IN THE COURT OF COMMON PLEAS
ATHENS COUNTY, OHIO

Bailey Martin, et al.

Plaintiffs,

-vs.-

The Ohio University, et al.

Defendants.

CASE No.: 21-CI-0221

JUDGE: HON. GEORGE P. MCCARTHY

PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS FIRST AMENDED COMPLAINT

For their brief in opposition to defendants' motion to dismiss the first amended complaint, plaintiffs Bailey Martin, Tyce Patt, Jack Noble, Isabel Thomas, John Thomas, Mary Thomas, Cameron May, Brandon Sand, Zane Maier, Fitzgerald Dwyer, Francesca Cerutti, Sydney Jones, Nikolas Dibiasio, Emanuel Seyboldt and Kyle Utt state as follows:

I. Standing

A. Introduction

Defendants argue that plaintiffs lack standing. To establish standing plaintiffs must demonstrate that they have sustained "(1) an injury that is (2) fairly traceable to the defendant's allegedly unlawful conduct, and (3) likely to be redressed by the requested relief". *Ohioans for Concealed Carry v. City of Columbus*, 2019-Ohio-3100, ¶ 12.

An injury for purposes of standing is "an invasion of a legally protected interest". *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560 (1992). "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss [a court] "presume[es] that general allegations embrace those specific facts that are necessary to support the claim". *Lujan* at 561. *Lujan* observed further that "[w]hen the suit is one challenging the legality of government action or inaction, the nature of the facts that must be

averred (at the summary judgment stage) or proved (at the trial stage) in order to establish standing depends considerably upon whether the plaintiff is himself an object of the action (or foregone action) at issue. **If he is, there is ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it."** *Id.* at 561. (Emphasis added.)

Defendants argue that plaintiffs have not alleged that the requirements, discriminatory effects or penalties of the Mandates have been applied to plaintiffs. However, it is well-settled under Ohio law that "[g]enerally, **threatened** injuries, including **threatened** discrimination, may serve as an 'injury' for common-law standing purposes." (Emphasis added.) *Hamilton v. Ohio Dept. of Health,* 42 N.E. 3d 1261, 2015-Ohio-4041, ¶19, citing *State ex rel. Ohio Academy of Trial Lawyers v. Sheward,* 86 Ohio St. 3d 451, 469 (1999). Plaintiffs have alleged that the Mandates provide that "[a]ll community members at any Ohio University campus or location must comply with all specific health requirements" of the Mandates, or "face discipline up to and including suspension or expulsion." Amended Complaint, Exhibit 2, pp. 1, 6. Plaintiffs further alleged that they are students or an employee of Ohio University and have specified how the Mandates have invaded their legal interests. Plaintiffs have generally alleged harm sufficient to meet the standing requirements as identified in *Lujan.* Amended Complaint, Count One and ¶49.

"[S]tanding does not depend on the merits of the plaintiff's contention that particular conduct is illegal or unconstitutional" but, instead, "turns on the nature and source of the claim asserted by the plaintiffs." *Moore v Middleton*, 133 Ohio St. 3d 55, 2012-Ohio-3897, ¶23. A plaintiff need not exhaust administrative remedies prior to instituting a declaratory judgement action "if there is no administrative remedy available which can provide the relief sought or if resort to administrative remedies would be wholly futile." *One Energy Enterprises v ODOT*,

2019-Ohio-359, ¶58. Standing must be demonstrated for each form of relief sought. *Ohioans for Concealed Carry*, ¶12.

Plaintiffs' claims include requests for declaratory relief regarding whether:

1) Defendants' mask mandate and other health orders exceed their constitutional and statutory authority and/or violate plaintiffs' constitutional right to refuse medical treatment;

2) Defendants' mask and vaccine mandates and other health orders are threats of official action to coerce plaintiffs to take actions on matters concerning which they have the legal freedom of choice in violation of R.C. 2904.12; and

3) Defendants' health orders discriminate between the unvaccinated and those vaccinated with emergency use authorized vaccines in violation of R.C. 3792.04.

Defendants cite *Wade v. University of Connecticut Board of Trustees*, 2021 WL 3616035, *8 (D. Conn. Aug. 16, 2021) for the principle that those who don't submit to a policy don't have standing to challenge the policy. *Wade* based this principle on *Libertarian Party of Erie County v. Cuomo*, 970 F. 3d 106, 121 (2nd Cir. 2020) which derived it from *Moose Lodge No. 107 v. Irvis*, 407 U.S. 163, 166-68 (1972). Moose Lodge explained at the cited pages that a party "may not seek redress for injuries done to others" (*Id*., at 166) and that since plaintiff hadn't applied for and been rejected for membership, he didn't have standing to challenge the membership policy.

Plaintiffs have obtained exemptions from the vaccine mandates but are seeking declaratory relief for other invasions of their legally protected interests as described above. They are seeking redress for injuries to themselves, not others. This is not a circumstance where they have not been impacted directly by the policies they are challenging.

Defendants claim that plaintiffs have not established standing because if they are exempted from the vaccine mandate, defendants argue that they have no injury. Plaintiffs are exempted from the vaccine mandate as alleged in the amended complaint, but have alleged other

injuries in the form of invasions of their legally protected interests that exist regardless of their vaccine exemption status.

Defendants argue that plaintiffs haven't applied for an exemption from the mask mandate. However, such an exemption is only for extraordinary circumstances and plaintiffs have alleged that they don't have a medical or religious reason to qualify for such an exemption. Amended Complaint, ¶20. This argument raises factual questions regarding the availability of an administrative remedy or the futility of such a remedy as discussed below, that must be determined by the test for Rule 12(b)(6) dismissals i.e. whether defendants have established beyond a reasonable doubt that plaintiffs can prove no set of facts consistent with the complaint entitling them to relief. Defendants are unable to meet this standard on this point.

Whether plaintiffs have stated claims for which relief can be granted requires a different analysis than that required for standing and will be addressed in the next section below.

A. Standing to Assert Claim of Lack of Authority

Plaintiffs allege that the Mandates described in the amended complaint exceed defendants' general authority to administer Ohio University. Ohio case law limits exercise of such general authority by requiring that the exercise of such authority be reasonable. See *State ex rel. Barno v Crestwood Bd. Of Edn.*, 134 Ohio App 3d. 494, 503 (11th Dist 1998). Reasonableness must be evaluated by the standards of "common sense… guided by considerations of public policy manifested in relevant statutory, administrative, and decisional law." *Id.* at 304; see *O'Neal v State*, 146 N.E. 3d 605, 2020-Ohio-506, ¶33. Defendants' unauthorized actions are a violation of the non-delegation doctrine or the separation of powers doctrine and are therefore unconstitutional. *Id.*, ¶¶ 34, 50.

Plaintiffs have alleged that public policy as manifest in Ohio's relevant statutory scheme (R.C.3209.212 and others) limits application of public health orders issued by defendants to those diagnosed with a disease or in direct contact with those so diagnosed. Standing does not depend on the merits of this claim. *Moore*, at ¶23. It depends only on the nature of the claim i.e. whether plaintiffs have asserted an invasion of their legal rights which can be remedied by the court.

Plaintiffs have alleged that the Mandates exceed defendants' authority because they are public health orders that apply to them, even if (contrary to R.C. 3209.212) they have not been diagnosed with a disease or been in direct contact with someone so diagnosed. This applies to all aspects of the Mandates including vaccines, masking, testing and limitations of activities. It applies to plaintiffs even though they are exempted from the vaccine because the masking, testing and activity limitations apply to those who are exempted from the vaccine. As a result, plaintiffs have met the test for standing on this claim.

B. Standing to Assert Claim of Violation of Right to Refuse Medical Treatment

Plaintiffs have alleged a violation of their right to refuse medical treatment under Article I, Section 1 of the Ohio Constitution. Plaintiffs allege that the requirement regarding use of masks, is a form of medical treatment given that such masks are authorized for emergency use as medical devices for a medical purpose. Amended Complaint, ¶43. This claim exists regardless of whether plaintiffs are exempted from the vaccine mandate.

Defendants argue that plaintiffs have not requested exemptions from the mask mandate. However, the Mandates do not provide for mask exemptions, except for extraordinary circumstances. Amended Complaint, Exhibit 2, p. 3. Further, plaintiffs have alleged that they don't have a medical or religious reason for an exemption, even if they were provided for in the

Mandates. Therefore, the failure to exhaust administrative remedies defense is not available because the Mandates don't provide for such a remedy. *One Energy Enterprises,* at ¶58. Moreover, even if there was such a remedy, it would be futile to apply for it given the lack of a basis for it. *Id.,* ¶58.

Accordingly, plaintiffs have met the test for standing with respect to the claims regarding the right to refuse medical treatment.

C. Standing to Assert Claim of Coercion

This must be considered in conjunction with R.C. 2904.12 which precludes coercion by threats of official action regarding matters for which persons have a legal freedom of choice. Defendants have threatened official action (expulsion, termination of employment) regarding a vaccination requirement, or in the alternative masking, testing and activity limitations if exempted from the vaccine mandate, all of which covers matters for which plaintiffs have a legal freedom of choice. With respect to R.C. 2904.12, the threat itself is a violation. Plaintiffs have therefore alleged an invasion of a legally protected interest which this court could remedy through declaratory relief and have met the test for standing on this claim.

D. Standing to Assert Claims of Violation of R.C. 3792.04.

Plaintiffs have also alleged injury from a violation of R.C. 3792.04 relating to: 1) mandating Covid-19 vaccines that are only authorized for emergency use and 2) discrimination between the unvaccinated and those vaccinated with vaccines authorized only for emergency use (the "EUA vaccines").

Regarding the first prong of the R.C. 3792.04 claim, defendants are alleged to have mandated vaccines authorized for emergency use only i.e. the Pfizer, Moderna and Johnson & Johnson Covid-19 vaccines (the "EUA vaccines"), which are the only Covid-19 vaccines

currently available. Amended Complaint, ¶34. Two Covid-19 vaccines have been fully authorized by the FDA, Comirnaty on August 23, 2021 and Spikevax on January 31, 2022, but are not currently available. This claim must be considered in conjunction with the coercion claim under R.C. 2914.12 as discussed below.

Plaintiffs allege that the Mandates imposes testing and quarantine requirements on them, which are not imposed on those who take EUA vaccines, and threatens them with discipline up to expulsion, if they don't comply. As a result, plaintiffs are being threatened with official action if they don't take the EUA vaccines, even though R.C. 3792.04 gives them the freedom not to take such vaccines.

The second prong of the R.C. 2904.12 claim relates to discrimination between the unvaccinated and those vaccinated with EUA vaccines. Plaintiffs allege that they are subject to restrictions that are not applicable to those who have taken EUA vaccines in violation of R.C. 2904.12's non-discrimination provision. Therefore, plaintiffs have met the test for standing regarding their R.C. 3792.04 claim.

II. Whether there is a Failure to State a Claim.

A. The Standard for Stating a Claim for Declaratory Relief.

Defendants seek dismissal of all claims for failure to state a claim for which relief can be granted pursuant to Civ. R. 12(b)(6). The test for such dismissal is demanding; defendants must establish beyond a reasonable doubt that plaintiffs can prove no set of facts entitling them to relief. *Jenson v. Christ Hospital, Inc.,* 2021-Ohio-1467, ¶13. R.C. 2721.03 provides that any person whose rights, status or other legal relations are affected by a constitutional provision or statute may obtain a declaration of their rights under it. Plaintiffs are seeking declaratory relief under this statute. "The essential elements for declaratory relief are: (1) a real controversy exists

between the parties, (2) the controversy is justiciable in character, and (3) speedy relief is necessary to preserve the rights of the parties." *One Energy Enterprises*, at ¶31. The purpose of declaratory relief "is to settle and afford relief from uncertainty with respect to rights…and [the declaratory relief statute] is to be liberally construed and administered. *Id*. at ¶30.

For a real controversy to exist "there must be a genuine dispute between parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgement." *Id.* at ¶31.

B. The University's Authority to Issue Public Health Orders

1. General Authority is Limited by Standard of Reasonableness as Defined by Public Policy Manifest in Statute; Non-Delegation and Separation of Powers Doctrines.

Defendants argue that the general authority to administer Ohio University granted by R.C. 3345.21 and 3345.021 provides them the authority to issue the vaccine mandate and other public health orders contained in the Mandate. Motion to Dismiss, p. 6. Plaintiffs contend that Ohio case law limits defendants' general authority to that which is reasonable as defined by public policy manifest in relevant statutes, including R.C. 3709.212. *State ex rel. Barno v. Crestwood Bd. of Edn*., 134 Ohio App. 3d 494, 503 (11th Dist. 1998). This case law is an application of the non-delegation doctrine described in *Capital Care Network v. Ohio Dept. of Health,* 153 Ohio St. 3d 362, 2018-Ohio-440, ¶110 and *Redman v. Ohio Dept. of Indus. Relations*, 75 Ohio St 3d 399, 406 (1996). ("A statute does not unconstitutionally delegate legislative power if it establishes, through legislative policy and such standards as are practical, an intelligible principle to which the administrative officer or body must conform…")

The Ohio Attorney General ("OAG") has repeatedly taken the position in courts on behalf of the state of Ohio that mandating Covid-19 vaccines based on statutes providing

generally authority violates the non-delegation doctrine. The OAG successfully argued that the federal contractor mandate likely violated the non-delegation doctrine in *Kentucky v. Biden*, 2021 WL 558746, *8 and that the OSHA mandate likely violated the non-delegation doctrine in *Nat'l Fed. of Ind. Business v. Dept. of Labor, OSHA,* 142 S. Ct. 661, 668-669 (2022). In *Biden v. Missouri,* 2022 WL 120950 the OAG unsuccessfully argued that the CMS mandate violated the non-delegation doctrine. Under Ohio case law the OAG may be judicially estopped from taking the inconsistent position that Covid-19 vaccines may be mandated pursuant to a state university's general authority in violation of the non-delegation doctrine. *Advanced Analytics Laboratories v. Kegen, Brown, Hill & Ritter*, 148 Ohio App. 3d. 440, 452, ¶37 (10th Dist., 2002).

Moreover, if it is determined that defendants have usurped legislative power that was not delegated to it, their unauthorized actions are unconstitutional under the separation of powers doctrine. *Id*., ¶28. This doctrine protects the legislative branch of governments from encroachments by the executive branch, so that its integrity and independence may be preserved. *Id*., ¶28.

Ohio courts have avoided the unconstitutional interpretation advocated in this case by the OAG, by construing a state school's general authority as limited by a standard of reasonableness defined by public policy manifest in statutes. The principle that university rules must be reasonable was applied in *McGinnis v Walker*, 40 N.E. 2d 488, 492 (1941) and *Long v. Board of Trustees*, 24 Ohio App. 261, 263-264 (1926). The principle that reasonableness is defined by public policy as manifest in statutes was applied in *State ex rel. Barno*, supra. This construction avoids an unconstitutional delegation of legislative authority to university administrators, which would arise if there was no intelligible principle to which university administrators must

conform. This interpretation is consistent with the principle of avoiding construing statutes as unconstitutional where reasonably possible. *Akron v. Rowland*, 67 Ohio St. 3d 374, 380 (1993).

2. Ohio Covid-19 Public Policy as Manifest in Ohio Statutes

Defendants argue that R.C. 3709.212 applies to local boards of health and therefore is not relevant to defendants' authority to issue Covid-19 public health orders. However, defendants miss the salient point that the Ohio Legislature has granted specific authority within limits to the Ohio Department of Health ("ODH") and the local health boards relating to Covid-19 public health orders and has not granted such authority to defendants. Moreover, in doing so the legislative sponsors of recently enacted Senate Bill 22 (including R.C. 3709.212) explicitly stated that their goal was to "give the citizens of the state of Ohio, through their elected officials in the General Authority, a voice in matters related to public health" and to provide a "sensible safeguard against state overreach." Sponsor Testimony, Senate Bill 22, Ohio Senate Government Oversight and Reform Committee, January 26, 2021. Senate Bill 22, including R.C. 3709.212, was enacted by a supermajority of Ohio legislators overriding the governor's veto and is a dramatic manifestation of relevant public policy limiting defendants' authority.

Ohio's relevant statutory scheme, as amended by Senate Bill 22, provides that ODH "shall have supervision of all matters relating to the preservation of the life and health of the people and have authority in matters of quarantine and isolation.." R.C. 3701.13(B)(1). The ODH's authority "is superior to the authority" of the local boards of health. R.C. 3701.13(B)(3). The ODH has authority to "approve methods of immunization against the diseases specified in section 3313.671", which does not include Covid-19. R.C. 3701.13(B)(4).

In construing R.C. 3701.13, the Ashland County Court of Common Pleas and two other common pleas courts have ruled that it granted no authority to ODH to order mandatory mask,

social distancing, or other similar type orders. Exhibit A, p. 6, *Cattlemans Inc. v Ashland County Health Department*, Ashland Case No. 20-CIV-104 (April 6, 2021).

On the other hand, the local health boards and "officers of state institutions" such as defendants are bound by R.C. 3701.56, which provides that they "shall enforce quarantine and isolation orders, and the rules the [ODH] adopts."

Local boards of health may issue orders and regulations for the public health or for the prevention or restriction of disease. R.C. §§ 3709.20 and 3709.21. However, pursuant to Senate Bill 22, such orders may only apply to persons medically diagnosed with a disease or who have come into direct contact with someone medically diagnosed with a disease. R.C. 3709.212. Defendants are required to follow the rules and order of local health boards by R.C. 3709.99.

Under Ohio's statutory scheme the only role assigned to defendants is the requirement to enforce the rules and quarantine and isolation orders of ODH and local health boards, which are subject to the limitations described above.

Nevertheless, defendants contend that general authority to administer Ohio University, includes far broader authority to issue public health orders than ODH or the local boards of health. They contend that they can mandate universal masking or a Covid-19 vaccine even though the Ohio Legislature has specified that they must enforce ODH rules which do not provide such authority. They contend that they can apply quarantine, isolation, masking and testing orders to persons who are not medically diagnosed with a disease, or in direct contact with those diagnosed even though the Ohio Legislature has specified that they must follow local health board regulations which explicitly prohibit such orders. R.C. 3709.99

3. Conclusion

Defendants lack authority in part to issue the public health orders in the Mandates, under Ohio's applicable statutory scheme and Ohio case law as described above. Defendants' argument, that the general authority to administer Ohio University provided by statute gives them broad public health authority, would render such statute unconstitutional under the non-delegation doctrine. In any event, defendants have not shown beyond a reasonable doubt that plaintiffs can prove no set of facts entitling them to declaratory relief, thereby precluding defendants' request for dismissal for failure to state a claim.

C. The Right to Refuse Medical Treatment Under the Ohio Constitution

Defendants argue that the right to refuse medical treatment under Article I, Section 1 of the Ohio Constitution is not implicated because masking is not a form of medical treatment. However, plaintiffs have alleged that the masks required by the Mandates are medical devices intended for a medical purpose which are regulated by the FDA and authorized for emergency use to prevent the spread of disease. Amended Complaint, ¶43. As such they are a form of medical treatment which plaintiffs have a constitutional right to refuse.

The Mandate issued effective August 31, 2021, required the use indoors of surgical, N95 or cloth masks. Amended Complaint, Ex. 1, p 2. The Mandate was revised on January 6, 2022, and now requires surgical, N95 or similar masks, and discourages the use of cloth masks. Amended Complaint, Ex. 2, p. 2.

Previously, on March 2 and 11, 2020, respirators (including N95s) were authorized for emergency use for the medical purpose of preventing the spread of Covid-19, and were thus deemed medical devices regulated by the FDA. Exhibit B. In January 2022, the Centers for Disease Control (the "CDC") issued guidance allowing the use of non-surgical respirators, covered by this EUA, by the general public. Exhibit C. On April 24, 2020, cloth masks (face

masks) were authorized for emergency use to prevent spread of disease and are thus regulated by the FDA as medical devices. Exhibit D, p. 1. Surgical masks are class II devices regulated by the FDA and authorized for emergency use to prevent spread of disease on August 5, 2020. Exhibit E, p. 1. The administration of medical devices to prevent the spread of disease is certainly medical treatment. For instance, employees required to wear respirators for health reasons must obtain medical clearance under 29 CFR 1910.134(c)(1)(ii). Plaintiffs have the right to refuse this medical treatment under the Ohio Constitution. Further, plaintiffs have the right to refuse the administration of products authorized for emergency use under 21 USC § 360bbb-3(e)(1)(A)(ii)(III).

Defendants argue that *Steele v Hamilton Cty. Community Mental Health Bd.*, 90 Ohio St. 3d 176 (2000) is someone limited by its facts relating to involuntary antipsychotic medication. However, *Steele* held that "the right to refuse medical treatment is a fundamental right in this country, where personal security, bodily integrity, and autonomy are cherished liberties." *Id.* at 180. Steele's holding applies broadly to all coerced medical treatments.

Defendants also argue that *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905) permits states to issue vaccine mandates. However, *Jacobson* said that while the Fourteenth Amendment permits states to exercise their police power to issue vaccine mandates, such police power also allows states to limit vaccine, mask and other health requirements as they in their wisdom may determine. *Jacobson* at 38. Ohio has in its wisdom determined that medical treatment may not be forced except under the *Steele* standards, and that the authority to issue vaccine and mask mandates is limited.

Accordingly, defendants are unable to show beyond doubt that plaintiffs can prove no set of facts entitling them to declaratory relief with respect to this claim.

D. R.C. 2905.12 (Coercion by Official Acts)

Defendants argue that the R.C. 2905.12 does not create a private cause of action and therefore doesn't support a claim for declaratory relief. However, R.C. 2905.12 is a criminal statute and it is well settled that declaratory relief is available for criminal statutes. *Petz v. City of South Euclid*, 11 Ohio St. 2d 128, 131 (1967).

Defendants cite to cases holding that R.C. 2905.12 doesn't provide a cause of action for damages. *Simpson v. Voiture Nahonale etc.* 2021-Ohio-2131, ¶26. Plaintiffs are not asserting a cause of action for damages under R.C. 2905.12. They are seeking declaratory relief which is available under the *Petz* case. Moreover, R.C. 2307.60 does provide for a cause of action for damages for violations of R.C. 2905.12. In *Simpson*, the court held that such a claim is conceivable. *Simpson* at ¶5. Nonetheless, plaintiffs are only seeking declaratory and injunctive relief, as permitted by *Petz*.

As discussed above, R.C. 2905.12 is to be considered in conjunction with the limits on defendants' authority, R.C. 3792.04 and the right to refuse medical treatment under the Ohio Constitution. Those statutory and constitutional provisions provide plaintiffs the freedom to choose on various matters. R.C. 2905.12 prohibits threats of official action to coerce plaintiffs' choices on those matters.

E. R.C. 3792.04

1. Prohibition of Mandates of EUA Vaccines.

R.C. 3792.04 clearly prohibits defendants from mandating Covid-19 vaccines that have not received full FDA approval. The Covid-19 vaccines currently available have only been authorized for emergency use and have not received full FDA approval. They include the Pfizer-BioNTech Covid-19 Vaccine (the "Pfizer vaccine") and the Moderna and Johnson & Johnson vaccines (the "EUA vaccines"). By mandating Covid-19 vaccines, when the only such vaccines available are not fully approved by the FDA, defendants have violated R.C. 3792.04. A Covid-19 vaccine called Comirnaty was fully approved by the FDA on August 23, 2021 and another one called Spikevax was approved on January 31, 2022, neither of which is yet available. Under R.C. 3792.04, defendants are prohibited from discriminating between the unvaccinated and those vaccinated with EUA vaccines, regardless of the approval or availability of Comirnaty or Spikevax.

Defendants state that the Pfizer vaccine has "been fully approved by the FDA". That statement is demonstrably incorrect. The Pfizer vaccine i.e. the Pfizer-BioNTech Covid-19 vaccine, has only been authorized for emergency use. Exhibit F, pp. 1-2, Emergency Use Authorization ("EUA") from the FDA dated August 23, 2021. It bears emphasis that the Pfizer vaccine's emergency use authorization was renewed on August 23, 2021, the same day that Comirnaty was approved. Regardless of Comirnaty's status, the Pfizer vaccine remains an EUA vaccine which may not be mandated by defendants by reason of R.C. 3792.04.

Defendants also state that "Comirnaty" is simply the marketing name of the Pfizer vaccine." This statement is also incorrect. Comirnaty is the marketing name for the product

known as the Covid-19 Vaccine, mRNA which was fully approved by the FDA on August 23, 2021. Exhibit G, pp. 1-2.

The connection between Comirnaty and the Pfizer vaccine was described by the FDA as follows:

> 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. Exhibit F, p. 2, n. 8. (Emphasis added.)

Under R.C. 3792.04, one of the legal distinctions between the Pfizer vaccine and Comirnaty is that defendants may not mandate the Pfizer vaccine, because it isn't fully approved by the FDA. There are many reasons why the Pfizer vaccine may not have received full approval from the FDA, including labelling, manufacturing facilities involved or others. Regardless of why the Pfizer vaccine has not received fill FDA approval, R.C. 3792.04 prohibits mandating vaccines that have not received such approval.

Defendants do not dispute that Comirnaty is unavailable. On September 13, 2021, the FDA published a notice that Pfizer does not plan to produce Comirnaty over the next few months. Exhibit H. The CDC website currently states that Comirnaty is not presently available. Exhibit I, p. 2.

The circumstances with Moderna and Spikevax are similar. On January 31, 2022, the same day that Spikevax was approved by the FDA, the Moderna vaccine's emergency use authorization was renewed. Exhibit J. Moderna remains an EUA vaccine, which the FDA says is interchangeable with, but legally distinct from, Spikevax. Exhibit J, p. 3, n. 9. One of the legal distinctions is that Moderna, as an EUA vaccine, may not be mandated by defendants. Spikevax is the name of a legally distinct COVID-19, mRNA product. Exhibit K.

The R.C. 3792.04 claim prohibiting EUA vaccine mandates as well as the claim regarding the right to refuse medical treatments must be considered in conjunction with R.C. 2905.12. Because plaintiffs have the freedom to choose regarding taking a vaccine or masking, as well as other matters, defendants may not threaten official action to coerce such choices. The threat itself is an invasion of a legally protected interest. As a result, defendants have failed to show beyond doubt that plaintiffs can prove no set of facts entitling them to relief.

2. Discrimination

Defendants also argue that there is no violation of R.C. 3792.04 because plaintiffs have not alleged that they have been required to engage in testing. In fact, the Mandates do require testing, as plaintiffs have alleged. Amended Complaint, Exhibit 2, p. 7.

Defendants further argue that there is no violation of R.C. 3792.04 because all persons are required to mask. However, plaintiffs are only alleging a violation of R.C. 3792.04 to the extent that the unvaccinated and EUA vaccinated are treated differently, such as quarantining, testing or masking outdoors when physical distancing can't be maintained. Amended Complaint, Exhibit 4, p. 4, Exhibit 3, p. 2, and Exhibit 2, p. 2.

R.C. 3792.04 requires defendants to distinguish between those vaccinated with EUA vaccines and those vaccinated with vaccines fully approved by the FDA. Defendants are prohibited from discriminating between the unvaccinated and those vaccinated with the EUA vaccines, even though they may discriminate between the unvaccinated and those vaccinated with fully approved vaccines. Plaintiffs have alleged that defendants have discriminated between the unvaccinated (themselves) and those vaccinated with EUA vaccines. Amended Complaint, ¶¶35-37.

Accordingly, defendants have not shown beyond doubt that plaintiffs can prove no set of facts entitling them to declaratory relief on their R.C. 3792.04 claim, thereby precluding defendants request for dismissal for failure to state such a claim.

III. Conclusion

For the above reasons, defendants' motion to dismiss should be denied.

Respectfully Submitted,

/s/ Thomas W. Connors
Thomas W. Connors (0007226)
Warner Mendenhall (0070165)
Mendenhall Law Group
190 North Union St., Ste 201
Akron, Ohio 44304
Counsel for Plaintiffs

Certificate of Service

I hereby certify that on February 4, 2022, a copy of the foregoing was electronically filed with the court and served via email to counsel for Defendants at the address listed:

Michael H. Carpenter
Michael N. Beekhuizen
Gregory R. Dick
CARPENTER LIPPS AND LELAND LLP
280 Plaza, Suite 1300
280 North High Street
Columbus, OH 43215
E-mail: capenter@carpenterlipps.com
beekhuizen@carpenterlips.com
dick@carpenterlipps.com

Counsel for Defendants

/s/ Thomas W. Connors
Counsel for Plaintiffs

IN THE COURT OF COMMON PLEAS, ASHLAND COUNTY, OHIO
GENERAL DIVISION

CATTLEMANS INC , ET AL,

Plaintiff, **CASE NO. 20-CIV-104**

vs.

ASHLAND COUNTY HEALTH DEPARTMENT , ET AL,

Defendant. **JUDGMENT ENTRY**

This matter came before the Court for a bench trial on September 25, 2020 and September 30, 2020 on Plaintiff's August 7, 2020 Complaint for Declaratory Judgment and Injunctive Relief. The bench trial was conducted by remote video with all parties participating. Upon the conclusion of the bench trial, the Court requested post-hearing legal memoranda from counsel. Defendant submitted its initial post-hearing memorandum on November 12, 2020. Plaintiff filed its post-hearing memorandum on November 19, 2020, and Defendant then filed a reply memorandum on November 25, 2020.

FACTUAL BACKGROUND

In the prayer for relief in their Complaint, Plaintiffs' request:

1. A permanent injunction prohibiting enforcement of a July 15, 2020 Cease and Desist Order issued by Defendants, or any materially identical order against Plaintiffs so long as Plaintiffs abide by the general safety strictures articulated in

EXHIBIT
A

Chapters 3717 of both the Ohio Revised Code and the Ohio Administrative Code;

2. A permanent injunction prohibiting Defendants or their agents from suspending business licenses (food service licenses) predicated solely on violations of the *Dine Safe Ohio Order*, including masking requirements;
3. A permanent injunction prohibiting Defendants and Defendants' agents from enforcing any Ohio Director of Health Order issued pursuant to R.C. 3701.13 to suspend business licenses (food service licenses);
4. A judgment entry declaring the Ashland County Health Department July 15, 2020 Cease and Desist Order is constitutionally and statutorily impermissible;
5. A permanent injunction prohibiting Defendants from enforcing penalties for non-compliance with any state or local order, or any other non-statutory limit, so long as Plaintiffs operate within the limits of the Ohio Revised Code and adhere to otherwise generally-appliable safety guidelines;
6. A judgment entry declaring Defendants' suspension of Plaintiffs' food service license without a prior hearing or prompt post-deprivation hearing violates Plaintiff's right to procedural due process under the Ohio Constitution; and
7. A judgment entry awarding Plaintiffs their costs, actual damages, nominal damages, and expenses incurred in bringing this action, including reasonable attorney fees, pursuant to R.C. 2335.39.

Defendants, in their responses to Plaintiffs' Complaint, filed a Settlement Memorandum (filed August 21, 2020) and a Motion to Dismiss (filed September 3,

2020). No settlement occurred and the Motion to Dismiss asserted, among other things, the following:

1. The cease-and-desist order was withdrawn by Defendants and Plaintiffs' food service license was reinstated, thereby ending the controversy;
2. That Plaintiffs' have failed to exhaust their administrative remedies;
3. Plaintiffs have failed to serve the Ohio Attorney General as required by R.C. 2721.12(A) and is therefore not entitled to any declaratory judgment relief as to the constitutionality of the Dine Safe Ohio Director of Health Order, R.C. 3701.13 or any other administrative regulations or Health Department Orders issued pursuant to R.C. 3701.13; and
4. No damages can be recovered for the alleged violations of the Ohio Constitution since no private cause of action is afforded under Article 1, Sections 1, 2, 16, 19 and 20, or Article II, Section 1.

Defendants conceded that the Court could assess court costs to the Defendants upon resolution of this matter. Defendants did not file an Answer to Plaintiffs' Complaint.

The *Dine Safe Ohio* Order issued by Ohio Department of Health Director Amy Acton on June 5, 2020, and a subsequent Ohio Department of Health Order regarding the general mandatory wearing of facial coverings issued by Interim Ohio Department of Health Director Lance D. Himes on July 23, 2020 were both stated to be issued pursuant to the authority granted the Ohio Director of Health in R.C. 3701.13 to "make special orders…for preventing the spread of contagious or infections diseases."

This dispute arose when the Ashland County Health Department, through its Director, issued a cease-and-desist order asserting violations by Plaintiffs of the *Dine*

Safe Ohio Oder as issued by the Ohio Director of Health, Amy Acton. It was thereafter alleged by Defendants that Plaintiffs failed to comply with the terms of the cease-and-desist order, as well as the provisions of the *Dine Safe Ohio* Order, although Plaintiffs dispute that claim. At the direction of Heather Reffett, Ashland County Director of Health, the food service license of Plaintiffs' restaurant business was revoked, without any meaningful opportunity for a pre- or post-revocation hearing. There was no meaningful evidence presented to this Court to support a finding that the license revocation (without a meaningful opportunity for hearing) was based on an immediate danger to public health as required by R.C. 3717.49.

As a result of the license revocation, Plaintiffs initiated this cause of action, and the Court issued a temporary restraining order: precluding Defendants from enforcing the July 15, 2020 cease-and desist order; reinstating the Plaintiffs' food service license; and permitting Plaintiffs to legally operate their food service business pending further order of the Court.

Following the issuance of the temporary restraining order, the Parties agreed to the terms of a stipulated judgment entry regulating the conduct of the parties for the remaining pendency of this matter. That judgment entry, which was filed on August 28, 2020, and further set forth an agreement as to method/procedure for final resolution of the pending matter.

The Court conducted a bench trial on September 25, 2020 and September 30, 2020. During the bench trial, Defendants conceded and stipulated that no further enforcement action would be taken in the future by Defendants based on any of the findings, facts, or circumstances leading to the July 15, 2020 cease-and-desist order, and that Plaintiffs'

food service license was fully reinstated and would remain so consistent with the prior orders of the Court.

LAW AND DECISION

An injunction is an extraordinary remedy, equitable in nature, that should only be granted when there is no adequate remedy at law, and where it is necessary to prevent a future wrong that the law cannot. To be entitled to an injunction, Plaintiffs must demonstrate by clear and convincing evidence that (1) the plaintiff will suffer irreparable injury if the injunction is not granted, (2) the rights of third parties will not be unjustifiably harmed if the injunction is granted, and (3) the injunction will serve the public interest. *Szuch v. FirstEnergy Nuclear Operating Co.*, 2016-Ohio-620, P56, 60 N.E.3d 494, 510, 2016 Ohio App. LEXIS 539, *34-35 *Arndt v. P & M Ltd.*, 11th Dist. No. 2007-P-0037, 2008-Ohio 2316; *Novy v. Ferrara*, 11th Dist. No. 2013-P-0063, 2014-Ohio-1776; *Szuch v. FirstEnergy Nuclear Operating Co.*, 2016-Ohio-620, 60 N.E.3rd 494 (6th Dist.).

This proceeding is not a proceeding pursuant to 42 USC § 1983. There is no authority granting Plaintiffs a cause of action for damages arising from this proceeding asserting a violation of the Ohio Constitution. *Autumn Care Ctr., Inc. v. Todd*, 2014-Ohio-5235, 22 N.E.3d 1105 (5th Dist.); *PDU, Inc. v. City of Cleveland*, 8th Dist. No. 81944, 2003-Ohio-3671.

Despite Defendants' contention that the food service license was suspended pursuant to R.C. 3717.49(C)(1), the basis for the suspension was non-compliance with the *Dine Safe Ohio* Order. R.C. 3713.49(C)(1) only sets forth the ability to revoke a license without hearing upon the finding of an immediate danger to public health. This Court finds and determines that "an immediate danger to public health" was never

factually established nor scientifically demonstrated in this case, nor in support of the actions of the Ashland County Health Department.

The nature of this case is not one new to the courts in Ohio. Similar cases raising similar challenges to COVID-19-related orders of the Director of the Ohio Department of Health have met challenge in Lake County, Ohio [*Rock House Fitness, Inc. et al. v. Amy Acton, Director of the Ohio Dept. of Health, et al.*, Lake C.P. No. 20CV000631 (May 20, 2020)], and Erie County, Ohio [*ILMV DEV SPE, LLC, DBA Kalahari Resorts & Conventions, et al. v. Amy Acton, et al.*, Erie C.P. No. 2020-CV-0201]. In those cases, the respective courts found the COVID-19 related orders of the Ohio Department of Health to be unconstitutional, whether authorized by R.C. 3701.13 or arguably R.C. 3701.14(A). While this Court generally agrees with the positions expressed by the common pleas courts of both Lake County and Erie County, it is more inclined to agree with the Erie County Common Pleas Court that R.C. 3701.13 grants no authority to the Director of the Ohio Department of Health to issue or enforce mandatory mask, social distancing, or other similar type orders since there is ***no*** stated or implied authority in R.C. 3701.13 which authorizes any action to prevent the spread of contagious or infectious disease (the orders' express purpose). Under R.C. 3701.13, the Ohio Department of Health only has ultimate authority in matters of ***quarantine and isolation***. Furthermore, the orders at issue in Erie County, Lake County, as well as the *Dine Safe Ohio* Order in this case, fail to accomplish anything scientifically demonstrable, or otherwise corroborated with empirical data, to prevent the spread of contagious or infectious disease even if that purpose were authorized by R.C. 3701.13.

That being said; this Court does not believe it needs to render a lengthy decision on the lack of validity of the Ohio Department of Health mask mandates or the *Dine Safe Ohio* Order, since in this case, there is no justiciable issue remaining.

This case was initiated due to what this Court finds to be improper conduct on the part of the Director of the Ashland County Department of Health. However, the improper conduct has been cured and the ability of Plaintiffs to operate their food service establishment was reinstated. Contrary to the assertions of Plaintiffs, the fact that there remains an asserted claim for damages does not cause the justiciability of the declaratory judgment causes of action to survive, when that asserted claim for damages is not a matter for which this Court can exercise jurisdiction. This Court has no authority to award damages in this matter.

And as conceded by Plaintiffs, despite being given repeated opportunity to join the Ohio Attorney General as a party in this matter, or to otherwise serve the Attorney General with summons and notice of the proceeding, Plaintiffs have declined to do so, thereby denying this Court jurisdiction to issue declaratory judgments regarding the orders of the Ohio Department of Health. R.C. 2721.12(A); *Avery v. Rossford Ohio Transportation Improvement Dist.*, 145 Ohio App.3d 155; 2001 Ohio App. LEXIS 3443 (6th Dist. 2001).

Regarding injunctive relief, with the concessions already made by the Ashland County Department of Health, this Court cannot make the requisite finding that Plaintiffs will suffer irreparable harm if an injunction is not granted, since there is no pending enforcement action currently being pursued against Plaintiffs by the Ashland County Department of Health, there is no current threat of enforcement, and the food service

licensure of Plaintiffs has been restored. Under current circumstances, Plaintiffs are operating as they were prior to the cease-and-desist order and should not be subject to any further enforcement action. As the position of this Court has been made known, any further attempt to enforce Ohio Department of Health Orders relating to COVID-19 mask restrictions, will likely result in further restraint of any such attempt.

Consistent with this opinion, the Court finds there is no justiciable controversy currently pending, hereby dismisses the Complaint of Plaintiffs, but assesses the costs of these proceedings to the Defendants.

It is so ordered.

Ronald P. Forsthoefel, Judge

U.S. FOOD & DRUG ADMINISTRATION

March 11, 2020

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention
1600 Clifton Rd., MS D-14
Atlanta, GA 30333

Dear Dr. Redfield:

This letter clarifies the Emergency Use Authorization ("EUA") issued by the Food and Drug Administration ("FDA") on March 2, 2020, a copy of which is attached. The EUA, issued pursuant to section 564 of the Food, Drug, and Cosmetic ("FDCA" or "Act"), permits the emergency use and distribution of filtering facepiece respirators ("FFR"), certified by the National Institute of Occupational Safety and Health ("NIOSH"),[1] that had previously been intended for general use. Those FFRs subject to the EUA are defined in footnote 1 to the March 2 letter and are listed in Appendix A to that letter and are added to Appendix B once authorized by FDA.

As a result of the Public Health Emergency associated with Coronavirus Disease 2019 ("COVID-19"), there is shortage of FFRs intended for use by healthcare workers and others to mitigate further transmission of COVID-19. To address that shortage, the March 2, 2020 EUA letter permits NIOSH-approved FFRs to be distributed to healthcare workers and to others to mitigate further transmission of COVID-19. Given the new intended medical uses of those FFRs, those FFRs are deemed to be medical devices within the meaning of section 201(h) of the FDCA and therefore, subject to section 564 of the Act. While the EUA remains in effect, FFRs included within its scope are eligible for the liability protections of the Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-148 (2005), 42 U.S.C. § 247d-6d.
Once the Public Health Emergency abates and the EUA terminates, those general use FFRs will cease being medical devices and will not be subject to the jurisdiction of the FDA, provided that they are not distributed, marketed, or labeled with an intended medical use.
We also wish to clarify that any statements in the March 2 letter about the effectiveness of FFRs are those of the Department of Health and Human Services and are not attributable to any manufacturer.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

cc: Robert P. Charrow, Esq.

[1] NIOSH is a sub-agency within the Centers for Disease Control and Prevention.

EXHIBIT
B

We have the tools to
Fight Omicron


Vaccines & Booster


Masks


Testing

Types of Masks and Respirators

Updated Jan. 28, 2022

Summary of Recent Changes

Updates as of January 28, 2022

- Added information to present similar content for masks and respirators
- Clarified that people can choose respirators such as N95s and KN95s, including removing concerns related to supply shortages for N95s
- Clarified that "surgical N95s" are a specific type of respirator that should be reserved for healthcare settings
- Clarified that some types of masks and respirators provide more protection to the wearer than others

View Previous Updates

Key Messages:

- Masking is a critical public health tool for preventing spread of COVID-19, and it is important to remember that any mask is better than no mask.
- To protect yourself and others from COVID-19, CDC continues to recommend that you wear the most protective mask you can that fits well and that you will wear consistently.
- Masks and respirators are effective at reducing transmission of SARS-CoV-2, the virus that causes COVID-19, when worn consistently and correctly.
- Some masks and respirators offer higher levels of protection than others, and some may be harder to tolerate or wear consistently than others. It is most important to wear a well-fitting mask or respirator correctly that is comfortable for you and that provides good protection.
- While all masks and respirators provide some level of protection, properly fitting respirators provide the highest level of protection. Wearing a highly protective mask or respirator may be most important for certain higher risk situations, or by some people at increased risk for severe disease.
- CDC's mask recommendations provide infor mprove how well their masks protect them.

For information about how to use your N95 cor 5 Respirator.

EXHIBIT
C

FDA U.S. FOOD & DRUG ADMINISTRATION

April 24, 2020

To: Manufacturers of Face Masks;
Health Care Personnel;
Hospital Purchasing Departments and Distributors; and
Any Other Stakeholders.

On April 18, 2020, in response to concerns relating to insufficient supply and availability of face masks,[1,2] the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) authorizing the use of face masks for use by members of the general public, including health care personnel (HCP)[3] in healthcare settings as personal protective equipment (PPE), to cover their noses and mouths, in accordance with Centers for Disease Control and Prevention (CDC) recommendations, to prevent the spread of the virus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) during the Coronavirus Disease 2019 (COVID-19) pandemic, pursuant to section 564 of the Federal, Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) 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

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[1] A face mask is a device, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. It includes cloth face coverings as a subset. It may be for single or multiple uses, and if for multiple uses it may be laundered or cleaned. There are many products marketed in the United States as "face masks" that offer a range of protection against potential health hazards. Face masks are regulated by FDA when they meet the definition of a "device" under section 201(h) of the Act. Generally, face masks fall within this definition when they are intended for a medical purpose. Face masks are regulated under 21 CFR 878.4040 as Class I 510(k)-exempt devices (non-surgical masks).

[2] Surgical masks are not covered within the scope of this authorization. Surgical masks are masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials and are regulated under 21 CFR 878.4040 as class II devices requiring premarket notification. Additionally, these masks meet certain fluid barrier protection standards and Class I or Class II flammability tests. More information on the distinction is provided in FDA guidance, titled "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency" available at https://www.fda.gov/media/136449/download.

[3] HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

EXHIBIT
D

citizens living abroad, and that involves the virus that causes COVID-19.[4] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.[5]

On April 24, 2020 in response to questions and concerns that have been received by FDA since issuance of the April 18, 2020 letter of authorization and having concluded that revising the April 18, 2020 EUA is appropriate to protect the public health or safety under section 564(g)(2)(c) of the Act (21 U.S.C. § 360bbb-3(g)(2)(c)), FDA is reissuing the April 18, 2020 letter in its entirety with amendments[6] incorporated. Specifically, FDA is clarifying through this re-issued letter that facemasks, including cloth face coverings, are authorized to be used by HCP only as source control[7,8] in accordance with CDC recommendations under this EUA.[9] As stated in the April 18 letter, face masks are authorized for use by the general public to cover their noses and mouths, in accordance with CDC recommendations.

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 face masks for use in accordance with CDC recommendations, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

For the most current CDC recommendations on the use of face masks by the general public during COVID-19, please visit CDC's webpage: Recommendation Regarding the Use of Cloth Face Coverings, Especially in Areas of Significant Community-Based Transmission For the most recent recommendations on use of face masks by HCPs in a healthcare setting, see: Strategies to Optimize the Supply of PPE and Equipment.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of face masks in accordance with CDC recommendations as source control as described in the Scope of Authorization (Section II) to

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[4] 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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020)

[5] 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 17335 (March 27, 2020).

[6] The amendments to the April 18, 2020 letter clarify that the eligible facemasks are to be used for source control only, and are not personal protective equipment, meaning they are not a substitute for filtering face piece respirators or for surgical face masks. This reissued EUA does not change any aspects of the April 18, 2020 letter with respect to the use of face masks by the general public.

[7] Source control refers to the use of a facemask or cloth face covering over the mouth and nose to contain that individual's respiratory secretions to help prevent transmission from infected individuals who may or may not have symptoms of COVID-19.

[8] https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html

[9] In addition, health care employers should refer to standards of the Occupational Safety and Health Administration (OSHA) that apply to PPE to protect workers and infectious disease hazards. *See* 29 CFR 1910 subpart I.

U.S. FOOD & DRUG ADMINISTRATION

August 5, 2020

To: Manufacturers of Surgical Masks;
Health Care Personnel;
Hospital Purchasing Departments;
Authorized Distributors and Authorized Importers; and
Any Other Stakeholders

The U.S. Food and Drug Administration (FDA) is issuing this Emergency Use Authorization (EUA) in response to concerns relating to the insufficient supply and availability of disposable, single-use surgical masks[1,2] (hereafter also referred to as "surgical masks") for use in healthcare settings by health care personnel (HCP)[3] as personal protective equipment (PPE)[4] to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the Coronavirus Disease 2019 (COVID-19) pandemic, pursuant to section 564 of the Federal, Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of 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 COVID-19.[5]

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[1] A surgical mask is a mask that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. Surgical masks are generally regulated by FDA as Class II devices under 21 CFR 878.4040 – Surgical apparel.

[2] FDA-cleared surgical face masks, non-surgical face masks, surgical masks with antimicrobial/antiviral agent, and all particulate filtering facepiece respirators are not within the scope of this authorization.

[3] For the purposes of this EUA, HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

[4] Surgical masks may be effective in blocking splashes and large particle droplets. While surgical masks are not protective against smaller airborne particulates as described in Section II, they are considered PPE because they are intended to be used to protect HCP from infectious disease hazards. Surgical masks are different from non-surgical face masks, which are only used as source control by the general public and are not considered PPE.

[5] 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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

EXHIBIT
E

Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.[6]

As discussed further below, I have concluded that a surgical mask meeting the criteria set forth in Section II meets the criteria for issuance of an EUA under Section 564(c) of the Act.

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 surgical masks that meet the criteria set forth in Section II pursuant to the Conditions of Authorization (Section IV) of this letter (referred to in this letter as "authorized surgical masks"). Authorized surgical masks will be added to this letter of authorization in Appendix A, as described in the Scope of Authorization (Section II).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of authorized surgical masks as described in the Scope of Authorization (Section II) of this letter for use in healthcare settings by HCP as PPE during the COVID-19 pandemic meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized surgical masks may be effective for use in healthcare settings by HCPs as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic, and that the known and potential benefits of the authorized surgical masks, when used consistent with the scope of this authorization (Section II), outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of these authorized surgical masks for use in healthcare settings by HCP to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic.[7,8]

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[6] 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 17335 (March 27, 2020).

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

[8] There are not sufficient quantities of surgical masks to meet the needs of the U.S. healthcare system. These articles of PPE are an integral part of patient care during the COVID-19 pandemic. Providing authorization for the introduction into interstate commerce of surgical masks by manufacturers, including those that do not customarily engage in the manufacture of medical devices, helps meet the needs of the healthcare system. Providing HCP who

U.S. FOOD & DRUG ADMINISTRATION

August 23, 2021

Pfizer Inc.
Attention: Ms. Elisa Harkins
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Harkins:

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 Federal Food, Drug, and Cosmetic 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.

EXHIBIT
F

10, 2021,[5] June 25, 2021,[6] and August 12, 2021.[7]

On August 23, 2021, FDA approved the biologics license application (BLA) submitted by BioNTech Manufacturing GmbH for COMIRNATY (COVID-19 Vaccine, mRNA) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.

On August 23, 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 12, 2021 letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses, and to authorize use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved 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 to update 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).

Pfizer-BioNTech COVID-19 Vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. 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.[8]

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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] 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.

U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125742/0

BLA APPROVAL

BioNTech Manufacturing GmbH
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

August 23, 2021

Dear Mr. Patel:

Please refer to your Biologics License Application (BLA) submitted and received on May 18, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, Mainz, Germany, under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

The review of this product was associated with the following National Clinical Trial (NCT) numbers: NCT04368728 and NCT04380701.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture COVID-19 Vaccine, mRNA drug substance at Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC, 1 Burtt Road, Andover, Massachusetts. The final formulated product will be manufactured, filled, labeled and packaged at Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium and at Pharmacia & Upjohn Company LLC, 7000 Portage Road, Kalamazoo, Michigan. The diluent, 0.9% Sodium Chloride Injection, USP, will be manufactured at Hospira, Inc., (b) (4) and at Fresenius Kabi USA, LLC, (b) (4) .

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EXHIBIT
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You may label your product with the proprietary name, COMIRNATY, and market it in 2.0 mL glass vials, in packages of 25 and 195 vials.
We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for COVID-19 Vaccine, mRNA shall be 9 months from the date of manufacture when stored between -90°C to -60°C (-130°F to -76°F). The date of manufacture shall be no later than the date of final sterile filtration of the formulated drug product (at Pharmacia & Upjohn Company LLC in Kalamazoo, Michigan, the date of manufacture is defined as the date of sterile filtration for the final drug product; at Pfizer Manufacturing Belgium NV in Puurs, Belgium, it is defined as the date of the (b) (4)

Following the final sterile filtration, (b) (4)

, no reprocessing/reworking is allowed without prior approval from the Agency. The dating period for your drug substance shall be (b) (4) when stored at (b) (4) We have approved the stability protocols in your license application for the purpose of extending the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

Please submit final container samples of the product in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations:

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EXHIBIT H

NEWS: DailyMed Announcements

NEWS FROM THE YEAR

2021

Pfizer received FDA BLA license on 8/23/2021 for its COVID-19 vaccine

Posted: September 13, 2021

Pfizer received FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older (COMIRNATY). At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename COMIRNATY and listed 2 new NDCs (0069-1000-03, 0069-1000-02) and images of labels with the new tradename.

At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may not publish these new codes until Pfizer has determined when the product will be produced with the BLA labels.

COVID-19 vaccine codes and crosswalks are provided in anticipation of potential vaccine availability under an approved Biologics License Application (BLA), Emergency Use Authorization (EUA), or as a potential vaccine submission for EUA (Pre-EUA) as of 12/09/2021. Codes will become effective for US vaccine administrations only upon EUA issuance and/or BLA approval of COVID-19 vaccine(s) by the FDA. All CVX codes are associated to the new Vaccine Group "COVID-19." CPT Codes shown are product codes. CPT administrative codes for doses are available on the AMA website. CPT product codes are added as the AMA approves and makes them available.

Manufacturer	FDA Authorization (BLA, EUA, Pre-EUA)	Sale Proprietary Name	Product Description	Unit of Sale NDC10 (UOS)	UoS Package	Unit of Use NDC10 (UOU)	UoU Presentation	CVX Code	CVX Long Description	CVX Short Description	MVX Code	CPT Product Code	CPT Description
Janssen Products, LP	EUA-authorized (18+)	Janssen COVID-19 Vaccine	5x10^10 viral particles/0.5 mL for adult 18+	59676-580-15	CARTON, 10 MULTI-DOSE VIALS	59676-580-05	VIAL, MULTI-DOSE	212	SARS-COV-2 (COVID-19) vaccine, vector non-replicating, recombinant spike protein-Ad26, preservative free, 0.5 mL	COVID-19 vaccine, vector-nr, rS-Ad26, PF, 0.5 mL	JSN	91303	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x1010 viral particles/0.5 mL dosage, for intramuscular use
Moderna US, Inc	EUA-authorized (18+)	Moderna COVID-19 Vaccine	100 mcg/0.5 mL for adult 18+ (existing product)	80777-273-99	CARTON, 10 MULTI-DOSE VIAL 5 mL EACH	80777-273-10	VIAL, 5 mL, MULTI-DOSE VIAL	207	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 100 mcg or 50 mcg dose	COVID-19, mRNA, LNP-S, PF, 100 mcg or 50 mcg dose	MOD	91301	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5 mL dosage, for intramuscular use
				80777-273-98	CARTON, 10 MULTI-DOSE VIAL 7 mL EACH	80777-273-15	VIAL, 7 mL, MULTI-DOSE VIAL						
Moderna US, Inc.	EUA-authorized (18+)	Moderna COVID-19 Vaccine	50 mcg/0.25 mL for booster adult 18+ (existing product)	80777-273-99	CARTON, 10 MULTI-DOSE VIAL 5 mL EACH	80777-273-10	VIAL, 5 mL, MULTI-DOSE VIAL					91306	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.25 mL dosage, for intramuscular use
				80777-273-98	CARTON, 10 MULTI-DOSE VIAL 7 mL EACH	80777-273-15	VIAL, 7 mL, MULTI-DOSE VIAL						
	BLA-licensed (16+) EUA-authorized (12+)	Pfizer-BioNTech COVID-19 Vaccine	30 mcg/0.3 mL ages 12+ (existing product)	59267-1000-2	CARTON, 195 MULTI-DOSE VIALS	59267-1000-1	MULTI-DOSE VIAL	208	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 30 mcg/0.3 mL dose	COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose	PFR	91300	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted, for intramuscular use
				59267-1000-3	CARTON, 25 MULTI-DOSE VIALS								
	EUA-authorized (16+)	Pfizer-BioNTech COVID-19 Vaccine	30 mcg/0.3 mL for booster (existing product)	59267-1000-2	CARTON, 195 MULTI-DOSE VIALS	59267-1000-1	MULTI-DOSE VIAL					91309	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, diluent reconstituted, for intramuscular use
				59267-1000-3	CARTON, 25 MULTI-DOSE VIALS								
	EUA-authorized	Pfizer-BioNTech COVID-19 Vaccine	Tris-sucrose formula, 30 mcg/0.3 mL for ages 12+	59267-1025-2	CARTON, 195 MULTI-DOSE VIALS	59267-1025-1	VIAL, 2.25 mL, MULTI-DOSE VIAL	217	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 30 mcg/0.3 mL dose, tris-sucrose formulation	COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose, tris-sucrose	PFR	91305	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use
				59267-1025-3	CARTON, 25 MULTI-DOSE VIALS								
				59267-1025-4	CARTON, 10 MULTI-DOSE VIALS								
Pfizer-BioNTech	EUA-authorized	Pfizer-BioNTech COVID-19 Vaccine	Tris-sucrose formula, 10 mcg/0.2 mL for ages 5 yrs to < 12 yrs	59267-1055-2	CARTON, 195 MULTI-DOSE VIALS	59267-1055-1	VIAL, 2 mL, MULTI-DOSE VIAL	218	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 10 mcg/0.2 mL dose, tris-sucrose formulation	COVID-19, mRNA, LNP-S, PF, 10 mcg/0.2 mL dose, tris-sucrose	PFR	91307	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use
				59267-1055-4	CARTON, 10 MULTI-DOSE VIALS								
Pfizer-BioNTech	Pre-EUA	Pfizer-BioNTech COVID-19 Vaccine	Tris-sucrose formula, 3 mcg/0.2 mL for ages 2 yrs to < 5 yrs	59267-0078-2	CARTON, 195 MULTI-DOSE VIALS	59267-0078-1	VIAL, 2 mL, MULTI-DOSE VIAL	219	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 3 mcg/0.2 mL dose, tris-sucrose formulation	COVID-19, mRNA, LNP-S, PF, 3 mcg/0.2 mL dose, tris-sucrose	PFR	TBD	TBD
				59267-0078-4	CARTON, 10 MULTI-DOSE VIALS								

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Pfizer-BioNTech	BLA-licensed (16+)	COMIRNATY	30 mcg/0.3 mL for adult 16+ (existing formula)	00069-1000-02	CARTON, 195 MULTI-DOSE VIALS	00069-1000-01	VIAL, 2 mL, MULTI-DOSE VIAL	**COMIRNATY products are not orderable at this time. NDCs are listed per FDA Structured Product Label (SPL) document for the BLA licensed product. These codes are not included in CDC Vaccine Code Set files at this time. Pfizer has provided the following statement regarding the COMIRNATY branded NDCs and labels:** **"Pfizer received FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older (COMIRNATY). At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename COMIRNATY and listed 2 new NDCs [0069-1000-03, 0069-1000-02] and images of labels with the new tradename.** **At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may not publish these new codes until Pfizer has determined when the product will be produced with the BLA labels."**					
				00069-1000-03	CARTON, 25 MULTI-DOSE VIALS								
AstraZeneca Pharmaceuticals LP	Pre-EUA	AstraZeneca COVID-19 Vaccine	5x10^10 viral particles/0.5 mL, adult	No active NDC codes for U.S. Market				210	SARS-COV-2 (COVID-19) vaccine, vector non-replicating, recombinant spike protein-ChAdOx1, preservative free, 0.5 mL	COVID-19 vaccine, vector-nr, rS-ChAdOx1, PF, 0.5 mL	AZ	91302	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, chimpanzee adenovirus Oxford 1 (ChAdOx1) vector, preservative free, 5x1010 viral particles/0.5 mL dosage, for intramuscular use
Novavax, Inc.	Pre-EUA	Novavax COVID-19 Vaccine	5 mcg/0.5 mL, adult	No active NDC codes for U.S. Market				211	SARS-COV-2 (COVID-19) vaccine, Subunit, recombinant spike protein-nanoparticle+Matrix-M1 Adjuvant, preservative free, 0.5mL per dose	COVID-19 vaccine, Subunit, rS-nanoparticle+Matrix-M1 Adjuvant, PF, 0.5 mL	NVX	91304	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5 mL dosage, for intramuscular use

Unspecified US COVID-19 Vaccine CVX Code

CVX Short Description	CVX Code	CVX Long Description	Note	Vaccine Status
SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED	213	SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED	Unspecified code for COVID-19 not to be used to record patient US administration. May be used to record historic US administration if product is not known. CVX code 500 should be used to record Non-US vaccine where product is not known.	Inactive

FDA U.S. FOOD & DRUG ADMINISTRATION

January 31, 2022

ModernaTX, Inc.
Attention: Ms. Michelle Olsen
200 Technology Square
Cambridge, MA 02139

Dear Ms. Olsen:

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 19, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Moderna COVID-19 Vaccine for the prevention of COVID-19 for individuals 18 years of age and older, pursuant to Section 564 of the Act. FDA reissued the letter of authorization on: February 25, 2021,[3] July 7, 2021,[4] August 12, 2021,[5]

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[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 Federal Food, Drug, and Cosmetic 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 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 ModernaTX, Inc.

[4] In the July 7, 2021 revision, FDA clarified terms and conditions that relate to export of Moderna COVID-19 Vaccine from the United States.

[5] In the August 12, 2021 revision, FDA authorized for emergency use a third dose of the Moderna COVID-19 vaccine administered at least 1 month following the two dose regimen of this vaccine in individuals 18 years of age

EXHIBIT
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October 20, 2021,[6] November 19, 2021,[7] and January 7, 2022.[8]

On January 31, 2021, FDA approved the biologics license application (BLA) submitted by ModernaTX, Inc. for SPIKEVAX (COVID-19 Vaccine, mRNA) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

On January 31, 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 January 7, 2022 letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Moderna COVID-19 Vaccine for the previously-authorized indication and uses, and to authorize the use of SPIKEVAX (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved BLA. In addition, FDA is revising the Fact Sheet for Recipients and Caregivers as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the Fact Sheet for the authorized Moderna COVID-19 Vaccine and information about the FDA-licensed vaccine, SPIKEVAX (COVID-19 Vaccine, mRNA), as well as the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers).

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or older who have undergone solid organ transplantation, or individuals 18 years of age or older who have been diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

[6] In the October 20, 2021 revision, FDA authorized for emergency use the administration of a single booster dose of Moderna 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 with frequent institutional or occupational exposure to SARS-CoV-2. Additionally, FDA authorized the administration of a single booster dose of the Moderna COVID-19 Vaccine as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose were the same as those authorized for a booster dose of the vaccine used for primary vaccination.

[7] In the November 19, 2021 revision, FDA authorized the use of Moderna COVID-19 Vaccine as a single booster dose in individuals 18 years of age or older at least 6 months after completing the primary series of this vaccine (i.e., as a homologous booster dose), and authorized the use of the vaccine as a single booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine (i.e., as a heterologous booster dose) in individuals 18 years of age or older. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

[8] In the January 7, 2022 revision, FDA revised the authorized dosing interval of the homologous booster dose to at least five (5) months after completion of the primary series of this vaccine. In addition, FDA revised the Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers to reflect this revision.

Moderna COVID-19 Vaccine is for use for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. The vaccine contains a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. SPIKEVAX (COVID-19 Vaccine, mRNA) is the same formulation as the Moderna COVID-19 Vaccine and can be used interchangeably with the Moderna COVID-19 Vaccine to provide the COVID-19 vaccination series.[9]

For the December 18, 2020 authorization for individuals 18 years of age and older, FDA reviewed safety and efficacy data from an ongoing phase 3 trial in approximately 30,000 participants randomized 1:1 to receive Moderna COVID-19 Vaccine or saline control. The trial enrolled participants 18 years of age and older. FDA's review of the available safety data from 30,351 participants 18 years of age and older, who were followed for a median of 7 weeks after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. Review of additional safety data from these participants with a median of 9 weeks of follow-up after receipt of the second dose did not change FDA's assessment of safety of the vaccine. FDA's analysis of the efficacy data from 28,207 participants 18 years of age and older without evidence of SARS-CoV-2 infection prior to dose 1 confirms the vaccine was 94.1% effective (95% confidence interval (CI) 89.3, 96.8) in preventing COVID-19 occurring at least 14 days after the second dose (with 11 COVID-19 cases in the vaccine group compared to 185 COVID-19 cases in the placebo group). In this final scheduled analysis participants had been followed for a median of 9 weeks following the second dose. This result is consistent with that obtained from an interim analysis of efficacy conducted after these participants had been followed for a median of 7 weeks after the second dose (vaccine efficacy 94.5%, 95% CI: 86.5, 97.8). Based on the safety and effectiveness data, and review of manufacturing information regarding product quality and consistency, it is reasonable to believe that Moderna COVID-19 Vaccine may be effective. Additionally, it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Moderna COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 18 years of age and older. Finally, on December 17, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

For the August 12, 2021 authorization of a third primary series dose of the Moderna COVID-19 vaccine in individuals 18 years of age or older who have undergone solid organ transplantation, or individuals 18 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 double-blind, randomized-controlled study conducted in 120 individuals who had undergone various

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[9] 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.

U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125752/0

BLA APPROVAL

ModernaTX, Inc.
Attention: Michelle Olsen
200 Technology Square
Cambridge, MA 02139

January 31, 2022

Dear Dr. Olsen:

Please refer to your Biologics License Application (BLA) submitted and received August 24, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2256 to ModernaTX, Inc., Cambridge, Massachusetts, under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product COVID-19 Vaccine, mRNA, which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

The review of this product was associated with the following National Clinical Trial (NCT) numbers: 04283461; 04405076; 04470427; 04649151; 04796896; 04860297; 04927065

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture COVID-19 Vaccine, mRNA, drug substance at ModernaTX, Inc., 1 Moderna Way, Norwood, MA, and Lonza Biologics, Inc., 101 International Drive, Portsmouth, NH. The final formulated product will be manufactured, filled, labeled and packaged at Catalent Indiana, LLC (a subsidiary of Catalent Pharma Solutions, LLC), 1300 S. Patterson Drive, Bloomington, IN, and Baxter BioPharma Solutions, 927 S. Curry Pike, Bloomington, IN.

You may label your product with the proprietary name SPIKEVAX and market it in 10 mL vials containing a maximum of 11 or 15 doses per vial (0.5 mL/dose), in packages of 10 multiple-dose vials.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

EXHIBIT
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ADVISORY COMMITTEE

We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for COVID-19 Vaccine, mRNA shall be 9 months from the date of manufacture when stored at -25°C to -15°C. The date of manufacture shall be defined as the date of final sterile filtration of the formulated drug product. Following the final sterile filtration, no reprocessing/reworking is allowed without prior approval from the Agency. The dating period for your drug substance shall be (b) (4) months when stored at (b) (4). We have approved the stability protocol in your license application for the purpose of extending the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

Please submit final container samples of the product in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations :

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