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FDA Understated Risk of Heart Damage From Moderna COVID Vaccine, New Study Suggests

A study published last week in the journal Vaccines found that among males ages 18-25, Moderna's COVID-19 vaccine was associated with 8%-52% more hospitalizations for vaccine-associated myocarditis and pericarditis than the number of COVID-19 hospitalizations it prevented. The findings contradict the risk-benefit analysis conducted by the FDA.

by **Michael Nevradakis, Ph.D.**

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Moderna's mRNA COVID-19 vaccine presented more risks than benefits for young males — contrary to models the U.S. Food and Drug Administration (FDA) used in 2022 to promote the vaccine as safe and effective, according to a new study.

The study, published last week in the **journal Vaccines**, found that among males ages 18-25, the Moderna mRNA-1273 COVID-19 **vaccine** was associated with 8%-52% more hospitalizations for vaccine-attributable **myocarditis** and **pericarditis** (VAM/P) than the number of COVID-19 hospitalizations it prevented.

Paul S. Bourdon, Ph.D., a retired University of Virginia professor of mathematics and lead author of the study, told **The Defender** the paper sought to determine whether the Moderna vaccine was more beneficial to young males, "given the high level of natural immunity in the population at the time of the FDA benefit-risk assessment."

The study found that the risks outweighed benefits for 18- to 25-year-old males, "except in scenarios projecting implausibly high Omicron-infection prevalence."

An **Australian study** last year found that myocarditis affected young men more severely than other groups.

The new study used data that were available to the FDA at the time it conducted its modeling. Bourdon said that despite this, the study's findings were "substantially different" than the FDA's.

Epidemiologist and public health research scientist **M. Nathaniel Mead**, who analyzed the new study's findings, told The Defender the FDA's "most likely scenario was a benefit-risk ratio of about 43:1 favoring vaccination."

"By comparison, Bourdon's reanalysis based on more realistic assumptions yielded a ratio of 0.67 — roughly 60 times lower. Over the assumed five-month protection window, the shots led to as much as 63% more myocarditis/pericarditis hospitalizations than **COVID-19** hospitalizations prevented," Mead said.

FDA model 'understated' myocarditis risk of Moderna vaccine

The FDA completed a **benefit-risk assessment** of the Moderna vaccine in January 2022, just before granting **full approval**. The data were published in 2023. The **new study** notes that the FDA conducts benefit-risk assessments because vaccines are often given to healthy people.

However, the FDA analysis contained a key shortcoming, according to Bourdon. While 18- to 25-year-old males are the highest risk group for vaccine-associated myocarditis/pericarditis, "the FDA assumed that hospital admission rates [for COVID-19] were uniform for males of ages 18-45."

Bourdon said this contradicted Centers for Disease Control and Prevention (CDC) models showing that hospitalization rates for males ages 30-49 are double the rates for 18- to 29-year-olds. Mead said this significantly altered the FDA's results.

"The FDA study lumped together hospitalization rates for ages 18-45, and this undoubtedly overestimated risks of getting hospitalized for the narrower 18-25 group," Mead said.

For their analysis, Bourdon and his team used the FDA's framework but also accounted for the benefits of natural immunity from prior COVID-19 infection.

Their model also accounted for "finer age stratification" in COVID-19 hospitalization rates, incidental hospitalizations (of patients who received treatment for another condition but tested positive for COVID-19), "more realistic projections of Omicron-infection rates, and more accurate VAM/P rates."

"At the time the FDA completed its assessment … approximately 70% of 18- to 25-year-old males had been infected by COVID-19 and studies indicated that the benefits of prior COVID-19 infection are at least equivalent to those of vaccination. However, the FDA omitted prior-infection benefits in its analysis," Bourdon said.

Mead said the FDA's 2022 analysis found an estimated myocarditis and pericarditis rate of 12.8 cases per 100,000 people who received the initial two-dose Moderna series — significantly lower than the rate the new analysis found.

"This big gap suggests the FDA model's myocarditis estimate may have been understated, potentially tilting the overall risk-benefit picture more favorably toward vaccination," Mead said.

According to Karl Jablonowski, Ph.D., senior research scientist for **Children's Health Defense** (CHD), the new analysis "runs counter to the one-size-fits-all approach to vaccinations" traditionally practiced by the FDA.

The new analysis showed that "the reality was worse than the worst-case scenario the FDA entertained," Jablonowski said.

'Beyond bad science'

Bourdon said the study's findings call into question popular **claims about the public health benefits** of COVID-19 vaccines.

"These assertions have typically counted any hospitalization of a patient testing positive for COVID-19 as a COVID-19 hospitalization. In other words, these prevention estimates typically include incidental COVID-19 hospitalizations prevented. Incidental rates can be quite high in younger age groups," Bourdon said.

Mead said it would have been "impossible for experts to say 'safe and effective' if the FDA's published analysis ... had included the assumptions made in the modified model used by Bourdon's team."

Mead suggested the FDA may have opted to develop its model in such a way to find lower risks associated with **vaccination**.

"It's hard not to see some amount of bias in the FDA's research angle given that they assigned zero benefit from prior infection in Omicron scenarios while simultaneously assuming the mRNA shots provided 72% effectiveness against hospitalization and 30% against infection for five months," he said.

According to Mead, the FDA's model likely also downplayed natural immunity after COVID-19 infection, which is "biologically solid and far more long-lasting than many people realize."

"The implications here are staggering," said Brian Hooker, Ph.D., CHD's chief scientific officer. "This goes beyond bad science. The FDA unfortunately wanted this product approved so badly that it worked backwards to an analysis that would accomplish that, despite the very clear fact that the risks of this jab outweighed the benefits."

Mead said that the FDA's omissions helped shape vaccine guidelines that put healthy young men at increased risk of heart inflammation and injury, especially after they had already been exposed to the virus.

Bourdon's study called on the FDA to administer "more rigorous" benefit-risk assessments, "capable of supporting stratification of vaccination recommendations not only based on age and sex but also on prior-infection and comorbidity status."

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'Clear evidence of frequent heart injury after the mRNA injections'

Mead said the study bolsters suggestions that healthy young people should not have been mandated to get the COVID-19 vaccine.

"We need to keep in mind that the actual danger from COVID-19 itself was minuscule for this age group. In 2021-22 the **infection fatality rate** for people under 19 was just 0.0003% … and even lower with Omicron," Mead said. He said the FDA should not have granted **emergency use authorization** for this age group.

Bourdon suggested that U.S. public health agencies could have followed **France's example**. France suspended use of Moderna's vaccine in October 2021, later revising its recommendations to authorize a half-dose for those over 30.

Instead, "in the same younger populations, there is now clear evidence of frequent heart injury after the mRNA injections — damage that can lead to serious problems and, in some cases, premature death both in the short and long term," Mead said.

Several studies have reached similar conclusions, including one that Mead and five other researchers co-authored and published last year in the **International Journal of Cardiovascular Research & Innovation**. They later submitted the study as evidence at a **U.S. Senate Hearing** on the government's **cover-up of COVID-19 vaccine risks**.

That study refuted several claims previously made by public health agencies and professional associations about the COVID-19 vaccines — including that COVID-19 infections led to a higher rate of myocarditis cases than the vaccines and that vaccine-induced myocarditis is typically rare, mild and transient.

A 2024 study of 9.3 million South Koreans published in **Nature Communications** uncovered a **620% higher risk of myocarditis** and 175% higher risk of pericarditis following mRNA COVID-19 vaccination.

Another 2024 study found that nearly **10% of people in Japan** who reported having myocarditis or pericarditis after receiving an mRNA COVID-19 shot died from the condition. **Fatality rates** were highest among **men under 30**.

Documents shared with CHD in 2024 showed that U.S. public health agencies were aware of a strong link between the COVID-19 vaccines and myocarditis at least as early as February 2021, but **concealed the evidence** from the public.

A 2024 report by the **National Academies of Sciences, Engineering, and Medicine** confirmed a **causal link** between mRNA COVID-19 vaccines and myocarditis.

Last year, the **FDA required Pfizer and Moderna** to revise their COVID-19 vaccine labels to include more detailed **warnings about the risks of heart damage**.

Pfizer drew criticism last year for delaying the completion of its **myocarditis safety study** for its COVID-19 vaccine to November 2030. The study was originally launched in 2022.

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Natural immunity continues to be SUPERIOR. If not, then how has humanity survived without vaccines for millennia?!?

”the FDA omitted prior-infection benefits in its analysis”

The lies a staggering!!! Because prior immunity would have shown the haccines are useless.

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"That study refuted several claims previously made by public health agencies and professional associations about the COVID-19 vaccines — including that COVID-19 infections led to a higher rate of myocarditis cases than the vaccines and that vaccine-induced myocarditis is typically rare, mild and transient."

The fact that no one heard a word about myocarditis, until young people were landing in the hospital with chest pain after a Covid shot, refuted the claims that C-19 infections led to a higher rate of myocarditis cases.

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"The findings contradict the risk-benefit analysis conducted by the FDA."

The risk-benefit propaganda by the FDA? The White House had a 17 page playbook on how to downplay myocarditis. The FDA's intent was to do the same. There is a video of FDA's Peter Marks downplaying myocarditis as nothing more than a "twinge of pain" that one went to the hospital for and received anti inflammatory drugs, laid off the exercising for 3 months and went on with your life. Israel was warning about myocarditis during the early days of the rollout. Did a followup study after a year and found a different result than Peter Marks rosy portrayal.

It was Peter Marks, who ignored all the associated Covax injuries and deaths, to approve and license Comirnaty in August 2021, so that Biden could mandate the dangerous Covid shot. In the fall of 2021 there was a six sigma spike in excess deaths. The public health agencies have totally ignored it. It was a coverup of deaths from the Covid shot.