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**VIA ELECTRONIC FILING**

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Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
Commissioner Stephen M. Hahn, M.D.
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

**UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE FOOD AND DRUG ADMINISTRATION**

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| **PETITION FOR ADMINISTRATIVE ACTION TO ENSURE ENFORCEMENT OF EUA CONDITIONS FOR ALL COVID-19 VACCINES** | **:** | **Docket No. _____** |

**CITIZEN PETITION**

This petition for administrative action is submitted on behalf of Informed Consent Action Network[1] ("**Petitioner**") pursuant to 21 C.F.R. § 10.30 and related and relevant provisions of law (including the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act) to request that the Commissioner of Food and Drugs (the "**Commissioner**") take the actions listed below to assure enforcement of the conditions in the emergency use authorization ("**EUA**") for COVID-19 vaccines.

In violation of the EUA for these vaccines, public health authorities and other stakeholders have been claiming that these vaccines are "approved" by the FDA and have been making other claims regarding these vaccines that are contrary to what is permitted by their EUAs. For example,

[1] Including, but not limited to, on behalf of its members that work for the Petitioner.

and as detailed below, various state health departments have removed or corrected promotional material regarding these vaccines that violate their EUAs after Petitioner notified them of same.

Given that the violations of the EUAs are rampant, and because of the compelling need to ensure that the public receives only accurate information regarding the safety and efficacy of the currently authorized COVID-19 vaccines, and to allow Petitioner the opportunity to seek emergency judicial relief should the Commissioner deny its Petition, **Petitioner respectfully requests that FDA act on the instant Petition by March 31, 2021.**

## A. ACTION REQUESTED

1. Provide public notice to all state health departments, major health insurance carriers, major health systems, and other stakeholders that they are to comply with the following "conditions of authorization" in the EUAs and in 21 U.S.C. § 360bbb-3(e), including that:

**a.** "All descriptive printed matter, advertising, and promotional material, relating to the use of the [] COVID-19 Vaccine[s] shall be consistent with the authorized labeling, as well as the terms set forth in [each] EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations;"

**b.** "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, 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; and The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner;" and

**c.** "[I]ndividuals to whom the product is administered are informed of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."

2. Ensure that each manufacturer of an FDA-authorized COVID-19 vaccine is complying with the requirement to "ensure that the terms of [its] EUA are made available to all relevant stakeholders," by requiring each to provide the FDA with a written list of the stakeholders to whom the manufacturer has notified of the terms of the EUA and provide a copy of the form of the notification sent by the manufacturer.

3. Ensure that emergency response stakeholders are complying with the FDA's requirement that "[e]mergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of [the EUA] letter of authorization, and the terms [t]herein," by

notifying emergency response stakeholders of this obligation and requesting they each submit to the FDA notification of the steps taken to comply with this requirement.

## B. STATEMENT OF GROUNDS

4. 21 U.S.C. § 360bbb-3 governs any issuance of an emergency use authorization ("**EUA**") for a medical product. This federal statute makes clear the conditions of authorization for such unapproved products.

5. The Secretary of Health and Human Services has the responsibility to ensure that these conditions are made clear and are met.

6. The public interest weighs strongly in favor of the requested relief because having adequate conditions met will comport with the best interests of all Americans slated to receive these unapproved products and will increase public confidence in the safety and efficacy of these products.

7. The FDA recently granted EUAs for three vaccines against COVID-19 sold by Moderna, Pfizer, and Janssen (the "**COVID-19 Vaccines**").

### *a. Manufacturers must make all stakeholders aware of the terms of their EUA and all stakeholders must ensure all vaccination providers are aware of same*

8. These emergency use authorizations granted by the FDA to Pfizer on December 11, 2020; to Moderna on December 18, 2020; and to Janssen on February 27, 2021 are communicated in letters to the manufacturers and include the terms and conditions of the authorization.

9. Despite the fact that these EUA letters are made public by the FDA,[2] based on the below, it is apparent that all stakeholders, including public health agencies, and vaccination providers are not aware of and/or are not abiding by the terms and conditions set by the FDA.

[2] *See* https://www.fda.gov/media/144416/download, https://www.fda.gov/media/144673/download at 9, and https://www.fda.gov/media/146303/download.

***b. All descriptive printed matter, advertising, and promotional material relating to the use of the COVID-19 Vaccines clearly and conspicuously shall state that: This product has not been approved or licensed by FDA***

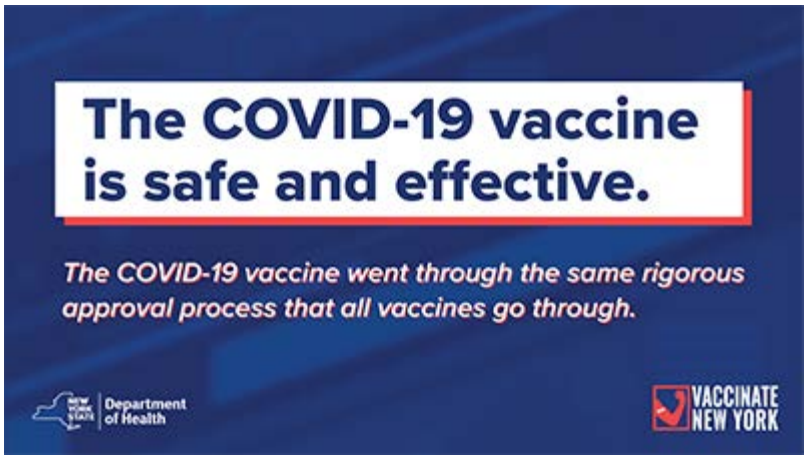
10. The following FDA requirements in the EUAs is simply not being followed or enforced: "All descriptive printed matter, advertising, and promotional material relating to the use of the COVID-19 Vaccines clearly and conspicuously shall state that: This product has not been approved or licensed by FDA."

11. It is the FDA's responsibility to enforce the terms of its own EUAs. It cannot be the work of Petitioner or any other non-profit, agency, independent attorneys, or private citizens to do the job of the FDA.

12. There are hundreds, if not thousands, of social media posts regarding COVID-19 Vaccines being publicly shared by health agencies in almost every state across the country. There are also emails, newsletters, mailings, and other communications being distributed to promote the vaccines. These messages are all promoting the COVID-19 Vaccines to the public and are not including the required disclosure that these vaccines are not approved or licensed by the FDA.

13. In fact, much of the messaging incorrectly refers to the COVID-19 Vaccines as "approved" or as vaccines that have gone through a rigorous "approval" process. This is in direct violation of federal law and is misleading to the public.

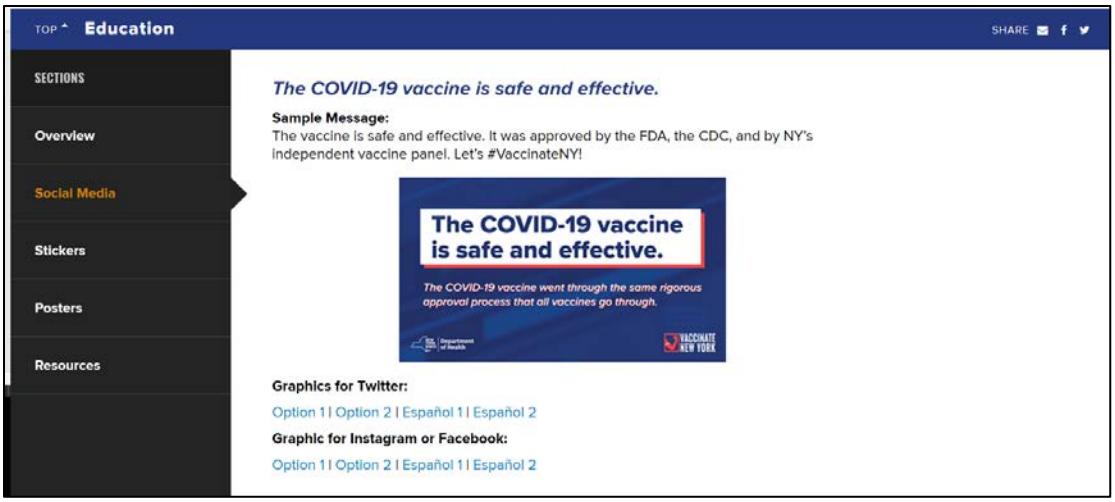
14. For example, On January 26, 2021, Petitioner's attorneys sent a letter to NYS DOH and Governor Cuomo informing them that they were violating federal law.[3] As part of Governor Cuomo's #VaccinateNY campaign, NYS's COVID-19 website provides materials to encourage and "educate" people about the COVID-19 Vaccines.[4] The social media materials are meant to be shared by New Yorkers to help spread the word and included the following poster:




[3] *See* https://www.icandecide.org/wp-content/uploads/2021/02/Letter-to-NYSDOH.pdf.

[4] *See* https://covid19vaccine.health.ny.gov/education.

15. Above this social media graphic, Cuomo and the NYS DOH provide the following "Sample Message" for individuals 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!"




16. This social media messaging – intended to be shared and spread widely – made the false claim that the FDA "approved" a COVID-19 vaccine. This is categorically false.

17. After being notified by Petitioner that failure to remove the inaccurate graphic and its false messaging would result in a lawsuit, New York State took it down.[5]

[5] *See* https://covid19vaccine.health.ny.gov/education.

18. As another example, on March 8, 2021, Petitioner's attorneys sent a letter to Michigan Department of Health and Human Services (MDHHS) informing them that they were violating federal law.[6] MDHHS' posted the following graphic and messaging on Facebook:


19. 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.

20. 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**...." Petitioner 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."[7]

21. 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.[8]

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[6] *See* www.icandecide.org/wp-content/uploads/2021/03/Letter-to-Michigan-DOH.pdf.

[7] *See* https://www.fda.gov/media/146305/download; https://www.fda.gov/media/144414/download; and https://www.fda.gov/media/144638/download.

[8] *See* https://www.icandecide.org/wp-content/uploads/2021/03/Response-ltr-from-MDHHS.pdf.

22. These are only two examples of a widespread and serious issue of incomplete and inaccurate information being shared with the public by health agencies and stakeholders. The FDA's inaction will, at best, allow this to continue and, at worst, will be seen as an implied approval of conduct that violates federal law.

***c. All descriptive printed matter, advertising, and promotional material, relating to the use of the COVID-19 Vaccines shall be consistent with the terms set forth in each EUA***

8. The FDA's Briefing Document granting the EUAs for the COVID-19 Vaccines lists 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,"
- "effectiveness against transmission of SARS-CoV-2,"
- "[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."[9]

23. Given these outstanding issues, and in compliance with the EUA provisions, it is imperative that all promotional material regarding COVID-19 Vaccines impart accurate and clear information.

24. The EUA letters issued by the FDA make the same finding for each of the three COVID-19 Vaccines: "it is reasonable to believe that the [] 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 the [] COVID-19 Vaccine outweigh its known and potential risks."[10] Therefore, for any unequivocal statement by any manufacturer, stakeholder, or vaccination provider that these vaccines are proven "safe and effective" is not consistent with the terms of the EUA and should not be permitted.

[9] "FDA Briefing Document Pfizer-BioNTech 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.

[10] *Id*.

25. The Centers for Disease Control and Prevention, for example, claims that "COVID-19 vaccines are safe and effective."[11] The FDA's core function is to determine whether a product is safe and effective, and only after making this finding, to grant it licensure. That determination has not yet occurred. It is improper, outside of the CDC's statutory mandate, and inconsistent with the FDA's EUAs for the CDC to usurp the FDA's core function and make this determination for an unapproved product.

26. As the FDA is well aware, stakeholders and public health agencies across the country (and across the world) take their cue from the CDC. It is therefore imperative that the CDC share only accurate, scientific data about the COVID-19 Vaccines that is consistent with the terms of the EUA.

27. Numerous public health agencies are mimicking the CDC's unsupported claim despite the inconsistency with the FDA's EUAs and are stating that these vaccines are proven safe and effective.

***d. Individuals to whom the product is administered must be informed of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and of the option to accept or refuse administration of the product***

28. This term of the EUAs that all individuals have "the option to accept or refuse administration of the product" is also being ignored and the FDA's silence is deafening. There are federal, state, and private employers across the country mandating that their employees receive COVID-19 vaccines which are unapproved and unlicensed. These mandates fly in the face of 21 U.S.C. § 360bbb-3 and the FDA's EUAs, including the Healthcare Provider and Recipient Fact Sheets, which make clear an individual's statutory right to refuse the product.

29. It is imperative that the FDA make clear that all individuals must retain their statutory right to refuse these unapproved products without facing penalty, coercion, or retaliation of any kind.

## C. ENVIRONMENTAL IMPACT

30. The undersigned hereby states that the relief requested in this petition will have no environmental impact and therefore an environmental assessment is not required under 21 C.F.R. Sections 25.30 and 25.31.

## D. ECONOMIC IMPACT

31. Economic impact information will be submitted upon request of the commissioner.

[11] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html.

## E. CERTIFICATION

32. The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

33. The Petitioner therefore respectfully urges that this request be granted forthwith.

Respectfully submitted,

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