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Dear Attorneys General,

We represent the Informed Consent Action Network ("**ICAN**"), one of the groups referenced in a document that is cited in your letter of March 24, 2021 with regard to "Vaccine Disinformation." [1] We write on its behalf to correct certain inaccurate information in your letter and advise that your letter is missing a disclaimer required by federal law.

Like each of you, our client is also deeply concerned about vaccine misinformation. Given this, our client believes you would appreciate our writing to advise you that your letter both promotes and contains vaccine misinformation.

[1] *See* https://ag.ny.gov/sites/default/files/ag_letter_to_tech_ceos.pdf.

Your letter praised Facebook for its updated community guidelines "established to prevent the spread of vaccine misfunction." But these very guidelines promote vaccine misinformation. For example, Facebook's new community guidelines assert that its users cannot state "that COVID-19 vaccines do not exist or have not been approved."[2] However, it *is* accurate to state that there is no approved COVID-19 vaccine. The Food & Drug Administration ("**FDA**") emergency use authorization ("**EUA**") for the COVID-19 vaccines could not be any clearer in stating that: "This product **has not been approved** or licensed by FDA, but has been authorized for emergency use by FDA."[3] It is, in fact, a violation of federal law to claim that any COVID-19 vaccine is approved, yet Facebook's guidelines would permit claiming it is approved (which is false) and prohibit claiming it is not approved (which is true). As such, your letter is praising Facebook for spreading vaccine misinformation.

Your letter similarly contains vaccine misinformation. For example, your letter states that the "end of this pandemic is in sight" as "safe and effective vaccines become available" and that reaching that end "depends on the widespread acceptance of these vaccines as safe and effective." However, claiming that COVID-19 vaccines are "safe and effective" is vaccine misinformation. "Safe and effective" is the standard for being granted approval and licensure by the FDA.[4] However, even the FDA admits that the data is not yet available to prove that these vaccines are "safe and effective," and therefore, these products have not yet been licensed or approved.

The COVID-19 vaccines have only been granted EUAs. In December 2020, the FDA granted EUA for two COVID-19 vaccines, one sold by Moderna and the other by Pfizer. Both are based on an RNA technology never before used in a licensed vaccine. In February, the FDA granted EUA for a third COVID-19 vaccine sold by J&J. This is a novel viral vector vaccine platform. The clinical trials that the FDA will rely upon to decide whether to license these vaccines are underway, but they are far from complete.

The EUA applications for these experimental vaccines were based on data which supports that they may reduce certain symptoms of COVID-19 for some individuals, but the FDA Briefing Documents for these products supporting their EUAs list the following as still **unknown**:

- "[e]ffectiveness in certain populations at high-risk of severe COVID-19,"
- "[e]ffectiveness in individuals previously infected with SARS-CoV-2,"
- "effectiveness against asymptomatic infection,"
- "effectiveness against long-term effect of COVID-19 disease,"
- "effectiveness against mortality," and
- "effectiveness against transmission of SARS-CoV-2."[5]

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[2] https://www.facebook.com/help/230764881494641/.

[3] EUA for Pfizer's COVID-19 Vaccine *available at* https://www.fda.gov/media/144412/download; EUA for Moderna's COVID-19 Vaccine *available at* https://www.fda.gov/media/144636/download; EUA for J&J's COVID-19 Vaccine *available at* https://www.fda.gov/media/146303/download.

[4] *See* 21 USC § 301 et seq.

[5] FDA Briefing Document Pfizer COVID-19 Vaccine *available at* https://www.fda.gov/media/144245/download; FDA Briefing Document Moderna COVID-19 Vaccine *available at* https://www.fda.gov/media/144434/download; FDA Briefing Document Janssen COVID-19 Vaccine *available at* https://www.fda.gov/media/146217/download.

The FDA Briefing Documents also make clear much is **unknown** about the safety of these products, including,

- "[a]dverse reactions that are very uncommon,"
- adverse reactions "that require longer follow-up to be detected," and
- whether the vaccines will cause "[v]accine-enhanced disease."[6]

As a result, the EUAs for the COVID-19 vaccines expressly provide that each is "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**, but has been authorized for emergency use by FDA."[7]

At best, what the FDA was able to conclude when granting emergency use authorization for these vaccines is that "**it is reasonable to believe** that [] COVID-19 Vaccine **may be effective**" and that it is "**reasonable to conclude …** that **the known and potential benefits** of [] COVID-19 Vaccine **outweigh the known and potential risks** of the vaccine."[8] While the FDA clearly has not yet concluded these vaccines are safe and effective, as can be seen from the recent CDC and FDA pause of J&J's COVID-19 vaccine, your letter demands that Facebook and Twitter enforce policies that promote "widespread acceptance of these vaccines as safe and effective." Demanding that these social media companies promote a conclusion about these vaccines not yet supported by the data is quintessential vaccine misinformation.

Given your states' concerns regarding vaccine misinformation, our client looks forward to a correction to your open letter to Facebook and Twitter.

Also, your letter may be missing a disclaimer required by federal law. Your letter, released to the public, is intended to promote the COVID-19 vaccines, including claiming that "the end of this pandemic … depends on the widespread acceptance of these vaccines," and touts that they are "safe and effective." The EUAs for these vaccines, as required by federal law,[9] provide that:

> All descriptive printed matter, advertising, and promotional material relating to the use of the [] COVID-19 Vaccine clearly and conspicuously shall state that: **This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older**.[10]

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[6] *Id*.

[7] EUA Memo for Pfizer's COVID-19 Vaccine *available at* https://www.fda.gov/media/144416/download; EUA Memo for Moderna's COVID-19 Vaccine *available at* https://www.fda.gov/media/144673/download; and EUA Memo for J&J's COVID-19 Vaccine *available at* https://www.fda.gov/media/146303/download.

[8] https://www.fda.gov/media/144636/download.

[9] Section 564 of the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. 360bbb-3.

[10] *See footnote 4*.

Your letter should include the above disclaimer since it is plainly intended to promote the use of the COVID-19 vaccines. That is manifestly the core reason it was signed by a dozen Attorney Generals and disseminated widely to the public.

Our client thanks you for promoting an end to vaccine misinformation and agrees that this is a real issue that needs to be addressed. To that end, kindly confirm that the issues within your letter in that regard have been corrected. If you will not correct the letter as provided herein, our client has requested we review whether your letter under color of state action has sought to encourage violation of first amendment rights. We hope that will not be necessary. We kindly request a reply on or before April 30, 2021.

Very truly yours,

Aaron Siri, Esq.
Elizabeth Brehm, Esq.
Jessica Wallace, Esq.