

Exhibit 311

The Commissioners Letter
Collier County Commissioners return
\$1.4 million NIH grant

<https://karenkingston.substack.com/p/the-letter-to-the-commissioners>

The Commissioners Letter

This is the blueprint on how to articulate to local government officials and law enforcement that the COVID-19 injections are bioweapons and how they can either report a crime or be an accomplice.



Karen Kingston ✓
14 hr ago

♡ 122

💬 21



This SubStack article is a copy of the letter I sent to Collier County Commissioners recommending that they return a \$1.4mm NIH grant that included funding 'educational' materials and programs that advocated for COVID-19 vaccination. This letter was the catalyst that enabled me to publicly present evidence that the COVID-19 injections are bioweapons to the commissioners and over 200 residents in a government building on February 14, 2023.

The commissioners voted unanimously to return 100% of the NIH funds.



The letter closes with my offer to assist the commissioners in educating Collier County residents regarding the dangers of the COVID-19 bioweapon injections and how the residents can move forward with criminal charges. I am eternally grateful to Commissioner Chris Hall for strongly advocating to give me the opportunity to speak at the February 14, 2023

Commissioners meeting. I am thankful for Commissioners Kowal and Saunders in supporting Commissioner Hall's stance. Commissioner LaCastro sent an email communication on February 15th encouraging me to follow-up with the county manager to provide additional educational materials for consideration to be distributed to Collier County residents.

Highlights of my presentation can be found [here](#) beginning at the [5:40 mark](#).

Date: February 5, 2023

From: Karen Kingston, Biotech Analyst and Med-Legal Advisor

RE: Recommendation to Terminate Collier County **Community Health Worker (CHW) *Extra Mile Program*** and NIH Grant due to Fraudulent COVID-19 'Vaccine' Educational Materials

Dear Board of Commissioners;

Thank you for taking the time to meet with me to discuss the Collier County NIH Grant for Community Health Workers (CHW) "*Extra Mile*" Program as well as concerns regarding the COVID-19 'vaccines.'

As an executive strategist and med-legal advisor with over 25 years of experience in the pharmaceutical and biotech industries, I've been hired by clients to advise on promotional, educational, and grassroots campaigns that placed my clients at potential risk for civil or criminal liability. Per my analysis, corrective actions often included the termination of programs and campaigns, as well as revised messaging.

The following educational materials noted from the *CHW Extra Mile* cover letter may put Collier County at risk for liability by supporting the *fraudulent promotion of biological injections that are allegedly proven to be a safe and effective vaccines to prevent COVID-19*;

- Pfizer Bivalent Booster VIS – Vaccine and information fact sheet, benefits and risks of vaccine
- Moderna Bivalent Booster – Vaccine and information fact sheet, benefits and risks of vaccine

The CHW Cover Letter is misleading in that it states that, "*at no time are community members advised to receive care or follow CDC guidelines such as getting vaccinated.*"

The attached materials were and are currently used for educational purposes only. Our team works to raise awareness and inform people about options and at no time are community members advised to receive care or follow CDC guidelines such as getting vaccinated and wearing a mask.

Educational resources include:

- Map General Location – Map of all Healthcare Network locations
- Brochure General Eng-Span – Overview of Healthcare Network services
- Pfizer Bivalent Booster VIS - Vaccine and information fact sheet, benefits and risks of vaccine
- NCHC General+ Map – Services available at Nichols Community Health Center
- Bifold Sliding Fee Scale – Explains a discount is available to those who may not have insurance or ability to pay for care.
- TDAP VIS English – What is TDAP, benefits and risks of vaccine
- 10 Things English – How to manage COVID-19 Symptoms
- Updated COVID Information -
- Immokalee General + Immokalee Map - Services available in Immokalee
- Moderna Bivalent Booster - Vaccine and information fact sheet, benefits and risks of vaccine
- TDAP VIS Spanish - Vaccine and information fact sheet, benefits and risks of vaccine
- COVID-19 Symptoms – Lists symptoms of COVID-19
- Influenza VIS - Vaccine and information fact sheet, benefits and risks of vaccine
- Updated COVID Information mRNA – How mRNA COVID-19 vaccine works

Healthcare Network CHW's fill an important role in our community. They work in at-risk communities like Immokalee and Golden Gate to break down barriers that prevent people from finding and using health and social systems.

We humbly request your continued support of our CHW program and The Extra Mile Grant, which allows us to reach our most vulnerable families living in Collier County.

Sincerely,




Jamie Ulmer
President & Chief Executive Officer
Healthcare Network

This is a false and deceptive statement. The 1st paragraph of the Moderna and Pfizer Fact Sheets (*provided by CHW*) state that the objective of the fact sheets is *to offer adults and children the COVID-19 mRNA vaccines*.

Not only is CHW misrepresenting their program's intentions in their cover letter, but the *educational materials CHW is distributing directly contradict the directives of Florida Surgeon General, Dr. Joseph Ladapo*.

**VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS
ABOUT COMIRNATY (COVID-19 VACCINE, mRNA), THE PFIZER-BIONTECH
COVID-19 VACCINE, AND THE PFIZER-BIONTECH COVID-19 VACCINE,
BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5) TO PREVENT CORONAVIRUS
DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 12 YEARS OF AGE AND
OLDER**

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FOR 12 YEARS OF AGE AND OLDER

You are being offered either COMIRNATY (COVID-19 Vaccine, mRNA), the Pfizer-BioNTech COVID-19 Vaccine, or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), hereafter referred to as the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

**VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND
CAREGIVERS**

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**ABOUT SPIKEVAX (COVID-19 VACCINE, mRNA), MODERNA COVID-19 VACCINE,
AND MODERNA COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON
BA.4/BA.5) TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)**

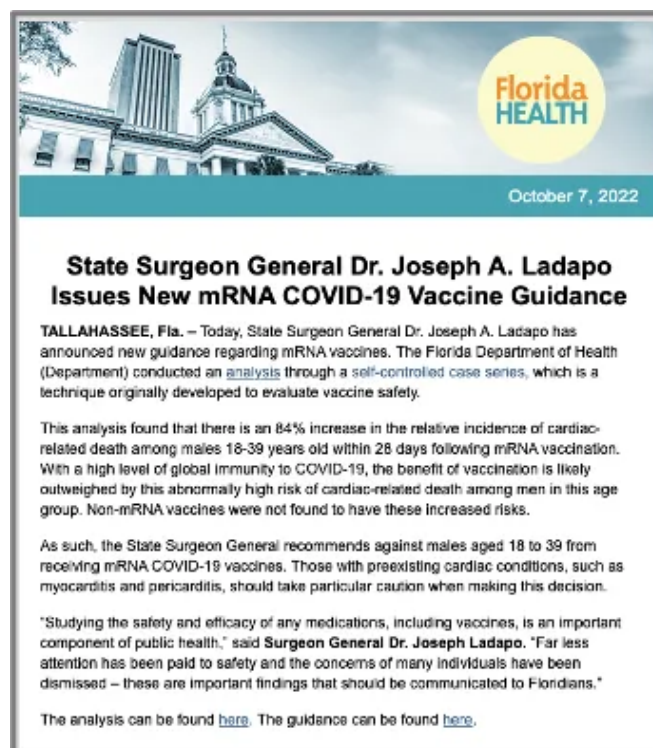
FOR 6 YEARS OF AGE AND OLDER

You or your child are being offered either SPIKEVAX (COVID-19 Vaccine, mRNA), Moderna COVID-19 Vaccine, or Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), hereafter referred to as Moderna COVID-19 Vaccine, Bivalent, to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

While the Pfizer Fact Sheet recommends the mRNA COVID-19 vaccine for 12 years of age and older and the Moderna Fact Sheet recommends the mRNA vaccine for 6 years of age and older; Dr. Ladapo has clearly stated that the state of Florida recommends against the COVID-19 mRNA vaccination for healthy children and is *against* COVID-19 mRNA 'vaccination' for males aged 18-39 years of age due to an 84% increased risk in vaccine-related cardiac death.

Whether for children or young male adults, Dr. Ladapo's expert clinical conclusions are clear; the risks for vaccine-related disease and death are greater than the potential benefits of allegedly preventing SARS-CoV-2 infection with a biological injection in young healthy adults and children.

If a child or young adult in Collier County is harmed or disabled by a COVID-19 vaccination after having received CHW education materials, written materials that directly contradict the Florida Surgeon General's public health recommendations, this could place those who support educational programs that promote the COVID-19 biological injections as safe and effective vaccines at risk for liability in the state of Florida.



Based on Dr. Ladapo's directives and the first paragraph of these two documents alone, I recommend Collier County terminate the *CHW Extra Mile Program* and return any unused funds from the NIH grant that is paying for this program with an itemized excel spreadsheet of funds used to date.

The remainder of this letter is an analysis of the increased health risks caused by the COVID-19 mRNA biological injections, as well as the potential liability risks for those advocating for COVID-19 vaccination.

“The only thing necessary for evil to triumph, is for good men to do nothing.”

Thank you for reading The Kingston Report.

This post is public so feel free to share it.

More American citizens, including Collier County residents are becoming aware that;

- COVID-19 ‘vaccines’ do not prevent transmission or infection of SARS-CoV-2 or coronavirus variants;
- the FDA research was fraudulently done and the claims from the trials are false; and
- the *new* COVID-19 biological injections/ ‘vaccines’ have been proven to cause disease, disabilities, and death in adults and children who were formerly healthy prior to vaccination.

There is also recent data demonstrating that with each additional injection (booster) given, the risk for COVID-19 increases. This is the exact opposite effect of what a vaccine is supposed to do, clearly demonstrating that **the injections are *not* vaccines**. Florida Governor DeSantis spoke out against the bivalent boosters on January 17, 2023, citing the fact that the risk for COVID-19 increases with each booster.

When the COVID-19 biological injections first became available, Americans were initially told that the new mRNA vaccines were **95% effective**, but then later told that **the injections are *not* effective at preventing SARS-CoV-2 infection or transmission**. If the ‘vaccines’ don’t prevent infection or transmission, what are they 95% effective at? (other than causing disease).

The initial answer to this question was that the *new mRNA vaccines* were *too complicated to understand*. We were told to simply *trust the science* and be confident in knowing that these *new* experimental biological agents went through the same rigorous FDA clinical trials in only nine (9) months that took previous vaccines more than 10 years of clinical evaluation. I believe most adults are intelligent enough to know that this was a lie and that both the near-term (within 2 years) and long-term side effects of a highly advanced biological agent cannot be known in 9 months of human testing, as we are unfortunately learning as a society today.

We are now aware that the COVID-19 injections are **NOT** safe and effective vaccines and that the claims regarding the integrity and validity of the FDA clinical trials were blatant lies.

Currently the CDC, FDA, NIH, other government officials, and some healthcare professionals are promoting the false claim that the COVID-19 biological injections prevent hospitalizations and severe disease.

If a vaccine can't reduce the risk for a viral infection, how can it reduce the risk for the severe disease that is caused by that viral infection? The answer is it can't.

A failed 'vaccine' increases the risk for severe disease. A vaccine that exposes the human immune system to a virus or part of a virus (the spike protein), but then does not stimulate the neutralizing antibodies required to protect against future viral infections, increases the risk for severe respiratory disease. This is a well-known, harmful experimental biological response known as **vaccine-associated enhanced respiratory disease (VAERD)**. The FDA states that VAERD is an **IMPORTANT POTENTIAL RISK** for both the Pfizer and Moderna mRNA injections in the FDA approval documents.

MODERNA FDA APPROVAL BLA, pg. 25

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Pharmacovigilance Plan

The Applicant's Risk Management Plan version 2.2 includes the following important risks and missing information in the pharmacovigilance plan:

- Important identified risks: Anaphylaxis; Myocarditis; Pericarditis
- Important potential risks: Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)
- Missing information: Use in pregnancy and lactation; Vaccine effectiveness; Long term safety and long-term effectiveness; Use with concomitant vaccines; Use in immunocompromised patients; Interaction with other vaccines; Use in frail subjects with unstable health conditions and comorbidities (COPD, T2DM, CVD, chronic neurological disease), Use in subjects with autoimmune or inflammatory disorders; Use in pediatric individuals < 18 years of age. <https://www.fda.gov/media/155931/download>

The FDA approvals for both Pfizer and Moderna also list MYOCARDITIS and PERICARDITIS as **IMPORTANT IDENTIFIED RISKS**, further substantiating Dr. Ladapo's expert insight that the mRNA injections increase the risk of sudden cardiac death in otherwise healthy male adults.

PFIZER FDA APPROVAL BLA, pg. 25

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Pharmacovigilance Plan (PVP)

The Applicant's proposed pharmacovigilance plan (version 1.1) includes the following important risks and missing information:

- Important identified risks: Anaphylaxis; Myocarditis and Pericarditis
- Important potential risk: Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)
- Missing information: Use in pregnancy and lactation; Vaccine effectiveness; Use in pediatric individuals <12 years of age

<https://www.fda.gov/media/151733/download>

Due to the increased risks for cardiac death from COVID-19 injections, Dr. Ladapo has advised against the use of these biological agents in healthy children and adult males. The risk for vaccine-associated enhanced respiratory disease (VAERD) is another reason to advise against the COVID-19 mRNA injections. In simple terms, increased risk for enhanced respiratory disease means that these mRNA injections *increase the risk* for COVID-19 infection, severe illness, and hospitalization.

Pfizer states that their mRNA injections increase the risk for COVID-19 per a September 2021, post-hoc analysis. Per the FDA Briefing Document; “An additional analysis appears to indicate that incidence of COVID-19 generally increased in each group of study participants with increasing time post-Dose 2.”

Vaccines and Related Biological Products Advisory Committee Meeting
September 17, 2021

Pfizer Phase 3 Post Hoc Analysis

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*“An additional analysis appears to indicate that **incidence of COVID-19 generally increased in each group of study participants with increasing time post-Dose 2.**”*

FDA Briefing Document

Application for licensure of a booster dose for COMIRNATY (COVID-19 Vaccine, mRNA)

Although not independently verified by FDA, the post hoc analysis appears to indicate that the incidence of SARS-CoV-2 during the analysis period among 18,727 study participants originally randomized to BNT162b2 (mean of 9.8 months post-Dose 2 at the beginning of the analysis period) was 70.3 cases per 1,000 person-years, compared with an incidence of 51.6 cases per 1,000 person-years among 17,748 study participants originally randomized to placebo and crossed over to BNT162b2 (mean of 4.7 months post-Dose 2 at the beginning of the analysis period). An additional analysis appears to indicate that incidence of COVID-19 generally increased in each group of study participants with increasing time post-Dose 2 at the start of the analysis period. Only 3 severe COVID-19 cases were reported during the analysis period, all of which occurred among study participants originally randomized to BNT162b2.

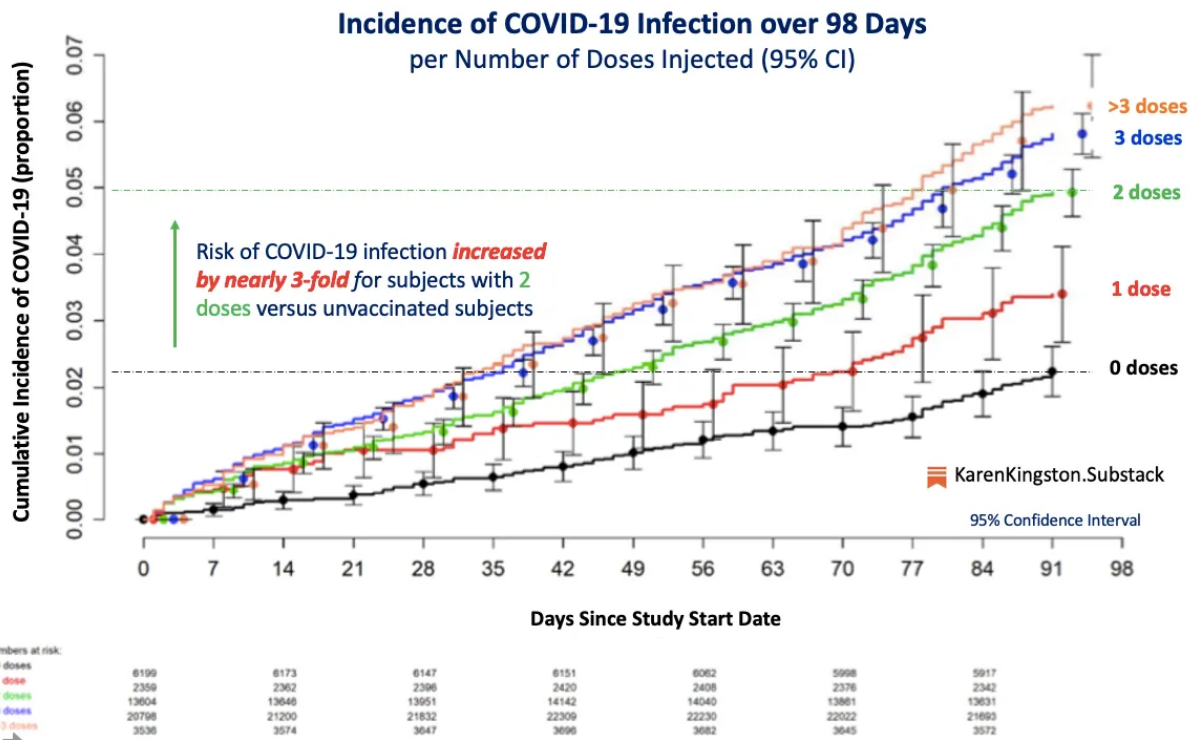
<https://www.fda.gov/media/152176/download>

Pfizer concluded that *the risk for COVID-19 infection increases in study subjects who received 2 doses of their mRNA injection*. The residents of Collier County were promised that the COVID-19 mRNA injections would reduce the risk for COVID-19 infection, yet Pfizer submitted data to the FDA stating the opposite of what was promised. The risk for COVID-19 infection increases with vaccination. This is clearly *not* a vaccine.

A recent study of 51,011 Cleveland Clinic employees *confirmed* that the risk for COVID-19 disease *increases* over time post 2nd dose versus being unvaccinated.

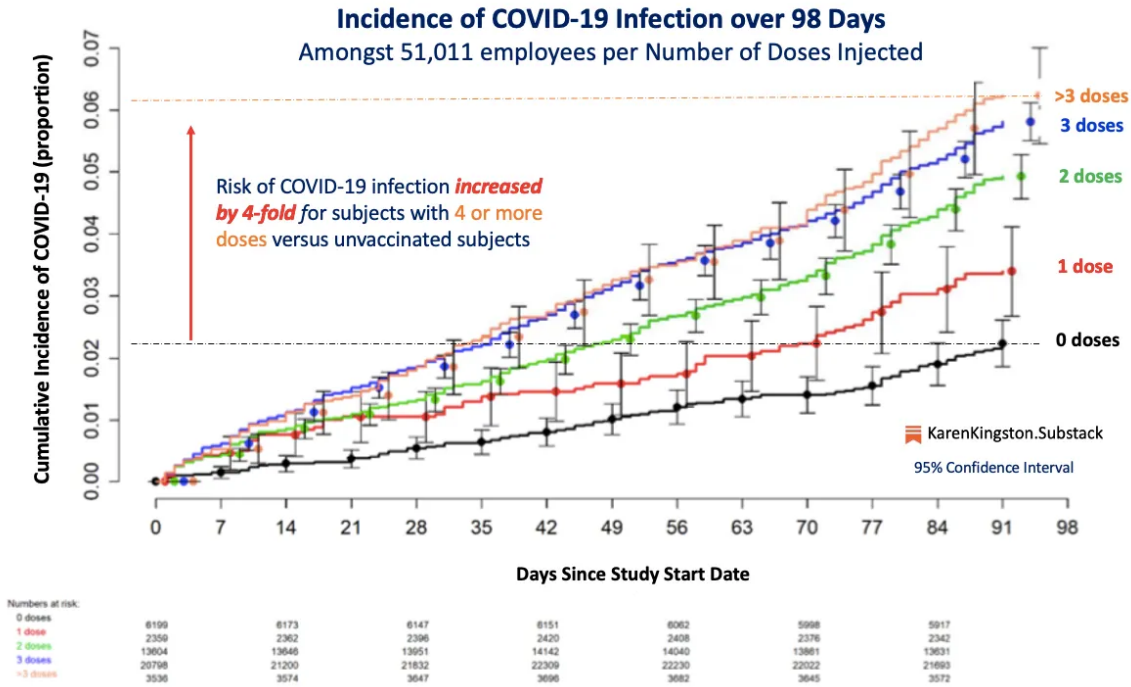
Effectiveness of the Coronavirus Disease 2019 (COVID-19) Bivalent Vaccine

<https://www.medrxiv.org/content/10.1101/2022.12.17.22283625v1.full.pdf>



AND that with each additional injection (booster), the risk for COVID-19 infection further increases versus remaining unvaccinated.

Effectiveness of the Coronavirus Disease 2019 (COVID-19) Bivalent Vaccine



COVID-19 is (or was) considered a threat to public health and safety because of the risk of overwhelming the hospitals and healthcare system with severely ill COVID-19 patients. It is well understood that the COVID-19 mRNA injections can increase the risk for infection, severe COVID-19 disease, and hospitalizations due to VAERD. In other words, higher vaccination rates may lead to higher hospitalization rates. Based on this fact alone, the mRNA injections themselves pose a threat to public safety and should be removed from communities to avoid the risk of overwhelming the healthcare system.

In Collier County, more than 70% of residence are fully-vaccinated (2 or more doses) and over 90% have received at least one dose. During the holiday week of December 16, 2022, ICU beds at Naples Hospital were over 118% capacity, in-patient beds were at 93%, and 30% of emergency room visits were due to COVID-19 (666/2,240). The high COVID-19 vaccination rates did not reduce the burden on the Naples Community Hospital. *High COVID-19 vaccination rates likely increase the burden to hospitals and the healthcare system.

In [Collier County](#), >70% of residence are fully-vaccinated (2 or more doses) and >90% have received at least one dose. During the holiday week of [December 16, 2022](#), **ICU beds at Naples Hospital were over 118% capacity, in-patient beds were at 93%, and 30% of emergency room visits were due to COVID-19 (666/2,240)**. The high COVID-19 vaccination rates did not reduce the burden on the Naples Community Hospital. *High COVID-19 vaccination rates likely increase the burden to hospitals and the healthcare system.

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Collier County Hospitals (Week of Dec. 16, 2022)

<https://data.naplesnews.com/covid-19-vaccine-tracker/florida/12/>

Hospital	7 Day Avg. of Bed Occupancy			7 Day Avg. of Hospitalized COVID-19 Patients		7 Day Sum of COVID-19 Admission		7 Day Sum of Emergency Department Visit	
	All hospital beds	Inpatient beds	ICU Beds	Adult	Pediatric	Adult	Pediatric	COVID-19 Confirmed	Total
LANDMARK HOSPITAL OF SOUTHWEST FLORIDA Long Term 1285 CREEKSIDE BLVD E, NAPLES, FL	None	54.1% 17.3 of 32.0 beds used	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NAPLES COMMUNITY HOSPITAL Short Term 350 7TH ST N, NAPLES, FL	610.8	93.2% 415.3 of 445.7 beds used	118.4% 25.7 of 21.7 beds used	45.1	N/A	25	N/A	666	2,240
PHYSICIANS REGIONAL MEDICAL CENTER - PINE RIDGE Short Term 6101 PINE RIDGE ROAD, NAPLES, FL	None	68.0% 249.0 of 366.0 beds used	67.9% 38.7 of 57.0 beds used	12.0	N/A	20	N/A	235	1,185

*The correlation between vaccination rates and COVID-19 hospitalizations due to respiratory and cardiac complications in Collier County is worthy of a closer look to determine causation.

***The correlation between vaccination rates and COVID-19 hospitalizations due to respiratory and cardiac complications in Collier County is worthy of a closer look to determine if there is statistical causation.**

The risk for cardiac injury, respiratory failure, and other COVID-19 vaccine-induced injuries and illnesses, including death, was *known* by the FDA on October 22, 2020. The FDA met with industry (i.e. Pfizer, Moderna) to discuss more than two dozen harmful outcomes and diseases *caused by the COVID-19 vaccines*.

FDA/CBER Plans for Monitoring COVID-19 Vaccine Safety & Effectiveness

Presented by: Steve Anderson, PhD, MPP – Dir. Office of Biostats & Epidemiology, CBER

October 22, 2020 – Vaccines & Related Biological Products Advisory Committee (VRBPAC) Meeting



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FDA Safety Surveillance of COVID-19 Vaccines : DRAFT Working list of possible adverse event outcomes

Subject to change

Violations of 21 U.S.C 312.42b1i/b2i
and 21 U.S.C 355

- | | |
|--|--|
| <ul style="list-style-type: none"> ▪ Guillain-Barré syndrome ▪ Acute disseminated encephalomyelitis ▪ Transverse myelitis ▪ Encephalitis/myelitis/encephalomyelitis/meningoencephalitis/meningitis/encephalopathy ▪ Convulsions/seizures ▪ <u>Stroke</u> ▪ Narcolepsy and cataplexy ▪ Anaphylaxis ▪ <u>Acute myocardial infarction</u> ▪ <u>Myocarditis/pericarditis</u> ▪ Autoimmune disease | <ul style="list-style-type: none"> ▪ <u>Deaths</u> ▪ <u>Pregnancy and birth outcomes</u> ▪ Other acute demyelinating diseases ▪ Non-anaphylactic allergic reactions ▪ Thrombocytopenia ▪ <u>Disseminated intravascular coagulation</u> ▪ Venous thromboembolism ▪ Arthritis and arthralgia/joint pain ▪ Kawasaki disease ▪ Multisystem Inflammatory Syndrome in Children ▪ Vaccine enhanced disease |
|--|--|

https://www.fda.gov/media/143557/download?fbclid=IwAR1SooRjTDuhBPqM4TID3O7vYgX4eAp3CCqB7SzCk04CMve_OzgtMNPfNkc

Note: On October 22, 2020, the FDA and industry *knew* that the COVID-19 biological injections placed adults and children at *unnecessary risk* for injuries, illnesses, and death, but the FDA still authorized both the Pfizer and Moderna mRNA injections as safe vaccines.

Further evidence that the FDA and Pfizer knew that the mRNA injections caused COVID-19 disease and would cause significant harm can be found in Pfizer's Phase 3 data submission.

Pfizer reported that *within 7 days* of subjects receiving the 1st or 2nd mRNA injection, “409 subjects in the vaccine group had *suspect* or *unconfirmed* COVID-19 which could have masked clinically significant adverse events.”

**Pfizer Could NOT Tell if it was mRNA Injections or SARS-2 that Caused Severe COVID-19 or Death.
In other words, the mRNA Injections *cause* severe COVID-19**

Pfizer Phase 3

- Significant acute renal, hepatic, or neurologic dysfunction;
- Admission to an ICU;
- Death. ←

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**409 Serious Adverse Events or 'Unconfirmed COVID-19'
within 7 DAYS of Dose 1 or 2, pg. 41**

Suspected COVID-19 Cases

<https://www.fda.gov/media/144416/download>

Among 3,410 total cases of suspected but unconfirmed COVID-19 in the overall study population, 1,594 occurred in the vaccine group vs. 1816 in the placebo group. Suspected COVID-19 cases that occurred within 7 days after any vaccination were 409 in the vaccine group vs. 287 in the placebo group. It is possible that the imbalance in suspected COVID-19 cases occurring in the 7 days postvaccination represents vaccine reactogenicity with symptoms that overlap with those of COVID-19. Overall though, these data do not raise a concern that protocol-specified reporting of suspected, but unconfirmed COVID-19 cases could have masked clinically significant adverse events that would not have otherwise been detected.



Analysis Karen Kingston© 2023

The clinically significant adverse events can include the outcomes listed in the previous slide, such as heart attack, stroke, respiratory failure, blood clotting, seizures, and death. Pfizer states that they are not sure if their 'mRNA vaccine' caused these harmful outcomes or if it was the SARS-CoV-2 virus. These 409 patients had negative PCR tests confirming they were not infected with SARS-CoV-2, but Pfizer did not count these patients as severe cases, nor did Pfizer include them as serious adverse events.

The 409 vaccinated *suspect* COVID-19 patients were part of a larger group of **1,594 vaccinated subjects who also became ill but were not counted** in the final analysis as the Sponsor (Pfizer/BioNTech) *believed them to potentially have COVID-19 or severe COVID-19, but they did not have a confirmed positive PCR test.*

Vaccine Efficacy Pre-set and Fraudulent (intended to deceive)

Table 6. Final Analysis of Efficacy of BNT162b2 Against Confirmed COVID-19 From 7 Days After Dose 2 in Participants Without Evidence of Prior SARS-CoV-2 Infection, Evaluable Efficacy Population

Pre-specified Age Group	BNT162b2 N ^a = 18198 Cases n1 ^b Surveillance Time ^c (n2 ^d)	Placebo N ^a = 18325 Cases n1 ^b Surveillance Time ^c (n2 ^d)	Vaccine Efficacy % (95% CI)	Met Predefined Success Criterion*
	All participants	8 2.214 (17411)	162 2.222 (17511)	95.0 (90.3, 97.6) ^e
16 to 55 years	5 1.234 (9897)	114 1.239 (9955)	95.6 (89.4, 98.6) ^f	NA
>55 years	3 0.980 (7500)	48 0.983 (7543)	93.7 (80.6, 98.8) ^f	NA

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*Success criterion: the posterior probability that true vaccine efficacy > 30% conditioning on the available data is >99.5% at the final

Among 3,410 total cases of suspected but unconfirmed COVID-19 in the overall study population, 1,594 occurred in the vaccine group vs. 1816 in the placebo group. Suspected

endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

^a n2 = Number of participants at risk for the endpoint.

^e Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time.

^f Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

<https://www.fda.gov/media/144416/download>

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Severe COVID-19 was a secondary outcome in Pfizer's trial, based on symptoms and a positive PCR test. Pfizer's clinical description of severe COVID-19 is similar to the list of the COVID-19 vaccine outcomes from the October 22, 2020, FDA meeting, including respiratory failure, kidney, liver and neurological dysfunction, admission to the ICU, and death.

SEVERE COVID-19 included ICU admission - Respiratory Failure Liver – Kidney – Neurological Dysfunction and DEATH

Pfizer Phase 3
Design

For another secondary endpoint, the case definition for a severe COVID-19 case was a confirmed COVID-19 case with at least one of the following:

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- Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO2 ≤93% on room air at sea level, or PaO2/FiO2 <300 mm Hg);
- Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO);
- Significant acute renal, hepatic, or neurologic dysfunction;
- Admission to an ICU; ←
- Death. ←

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<https://www.fda.gov/media/144416/download>

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Why does any of this matter? This matters because the FDA's authorization and then approval of the COVID-19 mRNA injections is in violation of the FDA's own safety laws 21 U.S.C

312.42b1i/b2i and 21 U.S.C 355 that are in place to protect American civilians and the resident of Collier County from being unknowingly exposed to harmful biological agents that can cause injury, illness, disability, or even death.

Thank you for reading The Kingston Report.

This post is public so feel free to share it.

Per 21 U.S.C 312.42b1i/b2i, during a Phase 1 trial of 20-80 healthy people, if a biological agent places humans at unreasonable and significant risk for illness or injury the experiment is to be terminated.

Title 21 / Chapter I / Subchapter D / Part 312 / Subpart C / § 312.42 Previous / Next / Top

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(b) Grounds for imposition of clinical hold -

(1) Clinical hold of a Phase 1 study under an IND. FDA may place a proposed or ongoing Phase 1 investigation on clinical hold if it finds that:

- (i) Human subjects are or would be exposed to an unreasonable and significant risk of illness or injury;**
- (ii) The clinical investigators named in the IND are not qualified by reason of their scientific training and experience to conduct the investigation described in the IND;**
- (iii) The investigator brochure is misleading, erroneous, or materially incomplete; or**
- (iv) The IND does not contain sufficient information required under § 312.23 to assess the risks to subjects of the proposed studies.**
- (v) The IND is for the study of an investigational drug intended to treat a life-threatening disease or condition that affects both genders, and men or women with reproductive potential who have the disease or condition being studied are excluded from eligibility because of a risk or potential risk from use of the investigational drug of reproductive toxicity (i.e., affecting reproductive organs) or developmental toxicity (i.e., affecting potential offspring). The phrase "women with reproductive potential" does not include pregnant women. For purposes of this paragraph, "life-threatening illnesses or diseases" are defined as "diseases or conditions where the likelihood of death is high**


<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312/subpart-C/section-312.42>


Based on the October 22, 2020, meeting alone, the FDA should have terminated the COVID-19 vaccine trials. Residents of Collier County should *never* have had access to these COVID-19 mRNA biological injections.

Per the FDA's guidance for EUA COVID-19 vaccines, the FDA *must determine* that the known benefits of a EUA vaccine (biological agent) outweighs the known risks before authorizing for use in the US population.

B. Emergency Use Authorization

- An Emergency Use Authorization (EUA) may be issued only after several statutory requirements are met (section 564 of the FD&C Act (21 U.S.C. 360bbb-2)) (Ref. 23). Among these requirements is a determination by FDA that the known and potential benefits of a product, when used to diagnose, prevent, or treat serious or life-threatening diseases, outweigh the known and potential risks of the product.



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- Issuance of an EUA (Ref. 23) may be appropriate for a COVID-19 vaccine provided the standard for issuing an EUA is met. Issuance of an EUA for a COVID-19 vaccine prior to the completion of large randomized clinical efficacy trials could reduce the ability to demonstrate effectiveness of the investigational vaccine in a clinical disease endpoint efficacy trial to support licensure, and such clinical disease endpoint efficacy trials may be needed to investigate the potential for vaccine-associated ERD. Thus, for a vaccine for which there is adequate manufacturing information, issuance of an EUA may be appropriate once studies have demonstrated the safety and effectiveness of the vaccine but before the manufacturer has submitted and/or FDA has completed its formal review of the biologics license application.
- In the case of investigational vaccines being developed for the prevention of COVID-19, any assessment regarding an EUA would be made on a case by case basis considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product, and the totality of the available scientific evidence relevant to the product.

<https://www.fda.gov/media/139638/download>

Per 21 U.S.C 355, the FDA must make a determination that the benefits of a product outweigh the risk before moving forward with FDA approval. The data the FDA had in their possession clearly demonstrated that the benefits of COVID-19 vaccines did not outweigh the risks. An HHS declared public health emergency to enable the use of an experimental biological agent by Americans is not a valid legal reason for the FDA, CDC, Pfizer or Moderna to knowingly and fraudulently promote a harmful biological agent as a safe and effective vaccine.

21 USC 355 -1**Risk Evaluation and Mitigation Strategies for Human Clinical Experiments****§355–1. Risk evaluation and mitigation strategies****(a) Submission of proposed strategy**  KarenKingston.Substack**(1) Initial approval**

If the Secretary, in consultation with the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug, determines that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug, and informs the person who submits such application of such determination, then such person shall submit to the Secretary as part of such application a proposed risk evaluation and mitigation strategy. In making such a determination, the Secretary shall consider the following factors:

- (A) The estimated size of the population likely to use the drug involved.
- (B) The seriousness of the disease or condition that is to be treated with the drug.
- (C) The expected benefit of the drug with respect to such disease or condition.
- (D) The expected or actual duration of treatment with the drug.
- (E) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.
- (F) Whether the drug is a new molecular entity.

[https://uscode.house.gov/view.xhtml?req=\(title:21%20section:355-1%20edition:prelim\)](https://uscode.house.gov/view.xhtml?req=(title:21%20section:355-1%20edition:prelim))

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There is no law in America or in the state of Florida that provides legal immunity to employees of a government agency or of a private organization who knowingly manufactured and provided access to known harmful biological agents for use on a civilian population under the guise of safe and effective vaccines.

The FDA, Pfizer, and Moderna cannot claim ignorance when it comes to placing American civilians at unnecessary risk, especially when it comes to children. The injection of children with mRNA biological agents was never merited. The risk of children contracting COVID-19 was insignificant per the FDA's documents.

On June 10, 2021, the FDA met to discuss the clinical endpoints for children's studies. Per the FDA briefing document, the committee states that conducting a pediatric trial where the primary endpoint is proving a reduction in risk for COVID-19 infection in vaccinated children versus unvaccinated children would be impossible (*infeasible*) to conduct, because children rarely become infected.



Vaccines and Related Biological Products Advisory Committee Meeting
June 10, 2021

Licensure and Emergency Use Authorization of Vaccines to Prevent COVID-19 for Use
Pediatric Populations

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Pediatric Populations

2.1.1. Clinical endpoint efficacy trials

The incidence and severity of COVID-19 disease in pediatric populations, especially in younger age groups, are generally lower than in adults. Depending on epidemiologic trends, an adequately powered clinical endpoint efficacy trial with sufficient case accrual across pediatric age groups may be very difficult, if not infeasible, to conduct. Furthermore, in considering the balance of benefits and risks to support licensure or emergency use authorization of COVID-19 vaccines for use in pediatric populations, it could be argued that the lower burden of disease in pediatric populations might warrant more stringent success criteria than for adults, at least for placebo-controlled trials. A very high VE point estimate, with a narrow confidence interval, observed in studies in adults might also warrant more stringent success criteria in pediatric trials to ensure that the vaccine is as effective in pediatric populations as it is in adult populations. Conversely, an argument could be made that demonstration of very high VE in adults could allow for a less stringent success criterion for the VE confidence interval lower bound in pediatric trials (and thus a smaller number of primary endpoint cases needed), provided that the VE point estimate is similar to that observed in adults. The choice of primary endpoint may also inform appropriately stringent success criteria for placebo-controlled pediatric trials, as data demonstrating prevention of infection (rather than prevention of disease, or prevention of severe disease) may be less likely for children vs. adults.

<https://www.fda.gov/media/149935/download>

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Despite the overwhelming body of evidence that children were never at any meaningful risk for infection or from becoming ill from COVID-19, the FDA authorized Pfizer and Moderna to conduct clinical trials in minors placing children and infants at unnecessary risk for injury and illness from a biological agent *known* to cause injury, illness, disabilities, and death.

Pfizer *knowingly* violated safety laws and placed children at unnecessary risk for injury and death per their November 20, 2020, FDA Phase 3 data submission. This report states that there was data from 100 children aged 12 to 15 years of age who experienced reactogenicity effects from the mRNA injections (i.e. Myocarditis, seizures, blood clots, death). However, the Sponsor (Pfizer/BioNTech) requested that the *data for these 100 children NOT be disclosed because the benefit-risk ratio was unfavorable*.


Verbatim from the FDA document;


“Reactogenicity data from a total of 100 adolescents 12 through 15 years of age were provided in the EUA submission. However, the Sponsor, did not request inclusion of this age group in the EUA because the data available... were insufficient to support a favorable benefit-risk determination at this time. Therefore, the reactogenicity data for participants 12 through 15 years of age are NOT presented in this document.”

Reactogenicity data from a total of 100 adolescents 12 through 15 years of age enrolled in C4591001 Phase 2/3 were provided in the EUA submission. However, the Sponsor did not request inclusion of this age group in the EUA because the available data, including number of participants and follow-up duration, were

15

Pfizer's November 2020, Phase 3 FDA Data submissions states that *the clinical effects (reactogenicity) of their mRNA injections are more harmful to children than beneficial aged 12-15 years of age.*

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Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Review Memorandum

insufficient to support favorable a benefit-risk determination at this time. Therefore, the reactogenicity data for participants 12 through 15 years of age are not presented in this document.

<https://www.fda.gov/media/144416/download>

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This November 20, 2020, benefit-risk statement regarding the COVID-19 mRNA vaccination of children is a blatant violation of 21 USC 355 and evidence that both Pfizer and the FDA knowingly broke the law. The bottom line is that the FDA's authorization and approval of the COVID-19 vaccines is both grossly unethical and criminal, as was Pfizer's and Moderna's manufacturing and promotion of these harmful biological injections as safe and effective vaccines.

It is evident that these biological injections are not vaccines. So the question is then, "What are these *NEW* biological agents that do NOT prevent transmission or infection, were NOT done under *bona fide* research, and are *known to cause* illness, injuries, disabilities, and death?"

These *NEW* COVID-19 biological injections exactly meet is the definition of a bioweapon per 18 USC 175.

A biological agent for use *other than* prophylactic (preventative), protective, *bona fide* research, or other peaceful purpose is a BIOWEAPON.

18 U.S.C. Ch.10: BIOLOGICAL WEAPONS

18 USC Ch. 10: BIOLOGICAL WEAPONS

From Title 18—CRIMES AND CRIMINAL PROCEDURE PART I—CRIMES



§175. Prohibitions with respect to biological weapons

(c) **Definition.**—For purposes of this section, the term "**for use as a weapon**" includes the development, production, transfer, acquisition, retention, or possession of **any biological agent, toxin, or delivery system for other than prophylactic, protective, *bona fide* research, or other peaceful purposes.**

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<https://uscode.house.gov/view.xhtml?path=/prelim@title18/part1/chapter10&edition=prelim>

The COVID-19 biological agents *do not* prevent infection or transmission; they *do not* protect against disease; the clinical trials *did not* adhere to the FD&C Act safety and efficacy laws; recipients of EUA injections *did not* receive informed consent; and the COVID-19 biological injections are *proven to cause serious illness, injury and even death, in previously healthy adults and children*. The COVID-19 biological injections are bioweapons that have been criminally promoted, distributed, and administered to American civilians, including the residents of Collier County, under the guise of safe and effective vaccines.

The FDA inadvertently destroyed the immunity shields for themselves, the manufacturers, and for *covered persons* because the FDA conspicuously violated most of the safety laws that regulate their agency and the manufacturers under the FD&C Act (21 USC) and Public Health and Welfare Act (42 USC), including the EUA/Public Health Emergency modifications to these acts that provided blanket, iron-clad legal immunity to manufacturers and *covered persons*.

Covered persons may include healthcare workers, employers, or public officials who believe they can *willfully ignore* the injuries and illnesses caused by the COVID-19 bioweapon injections because they believe they have immunity. *May covered persons* may be under the impression that by simply receiving COVID-19 financial compensation (from HHS, CDC, or the NIH) and by following HHS guidance or rules under the COVID-19 public health emergency (PHE) declaration, that they have civil and criminal immunity.

Manufacturers and *covered persons* are gravely mistaken. There are no laws that exist in the United States of America or in the state of Florida that provide immunity to;

- *manufacturers* for manufacturing bioweapons (harmful biological injections) for use on a civilian population;
- *covered persons* for *knowingly* administering a bioweapon (experimental biological injection) to a civilian adult or child;
- *covered persons* for *knowingly* making bioweapons accessible to American adults and children; or
- *covered persons* or *manufacturers* for *knowingly* and fraudulently promoting bioweapon injections as safe and effective vaccines.

As more and more Americans and Collier County residents become aware that a crime has been committed against them and their children under the guise of ‘public safety’ not only will manufacturers be criminally charged for manufacturing and promoting bioweapons as a safe and effective vaccines, but government and public officials, as well as healthcare providers, will also be at high risk for civil and criminal liability for making the COVID-19 bioweapon injections readily available to their community and for assisting in the fraudulent promotion of these bioweapons as safe and effective vaccines, unless they quickly correct course.

Now that the Collier County Commissioners are aware that COVID-19 biological injections do not meet the criteria for a vaccine but only meet the criteria for a bioweapon, I strongly recommend that Collier County Commissioners return the funds from the NIH grant for COVID-19 related educational activities, including CHW’s *Extra Mile* program which advocates for COVID-19 vaccination.


The unfortunate reality is that regardless of our profession, educational level, or even our ‘vaccine status’ nearly all Americans were manipulated by federal healthcare agencies, manufacturers, and the coordinated media effort. We were deceived into believing that the COVID-19 biological injections were evaluated under legitimate FDA clinical trials and were determined to be safe and effective vaccines.

Due to the mass coordinated propaganda, censoring, and social pressure to ‘*not say anything bad*’ about the COVID-19 injections, at some level, we all ***unknowingly participated in the deception that may have caused ourselves, our loved ones, and/or community members to be injected with a biological agent that has only been proven to be effective as a bioweapon in causing injury, illness, disabilities, and death. and meets the exact criteria of a bioweapon under 18 USC 175.***

While there may be some doctors and medical experts who passionately opine that the COVID-19 biological injections are safe and effective vaccines, the overwhelming body of clinical and real-world evidence does not support their passionate, biased, and often financially incentivized opinions.

(This evidence was not part of the original letter as I received it after Feb 5). The bonus incentives that were offered to healthcare providers (HCPs) by insurance companies to vaccinate members were so obscene, one could describe them as bribery. Anthem Blue Cross Blue Shield (BCBS) offered HCPs up to \$250 per newly vaccinated member. The BCBS COVID-19 vaccine bonus program was structured so that the more patient members a medical practice vaccinated, the higher the per vaccinated member rate was, pressuring all HCPs of a practice to be a ‘good sport’ and push the COVID-19 mRNA injections.

BCBS HCPs Paid Up to \$250 per BCBS Member Injected with COVID-19 Injection Up to more than 10x’s Standard Bonus Reimbursement

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Appendix

Below are examples to help illustrate Anthem Blue Cross and Blue Shield Medicaid (Anthem) COVID-19 Provider Incentive program payments.

Payment calculation examples

Wouldn’t doctors if the mRNA injections were killing people?

Payment thresholds		Initial Payment for Existing Vaccinated (Per Member)	Final Payment for Incremental Vaccinated (Per Member)
Percent of Anthem Members Vaccinated			
30%		\$20	\$100
40%		\$45	\$150
50%		\$70	\$175
60%		\$100	\$200
75%		\$125	\$250

https://providers.anthem.com/docs/gpp/KY_CAID_PU_COVID19VaccineProviderIncentiveProgram.pdf?v=202110121818

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Collier County Commissioners now have a new opportunity to educate county residents regarding the reality of the situation, that many of them have been injected with a bioweapon and are victims of a crime.

Despite the chaos and confusion regarding whether the COVID-19 injections were EUA product versus FDA-approved product, there is no law that protects any person or organization for being criminally charged for manufacturing, distributing, making accessible, promoting, or

administering a bioweapon (harmful, experimental biological agent) under the guise of a safe and effective vaccine. For this reason, in addition to returning the NIH grant, I recommend that the Collier County Commissioners convene a panel to work quickly to educate residents regarding the known harmful clinical outcomes of the COVID-19 bioweapon injections per the data from the manufacturers' FDA clinical trials, peer-reviewed publications of real-world evidence, and testimonials from local victims who have been harmed or has a loved one was harmed.

It is important for Collier County residents to understand that the FDA trials were not in compliance with the laws that regulate the biologics industry or vaccine research, and that the safety and efficacy claims derived from these studies were false and intentionally misleading. There are Collier County doctors who have successfully treated patients who were injured by the COVID-19 bioweapon injections and can assist in providing educational material to help restore the health of anyone injured by one of these injections.

I recommend educating residents on how to take criminal action *against the manufacturers* under State and Federal laws that regulate the use of bioweapons because those who have been injured have the right to pursue criminal charges.

As more experts and government leaders are coming forward to speak out against the harmful COVID-19 biological injections, such as Surgeon General Ladapo and Governor DeSantis, and research and analysis such as what I've done regarding these bioweapon injections is gaining more media coverage and public awareness, there is a brief window of opportunity for all of us to get on the right side of history.

When confronted with the evidence that the COVID-19 biological injections are bioweapons, I believe good men and women will not continue to play along with the false and harmful claim that these COVID-19 bioweapon injections are safe and effective vaccines, in order to avoid conflict with their colleagues, friends, and community. I believe American citizens who believe in our unalienable God-given rights and genuinely care about the well-being of others would rather face conflict in sharing the truth with our communities; rather than standby and silently witness the steady, ongoing injury and illness that is being inflicted on our family, friends, colleagues, and community members under the guise of 'wellness and public health safety.'

I believe the Commissioners of Collier County are going to do everything in their power to protect the health and well-being of Collier County residents and I would be honored to be of service in your efforts to do so.

Sincerely,

Karen Kingston

Biotech Analyst, Med-Legal Advisor

The Kingston Report. TRUTH WINS.

Psalm 94: 8-17

Take notice, you senseless ones among the people; you fools, when will you become wise?

Does he who fashioned the ear not hear? Does he who formed the eye not see? Does he who disciplines nations not punish? Does he who teaches mankind lack knowledge?

The Lord knows all human plans; he knows that they are futile.

Blessed is the one you discipline, Lord, the one you teach from your law; you grant them relief from days of trouble, till a pit is dug for the wicked. For the Lord will not reject his people; he will never forsake his inheritance. Judgment will again be founded on righteousness, and all the upright in heart will follow it.

*Who will rise up for me against the wicked? Who will take a stand for me against evildoers **Unless the Lord had given me help, I would soon have dwelt in the silence of death.***

Take Down COVID-19

The uncomfortable truth is that we all have been lied too and deeply betrayed by leaders we trust, and some we even adored. All offices of power across our nation; from our President and Federal Healthcare agencies to our local governors, mayors, city council members, and even our health care service providers, employers, and school boards members. If you're questioning on how to know if a government, public official or even if your employer or school is an ally of the American people of our children, there is a simple challenge to give them;

Demand Local Officials Take Down COVID-19.

Call for governors, attorney generals, mayors, school boards, colleges and universities, health care officials, health care centers, businesses, and churches to;

Make a public declaration that COVID-19 mRNA vaccines cause disease and death and must be banned and recalled immediately

Immediately STOP ALL COVID-19 testing, treatments and mRNA vaccines

REJECT and STOP ALL FUNDING for all COVID-19 programs

*CALL FOR GOVERNORS and Attorney Generals to CRIMINALIZE the promotion and administration of mRNA vaccines

*Governors have the power to reject the HHS declaration that SARS-CoV-2 is a threat to public health and national security and to criminalize the use of all EUA designated COVID-19 products, tests, and mRNA vaccines. Attorney generals have the right to seize and destroy all COVID-19 mRNA injections. Demand that they do.

21 Comments



Write a comment...



Michelle 13 hr ago Liked by Karen Kingston

YAAAAYYY!!!!!! Read this on my morning break at work. Will be sharing this widely. The battle has picked up steam due to your efforts! I cried joyful tears listening to your testimony in Collier County. Continued prayers for you Karen and all that you love! Thank you! Michelle

15 Reply Collapse ...



Escaped Rebel HCP 12 hr ago Liked by Karen Kingston

Karen... I have been following you since you bravely came forward, the Holy Spirit guides you...and many of us pray for your safety. Thank you & is there a template we can all use for our elected peoples in our areas? This is a battle between Evil & our God, but we need all of us to push forward.

12 Reply Collapse ...

1 reply

19 more comments...

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