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CHD Asks FDA to Revoke COVID Vaccine Licenses, Calls on Public to Submit 'Hundreds of Thousands' of Comments

by Brenda Baletti, Ph.D.
DECEMBER 9, 2020

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Children's Health Defense (CHD) is asking the U.S. Food and Drug Administration to revoke the licenses for all three Biologics License Applications (BLA) granted without meeting the required standards for that approval.

Legal counsel for the FDA to **lift the stay** that the vaccines and BLA approval without meeting the requirements of the Public Health Service Act.

It is important to point out that the petition is not about science, safety or efficacy of these vaccines. CHD's petition is about the process and procedures that the FDA used to circumvent the violations of the BLA standards that mandate those requirements.

The petition calls on the FDA to properly implement the Public Health Service Act (PHSA) 351 statute for as long as the U.S. Department of Health and Human Services (HHS) **Declaration** of Public Health Emergency (PHE) has been in effect. The PHE was declared on January 31, 2020, pursuant to the PHSA 319, Section 319.

Currently, the emergency declaration is set to **last until the end of 2020.**

Read the **full petition and cover letter here.**

Total vaccines cannot be recently vaccinated cohort a BLA? Read

Both Pfizer's **Comirnaty** and Moderna's **Spikevax** were initially developed and deployed under EUA and to the COVID-19 emergency period.

Drugs made available under EUA don't have the same rigorous manufacturing, testing and approval standards as those approved under BLA. Under EUA, the FDA can authorize the use of unapproved medical products or unapproved uses of approved medical products in an emergency. Often, definition of a vaccine.

The petition alleges the FDA allowed the vaccines to "jump the" by transitioning them from EUA status to full licensure without requiring Phase 3 clinical trials to be completed. The petition also claims the FDA violated its own rules when it:

- Failed to properly establish that the vaccines were safe and effective.
- Failed to establish adequate manufacturing controls.
- Failed to establish adequate facility inspection.

Pfizer's phase 3 licensure for adults 16 and older also did not require participants to undergo a placebo-controlled trial.

FDA failed to follow its own regulatory guidelines'

The petition cites the FDA Tiberius Rules to its own regulatory guidelines when it illegally granted BLAs to COVID-19 mRNA vaccines.[1]

According to the petition, leaked European Medicines Agency (EMA) documents from 2020 to 2021 **"cast doubt on the Pfizer/BioNTech and Moderna applications"** and "call into question the agency's regulatory assessment of Pfizer's manufacturing process, which the vaccine maker out of compliance with existing regulations.

The leaked documents showed also inspectors between the material used to make the shots stored in the vials **"could not be guaranteed to be sterile and free of microbial contamination."**

Food and Drug Administration Division Director Dr. Peter Marks said in a statement that the FDA reviewed that U.K. regulatory "were under intense political pressure to override all regulatory deficiencies," and that the concerns raised by staff were known and ignored.

The CHD petition also alleges:

- Pfizer's trial data were materially false on the basis for BLA labeling because clinical site teachers were produced through a different process than those later used for the commercial batches, as well as the fact that the vaccine was not stable for the duration of the clinical trials.
- Pfizer and Moderna misled human testing by using placebos with components of the vaccine, thereby concealing serious adverse events.
- The toxicology and biodistribution studies for the Pfizer vaccine were inadequate. Pfizer failed Laboratory Practices, and sometimes relied on surrogate mRNA constructs that were used on a different species of animal.
- Moderna's toxicity biodistribution study was conducted incorrectly on male rats, but the vaccine is approved for use in humans. The Pfizer study also had statistically significant skewed observations between male and female rats, which Pfizer failed to explain. The study also failed to report on the Moderna vaccine.
- Because the vaccines were treated as EUA countermeasures rather than new products under development, the FDA failed to require the BLA applicants to submit adequate chemistry, manufacturing and controls (CMC) information.

The petition **cites public FDA advisory committee discussions** and a declaration by former FDA official Dr. **Theresa Chmura**, a batch officials explicitly stated that the vaccines could not be the typical investigational regulatory pathways, because they didn't want Operation Warp Speed to be delayed by the requirements of BLA and clinical testing.

The vaccines — released today as a full vaccine — did not fit the products "in diagnosis," bearing BLA licensure and should have undergone clinical trials.

CHD calls on the public to submit comments on FDA's website

The FDA is now obligated to review the petition and respond within **180 days**, although the agency may extend that timeframe.

In the meantime, CHD said it hopes that hundreds of thousands of people will read the petition on the agency's website and submit comments in support of the petition.

Attorney Kay Hanna, counsel to CHD and one of the petition's signatories, said the petition "should have been granted" but for pressing COVID-19 concerns.[2]

He said that, like a bulwark petition or not when people, complain can upload comments with supporting documents or can view that supported by other people's comments.

"Since it is CHD's desire to correct rather than sue, and not to depend on the courts at the time, the petition allows the public to have a voice in the process," Hanna said in a statement to The Defender.

Hodapp called on the public for support.

"I hope the public will join the call for the FDA to do its job," Hodapp said. "Let the FDA and Pfizer and Moderna the licenses, and restore the EUA for those products if it chooses to keep them on the market."

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- **Pfizer, Moderna Must Add Warnings About Possible Heart Damage From COVID Vaccines, Doctors Say**
- **Fauci Lied About Regulatory Red Flags' Concerns About Moderna Vaccine**
- **FDA Licensed Pfizer Vaccine Without Following Normal Approval Process, Documents Reveal**

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Brenda Baletti, Ph.D.
Brenda Baletti, Ph.D., is a senior writer for The Defender. She wrote and taught about capitalism and politics for 10 years in the writing program at Duke University. She holds a Ph.D. in human geography from the University of Colorado Boulder and a master's degree in journalism from New York University.

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I support the Children's Health Defense Citizen Petition (FDA-2025-P-6831) calling for revocation of Biologics License Applications for mRNA COVID-19 vaccines, including Pfizer-BioNTech's Comirnaty, and urge Commissioner Marty Makary to launch an immediate formal investigation into the novel lipid excipient ALC-0315 under the FDA's post-approval authority [21 U.S.C. § 355(o)]. As a scientist with experience compiling Safety Data Sheets (SDS), I am acutely aware of the critical information these documents provide, as well as their shortcomings, such as incomplete sections that hinder proper toxicological evaluation. The Cayman Chemical SDS for ALC-0315, dated September 22, 2021, explicitly states the product is "for research use - Not for human or veterinary diagnostic or therapeutic use," yet this substance was incorporated into vaccines administered to billions worldwide without adequate disclosure or testing for human safety. The SDS classifies ALC-0315 (5% in 95% ethanol) as highly flammable (H225), carcinogenic (H350, Category 1A, "May cause cancer"), a skin irritant (H315), eye irritant (H319), and respiratory irritant (H335; STOT SE 3), with symptoms including anemia, cough, CNS depression, drowsiness, headache, heart damage, lassitude, liver damage, narcosis, reproductive effects, and teratogenic effects--primarily attributed to ethanol but with no separate data for ALC-0315 itself, as

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CHD, please find my failed submission below:

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jenn
6 days ago

I heard Judy Mikovits say that all vaccines have contained mRNA since (I forget what year?). If biologics are medications made from living organisms, would they contain RNA or DNA?

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7 days ago

$20 billion payout for vaccine induced autism

https://rumble.com/v72ukq8-highwire-9-dec-2025.html

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jenn
7 days ago

There are many vaccine safety departments within HHS. I would appreciate reports on these.

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SafariTLion
7 days ago edited

The FDA registers adulterated and misbranded drugs; Bioweapons disguised as vaccines.

This isn't an administrative error; it's criminal intent to inflict harm and deploy DARAPR (Pentagon) funded Bioweapons. The list of side effects on the "vaccine" labels are the intended harm, and denial of vaccine exemptions proof harm (so called 'vaccine injury') is intended.

RFK Jr. needs to pull these Bioweapons from the market.

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All these Covid-19 crimes were made possible - because there is no independent justice system:

Retired UK police officer Mark Sexton explains it from a UK perspective.

Mark Sexton: "The police must be seen to be enforcing criminal law, not to appear to act as the coercive agents of ministers."

https://rumble.com/v72qqzm-mark-sexton.html?ref=sn_v1_clfk2t2snc_v1_upp_a

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If Pfizer's Covid-19 vaccine was "safe and effective", Pfizer CEO Albert Bourla and his board of Directors would be the first to take it. Albert Bourla's body language and stuttering is priceless !!

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SafariTLion ➧ SafariTLion
7 days ago edited

Just look at the hypocrisy:

The situation was 'so critical' that Pfizer's CEO Albert Bourla had the Luxury of time to wait to take the vaccine.

The situation was 'so critical' that the vaccine weren't recommended for members of congress, politicians, judges and the 59 year old CEO of Pfizer.

The virus was so deadly, and the situation so critical, that Pfizer's board of directors had the luxury of time to wait whilst manufacturing millions of doses for others (Peps).

Many mandated individuals would have given / donated their dose to Pfizer's own CEO and his board - but they didn't want to take it. They supported vaccine mandates whilst refusing to take donated vaccine doses themselves.

This 'vaccine' turned out to have an ARR (Absolute Risk Reduction) of 0.84%, meaning **it was utterly useless in preventing Covid-19.**

According to Pfizer's official Covid-19 vaccine label, Covid-19 is a recognized and official side effect of their own vaccine. It appears if 'the deadly disease' called Covid-19 was actually caused by Pfizer's own vaccines. It was never isolated elsewhere. This clearly makes the vaccine a Bioweapon.

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jenn ➧ SafariTLion
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COVID-19
COVID-19 immunisation
COVID-19 pneumonia
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SafariTLion ➧ jenn
7 days ago

Certificate
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Vaccination
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If a virus cannot be isolated, it doesn't exist. The Covid-19 virus doesn't exist. You can get COVID by taking Pfizer's Covid-19 vaccine. Covid-19 is listed as side effect on Pfizer's official vaccine label. Viruses doesn't exist - Diseases are caused by substances in vaccinations. Almost every vaccine label list the disease it's suppose to prevent as side effect. Vaccinations are a scam.

see more

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Johnson & Johnson's employees clearly knew their Covid-19 vaccine was unsafe and ineffective. None of these products would be on the market if the FDA didn't approve it.

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SafariTLion
6 days ago

An excellent summary of problems related to Covid-19 vaccination can be downloaded from the website below. It's a 459 page document

https://coronacomplaint.ch/criminal-complaint/

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Drummer
6 days ago

This sounds like a waste of time, with the jabs staying on the market. What is it that you will really accomplish by having the jabs reclassified as ELAV like acid or even asprine, correct?

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