

Safety Signals for COVID Vaccines Are Loud and Clear. Why Is Nobody Listening?

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The public deserves a complete and transparent accounting of the Centers for Disease Control and Prevention’s safety monitoring, including the results of all interim reports and analyses, whether through a Freedom of Information Act request, Congressional order or some other means.

Summary:

- There is a disproportionately large number of adverse events reported to the [Vaccine Adverse Event Reporting System](#) (VAERS) from [COVID-19](#) vaccines compared with other vaccines.
- There are 91x the number of deaths and 276x the number of [coagulopathy](#) events reported after COVID-19 vaccination than after [flu vaccination](#).
- Safety signals were found for 242 adverse events using the Centers for Disease Control and Prevention’s (CDC) methodology.
- Full transparency of CDC and U.S. Food and Drug Administration (FDA) safety monitoring is urgently needed.

On Aug. 30, the CDC Advisory Committee on Immunization Practices (ACIP) [voted to recommend](#) Pfizer/BioNTech’s mRNA COVID-19 vaccine for people 16 years and older.

In comments I [submitted to the committee](#) along with my collaborators, we provided evidence of large safety signals from VAERS, using published CDC methods to analyze the data.

In this article, I describe the safety signals highlighted in our comments, which raise pressing questions about the CDC’s and FDA’s COVID vaccine safety monitoring efforts.

To begin with, there has been an unprecedented increase in the number of [adverse event reports](#) to VAERS associated with COVID-19 vaccines. The chart below shows the number of

deaths for all other vaccines reported to VAERS annually since the system's inception in 1990, compared to deaths reported for COVID-19 vaccines, from both domestic and foreign sources.

Number of Deaths Reported to VAERS Since 1990

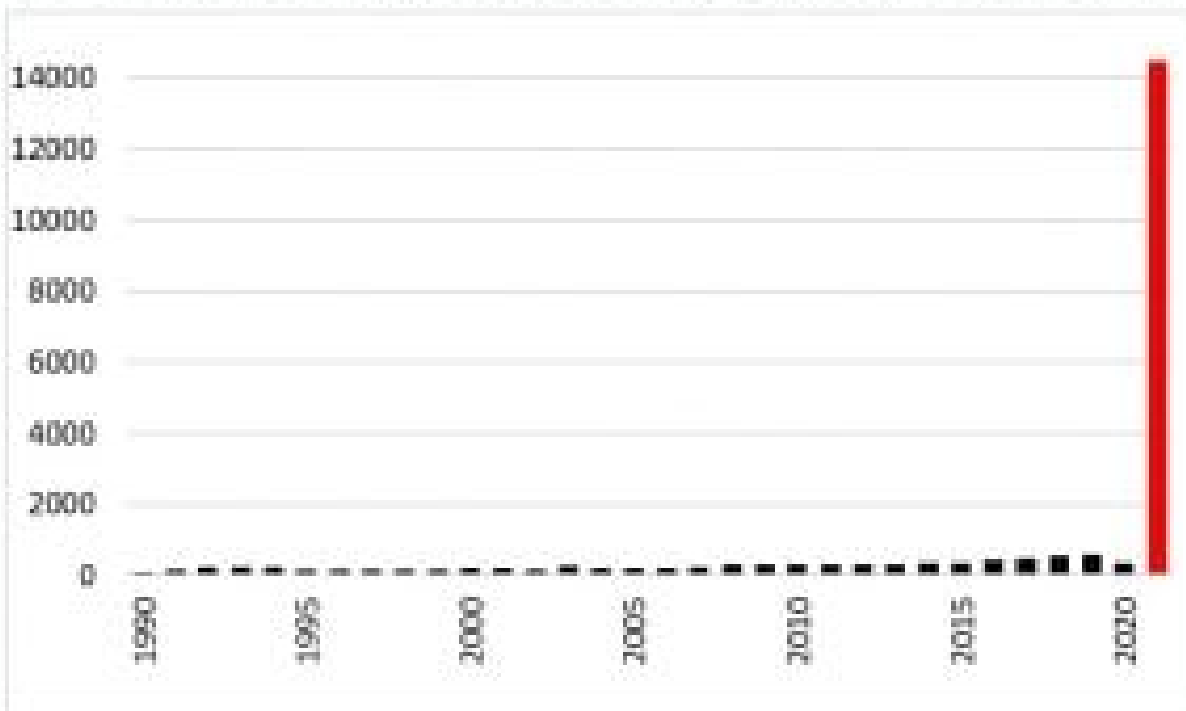


Figure 1. Number of Deaths Reported to VAERS Since 1990

As of early September, there have been 14,506 deaths reported to VAERS for COVID-19 vaccines, compared to 8,673 for the preceding 30 years for all other vaccines. That is already more than 50 times the annual average — and we still have four months left to go until the end of the year.

It is hard to imagine how anyone can look at these numbers and not be at least a little bit concerned. Yet many people are dismissive, saying the unprecedented number of reports is due to the unprecedented number of vaccinations being administered.

I crunched the numbers, and even after taking into account the total number of vaccinations, the number of reports for COVID vaccines still towers over previous years.

See, for example, Figure 2 below, which shows the number of deaths reported per million vaccine doses from 2010-2020 and for COVID-19 vaccines. That's nearly 40 deaths reported per million COVID vaccines versus an average of 1.6 for all other vaccines from the previous 10 years.

No matter what I did to the data, or what types of adverse events I looked at, I could not make the big jump in COVID vaccine reports go away.

Deaths Reported to VAERS per Million Vaccine Doses Since 2010

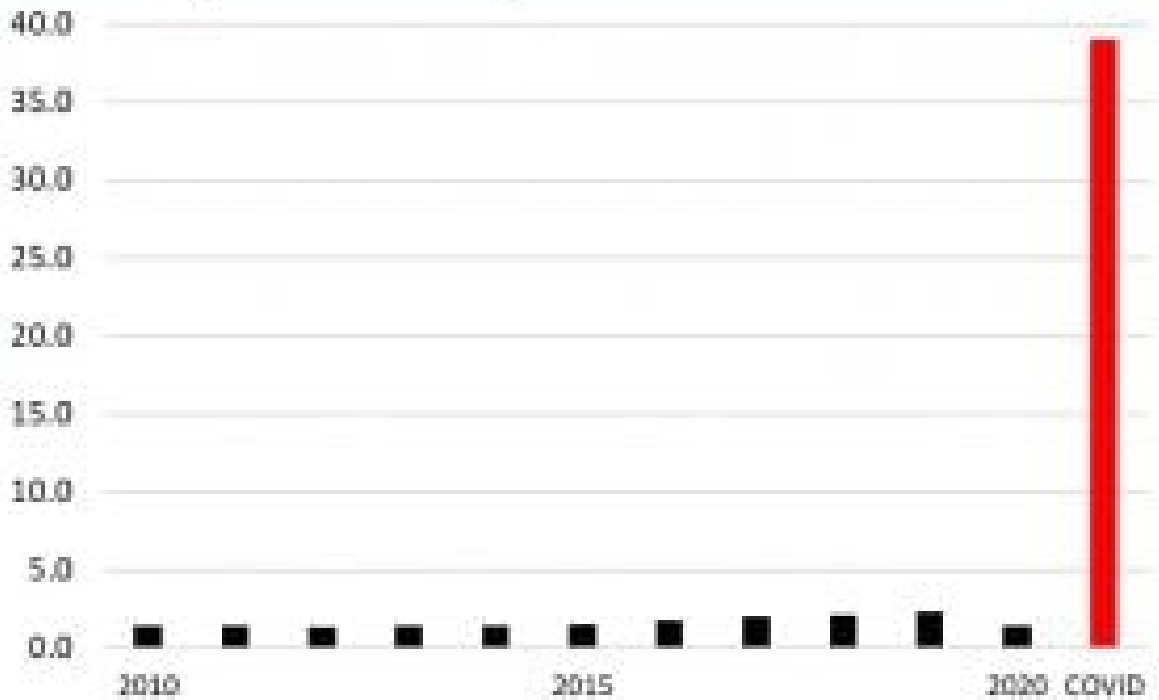


Figure 2. Deaths Reported to VAERS per Million Vaccine Doses Since 2010

So why do the CDC and FDA not seem to be concerned about this? I don't know, but to try to answer that question, we have to take a step back to talk about VAERS and how the CDC uses it to detect safety signals.

VAERS, which is jointly administered by the CDC and FDA, is typical of [all reporting systems](#) used to monitor the safety of medicinal products. Although widely used, there are many [known limitations](#) with this type of system. Probably the biggest is that it is passive or spontaneous, meaning it relies on the willingness of people and medical professionals to "spontaneously" submit reports. So reporting rates are [low and inconsistent](#).

READ + SHARE my letter to Dr. Kessler, newly named co-chair of Biden's [#COVID-19](#) Advisory Committee, requesting he immediately fix Vaccine Adverse Event Reporting System ([#VAERS](#)), system that monitors adverse outcomes following vaccination. [#TheDefenderhttps://t.co/Jw77i8NrOA](https://t.co/Jw77i8NrOA)

— Robert F. Kennedy Jr (@RobertKennedyJr) [December 19, 2020](#)

Another limitation is that reports cannot be used reliably to show a causal connection between a vaccine or medication and an adverse event. So what are they good for?

They are used to provide a kind of early warning system. When enough reports accumulate about a particular type of event, those reports produce a safety signal, like an alarm bell. When the alarm rings, it doesn't mean there is definitely a problem, but it is supposed to alert authorities to a possible problem and prompt further investigation.

In late January, the CDC released a [briefing document](#) outlining the agency's standard

operating procedures for ongoing monitoring of VAERS for safety signals from COVID-19 vaccines.

The document lays out plans to produce weekly reports that would highlight any safety signals found across a range of different adverse events. Although those reports have not been made public, we don't need to rely on the CDC, as VAERS data is publicly available.

To detect safety signals with new vaccines, I took my lead from [a study published by CDC researchers](#) who were trying to detect safety signals for the new H1N1 swine flu vaccines introduced in 2009. The researchers compared VAERS reports for H1N1 vaccines to reports for regular [flu vaccines](#).

So I took a similar approach and compared adverse events reported for COVID-19 to events reported for flu vaccines. This comparison makes a lot of sense, as flu vaccines are the only other type of vaccine administered to adults and the elderly in large numbers.

Of course, because the number of flu and COVID-19 vaccines administered is not the same, it makes sense to look at the number of reports per dose administered, something not specified in the CDC briefing document.

Table 1 (below) shows a comparison of VAERS reports for COVID-19 vaccines versus flu vaccines per million doses administered for a range of different event types and age groups.

Ages	All Reports	Serious Reports	Death	GBS	Coagulopathy	Myocardial Infarction	Myo-pericarditis
12-17	25	14	12	7	74	n.e.	1251
18-49	26	25	64	3	226	403	81
50-64	18	26	85	3	239	121	22
65+	11	30	98	3	370	88	10
Overall	19	28	91	3	276	126	136

Notes: The COVID-to-Flu ratio is the ratio of the COVID-19 reporting rate to the flu reporting rate per million vaccine doses. All differences between COVID-19 and flu reporting rates are statistically significant. Myocardial infarctions for 12-17 year-olds is non-estimable (n.e.) because there were no reports of M.I. for flu vaccines in that age group. GBS is Guillain-Barré Syndrome. Flu reporting rates represent the total reports to VAERS across the 2015/16 to 2019/20 flu seasons for each age group. COVID-19 reporting rates include all reports to VAERS for COVID-19 vaccines for each age group from Dec. 21, 2020 through Aug. 6, 2021. Vaccine doses estimated using data from the CDC and the US Census Bureau. COVID-19 vaccination rates are from Aug. 3, 2021. All reports with SARS-CoV-2 infection or COVID-19 were excluded from counts. Only reports that originated from U.S. states and D.C. were included.

Table 1. COVID-to-Flu Ratio Reporting Ratios per Million Vaccine Doses

For each adverse event type, the table shows the COVID-to-flu ratio, which simply shows how many more events were reported per million doses of COVID-19 vaccines compared to the number per million doses of seasonal influenza vaccines.

The comparison is based on all reports to VAERS following COVID-19 vaccines (from Dec. 15 - Aug. 6) to all reports for all seasonal influenza vaccines from the previous five influenza seasons (from 2015/16 to 2019/20).

Keep in mind that for all the analyses, I excluded all reports that came from people with an indication of a SARS-CoV-2 infection, such as a positive test result or even a suspicion of

COVID-19 — so the adverse events can't be blamed on that.

The first thing to notice is that for every type of adverse event for every age group, there were more reports per million doses of COVID-19 vaccines than for flu vaccines. If you look at the bottom row for all age groups (12 and older), you see that for every million vaccine doses administered, there were 19 times more reports to VAERS for COVID-19 vaccines than for flu vaccines, 28 times more [serious events](#), 91 times more deaths, 3 times more reports of [Guillain-Barré syndrome](#) (GBS), 276 times more reports of [coagulopathy](#); 126 times as many reports of myocardial infarction; and 136 times more reports of [myopericarditis](#).

Also notable is the variation across age groups. For example, death and coagulopathy were more preponderant for older age groups, whereas GBS and [myopericarditis](#) were more frequent for younger age groups.

The ratios for myopericarditis put the full significance of these results into perspective, since it is an officially recognized side effect of COVID-19 vaccines, especially among men under age 50. See for example [this FDA press release](#) and the below slide from an Aug. 30 [CDC presentation](#) to the ACIP:

Expected vs. Observed reports after mRNA vaccination dose 2, 7-day risk period (N=765)*

Age group, years	Females		Males	
	Cases of myopericarditis, expected	Cases of myopericarditis, observed	Cases of myopericarditis, expected	Cases of myopericarditis, observed
12-15†	0-3	12	1-5	117
16-17†	0-2	15	0-3	121
18-24†	1-8	24	1-11	213
25-29†	1-6	16	1-9	96
30-39	2-21	10	2-19	72
40-49	2-22	22	2-19	45
50-64	4-40	15	4-35	13
65+	4-44	6	4-36	8



* As of Aug. 26, 2021, among 17.1 million vaccinees under age 65, 765 cases of myopericarditis were reported among 17.1 million vaccinees under age 65. The expected number of cases of myopericarditis is based on the expected number of cases of myopericarditis among 17.1 million vaccinees under age 65. The observed number of cases of myopericarditis is based on the observed number of cases of myopericarditis among 17.1 million vaccinees under age 65.

Slide from Aug. 30 CDC presentation to the Advisory Committee on Immunization Practices

While the COVID-to-flu ratio for myopericarditis among 12- to 17-year-olds in Table 1 is in a league of its own at 1251-to-1, the ratio for the 18- to 49-year-olds is 81-to-1, which is well within the range of many of the other ratios in the table — and even smaller than many of them. (I used the reporting rates per million vaccine doses from the ACIP report, slide 30, to calculate the COVID-to-flu ratios for myopericarditis, which were slightly smaller than my own calculations.)

Because the [CDC has acknowledged](#) that mRNA COVID-19 vaccines can cause myocarditis in this age group, a reporting ratio of at least 81 is like an alarm bell going off to warn us of a potential safety problem. And the much larger ratios for coagulopathy and myocardial infarctions are like a 4-alarm fire.

So why does the CDC seem to be unconcerned about these safety signals? Is it possible they haven't picked up on them?

Admittedly, comparing reports for COVID versus flu after taking the number of doses into account is not the same exact methodology anticipated in the CDC's briefing document. Although it is arguably superior for a variety of reasons I won't get into here, just to be sure I went ahead and did the exact same type of analysis outlined in the briefing document and found unambiguous safety signals.

Before showing the results, I need to explain how it works, but to do that we'll have to get a bit deep in the weeds.

The method is a [well-established pharmacovigilance technique](#) based on calculating what's known as the "Proportional Reporting Ratio" or PRR. To calculate the PRR, you first have to calculate the proportion of each type of event out of all events reported for that vaccine (COVID-19 and flu).

So for example, we take the number of VAERS reports of myocarditis for COVID-19 vaccines and divide that by the total number of all events reported for COVID-19 vaccines. Then we do the same for flu vaccines.

Then, to get the proportional reporting ratio (PRR), we divide the proportion of reports for a given type of event (like myopericarditis) for COVID-19 vaccines by the proportion for flu vaccines.

If the proportion for COVID-19 vaccines is large relative to the proportion for flu vaccines, that sends a signal alerting us to a potential safety problem. A safety signal is defined as a PRR that is greater than 2, statistically significant (with what's known as a [Chi-square value](#) above 4) and has at least three of that type of event reported for each vaccine.

Table 2 below shows the PRR's I calculated for several different adverse events across different age groups. All of the PRR's in bold fit the CDC's definition of a safety signal. This includes all PRR's for death, except for the youngest age group, all PRR's for coagulopathy and myopericarditis, and all PRR's for myocardial infarction, except for the youngest age group because there were no myocardial infarctions reported for influenza vaccines.

Age	Serious Events	Deaths	GBS	Coagulopathy	Myocardial Infarction	Myopericarditis
Age 13-17	1.4*	1.24	0.3*	2.9*	n.a.	66.8*
Age 18-49	0.99	2.9*	0.1*	8.8*	15.8*	9.6*
Age 50-64	1.5*	4.7*	0.1*	13.2*	6.7*	7.4*
Age 65+	2.8*	9.2*	0.3*	37.0*	8.3*	4.0*
Overall	1.5*	4.9*	0.2*	14.8*	6.8*	7.9*

Notes: The PRR is the ratio of the proportion of a specific type of event out of all reports for COVID-19 to the proportion of that type of event out of all reports for the combined 2013/14-2020/21 flu seasons. PRR's in bold fit the CDC's definition of a safety signal. A "*" indicates a statistically significant difference between the proportion of COVID-19 and flu reports for that age group and event type. Myocardial infarctions for 13-17 year-olds is non-estimable (n.a.) because there were no reports of M.I. for flu vaccines in that age group. GBS is Guillain-Barre Syndrome. Flu reporting rates were calculated based on the total reports to VAERS across the 2020/21-2021/22 flu seasons for each age group. Covid-19 reporting rates were based on all reports to VAERS for COVID-19 vaccines from Dec. 15, 2020, through Aug. 8, 2021. All reports with codes for SARS-CoV-2 infection or COVID-19 were excluded from AE counts. Only reports that originated from U.S. states and D.C. were included.

Table 2. COVID-19 vs. Flu Vaccines: Proportional Reporting Ratios (PRR's)

Note that, by default, the PRR method will never detect a safety signal for events that have never been reported for the comparator vaccine — like the zero teenage myocardial infarctions reported for flu vaccines ever compared to 10 for COVID-19 vaccines — which arguably should be seen as an even stronger indication that something is amiss.

The only event that makes up a larger proportion of flu vaccine reports than COVID-19 vaccines is GBS.

Here, too, the PRRs for myopericarditis are instructive. Even though the PRR value for myopericarditis in the youngest age group is off the scale, the values for the 18 to 49 age group is similar to or even lower than the PRR's for deaths, myocardial infarctions and coagulopathy.

Because the signal for myopericarditis is indicative of an actual, acknowledged safety problem, other signals of similar size might very well be alerting us to actual but unacknowledged problems.

I then went a step further and calculated PRRs for all adverse events submitted to VAERS. I found 242 adverse events that satisfied the definition of a safety signal according to the CDC.

Some of them were minor, like abnormal dreams or vaccination site discomfort. But many of them were very serious and included, in addition to the events shown in Table 2: cardiac arrests; cerebral hemorrhages; cerebrovascular accidents (strokes); renal failure; and vaginal hemorrhages — and that's just the tip of the iceberg of serious events that show unambiguous safety signals.

An additional 87 types of events didn't qualify as a safety signal just because they had been reported only once or twice for flu vaccines. An additional 6,159 types of events had never been reported for flu vaccines, despite more than 600 million flu vaccines administered among the age groups I examined.

For these events, it could be argued the safety signal is infinite, since the number of events in the denominator is zero. But instead of raising an alarm, they are by definition considered unworthy of concern.

No matter how I sliced and diced the data, the safety signal for COVID-19 vaccines rang loud and clear. It's hard to imagine how anyone could miss it. It would be like taking a hike in Arizona and falling into the Grand Canyon because you didn't see the big hole in the ground.

Some people are dismissive when presented with this evidence. "VAERS data can't be trusted," they say. "Anyone can submit a report and some of the reports are fraudulent."

Yes, anybody can submit a report, and some might be fraudulent. But the CDC hasn't raised any concerns about this and continues to use VAERS to monitor for safety signals.

[A recent study](#) found 67% of VAERS reports were submitted by healthcare workers, and [the CDC confirmed](#) that 88% of VAERS myopericarditis reports they examined fit their case definition.

Yes, VAERS is imperfect, but the large majority of reports are legitimate and reliable.

Another objection is that the increase in reporting is artificial. Many people are scared of these new vaccines. Awareness of VAERS is higher than it has ever been. And the government has actively encouraged, and in some cases required, people to report adverse events — so of course VAERS reports are going to increase.

But that doesn't mean there are really more events. This phenomenon is known as "stimulated reporting."

Nobody at any of the recent CDC advisory committee meetings raised any concern that VAERS reports were inflated. If the unprecedented increase in VAERS reports was just due to stimulated reporting, [CDC researchers tell us](#) we should expect to see COVID-to-flu ratios and PRRs that are roughly similar across different types of events. So if there was a 20-fold increase in reporting of serious events, say, then there should be a similar increase in other types of events.

A brief glance at Tables 1 and 2 clearly shows this is not the case — the reporting rates vary greatly across different types of events, and also across different age groups for the same event.

This is a huge giveaway that the increase — or at least a large portion of it — is not due to stimulated reporting. Indeed, underreporting is usually a bigger concern with data like VAERS, and [there are good reasons](#) to think the true number of adverse events is much larger.

But if the safety signal from VAERS is loud and clear and VAERS reports can be trusted, then how is the CDC not picking up on this? Or are they ignoring it? It's hard to say.

It might have to do with how the CDC handles signals once they are detected. The agency's protocols call for a thorough clinical review of events that trigger a safety signal in order to determine if the event could plausibly be caused by the vaccine. If that's the case, it's conceivable they found safety signals, but then determined that there was no plausible connection and therefore no cause for concern.

What this means in practice, however, is that if the CDC investigators do not understand how these novel vaccines — which [use gene therapy technology](#) and have had only limited use in humans — might cause a particular type of adverse event, the presumption is that there is no plausible connection.

For example, the [CDC has declared](#) after reviewing over 7,000 reports of deaths reported in the U.S. as of Sept. 7, they were not able to determine a plausible causal relationship for any of them, [except for three](#) due to thrombotic thrombocytopenic purpura (TTP) from the Janssen vaccine.

But the methods and criteria they use to make these determinations aren't published anywhere, assuming they even exist. It would be easier to take their word for it if their decision-making process wasn't hidden behind a veil of secrecy.

And maybe that's the biggest problem of all: lack of transparency. VAERS reports are public, which is laudable, but what the CDC does with those reports is mostly hidden from view.

For example, the CDC briefing document outlining plans to monitor VAERS speaks of producing some dozen or more tables every week detailing the agency's search for safety signals. To my knowledge, none of these have ever been made public.

And keep in mind that VAERS isn't the only data source the CDC uses for safety monitoring. The other main source is the [Vaccine Safety Datalink](#) (VSD), which should be more reliable than VAERS because it uses patient medical records from some of the nation's largest HMO's.

There are several ongoing COVID-19 [vaccine monitoring initiatives](#) that use the VSD, including "COVID-19 Vaccine Safety Evaluation in Pregnant Women and their Infants," "Mortality and Vaccination with COVID-19 Vaccines," "COVID-19 Vaccine Safety, Spontaneous Abortion (SAB) and Stillbirth," and "COVID-19 Vaccine-Mediated Enhanced Disease (VMED) and Vaccine Effectiveness."

While these monitoring efforts are certainly praiseworthy, of the five that should have already started yielding initial results and interim reports, only partial results from two of them have been presented to the CDC advisory committee or made public in any way.

Where are the others? And how could forcing workers to get vaccinated ever be justified when so much of the evidence regarding their safety is still missing?

A complete and transparent accounting of the CDC's safety monitoring is urgently needed, including internal communications and the results of all interim reports and analyses, whether through a Freedom of Information Act request, Congressional order or some other means.

The public deserves to know how the CDC reached the conclusion there was no plausible connection between the COVID-19 vaccines and the thousands of deaths they've reviewed, and also why they have failed to detect safety signals — or if they have, why they are being ignored.

Postscript: Since completing this article, I and others [submitted comments](#) to the meeting of FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) on Sept. 17, which [voted 16 to 2](#) to not approve a booster dose for people under 65 years old, citing a lack of sufficient safety and efficacy data. However the [FDA overruled](#) its advisory committee, as [did the CDC](#) after its vaccine safety committee recommended against authorizing a third Pfizer dose for anyone other than people 65 and older, long-term care facility residents and certain people with underlying conditions.

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