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January 26, 2021

VIA EMAIL AND FEDEX

New York State Department of Health
Dr. Howard A. Zucker, Commissioner
Corning Tower Building, 14th Fl.
Empire State Plaza
Albany, NY 12237
Howard.Zucker@health.ny.gov

Governor Andrew Cuomo
NYS State Capitol Building
Albany, NY 12224
Gov.Cuomo@chamber.state.ny.us
Andrew.Cuomo@exec.ny.gov

Re: *COVID-19 #VaccinateNY Campaign*

Dear Dr. Zucker and Governor Cuomo:

In violation of federal law, part of your social media messaging falsely claims that the FDA “approved” a COVID-19 vaccine. Therefore, our clients, the Informed Consent Action Network, and several concerned New Yorkers, 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. NYS’s Social Media Posts Falsely Claim COVID-19 Vaccine Approved

The New York State’s COVID-19 website includes the following graphic for government officials, health care providers, and the public to use on social media:



Above this social media graphic is a “Sample Message” for these stakeholders to use on social media: “The vaccine is safe and effective. **It was approved by the FDA**, the CDC, and NY’s independent vaccine panel. Let’s #VaccinateNY!”



The screenshot shows a web page with a dark blue header containing 'TOP ^ Education' and 'SHARE' with social media icons. A left sidebar lists 'SECTIONS' with 'Social Media' highlighted. The main content area features the heading 'The COVID-19 vaccine is safe and effective.' followed by a 'Sample Message' that repeats the text from the paragraph above. Below this is a graphic with a blue background and white text: 'The COVID-19 vaccine is safe and effective.' and 'The COVID-19 vaccine went through the same rigorous approval process that all vaccines go through.' Logos for the Department of Health and 'VACCINATE NEW YORK' are at the bottom. Further down, there are links for 'Graphics for Twitter' and 'Graphic for Instagram or Facebook', each with four options.

This graphic and sample message are described as part of Governor Cuomo’s vaccination campaign and as “materials that New Yorkers can use to help build awareness of the facts and to educate their family, friends and communities about the COVID-19 vaccines.” See <https://covid19.vaccine.health.ny.gov/education>.

B. NYS’s Social Media Posts Violate Federal Law

This graphic, and its accompanying message, violate federal law by falsely claiming that the FDA has approved a COVID-19 vaccine. There is no COVID-19 vaccine that has been “approved” by the FDA. The only two 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 both of the two 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”); <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”) (emphasis added).

In violation of federal law, the state’s official promotional graphic and message described above falsely claim the COVID-19 vaccines have been “approved by the FDA” 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 Sample Message text the CDC does not “approve” vaccines and hence it is false to claim that the CDC has approved any COVID-19 vaccine. Furthermore, the two 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 “went through the same rigorous approval process that all vaccines go through.”

You are hereby notified to remove all instances of this graphic, its text, and its accompanying “sample message” and to issue an appropriate retraction on or before 5 p.m. on Thursday, January 28, 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 read 'ASiri', written over a horizontal line.

Aaron Siri, Esq.

Elizabeth A. Brehm, Esq.