

MICHIGAN DEP'T OF HEALTH IS SECOND PUBLIC HEALTH AGENCY TO COMPLY WITH ICAN'S LEGAL DEMAND THAT THEY REMOVE "MISINFORMATION" REGARDING THE COVID-19 VACCINES FROM THEIR SOCIAL MEDIA POSTS

ICAN achieved another victory in its ongoing campaign to ensure the government does not spread false information about vaccines. Michigan's Department of Health and Human Services posted a graphic and accompanying message on its public Facebook page. The text falsely stated that "on the journey to FDA approval, each COVID-19 vaccine had to pass through the same thresholds of research & testing as every other vaccine." It went on to include additional, incorrect information: "all three of the approved COVID-19 vaccines were proven to be safe and 100% effective in preventing hospitalization and death in the clinical trials." ICAN, through its attorneys, wrote to the Director and to the Chief Deputy of Health of MDHHS demanding they remove the false graphics and messaging regarding COVID-19 vaccines. They quickly complied within 48 hours and removed the relevant false messaging.

Soon after ICAN successfully challenged the New York State Department of Health's false social media messaging regarding COVID-19 vaccines, on March 8, 2021, ICAN's attorneys sent a [letter](#) to Michigan Department of Health and Human Services (MDHHS) informing them that they were violating federal law. MDHHS' posted the following graphic and messaging on Facebook:



This social media messaging – intended for the public – made numerous false claims. First, it claims that the FDA “approved” a COVID-19 vaccine. This is categorically false. There is no COVID-19 vaccine that has been “approved” by the FDA. The only three COVID-19 vaccines currently in use are authorized by the FDA pursuant to an emergency use authorization (“EUA”). In fact, the FDA [authorization letters](#) for both COVID-19 vaccines expressly provide that the vaccines are each “an investigational vaccine **not licensed** for any indication” and require that “[a]ll promotional material relating to the COVID-19 Vaccine clearly and conspicuously ... state that this product has not been approved or licensed by the FDA.”

In addition, the three COVID-19 vaccines are still undergoing clinical trials, hence they were also spreading misinformation when they claimed that these EUA authorized products “had to pass through **the same thresholds of research & testing as every other vaccine...**” ICAN had to point out to a health agency that the [Fact Sheets](#) for [Recipients](#) for each of these vaccines unambiguously state that the vaccines “ha[ve] not undergone the same type of review as an FDA-approved or cleared product.”

Further, the Facebook post claimed that all three vaccines’ clinical trials have proven to be “100% effective in preventing hospitalization and death.” This is also categorically false. The FDA’s review memorandum on each of the vaccines lists as one of the “Unknown Benefits/Data Gaps” “effectiveness against mortality.” The [FDA makes clear](#): “A larger number of individuals at high risk of COVID-19 and higher attack rates would be needed to confirm efficacy of the vaccine against mortality.” Additionally, the FDA’s [Review Memorandum](#) for Moderna’s vaccine states: “There were no deaths due to COVID-19 at the time of the interim analysis to enable an assessment of vaccine efficacy against death due to COVID-19.”

It is also false to claim that these vaccines have been proven to prevent 100% of hospitalizations. In the [Moderna trial](#), one participant in the mRNA-1273 group, a participant >65 years of age who had risk factors for severe COVID-19, was hospitalized due to oxygen saturation of 88% on room air 2 months after receiving the second dose of vaccine.” In the [Janssen trial](#), in a post hoc analysis of all COVID-19 related hospitalizations starting 14 days after vaccination, including non-centrally confirmed cases, **there were 2 cases in the vaccine group**. Likewise, the [Pfizer trial](#) reported two serious cases of suspected but unconfirmed COVID-19, both in the vaccine group, where both vaccine recipients were hospitalized.

Michigan’s Department of Health needed to be fact checked. We are pleased to tell you that, after being notified that failure to remove the inaccurate graphic and its false messaging would result in a lawsuit, MDHHS [responded](#) and removed any reference to “approved” vaccines and to the completely false claim that the vaccines are 100% effective in reducing hospitalizations and death.” This is another victory that should serve to remind MDHHS, and every other public health department, that someone is watching. And **if the FDA and our federal health authorities will not ensure that the public is receiving true and accurate information, ICAN will**. ICAN’s message should be heard loud and clear: you may not spread “misinformation” about vaccines.

To that end, the revised post, while clear of two false assertions, is still misleading:



ICAN’s attorneys sent another [letter](#) to MDHHS explaining that it is still not accurate to state that the COVID-19 vaccines “had to pass the same thresholds of research & testing as every other vaccine.” Every other vaccine that MDHSS is referencing has been licensed and approved. In stating that the COVID-19 vaccines have undergone the same review, MDHHS is not “[clearly and conspicuously](#)” stating that this product has not been approved or licensed by the FDA. Quite the opposite is true.

Additionally, the post now states that the vaccines were “proven to be safe and effective.” In fact, the [FDA has stated](#) this is not the case: “Based on the safety and effectiveness data, and review of manufacturing information regarding product quality and consistency, **it is reasonable to believe** that Moderna COVID-19 Vaccine **may be effective**. Additionally, it is **reasonable to conclude**, based on the totality of the scientific evidence available, that **the known and potential benefits** of Moderna COVID-19 Vaccine **outweigh the known and potential risks** of the vaccine, for the prevention of COVID-19 in individuals 18 years of age and older.” It is highly misleading for a health agency to state in unambiguous terms what the FDA has not yet proven or stated itself. We will keep you apprised of any response to the latest letter.

Again, in less than 48 hours, MDHHS’s post was again revised to remove the claim about the vaccines passing the same thresholds or research and testing as other vaccines, and currently reads as follows:



Michigan Department of Health and Human Services

March 6 at 10:05 AM

The FDA has authorized the emergency use of each of the three COVID-19 vaccines after determining the vaccines meet FDA requirements. And it's important to know that all three of the authorized COVID-19 vaccines were proven to be safe and effective in reducing the risk of severe illness, hospitalizations and death as caused by the virus. Discover all the facts at Michigan.gov/COVIDvaccine



ICAN's attorneys contacted MDHHS once more to explain that vaccines have not proven to be effective against death. Importantly, ICAN also notified MDHHS that it had [written to the CDC](#) about its claim that the vaccines are "safe and effective" and demanding that the CDC refrain from making this statement at least until the FDA itself actually makes this claim.

When granting EUAs for the vaccines, the FDA concluded that:

Based on the safety and effectiveness data ... **it is reasonable to believe** that [] COVID-19 Vaccine **may be effective**. Additionally, it is **reasonable to conclude**, based on the totality of the scientific evidence available, that **the known and potential benefits** of [] COVID-19 Vaccine **outweigh the known and potential risks** of the vaccine... (emphasis added).

Contrary to the CDC's [statements](#) that "COVID-19 vaccines are safe and effective," the FDA has not found nor stated that the vaccines are "safe and effective." Rather, since it has not yet been proven that they are safe and effective, a standard required for licensure, the FDA has never made this statement and would not make this statement until licensed. Instead, as quoted above, the FDA has only concluded thus far that "it is reasonable to believe" they "may be effective" and that with regard to safety, only that at present it appears "the known and potential benefits ... outweigh the known and potential risks."

ICAN will provide an update when one is available regarding MDHHS and the CDC. In the meantime, it will continue to do the FDA's job for it and ensure that the public is only receiving accurate and proven data about vaccines.