UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

ZULAY RODRÍGUEZ VÉLEZ, et al. **Plaintiffs,** **v.** **HON. PEDRO R. PIERLUISI URRUTIA,** **Defendant.**	**CIVIL NO. 21-1366 (PAD)**

MEMORANDUM IN OPPOSITON TO MOTION FOR PRELIMINARY INJUNCTION

TO THE HONORABLE COURT:

COMES NOW Pedro R. Pierluisi Urrutia, in his official capacity as Governor of the Commonwealth of Puerto Rico, through the undersigned counsel, without waiving any right, objection or defense arising from the Title III of Puerto Rico Oversight, Management and Economic Stability Act ("PROMESA"), 48 U.S.C. §§2101 et seq., the Commonwealth's Petition under said Title or under this case, and respectfully states and prays as follows:

I. INTRODUCTION

Vaccination against COVID-19 has become one of the most critical preventive measures to eradicate the pandemic being experienced worldwide.[1] The COVID-19 vaccine is available in the United States and the Center for Diseases Control and Prevention ("CDC") recommends it for everyone 12 years of age and older. Recently, in a key milestone for Public Health, the Federal Drug Administration ("FDA") fully approved the Pfizer vaccine for the prevention of

[1] Center for Disease Control and Prevention, *Science Brief: COVID-19 Vaccines and Vaccination*, July 21, 2021, https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html (retrieved on August 30, 2021).

COVID-19 disease in individuals 16 years of age and older. (*See* Exhibit A). The present case arises in a context where more than a year has passed since a state of emergency has been decreed in Puerto Rico caused by the COVID-19 pandemic and, fortunately, with three vaccines to stop the spread of this fatal disease, of which one—Pfizer-- has been fully approved by the FDA.

On July 28, 2021, in order to safeguard the public health and public safety of the entire population, the Governor of Puerto Rico announced through Executive Order 2021-058 (hereinafter "Executive Order" or "OE-2021-058") that, effective August 16, 2021, all governmental agencies must require all their employees who work in person to be duly vaccinated against COVID-19. As an exception, the Executive Order allows for public employees to be exempted from vaccination for medical and religious reasons, and instead get tested on a weekly basis and provide, at the beginning of each week, a negative result for the COVID-19 test. Also, public employees who do not wish to get vaccinated for whatever reason are required to get tested on a weekly basis and provide a negative COVID-19 test result at the beginning of each week.

On August 17, 2021, twenty (20) days after the Governor announced the Executive Order, six (6) days after filing the original complaint, and one (1) day after the Executive Order went to effect, Plaintiffs filed a Motion for Preliminary Injunction to enjoin Defendant from implementing the Executive Order. Plaintiffs delay in presenting this extraordinary remedy under Fed. R. Civ. P. 65, in and of itself shows a lack of urgency on behalf of Plaintiffs that goes against the very purpose of such relief.

Plaintiffs understand that the Executive Order violates the Fourteenth Amendment to the United States Constitution, the Religious Freedom Restoration Act ("RFRA"), 42 U.S.C. §

2000bb–2000bb(4), and the Food and Drug Administration's Emergency Use Authorization statute ("EUA"), 21 U.S.C. § 360bbb-3. (Docket No. 16 at 1). Likewise, Plaintiffs include supplemental claims under the Constitution of the Commonwealth of Puerto Rico, P.R. Const. Art. II, §§ 1; 8. *Id* at 2. Additionally, Plaintiffs further allege that they meet all the elements to obtain a preliminary injunction because, if not enjoined, they will suffer loss of bodily autonomy, loss of current and future earning potential, incurring in substantial expenses, and loss of medical privacy. As well, Plaintiffs contend that they have no adequate remedy at law for their losses; they cannot recover their lost bodily autonomy, time, or privacy. And finally, Plaintiffs posit that the Commonwealth will not lose any government employees if the "Vaccine Mandate" is enjoined. (Docket No. 16 at 3).

Plaintiffs' arguments on preliminary injunction miss the mark and fail at establishing the required four (4) elements for such an extraordinary remedy.[2] Importantly, it is unlikely that Plaintiffs will succeed on the merits of their Fourteenth Amendment substantive and procedural due process claims, the RFRA claim, their Supremacy Clause claim under the EUA, and supplemental claims; they will not suffer any irreparable harm if the preliminary injunction is denied, failing at their burden of demonstrating a real and concrete harm and in light of reasonable (and less onerous) "opt outs"; and the balance of equities weigh in favor of the public health interests. The aforementioned is buttressed by the growing court decisions that are validating the requirement for the COVID-19 vaccine. Specifically, the Northern District of Indiana recently denied a motion for preliminary injunction seeking to enjoin Indiana

[2] Simultaneously with the filing of the instant motion, Defendants will file a *Motion to Dismiss*, which will discuss additional grounds on why the instant case has no probabilities to succeed on the merits.

University from enforcing a COVID-19 vaccine mandate for students. *Klaassen v. Trustees of Indiana Univ.*, No. 1:21-CV-238 DRL, 2021 WL 3073926 (N.D. Ind. July 18, 2021) (affirmed by *Klaassen v. Trustees of Indiana*, No. 21-2326, 7 F.4th 592 (7th Cir. Aug. 2, 2021)); s*ee also In re Ryan Klaassen, et al.*, Case No. 21A15 (Aug. 12, 2021)(whereby Supreme Court Justice Amy Coney Barrett denied the plaintiffs' Emergency Application for Writ of Injunction related to Indiana University's vaccine mandate).

Furthermore, the Executive Order is supported by the decision in *Jacobson v. Massachusetts*, 197 U.S. 11, 27 & 29 (1905) (recognizing, under a rational basis review, that "a community has the right to protect itself against an epidemic of disease which threatens the safety of its members" and describing a state's police power to enforced reasonable regulations for the safety of the general public so as to combat an epidemic). This principle has been repeatedly acknowledged by the Supreme Court. *See, e.g.*, *Lawton v. Steele*, 152 U.S. 133, 136-137 (1894) (recognizing that "the state may interfere wherever the public interests demand it"; "and that the means are reasonably necessary for the accomplishment of the purpose, and not unduly oppressive upon individuals."); *see also Compagnie Francaise de Navigation a Vapeur v. La. State Bd. of Health*, 186 U.S. 380, 393 (1902) (upholding Louisiana's right to quarantine passengers aboard vessel—even where all were healthy—against a Fourteenth Amendment challenge); *Prince v. Massachusetts*, 321 U.S. 158, 166–67 (1944) (noting that "[t]he right to practice religion freely does not include liberty to expose the community … to communicable disease"); *United States v. Caltex*, 344 U.S. 149, 154 (1952) (acknowledging that "in times of imminent peril—such as when fire threatened a whole community—the sovereign could, with immunity, destroy the property of a few that the property of many and the lives of many more could be saved").

While individual rights secured by the Constitution do not disappear during a public health crisis, during the present health emergency, Plaintiffs' constitutional challenges to the Executive Order are not only meritless but are a subterfuge to further their anti-vaccine agenda through a federal court. Under the guidance of the Supreme Court in *Jacobson*, *supra*, as well as recent court decisions validating the requirement for the COVID-19 vaccine, the discussion further on will show that the Executive Order: (i) does not violate the Fourteenth Amendment substantive due process right being that it passes either a rational (or strict) scrutiny since it has a "real or substantial relation" to public health and safety interests, is not "arbitrary and oppressive", and, through its exceptions or "opt outs ", it uses less onerous means to advance its compelling public health interests in safeguarding the lives and health of its citizens; (ii) does not violate the Fourteenth Amendment procedural due process right because Plaintiffs have not been deprived of property interest; (iii) does not violate Plaintiffs' freedom to exercise their religious rights under RFRA; (iv) does not violate the Supremacy Clause, inasmuch as it is not at odds with federal law (EUA); and Plaintiffs' arguments under EUA are moot in light of the recent full approval of Pfizer's COVID-19 vaccine; and (v) absent a cognizable federal claim, this Court should abstain from exercising its supplemental jurisdiction as to the Commonwealth constitutional claims; nonetheless, the pendant claims fall flat in light of the recent PR Court of First Instance decision on the matter. Therefore, Plaintiffs' request to enjoin the Government from constitutionally exercising its broad police powers during a pandemic with the reasonable and compelling interest of safeguarding the health and lives of its employees and citizens, swiftly passing any applicable constitutional scrutiny, must be dismissed with prejudice. *See S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613

(2020) (Roberts, C.J., concurring in denial of application for injunctive relief to allow full operation of churches during the COVID-19 pandemic).

II. THE SCOPE OF THE EXECUTIVE ORDER REVEALS A REASONABLE AND THE LESS RESTRICTIVE MEANS TO ACHIEVE A COMPELLING GOVERNMENT PUBLIC HEALTH AND SAFETY INTEREST.

On July 28, 2021, Hon. Pedro Pierluisi-Urrutia, Governor of Puerto Rico ("Defendant" or "Governor'), issued Administrative Bulletin No. OE-2021-058 (Docket No. 11-1). The Executive Order was promulgated to take governmental action to control the COVID-19 pandemic by requiring public employees to be vaccinated to work in person, and for safeguarding the public health and public safety. The Governor undertook this action for the reasons stated in the preamble of the Executive Order (Docket No. 11-1), considering the data given by the Department of Health, on a daily basis, regarding the spread of the COVID-19 pandemic throughout the population of Puerto Rico.

Section 1 of the Executive Order covers the vaccination requirement on public employees who will be going to work in person. These employees shall have completed their vaccination by September 30, 2021. Section 2 of the Executive Order covers the exceptions that employees who refuse to get vaccinated vaccine and voluntarily want to state either a medical or religious reason for said refusal. Under the medical exception, the employees "whose immune system is compromised, are allergic to vaccines, or have a medical contraindication to the receipt of the vaccine shall be exempt from the COVID-19 vaccination requirement. This shall be certified by a physician authorized to practice in Puerto Rico." (Docket No. 11-1 at 10). The second exception that the public employee may invoke is:

> on the basis of religious beliefs-provided that the vaccines are against the employee's religious observance. To comply with this exception, the employee must furnish an affidavit of religious objection whereby the employee, together

> with the minister or spiritual leader of his church or religion, state under oath and under penalty of perjury that, on the basis of his religious beliefs, the employee cannot receive a COVID-19 vaccine." In addition, the employees who voluntarily choose to request an exception to vaccination, pursuant to Section 2 of the Executive Order, shall be tested every week through a qualified virus test SARS-CoV2 (Nucleic Acid Amplification Test or NAAT and antigen tests) performed within a maximum of seventy-two (72) hours prior...

Id. at 10-11.

Section 3 of the Executive Order refers to Vaccination refusal. This section provides that:

> Any government employee to which this Executive Order applies who fails to furnish the COVID-19 Vaccination Record Card or document attesting to the completion or beginning of the vaccination process, shall be responsible for furnishing on the first business day of each week -for the duration of the emergency declared in Administrative Bulletin No. OE-2020-020- a negative COVID-19 test result from a qualified virus test SARS-CoV2 (Nucleic Acid Amplification Test or NAAT and antigen tests) performed within a maximum of seventy-two (72) hours.

Docket No. 11-1 at 11 (emphasis added). Section 3 further states that:

> Any employee who fails to furnish the COVID-19 Vaccination Record Card, the weekly negative COVID-19 test result, or the positive COVID-19 test result enclosed with the recovery documents, and who does not comply with exceptions provided in this Executive Order may not work in person. ... Said employees shall be afforded **the option** to use their compensatory time or regular leaves available as applicable. If the employee depleted any accrued leaves, the employee **may** request an unpaid leave for the duration of the emergency.

Docket 11-1 at 12 (emphasis added).

As this Court can attest, nowhere in the Executive Order does it states that public employees working in-person must be vaccinated or are obligated to embrace one of the two exceptions established in Section 2. Contrarywise, the Executive Order clearly and unambiguously provides a general alternative to public employees that simply do not want to

be inoculated with a COVID-19 vaccine, regardless of the reason not to do so.[3] Precisely, Section 3 of the Executive Order provides an alternative that requires that the public employee provides a negative result of qualified SARS-CoV2 virus test or NAAT and antigen test on weekly basis. In that sense, to suggest that public employees, including the Plaintiffs, had only two options to "opt-out" of the vaccination mandate is utterly false and misleading to the Court.

Thus, this Court will be able to conclude that, either under a rational or strict scrutiny, the Executive Order: (i) is pellucidly clear and specific as to its contents; (ii) that it is to be applied generally to all public employees in the executive branch who work in-person; and (iii) that all employees have "opt-outs" to the vaccination requirements available within the Executive Order. This less restrictive approach, when compared with the vaccine mandates that were upheld by the Supreme Court in *Jacobson* and in *Zucht v. King*, 260 U.S. 174, 176, 177 (1922), requiring compulsory inoculation without exceptions, can easily survive a constitutional challenge under any scrutiny.

III. A PRELIMINARY INJUNCTION IS UNWARRANTED IN THE PRESENT CASE

A preliminary injunction is an "extraordinary and drastic remedy," never awarded as of right. *Munaf v. Green,* 553 U.S. 674, 690 (2008). Courts in the First Circuit evaluate four factors in determining whether to issue a preliminary injunction, to wit: (1) the movant's probability of success on the merits; (2) the likelihood of irreparable harm absent preliminary injunctive relief; (3) a comparison between the harm to the movant if no injunction issues and the harm

3 Although Plaintiffs imprecisely assert in the *Motion for Preliminary Injunction* that the Executive Order is "vague," Docket 16 at 22, first paragraph, they failed to develop a plausible argument substantiating the alleged vagueness. Thus, Defendant will not further discuss an undeveloped vagueness argument because the Court must disregard any conclusory not well-pleaded facts. *See Zannino,* 895 F.2d at 17 (holding that "[i]t is not enough merely to mention a possible argument in the most skeletal way, leaving the court to do counsel's work, create the ossature for the argument, and put flesh on its bones.").

to the objectors if one does issue; and (4) how the granting or denial of an injunction will interact with the public interest. *See New Comm Wireless Services v. SprintCom, Inc.,* 287 F.3d 1, 8-9 (1st Cir. 2002); *see also Ross–Simons of Warwick, Inc. v. Baccarat, Inc.,* 102 F.3d 12, 15 (1st Cir. 1996). Whether to issue a preliminary injunction depends on balancing equities where the requisite showing for each of the four factors turns, in part, on the strength of the others. *Concrete Machinery Co., Inc. v. Classic Lawn Ornaments, Inc.,* 843 F.2d 600, 611–13 (1st Cir.1988). Although a hearing is often held prior to entry of a preliminary injunction, a hearing is not an indispensable requirement. *Aoude v. Mobil Oil Corp.*, 862 F.2d 890, 893 (1st Cir. 1988). As it will be discussed below, Plaintiff failed to meet all the four prongs that are required to be satisfied for the issuing of a preliminary injunction, therefore Plaintiffs' request for a Preliminary Injunction must be DENIED.

Being that the matters to be discussed in the instant Response were also the subject of Defendant's Motion to Dismiss pursuant to Fed.R.Civ.P. 12(b)(6), the Defendant hereby incorporates by reference the arguments raised in said Motion as if fully set forth herein.

A. Plaintiffs is Unlikely to Succeed on The Merits.

1. *The Executive Order vaccination requirement is a valid exercise of the Commonwealth's police powers to protect the health and lives of its employees and citizens and does not breach fundamental rights under the Fourteenth Amendment, therefore rational basis review must be applied.*

The Executive Order is a clearly a constitutional exercise of the Commonwealth's police powers to safeguard the health and lives of its employees and citizens. *See Jacobson*, 197 U.S. 11 (ruling that states are entitled to choose between the theory of those of the medical profession who think vaccination worthless and the opposite theory, which is in accord with common belief and is maintained by high medical authority, and is not compelled to commit a matter

of this character, involving the public health and safety, to the final decision of a court or jury); *see also Am. Cruise Ferries, Inc. v. Vázquez-Garced*, CV 20-1633 (DRD), 2020 WL 7786939, at *17 (D.P.R. Dec. 17, 2020) (recognizing that the U.S. Constitution provides the Commonwealth with broad police powers to place public health restrictions in the context of the COVID-19 pandemic).[4]

The Executive Order does not violate the Fourteenth Amendment's substantive due process clause because it passes both a rational or strict scrutiny since, through its exceptions or "opt outs", it uses less onerous means to advance the compelling public health interest in safeguarding the lives and health of its citizens.

a. *The Executive Order's vaccine mandate is rationally related to the Commonwealth's legitimate governmental interest*.

As argued in Defendant's Motion to Dismiss, rational basis review is the test this Court *normally* applies to Fourteenth Amendment challenges, so long as they do not involve suspect classifications based on race or some other ground, or a claim of fundamental right. *Roman Catholic Diocese of Brooklyn v. Cuomo*, ---U.S. ---, 141 S.Ct. 63, 70, 208 L.Ed.2d 206 (2020)(Gorsuch, J., concurring). It is less stringent than strict scrutiny. Under rational basis review, "legislation is presumed to be valid and will be sustained if the classification drawn by the statute is rationally related to a legitimate state interest." *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 440, 105 S.Ct. 3249, 87 L.Ed.2d 313 (1985).

In the instant case, Plaintiffs argue that the Executive Order's violation of their substantive due process rights "triggers not rational-basis scrutiny as in [*Jacobson*] [...], but

[4] For a more elaborate exposition of this argument, see Defendant's Motion to Dismiss, Docket No. __, pages 4-5 and 13 et seq.

rather a strict constitutional scrutiny." Docket No. 11 at 2, ¶3. However, the Executive Order did not violate any of Plaintiffs' substantive due process rights. Moreover, Plaintiffs were unable to provide the Court with any binding or persuasive case law that has declined to apply *Jacobson's* rationale basis scrutiny to a vaccine mandate in favor of a strict scrutiny. Thus, the Court must apply the *Jacobson* rational basis standard, until the Supreme Court squarely overrules the same. *See U.S. v. Moore-Bush*, 963 F.3d. 29, 31 (1st Cir. 2020) ("Under the doctrine of stare decisis, all lower federal courts must follow the commands of the Supreme Court, and only the Supreme Court may reverse its prior precedent"); *see also In re Rutledge*, 956 F.3d 1018, 1028 (8th Cir. 2020) (stating that "district court's failure to apply the *Jacobson* framework produced a patently erroneous result.").

As a general matter, the Executive Order's vaccine mandate is rationally related to the Commonwealth's legitimate governmental interest. *See Jacobson*, 196 U.S. at 36 (holding that vaccine mandate was a valid exercise of the State's police power). Defendant clearly established that the Executive Order followed specific purposes "to prevent and stop the spread of COVID-19, as well as to safeguard the health, life, and safety of the residents of Puerto Rico." Docket No. 11-1 at 8-9. This is a legitimate governmental interest.

b. The Executive Order fully complies with the strict scrutiny standard.

In an abundance of caution, Defendant will argue that, should the Court understand that the Executive Order should be examined under a strict scrutiny—which Defendant vehemently denies—it would easily pass said test since it is narrowly tailored to serve a compelling state interest: the health and lives of all public employees and citizens during a growing pandemic.

If the government infringes on a fundamental right, the courts often apply a strict scrutiny to the government's action. *See Glucksberg*, 521 U.S. at 721. In such circumstances, the Fourteenth Amendment "forbids the government to infringe [...] fundamental liberty interests *at all*, no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest." *Id.* (quoting *Reno v. Flores*, 507 U.S. 292, 302 (1993)). This is the most rigorous form of constitutional scrutiny of government action. Infringements on other rights or liberties, as in the instant case, usually must meet the rational basis review. *Id*. at 722.

First, if a strict scrutiny were to be applied, the Executive Order followed specific purposes "to prevent and stop the spread of COVID-19, as well as to safeguard the health, life, and safety of the residents of Puerto Rico." Docket No. 11-1 at 8-9.

Second, the Executive Order is narrowly tailored because: (1) does not create suspect classifications, as it is of general application to **all** public employees of the Executive Branch that work in-person; (2) mandates vaccination to all employees that work in-person, but has exceptions (religious and medical) and general "opt-outs" that equally apply to **all** public employees that do not want to be immunized against COVID-19; (3) requires that **all** public employees that work in-person and decide not to be immunized, either by an exception or a general "opt-out," to provide a weekly negative COVID-19 test; and (4) creates an alternative for employees that do not desire to be inoculated nor be tested by allowing them to take a regular or compensatory time paid leave, as well as an unpaid leave.

The fact is that the Executive Order does not involve suspect classifications, as it is of general application to <u>all</u> public employees in the executive branch who work in person; and it has "<u>opt-outs</u>" which also apply to <u>all</u> those who refuse vaccination, either by means of an exception in Section 2 or not. It is undeniable that Section 3 of the Executive Order is clear,

regardless of Plaintiffs' obtuse interpretation, that all employees who refuse vaccination will have to take a weekly COVID-19 test and provide a negative result in order to go to work in person the following week.

As the Defendant has established a "legitimate state interest" required by the rational basis scrutiny, and also that the Executive Order is "narrowly tailored to serve a compelling state interest", even though no fundamental rights were violated by the Executive Order, nor suspect classifications were created by it, and the fact that the Government has many places available where to get tested for COVID free of charge, it is to be concluded that the Executive Order is constitutional and must remain in place in order to protect the population of the Commonwealth of Puerto Rico from the spread of the COVID-19 virus.

2. *The Executive Order does not violate the Fourteenth Amendment procedural due process right because Plaintiffs have not been deprived of property interest, thus, they lack Article III standing.*

Defendant incorporates by reference its discussion of Plaintiffs' procedural due process claim in pages 28-30 of their Motion to Dismiss.

Plaintiffs allege that the "vaccine mandate [...] seems to constructively discharge those employees who do not want to get vaccinated and lack either a medical or a religious exception". Docket No. 11 at 17, ¶56. However, none of the Plaintiffs alleged to have resigned from their public employments because of the application of the Executive Order. Certainly, Plaintiffs "cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending." *Clapper v. Amnesty Intern. USA*, 568 U.S. 398, 416 (2013). Therefore, since Plaintiffs have not pleaded to have suffered a constructive discharge—which is sufficient to dismiss this claim pursuant to Rule 12(b)(6)—all allegations related to a procedural due process violation must be dismissed for lack of Article

III standing. *See Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010) (holding that to establish Article III standing, an injury must be "concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling.").

Plaintiffs further allege that the Executive Order "violates the employees' procedural due process rights under the Fourteenth Amendment, which bars the Commonwealth from discharging, without due process of law, a government employee who has a property interest in continued public employment." Docket No. 11 at 44, ¶135. Moreover, Plaintiffs argue that the Executive Order "effectively removes their property interest—by relegating them to an indefinite "unpaid leave"— [depriving them] of their continued employment." *Id*. at 45, ¶139.

At the outset, Plaintiffs' claim of a procedural due process violation for allegedly putting public employees on unpaid leave suffers the same ill fate as the constructive employment claim because none of them alleged to be on unpaid leave. *See Clapper*, 568 U.S. at 416. Thus, Plaintiffs lack Article III standing to raise any procedural due process claim regarding the unpaid leave contemplated by the Executive Order. *See Geertson Seed Farms*, 561 U.S. at 149 (holding that to establish Article III standing, an injury must be "concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling.").

The Executive Order primarily contemplates regular or compensatory **paid leave** for public employees that decide not to immunize and refuse to provide their employer with a weekly negative COVID-19 test result. (Docket No. 11-1 at 13). Alternatively, the unpaid leave provision of the Executive Order offers a viable option for public employees that do not have any regular or compensatory time accrued and that decide not to comply with any of the Executive Order's requirements for in-person work. Thus, since unpaid leave is a **choice**

provided by the Executive Order for those public employees that decide not to immunize, not to provide a negative COVID-19 test result and that have no regular or compensatory time accrued. Given all alternatives available to avoid an unpaid leave, no procedural due process claim has been plausibly pleaded.

3. *OE-2021-058 Does Not Substantially Burden Plaintiffs' Exercise of Religion and It Infringes Upon No Right*.

Plaintiffs claim that the Executive Order infringes on their fundamental right to freely exercise their religion. As discussed in Defendant's Motion to Dismiss, this couldn't be farther from the truth. Defendant incorporates by reference its discussion of Plaintiffs' RFRA violation claim in pages 31-38 of their Motion to Dismiss.

Plaintiffs invite the Court to apply the strict scrutiny to the alleged violation of their free exercise of religion. However, Defendant argues that the Executive Order does not violate Plaintiffs' freedom to exercise their religion of choice. The Supreme Court applied the strict scrutiny in a recent case, questioning an Executive Order dealing with the COVID-19 pandemic, where plaintiffs alleged a violation to their First Amendment right of freedom to exercise their religion. Specifically, in *Roman Catholic Diocese of Brooklyn*, 141 S.Ct. at 63, the Supreme Court was faced with a case where defendant (the New York Governor)—in attention to the COVID-19 pandemic—issued an Executive Order imposing severe restrictions on attendance at religious services that were not equally imposed to business activities. The Supreme Court held that the challenged restrictions were not "neutral" and of "general applicability" and that they failed the strict scrutiny because were not narrowly tailored to serve a compelling state interest. *Id.* at 67. However, the instant case is clearly distinguishable since, contrary to the *Roman Catholic Diocese of Brooklyn's* challenged Executive Order, which targeted religious

institutions, Defendant's Executive Order is to be generally applied to all public employees who work in-person within the Executive Branch's covered agencies, regardless of their religious denomination.

Plaintiffs claim that the "vaccine mandate substantially burdens plaintiffs' exercise of religion, because it obligates them to furnish an affidavit in which both she and her 'ecclesiastical leader of their religion or sect, swear under penalty of perjury that, because of their religious beliefs, she cannot be inoculated against COVID-19." (Docket No. 11 at 46, ¶149). Yet, as discussed in the Motion to Dismiss, the Executive Order does not promote a classification between employees based on any factor other than being public employees in the Executive Branch. Quite the contrary, the Executive Order applies neutrally to all public employees that opt not to immunize in the same fashion. The exceptions and "opt out" alternative apply neutrally to every employee that refuses to be immunized by requiring **all** to show weekly negative COVID-19 test in order to work in-person.

Simply put, the Executive Order does not violate RFRA since it does not impose any undue burden on public employees 'religious practices, as they can exercise their free will and choose between any of the exceptions or "opt out" alternatives in order to comply with the mandate. *See* CHEMERINSKY & GOODWIN, 110 Nw. U.L. Rev. at 610 (concluding that RFRA does not provide a "basis for challenging compulsory vaccination laws.").

4. *Plaintiff's Preemption claim is moot in light of the FDA's full approval of the Pfizer vaccine*.

Plaintiffs go to great lengths to argue that Section 564 of the *Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3—which authorizes the emergency use authorization ("EUA") of a vaccine—preempts the Executive Order because the statute expressly mandates informed and

voluntary consent. (Docket No. 11 at 49, ¶172). However, this argument falls flat because on August 23, 2021, the FDA fully approved the Pfizer vaccine which will now be marketed as Comirnaty (koe-mir'-na-tee). *See* **Exhibit A.** The fact that Plaintiffs can choose a vaccine that is fully approved by the FDA means that there is no longer a controversy as to any preemption claim under the EUA. Specifically, the Pfizer vaccine is no longer under the authorization of the FDA's EUA. Hence, since there can be no preemption claim as to a vaccine that has advanced from the EUA into full approval, it follows that Plaintiffs preemption claim is moot.

Plaintiffs cannot reconcile their preemption claim with the defunct presumption that all available vaccines were being administered under the FDA's EUA. (*See* Docket No. 11 at 49, ¶170). This Court cannot provide relief for a claim that no longer exists as it stood when the complaint was filed; any other way would constitute an advisory opinion. *See Golden v. Zwickler*, 394 U.S. 103, 108 (1969) ("[T]he federal courts established pursuant to Article III of the Constitution do not render advisory opinions."). Further, declaratory judgment deeming past conduct illegal is generally not permissible as it would be merely advisory. *Am. Civil Liberties Union of Massachusetts v. U.S. Conference of Catholic Bishops*, 705 F.3d 44, 53 (1st Cir. 2013).

Defendant incorporates by reference its discussion of Plaintiffs' preemption claim in pages 38-42 of their Motion to Dismiss, including the argument on the merits, which Defendant deems unnecessary due to the mootness argument.[5]

[5] To avoid sounding repetitive, Defendant directs the Court's attention to his arguments regarding the supplemental claims brought in the Motion to Dismiss, as if fully set forth herein. Additionally, the Puerto Rico Court of First Instance has ruled that vaccine mandates similar to the ones challenged here do not violate the Constitution of the Commonwealth of Puerto Rico.

B. Plaintiffs have not suffered an irreparable harm that warrants the issuance of a preliminary injunction.

Irreparable harm is a necessary threshold for awarding preliminary injunctive relief. Preliminary injunctions are strong medicine, and they should not be issued merely to calm the imaginings of the movant. *Matos ex rel. Matos v. Clinton Sch. Dist.*, 367 F.3d 68, 73 (1st Cir. 2004). A preliminary injunction should not issue except to prevent a real threat of harm. *Ross–Simons,* 102 F.3d at 19; 11A Charles Alan Wright, Arthur R. Miller, & Mary Kay Kane, Federal Practice & Procedure § 2948.1, at 153–54 (2d ed.1995). A threat that is either unlikely to materialize or purely theoretical will not do. *Ross–Simons,* 102 F.3d at 19; *Pub. Serv. Co. v. Town of W. Newbury,* 835 F.2d 380, 382 (1st Cir.1987). If a case can be adjudicated on the merits before the harm complained of will occur, there is no sufficient justification for preliminary injunctive relief. 11A Wright, Miller, & Kane, *supra* § 2948.1, at 149. The irreparable harm must be "neither remote nor speculative, but actual and imminent". *In re Bora Bora, Inc.*, 424 B.R. 17, 26 (Bankr. D.P.R. 2010).

The Supreme Court has frequently reiterated that the standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction. *Los Angeles v. Lyons,* 461 U.S. 95, 103 (1983). Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief. *Mazurek v. Armstrong,* 520 U.S. 968 (1997) (*per curiam*). In each case, courts "must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief." *Amoco Production Co.,* 480 U.S., at 542.

In most cases, irreparable harm constitutes a necessary threshold showing for an award of preliminary injunctive relief. Irreparable harm is "an essential prerequisite" for receiving such redress. The burden of demonstrating that a denial of interim relief is likely to cause irreparable harm rests squarely upon the movant. *Charlesbank Equity Fund II v. Blinds to Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004) (Internal citation omitted). A finding of irreparable harm must be grounded on something more than conjecture, surmise, or a party's unsubstantiated fears of what the future may have in store. *Regan v. Vinick & Young* (*In re Rare Coin Galleries of Am., Inc.*), 862 F.2d 896, 902 (1st Cir.1988). An injunction should issue only where the intervention of a court of equity "is essential in order effectually to protect property rights against injuries otherwise irremediable." *Cavanaugh v. Looney*, 248 U.S. 453, 456 (1919).

In the case at hand, Plaintiffs utterly failed to specify the necessary factual allegations of irreparable harm needed to clear the threshold for an award of preliminary injunctive relief. Instead, Plaintiffs aver in a slapdash fashion that they made a strong showing of irreparable harm because they will allegedly suffer (1) loss of bodily autonomy; (2) loss of money; and (3) medical privacy. (Docket No. 16 at 32). This is an incorrect presumption on the part of Plaintiffs. Defendant has already demonstrated Plaintiffs' unlikelihood of success based on those meritless allegations. Predominantly, Plaintiffs have the choice to submit a weekly negative COVID-19 test instead of being vaccinated. The Seventh Circuit determined that it was easier in *Klaassen* to determine a lack of substantive due process violation than in *Jacobson* because the latter lacked exception for adults, and Indiana University did not require every adult member of the public to be vaccinated. *Klaassen*, 7 F.4th 592.

Here, similarly, the Executive Order provides exceptions as the ones in the *Klaassen* case, that is, medical and religious exemptions and a generic opt out subject to preventative

measures such as COVID-19 testing and mask-wearing. If Plaintiffs understand that they will suffer a loss of bodily autonomy and medical privacy by being vaccinated, they have the alternative to submit a negative weekly test of Covid 19. The District Court in Klaassen applied *Jacobson* and found that there is no "fundamental constitutional right to not be tested for a virus before entering a place of public accommodation". *Klaassen*, No. 1:21-CV-238 DRL, 2021 WL 3073926, at *38.

Notwithstanding the above, Plaintiffs insist that the accommodations provided by the Commonwealth are "heavily burdensome, unreasonable, and almost impossible to meet." (Docket No. 16 at 14). However, as previously discussed under the rational basis review in *Jacobson*, the requirement to obtain weekly test is more than justified and clearly a less onerous mean to obtain its compelling public health objectives. In addressing claims similar to Plaintiffs, the District Court in *Klaassen* stated:

> These [substantive due process rights] aren't rights so "deeply rooted in this Nation's history and tradition" and so "implicit in the concept of ordered liberty" such that "neither liberty nor justice would exist if they were sacrificed." *Washington v. Glucksberg*, 521 U.S. 702, 721, 117 S.Ct. 2258, 138 L.Ed.2d 772 (1997)[...]. These aren't issues of fundamental constitution import, but often transient and trivial inconveniences.

No. 1:21-CV-238 DRL, 2021 WL 3073926, at *39.

Plaintiffs' unwarranted and fickle challenge to the Executive Order cannot trump over the safety of the citizens of Puerto Rico. The Governor of Puerto Rico has a legitimate and compelling interest in safeguarding the lives and health of its citizens. Providing a weekly negative testing result before entering a public building is not only a reasonable measure, but a less restrictive means of advancing its public health goal, hence, showing no irreparable harm warranting the issuance of a preliminary injunction.

Regarding the alleged economic injury for doctor referrals, covid tests, and loss of potential and current earnings, it is important to highlight that "mere injuries, however substantial, in terms of money, time and energy necessarily expended … are not enough [to establish irreparable harm]. The First Circuit has concluded that the right to "make a living" is not a "fundamental right," for either equal protection or substantive due process purposes. *Medeiros v. Vincent*, 431 F.3d 25, 32 (1st Cir. 2005) (abrogated in part on other grounds by *Bond v. United States*, 564 U.S. 211 (2011). The possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation, weighs heavily against a claim of irreparable harm." *Sampson v. Murray*, 415 U.S. 61, 90 (1974) (alteration in original). Courts have long held that traditional economic damages are remedied by compensatory awards, and thus do not rise to the level of being irreparable that is required to issue a preliminary injunction. *Puerto Rico Hosp. Supply, Inc. v. Boston Scientific Corp.*, 426 F.3d 503, 507 (1st Cir. 2005).

A preliminary injunction will not be issued simply to prevent the possibility of some remote future injury. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (*per curiam*). The Southern District of Florida Court has expressed similar views under the COVID-19 vaccine context, stating:

> It is also unlikely that Plaintiffs would be able to meet their burden of establishing irreparable harm. If Plaintiffs are terminated for failing to get vaccinated and United's actions are later deemed to have violated Plaintiffs' rights, then Plaintiffs can be made whole with monetary damages—just like in any other employment dispute.

Ron Hencey, et al., v. United Airlines, Inc., et al., No. 21-61702-CIV, 2021 WL 3634630, at n.3 (S.D. Fla. Aug. 17, 2021).

Moreover, Plaintiffs misguidedly allege, as economic damages, that they would have to obtain medical referrals, at their own expense, for each weekly COVID-19 test. This is far from the truth, as El Nuevo Día has published a list of venues, throughout the entire island, where free COVID-19 tests are available.[6] These venues are available to Plaintiffs, as well as all other persons who require testing. Therefore, Plaintiffs lack an irreparable harm due to the Vaccine Requirement in the Executive Order.

Plaintiffs also allege that they could face the pain of losing all their accrued vacation and sick days, and eventually their salaries. This is mere speculation and refers to a future possible harm, which fails to comply with the irreparable harm requirement for preliminary injunction. Furthermore, as stated in the previous paragraph, there are multiple venues where the Plaintiffs can have COVID-19 tests free of charge, and even at their convenience. *See League of Independent Fitness Facilities and Trainers, Inc. v. Whitmer,* 814 Fed. Appx. 125, 129 (6th Cir. 2020)*(citing Maryland v. King*, 567 U.S. 1301, 1301, 133 S.Ct. 1, 183 L.Ed.2d 667 (2012)(Enjoining the actions of elected state officials, especially in a situation where an infectious disease can and has spread rapidly, causes irreparable harm.). Therefore, there is no impending need for Plaintiffs to exhaust their accrued vacation, sick leave, or unpaid leave.

Plaintiffs have not shown that, without an injunction, they would suffer an irreparable harm, not economic in nature. Furthermore, Plaintiffs are not able to recover monetary losses against the Commonwealth, its agencies or its officers, in their official capacity, in light of the sovereign immunity. Plaintiffs have readily available administrative remedies if they understand that the agency in which they work has retained any economic compensation.

6 https://www.elnuevodia.com/noticias/locales/notas/pruebas-de-covid-19-mira-los-lugares-donde-te-las-puedes-realizar-gratis-en-puerto-rico/

Therefore, this Court must **DENY** the preliminary injunctive relief because Plaintiffs have not shown the potential for irreparable harm if the relief is denied.

C. The balance of equities and the effect of the Court's ruling on the public interest undisputedly tip the balance in favor of denying a preliminary injunctive relief.

The Supreme Court has stated that the final two factors—"assessing the harm to the opposing party and weighing the public interest"—typically "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). Accordingly, the Court should analyze these factors together. A preliminary injunction is a potent weapon that should be used only when necessary to safeguard a litigant's legitimate interests. *Charlesbank Equity Fund II v. Blinds to Go, Inc.,* 370 F.3d 151, 163 (1st Cir. 2004). Crafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as well as the substance of the legal issues it presents. *See Winter v. Natural Resources Defense Council, Inc.,* 555 U.S. 7, at 20 & 24 (2008). The purpose of such interim equitable relief is not to conclusively determine the rights of the parties, but to balance the equities as the litigation moves forward. *University of Tex. v. Camenisch,* 451 U.S. 390, 395 (1981).

In each case, courts "must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief." *Amoco Production Co.,* 480 U.S. at 542. "In exercising their sound discretion, courts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Weinberger,* 456 U.S. 305, 312 (1982). Thus, "[a]n injunction should issue only where the intervention of a court of equity is essential to effectually protect property rights against injuries otherwise irremediable." *Voice of the Arab World, Inc. v. MDTV Med. News Now, Inc.*,

645 F.3d 26, 32 (1st Cir. 2011). This involves weighing "the balance of relevant hardships as between the parties." *Vaquería Tres Monjitas, Inc. v. Irizarry*, 587 F.3d 464, 482 (1st Cir. 2009). The Court must balance "the hardship that will befall the nonmovant if the injunction issues … with the hardship that will befall the movant if the injunction does not issue." *Mercado-Salinas v. Bart Enterprises Int'l, Ltd.*, 671 F.3d 12, 19 (1st Cir. 2011). A preliminary injunction is not appropriate unless there is "a fit (or lack of friction) between the injunction and the public interest." *Nieves–Marquez v. Puerto Rico,* 353 F.3d 108, 120 (1st Cir. 2003).

In the instant case, the public interest is great, where COVID-19 has infected and taken the lives of 2,860 residents in Puerto Rico (as of August 30, 2021)[7] with the potential to infect more. Defendant takes issue with Plaintiffs' rash and irresponsible allegation that the Governor's public health policy regarding COVID-19 "is the government's attempt to protect the unvaccinated population, who chose to assume the risk of not getting vaccinated, from themselves." (Docket No. 16 at 17). Plaintiffs selfishly overlook the fact that at the moment children under twelve years old cannot get a vaccine to protect themselves against COVID-19. According to the CDC, hospitalization rates tripled in children age 4 and younger the week of July 17 compared to June 26.[8] The public policy of the Government of Puerto Rico is mainly directed toward preventing the spread of the virus and saving lives, including those who are unable to consent to the COVID-19 vaccines.

The Governor's interest in combatting COVID-19 is of utmost importance to all residents of Puerto Rico. To date, the disease has infected more than a hundred thousand, thousands also have died, and it has shown the potential of infecting many more with the

7 https://covid19datos.salud.gov.pr/#resumen
8 https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/transmission_k_12_schools.html

advent of the Delta variant. At the moment, along with social distancing and face masks, the best weapon available against COVID-19 is the vaccine. That the public interest weighs in favor of a denial of a preliminary injunction is apparent for the same reason. *League of Indep. Fitness Facilities & Trainers, Inc. v. Whitmer*, 814 F. Appx 125, 129–30 (6th Cir. 2020).

Defendant understood when issuing the Executive Order that some employees would not be able to get vaccinated because of medical reasons, would refuse to get vaccinated for religious reasons, or would rather not get vaccinated for personal belief. In any of those cases, the Executive Order provides the employees of the executive branch with opt-outs to the COVID-19 vaccine, which are contained in Sections 2 and 3 of the Executive Order. Crises like the COVID-19 pandemic can call for quick, decisive measures to save lives. Yet, the Governor's order need not be the most effective or least restrictive measure possible to attempt to stop the spread of COVID-19. *League of Indep. Fitness Facilities & Trainers, Inc.,* 814 F. Appx at 129 *(citing Heller*, 509 U.S. at 321, 113 S.Ct. 2637 (courts are compelled under rational-basis review to accept a legislature's generalizations even when there is an imperfect fit between means and ends)). These measures can create collateral effects that often are not borne evenly. The responsibility to adopt the measures to be taken in a public health emergency rest with the political branches of government and it is them who will also respond to the citizens. *S. Bay United Pentecostal Church*, 140 S. Ct. at 1613. The First Circuit has acknowledged the importance of the public interest weighing in favor of denying a preliminary injunction. *See Water Keeper All. v. U.S. Dep't of Def.,* 271 F.3d 21, 35 (1st Cir. 2001) (determining that any injury is outweighed by the public interest).

In contrast, when the interest of the state governments is not outweighed by public interest, Courts have granted preliminary injunctions. For instance, a District Court in Florida

upheld preliminary injunction because the balance of harm and public interest weighed in favor of enjoinment. *Norwegian Cruise Line Holdings, Ltd. v. Rivkees*, No. 21-22492-CIV, 2021 WL 3471585 (S.D. Fla. Aug. 8, 2021) Specifically, that the balance of harm and public interest weighed in favor of preliminary injunction barring the State of Florida from enforcing statute prohibiting businesses from requiring their patrons to present documentation certifying COVID-19 vaccination or post-infection recovery for access or services. *Id*. The Court determined that public health would be jeopardized if it required to suspend its vaccination requirement. *Id*.

Here, public health and safety during the emergency of the COVID-19 pandemic are factors that outweigh any other consideration presented by Plaintiffs. Specially, when Plaintiffs' objections to the opt-outs in the Executive Order are mere inconveniences and general grievances. These inconveniences and general grievances compared with the fact that COVID-19 is spreading fast among the population of Puerto Rico, where more than a hundred thousand have been infected, and over two thousand have died as a consequence of contracting COVID-19, the balance of equities undisputedly tip in favor of the public health and safety policy established by the Governor. Therefore, Plaintiffs' request for a preliminary injunction must be **DENIED**.

D. Plaintiff has not posted the required security deposit for the issuance of a preliminary injunction.

Plaintiffs insist that this Court waives any bond requirement pursuant to Rule 65(c) of Federal Rules of Civil Procedure (Docket No. 16 at 34), but that is not possible. Rule 65(c) states that "[n]o restraining order or preliminary injunction shall issue except upon the giving of security by the applicant, for the payment of such costs and damages as may be incurred or

suffered by any party who is found to have been wrongfully enjoined or restrained." Fed.R.Civ.P. 65(c). Although "the amount of the bond is left to the discretion of the court, the posting requirement is much less discretionary." *See Frank's GMC Truck Ctr., Inc. v. Gen. Motors Corp.*,847 F.2d 100, 103 (3d Cir.1988) ("While there are exceptions, the instances in which a bond may not be required are so rare that the requirement is almost mandatory.") In other words, Rule 65(c) "mandates that a court when issuing an injunction must require the successful applicant to post adequate security." *Id*. Therefore, since the instant case is not within any exception, Defendant argues that due to the adverse impact that an issuance of a preliminary injunction of this nature could have on the public health and safety in the midst of a COVID-19 pandemic, a bond of no less than $35,000 is required to be posted.

IV. CONCLUSION

As discussed above, Puerto Rico is suffering a public health crisis, the exigency of which has not yet diminished. During pandemic times, *Jacobson* instructs that courts should only overturn state action when it lacks a "real or substantial relation to the protection of the public health" or represents "a plain, palpable invasion of rights secured by the fundamental law." (*Jacobson*, 197 U.S. at 31, 25 S.Ct. 358). The Executive Order vaccine mandate and its exemptions have a real and substantial relation to the protection of the public health of all citizens in Puerto Rico.

Plaintiffs' allegations do not meet any of the necessary requirements that must be established for the issuance of such an extraordinary relief (the preliminary injunction). First, Plaintiffs are unlikely to succeed on the merits because of the arguments espoused in the Motion to Dismiss, adopted by reference as if fully set forth herein and discussed in this Response. Second, Plaintiffs have failed to set forth an irreparable harm and their alleged

economic damages cannot be considered irreparable harm because those type of damages can be awarded later like any other employment dispute and are easily avoidable should the Plaintiffs have their COVID-19 tests in one of the venues where they are free of charge, as published by El Nuevo Día. Lastly, the public health and safety during an emergency are factors that outweigh any other consideration presented by Plaintiffs.

The requirement of vaccination against COVID-19 for public employees who work in person in the executive branch is a necessary measure to achieve the pressing Government interest of guaranteeing public health and safety, mitigating the harmful effects of the pandemic, and finally achieving immunity herd in Puerto Rico. Although the power of the government is not unrestricted, even in a state of emergency such as this one, the vaccination requirement at this time is the least burdensome means and respond to a compelling interest to achieve these government objectives, thus fulfilling any standard of scrutiny. Returning to full remote work for all public employees and curtailing the Governments services to the public or other restrictions of social isolation, such as curfews or closures in the social and economic environment ("lockdown"), including the closing of schools and return to virtual learning are more restrictive and burdensome, but required if the present less restrictive measure do not achieve the Government's compelling interest in public health and safety.

If the remedy requested by Plaintiffs is granted, the repercussions could be catastrophic, since the residents of Puerto Rico would be exposed to an exponential growth of persons infected with COVID-19; unnecessary deaths, hundreds or thousands of people hospitalized in already saturated hospitals, until the collapse of our health system. Science and public safety must prevail over subtle inconveniences and general grievances of those who choose not to be vaccinated. Even one life lost to the enjoinment of the Executive Order would be too much to

bear. It is respectfully pleaded that this Court maintain the status quo and deny the request for preliminary injunction to allow the Government of Puerto Rico to prevent the spread of this deadly virus through the Executive Order. Indeed, any other determination would undoubtedly cause irreparable harm and put lives at risk.

WHEREFORE, based on the arguments set forth in the instant motion, it is respectfully requested that the Court **DENIES** a preliminary injunctive relief.

I HEREBY CERTIFY that on this same date, I electronically filed the foregoing with the Clerk of the Court using CM/ECF system which will send notification of such filing to all attorneys of record.

RESPECTFULLY SUBMITTED.

In San Juan, Puerto Rico, on August 31st, 2021.

DOMINGO EMANUELLI-HERNÁNDEZ
Secretary of Justice

SUSANA I. PEÑAGARÍCANO-BROWN
Deputy Secretary in Charge of Litigation

S/Idza Díaz Rivera
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FDA NEWS RELEASE

FDA Approves First COVID-19 Vaccine

Approval Signifies Key Achievement for Public Health

For Immediate Release:

August 23, 2021

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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