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November 1, 2021

**VIA EMAIL and DOCKET NO. CDC-2021-0112**

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Re: *November 2, 2021 Meeting Regarding Recommendation for Pfizer's COVID-19 Vaccine for 5-11-year-olds*

Dear ACIP Members:

We write on behalf of the Informed Consent Action Network (“**ICAN**”) and in advance of tomorrow’s meeting regarding one of the most important issues in this country right now: COVID-19 vaccination in the pediatric population. To date, Pfizer’s Comirnaty is approved for children ages 16 and 17 and Pfizer-BioNTech’s COVID-19 vaccine is authorized for emergency use in children 5 through 15. On November 2, 2021, as members of the Advisory Committee on Immunization Practices (“**ACIP**”), you will meet to discuss recommending Pfizer’s vaccine for children 5–11 years of age. We implore you to carefully consider the information in this letter before recommending the Pfizer vaccine for children in this age group.

**A. COVID-19 in Children and the Lack of Emergency for 5-11-year-olds**

There are approximately 24.3 million children between the ages of 5 through 11 living in the United States.<sup>2</sup> Of these children, only 94 have died *with* COVID-19 between January 1, 2020 to October 16, 2021.<sup>3</sup> Less than 2% of all deaths in this age group were due to COVID-19.<sup>4</sup>

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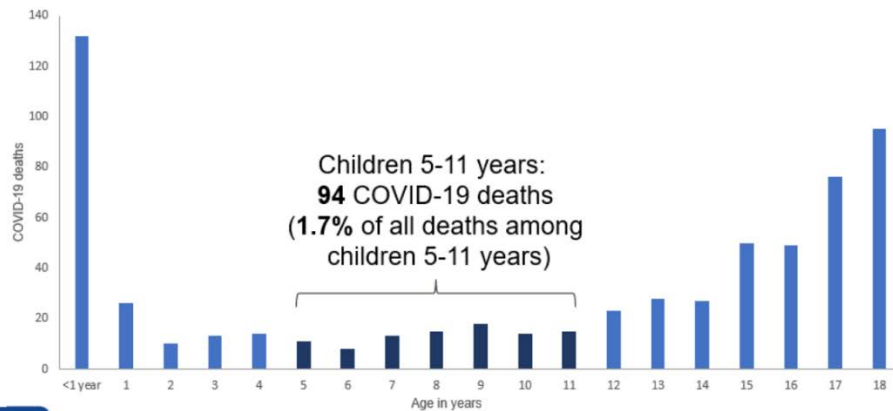
<sup>1</sup> A list of ACIP recipients is appended hereto.

<sup>2</sup> <https://www.childstats.gov/americaschildren/demo.asp>.

<sup>3</sup> <https://data.cdc.gov/NCHS/Provisional-COVID-19-Death-Counts-by-Age-in-Years-/3apk-4u4f/data>.

<sup>4</sup> *Id.*

## COVID-19 Deaths by Age Group, NCHS — January 1, 2020–October 16, 2021



<https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Counts-by-Age-in-Years/3apk-4u4f/data>

For perspective, children 5–11 years of age were more likely to die from influenza and pneumonia, 3 times more likely to die from homicide, 8 times more likely to die from cancer, and nearly 15 times more likely to die from accidents and unintentional injuries than to die with COVID-19 over the past year.<sup>5</sup> In other words, **there is no COVID-19 pandemic emergency for children 5 through 11 years of age in the United States of America.**

## Leading Causes of Death in Children 5-11 Years of Age, NCHS, 2019

Causes of Death	Death (n)	Crude rate per 100,000
Accidents (unintentional injuries)	969	3.4
Malignant neoplasms	525	1.8
Congenital malformations, deformations and chromosomal abnormalities	274	1.0
Assault (homicide)	207	0.7
Diseases of the heart	115	0.4
Chronic lower respiratory diseases	107	0.4
Influenza and pneumonia	84	0.3
Intentional self-harm (suicide)	66	0.2
Cerebrovascular diseases	56	0.2
Septicemia	48	0.2

66 COVID-19 associated deaths in children 5-11 10/3/20-10/2/2021



Total population 5-17 years, 2019: 52,715,248  
 CDC NCHS WONDER Online Database. Accessed at <http://wonder.cdc.gov/ucd-icd10.html> on May 6, 2021

A White Paper written by a research team at Johns Hopkins analyzed approximately 48,000 children under 18 years old diagnosed with COVID-19 and found a **mortality rate of zero** among

<sup>5</sup> <https://www.fda.gov/media/153508/download>

children who did not have a pre-existing medical condition such as leukemia.<sup>6</sup> Neither the FDA nor the CDC have put forth data to dispute this, and the available data from the agencies is for “deaths involving COVID-19” – not deaths caused by COVID-19.<sup>7</sup>

For children 5–11 years of age, the weekly rate of COVID-19-associated hospitalization has ranged from zero to a pandemic peak of 1.1 per 100,000 population.<sup>8</sup> Even this metric, however, does not necessarily correlate with severe cases of pediatric COVID-19 because it “may be inflated by the detection of mild or asymptomatic infection via universal screening.”<sup>9</sup> At least one study that analyzed 117 pediatric hospitalizations with confirmed cases of COVID-19 found that 39.3% of pediatric COVID-19 hospital admissions were asymptomatic and 45% of admissions were *unlikely* to have been caused by COVID-19.<sup>10</sup>

Given these data and the extraordinarily low risk of severe morbidity and mortality from COVID-19 in children 5–11 years of age, there is no current emergency for children as it relates to COVID-19 and, therefore, there is no justification for a universal recommendation of an emergency use authorized COVID-19 vaccine for children in this low-risk age group.

## **B. FDA’s Flawed Risk-Benefit Analysis**

The Vaccines and Related Biological Products Advisory Committee (“**VRBPAC**”) and the FDA’s decision to authorize emergency use of Pfizer’s COVID-19 vaccine for children 5–11 years of age was based on a deeply flawed risk-benefit analysis that failed to account for at least 5 critically important factors. ACIP should not compound this error with a universal recommendation (leading to widespread mandates) of COVID-19 vaccination for 5-11-year-olds.

### **1. Natural Immunity**

According to CDC data, an estimated 42% of children ages 5-11 had seroprevalence of previous SARS-CoV-2 infection as of June 2021.<sup>11</sup> Current estimates would suggest even higher seroprevalence rates among children, given that four months have passed since the time of this data point, during which the Delta variant has been predominant. The FDA’s risk-benefit analysis failed to account for the approximate half of children who likely already have natural immunity against COVID-19.

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<sup>6</sup> <https://s3.amazonaws.com/media2.fairhealth.org/whitepaper/asset/Risk%20Factors%20for%20COVID-19%20Mortality%20among%20Privately%20Insured%20Patients%20-%20A%20Claims%20Data%20Analysis%20-%20A%20FAIR%20Health%20White%20Paper.pdf>.

<sup>7</sup> <https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Focus-on-Ages-0-18-Yea/nr4s-juj3>.

<sup>8</sup> [https://gis.cdc.gov/grasp/COVIDNet/COVID19\\_3.html](https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html).

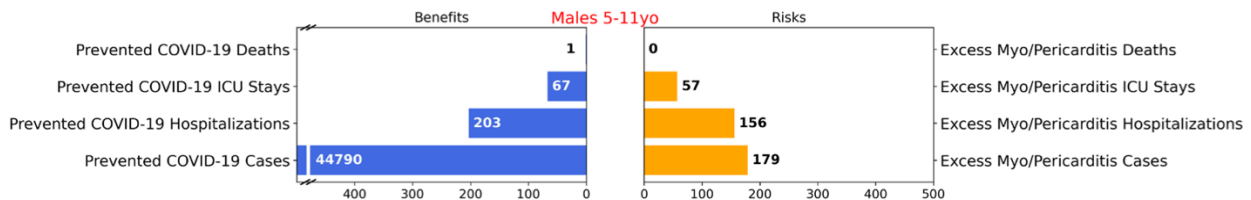
<sup>9</sup> <https://hosppeds.aappublications.org/content/11/8/e151.long>.

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

<sup>11</sup> <https://www.fda.gov/media/153508/download>.

Dozens of studies show that natural immunity to COVID-19 is superior to vaccine-induced immunity.<sup>12</sup> Therefore, for tens of millions of children in the United States, there is only risk with no meaningful benefit to be conferred by COVID-19 vaccination. An FDA senior advisor, Dr. Hong Yang, admitted at the October 26, 2021 VRBPAC meeting that should natural immunity be equal to vaccine-induced immunity, that would result in a 45% reduction of all benefits in the FDA’s risk-benefit analysis.<sup>13</sup>

### MALES (Cases Per Million)



*FDA’s “base” modeling scenario #1 risk-benefit analysis (5-11 year old males)*

Using the FDA’s “base” risk-benefit analysis (shown above),<sup>14</sup> and adjusting for the roughly 45% of children who have already acquired natural immunity through prior infection, **the risks of Pfizer’s COVID-19 vaccination in boys outweigh the benefits.** After adjusting for natural immunity, the calculations demonstrate that 112 hospitalizations would be prevented by vaccination, but that vaccination would result in 156 excess vaccine-associated myocarditis and/or pericarditis hospitalizations. Additionally, while 37 COVID-19 ICU stays may be prevented by vaccination, there would be 57 excess vaccine-associated myocarditis and/or pericarditis ICU stays. Natural immunity cannot be ignored and when it is represented in the relevant calculations, the risk of vaccination clearly outweighs the benefits for this age group.

## 2. Pediatric COVID-19 Hospitalizations

A CDC medical officer, Dr. Fiona Havers, noted at the recent VRBPAC meeting, that in COVID-NET data, 18-19% of younger children who were classified as COVID-19 hospitalizations were not primarily hospitalized due to COVID-19.<sup>15</sup> The FDA also failed to adjust for this in its risk-benefit analysis.

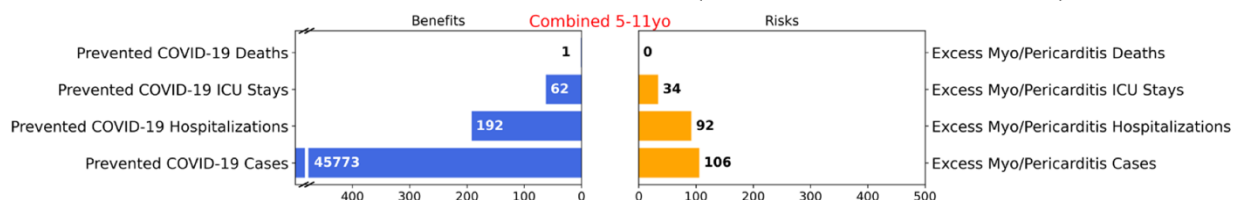
<sup>12</sup> See <https://www.icandecide.org/wp-content/uploads/2021/10/Legal-update-July-6-petition.pdf>; [https://www.icandecide.org/wp-content/uploads/2021/10/Legal-update-Supplement-to-Petition-re-convalesced\\_FINAL.pdf](https://www.icandecide.org/wp-content/uploads/2021/10/Legal-update-Supplement-to-Petition-re-convalesced_FINAL.pdf).

<sup>13</sup> [https://youtu.be/laaL0\\_xKmma?t=20766](https://youtu.be/laaL0_xKmma?t=20766) at 5:46:06.

<sup>14</sup> <https://www.fda.gov/media/153507/download>.

<sup>15</sup> [https://youtu.be/laaL0\\_xKmma?t=20971](https://youtu.be/laaL0_xKmma?t=20971) at 5:49:3.

## MALES AND FEMALES (Cases Per Million)



*FDA's "base" modeling scenario #1 risk-benefit analysis (5-11-year-old males and females)*

Using the FDA's "base" risk-benefit analysis (shown above),<sup>16</sup> and adjusting for 45% of children having natural immunity and an 18% inflation of pediatric COVID-19 hospitalizations, the risks of Pfizer's COVID-19 vaccine outweigh the benefits with regards to more excess hospitalizations due to vaccine-associated myocarditis and/or pericarditis, compared to vaccine-prevented hospitalizations in boys and girls combined. This data must be taken into account when weighing the risks versus benefits.

### 3. COVID-19 Vaccine-Induced Immunity Wanes Over Time

The FDA's risk-benefit analysis assumed a constant vaccine efficacy over a time span of six months. This is an inappropriate assumption, as it is well established that the efficacy of Pfizer's COVID-19 vaccine decreases over time, with one study showing a drop below 50% efficacy after five months.<sup>17</sup> Pfizer itself has recognized that the efficacy declines an average of 6% every two months.<sup>18</sup> Moreover, the FDA's risk-benefit analysis was not of sufficient duration to account for potential future booster doses after six months. Each booster dose would carry an additional risk of myocarditis and/or pericarditis, along with other potential adverse events. This inflation of purported efficacy also distorts the risk-benefit analysis, wrongly, in favor of vaccination.

### 4. Adverse Reactions and Other Adverse Events

The FDA only accounted for risks from vaccine-associated myocarditis and pericarditis but failed to account for other adverse reactions in its risk-benefit analysis. Over a six-month timespan, the FDA estimated that approximately 46,000 cases of COVID-19 could be prevented by fully vaccinating one million children ages 5–11.<sup>19</sup> However, this would come at the risk of approximately 1.4 million instances of pain at the injection site, 500,000 headaches, 90,000 cases of fever, and many instances of fatigue, chills, vomiting, diarrhea, and muscle or joint pain<sup>20</sup> – all potentially worse than the clinical presentation of COVID-19 in this age range – not to mention

<sup>16</sup> <https://www.fda.gov/media/153507/download>.

<sup>17</sup> <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2902183-8>.

<sup>18</sup> <https://www.cnbc.com/2021/07/28/pfizers-ceo-says-covid-vaccine-effectiveness-drops-to-84percent-after-six-months.html>.

<sup>19</sup> <https://www.fda.gov/media/153507/download>.

<sup>20</sup> <https://www.fda.gov/media/153447/download>.

the risk of anaphylaxis, Bell’s palsy, lymphadenopathy, or any rare adverse events that were not captured in Pfizer’s under-powered trial. Furthermore, data shows that individuals with prior COVID-19 infection are at greater risk of experiencing adverse events after vaccination.<sup>21</sup> As was bluntly stated by Dr. Eric Rubin at the October 26, 2021 VRBPAC meeting: **“We’re never going to learn about how safe the vaccine is unless we start giving it, and that’s just the way it goes.”**

## 5. The Opportunity Cost

The FDA’s “base” risk-benefit analysis estimated that fully vaccinating one million children ages 5–11 would prevent one COVID-19 death.<sup>22</sup> At a pandemic price of \$19.50 per dose of Pfizer’s vaccine (likely to increase over time),<sup>23</sup> it would cost \$39 million to prevent a single COVID-19 death in children 5–11 years of age. The question then becomes: how many more lives could be saved if \$39 million in tax-payer revenues were instead spent on something else, such as prevention of one of the top 3 causes of death in this age range, including malignant neoplasms or diseases of the heart?

### C. COVID-19 Vaccines Do Not Prevent Infection and Transmission

According to CDC Director Rochelle Walensky, infection with the COVID-19 Delta variant resulted in similarly high SARS-CoV-2 viral loads in vaccinated and unvaccinated people, with both being able to transmit the virus.<sup>24</sup> The science agrees. A preprint paper titled *Shedding of Infectious SARS-CoV-2 Despite Vaccination* found that for people with symptomatic COVID-19, fully-vaccinated individuals are just as contagious as unvaccinated individuals.<sup>25</sup> These same researchers concluded that asymptomatic, fully-vaccinated individuals are also capable of spreading the virus to others, perhaps even more so than their unvaccinated peers.<sup>26</sup> In another study titled *Increases in COVID-19 are unrelated to level of vaccination across 68 countries and 2,497 counties in the United States*, researchers concluded that “countries with higher percentage of population fully vaccinated have higher COVID-19 cases per 1 million people.”<sup>27</sup>

The above research findings help explain why the state of Vermont, despite having the highest COVID-19 vaccination rate in the country,<sup>28</sup> is currently experiencing the highest number of active COVID-19 cases the state has had since the beginning of the pandemic.<sup>29</sup> Similarly, the

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<sup>21</sup> [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(21\)00224-3/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00224-3/fulltext).

<sup>22</sup> <https://www.fda.gov/media/153507/download> at 10.

<sup>23</sup> <https://www.fiercepharma.com/pharma/pfizer-eyes-higher-covid-19-vaccine-prices-after-pandemic-exec-analyst>.

<sup>24</sup> <https://www.cdc.gov/media/releases/2021/s0730-mmwr-covid-19.html>.

<sup>25</sup> <https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v5>.

<sup>26</sup> *Id.*

<sup>27</sup> [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8481107/pdf/10654\\_2021\\_Article\\_808.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8481107/pdf/10654_2021_Article_808.pdf).

<sup>28</sup> See <https://fortune.com/2021/08/12/vermont-covid-cases-vaccination-rate/> (“Vermont has the highest vaccination rate in the country and is outpacing the national vaccination rate”). In Vermont, 90% of individuals 12 and older have received at least one dose of a COVID-19 vaccine. <https://www.healthvermont.gov/covid-19/vaccine/covid-19-vaccine-dashboard>.

<sup>29</sup> <https://www.worldometers.info/coronavirus/usa/vermont/>.

country of Singapore, with 84% of their population fully vaccinated against COVID-19,<sup>30</sup> is currently experiencing their largest wave of COVID-19 cases and deaths since the beginning of the pandemic.<sup>31</sup>

Based on these data, COVID-19 vaccines do not stop community spread of SARS-CoV-2. Since COVID-19 vaccines do not prevent infection and transmission of the virus, public health experts cannot rely on vaccine-induced herd immunity to protect people from COVID-19.<sup>32</sup> There is no emergency nor health need for vaccination of 5-11-year-olds and further, there is no reason to vaccinate this age cohort in order to benefit others around them.

#### **D. ACIP is Uniquely Responsible for the Recommendation of the Vaccine and is Not Forced to Answer or Enforce the Binary Question Previously Put to VRBPAC**

At the October 26, 2021 VRBPAC meeting, many of the members expressed concern and took issue with the binary question on which they were forced to vote: “Based on the totality of scientific evidence available, do the benefits of the Pfizer-BioNTech COVID-19 Vaccine when administered as a 2-dose series ... outweigh its risks for use in children 5-11 years of age?”<sup>33</sup>

During VRBPAC’s discussion, it was clear that some on the committee felt that the vaccine should be an option for some in the relevant age range but perhaps is not needed by all in the age range. Despite this, Dr. Arnold Monto, the Chair of VRBPAC, made clear, more than once, that the answer to the voting question is binary: members were forced to vote “yes” or “no” with regard to whether the benefits of vaccination outweigh the risks for *all children* ages 5-11 years old.

Seeming to understand the realistic ramifications of VRBPAC’s recommendation, Dr. Meissner raised concerns that school mandates for *all children* would follow any authorization and recommendation for the vaccine in this age group and that he opposed same. Dr. Ofer Levy, similarly, asked if the wording of the voting question could be changed to allow more nuance and flexibility for the committee. In the face of these concerns, Dr. Marks repeatedly asked the committee to vote on the question as it was presented: “first vote on this question and ... we can make a determination thereafter and ... we could potentially either poll the committee or vote on something else.”<sup>34</sup> Dr. Marks later clarified precisely what this meant: “the way this process has been set up is that, it’s this body’s decision to make sure that the data supports the safety and effectiveness and that the Advisory Committee on Immunization Practices then discusses the deployment of the vaccine ... I would suggest that we take a vote on the question as it’s written

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<sup>30</sup> <https://www.straitstimes.com/multimedia/graphics/2021/06/singapore-covid-vaccination-tracker/index.html>.

<sup>31</sup> <https://www.worldometers.info/coronavirus/country/singapore/>.

<sup>32</sup> <https://www.cdc.gov/pertussis/about/faqs.html#immunity> Just as acellular pertussis vaccines cannot be relied upon for herd immunity as they do not prevent colonization (carrying the bacteria in your body without getting sick) or spread of the bacteria, similarly, COVID-19 vaccines do not prevent infection and spread of the virus, and therefore cannot be relied upon for herd immunity.

<sup>33</sup> [https://www.youtube.com/watch?v=laaL0\\_xKmmA&t=20971s](https://www.youtube.com/watch?v=laaL0_xKmmA&t=20971s) at 6:45:02.

<sup>34</sup> [https://www.youtube.com/watch?v=laaL0\\_xKmmA&t=20971s](https://www.youtube.com/watch?v=laaL0_xKmmA&t=20971s) at 7:08:30.

and then if the vote fails, then we can tailor the vote to a sub-population at that point.”<sup>35</sup> That did not happen, because the FDA got the result it wanted without having to do so.

Reflecting on the fact that many VRBPAC members voiced concerns and hesitations during the meeting yet voted “yes” in the end, Dr. Paul Offit, said, “We do that ... We express all our concerns, just get it out there. That makes everyone feel better and then we vote the way we should have voted right from the beginning ... The fact of the matter is **you’re basing a decision for millions of children on a study of 2,400, really,**” he said. “**And that’s uncomfortable.** So you want caveats. But you don’t get ’em. As [chair] Dr. Monto said over and over again, it’s a binary decision.”<sup>36</sup>

Unlike VRBPAC, ACIP can create caveats and can tailor recommendations to sub-populations as appropriate. ACIP is tasked with “provid[ing] advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States.”<sup>37</sup> More specifically:

For each vaccine, the committee advises on population groups and/or circumstances in which a vaccine or related agent is recommended. The committee also provides recommendations on contraindications and precautions for use of the vaccine and related agents and provides information on recognized adverse events. The committee also may provide recommendations that address the general use of vaccines ... as well as special situations or populations that may warrant modification of the routine recommendations.<sup>38</sup>

Because of these duties specific to ACIP, “the question of how broadly to use [the vaccine in this age group] is a substantial one” and, according to Dr. Rubin, **VRBPAC is “kind of punting that to ACIP.”**<sup>39</sup> This is a critical issue to punt and is solely within the discretion of ACIP and then the CDC. Dr. Hildreth appeared to agree with Dr. Rubin in stating that, “in some ways, we are vaccinating children to protect the adults and it should be the other way around – that if 30 million children already have some sort of immunity, they’ve made their contribution to herd immunity already and our focus should be to get the adults vaccinated to protect the children ... I do believe that children at highest risk do need to be vaccinated but vaccinating all of the children to achieve that just seems a bit much to me.”<sup>40</sup>

To be clear, simply because VRBPAC recommended that the vaccine be authorized and simply because the FDA followed that recommendation for all children ages 5-11, ACIP is not

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<sup>35</sup> [https://www.youtube.com/watch?v=laaL0\\_xKmmA&t=20971s](https://www.youtube.com/watch?v=laaL0_xKmmA&t=20971s) at 7:17:38.

<sup>36</sup> <https://www.statnews.com/2021/10/26/pfizer-covid19-vaccine-kids-vrbpac-fda/>.

<sup>37</sup> <https://www.cdc.gov/vaccines/acip/committee/acip-charter.pdf>.

<sup>38</sup> *Id.*

<sup>39</sup> [https://www.youtube.com/watch?v=laaL0\\_xKmmA&t=20971s](https://www.youtube.com/watch?v=laaL0_xKmmA&t=20971s) at 6:52:09.

<sup>40</sup> [https://www.youtube.com/watch?v=laaL0\\_xKmmA&t=20971s](https://www.youtube.com/watch?v=laaL0_xKmmA&t=20971s) at 6:53:40.



obligated and, plainly, *should not* recommend the vaccine for that age range, universally. That analysis is uniquely for ACIP, as acknowledged by VRBPAC, and must take into account all of the foregoing data.

#### **E. Conclusion**

Healthy children ages 5–11 in the United States are at infinitesimally low risk of dying from COVID-19. The risk-benefit analysis relied upon by the FDA to grant an EUA for Pfizer’s COVID-19 vaccine failed to account for, at a minimum, the large proportion of children who already have natural immunity, over-classification of pediatric COVID-19 hospitalizations, waning of vaccine-induced immunity, and vaccine side effects aside from, among other things, myocarditis and pericarditis. COVID-19 vaccines do not prevent infection and transmission of SARS-CoV-2 and therefore cannot be relied upon to confer herd immunity (unlike close to 30 million children who already have contributed to same).

ICAN requests that ACIP (i) respond to ICAN’s concerns; (ii) properly assess a nuanced recommendation where VRBPAC’s hands were tied in doing so; and (iii) decline to recommend Pfizer’s COVID-19 vaccine for healthy 5–11-year-old children.

Yours truly,



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## ACIP Member Recipients<sup>41</sup>

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<sup>41</sup> <https://www.cdc.gov/vaccines/acip/members/index.html>.