"Declaration of Jennifer Greenslade" History

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-  Agreement completed.
2021-05-12 - 9:47:59 PM GMT

DECLARATION OF STEVEN M. ROTH, MD

Steven M. Roth, MD, hereby declares:

I have been a practicing emergency medicine physician for 13 years. As part of my practice, I see patients of all ages. I am aware of the risks and benefits of these investigational agents as well as the current vaccine schedule for other diseases. Based on the most recent numbers from the CDC from May 5, 2021, anyone under the age of 17 has statistically zero risk of dying of Covid 19.

I have not seen a COVID-19 patient in many months, but I am seeing many patients come to the emergency department patients post-COVID-19 shot. All of these patients came in with COVID-like symptoms that occurred within 48 hours of the shot.

All of these patients required hospital admission.

Several of these patients progressed to death. From the vaccine.

My concern is that based upon what I am seeing in the community, and because of the schools asking for vaccines and putting obstacles around those who do not take it, young people are being pressured to take an experimental shot and many are succumbing to that pressure. This is very concerning because it is universally known that children virtually never die from COVID-19 and given that children have a very strong immune system, they

are more likely than adults to have an over-reaction to the shot. Meaning that there is zero benefit and only risk. Also, with all prior viruses and vaccines, it is accepted that natural immunity is superior to vaccination, and there is no basis to believe that would be different with SARS-CoV-2, meaning it is actually not preferable to give the vaccine even if it was definitely safe, which it is not.

I am extraordinarily concerned that there are no animal studies, no long-term animal studies because prior coronavirus vaccines all caused death in the animal studies portion, which was simply skipped this time.

I am aware of many thousands of physicians who agree with me, but we are pressured to not say anything. I am speaking up now, at great personal cost to myself, because I cannot live with myself if this is given to kids universally and we see death and destruction over the years. It is unconscionable that an experimental therapy will be given to children. Children are not mini-adults. Their organs are still forming and they are more vulnerable than adults to developing auto-immune disease in this situation.

I would be directly affected by a change in FDA guidelines regarding vaccines for young people, and as a result I am requesting an immediate TRO to halt this request. In addition to the direct threat posed to my young patients, an additional unwelcome consequence of using coercion to mandate

the participation of healthy young people who are statistically at zero risk is sharply reducing the public trust in all vaccines.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on May 12, 2021.

Steven M. Roth MD
Steven M. Roth MD (May 12, 2021 22:14 CDT)

Steven M. Roth, MD






Declaration of Steven M Roth MD

Final Audit Report

2021-05-13

Created:	2021-05-12
By:	Nancy Vazquez (nancy@joeygilbertlaw.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAANSNMBiD9ucnDn9aDD5eHd-o5AkDcgOIF

"Declaration of Steven M Roth MD" History

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-  Email viewed by Steven M. Roth MD (smrothmd@gmail.com)
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-  Document e-signed by Steven M. Roth MD (smrothmd@gmail.com)
Signature Date: 2021-05-13 - 3:14:36 AM GMT - Time Source: server- IP address: 96.94.171.57
-  Agreement completed.
2021-05-13 - 3:14:36 AM GMT

DECLARATION OF MATT SCHWEDER

Matt Schweder of Lexington, Kentucky, hereby declares:

I am the father of one minor daughter, age 15 years, and an adult son, age 25 years, who is in the Advanced Nurse Practitioner Program at Vanderbilt, University. I oppose the emergency use authorization for adolescents ages 12-15 and older. I feel my children face substantial risk if emergency use of the COVID-19 experimental vaccine is granted to adolescents.

My family has been receiving a weekly barrage of emails from my daughter's school about COVID-19, and my daughter has been subjected to peer pressure. My daughter told me the vaccine is a constant topic of conversation on her group chats, and during soccer practice. (See attached Exhibit A)

My son is extremely concerned over his future and the potential of his school and/or professional employer making vaccines mandatory, which will put his education to waste.


I have done my research and know that there is essentially zero percent risk for young people dying of COVID-19 and fiercely oppose the use of an experimental, untested product in healthy children with no risk for a number of reasons. Furthermore, I know there are effective and safe treatments available to treat COVID-19 and oppose suppression of those

treatments in favor of using untested and potentially life-threatening agents.

I am very concerned about the way the emergency use authorizations have been rolled out and feel strongly that everyone has the right to choose medical treatment, especially potentially risky experimental treatment. Furthermore, the pressure being presented to adolescents, who are less informed, less independent, and less willing to stand up for their rights is more than concerning to me.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on May ____, 2021.

 (May 12, 2021 23:45 EDT)

Matt Schweder

Declaration of Matt Schweder (1)

Final Audit Report

2021-05-13

Created:	2021-05-13
By:	Nancy Vazquez (nancy@joeygilbertlaw.com)
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"Declaration of Matt Schweder (1)" History

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-  Document emailed to Matt Schweder (mschweder@twc.com) for signature
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Signature Date: 2021-05-13 - 3:45:56 AM GMT - Time Source: server- IP address: 65.189.252.208
-  Agreement completed.
2021-05-13 - 3:45:56 AM GMT

Exhibit A – Declaration of Matt Schweder

**Representative Emails from
Fayette County Public Schools
Pressuring Students and
Families to Vaccinate.**

From: "noreply@fayette.kyschools.us"
To: "Fayette County Public Schools Recipients"
Cc:
Sent: Tuesday March 16 2021 7:44:34PM
Subject: 3.16.21 FCPS In-Person Learning Update from Dr. Helm

March 16, 2021

Dear Fayette County Public Schools Families:

Just like our clocks, our return to in-person learning leapt forward this week with the arrival of our students in preschool, and grades 7, 8, 10, and 11 at school on Monday. With students at every grade level now back on campus, we feel reconnected and reenergized about the days ahead.

Our community continues to harness the spread of COVID-19 and today's 7-day average of new cases has fallen to 41! Each Tuesday, we review multiple data points as part of our FCPS In-Person Matrix, and we are pleased to report that all other indicators continue to support our return to campus.

Utilizing hubs, shuttles, vans and schedule adjustments, our transportation team has worked diligently to find a solution that will enable us to bring back the middle and high school students whose families have chosen in-person learning for the remainder of our special programs on Monday, March 22.

Families whose children are impacted have already begun to receive communication with specifics from Carter G. Woodson Academy, Eastside Technical Center, Family Care Center, Locust Trace AgriScience Center, Martin Luther King Academy, Opportunity Middle College, Southside Technical Center, STEAM Academy, Success Academy, The Learning Center, and The Stables.

As we pass the one-year mark of the pandemic, I believe we all recognize that our lives have been forever changed in some way by COVID-19. My hope is that the challenges of the past 12 months inspire us to all to make the necessary individual decisions in order to collectively keep the virus at bay so our schools can stay open.

With spring break on the horizon, we will need everyone's help to avoid another surge of cases like the one we saw in January after winter break. Just this afternoon, the governor announced that a new variant of COVID-19 has been found in the Commonwealth. Now is not the time to let our guard down.

Unlike a year ago, we now know how to beat COVID-19. Together we can and together we will!

Sincerely,

Marlene Helm

Fayette County Public Schools Acting Superintendent

From: "noreply@fayette.kyschools.us"
To: "Fayette County Public Schools Recipients"
Cc:
Sent: Tuesday March 23 2021 8:16:15PM
Subject: FCPS In-Person Learning Matrix Update 3.23.21

March 23, 2021

Dear Fayette County Public Schools Families:

Your safe choices made it possible for us to return to campus, and we are grateful for the opportunity to be back in person with students whose families chose that option.

When you consider that Fayette County spent the whole month of January in purple – hitting a high of 264 average daily cases – our progress is truly remarkable. At 34, today's 7-day average of new cases is just on the edge of yellow – a level our community has not seen in nearly nine months.

Now that our students are back in person, we need your help again. With just three days left before spring break, we hope everyone continues to practice the healthy habits that have helped reduce COVID-19 infections. These precautions include avoiding crowds and group gatherings whenever possible, ordering take out, socializing outdoors, wearing masks, and washing hands frequently.

If you are planning a staycation, spring break would also be a great time to make arrangements to be vaccinated. All members of the Fayette County community, 16 years of age and older, are encouraged to sign up to receive the free, safe, vaccine at <https://ukhealthcare.uky.edu/covid-19/vaccine>. Those 18 or older can also sign up at www.lfchd.org/vaccine. Free rides to COVID-19 vaccination clinics are available through Federated Transportation Services of the Bluegrass. Please call 1-888-848-0989 in advance to schedule a ride.

Before returning to campus after spring break, please review the Family Assurance of Student Health document attached to this email and be especially thoughtful in assessing your child's possible symptoms before sending them to school.

Although we have not had any spread of the virus at schools, we have received reports of students contracting COVID-19 from sleepovers, parties, and traveling youth activities. Those individual weekend decisions have then forced other students into quarantine. It took all of us to get back on campus and it will take all of us to keep our schools open.

This has been a school year like none other. We hope that our families have an enjoyable spring break and look forward to seeing everyone healthy and back on campus April 5!

Sincerely,

Marlene Helm

Acting Fayette County Public Schools Superintendent

Attachments:

messages/attachments/58cc73f8db435f8b7bbb037593828384/FCPS_Family_Assurance_of_Student_Health_Agreement_English.pdf (100.3 KB)



**Fayette County Public Schools
Family Assurance of Student Health Agreement**

We all play a role in protecting the health, safety, and well-being of our students, staff and families. One of the most important things we can do to prevent the potential spread of COVID-19 is to stay home when we are sick or have been exposed to someone who is sick.

Before sending your child to campus for in-person learning, please sign and return this form showing that you agree to the following:

1. I will NOT send my child to school until they are released from quarantine by the health department if:
 - My child has been in close physical contact (6 feet or closer for at least 15 minutes) with a person who is known to have COVID-19.
 - Anyone in our household tests positive COVID-19.
 - My child has traveled out of the country.
2. I will check my child each day for the following known symptoms of COVID-19 and will NOT send my child to school if they are experiencing:
 - Fever (temperature of 100.4°F or greater) or chills Sore throat
 - New uncontrolled cough that causes difficulty breathing (for students with chronic allergic/asthmatic cough, a change in their cough from baseline)
 - Diarrhea, vomiting, or abdominal pain New onset of severe headache
3. If my child is tested for COVID-19 for any reason, I will not send them to school until I receive their results. If they test positive, I will NOT send them to school until cleared to do so by a medical professional. I understand I am required to report a positive test result to FCPS within 24 hours of receiving the results.
4. If my child meets any of the conditions above or is exhibiting any of the symptoms of COVID-19, I will notify the school of my child's absence.
5. If my child develops any symptoms of COVID-19 during the school day, I agree that I, or my designee, will pick up my child as soon as possible.

Student Name: _____

School: _____

Parent/Guardian Signature: _____

Date: _____



FAYETTE COUNTY PUBLIC SCHOOLS



To: "mschweder@twc.com" <mschweder@twc.com>
Subject: FW: Spring Break and Summer Ignite

...

From: "noreply@fayette.kyschools.us"
To: "Fayette County Public Schools Recipients"
Cc:
Sent: Friday March 26 2021 8:12:45PM
Subject: Spring Break and Summer Ignite

March 26, 2021

Dear Fayette County Public Schools Families:

Having our students back on campus has been a joy! Our new safety routines are working well, and our students have become pros at adapting.

We hope everyone will continue those good habits during Spring Break, so we can keep the numbers of new COVID-19 cases in our community down. As we take cautious steps toward a feeling of normal, it may be tempting to return to the habits and behaviors we enjoyed pre-COVID, but experts continue to caution that it is not safe to do so yet.

Now that we have cleared the hurdle of returning all of our students whose families have chosen in-person learning back to campus, we can shift some of our attention to promoting summer learning opportunities.

Fayette County Public Schools is excited to announce that our schools will offer a program called Summer Ignite to supplement student learning.

When we return in April, schools will begin sharing specific information with their families. Each school has been working to design a Summer Ignite program aligned to their individual school offerings in order to best serve their students. As you know, in Kentucky, this determination falls within the responsibility of each School-Based Decision Making Council.

Summer Ignite will operate during three sessions:

- Session 1 – June 8–June 25
- Session 2 – July 6–July 23
- Session 3 – July 26–30 for students entering kindergarten, sixth grade and ninth grade

Hours of each session will be:

- Elementary programs will run from 8 a.m. to noon.
- Middle and high school programs will be from 9 a.m. to 1 p.m.

Decisions about what the program will look like and which students **will be invited** to participate are determined by the SBDM at each school, led by the school principal. Priority will be placed on:

- Students whose achievement data shows the need for additional learning opportunities in order to be prepared for the 2021-22 school year,
- Students in need of credit recovery, and
- Students who may need an opportunity to extend learning through inquiry and project-based learning to enhance skills and content knowledge.

As a district, Fayette County Public Schools is supporting Summer Ignite by:

- Providing materials and resources for schools,
- Setting a shared schedule,
- Creating a planning framework for schools,
- Coordinating transportation for students,
- Recruiting community partners for schools,
- Serving breakfast and lunch to students,
- Investing federal stimulus funding to cover the cost of staffing, including coordinators at each location and increased pay to help attract staff for the program.

I encourage anyone with questions about the program that might be available to your child to look for additional communication from the school. You can also visit www.fcps.net/ignite.

We are excited for you to see and hear the innovative ideas our schools have developed to meet the needs of the children who will be served! We are fortunate in Fayette County Public Schools to have such a wide variety of learning options available to help students reach their unlimited potential.

Thank you for your continued support and engagement. Please have a wonderful spring break!

Sincerely,

Marlene Helm

Fayette County Public Schools Acting Superintendent

From: "noreply@fayette.kyschools.us"
To: "Fayette County Public Schools Recipients"
Cc:
Sent: Saturday April 24 2021 7:21:13PM
Subject: COVID-19 vaccines available Tuesday at six FCPS high schools

April 24, 2021

Dear Fayette County Public Schools Families:

I am writing this afternoon with great news! Fayette County Public Schools has partnered with Wildhealth and LFUCG to offer the COVID-19 vaccine at our six high schools on **Tuesday, April 27, 2021**.

All FCPS students 16 years of age or older are eligible to be vaccinated, as are our families and employees. Students who are fully vaccinated (two weeks past the second dose) may not need to quarantine, should they be exposed to COVID-19 in the future.

Vaccination sign-ups are available at: kyvax.wildhealth.com. The site includes a way for families to give consent for 16- and 17-year-olds to receive the vaccine. When you register, please reserve a spot for the first vaccine on April 27th and a second dose on May 18th.

If you have any questions or difficulty with the registration process, please contact the Wildhealth Help Desk at 859-217-4679. Federated Transportation Services of the Bluegrass is offering FREE rides to COVID-19 vaccine clinics for those in need. Schedule a ride by calling 888-848-0989.

This opportunity is open to ALL students, their families, and staff in FCPS, regardless of school affiliation.

This clinic will offer the Pfizer-BioNTech COVID-19 Vaccine, which is administered as a shot in the arm in a series of two doses, three weeks apart. Studies show this vaccine is 95% effective at preventing COVID-19 illness.

There is no cost to get the vaccine.

Many students have already been vaccinated, and I encourage you to do the same for yours.

Sincerely,

Marlene Helm

Fayette County Public Schools Acting Superintendent

From: "noreply@fayette.kyschools.us" <donotreply@blackboard.com>
Date: May 4, 2021 at 6:56:27 PM EDT
To: Fayette County Public Schools Recipients <recipients@FCSD.parentlink.net>
Subject: FCPS In-Person Learning Matrix Update 5.4.21
Reply-To: FCPS Schools <noreply@fayette.kyschools.us>

...

May 4, 2021

Dear Fayette County Public Schools Families:

With just two Tuesdays left in the school year, COVID-19 cases in our community are holding steady. The current 7-day average of new cases in Fayette County is 37, keeping us in orange on the FCPS In-Person Learning Matrix.

After an uptick last week, positive COVID-19 cases among students and staff are down to 41 in the past week and the number of individuals placed into quarantine due to possible exposure is at a three-week low of 430.

We remain on track to complete the school year in person and celebrate our Class of 2021 in Rupp Arena.

During our meeting today with the Lexington-Fayette County Health Department, we talked at length about the evolving guidance regarding outdoor mask use from the Governor, Kentucky Department of Education, and Centers for Disease Control.

In the end, we determined that our current mask protocols **will remain in place for the rest of the school year**. That means all students and adults (with the exception of those who have a medical exemption or ARC-determined exemption) are required to wear masks while on school property.

Many of our schools already allow students to be outdoors without masks as long as they are with their cohort. CDC guidance remains clear that those who are not fully vaccinated (which includes most of our students) should continue wearing a mask. We will revisit these guidelines for summer activities.

In closing, I want to make families, students and employees aware of another COVID-19 vaccination opportunity at one of our schools. Appointments are available from 9 a.m. to 1 p.m. on Thursday, May 13, at STEAM Academy, located at 1555 Georgetown Road. To register, visit [kyvax.wildhealth.com](https://www.kyvax.wildhealth.com). Stakeholders are also invited to sign up for appointments at Bryan Station, Frederick Douglass, Henry Clay, Lafayette, Paul Laurence Dunbar, and Bates Creek high schools on May 18.

Thank you once again for your continued support.

Sincerely,

Marlene Helm

Fayette County Public Schools Acting Superintendent

Gov/Big Pharma Conflict

The vaccine is called mRNA-1273 and was developed by NIAID scientists and their collaborators at the biotechnology company Moderna, Inc., based in Cambridge, Massachusetts. The Coalition for Epidemic Preparedness Innovations (CEPI) supported the manufacturing of the vaccine candidate for the Phase 1 clinical trial.

“Finding a safe and effective vaccine to prevent infection with SARS-CoV-2 is an urgent public health priority,” said NIAID Director Anthony S. Fauci, M.D. “This Phase 1 study, launched in record speed, is an important first step toward achieving that goal.”¹

To receive a share of the profit from the sale of mRNA-1273, the inventors of this product within NIAID would submit an Employee Invention Report to the NIH Office of Technology transfer.² Each inventor stands to receive a personal payment of up to \$150k annually from the sales of mRNA-1273.³ In addition, NIAID stands to earn millions of dollars in revenue from the sale of mRNA-1273.⁴

Moderna will pay license fee to NIAID to use its patents related to mRNA-1273 and a portion of those fees are then paid directly to the inventors within NIAID who developed those patents.⁵

NIH has produced reports which confirm that these individuals are listed as inventors.⁶

- Barney Graham, Deputy Director, NIAID Vaccine Research Center
- Kizzmekia Shanta Corbett, Scientific Lead, NIAID's Coronavirus Vaccine Program
- Michael Gordon Joyce, NIAID
- Hadi Yassine, NIAID
- Masaru Kanekiyo, NIAID
- Olubukola Abiona, NIAID

HHS awarded \$483 million to accelerate development of mRNA-1273.⁷ The US Government has reached a 1.525 billion deal to purchase 100 million doses of mRNA-1273.⁸

In 2013, the Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT) program awarded grant funding to Moderna Therapeutics for the development of a new type of vaccine based on messenger RNA. The initial DARPA grant was W911NF-13-1-0417. ***The company used that technology to develop its COVID-19 vaccine, currently undergoing Phase I clinical trials in conjunction with NIH.***⁹

FDA Vaccines and Related Biological Products Advisory Committee Roster

Content current as of 4/9/21¹⁰

Any consideration of financial conflict of interest at the Vaccines and Related Biological Products Advisory Committee must be set against the historical backdrop of the profound financial conflicts of interest seen in the during the H1N1 pandemic ten years ago. At that time, five of the sixteen experts were found to have ties to the pharmaceutical industry. There were “calls from the British Medical Journal, to release the names of committee members and their conflicts of interest, in the interest of transparency and to monitor any possible commercial influence.” That earlier “pandemic has proved profit-making for the industry, with one estimate (by JP Morgan) putting 2009 vaccine profits alone at \$7-10 billion.”¹¹

There appear to be significant conflicts of interest today especially among committee leaders. The items reported in this memo are the results of a quick preliminary check on conflicts and are not a complete representation. Plaintiffs intend to conduct a more thorough investigation before trial.

Chair

Hana El Sahly, M.D.

Expertise: Vaccines, Infectious Diseases

Term: 06/21/2019-01/31/2022

Professor

Department of Molecular Virology and Microbiology

Department of Medicine

Section of Infectious Diseases

Baylor College of Medicine

Houston, TX 77030

hanae@bcm.edu

- Top FDA vaccine adviser recuses herself over tie to Moderna.¹²
- Associate Professor Baylor. She currently serves as the Principal Investigator of the Vaccine and Treatment Evaluation Unit at Baylor College of Medicine.¹³
- Federal database shows since 2013 \$693,001.78 in general payments and \$5,315,014.60 in research payments made to “Chi St. Lukes Health Baylor Med Ctr” – 6720 Bertner Ave, Houston, TX from various companies.¹⁴
- Dr. El Sahly was appointed as one of three lead investigators for Moderna’s 30,000-person trial in July. Reuters reported that Dr. El Sahly had to recuse herself from an important committee meeting on Oct. 22, 2020.^{15, 16} There are multiple citations of this. e.g. 17, 18, 19 & 20 Ironically, there is no compensation of Dr. El Sahly reported on the openpaymentsdata.cms.gov website. This raises serious questions as to the completeness of the conflict

data reported on that site. The University of Florida Conflicts of Interest Program and the Project on Government Oversight reported conflicts of interest of Drs. El Sahly, Monto, and Chatterjee.^{21, 22}

Paula Annunziato, M.D

Expertise: Industry Representative

Term: 02/01/2020-01/31/2024

Vice President and Therapeutic Area Head

Vaccines Clinical Research

Merck

North Wales, PA 19454

- Past (or current?) involvement in supervising Moderna's Covid-19 vaccine clinical trial.²³
- Not listed in the openpaymentsdata.cms.gov website.

Acting Chair

Arnold Monto, M.D.

Thomas Francis Jr. Collegiate Professor of Public Health

Professor of Epidemiology

Department of Epidemiology University of Michigan

School of Public Health

Ann Arbor, MI 48109

- Acting chairman of the committee, Dr. Arnold Monto received \$54,114 from 2013 through 2019 from vaccine contenders Sanofi, GlaxoSmithKline, Pfizer, and Shionogi, according to the database. He also received \$10,657 from Novartis, which has a deal to manufacture a coronavirus vaccine.²⁴
- Dr. Monto received a total of \$194,254 from pharmaceutical companies.²⁵ The largest contributor was Seqirus, a company developing COVID vaccine in Australia.²⁶ The University of Florida Conflicts of Interest Program and the Project on Government Oversight reported conflicts of interest of Drs. El Sahly, Monto, and Chatterjee.^{27, 28}

Archana Chatterjee, M.D., Ph.D.

Expertise: Pediatrics, Infectious Diseases

Term: 06/21/2019-01/31/2023

Dean Chicago Medical School

Vice President for Medical Affairs

Rosalind Franklin University of Medicine and Science

North Chicago, IL 60064

- A federal database shows that, in 2019, advisory committee member Dr. Archana Chatterjee, for instance, received \$23,904 from Pfizer (including Pfizer International LLC), \$11,738 from Merck, and \$11,480 from Sanofi, each of which is in the race for a coronavirus vaccine. Since 2013, she has received more than \$200,000 in consulting fees, travel and lodging, and other payments from those companies and others working on coronavirus vaccines, according to the database.²⁹
- She is a professor of epidemiology at the University of Michigan, which has announced that it is partnering with pharmaceutical company, AstraZeneca on a clinical trial of a potential Covid-19 vaccine.³⁰
- General payments to Dr Chaterjee total \$245,810. Associated research funding totals \$142,344. Largest funders include: Pfizer Inc., Merck Sharp & Dohme Corporation, Seqirus USA Inc., and AstraZeneca Pharmaceuticals.³¹ The University of Florida Conflicts of Interest Program and the Project on Government Oversight reported conflicts of interest of Drs. El Sahly, Monto, and Chaterjee.^{32, 33}

CAPT Amanda Cohn, M.D.

Expertise: Pediatrics, Vaccines

Term: 02/01/2020-01/31/2024

Chief Medical Officer

National Center for Immunizations and Respiratory Diseases

Centers for Disease Control and Prevention

Atlanta, GA 30333

Telephone: (404) 639-6039

E-mail: acohn@cdc.gov

Hayley Gans, M.D.

Expertise: Pediatrics, Infectious Diseases

Term: 06/21/2019-01/31/2023

Professor of Pediatrics

Department of Pediatrics

Stanford University Medical Center

Stanford, CA 94305

Holly Janes, Ph.D.

Expertise: Biostatistics

Term: 02/01/2020-01/31/2023

Associate Member

Fred Hutchinson Cancer Research Center

Vaccine and Infectious Disease Division

Division of Public Health Sciences

Seattle, WA 98109

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Michael Kurilla, M.D., Ph.D.

Expertise: Infectious Diseases, Pathology
Term: 08/06/2018-01/31/2022
Director, Division of Clinical Innovation
National Center for Advancing Translation Sciences
National Institutes of Health
Bethesda, MD 20852
Michael.kurilla@nih.gov

Myron Levine, M.D., D.T.P.H., F.A.A.P

Expertise: Infectious Diseases
Term: 05/09/2018-01/31/2022
Simon & Bessie Grollman Distinguished Professor
Associate Dean for Global Health
Vaccinology and Infectious Diseases
Center for Vaccine Development
University of Maryland School of Medicine
Baltimore, MD 21201

- Dr. Myron Levine is associate dean for global health, vaccinology, and infectious diseases at the University of Maryland School of Medicine. The school is participating in a clinical trial of a COVID-19 vaccine being developed by Moderna and the National Institute of Allergy and Infectious Diseases.³⁴
- Since 2013, for research in which Levine played a principal role, GlaxoSmithKline has paid the University of Maryland Baltimore Foundation Inc. and another institution more than \$2.3 million.³⁵
- Dr. Levine received general payments of \$41,635 and associated research funding of \$2,314,178. Dr. Levin's 2019 funding was about six times the mean of similar physicians.³⁶ His largest source of funding was Sanofi Pasteur who is developing a COVID vaccine as above.³⁷
- UM School of Medicine's Myron M. Levine, MD, DTPH, to Receive Prestigious Lifetime Award for Five Decades of Pioneering Vaccine Research³⁸

- Was on a WHO sponsored advisory group that considered feasibility of doing Covid-19 challenge studies in young, healthy volunteers. No conflict of interest declared. Also on the panel was Sheng-Li Shi from WIV.³⁹

H. Cody Meissner, M.D. (aka Herman Meissner)

Expertise: Infectious Diseases

Term: 08/06/2018-01/31/2022

Professor of Pediatrics

Tufts University School of Medicine

Director, Pediatric Infectious Disease

Tufts Medical Center

Boston, MA 02111

- Tufts Children's Hospital - Division of Pediatric Infectious Disease. Head of all clinical trials for all of Tufts Children's Hospital.⁴⁰
- Since 2013, Tufts University has been paid general payments of \$13,241,677.43 by companies including Pfizer, Boston Scientific, Gyrus Acmi, Inc., Janssen Scientific, Biogen, Inc., Bayer Healthcare, Sanofi-Aventis, Genentech, Otsuka Pharmaceutical, Amgen, Inc.⁴¹
- Since 2013, Tufts University has been paid research payments of \$34,183,399.06 by companies including Pfizer, Inc., Merck Sharp & Doh, Shire North America, Abiomed, Gilead Sciences, Inc.)⁴²

Paul Offit, M.D.

Expertise: Infectious Diseases

Term: 02/01/2018-01/31/2022

Professor of Pediatrics

Division of Infectious Diseases

Abramson Research Building

The Children's Hospital of Philadelphia

Philadelphia, PA 19104

- Director of the Vaccine Education Center and an attending physician in the Division of Infectious Diseases at Children's Hospital of Philadelphia.⁴³
- Since 2013, The Children's Hospital of Philadelphia has received general payments of \$4,559,116.78 and research payments of \$32,013,340.94 from companies including Spark Therapeutics, United Therapeutics, Novartis Pharmaceuticals, Amgen, Inc., Pfizer, Inc.⁴⁴
- ***Vaccine Safety: Myths and Misinformation.*** No Conflict of Interest Declared.⁴⁵
- ***The science of vaccine safety: Summary of meeting at Wellcome Trust,*** Conflict of interest statement: Declaration of Competing Interest The authors declare that they have no known competing financial interests or personal

relationships that could have appeared to influence the work reported in this paper.⁴⁶

Steven Pergam, M.D.

Expertise: Infectious Diseases

Term: 02/01/2020-01/31/2024

Medical Director

Infection Prevention

Seattle Cancer Care Alliance

Seattle, WA 98109

Phone: 206.667.7126

Email: spergam@fredhutch.org

- Associate Professor, Vaccine and Infectious Disease Division, Fred Hutch
 - Associate Professor, Clinical Research Division, Fred Hutch⁴⁷
 - Since 2013, Dr. Pergam has received \$4167.00 in general payments from Merck and Gilead and \$140,311.19 research funding from Merck, Sharp and Dohme.⁴⁸
 - ***Potential conflicts of interest.*** A. L. G. reports personal fees from Abbott Molecular outside the submitted work. S. A. P. reports grant support from Global Life Technologies, Inc, participates in research trials with Chimerix, Inc, and has participated in research with Merck & Co. He is currently participating in a clinical trial sponsored by the National Institute of Allergy and Infectious Diseases (NIAID; U01-[AI132004](#)); vaccines for that trial are provided by Sanofi-Aventis.
-

Andrea Shane, M.D., M.P.H., M.Sc.

Expertise: Pediatric & Infectious Diseases

Term: 02/01/2018-01/31/2022

Professor of Pediatrics

Director

Division of Pediatric Infectious Diseases

Emory University School of Medicine

Atlanta, GA 30322

404-727-9880 (direct)

.....

404-727-5642 (main)

Email: ashane@emory.edu

- Medical Director Children's Healthcare of Atlanta; Curriculum vitae⁴⁹
- Since 2013, Egleston Childrens Hospital at Emory has received \$114,148.01 in general payments and \$814,977.27 in research payments from companies including Jazz Pharmaceuticals, Genmark Diagnostics, WL Gore & Associates, etc.⁵⁰

- Since 2013, Emory University Hospital has received \$44,133,351.66 in general payments and \$170,711,591.68 in research payments. At the top of the research companies are ER Squibb & Sons and Pfizer, Inc.⁵¹
- Since 2013, Wesley Woods Center of Emory University has received \$41,205.70 in general payments and \$3,429,327.48 in research payments. Topping the research companies are E.R. Squibb & Sons and Janssen Research.⁵²

Paul Spearman, M.D.

Expertise: Pediatric & Infectious Diseases

Term: 05/09/2018-01/31/2022

Director, Division of Infectious Diseases

Albert B. Sabin Chair in Pediatric Infectious Diseases

Cincinnati Children's Hospital

Medical Center

Professor, Department of Pediatrics

University of Cincinnati School of Medicine

Cincinnati, OH 45229

513-636-4509

Paul.spearman@cchmc.org

- Between 2013-2015, Dr. Spearman received \$39,459.84 in research funding from Glaxosmithkline, LLC and Astrazenica. No data available for years 2016-2019⁵³
- Since 2013, University of Cincinnati Medical Center has received \$2,236,276.81 in general payments and \$4,281,617.38 in research payments. Topping the list of companies on both accounts is Pfizer, Inc.⁵⁴
- Had to be recused from some meetings because his hospital, Cincinnati Children's Hospital is also a COVID vaccine clinical trial site.⁵⁵ Dr. Spearman received \$39,46060 in associated research funding primarily from Glaxosmithkline, LLC. and AstraZeneca Pharmaceuticals LP.⁵⁶
- No conflict of interest declared in *Warp Speed for COVID-19 Vaccines: Why are Children Stuck in Neutral?*⁵⁷

Conclusions: Children are at substantial risk of COVID-19. Delays in starting Phase II vaccine clinical trials in children will delay our recovery from COVID-19 and unnecessarily prolong its impact upon children's health and emotional well-being, their education, and equitable access to opportunities for development and social success, as well as the country's economy. Understanding the safety, immunogenicity, and efficacy of COVID-19 vaccines in children is critical to protect children and adults. For children, a vaccine has the added benefit of returning them safely to school and extracurricular activities, and allowing them to engage with their world face-

to-face once again. Ensuring acceleration of vaccine clinical trials to warp speed for children will be critical in making this our future reality.

Geeta K. Swamy, M.D.

Expertise: Infectious Diseases

Term: 08/06/2018-01/31/2022

Senior Associate Dean

Vice Chair for Research & Faculty Development

Associate Professor, ObGyn

Department of Obstetrics & Gynecology

Division of Maternal-Fetal Medicine

Duke University

Durham, NC 27710

- Since 2013, Dr. Swamy has received general payments of \$63,040.09 (Glaxosmithkline, LLC, Sanofi, Pfizer, et al) and research payments of \$206,038.64 from Glaxosmithkline, LLC.⁵⁸
- Since 2013, Duke University Hospital has received \$7,599,234.72 in general payments and \$40,585,472.53 in research payments from various companies. Pfizer, Inc. contributed general payments of \$866,119.65 and research payments of \$2,677,484.45.⁵⁹
- Dr. Swamy had to recuse herself from committee meetings because Duke University, where she is associate vice president for research, is a clinical trial site for the Pfizer-BioNTech and AstraZeneca vaccines.⁶⁰ Dr. Swamy received payments from pharmaceutical companies totaling \$63,040. Her associated research funding totaled \$206,039, about three times that of similar physician. Dr. Swamy's largest sources of funding are Glaxosmithkline, LLC., Sanofi Pasteur Inc., Pfizer Inc. and Novartis Vaccine.⁶¹
- ***Vaccination of pregnant women with respiratory syncytial virus vaccine and protection of their infants.*** Study funded by Novavax and the Bill and Melinda Gates Foundation.⁶²

Gregg Sylvester, M.D., M.P.H. ±

Expertise: Alternate Industry Representative

Term: 02/01/2020-01/31/2024

Vice President

Medical Affairs

Seqirus Inc.

Summit, NJ 07901

- Chief Medical Officer, Seqirus - Dr Gregg Sylvester has led Seqirus Medical Affairs since 2016, overseeing the global team that scientifically differentiates our vaccines by generating Real World Evidence and presenting Seqirus research to national vaccine recommending organizations.
- According to the Federal database, Seqirus USA, Inc. has made general payments in the sum of \$569,854.35 and research payments in the sum of \$44,159,881.83. Topping the list of receivers of general payments are **Arnold Simon Monto and Archana Chatterjee**.⁶³

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