Informed Consent Action Network (ICAN): New Challenge to FDA on 12-15-Year-Old Covid Injections

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by **Informed Consent Action Network (ICAN)**
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ICAN has filed a Citizen Petition with the FDA calling on the agency to reverse its reckless course on Covid-19 injections for teenagers. The Petition demands that the FDA revoke its emergency use authorization (EUA) for Pfizer's product in children aged 12 through 15 and deny Moderna any future EUA for children aged 12 through 17.

The document, submitted through ICAN's legal team, spans 20 pages, cites dozens of medical studies, and includes 94 footnotes and roughly 1,500 pages of sources, but it boils down to a few simple principles: There never was any emergency with this age group in the first place, rendering EUAs illegal under federal law; the clinical trials relied upon to authorize the vaccines were woefully deficient; almost all in the 12-15 age demographic currently have natural immunity to Covid-19; and the injury risks from injection are catastrophically higher than any purported benefit.

The Petition cites a *Lancet* article of March 2021 that found Covid's death toll among children was a negligible 0.17 per 100,000 population. Since then, a large U.K. study posted in July 2021 found a Covid-19 fatality rate of just 0.005% among

all those under 18. “Based on these facts, the current EUA for Pfizer’s vaccine for this population is without legal foundation or necessity,” the Petition observes, “because COVID-19 does not present a current emergency for children.”

Furthermore, the population has been developing robust natural immunity against the disease. As of February 2022, according to a study published on the CDC’s website, 75% of children aged 12-17 had developed infection-induced antibodies. NIH data showed an even higher percentage of natural protection, at 89.4%, for all children under 18. And that percentage could only have increased since.

But the gaps in FDA logic do not begin and end with its misappropriation of the word “emergency,” nor with its selective blindness on natural immunity. As our Petition reminds the agency, quoting international scientists in an August 2008 PLOS Medicine paper, “inadequately powered studies should themselves be considered a breach of ethical standards.”

The FDA’s authorization for Pfizer’s injection rests on a trial in which only 1,131 children received the experimental product. Yet, even among that small and statistically insignificant group, at least seven recipients “had at least one serious adverse event.” Among them was Maddie de Garay who, at 12 years old, was paralyzed from the waist down after receiving her second shot. Among a multitude of horrific injuries, she became incontinent, and can now only receive nutrition through a feeding tube.

But Pfizer recorded her life-altering reaction as mere “functional abdominal pain” in the safety-evaluation data it turned over to the FDA and has since failed to ensure adequate medical care, including an appropriate diagnosis and treatment.

Nor has the safety profile for the mRNA shots improved since

their problematic trials. As early as June 2021, the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) examined the growing issue of vaccine-induced myocarditis, where the heart muscle becomes inflamed and thereby weakened, especially in individuals under 30 years old. Moreover, as the Petition points out, "Moderna's vaccine presents an even higher risk profile to this age group than Pfizer's vaccine."

Meanwhile, the Vaccine Adverse Events Reporting System (VAERS), though vastly understating the full extent of injection injuries, had accumulated 31,549 reports of adverse events among children under 18 as of May 6, 2022. Of these, 1,812 were rated as serious and 44 were deaths. This is to say nothing of the long-term effects.

And, if the glaring safety signals were not enough for the FDA to revoke its EUA for minors, the Petition also points out that several studies now show there is virtually no benefit from these shots since their efficacy wanes dramatically within just months or even weeks after inoculation.

The FDA has played very fast and extremely loose with its EUA powers when it comes to children's health, invoking an emergency that never existed and accepting data that was never adequate. Moreover, it has continued doubling down on its failed approach in spite of the overwhelming case against it. Numerous additional VRBPAC meetings are scheduled to discuss authorizations for additional vaccines and age groups and ICAN plans to file as many petitions as are necessary to address the concerns of each.

The FDA's increasingly reckless actions have prompted ICAN to file several Petitions with the FDA. These include demands the agency adhere to federal law requiring promotional material for EUA vaccines to "clearly and conspicuously" state the product has not been approved or licensed by FDA, but only authorized for emergency use. We

have also called on the FDA to publicly clarify an individual's statutory right to refuse medical products without coercion, penalty, or retaliation of any kind, and we have demanded that it obtain proper data before vaccine approvals. On all counts, the FDA has failed miserably and ICAN will continue to hold its feet to the fire.

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