

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

March 10, 2021

VIA EMAIL AND FEDEX

Michigan Department of Health and Human Services
Matthew H. Rick, Senior Deputy Director
Legal Affairs Administration
333 South Grand Avenue
P.O. Box 30195
Lansing, Michigan 48909
rickm@michigan.gov

Re: *COVID-19 Facebook Post*

Dear Mr. Rick:

We thank you for your letter of March 10, 2021 and for removing certain claims regarding COVID-19 vaccines from the Michigan Department of Health and Human Services (MDHHS) Facebook page. The post, however, still contains false information that must be corrected. As you know, correcting misinformation about vaccines has been lauded by health departments as a matter of national urgency.

As of today, the MDHHS Facebook page includes the following graphic and messaging:



As pointed out in our first letter, it is 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 you are referencing has been licensed and approved. In stating that the COVID-19 vaccines have undergone the same review, you are not “clearly and conspicuously” stating that this product has not been approved or licensed by the FDA.¹ Quite the opposite is true. Again, 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>. “Other vaccines” are FDA-approved or cleared products. Therefore, MDHHS’s remaining Facebook statement is false.

Additionally, the post 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.” <https://www.fda.gov/media/144636/download>.² It is highly misleading for a health agency to state in unambiguous terms what the FDA has not yet proven or stated itself.

¹ 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). 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.”)

² See also <https://www.fda.gov/media/144412/download> and <https://www.fda.gov/media/146303/download>.

Please advise that the foregoing has also been corrected within three days of this letter. All rights reserved. If you would like to discuss any of the foregoing, I am available and willing to do so at any time.

Very truly yours,

A handwritten signature in blue ink, appearing to read 'ASiri', written over a horizontal line.

Aaron Siri, Esq.

Elizabeth A. Brehm, Esq.