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VIA EMAIL AND FEDEX

Charlotte A. Burrows, Chair
Jocelyn Samuels, Vice Chair
Janet Dhillon, Commissioner
Andrea R. Lucas, Commissioner
Keith E. Sonderling, Commissioner
U.S. Equal Employment Opportunity Commission
131 M Street, NE
Washington, DC 20507
info@eeoc.gov

Re: *Clarification of EEOC's Guidance Regarding Vaccine Mandates Under Emergency Use Authorization*

Dear Chair Burrows, Vice Chair Samuels, and Commissioners Dhillon, Lucas, and Sonderling:

We write on behalf of Informed Consent Action Network to seek clarification on the EEOC's "What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws" (the "**Guidance**"), dated December 16, 2020.[1]

Specifically, we are seeking clarification on the EEOC's position with regard to employer mandates of the COVID-19 vaccinations while these vaccines are in use pursuant to emergency use authorization ("**EUA**"). The language in the Guidance does not explicitly address mandates while these products are experimental and not fully licensed or approved by the FDA. Because of this lack of clarity, the Guidance is being interpreted by some employers, and others, to mean that the EEOC's position is that employers may mandate the COVID-19 vaccines in the workforce despite the fact that requiring an EUA product is prohibited by the Federal Food, Drug and Cosmetic Act (the "**Act**").

Emergency Use Authorization of COVID-19 Vaccines

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

[1] *See* https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.

Janssen. 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 these products may reduce certain symptoms of COVID-19 for some individuals, but the FDA's EUA authorizations made clear that there is no evidence the COVID-19 Vaccines can prevent recipients from becoming infected with and transmitting the virus.[2] As the FDA explains, the data was "not available to make a determination about how long the vaccine will provide protection, **nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 [*i.e.*, the virus that causes COVID-19] from person to person**."[3]

In fact, the FDA Briefing Documents for the COVID-19 Vaccines supporting the grant of an EUA 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."[4]

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."[5]

As a result, the authorization letters for both COVID-19 Vaccines 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 …**

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[2] *See* https://www.fda.gov/media/144416/download, https://www.fda.gov/media/144673/download, and https://www.fda.gov/media/146338/download ("Data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination.").

[3] "FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine" available at https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid (emphasis added).

[4] "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.

[5] *Id*.

state that this product has not been approved or licensed by the FDA, but has been authorized for emergency use by FDA."[6]

The authorization letters also expressly approved fact sheets for health care providers and fact sheets for patients regarding the COVID-19 Vaccines, both of which provide that the receipt of any of the three vaccines must be optional.[7]

Federal Law Prohibits Mandating Products Granted EUA

The same section that authorizes the FDA to grant an EUA, Section 564 of the Federal Food, Drug, and Cosmetic Act (the "**Act**"), codified at 21 U.S.C. 360bbb-3, requires that the public have "**the option to accept or refuse administration of the product**." 21 U.S.C. 360bbb-3(e). It even provides that the Secretary of HHS is to "ensure that individuals to whom the product is administered are informed" of "the option to accept or refuse administration of the product." (*Id.*)

The FDA and CDC's guidance and regulations reflect the statutory prohibition from mandating that an individual receive a product that has only been granted EUA. For example, the FDA guidance entitled *Emergency Use Authorization of Medical Products and Related Authorities* provides that:

> …section 564 does provide EUA conditions to ensure that recipients are informed about the MCM [medical countermeasure] they receive under an EUA. For an unapproved product [such as the COVID-19 vaccines], the statute requires that **FDA ensure that recipients are informed** to the extent practicable given the applicable circumstances … **That they have the option to accept or refuse the EUA product**…[8]

Similarly, when responding to an inquiry regarding whether the COVID-19 Vaccines can be required, the Executive Secretary of the CDC's Advisory Committee on Immunization Practices ("**ACIP**"), Dr. Amada Cohen, publicly stated that under an **"EUA, vaccines are not allowed to be mandatory**. So, early in this vaccination phase, **individuals will have to be consented and they won't be able to be mandatory**."[9] Dr. Cohen then reaffirmed to the FDA's Vaccine and Related Biological Products Advisory Committee that no organization, public or private – including hospitals – can mandate the COVID-19 Vaccines:

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[6] *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.

[7] *Id.*

[8] FDA's *Emergency Use Authorization of Medical Products and Related Authorities – Guidance for Industry and Other Stakeholders* available at https://www.fda.gov/media/97321/download (emphasis added).

[9] Advisory Committee on Immunization Practices' August 26, 2020 Summary Report available at https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-2020-08-508.pdf at 56.

> Organizations, such as hospitals, with licensed products do have capability of asking their workers to get the vaccine. But in the setting of an EUA, patients and individuals will have the right to refuse the vaccine.[10]

The EUAs for the COVID-19 Vaccines Repeats this Prohibition

The EUA letters for Pfizer, Moderna, and Janssen provide that each

> COVID-19 Vaccine is authorized for emergency use with the following product specific information required to be made available to the vaccination providers and recipients, respectively (referred to as 'authorized labeling'):
>
> - Fact Sheet for Health Care Providers Administering Vaccine
>
> … [and]
>
> - Fact Sheet for Recipients and Caregivers.[11]

These facts sheets each provide that the receipt of the vaccine must be optional. The Fact Sheets for Healthcare Providers for the three COVID-19 vaccines state that: "The recipient or their caregiver **has the option to accept or refuse** [the] COVID-19 Vaccine."[12] Similarly, the Fact Sheets for Recipients and Caregivers for each COVID-19 vaccine state on the first page: "**It is your choice to receive the [] COVID-19 Vaccine**."[13]

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[10] FDA's October 22, 2020 Center for Biologics Evaluation and Research (CBER) 161st Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting Transcript available at https://www.fda.gov/media/143982/download at 156.

[11] Pfizer COVID-19 vaccine Emergency Use Authorization letter from the FDA available at https://www.fda.gov/media/144412/download at 4; Moderna COVID-19 vaccine Emergency Use Authorization letter from the FDA available at https://www.fda.gov/media/144636/download. Janssen COVID-19 vaccine Emergency Use Authorization letter from the FDA available at https://www.fda.gov/media/146303/download.

[12] *Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)* available at https://www.fda.gov/media/144637/download; *Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)* available at https://www.fda.gov/media/144413/download; *Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)* available at https://www.fda.gov/media/146304/download.

[13] *Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age or Older* available at https://www.fda.gov/media/144638/download; *Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 16 Years of Age and Older* available at https://www.fda.gov/media/144414/download; *Fact Sheet for*

The Fact Sheet for Recipients and Caregivers for each of the COVID-19 Vaccines also set forth in sequence the information required to be provided to recipients of the vaccine pursuant to section 564 of the Act.[14] That section requires that every individual receiving an EUA product must be informed that:

- "that the Secretary has authorized the emergency use of the product";
- "the significant known and potential benefits and risks of such use";
- "the extent to which such benefits and risks are unknown";
- "the option to accept or refuse administration of the product";
- "the consequences, if any, of refusing administration of the product"; and
- "the alternatives to the product that are available and of their benefits and risks."

21 U.S.C. 360bbb-3(e)(1)(A)(ii). Both of the COVID-19 Vaccine Fact Sheets provide the relevant information to satisfy each of these requirements in sequence, including explaining "the option to accept or refuse administration of the product" and "the consequences, if any, of refusing administration of the product." Indeed, the Fact Sheets clearly tell potential recipients: "It is your choice to receive or not receive the [Pfizer/Moderna/Janssen] COVID-19 Vaccine[,]" and that if "you decide to not receive it, it will not change your standard of medical care."[15]

The EEOC Guidance Needs Clarification to Avoid Violating the Act

Requiring a COVID-19 vaccine distributed only under an EUA would violate federal law.

As described above, when the FDA grants EUA for a vaccine, many questions about the product cannot yet be answered. Given the open questions, when Congress granted the authority to issue EUAs, it chose to require that every individual should be allowed to decide for himself or herself whether or not to receive or refuse an EUA product. The FDA and CDC consider this fundamental requirement of choice so important that, even during the height of the COVID-19 pandemic, they reinforced that policy decision when discussing and considering authorization and recommendation of the COVID-19 vaccines.

This means that an employer will violate federal law if it requires its employees to get a COVID-19 vaccine that is in use pursuant to EUA.

Additionally, state law often prohibits retaliating against an employee for refusing to participate in a violation of federal law. Organizations that require COVID-19 vaccination in violation of federal law may face lawsuits under these state laws not only to block the policy but also for damages and attorneys' fees.

Recipients and Caregivers Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age or Older available at https://www.fda.gov/media/146305/download.

[14] *Id.*

[15] *Id*.

Based on the wording in the Guidance, however, some members of the public appear to have been misled into believing that an employer can require a COVID-19 vaccine distributed under EUA.. For example, the Guidance provides an answer to this question without specifying if the answer also applies when the COVID-19 vaccine has only been granted EUA:

> **K.6. If an employer requires vaccinations when they are available, how should it respond to an employee who indicates that he or she is unable to receive a COVID-19 vaccination because of a disability?**[16]

Since it is not clear whether the word "available" in the above question refers to an authorized product or an approved product, the reader of the answer to this question could be misled into thinking federal law permits an employer to require an EUA product.

Further, because this question immediately follows a question about EUA (K.5.), one might assume that the EEOC is indicating that, despite their current EUA status, employers may require an EUA vaccine. These ambiguities in the Guidance could lead to employers erroneously mandating the vaccine while still under EUA in violation of federal law and, derivatively, state laws.

To that point, we are asking the EEOC to amend its Guidance to make clear that (1) an employer cannot require an employee to receive a product that has only been granted Emergency Use Authorization, and (2) that the other considerations discussed in the Guidance, such as Title VII and ADA considerations, are for future use, if and when these vaccines are licensed by the FDA.

We are available to discuss the foregoing at your convenience, thank you for your immediate attention to this important matter, and anticipate a prompt reply.

Very truly yours,

EABrehm

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Elizabeth A. Brehm, Esq.
Dawn Orlacchio, Esq.

[16] Available at https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws (emphasis in original).