IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
NORTHEASTERN DIVISION

HUNTER CREGER, BENJAMIN EASTMAN, SHERRIE MAINE, LANCE NORWOOD, and ZACHARY BRELAND, individually and on behalf of all others similarly situated, *Plaintiffs,* v. UNITED LAUNCH ALLIANCE, LLC, *Defendant*.	Civil Action No.: CLASS ACTION Jury Trial Demanded

CLASS ACTION COMPLAINT

1. Plaintiffs Hunter Creger, Benjamin Eastman, Sherrie Maine, Lance Norwood, and Zachary Breland (collectively, "Plaintiffs"), on behalf of themselves and all others similarly situated, complain as follows against Defendants United Launch Alliance, LLC ("ULA").

2. This is a class action brought to remedy ULA's pattern of discrimination against employees who requested religious or medical accommodations from ULA's mandate that its employees receive the COVID-19 vaccine.

3. Rather than complying with its obligations under Title VII of the Civil Rights Act of 1964 ("Title VII") and the Americans with Disabilities Act ("ADA"), as well as new Alabama Act 2021-561 (SB9), ULA responded by informing the requesting employees that they would be effectively terminated.

4. ULA's actions have left Plaintiffs with the impossible choice of either taking the COVID-19 vaccine, at the expense of their religious beliefs and/or their health, or losing their livelihoods. In doing so, ULA has violated Title VII and the ADA by failing to engage in the interactive process and provide reasonable accommodations, and has violated Alabama Act 2021-561 by moving to terminate employees pending appeal of the denial of their religious and/or medical accommodation requests.

PARTIES

5. **Plaintiff HUNTER CREGER** ("Creger") is laser weld technician with United Launch Alliance ("ULA"). Mr. Creger requested a religious accommodation from ULA's vaccine mandate, which ULA denied, contending that it had received too many religious accommodation requests to be able to accommodate. ULA advised Mr. Creger that it would deem him to have "voluntarily resigned" if he had not received the first dose (or, in the case of a single-dose vaccine, the only dose) of an approved Covid-19 vaccine by Friday, October 29, 2021. On October 22, 2021, Mr. Creger filed an appeal of the denial of his religious accommodation request through the union grievance process. That grievance is still pending, but Mr. Creger was suspended by ULA on October 27, 2021, during the pendency of his appeal. Mr. Creger suspects this is due to his involvement in the legal protest of the vaccine mandate. Mr. Creger filed a complaint with the Equal Employment Opportunity Commission on October 23, 2021. Mr. Creger also renewed his request for religious accommodation under new Alabama Act 2021-561 on November 9, 2021, and intends to file an appeal with the Alabama Department of Labor of any further denial. Because Mr. Creger's religious beliefs bar him from taking a vaccine that was manufactured and/or tested on cell lines derived from stem cells of aborted fetuses, as all of the currently available Covid-19 vaccines are, he cannot in good conscience comply with the new condition that has unilaterally been imposed by ULA on his employment. Mr. Creger is a citizen and resident of Alabama, and

lives in the Northern District of Alabama.

6. **Plaintiff BENJAMIN EASTMAN** ("Eastman") is a tools engineer with ULA. On September 21, 2021, Mr. Eastman requested a religious accommodation from ULA's vaccine mandate, which ULA denied on October 21, 2021, contending that it had received too many religious accommodation requests to be able to accommodate. ULA advised Mr. Eastman that it would deem him to have "voluntarily resigned" if he had not received the first dose (or, in the case of a single-dose vaccine, the only dose) of an approved Covid-19 vaccine by Friday, October 29, 2021, but then instead placed Mr. Eastman on unpaid administrative leave pending his appeal of the denial of his religious accommodation request. ULA denied Mr. Eastman's appeal on November 4, 2021 and advised Mr. Eastman that he had "3 calendar days" to receive his "first (Moderna or Pfizer) or final (Johnson & Johnson) COVID 19 vaccination and provide [his] vaccination card to ULA Medical" or else be "separate[d] from ULA." Because Mr. Eastman's religious beliefs bar him from taking a vaccine that was manufactured and/or tested on cell lines derived from stem cells of aborted fetuses, as all of the currently available Covid-19 vaccines are, he cannot in good conscience comply with the new condition that has unilaterally been imposed by ULA on his employment. Mr. Eastman filed a complaint with the Equal Employment Opportunity Commission on November 5, 2021, and was notified that his initial interview would be held on February 18, 2022. Mr. Eastman also filed a renewed request for religious exemption pursuant to new Alabama Act 2021-561 on November 10, 2021, and advised ULA that he intended to file an appeal with the Alabama Department of Labor under the time frame allowed by that law. Mr. Eastman is a citizen and resident of Alabama, and lives in the Northern District of Alabama. His wife is in her second trimester of pregnancy with their first child, so the loss of health insurance benefits will be particularly burdensome for Mr. Eastman and his family.

7. **Plaintiff SHERRIE MAINE** ("Maine") is a Quality Inspector with United Launch

Alliance ("ULA"). In early October 2021, Mrs. Maine requested a Medical Exemption due to natural antibodies present. At the time, ULA's President and CEO had announced that a serology test demonstrating antibodies would qualify for a medical exemption, but ULA denied Mrs. Maine's Medical Exemption request on October 20, 2021. Although that was after the arbitrary October 1, 2021, deadline for filing any exemption requests, Mrs. Maine then filed a request for religious exemption on October 27, 2021, which was denied that same day as untimely on the ground that ULA "will not be conducting any additional interactive interviews." ULA advised Mrs. Maine that it would deem her to have "voluntarily resigned" if she had not received the first dose (or, in the case of a single-dose vaccine, the only dose) of an approved Covid-19 vaccine by Friday, October 29, 2021. Mrs. Maine filed a grievance with her union challenging the denial of her exemption requests. Pending resolution of that grievance, she has been placed on unpaid administrative leave. Because Mrs. Maine's religious beliefs bar her from taking a vaccine that was manufactured and/or tested on cell lines derived from stem cells of aborted fetuses, as all of the currently available Covid-19 vaccines are, she cannot in good conscience comply with the new condition that has unilaterally been imposed by ULA on her employment. Mrs. Maine filed a complaint with the Equal Employment Opportunity Commission on October 28, 2021. Mrs. Maine is a citizen and resident of Alabama, and lives in the Northern District of Alabama. She is close to retirement, and was planning on retiring from ULA in the near future. Her husband has medical issues and may be forced into Social Security Disability in the near future so losing her medical insurance will a great burden.

8. **Plaintiff LANCE NORWOOD** ("Norwood") is a mechanical design engineer with United Launch Alliance ("ULA"). Mr. Norwood requested a religious accommodation from ULA's vaccine mandate, which ULA denied, contending that it had received too many religious accommodation requests to be able to accommodate and therefore claiming undue hardship. ULA

has advised Mr. Norwood that it would deem him to have "voluntarily resigned" if he had not received the first dose (or, in the case of a single-dose vaccine, the only dose) of an approved Covid-19 vaccine by Friday, October 29, 2021. Because Mr. Norwood's' religious beliefs bar him from taking a vaccine that was manufactured and/or tested on cell lines derived from stem cells of aborted fetuses, as all of the currently available Covid-19 vaccines are, he cannot in good conscience comply with the new condition that has unilaterally been imposed by ULA on his employment. He had been advised that he would be deemed to have "voluntarily resigned" effective close of business on October 29, 2021 if he had not received the first dose of a Covid vaccine by then, but ULA instead placed Mr. Norwood on unpaid administrative leave pending his appeal of the denial of his religious accommodation request. ULA denied Mr. Norwood's appeal on November 4, 2021, and advised Mr. Norwood that he had "3 calendar days" to receive his "first (Moderna or Pfizer) or final (Johnson & Johnson) COVID 19 vaccination and provide [his] vaccination card to ULA Medical" or else be "separate[d] from ULA." Mr. Norwood filed a complaint with the Equal Employment Opportunity Commission on October 27, 2021. Mr. Norwood is a citizen and resident of Alabama, and lives in the Northern District of Alabama. Mr. Norwood is married and is a first time father to a daughter who is nine months old, so the loss of health insurance benefits will be particularly burdensome for Mr. Norwood and his family.

9. **Plaintiff ZACHARY BRELAND** ("Breland") is an aerospace technician/welder with United Launch Alliance ("ULA"). Mr. Breland requested a religious accommodation from ULA's vaccine mandate, which ULA denied, contending that it had received too many religious accommodation requests to be able to accommodate. Mr. Breland also filed a medical exemption, signed by his physician who stated he did not need to take the vaccine due to an underlying health condition, which the company also denied stating (contrary to his physician's direction) that his condition did not warrant him not taking the vaccine. ULA advised Mr. Breland that it would deem

him to have "voluntarily resigned" if he had not received the first dose (or, in the case of a single-dose vaccine, the only dose) of an approved Covid-19 vaccine by Friday, October 29, 2021. Mr. Breland filed a grievance for appeal with LL44 Union. The grievance is still pending, but Mr. Breland has been placed on unpaid administrative leave pending resolution of the grievance. Mr. Breland filed a complaint with the Equal Employment Opportunity Commission on November 9, 2021. Because Mr. Breland's religious beliefs bar him from taking a vaccine that was manufactured and/or tested on cell lines derived from stem cells of aborted fetuses, as all of the currently available Covid-19 vaccines are, he cannot in good conscience comply with the new condition that has unilaterally been imposed by ULA on his employment. Mr. Breland is a citizen and resident of Alabama, and lives in the Northern District of Alabama. His wife is a stay-at-home mother with 2 children ages 2 and 5, so the loss of health insurance benefits and income will be particularly burdensome for Mr. Breland and his family.

10. **Defendant United Launch Alliance LLC** ("ULA") is a Delaware corporation headquartered in Denver, Colorado, with its primary manufacturing, assembly, and integration facility in Decatur, Alabama. The Decatur facility is located within this judicial district.

JURISDICTION AND VENUE

11. This Court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331, 1343, 1367, and42 U.S.C. § 2000e-5(f)(3).

12. Plaintiffs' claims for declaratory and injunctive relief are authorized by 28 U.S.C. §§ 2201 and 2202.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events complained of herein occurred in this District and Division.

14. This case challenges ULA's decision to implement a COVID-19 vaccine mandate without also granting reasonable accommodations as required under Title VII and the ADA, as

well as Alabama Act 2021-561. On information and belief, several activities and occurrences related to the development of the mandate and the determination for how to respond to accommodation requests occurred in this District.

15. Moreover, ULA's actions are felt by Plaintiffs in this District, and this is where the unlawful employment practices occurred. Plaintiffs received ULA's e-mail communications about the vaccine mandate while located in this District. Moreover, if Plaintiffs elect to receive the COVID-19 vaccine, those who reside in this District will likely do so here. And finally, if terminated, they will be harmed in this District.

FACTUAL ALLEGATIONS

A. The COVID-19 Pandemic and Response

16. By Spring 2020, the novel coronavirus SARS-CoV-2, which can cause the disease COVID-19, spread rapidly around the world.

17. Around this same time, ULA began implementing certain mitigation procedures for its workforce, including several of the following requirements for its employees: 100% of the workforce worked remotely for a month, and then 50% of the workforce worked remotely for six months thereafter; ULA required that employees wear masks inside; employees had their temperatures checked at the guard house before entering the ULA premises; employees who came into contact with anyone who had tested positive for COVID were encouraged to take personal leave to self-quarantine; many ULA employees at the Colorado headquarters mostly worked remotely and are continuing to do so; plexiglass barriers were put up between employees in all cubicles; meetings were limited to 10 or less people; and a plan was implemented for cleaning work surfaces multiple times a day throughout the office.

18. Since that time, at least three separate COVID-19 vaccines have been developed and authorized for emergency use in the United States. The Food and Drug Administration

("FDA") issued an Emergency Use Authorization ("EUA") for the Pfizer-BioNTech vaccine on December 1, 2020.One week later, the FDA issued a second EUA for the Moderna COVID-19 vaccine. Finally, the FDA issued an EUA for the Johnson & Johnson COVID-19 vaccine on February 27, 2021.

19. On August 23, 2021, the FDA issued full approval for the Pfizer vaccine Comirnaty for individuals 16 years of age and older, but as of this date, that particular "legally distinct" vaccine is not available in the United States. Pfizer's EUA for the Pfizer-BioNTech vaccine (which it has attempted to rebrand as Comirnaty) remains in place.[1]

20. To date, the FDA has not yet issued any other approvals for either the Moderna or Johnson & Johnson vaccine.

B. ULA's Vaccine Mandate

21. On August 25, 2021, ULA's President and CEO, Tony Bruno, announced in an email to "All ULA Teammates" that "ULA will require the COVID vaccination as a condition of employment beginning Sept. 1, 2021."

22. On September 1, 2021, ULA announced the new policy that "requires all employees and contractors with badged, unescorted access to ULA facilities to be vaccinated against COVID-19 as part of its continued efforts to maintain a safe workplace."

23. In Vaccination Process Instructions issued that same day, ULA announced that "Effective October 1, 2021, ULA will begin requiring all employees to be vaccinated against COVID-19 as a condition of employment."

24. The Instructions further provided that "Those employees or On-Site Contractors who are not already fully vaccinated will need to receive the first dose of the Pfizer or Moderna

[1] Letter from FDA to Pfizer, Inc. 2 n.9, 3 n.10, U.S. FOOD AND DRUG ADMIN. (Sep. 22, 2021) (recognizing factual and legal distinctions between the Comirnaty vaccine and the Pfizer vaccine reauthorized under an EUA) (attached as Exhibit B). This document appears to have been published on the FDA's website and then taken down. *See* FDA Approval of the Pfizer-BioNTech COVID-19 Vaccine: Frequently Asked Questions 1 n.3, CONGRESSIONAL RESEARCH SERVICE (last updated Sep. 29, 2021) (providing a link to the September 22 letter that now directs users to an October 29 letter). The copy attached comes from litigation currently before the United States District Court for the Middle District of Florida. *See* Complaint Exhibit F, *Navy SEAL 1 v. Biden*, No. 8:21-cv-02429 (M.D. Fla. Oct. 15, 2021).

vaccine, or the single dose of the Johnson & Johnson vaccine, by October 29, 2021. They will need to receive the second dose of the Pfizer or Moderna vaccine by November 30, 2021."

25. Pursuant to the Instructions, "all employees" were required to either document they have received the required vaccinations by the specified deadlines or "obtained an approved exemption as an accommodation." Otherwise, the Instructions noted that "Employees who do not receive the vaccine or obtain an accommodation by the stated deadlines will be deemed to have voluntarily resigned their position."

26. Absent an approved exemption, ULA's mandate is absolute—there is no alternative for periodic testing, mask wearing, or social distancing, even for employees who have already had COVID-19 and still enjoyimmunity from the disease and even for employees who are working remotely. Employees must choose vaccination or termination.

27. This policy from ULA contrasts with the Federal Government's recent announcement that the Department of Labor is developing a rule to require certain large employers to mandate vaccination *or* periodic testing for its employees. ULA is not offering the option of periodic testing, either in general or for employees who receive an accommodation.

28. This policy from ULA also differs substantially from the European Union's digital COVID-19 certificate, which considers the following as equivalent: (1) a COVID-19 vaccine; (2) a negative COVID-19 test; or (3) having previously recovered from COVID-19. *See EU Digital COVID Certificate*, EUROPEAN COMMISSION, https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate_en.

29. When ULA announced the vaccine mandate, it stated that employees could request accommodations for religious or health reasons, and specifically advised that having a serology test confirming antibodies from a prior COVID infection would suffice for a medical exemption.

This is in line with Equal Employment Opportunity Commission ("EEOC") guidance on private employers issuing such mandates. *See What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws* §§ K.1 & K.2., EEOC (May 28, 2021), https://www.eeoc.gov/wysk/what-you-should-know- about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.

30. In its ULA COVID Vaccination Process Instruction, ULA provided instructions on how to request either a medical or religious exemption as an accommodation. The requests were to be submitted on specified forms and submitted either to ULA Medical (for medical exemption requests) or to the employee's Human Resources Business Partner (for religious exemption requests) by October 1, 2021.

31. After that date, employees were not permitted to submit accommodation requests to ULA. Requests received after October 1, 2021, were automatically denied as untimely.

32. In other words, any employee who determines that he or she has a religious or medical basis for not receiving the vaccine after October 1, 2021, is left without a mechanism for requesting an accommodation from ULA that the company will consider. Such employees must either receive the vaccine or be terminated.

33. ULA's Religious Accommodation Request Form required employees to state, whether their religious belief was based on "an organized religious faith" or, if not, to "describe the basis of the religious belief, practice, or observance" that was causing the employee to seek an accommodation.

34. ULA's Religious Accommodation Request Form also required employees to answer whether they had received other vaccinations previously and, if so, what their identified religious belief, practice, or observance did not prevent them from getting that vaccination.

35. On information and belief, ULA denied all requests for religious accommodation, contending that it have received too many religious exemption requests to be able to accommodate

them without creating an undue burden for ULA.

36. ULA's Medical Accommodation Form required, among other things, employees to have their health care providers provide details that, in their medical opinion, supported the employee's medical exemption and also whether there were any reasonable accommodations that could be provided to the employees.

37. On information and belief, ULA denied most requests for medical accommodation, specifically rejecting, *inter alia*, claims based on prior COVID infection that had resulted in the employee's having antibodies/natural immunity equal to or greater than immunity provided by existing vaccines.

38. According to ULA, this vaccination mandate is aimed at increased safety. Yet, on information and belief, ULA does not require its customers to be vaccinated, and it does not test its vaccinated employees, even though the CDC has acknowledged that the existing vaccines to not prevent infection or transmission of the COVID virus.

C. Federal law prohibiting religious and disability discrimination and retaliation

39. Title VII prohibits ULA from discriminating against employees based on their religion. This "include[s] all aspects of religious observance and practice, as well as belief, unless an employer demonstrates that he is unable to reasonably accommodate an employee's . . . religious observance or practice without undue hardship on the conduct of the employer's business." 42 U.S.C. § 2000e(j).

40. In other words, "[a]n employer has the statutory obligation to make reasonable accommodations for the religious observances of its employees, but is not required to incur undue hardship." *Weber v. Roadway Express*, 199 F.3d 270, 273 (5th Cir. 2000);); *see also Dixon v. The Hallmark Cos.*, 627 F.3d 849, 855 (11th Cir. 2010) (holding that once "a prima facie case is established, the burden shifts to the employer to demonstrate that he is unable to reasonably

accommodate an employee's religious observance or practice without undue hardship on the conduct of the employer's business.")

41. Similarly, under the ADA, ULA may not "discriminate against a qualified individual on the basis of disability." *Lewis v. City of Union City*, 934 F.3d 1169, 1179 (11th Cir. 2019).

42. Such discrimination includes "fail[ing] to make 'reasonable accommodations to the known physical or mental limitations of an otherwise qualified individual with a disability . . . unless . . . the accommodation would impose an undue hardship.'" *Holly v. Clairson Indus.*, 492 F.3d 1247, 1258 (11th Cir. 2007) (quoting 42 U.S.C. § 12112(b)(5)(A), emphasis added).

D. Alabama law barring termination or reduction of compensation pending resolution of appeal to the Alabama Department of Labor prohibiting religious and disability discrimination and retaliation

43. On November 4, 2021, the Alabama legislature passed, and on November 5, 2021, the Governor signed into law, Alabama Act 2021-561 (SB9). A true and correct copy of that law is attached hereto as Exhibit A. That new law specifically mandates that "An employer shall exempt vaccination as a condition of employment for any employee who has completed and submitted [a prescribed] exemption form." § 1(c). Eligibility for exemption requests are to be "liberally construe[d] in favor of the employee. §1(d).

44. Act 2021-561 also allows employees whose requests for exemption are denied to file an appeal with an administrative law judge to be appointed by the Secretary of Labor, pursuant to rules that the statute directs the Department of Labor to adopt not more than 21 days after the November 5, 2021, effective date of the Act. §1(g)(1).

45. Act 2021-561 prohibits employers from terminating any employee on the basis of failing to receive a vaccination for 7 calendar days after the denial of his exemption request, "or if an appeal was made, until the administrative law judge or the court issues a final ruling in the

employer's favor." §1(h)(1). It also requires the employer to continue compensating such employees at the same rate of compensation received prior to the filing of an exemption request, pending resolution of any appeal. §1(h)(2).

CLASS ALLEGATIONS

46. Plaintiffs bring this class action under Federal Rules of Civil Procedure 23(a) and (b).

47. Through this action, Plaintiffs seek to represent a class of all ULA employees based at ULA's Decatur, Alabama facility whohave requested or will request accommodations from ULA's vaccine mandate and who have hadthose accommodation requests either formally or effectively denied and are thus faced with the decision of either taking a vaccine to which they object, or suffering termination (or who have already resigned because of the vaccine mandate).

48. Plaintiffs anticipate that they will ultimately seek three subclasses when they move for class certification: (1) employees who have sought either a religious or medical accommodation and previously recovered from COVID-19, possess antibodies against COVID-19, and are willing to produce periodic proof to ULA showing that they remain antibody positive; (2) employees who sought religious accommodations, lack COVID-19 antibodies, and are willing to submit to mitigation measures such as periodic COVID-19 testing and/or wearing masks; and (3) employees who sought medical accommodations, lack COVID-19 antibodies, and are willing to submit to mitigation measures like periodic COVID-19 testing and/or wearing masks.

49. By effectively treating all accommodation requesters the same, ULA's actions are generally applicable to the entire class of ULA employees for whom ULA failed to grant reasonable accommodations. Accordingly, the Court may grant relief to the entire affected class to prevent ULA's continue violation of federal civil rights laws. Additionally, the class is so numerous that joinder of all members is impractical.

50. While the exact class size is unknown to Plaintiffs at this time, it is expected to exceed 200 employees. The precise number and identification of the class members will be ascertainable fromULA's records during discovery.

51. There are questions of law and fact common to all members of the class. Those common questions include, but are not limited to, the following:

a. Did ULA provide its employees with an adequate mechanism for requesting an accommodation when it required requests to be submitted byan arbitrary date (October 1, 2021)?

b. Did ULA comply with its obligations under federal law to engage in the interactive process when responding to each accommodation request?

c. Did ULA comply with its obligations under federal law to reasonably accommodate employees with religious objections to the vaccinemandate when it denied all religious exemptions?

d. Did ULA comply with its obligations under federal law to reasonably accommodate employees with medical objections to the vaccinemandate when it denied all medical exemption requests that were based on prior COVID infection?

e. Did ULA violate Alabama law by terminating or reducing the compensation of employees who appealed the denial of their exemption requests, while those appeals were pending?

52. Plaintiffs' claims are typical of the claims of the class because they, like the class members, requested accommodations from ULA's vaccine mandate and ULA formally or effectively denied those requests without meaningfully engaging in the interactive process.

53. For the same reason, Plaintiffs will fairly and adequately protect the interests of the class.

54. The questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and a class action is superior to other available methods for fairly and efficiently adjudicating Plaintiffs' claims. Joinder of all members is impracticable.

COUNT I
Violation of Title VII, 42 U.S.C. § 2000e, *et seq.*
Religious discrimination—failure to accommodate
On behalf of Plaintiffs Creger, Eastman, Maine, Norwood, and Breland, and others similarly situated

55. Plaintiffs restate the foregoing paragraphs as if set forth fully herein.

56. Plaintiffs Creger, Eastman, Maine, Norwood, and Breland, and others similarly situated, hold sincere religious beliefs that preclude them from receiving a COVID-19 vaccine.

57. Plaintiffs Creger, Eastman, Maine, Norwood, and Breland informed ULA ofthose beliefs and requested religious accommodations from the vaccine mandate.

58. ULA refused to engage in a meaningful interactive process with Plaintiffs regarding their religious accommodation requests and instead only responded to Plaintiffs with questions designedto challenge the sincerity of Plaintiffs' religious beliefs. ULA failed to provide Plaintiffs with reasonable accommodations for their religious beliefs, instead placing Plaintiffs on unpaid administrative leave and then advising Plaintiffs that they would be deemed to have "voluntarily resigned" if they did not obtain by November 7, 2021 (or resolution of the grievance process), a vaccine in violation of their sincerely-held religious beliefs.

59. ULA thereby discriminated against Plaintiffs because of their religious beliefs.

60. ULA's failure to provide religious accommodations has harmed and will continueto harm Plaintiffs.

61. By failing to engage in the interactive process or offer any reasonable accommodation, ULA's discriminatory actions were intentional and/or reckless and in violationof

Title VII.

62. Plaintiffs have filed charges with the EEOC complaining of these discriminatory actions. Although Plaintiffs' EEOC charges remain pending, this Court may exercise its equity jurisdiction to grant preliminary injunctive relief to preserve the status quo pending completion of the EEOC's administrative process. *See Drew v. Liberty Mut. Ins. Co.*, 480 F.2d 69, 74 (5th Cir. 1973); *see also Hicks v. Dothan City Bd. of Educ.*, 814 F. Supp. 1044, 1052 (M.D. Ala. 1993) (citing and applying *Drew*).

COUNT II
Violation of the ADA, 42 U.S.C. § 12101, *et seq*.
Disability discrimination—failure to accommodate
On behalf of Plaintiffs Maine and Breland, and others similarly situated

63. Plaintiffs restate paragraphs 1-54 as if set forth fully herein.

64. Plaintiffs Maine and Breland informed ULA of their medical conditions requiring an exemption from ULA's vaccine mandate or obviating the need for obtaining a vaccine.

65. Plaintiffs Maine and Breland requested reasonable medical accommodations from ULA's vaccine mandate for their medical conditions.

66. ULA refused to engage in the interactive process with Plaintiffs regarding their medical accommodation requests.

67. ULA violated the ADA when it denied Plaintiffs' accommodation requests.

68. ULA thereby discriminated against Plaintiffs because of their medical conditions.

69. ULA's failure to provide medical accommodations has harmed and continues to harm Plaintiffs.

70. By failing to engage in the interactive process or offer any reasonable accommodation, ULA's discriminatory actions were intentional and/or reckless, and in violationof the ADA.

71. Plaintiffs have filed charges with the EEOC complaining of these discriminatory

actions. This Court may exercise its equity jurisdiction to grant preliminary injunctive relief to preserve the status quo pending completion of the EEOC's administrative process. *See Drew*, 480 F.2d at 74.

COUNT III
Violation of Alabama Act 2021-561
Failure to Accommodate; Unlawful Termination
On behalf of All Plaintiffs, and others similarly situated

72. Plaintiffs restate paragraphs 1-54 as if set forth fully herein.

73. Plaintiffs hold sincere religious beliefs that preclude them from receiving a COVID-19 vaccine.

74. Plaintiffs requested religious exemption from ULA's vaccine mandate, as authorized by Alabama Act 2021-561, § 1(e).

75. Plaintiffs Maine and Breland requested medical exemption from ULA's vaccine mandate, as authorized by Alabama Act 2021-561, § 1(e).

76. ULA denied Plaintiffs' requests for exemption without "liberally construe[ing] [Plaintiffs'] eligibility for an exemption in favor of the employee," as required by Alabama Act 2021-561, § 1(d).

77. Plaintiffs have notified ULA of their intent to file appeals with the Alabama Department of Labor within the time frame set by Alabama Act 2021-561, § 1(g)(1).

78. ULA has placed Plaintiffs on unpaid administrative leave before resolution of their appeals, in violation of Alabama Act 2021-561 § 1(h)(2).

79. ULA has terminated or will soon be terminating Plaintiffs before resolution of their appeals, in violation of Alabama Act 2021-561 § 1(h)(1).

PRAYER FOR RELIEF

Plaintiffs request that the Court:

a. Certify this action as a class action under Federal Rules of Civil Procedure 23(a) and (b).

b. Certify at least three subclasses: (1) employees who have sought either a religious or medical accommodation and previously recovered from COVID-19 and possess antibodies against COVID-19; (2) employees who sought religious accommodations and lack COVID-19 antibodies; and (3) employees who sought medical accommodations and lack COVID-19 antibodies.

c. Declare that ULA has violated Title VII and the ADA by failing to engage in the interactive process in response to requests for accommodations to its COVID-19 vaccine mandate.

d. Declare that ULA has violated Title VII and the ADA by discriminating against its employees by failing to provide reasonable accommodations to its COVID-19 vaccine mandate.

e. Declare that ULA has violated Alabama Act 2021-561 by terminating or reducing the compensation of employees denied religious or medical exemptions while appeals of those denials are pending.

f. Issue a temporary restraining order and/or preliminary injunction, *see Drew*, 480 F.2d at 74, followed by a permanent injunction, enjoining ULA from terminating or deeming "voluntarily resigned" any employee who has a religious or medical basis for seeking an accommodation. The Court should enjoin such actions until ULA has completed the interactive process for all employees who request such an accommodation and granted reasonableaccommodations as required by federal law—which could include: (i) for those who test positivefor antibodies against COVID-19, allowing them to be accommodated through regular antibody testing and mask wearing; and (ii) for those otherwise qualifying for medical and religious accommodations, allowing them to work remotely where feasible, or to attend work wearing a mask while around others, and submitting to periodic COVID-19 testing. The Court should also enjoin such actions until resolution of any appeal authorized by Alabama

Act 2021-561.

g. Award Plaintiffs, and those similarly situated, damages, including back pay, reinstatement or front pay, pre-judgment and post-judgment interest, punitive damages, and compensatory damages.

h. Award Plaintiffs reasonable attorneys' fees and costs.

i. Grant any other relief that the Court deems just, proper, and equitable.

j. Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs demand a jury trial on all issues upon which there is a federal right to a jury trial.

November 12, 2021

Respectfully submitted,

/s/ Matthew J. Clark
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* *Pro hac vice* motion forthcoming

Counsel for Plaintiffs and the Proposed Class

EXHIBIT A

Alabama Act 2021-561 (SB9)
Signed into Law and Effective November 5, 2021

SB9

215650-6

By Senators Elliott, Givhan, Roberts, Barfoot, Gudger, Weaver, Shelnutt, Melson, Marsh, Chesteen, Butler, Sessions, Williams, Chambliss, Livingston, Allen, Waggoner, Orr, Scofield and Jones

RFD: Finance and Taxation General Fund

First Read: 28-OCT-21

SB9

ENROLLED, An Act,

Relating to vaccines; to require employers to allow employees to claim an exemption from the COVID-19 vaccination for medical reasons or sincerely held religious beliefs; to provide for submission of a standard form requesting the exemption; to provide standard language for the exemption form; to prohibit an employer from requiring a COVID-19 vaccine if an exemption form is completed and submitted; to authorize appeals to an administrative law judge for the Department of Labor for denials of exemptions; to require the Department of Labor to adopt an emergency rule; to provide an appeal of determinations by the administrative law judge; to generally provide for compensation of employees; and to provide for repeal of the act on a certain date.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. (a) For purposes of this section, the term "vaccination" means any injection intended to prevent the spread of COVID-19 or minimize the effects of COVID-19, irrespective of whether or not the injection meets the classical definition of vaccine.

(b) An employer may not require any employee to receive a vaccination as a condition of employment without

providing the employee the opportunity to be exempted from the vaccination mandate for religious or medical reasons in accordance with applicable law, rules, regulations, official guidance, and this section.

(c) An employer shall exempt vaccination as a condition of employment for any employee who has completed and submitted the exemption form described in subsection (e). An employer shall make this form readily available to all employees to whom this section applies, along with directions for submitting the form.

(d) When evaluating an employee's exemption request, the employer shall liberally construe the employee's eligibility for an exemption in favor of the employee, consistent with applicable law.

(e) The exemption form must be completed and signed by the employee and if applicable, signed by a health care provider. The form shall read as follows:

"Any individual in the State of Alabama who is subject to a requirement that he or she receive one or more COVID-19 vaccinations as a condition of employment may claim an exemption for medical reasons, because the vaccination conflicts with sincerely held religious beliefs, or both.

You may request either a medical or a religious exemption from the COVID-19 vaccination by completing this form and submitting the form to your employer.

In the event your employer denies this request, you have a right to file an appeal with the Department of Labor within 7 days. Your employer will provide you with information on how to file an appeal.

I am requesting exemption from the COVID-19 vaccine requirements for one of the following reasons: (check all that apply)

___ My health care provider has recommended to me that I refuse the COVID-19 vaccination based on my current health conditions and medications. (NOTE: You must include a licensed health care provider's signature on this form to claim this exemption.)

___ I have previously suffered a severe allergic reaction (e.g., anaphylaxis) related to vaccinations in the past.

___ I have previously suffered a severe allergic reaction related to receiving polyethylene glycol or products containing polyethylene glycol.

___ I have previously suffered a severe allergic reaction related to receiving polysorbate or products containing polysorbate.

___ I have received monoclonal antibodies or convalescent plasma as part of a COVID-19 treatment in the past 90 days.

___ I have a bleeding disorder or am taking a blood thinner.

___ I am severely immunocompromised such that receiving the COVID-19 vaccination creates a risk to my health.

___ I have been diagnosed with COVID-19 in the past 12 months.

___ Receiving the COVID-19 vaccination conflicts with my sincerely held religious beliefs, practices, or observances.

I hereby swear or affirm that the information in this request is true and accurate. I understand that providing false or misleading information is grounds for discipline, up to and including termination from employment.

_____

Employee's Printed Name

_____

Employee's Signature

_____

Date

(Note: The following must be completed ONLY if claiming the first medical exemption listed above.)

Certification by a licensed health care provider as to the accuracy of information provided above:

_____

Name of Health Care Provider

_____

Signature of Health Care Provider

_____

Date"

(f) The submission of the completed form creates a presumption that the employee is entitled to the exemption.

(g)(1) Notwithstanding the Alabama Administrative Procedures Act, the Department of Labor, not more than 21 days after the effective date of this act, shall adopt an emergency rule establishing a process to permit an employee to file an appeal of an employee's denial of a request for an exemption with an administrative law judge or judges appointed by the Secretary of Labor. The rule shall require an aggrieved employee to file his or her appeal no later than the latter of 7 calendar days following the denial of a request for an exemption or 3 business days following the adoption of the rule. The rule shall also require the administrative law judge to issue a ruling within 30 calendar days of receiving the claim.

(2) An employee whose denial is upheld by an administrative law judge, within 14 calendar days of the ruling, may file an appeal with a court of competent jurisdiction.

(h)(1) An employer who has denied an employee's request may not terminate the employee on the basis of failing to receive a vaccination for a period of 7 calendar days after the denial was issued by the employer, or if an appeal was made, until the administrative law judge or the court issues a final ruling in the employer's favor.

(2) Notwithstanding subdivision (1), an employer must compensate an employee whose request has been denied, at the same rate of compensation the employee received prior to submitting an exemption form, for a period of 7 calendar days after the denial was issued by the employer, or if an appeal was made, until the administrative law judge issues a ruling in the employer's favor.

(i) Nothing in this section shall be construed to alter or amend the ability of an employer to terminate an employee for reasons other than the employee's COVID-19 vaccination status.

(j) This section does not create or imply a private cause of action for employees who are terminated after refusing to receive a vaccination mandated by their employer.

(k) Unless extended by an act of the Legislature, this section shall be repealed on May 1, 2023.

Section 2. Notwithstanding subdivision (h)(2) of Section 1, any employee whose request for exemption is denied and who, before the date the Department of Labor has adopted

rules pursuant to subdivision (g)(1) of Section 1, fails to receive a vaccination, must receive full compensation through the last date on which the employee has the opportunity to appeal the denial to an administrative law judge.

Section 3. The Legislature shall appropriate funds necessary to cover the cost of administrative law judges to implement Section 1.

Section 4. This act shall become effective immediately following its passage and approval by the Governor, or its otherwise becoming law.

President and Presiding Officer of the Senate

Speaker of the House of Representatives

SB9

Senate 02-NOV-21
I hereby certify that the within Act originated in and passed the Senate, as amended.

Senate 04-NOV-21
I hereby certify that the within Act originated in and passed the Senate, as amended by Conference Committee Report.

Patrick Harris,
Secretary.

House of Representatives
Passed: 04-NOV-21, as amended

House of Representatives
Passed: 04-NOV-2021, as amended by Conference Committee Report.

By: Senator Elliott

EXHIBIT B

Letter from FDA to Pfizer
U.S. FOOD AND DRUG ADMIN. (Sep. 22, 2021)

September 22, 2021

Pfizer Inc.
Attention: Mr. Amit Patel
235 East 42nd St
New York, NY 10017

Dear Mr. Patel:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act. FDA reissued the letter of authorization on: December 23, 2020,[3] February 25, 2021,[4] May

[1] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FD&C Act, 21 U.S.C. § 360bbb-3, February 4, 2020.

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

[3] In the December 23, 2020 revision, FDA removed reference to the number of doses per vial after dilution from the letter of authorization, clarified the instructions for vaccination providers reporting to VAERS, and made other technical corrections. FDA also revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to clarify the number of doses of vaccine per vial after dilution and the instructions for reporting to VAERS. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers were revised to include additional information on safety monitoring and to clarify information about the availability of other COVID-19 vaccines.

[4] In the February 25, 2021 revision, FDA allowed flexibility on the date of submission of monthly periodic safety reports and revised the requirements for reporting of vaccine administration errors by Pfizer Inc. The Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers) was revised to provide an update to the storage and transportation temperature for frozen vials, direct the provider to the correct CDC website for information on monitoring vaccine recipients for the occurrence of immediate adverse reactions, to include data from a developmental toxicity study, and add adverse reactions that have been identified during post authorization use. The Fact Sheet for Recipients and Caregivers was revised to add adverse reactions that have been identified during post authorization use.

10, 2021,[5] June 25, 2021,[6] August 12, 2021,[7] and on August 23, 2021, FDA approved COMIRNATY (COVID-19 Vaccine, mRNA)[8] and reissued the letter in its entirety for both Pfizer-BioNTech COVID-19 Vaccine and certain uses of COMIRNATY (COVID-19 Vaccine, mRNA).[9]

On September, 22 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the August 23, 2021 letter of authorization in its entirety with revisions incorporated to authorize for emergency use the administration of a single booster dose of COMIRNATY (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine at least 6 months after completing the primary series of this vaccine in individuals: 65 years of age and older;18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

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[5] In the May 10, 2021 revision, FDA authorized Pfizer-BioNTech Vaccine for the prevention of COVID-19 in individuals 12 through 15 years of age, as well as for individuals 16 years of age and older. In addition, FDA revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to include the following Warning: "Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting." In addition, the Fact Sheet for Recipients and Caregivers was revised to instruct vaccine recipients or their caregivers to tell the vaccination provider about fainting in association with a previous injection.

[6] In the June 25, 2021 revision, FDA clarified terms and conditions that relate to export of Pfizer-BioNTech COVID-19 Vaccine from the United States. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to include a Warning about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine. The Fact Sheet for Recipients and Caregivers was updated to include information about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine.

[7] In the August 12, 2021 revision, FDA authorized a third dose of the Pfizer-BioNTech COVID-19 Vaccine administered at least 28 days following the two dose regimen of this vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

[8] COMIRNATY (COVID-19 Vaccine, mRNA) was approved for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

[9] In the August 23, 2021 revision, FDA clarified that, subsequent to the FDA approval of COMIRNATY (COVID-19 Vaccine, mRNA) for the prevention of COVID-19 for individuals 16 years of age and older, this EUA would remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses. It also authorized COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved biologics license application (BLA). In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to provide updates on expiration dating of the authorized Pfizer-BioNTech COVID-19 Vaccine and updated language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers was updated as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

COMIRNATY (COVID-19 Vaccine, mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide the COVID-19 vaccination series.[10]

For the December 11, 2020 authorization for individuals 16 years of age and older, FDA reviewed safety and efficacy data from an ongoing Phase 1/2/3 trial in approximately 44,000 participants randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. The trial has enrolled participants 12 years of age and older. FDA's review at that time considered the safety and effectiveness data as they relate to the request for emergency use authorization in individuals 16 years of age and older. FDA's review of the available safety data from 37,586 of the participants 16 years of age and older, who were followed for a median of two months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of the available efficacy data from 36,523 participants 12 years of age and older without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirmed that the vaccine was 95% effective (95% credible interval 90.3, 97.6) in preventing COVID-19 occurring at least 7 days after the second dose (with 8 COVID-19 cases in the vaccine group compared to 162 COVID-19 cases in the placebo group). Based on these data, and review of manufacturing information regarding product quality and consistency, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 16 years of age and older. Finally, on December 10, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

For the May 10, 2021 authorization for individuals 12 through 15 years of age, FDA reviewed safety and effectiveness data from the above-referenced, ongoing Phase 1/2/3 trial that has enrolled approximately 46,000 participants, including 2,260 participants 12 through 15 years of age. Trial participants were randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. FDA's review of the available safety data from 2,260 participants 12 through 15 years of age, who were followed for a median of 2 months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of SARS-CoV-2 50% neutralizing antibody titers 1 month after the second dose of Pfizer-BioNTech COVID-19 Vaccine in a subset of participants who had no serological or virological evidence of past SARS-CoV-2 infection confirm that the geometric mean antibody titer in participants 12 through 15 years of age was non-inferior to the geometric mean antibody titer in participants 16 through 25 years of age. FDA's analysis of available descriptive efficacy data from 1,983 participants 12 through 15 years of age without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirm that the vaccine was 100% effective (95% confidence interval 75.3, 100.0) in preventing COVID-19 occurring at least 7 days after the second dose

[10] The licensed vaccine has the same formulation as the EUA-authorized 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.

(with no COVID-19 cases in the vaccine group compared to 16 COVID-19 cases in the placebo group). Based on these data, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in individuals 12 through 15 years of age. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 12 through 15 years of age.

For the August 12, 2021 authorization of a third dose of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise, FDA reviewed safety and effectiveness data reported in two manuscripts on solid organ transplant recipients. The first study was a single arm study conducted in 101 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) a median of 97±8 months earlier. A third dose of the Pfizer-BioNTech COVID-19 Vaccine was administered to 99 of these individuals approximately 2 months after they had received a second dose. Levels of total SARS-CoV-2 binding antibodies meeting the pre-specified criteria for success occurred four weeks after the third dose in 26/59 (44.0%) of those who were initially considered to be seronegative and received a third dose of the Pfizer-BioNTech COVID-19 Vaccine; 67/99 (68%) of the entire group receiving a third vaccination were subsequently considered to have levels of antibodies indicative of a significant response. In those who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 events were reported. A supportive secondary study describes a double-blind, randomized-controlled study conducted in 120 individuals who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years earlier (range 1.99-6.75 years). A third dose of a similar mRNA vaccine (the Moderna COVID-19 vaccine) was administered to 60 individuals approximately 2 months after they had received a second dose (i.e., doses at 0, 1 and 3 months); saline placebo was given to 60 individuals for comparison. The primary outcome was anti-RBD antibody at 4 months greater than 100 U/mL. This titer was selected based on NHP challenge studies as well as a large clinical cohort study to indicate this antibody titer was protective. Secondary outcomes were based on a virus neutralization assay and polyfunctional T cell responses. Baseline characteristics were comparable between the two study arms as were pre-intervention anti-RBD titer and neutralizing antibodies. Levels of total SARS-CoV-2 binding antibodies indicative of a significant response occurred four weeks after the third dose in 33/60 (55.0%) of the Moderna COVID-19 vaccinated group and 10/57 (17.5%) of the placebo individuals. In the 60 individuals who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 adverse events were reported. Despite the moderate enhancement in antibody titers, the totality of data (i.e., supportive paper by Hall et al. demonstrated efficacy of the product in the elderly and persons with co-morbidities) supports the conclusion that a third dose of the Pfizer-BioNTech COVID-19 Vaccine may be effective in this population, and that the known and potential benefits of a third dose of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine for immunocompromised individuals at least 12 years of age who have received two doses of the Pfizer-BioNTech COVID-19 Vaccine and who have undergone solid organ

transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

For the September 22, 2021 authorization of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine administered at least 6 months after completing the primary series in individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19, FDA reviewed safety and effectiveness data from the above-referenced, ongoing Phase 1/2/3 trial in which 329 participants 18 through 75 years of age received a booster dose of the Pfizer-BioNTech COVID-19 Vaccine approximately 6 months (range 4.8 to 8.8 months) after completion of the primary series. FDA's review of the available safety data from 329 participants 18 through 75 years of age, who had been followed for a median of 2.6 months after receiving the booster dose, did not identify specific safety concerns that would preclude issuance of an EUA. The effectiveness of the booster dose of the Pfizer-BioNTech COVID-19 Vaccine is based on an assessment of 50% neutralizing antibody titers (NT50) against SARS-CoV-2 (USA_WA1/2020). FDA's analysis of SARS-CoV-2 NT50 one month after the booster dose compared to 1 month after the primary series in study participants 18 through 55 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after the booster dose confirmed noninferiority for both geometric mean ratio and difference in seroresponse rates. Based on the totality of the scientific evidence available, including data from the above-referenced clinical trial, FDA concluded that a booster dose the Pfizer-BioNTech COVID-19 Vaccine may be effective, and that the known and potential benefits of a single booster dose at least 6 months after completing the primary series outweigh the known and potential risks for individuals 65 years of age and older; individuals 18 through 64 years of age at high risk of severe COVID-19; and individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization. Additionally, as specified in subsection III.BB, I am authorizing use of Pfizer-BioNTech COVID-19 Vaccine and of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA when used to provide: a two-dose regimen for individuals aged 12 through 15 years; a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise; or a single booster dose at least 6 months after completing the primary series to individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Pfizer-BioNTech COVID-19 Vaccine[11] for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

A. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

B. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

C. There is no adequate, approved, and available alternative[12] Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.[13]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Pfizer Inc. will supply Pfizer-BioNTech COVID-19 Vaccine either directly or through authorized distributor(s),[14] to emergency response stakeholders[15] as directed by the U.S.

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[11] In this section (Section I), references to Pfizer-BioNTech COVID-19 Vaccine also apply to COMIRNATY (COVID-19 Vaccine, mRNA).

[12] 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. Additionally, there are no products that are approved to prevent COVID-19 in individuals age 12 through 15, or to provide: an additional dose to the immunocompromised population, or a booster dose to the authorized population described in this EUA.

[13] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[14] "Authorized Distributor(s)" are identified by Pfizer Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Pfizer-BioNTech COVID-19 Vaccine.

[15] For purposes of this letter, "emergency response stakeholder" refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction's COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers" (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;

- The Pfizer-BioNTech COVID-19 Vaccine covered by this authorization will be administered by vaccination providers[16] and used only to prevent COVID-19 in individuals ages 12 and older with a two-dose regimen, to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise, and to provide a single booster dose at least 6 months after completing the primary series of the vaccine to individuals: 65 years of age or older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19; and
- Pfizer-BioNTech COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide: a two-dose regimen for individuals aged 12 through 15 years; a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise; or a single booster dose at least 6 months after completing the primary series to individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

Product Description[17]

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative.

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[16] For purposes of this letter, "vaccination provider" refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. If the vaccine is exported from the United States, a "vaccination provider" is a provider that is authorized to administer this vaccine in accordance with the laws of the country in which it is administered. For purposes of this letter, "healthcare provider" also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration*. 85 FR 79190 (December 9, 2020).

[17] For COMIRNATY (COVID-19 Vaccine, mRNA) product description, please see the COMIRNATY (COVID-19 Vaccine, mRNA) prescribing information, found here: *https://www.fda.gov/media/151707/download*.

Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection) contributes an additional 2.16 mg sodium chloride per dose.

The dosing regimen is a primary series of two doses of 0.3 mL each, 3 weeks apart. A third primary series dose may be administered at least 28 days following the second dose to individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. A single booster dose (0.3 mL) may be administered at least 6 months after completing the primary series to individuals: 65 years of age or older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

The manufacture of the authorized Pfizer-BioNTech COVID-19 Vaccine is limited to those facilities identified and agreed upon in Pfizer's request for authorization.

The Pfizer-BioNTech COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization." The Pfizer-BioNTech COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling"):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

- Vaccine Information Fact Sheet for Recipients and Caregivers About COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease (COVID-19).

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine,[18] when used to prevent COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Pfizer-BioNTech COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Pfizer-BioNTech COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), Pfizer-BioNTech COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 12 years of age and older as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Pfizer Inc. and Authorized Distributor(s)

A. Pfizer Inc. and authorized distributor(s) will ensure that the authorized Pfizer-BioNTech COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.

B. Pfizer Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. Pfizer Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving authorized Pfizer-BioNTech COVID-19 Vaccine. Pfizer Inc. will provide to all relevant stakeholders a

[18] The conclusions supporting authorization stated in this Section (Section II) also apply to COMIRNATY (COVID-19 Vaccine, mRNA).

copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.

D. Pfizer Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.

E. Pfizer Inc. may request changes to this authorization, including to the authorized Fact Sheets for the vaccine. Any request for changes to this EUA must be submitted to Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[19]

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
   - Serious adverse events (irrespective of attribution to vaccination);
   - Cases of Multisystem Inflammatory Syndrome in children and adults; and
   - Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer Inc.

   These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Pfizer Inc.

G. Pfizer Inc. must submit to Investigational New Drug application (IND) number 19736 periodic safety reports at monthly intervals in accordance with a due date agreed upon with the Office of Biostatistics and Epidemiology (OBE)/CBER beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:
   - A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest;
   - A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval;
   - Newly identified safety concerns in the interval; and

[19] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and concurrence is required from the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS).

- Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by FDA.

I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

J. Pfizer Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.

K. Pfizer Inc. will submit to the EUA file quarterly manufacturing reports, starting in July 2021, that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report.

L. Pfizer Inc. and authorized distributor(s) will maintain records regarding release of Pfizer-BioNTech COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).

M. Pfizer Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

N. Pfizer Inc. will conduct post-authorization observational studies to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified list of adverse events of special interest, including myocarditis and pericarditis, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Pfizer-BioNTech COVID-19 Vaccine under this EUA in the general U.S. population (12 years of age and older), individuals that receive a booster dose, populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. Pfizer Inc. will provide protocols and status update reports to the IND 19736 with agreed-upon study designs and milestone dates.

Emergency Response Stakeholders

O. Emergency response stakeholders will identify vaccination sites to receive authorized Pfizer-BioNTech COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.

P. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Vaccine Information Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

Q. Emergency response stakeholders receiving authorized Pfizer-BioNTech COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

R. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.

S. Vaccination providers will provide the Vaccine Information Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose and/or third dose.

T. Vaccination providers administering the vaccine must report the following information associated with the administration of the vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1985 or by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-8337.

U. Vaccination providers will conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

V. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements

concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.

W. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

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

Y. 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:
- 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 12 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.

Condition Related to Export

Z. If the Pfizer-BioNTech COVID-19 Vaccine is exported from the United States, conditions C, D, and O through Y do not apply, but 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) the intended use of the vaccine will comply in all respects with the laws of the country in which the product will be used. The requirement in this letter that the authorized labeling (i.e., Fact Sheets) be made available to vaccination providers, recipients, and caregivers in condition A will not apply if the authorized labeling (i.e., Fact Sheets) are made available to the regulatory authorities of the country in which the vaccine will be used.

Conditions With Respect to Use of Licensed Product

AA. COMIRNATY (COVID-19 Vaccine, mRNA) is now licensed for individuals 16 years of age and older. There remains, however, a significant amount of Pfizer-BioNTech COVID-19 Vaccine that was manufactured and labeled in accordance with this emergency use authorization. The authorization remains in place with respect to the Pfizer-BioNTech COVID-19 Vaccine.

BB. This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide: a two-dose regimen for individuals aged 12 through 15 years; a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise; or a single booster dose at least 6 months after completing the primary series to individuals: 65 years of age or older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19. Conditions A through W in this letter apply when COMIRNATY (COVID-19 Vaccine, mRNA) is provided for the uses described in this subsection III.BB, except that product manufactured and labeled in accordance with the approved BLA is deemed to satisfy the manufacturing, labeling, and distribution requirements of this authorization.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures