

# Siri | Glimstad

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March 8, 2020

## **VIA EMAIL AND FEDEX**

Michigan Department of Health and Human  
Services  
Elizabeth Hertel, Director  
333 S. Grand Ave.  
P.O. Box 303195  
Lansing, MI 48909  
SimsT2@michigan.gov  
CommOffice@michigan.gov

Michigan Department of Health and  
Human Services  
Joneigh Khaldun, Chief Deputy for  
Health  
333 S. Grand Ave.  
Lansing, MI 48913  
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Re: *COVID-19 Facebook Post*

Dear Ms. Hertel and Dr. Khaldun:

In violation of federal law, part of your social media messaging falsely claims that the FDA “approved” COVID-19 vaccines. Your messaging also falsely states that “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.” Therefore, our clients, the Informed Consent Action Network, and several concerned Michigan citizens, demand that you remove all these false claims and issue a correction within two business days of receipt of this letter. Failure to do so will result in a lawsuit against you seeking an injunction against this illegal conduct.

### **A. Michigan’s Social Media Posts Falsely Claim COVID-19 Vaccine Approved**

The Michigan Department of Health and Human Services’ Facebook page includes the following graphic and messaging:



This graphic is accompanied by the language: “On the journey to FDA **approval**, each COVID-19 vaccine had to pass through **the same thresholds of research & testing as every other vaccine**. And it’s important to know that **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. Discover all the facts at [Michigan.gov/COVIDvaccine](https://www.michigan.gov/COVIDvaccine).” <https://www.facebook.com/michiganhhs/posts/10157742846626746> (emphasis added).

### **B. Michigan’s Department of Health Social Media Posts Violate Federal Law**

This Facebook message violates federal law by falsely claiming that the FDA has approved each of the COVID-19 vaccines. 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”). The EUAs for these products expressly provide that they are not approved and that it is a violation of federal law to represent that they are approved.

The federal statute that authorizes the FDA to grant an emergency use authorization, Section 564 of the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. 360bbb-3, states that “[t]he Secretary may establish conditions on advertisements and other promotional descriptive

printed matter that relate to the emergency use of a product for which an authorization under this section is issued.” 21 U.S.C. 360bbb-3(e)(4).

The Secretary, through the FDA’s authorizations for each of the three COVID-19 vaccines currently in use pursuant to the EUAs 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.” See <https://www.fda.gov/media/144636/download> (“All descriptive printed matter, advertising, and promotional material relating to the use of the Moderna COVID-19 Vaccine clearly and conspicuously shall state that: This product has not been approved or licensed by FDA”) (emphasis added).<sup>1</sup>

In violation of federal law, the state’s official promotional graphic and message described above falsely claim the COVID-19 vaccines have “FDA approval” which is not only categorically false but is also directly prohibited by the conditions for the promotion of this product under 21 U.S.C. 360bbb-3(e)(4) and related federal law and regulations.

This is not the only false or inaccurate statement in the messaging. Contrary to your post, the three COVID-19 Vaccines are still undergoing clinical trials, which are expected to continue for more than a year more, before they are ready for approval and licensure by the FDA. As such, it is incorrect to claim that these EUA authorized products “had to pass through **the same thresholds of research & testing as every other vaccine.**” To be clear, 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.” See <https://www.fda.gov/media/146305/download>; <https://www.fda.gov/media/144414/download>; and <https://www.fda.gov/media/144638/download>.

Further, to claim that all three vaccines’ clinical trials have proven to be “100% effective in preventing hospitalization and death” is 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.” See <https://www.fda.gov/media/144673/download>; <https://www.fda.gov/media/146338/download>; and <https://www.fda.gov/media/144416/download>. 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.” <https://www.fda.gov/media/144673/download>. 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

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<sup>1</sup> See also <https://www.fda.gov/media/144412/download> (“All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that: This product has not been approved or licensed by FDA”); <https://www.fda.gov/media/146303/download> (“All descriptive printed matter, advertising, and promotional material relating to the use of the Janssen COVID-19 Vaccine clearly and conspicuously shall state that: This product has not been approved or licensed by FDA.”)

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.” See <https://www.fda.gov/media/144673/download>. 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.** See <https://www.fda.gov/media/146338/download> (emphasis added). 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. See <https://www.fda.gov/media/144416/download>.

You are hereby notified to remove all instances of this graphic and its accompanying false message and to issue an appropriate retraction on or before 5 p.m. on Wednesday, March 10, 2021. Failure to do so will result in a lawsuit on behalf of our clients seeking an injunction to force your compliance with the applicable federal law.

Very truly yours,

A handwritten signature in blue ink, appearing to be 'AS', is written over a horizontal line.

Aaron Siri, Esq.  
Elizabeth A. Brehm, Esq.