LSU Faculty Senate Resolution 21-09:
Correcting LSU’s Misquotation of the FDA’s Vaccine Letters

By Charles Berryman, Charles Delzell, Carol Friedland, Robert Rohli, and Boris Rubin

1. Whereas on August 24 and 27, 2021, the LSU Administration wrote to all LSU students and employees, declaring:

   [Y]esterday the FDA granted full approval to the Pfizer vaccine for anyone 16 and over....¹

and

   [T]he FDA has granted full approval to the Pfizer vaccine,²

2. Whereas on Aug. 23, 24, and 26, the Reveille declared:

   The Food and Drug Administration granted full approval to Pfizer's COVID-19 vaccine Monday morning...³

and

   ... the U.S. Food and Drug Administration’s full approval of the Pfizer shot⁴

and

   ... the Food and Drug Administration approved the Pfizer vaccine ...

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3. Whereas the above references to “the” Pfizer COVID-19 vaccine give the impression that there is only one Pfizer COVID-19 vaccine, when in reality there are two:

   1. “Comirnaty (COVID-19 Vaccine, mRNA),” and
   2. “Pfizer-BioNTech COVID-19 Vaccine”;

4. Whereas on August 23 the FDA wrote two separate letters, one for each of these vaccines,

5. Whereas the letter for Comirnaty⁶ approved Comirnaty, whilst the letter for the Pfizer-BioNTech COVID-19 Vaccine⁷ merely reissued the Emergency Use Authorization (EUA) for that vaccine and declared (on pages 11-12 of the Aug. 23, 2021 version of the letter):

   6. https://www.fda.gov/media/151710/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 [t]his 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 12 years of age and older ....

6. Whereas the above passage (which is repeated by the Louisiana Department of Health⁸) cannot be construed to mean that Pfizer-BioNTech COVID-19 Vaccine has been approved for some age-group, considering that Pfizer’s Oct. 29 “Fact-Sheet for Healthcare Providers Administering Vaccine” declares (page 14):

   FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine;⁹

7. Whereas the Aug. 23 FDA letter to Pfizer also declared (on page 2):

   The licensed vaccine [Comirnaty] has the same formulation as the EUA-authorized vaccine [Pfizer-BioNTech COVID-19 Vaccine] and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness;

   and (on page 5):

   Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA....

8. Whereas the only vaccine available at the LSU Student Union Theatre is Pfizer-BioNTech (not Comirnaty); the Louisiana Department of Health has no Comirnaty available; and the CDC’s page vaccines.gov/search/ can search any zip-code for available Pfizer-BioNTech, J&J, and Moderna vaccines (all non-approved), but not for available Comirnaty;

9. Whereas the FDA’s letters give no rationale for the FDA’s “legal distinction” between the two Pfizer COVID vaccines, or why the FDA approved the vaccine that it says is not sufficiently available in the U.S., but did not approve the vaccine that is available,

Therefore be it resolved that the LSU Faculty Senate recommends that the LSU administration and the Reveille correct their various August statements above, and declare that as of October 2021, the FDA has not approved the Pfizer-BioNTech COVID-19 Vaccine or any other COVID vaccine available in the U.S.

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⁸ https://ldh.la.gov/index.cfm/page/4103
⁹ https://www.fda.gov/media/153713/download