IN THE COURT OF COMMON PLEAS
ATHENS COUNTY, OHIO

BAILEY MARTIN, ET AL.	:	
	:	Case No.: 21CI0221
Plaintiffs,	:	
	:	JUDGE MCCARTHY
v.	:	
	:	
OHIO UNIVERSITY, ET AL.,	:	
	:	
Defendants.	:	
	:	

DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' COMPLAINT

Pursuant to Ohio Rule of Civil Procedure 12(B)(6), defendants Ohio University and its Board of Trustees, Cary Cooper, Lorrie Platt, Scott Borgemenke, Misty Crosby, Janelle Coleman, Steve Casciani, Diane Smullen, Peggy Viehweger, and Matthew Evans (collectively "Defendants"), respectfully move the Court to dismiss Plaintiffs' Complaint in its entirety and with prejudice. The grounds for this Motion are set forth in the accompanying Memorandum in Support.

Respectfully submitted,

DAVID A. YOST
ATTORNEY GENERAL OF OHIO

By: /s/ Michael N. Beekhuizen

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MEMORANDUM IN SUPPORT

I. INTRODUCTION.

More than four months ago, Ohio University adopted a Community Health Directive to address the ongoing risks associated with the COVID-19 pandemic. Plaintiffs (a group of students and an employee) now contend that the Community Health Directive's vaccine and mask provisions are illegal. Plaintiffs' claims, however, plainly lack merit and should be dismissed for multiple reasons.

First, the Butler County Court of Common Pleas recently dismissed a nearly identical complaint filed by the same counsel against Miami University. *See Siliko v. Miami University*, Butler C.P. No. CV-2021-10-1467 (Dec. 6, 2021) (attached as Ex. A.). In *Siliko*, the court held the plaintiffs lacked standing because they either had failed to apply for the exemption available under Miami University's vaccine policy or had applied for and received an exemption. *Id.* at 2-3. Here, Ohio University's Community Health Directive likewise provides for exemptions. *See* Complaint, Exhibit 1 at 3, 6. Plaintiffs fail to allege that they have applied for (or have been denied) the available exemptions. Accordingly, as in *Siliko*, Plaintiffs lack standing to challenge the Community Health Directive.

Second, Plaintiffs allege that the Community Health Directive violates O.R.C. § 3792.04, which became effective on October 13, 2021. Section 3792.04 generally prohibits discrimination between unvaccinated persons and persons who have received an emergency use vaccine. Section 3792.04, however, does not apply where an FDA approved vaccine exists. Here, the FDA has approved the Pfizer vaccine. But even if § 3792.04 applied here – and it does not – the Community Health Directive's vaccine provisions do not discriminate because an exemption is available for any person who does not want to be vaccinated. The Directive's mask provisions likewise do not

discriminate because they apply equally to students and staff regardless of vaccination status. And, Plaintiffs fail to allege that they have been required to participate in testing or have been subjected to any actual penalties as a result of their vaccination status. In other words, Plaintiffs fail to allege any actual instances of discrimination against themselves, let alone since the October 13, 2021 date that O.R.C. § 3792.04 became effective.

Third, Plaintiffs assert claims under statutes that plainly have no application here. Plaintiffs, for example, allege the Community Health Directive violates O.R.C. § 3709.212, which only applies to the boards of health of cities or general health districts. It does not apply to public universities like Ohio University. Plaintiffs also allege the Community Health Directive violates O.R.C. § 2905.12, which is a criminal statute prohibiting coercion. As several courts have held, § 2905.12 does not create a civil cause of action.

Lastly, Plaintiffs contend that the Community Health Directive's mask provisions violate Plaintiffs' alleged constitutional right to refuse medical treatment. The Directive's mask provisions, however, do not require any medical treatment and are well within the statutory and constitutional authority of Ohio University to protect students and staff from the ongoing COVID-19 pandemic. There is no constitutional violation here. Plaintiffs' claims should be dismissed as discussed further below.

II. PLAINTIFFS' ALLEGATIONS.

Plaintiffs allege that they are students and an employee at Ohio University. Complaint ¶¶ 10, 11. They further allege that Ohio University adopted a Community Health Directive on August 31, 2021, which provides members of the Ohio University community with updated guidance on a variety of topics including COVID testing, contact tracing, quarantines, vaccine requirements, social distancing, and masking while indoors and while riding public transportation on campus.

Complaint ¶ 2; *see also* Directive at pp. 2-6 (attached as Ex. 1 to Complaint). Plaintiffs allege the vaccine and mask provisions of the Directive violate O.R.C. §§ 2905.12, 3709.212, and 3792.04, as well as Article I, Section 1 of the Ohio Constitution. Complaint ¶¶ 6-9. Based on these allegations, Plaintiffs seek both a declaration that the Community Health Directive is void and an injunction to stop its enforcement. Complaint ¶¶ 14-17, 36-41.

Plaintiffs fail to mention, however, that the Community Health Directive contains several exemptions from its vaccine and mask provisions. The Directive's vaccine provisions, for example, expressly provide an exemption not only for medical reasons, but also "for reasons of conscience, including ethical and moral belief or sincerely held religious beliefs." *See* Complaint Ex. 1 (Directive at p. 6, § 7). The Directive's mask provisions, likewise, provide several exceptions and a general exemption, which may be applied for. *Id.* (Directive at p. 3, § 1.g). The mask provisions also apply equally to all students and staff regardless of vaccination status. *Id.* (Directive at p. 2, § 1 ("All individuals are required to wear masks in indoor public spaces on OHIO campuses, and on public transportation")). Plaintiffs fail to allege that they have applied for (or been denied) the exemptions available to them under the Directive. Lastly, Plaintiffs also fail to allege that they have been subjected to any penalties under the Directive.[1]

III. PLAINTIFFS LACK STANDING.

Under Ohio law, "[a] matter is justiciable only if the complaining party has standing to sue." *ProgressOhio.org, Inc. v. JobsOhio*, 139 Ohio St.3d 520, 2014-Ohio-2382, 13 N.E.3d 1101, ¶ 11. To establish standing, a litigant must show that he or she has suffered "(1) an injury that is

[1] O.R.C. §§ 3345.21 and 3345.021 provide the Ohio University Board of Trustees with full authority to regulate "the use of the grounds, buildings, equipment, and facilities" of the university as well as "the conduct of the students, staff, faculty, and visitors to the campus[.]" The Community Health Directive falls squarely within this statutory authority.

(2) fairly traceable to the defendant's allegedly unlawful conduct and (3) likely to be redressed by the requested relief." *Moore v. Middletown*, 133 Ohio St.3d 55, 2012-Ohio-3897, 975 N.E.2d 977, ¶ 22 (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–561, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992)).

Here, Plaintiffs lack standing because they do not allege they have applied for (or been denied) the exemptions available to them under the Community Health Directive. The Butler County Court of Common Pleas recently reached the same conclusion in a virtually identical case filed by the same counsel against Miami University. *See Siliko v. Miami University*, Butler C.P. No. CV-2021-10-1467 (Dec. 6, 2021) (attached as Ex. A.). As the *Siliko* court explained, a plaintiff who "fails to submit to the procedural requirements of a policy that offers an exemption" cannot show that he or she has been injured by the policy's requirements and thus lacks standing to challenge that policy. *Id.*

Furthermore, the *Siliko* court's decision is consistent with other courts that have held plaintiffs lack standing to challenge a university's vaccine policy, where plaintiffs either received an exemption or had not requested one. *See, e.g., Wade v. University of Connecticut Board of Trustees*, 2021 WL 3616035 at *8 (D. Conn. Aug. 16, 2021) ("a plaintiff who fails to submit to the procedural requirements of a law or policy that offers an exemption or other relief from its mandate does not have standing to challenge the restrictions imposed by the law or policy").

In summary, Plaintiffs lack standing because they have not alleged they have applied for (or been denied) the available exemptions under the Community Health Directive. Plaintiffs simply have failed to allege any actual injury traceable to Defendants' alleged conduct. *Id.* Plaintiffs' claims therefore should be dismissed for lack of standing.

IV. PLAINTIFFS ARE NOT ENTITLED TO DECLARATORY OR INJUNCTIVE RELIEF.

In addition to lack of standing, Plaintiffs' claims also fail because they have not identified any substantive grounds entitling them to declaratory or injunctive relief. The statutory and constitutional provisions cited by Plaintiffs plainly do not apply here, as discussed further below.

A. O.R.C. § 2905.12 Does Not Apply Because It Is A Criminal Statute And Does Not Give Rise To A Civil Cause Of Action.

O.R.C. § 2905.12 makes it a *crime* to "coerce another into taking or refraining from action" under certain specified circumstances. However, "[i]n the absence of a specific provision to the contrary, criminal statutes generally do not create a private cause of action, but give rise only to a right of prosecution by the state." *George v. State*, 10th Dist. Franklin No. 10AP-4, 2010-Ohio-5262, ¶ 32. In fact, other courts have held that O.R.C. § 2905.12 does not give rise to a civil cause of action. *Simpson v. Voiture Nationale La Societe Des Quarante Hommes*, 2d. Dist. Montgomery No. 29016, 2021-Ohio-2131, ¶ 25; *Heskett v. Van Horn Title Agency, Inc.*, 10th Dist. Franklin No. 06AP-549, 2006-Ohio-6900, ¶ 26. Accordingly, O.R.C. § 2905.12 has no application here and does not support Plaintiffs' claims for declaratory or injunctive relief.

B. O.R.C. § 3709.212 Does Not Apply Because Defendants Are Not a City Or General Health District.

O.R.C. § 3709.212 places certain restrictions on public health orders "issued by a board of health of a city or general health district[.]" For purposes of O.R.C. § 3709.212, "[e]ach city constitutes a city health district" and the "townships and villages in each county shall be combined into a general health district." O.R.C. § 3709.01. Here, Defendants are not a city, a township, or a village, let alone a city or general health district. Accordingly, O.R.C. § 3709.212 has no application here and does not support Plaintiffs' claims for declaratory or injunctive relief.

C. O.R.C. § 3792.04 Has No Application Here Because The Community Health Directive Contains Exemptions And Because The Pfizer Vaccine Has Received Full FDA Approval.

O.R.C. § 3792.04 became effective on October 13, 2021. Generally, § 3792.04(B)(1) prohibits state institutions of higher education from "[r]equir[ing] an individual to receive a vaccine for which the United States food and drug administration has not granted full approval." Section 3792.04(B)(2), in turn, prohibits state institutions of higher education from "[d]iscriminat[ing] against an individual who has not received a vaccine as described in division (B)(1) of this section[.]" This statute does not apply here for several reasons.

First, O.R.C. § 3792.04 only applies with respect to vaccines, which have *not* received full approval from the FDA. *See* O.R.C. §§ 3792.04(B)(1) & (2). The Pfizer vaccine, however, has been fully approved by the FDA. *See* August 23, 2021 FDA Press Release, *FDA Approves First COVID-19 Vaccine* (copy attached as Ex. B). In an effort to avoid this undisputable fact, Plaintiffs allege that only the "Comirnaty" vaccine has been approved. *See* Complaint ¶ 25. But, as the FDA itself has explained, "Comirnaty" is simply the marketing name of the Pfizer vaccine and has the "same formulation." *See* Ex. B at p.1, 2 (the vaccine "known as the Pfizer-BioNTech COVID-19 vaccine" will "now be marketed as Comirnaty"; "Comirnaty has the same formulation as the EUA vaccine"); *see also* January 4, 2022 FDA *Q&A for Comirnaty (COVID-19 Vaccine mRNA)* at p. 2 (attached as Ex. C) ("doses distributed under the EUA are interchangeable with the licensed doses"). Accordingly, because there is an FDA approved vaccine, O.R.C. § 3792.04 has no application here.

Second, even if O.R.C. § 3792.04 somehow applied – and it does not – Plaintiffs have failed to allege any actual violation of the statute. As discussed, the Directive does not require anyone to take a vaccine inasmuch as exemptions are available to students and staff who apply for

them. While the Directive also provides an alternative weekly testing program for unvaccinated individuals, Plaintiffs do not allege they have been required to engage in any such testing. *See* Complaint Ex. 1 (Directive at p. 5, § 6). And, with respect to masks, the Directive's mask provisions apply equally to all students and staff *regardless* of vaccination status. *See* Complaint Ex. 1 (Directive at p. 2, § 1). In summary, Plaintiffs simply fail to allege any facts demonstrating any actual statutory violation. Section 3792.04 does not support Plaintiffs' claims for declaratory and injunctive relief.

D. The Community Health Directive Does Not Violate Article 1, Section 1 Of The Ohio Constitution.

In a last-ditch argument, Plaintiffs cite to the Ohio Supreme Court's *Steele* decision for the proposition that the Community Health Directive's mask provisions somehow constitute a violation of their alleged constitutional right to refuse medical treatment. *See* Complaint ¶ 28; *see also Steele v. Hamilton Cty Community Mental Health Bd.*, 90 Ohio St.3d 176, 180, 736 N.E.2d 10 (2000). Plaintiffs are wrong again.

The *Steele* case involved the forced administration of antipsychotic medication to an involuntarily admitted mentally ill patient. *See Steele* at 180. This is in stark contrast to the Directive's mask provisions, which only require the temporary wearing of a cloth mask while indoors or on public transportation. The Directive's mask provisions do not require any forced medication. They do not require any invasive medical procedures. They do not require any medical treatment. And, should any doubt remain, the mask provisions also provide for several exceptions and an exemption, which may be applied for. *Id.* (Directive at p. 3, § 1.g). The mask provisions simply do not implicate any constitutional concerns regarding medical treatment.

Furthermore, multiple courts have rejected constitutional challenges to university COVID-19 policies like the one at issue here. *See, e.g., Klaassen v. Trustees of Indiana Univ.*, 7 F.4th 592

(7th Cir.2021) (rejecting constitutional challenge to Indiana University's vaccine and mask policies); *Messina v. The College Of New Jersey*, 2021 WL 4786114 (D. N.J. Oct. 14, 2021) (rejecting constitutional challenge to college's vaccine policy); *Children's Health Defense, Inc. v. Rutgers, The State University Of New Jersey*, 2021 WL 4398743 (D. N.J. Sept. 27, 2021) (same); *Harris v. University of Massachusetts*, 2021 WL 3848012 (D. Mass. Aug. 27, 2021) (same). This Court should do the same.

Lastly, the United States Supreme Court has long held that vaccinations can be mandated under a state's police powers. *Jacobson v. Massachusetts*, 197 U.S. 11, 25 S.Ct. 358, 49 L.Ed. 643 (1905). Certainly, if the state can require people to be vaccinated, it is constitutionally permissible for Defendants to require the use of a mask while inside university buildings or on campus buses. *See Klaassen* at 593 (discussing *Jacobson*). There is no constitutional violation here.[2]

V. CONCLUSION.

Plaintiffs lack standing to pursue their claims because they do not allege they have applied for (or been denied) the exemptions available to them under the Community Health Directive. Plaintiffs also lack standing because they fail to allege any actual injury traceable to Defendant's alleged conduct.

Plaintiffs' claims likewise have no substantive merit. The statutes cited by Plaintiffs do not apply for multiple reasons: (a) O.R.C. § 2905.12 does not apply because there is no civil cause of action for criminal coercion; (b) O.R.C. § 3709.212 does not apply because Defendants are not

[2] Plaintiffs' constitutional arguments appear to be limited to the Community Health Directive's mask provisions. In any event, there also is no constitutional violation with respect to the vaccination provisions because, as noted, exemptions are available to students and staff who request one. It also is constitutionally permissible to mandate vaccines, as the United States Supreme Court has held. *See Jacobson*, *supra.*

a city or general health district; and (c) O.R.C. § 3792.04 does not apply because the Pfizer vaccine has been fully approved by the FDA, and furthermore, Plaintiffs fail to allege any actual instances of discrimination against themselves. There also is no constitutional violation because Plaintiffs are not being forced to undergo any medical treatment. Accordingly, for the foregoing reasons, Defendants respectfully request that the Court grant this Motion and dismiss Plaintiffs' Complaint in its entirety with prejudice.

Respectfully submitted,

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ATTORNEY GENERAL OF OHIO

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CERTIFICATE OF SERVICE

I certify that, pursuant to Civ.R. 5(B)(2)(f), a copy of the foregoing MOTION TO DISMISS and the accompanying MEMORANDUM IN SUPPORT were served on January 5, 2022 by e-mail on:

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IN THE COURT OF COMMON PLEAS
ATHENS COUNTY, OHIO

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	:	JUDGE MCCARTHY
v.	:	
	:	
OHIO UNIVERSITY, ET AL.,	:	
	:	
Defendants.	:	
	:	

EXHIBITS TO DEFENDANTS' MEMORANDUM IN SUPPORT

Exhibit A - Decision and Entry of the Butler County Common Pleas Court, filed on 12/06/2021.

Exhibit B - FDA Press Release Announcing the Approval of Pfizer–BioNTech COVID-19 Vaccine.

Exhibit C - FDA's Q&A Page for Comirnaty COVID-19 Vaccine.

IN THE COMMON PLEAS COURT
GENERAL DIVISION
BUTLER COUNTY, OHIO

Jennifer Siliko, et. al.	*	Case No.: CV2021 10 1467
Plaintiffs,	*	JUDGE: J. GREGORY HOWARD
vs.	*	
Miami University, et. al.	*	**DECISION AND ENTRY GRANTING DEFENDANTS' MOTION TO DISMISS**
Defendants	*	
	*	Final Appealable Order

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This matter is before the Court on Plaintiffs' Motion for Preliminary Injunction and Defendants' Motion to Dismiss.

Plaintiffs are employees of Miami University. Defendants are Miami University and its board of trustees (collectively "Miami University" or "University"). Plaintiffs are challenging the University's vaccine policy.. The vaccine policy requires all employees of the University who will have any on-campus presence to either receive a COVID-19 vaccination or request an exemption. (See Amended Complaint, Exhibit A). Individuals with approved exemptions are required to comply with COVID-19 testing and other educational or preventive health and safety measures. (See Amended Complaint, Exhibit A). The University's COVID-19 employee testing and safety measures do not distinguish between vaccinated and unvaccinated employees. (Fahner Aff. ¶3)

Prior to the filing of this case two of the plaintiffs, Ronald Siliko and Judy Vest, applied for and received exemptions. (See Plaintiffs' reply to Defendants' opposition to

Judge
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Common Pleas Court
Butler County, Ohio

EXHIBIT
A

motion for preliminary injunction p. 3) One of the plaintiffs, Jennifer Siliko, had not applied for an exemption at the time of filing. (See Plaintiffs' reply to Defendants' opposition to motion for preliminary injunction p. 3). Jennifer Siliko has since applied for, and received an exemption. (See Plaintiffs' reply to Defendants' opposition to motion for preliminary injunction p. 3-4).

Miami University raises the issue of standing in its opposition to Plaintiffs' motion for preliminary injunction and in its motion to dismiss. Defendants argue Jennifer Siliko's claims must be addressed under the doctrine of mootness, not standing, since she received the exemption after commencement of the case.

Standing is required to invoke the jurisdiction of a court. *Bank of Am., N.A. v. Kuchta*, 141 Ohio St.3d 75, 2014-Ohio-4275, ¶22. A lack of standing is a fundamental flaw that requires a court to dismiss the action. *Bank of Am., N.A. v. Kuchta*, 141 Ohio St.3d 75, 2014-Ohio-4275, ¶23. Standing looks to the rights of the individual parties to bring the action; they must assert a personal stake in the outcome of the action. *Id.* citing *Ohio Pyro, Inc. v. Ohio Dept. of Commerce*, 115 Ohio St.3d 375, 2007-Ohio-5024, ¶27. To establish standing, a party must show they suffered: "(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." *Moore v.* Middletown, 133 Ohio St. 3d 55, 2012-Ohio-3897, ¶ 22. The injury must be concrete not speculative. *State ex rel Food and Water Watch v. State*, 153 Ohio St.3d 1, 2018-Ohio-555, ¶20.

At the time of the filing, Ronald Siliko and Judy Vest, had applied for and received an exemption. Thus, Ronald Siliko and Judy Vest are not required to take the vaccine.

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Butler County, Ohio

Additionally, as unvaccinated employees Ronald Siliko and Judy Vest are subject to the same testing and safety measures as vaccinated employees. They are not subject to any additional requirements. Ronald Siliko and Judy Vest have not established an injury. *Wade v. Univ. of Conn. Bd. Of Trs.*, No. 3:21-cv-924, 2021 WL 3616035, *7 (D. Conn. Aug. 16, 2021) ("In light of the granting of their exemption requests [plaintiffs] have no continuing real or expected imminent injury from [the University's] vaccination requirement"). Without an injury, Ronald Siliko and Judy Vest lack standing.

Jennifer Siliko, at the time of filing, had not requested an exemption. By failing to request the exemption Jennifer Siliko cannot show she is injured by the policy requirements. *Wade v. Univ. of Conn. Bd. Of Trs.*, No. 3:21-cv-924, 2021 WL 3616035, *7-8 (D. Conn. Aug. 16, 2021) (A plaintiff who fails to submit to the procedural requirements of a policy that offers an exemption does not have standing to challenge the policy.). Without injury, Jennifer Siliko lacks standing.

None of the Plaintiffs in this case are being forced to receive a COVID-19 vaccination. All of the Plaintiffs in this case lack standing.

IT IS THEREFORE ORDERED, ADJUDGED AND DECREED that the motion to dismiss of Defendants' is hereby **GRANTED.**

SO ORDERED,

J. Gregory Howard, Judge

Judge
J. Gregory Howard
Common Pleas Court
Butler County, Ohio

EXHIBIT
B

FDA NEWS RELEASE

FDA Approves First COVID-19 Vaccine

Approval Signifies Key Achievement for Public Health

For Immediate Release:

August 23, 2021

Español (https://www.fda.gov/news-events/press-announcements/la-fda-aprueba-la-primera-vacuna-contra-el-covid-19)

Today, the U.S. Food and Drug Administration approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty (koe-mir'-na-tee), for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

"The FDA's approval of this vaccine is a milestone as we continue to battle the COVID-19 pandemic. While this and other vaccines have met the FDA's rigorous, scientific standards for emergency use authorization, as the first FDA-approved COVID-19 vaccine, the public can be very confident that this vaccine meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product," said Acting FDA Commissioner Janet Woodcock, M.D. "While millions of people have already safely received COVID-19 vaccines, we recognize that for some, the FDA approval of a vaccine may now instill additional confidence to get vaccinated. Today's milestone puts us one step closer to altering the course of this pandemic in the U.S."

Since Dec. 11, 2020, the Pfizer-BioNTech COVID-19 Vaccine has been available under EUA in individuals 16 years of age and older, and the authorization was expanded to include those 12 through 15 years of age on May 10, 2021. EUAs can be used by the FDA during public health emergencies to provide access to medical products that may be effective in preventing, diagnosing, or treating a disease, provided that the FDA determines that the known and potential benefits of a product, when used to prevent, diagnose, or treat the disease, outweigh the known and potential risks of the product.

FDA-approved vaccines undergo the agency's standard process for reviewing the quality, safety and effectiveness of medical products. For all vaccines, the FDA evaluates data and information included in the manufacturer's submission of a biologics license application (BLA). A BLA is a

comprehensive document that is submitted to the agency providing very specific requirements. For Comirnaty, the BLA builds on the extensive data and information previously submitted that supported the EUA, such as preclinical and clinical data and information, as well as details of the manufacturing process, vaccine testing results to ensure vaccine quality, and inspections of the sites where the vaccine is made. The agency conducts its own analyses of the information in the BLA to make sure the vaccine is safe and effective and meets the FDA's standards for approval.

Comirnaty contains messenger RNA (mRNA), a kind of genetic material. The mRNA is used by the body to make a mimic of one of the proteins in the virus that causes COVID-19. The result of a person receiving this vaccine is that their immune system will ultimately react defensively to the virus that causes COVID-19. The mRNA in Comirnaty is only present in the body for a short time and is not incorporated into - nor does it alter - an individual's genetic material. Comirnaty has the same formulation as the EUA vaccine and is administered as a series of two doses, three weeks apart.

"Our scientific and medical experts conducted an incredibly thorough and thoughtful evaluation of this vaccine. We evaluated scientific data and information included in hundreds of thousands of pages, conducted our own analyses of Comirnaty's safety and effectiveness, and performed a detailed assessment of the manufacturing processes, including inspections of the manufacturing facilities," said Peter Marks, M.D., Ph.D., director of FDA's Center for Biologics Evaluation and Research. "We have not lost sight that the COVID-19 public health crisis continues in the U.S. and that the public is counting on safe and effective vaccines. The public and medical community can be confident that although we approved this vaccine expeditiously, it was fully in keeping with our existing high standards for vaccines in the U.S."

FDA Evaluation of Safety and Effectiveness Data for Approval for 16 Years of Age and Older

The first EUA (https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19), issued Dec. 11, for the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 years of age and older was based on safety and effectiveness data (https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19) from a randomized, controlled, blinded ongoing clinical trial of thousands of individuals.

To support the FDA's approval decision today, the FDA reviewed updated data from the clinical trial which supported the EUA and included a longer duration of follow-up in a larger clinical trial population.

Specifically, in the FDA's review for approval, the agency analyzed effectiveness data from approximately 20,000 vaccine and 20,000 placebo recipients ages 16 and older who did not have evidence of the COVID-19 virus infection within a week of receiving the second dose. The safety of Comirnaty was evaluated in approximately 22,000 people who received the vaccine and 22,000 people who received a placebo 16 years of age and older.

Based on results from the clinical trial, the vaccine was 91% effective in preventing COVID-19 disease.

More than half of the clinical trial participants were followed for safety outcomes for at least four months after the second dose. Overall, approximately 12,000 recipients have been followed for at least 6 months.

The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle or joint pain, chills, and fever. The vaccine is effective in preventing COVID-19 and potentially serious outcomes including hospitalization and death.

Additionally, the FDA conducted a rigorous evaluation of the post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine and has determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support. Information is not yet available about potential long-term health outcomes. The Comirnaty Prescribing Information includes a warning about these risks.

Ongoing Safety Monitoring

The FDA and Centers for Disease Control and Prevention have monitoring systems in place to ensure that any safety concerns continue to be identified and evaluated in a timely manner. In addition, the FDA is requiring the company to conduct postmarketing studies to further assess the risks of myocarditis and pericarditis following vaccination with Comirnaty. These studies will include an evaluation of long-term outcomes among individuals who develop myocarditis following vaccination with Comirnaty. In addition, although not FDA requirements, the company has committed to additional post-marketing safety studies, including conducting a pregnancy registry study to evaluate pregnancy and infant outcomes after receipt of Comirnaty during pregnancy.

The FDA granted this application Priority Review (https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review). The approval was granted to BioNTech Manufacturing GmbH.

Related Information

- Comirnaty Prescribing Information (http://www.fda.gov/vaccines-blood-biologics/comirnaty)
- Cormirnaty and Pfizer-BioNTech COVID-19 Vaccine | FDA (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine)

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Q&A for Comirnaty (COVID-19 Vaccine mRNA)

Español (https://www.fda.gov/vaccines-blood-biologics/preguntas-y-respuestas-sobre-comirnaty-vacuna-de-arnm-contra-el-covid-19)

How did the FDA arrive at the decision to approve Comirnaty (COVID-19 Vaccine mRNA)? What is different now when compared to the December 2020 authorization of Pfizer-BioNTech COVID-19 Vaccine?

FDA conducted a thorough evaluation of the data and information submitted in the Biologics License Application (BLA) for Comirnaty before making a determination that the vaccine is safe and effective in preventing COVID-19 in individuals 16 years of age and older.

The EUA (https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19) for the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 years of age and older was based on safety and effectiveness data from a randomized, controlled, blinded ongoing clinical trial in approximately 18,000 individuals who received the vaccine and approximately 18,000 who received a placebo. The vaccine was 95% effective in preventing COVID-19 disease among these clinical trial participants with eight COVID-19 cases in the vaccine group and 162 in the placebo group. The duration of safety follow-up for the vaccinated and placebo participants was a median of two months after receiving the second dose.

Follow-up data from this ongoing clinical trial was analyzed by FDA to determine the safety and effectiveness of Comirnaty. The updated analysis to determine effectiveness for individuals 16 years of age and older included approximately 20,000 Comirnaty and 20,000 placebo recipients who did not have evidence of SARS-CoV-2 infection through seven days after the second dose. Overall, the vaccine was 91% effective, with 77 cases of COVID-19 occurring in the vaccine group and 833 COVID-19 cases in the placebo group.

The safety was evaluated in approximately 22,000 Comirnaty and 22,000 placebo recipients 16 years of age and older. More than half of the vaccine and placebo recipients were followed for safety for at least four months after the second dose. After issuance of the EUA, participants were unblinded in a phased manner over a period of months to offer placebo participants Comirnaty. Overall, in blinded and unblinded follow-up, approximately 12,000 Comirnaty recipients have been followed for at least 6 months.

How safe and effective is Comirnaty (COVID-19 Vaccine mRNA)?

Overall, the vaccine was 91% effective in preventing COVID-19 disease, with 77 cases of COVID-19 occurring in the vaccine group and 833 COVID-19 cases in the placebo group.

The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle pain, chills, joint pain and fever.

The FDA conducted a rigorous evaluation of the of post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of Pfizer-BioNTech COVID-19 Vaccine and determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support Information is not yet available about potential long-term health outcomes. The Comirnaty Prescribing Information (https://www.fda.gov/media/151707/download) includes a warning about these risks.

What are the most commonly reported side effects by those who received Comirnaty (COVID-19 Vaccine mRNA)?

The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever.

How long will Comirnaty provide protection?

Data are not yet available to inform about the duration of protection that the vaccine will provide.

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Can people who have already had COVID-19 get Comirnaty?

Yes. Available data suggest that previously infected individuals are at risk of COVID-19 (i.e., reinfection) and could benefit from vaccination.

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Does Comirnaty protect against asymptomatic SARS-CoV-2 infection (i.e. the individual is infected with SARS-CoV-2, but does not have signs or symptoms of COVID-19)?

It is not known if Comirnaty protects against asymptomatic SARS-CoV-2 infection.

If a person has received Comirnaty, will the vaccine protect against transmission of SARS-CoV-2 from individuals who are infected despite vaccination?

Most vaccines that protect from viral illnesses also reduce transmission of the virus that causes the disease by those who are vaccinated. While it is hoped this will be the case, the scientific community does not yet know if Comirnaty will reduce such transmission.

Can Comirnaty cause infertility in women?

There is no scientific evidence to suggest that the vaccine could cause infertility in women. In addition, infertility is not known to occur as a result of natural COVID-19 disease, further demonstrating that immune responses to the virus, whether induced by infection or a vaccine, are not a cause of infertility. Reports on social media have falsely asserted that the vaccine could cause infertility in women and the FDA is concerned that this misinformation may cause women to avoid vaccination to prevent COVID-19, which is a potentially serious and life-threatening disease. SARS-CoV-2 is the virus that causes COVID-19. The symptoms of COVID-19 vary and are unpredictable; many people have no symptoms or only mild disease, while some have severe respiratory disease including pneumonia and acute respiratory distress syndrome (ARDS), leading to multi-organ failure and death. Comirnaty is a mRNA vaccine. It contains a piece of the SARS-CoV-2 virus's genetic material that instructs cells in the body to make the virus's distinctive "spike" protein. After a person is vaccinated, their body produces copies of the spike protein, which does not cause disease, and triggers the immune system to learn to react defensively, producing an immune response against SARS-CoV-2. Contrary to false reports on social media, this protein is not the same as any involved in the formation of the placenta.

After FDA granted the emergency use authorization of the Pfizer BioNTech COVID-19 Vaccine were clinical trial participants unblinded so that the placebo recipients could be offered the vaccine?

Yes. After issuance of the EUA, clinical trial participants were unblinded in a phased manner over a period of months to offer the authorized Pfizer-BioNTech COVID-19 Vaccine to placebo participants. These participants were followed for safety outcomes. Overall, in blinded and unblinded follow-up, approximately 12,000 Pfizer-BioNTech COVID-19 Vaccine recipients have been followed for at least 6 months.

Will the emergency use authorization (EUA) for Pfizer-BioNTech COVID-19 Vaccine remain in effect after the approval?

Yes. The EUA remains in effect for the two dose primary series in individuals 12 years of age (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use) and older and as a third primary dose for individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise. Additionally, the FDA authorized the vaccine for emergency use to allow for a single booster dose administered at least 6 months after completion of the vaccination primary series in certain populations.

How is Comirnaty (COVID-19 Vaccine, mRNA) related to the Pfizer-BioNTech COVID-19 Vaccine?

The FDA-approved Comirnaty (COVID-19 Vaccine, mRNA) and the two EUA authorized formulations of Pfizer-BioNTech COVID-19 Vaccine for ages 12 years and older, when prepared according to their respective instructions for use, can be used interchangeably without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under EUA to administer the vaccination series as if the doses were the licensed vaccine. For purposes of administration, doses distributed under the EUA are interchangeable with the licensed doses. The Vaccine Information Fact Sheet for Recipients and Caregivers (https://www.fda.gov/media/144414/download) provides additional information about both the approved and authorized vaccines.

Is Comirnaty interchangeable with other COVID-19 vaccines?

The FDA-approved Comirnaty (COVID-19 Vaccine, mRNA) and the two EUA authorized formulations of Pfizer-BioNTech COVID-19 Vaccine for ages 12 years and older, when prepared according to their respective instructions for use, can be used interchangeably without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

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