

First version read October 28, 2021
Revised version read December 7, 2021
Further revised version debated January 25, 2022

**LSU Faculty Senate Resolution 21-09:
Correcting LSU's Misquotation of FDA's Vaccine Letters**

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

1. *Whereas* during August 23-27, 2021, the LSU Administration and the LSU Reveille published statements such as:

[T]he FDA has granted full approval to the Pfizer vaccine...;¹

2. *Whereas* the above reference to “the” Pfizer COVID-19 vaccine gives 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”;

3. *Whereas* on August 23 FDA wrote two separate letters to Pfizer, one for each of these vaccines; the letter for Comirnaty² approved Comirnaty, whilst the letter for the Pfizer-BioNTech COVID-19 Vaccine³ merely reissued the Emergency Use Authorization (EUA; which necessarily entails non-approval) for that vaccine and declared (on pages 11-12):

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.

... export is permitted only if 1) the regulatory authorities of the country in which the vaccine will be used are fully informed that this vaccine is subject to an EUA and is not approved or licensed by FDA and 2)

¹ <https://www.lsu.edu/president/messages/2021/08-24-welcome-students.php>
<https://www.lsu.edu/president/messages/2021/08-24-welcome-employees.php>
<https://www.lsu.edu/mediacenter/news/2021/08/24vaccinationmandate.eb.php>
<https://www.lsu.edu/roadmap/messages/2021-08-27-employee-vaccine-requirement.php>
https://www.lsureveille.com/news/fda-approves-pfizer-vaccine-lsu-mandate-pending/article_80920b9a-042d-11ec-96fd-d3428e9f5e7b.html
https://www.lsureveille.com/news/lsu-mandates-covid-19-vaccine-for-students-faculty-and-staff-members/article_71384dc2-04e5-11ec-a011-cf790f3ce6bd.html
https://www.lsureveille.com/news/heres-how-lsu-plans-to-implement-new-vaccine-mandate-following-fda-approval/article_edb09412-05f4-11ec-a777-23ac16d4e340.html

² <https://www.fda.gov/media/151710/download>

³ FDA's August 23, 2021 letter for the Pfizer-BioNTech COVID-19 Vaccine was part of a series of FDA letters granting an EUA for this vaccine, dated December 11 and 23, 2020, and February 25, May 10, June 25, August 12 and 23, September 22, October 20 and 29, November 19, and December 9 and 16, 2021, and January 3, 2022. The latest of these letters is here: <https://www.fda.gov/media/150386/download>. For earlier versions (going back to the June 25 version), enter that URL into: archive.org. All versions of this letter available through archive.org also have the above statements, and they contain no statements to the contrary.

4. *Whereas* the above passages (and a similar one at the Louisiana Department of Health⁴) cannot be construed to mean that Pfizer-BioNTech COVID-19 Vaccine has been approved for some age-group, considering that Pfizer’s January 3, 2022 “Fact-Sheet for Healthcare Providers Administering Vaccine”⁵ declares:

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine.... [page 13]

In order to mitigate the risks of using this unapproved product under EUA....
Use of unapproved Pfizer-BioNTech COVID-19 Vaccine ... under this EUA is limited to.... [p. 14]

FDA has issued an EUA for the unapproved product, Pfizer-BioNTech COVID-19 Vaccine.... [p. 17]

... ongoing safety evaluation of this unapproved vaccine. [p. 42]

5. *Whereas* the August 23, 2021 FDA letter on Pfizer-BioNTech 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....

6. *Whereas* the CDC’s page [vaccines.gov/search/](https://www.cdc.gov/vaccines/imz/downloads/#vaccines) can search any zip-code for available Pfizer-BioNTech, J&J, and Moderna vaccines (all unapproved), but not for available Comirnaty, which isn’t mentioned. And elsewhere the CDC declares: “COMIRNATY products are not orderable at this time.”⁶ And upon calling Pfizer at 800-438-1985, one is told that “Pfizer has no information on when Comirnaty will be available” in the U.S. In particular, the only vaccine available at the LSU Student Union Theatre is Pfizer-BioNTech (not Comirnaty), and the Louisiana Department of Health has no Comirnaty, either;

7. *Whereas* the only primary sources for determining whether FDA approved either of the Pfizer vaccines on August 23, 2021 are FDA’s two August 23, 2021 letters to Pfizer, which are written documents and, as such, are the best evidence of their contents and speak for themselves, so that secondary sources may not be used to negate or vary the contents of those primary sources;

8. *Whereas* FDA's letters don't explain the “certain differences” between the two Pfizer COVID vaccines, and give no rationale for FDA’s “legal distinction” between the two vaccines, and

⁴ <https://ldh.la.gov/index.cfm/page/4103>

⁵ The latest version of Pfizer’s Fact Sheet is at <https://www.fda.gov/media/153713/download>. To see the October 29, November 19, and December 16, 2021 versions, enter this URL into the WayBack Machine: archive.org.

⁶ <https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html>

don't explain why FDA approved the vaccine that it says is not sufficiently available in the U.S., but did not approve the vaccine that is available;

9. Whereas a great university should be scrupulously accurate in its public statements;

Therefore be it resolved that the LSU Faculty Senate recognizes that FDA's two August 23, 2021 letters to Pfizer approved "Comirnaty (COVID-19 Vaccine, mRNA)" but not "Pfizer-BioNTech COVID-19 Vaccine," and that the two vaccines are legally distinct, and that as of January 2022, Comirnaty is not readily available in the U.S.

Summary:

	Authorized (EUA)	Approved
Pfizer-BioNTech (available in U.S.)	Yes (December 11, 2020)	No
Comirnaty (not available in U.S.)	No	Yes (August 23, 2021)