IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

ZULAY RODRÍGUEZ VÉLEZ; YOHAMA GONZÁLEZ MILÁN; LEILA G. GINORIO CARRASQUILLO; AND JULISSA PIÑERO *Plaintiffs,* v. **HON. PEDRO PIERLUISI URRUTIA,** in his official capacity as Governor of the Commonwealth of Puerto Rico *Defendants*.	**CIVIL No.** 21-1366 (PAD) **Jury Trial Demanded**

MOTION TO DISMISS

TO THE HONORABLE COURT:

COME NOW, Defendant **Hon. Pedro R. Pierluisi-Urrutia**, in his official capacity as Governor of Puerto Rico, without waiving any right or defense arising from Title III of *Puerto Rico Oversight, Management and Economic Stability Act* ("PROMESA"), 48 U.S.C. §§2101 *et seq*., and the Commonwealth's Petition under said Title or under this case and without submitting to the Court's jurisdiction, and through the undersigned attorney, very respectfully **STATES** and **PRAYS** as follows:

I. INTRODUCTION

As the hospitalizations and death tolls in Puerto Rico continue to dramatically spike due to the new Delta variant of COVID-19,[1] on August 16, 2021, Ms. Zulay Carrasquillo-Vélez; Ms. Yohama González-Milán; Ms. Leila G. Ginorio Carrasquillo; and Ms. Julissa Piñero

[1] This Court can take judicial knowledge that the Commonwealth's Department of Health has reported the following data: (i) 479 hospitalized adults, of which 130 are in the Intensive Care Unit ("ICU'); (ii) 35 hospitalized minors, of which 1 is in ICU; (iii) 394 confirmed cases in a day, as of August 30, 2021; (iv) 281 probable (antigen test) cases in a day; and (v) 8 deaths in a day, as of August 30, 2021. *See COVID-19 Statistics in Puerto Rico*, Department of Health, https://covid19datos.salud.gov.pr/#resumen (retrieved on August 31, 2021); *see also* Rule 201 (b) (2) of Federal Rules of Evidence ("The court may judicially notice a fact that is not subject to reasonable dispute because it: [...] can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.")

("Plaintiffs"), four public employees that work in the Commonwealth of Puerto Rico's ("Commonwealth") Department of the Family, Gaming Commission, Department of Labor and Human Resources, and the Department of Public Safety, respectively (Docket No. 11 at 15-16, ¶¶42-45), filed the instant case in an attempt to obstruct Executive Order No. 2021-058 ("Executive Order") issued by the Hon. Pedro R. Pierluisi-Urrutia, Governor of Puerto Rico ("Governor" or "Defendant"), in a compelling effort of tackling the alarming growth in positive cases of COVID-19 in Puerto Rico, resulting in hospitalization, oversaturated hospitals, and deaths.[2] Essentially, the Executive Order requires that all public employees of the Executive Branch vaccinate against COVID-19 or, alternatively, provide a weekly negative COVID-19 test result if he or she does not want to vaccinate or falls within a religious or medical exception. *See* Docket No. 11-1 at 10-11.

As to the specific arguments raised in the Amended Complaint, Plaintiffs set forth a facial and as applied challenge to the Executive Order alleging the following: (1) that by putting it into effect, the Commonwealth is being "arbitrary and capricious [for] coercing and *deceiving* its public employees into getting vaccinated without any regard to their fundamental rights to personal autonomy, religious liberty, and medical decision making," Docket No. 11 at 8, ¶17; (2) that the "so-called" religious and medical exceptions to vaccination established by the Governor are vague and unclear, *id.*, ¶20; (3) that the Commonwealth does not understand its "own orders, or … [is] purposely deceiving public employees into believing that only if they have a medical condition or religious objection may they choose to submit to weekly COVID-

[2] Plaintiffs argue that they are challenging other Commonwealth's "rolling executive orders," Docket No. 11 at 1, ¶1, but fail to identify the orders and the grounds for the constitutional challenge. Therefore, since Plaintiffs failed to plausibly plead a constitutional challenge of other specific executive orders, this Court must disregard any arguments set forth against unknown legal precepts. *See U.S. v. Zannino,* 895 F.2d 1, 17 (1st Cir. 1990) (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.").

19 tests instead of getting vaccinated," *id.* at 9, ¶24; (4) that the Commonwealth is discriminating "against those with medical conditions and religious beliefs by imposing additional burdens," *id*. at 11, ¶27; and (5) that the Commonwealth is "willing to do anything to force the plaintiffs, and other Puerto Ricans, even by deceit, into getting vaccinated, with little regard to their fundamental right to personal autonomy, religious beliefs, and medical choice." *id*., ¶29.

Consequently, Plaintiffs allege that the Executive Order violates: (1) the U.S. Constitution Fourteenth Amendment's substantive and procedural Due Process Clause; (2) the Religious Freedom Restoration Act ("RFRA"), 42 U.S.C. §§ 2000bb-1 *et seq*.; (3) the Food and Drug Administration's Emergency Use Authorization statute, 21 U.S.C. § 360bbb-3; and (4) the Constitution of the Commonwealth of Puerto Rico, P.R. Const. Art. II, §§ 1 & 8. Further, in their blatant attempt to formulate the Commonwealth's public health policy regarding COVID-19 through this case, Plaintiffs propose "less intrusive means that the government can implement to attain its objective of preventing the spread of COVID-19 in government facilities without unduly burdening the plaintiffs' constitutional rights." Docket No. 11 at 12-13, ¶¶30-34.

Defendant will put this Court in position to confirm that Plaintiffs' reckless theories are based on flawed statistical and public policy conclusions that are more fit to be analyzed and rebutted in scientific or political forums rather than in a court of law. *See S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613 (2020) (Roberts, C.J., concurring opinion) ("Our Constitution principally entrusts '[t]he safety and the health of the people' to the politically accountable officials of the States 'to guard and protect. [...] Where [public officials'] broad limits are not exceeded, they should not be subject to second-guessing by an 'unelected federal judiciary,' **which lacks the background, competence, and expertise to assess public**

health and is not accountable to the people."); *see also Klaassen v. Trustees of Indiana U.*, 1:21-CV-238 DRL, 2021 WL 3073926, at *46 (N.D. Ind. July 18, 2021) ("Reasonable social policy is for the state legislatures and its authorized arms, and for the People to demand through their representatives."). Moreover, Defendant will establish that the Executive Order is clearly a constitutional exercise of the Commonwealth's police powers to safeguard the health and lives of its employees and citizens. *See Jacobson v. Cmmw. of Massachusetts*, 197 U.S. 11 (1905) (holding 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).

Clearly, 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. In that sense, based on the ensuing grounds, the Court will be able to conclude that the Executive Order: (i) does not violate the Fourteenth Amendment's substantive due process being that it passes either a rational or strict scrutiny since, through its exceptions or "opt outs" —although not constitutionally required—, it uses less onerous means to advance the compelling public health interest in safeguarding the lives and health of its citizens; (ii) does not violate the Fourteenth Amendment's procedural due process because Plaintiffs' have not been deprived of a proprietary 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 the 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's constitutional claims; nonetheless, the pendent claims fall flat in light of the recent Puerto Rico Court of First Instance's decision on the matter. Therefore, Defendant requests that the case be **DISMISSED with prejudice** pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure on the grounds that, even after taking all well pleaded allegations as true, the Executive Order is a constitutional exercise of the Commonwealth's police powers to safeguard the health and lives of its employees and citizens, which swiftly passes any applicable constitutional standard.

II. THE SCOPE OF EXECUTIVE ORDER 2021-058

On July 28, 2021, the Governor issued the Executive Order, OE-2021-058, to address the alarming spike of positive cases, hospitalizations, and death tolls because of the Delta variant of the COVID-19. *See* Docket No. 11-1. The Executive Order requires that public employees of the Executive Branch that work in-person be vaccinated to safeguard the health and lives of their peers and of all the citizens that seek in-person services in government agencies. *See id*. Specifically, Section 1 of the Executive Order requires that all public employees that work in-person be fully vaccinated by September 30, 2021. *Id*. at 9-10. This requirement is met by simply providing a copy of the COVID-19 Vaccination Record Card or a document attesting to the completion or beginning of the vaccination process. *Id*. at 10.

However, the Executive Order is not an absolute mandate for public employees to be vaccinated, as it contemplates certain exceptions or "opt-out" alternatives for those that do not want to be inoculated with the COVID-19 vaccines. Docket No. 11-1 at 10-12. In that sense, Section 2

of the Executive Order establishes two exceptions or "opt-outs" available for public employees that do not want to be inoculated with a COVID-19 vaccine and that want to voluntarily state either a medical or religious motive for not complying. *Id*. at 10-11. **First**, the medical exception provides that public 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," but must provide a certification issued "by a physician authorized to practice in Puerto Rico." *Id*. at 10. **Second**, the religious exception provides that a public employee may voluntarily embrace that he or she cannot be vaccinated "on the basis of religious beliefs- provided that the vaccines are against the employee's religious observance," but "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." *Id*. at 11. **In addition**, public employees that opt to invoke one of the exceptions or "opt-outs" for mandatory vaccination pursuant to Section 2 of the Executive Order, must provide a weekly negative SARS-CoV2 test (Nucleic Acid Amplification Test ("NAAT") and antigen tests) performed within a maximum of seventy-two (72) hours prior. *Id*. at 11.

Further, Section 3 of the Executive Order provides a general "opt-out" alternative for public employees that plainly refuse inoculate for any reason. Precisely, Section 3 establishes that "**[a]ny** government employee [...] 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). Inversely, Section 3 clearly states that "[a]ny 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." *Id.* However, "[public employees that do not comply with the Executive Order] 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." *Id*. 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 provides a general alternative to public employees that simply do not want to inoculate with a COVID-19 vaccine, regardless of the reason not to do so. 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 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. Either way, at the end, both groups—exempts and not exempts—will have to get tested for COVID-19 at least 72 hours before returning to work in-person every Monday.

The Executive Order provides clear and unambiguous reasonable alternatives for public employees that refuse to be inoculated with a COVID-19 vaccine, like medical and religious exceptions, as well as a to those who do not want to be vaccinated for reasons not contemplated in said exceptions.[3] Thus, this Court will be able to conclude that, either under a rational or strict

[3] Although Plaintiffs imprecisely assert in the Amended Complaint that the Executive Order is "vague," Docket 11 at 8, ¶¶18-20, 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.").

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.

III. STANDARD OF REVIEW PURSUANT TO RULE 12(b)(6) OF FEDERAL CIVIL PROCEDURE

To survive a Rule 12(b)(6) motion to dismiss, Plaintiff's "well-pleaded facts must possess enough heft to show that they are entitled to relief." *Clark v. Boscher*, 514 F.3d 107, 112 (1st Cir. 2008). That is, a complaint must contain sufficient factual matter "to state a claim to relief that is plausible on its face." *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In doing so, the court must accept as true all "well-pleaded facts [and indulge] all reasonable inferences in plaintiffs' favor." *Id.*; *see also Ocasio-Hernández v. Fortuño-Burset*, 640 F.3d 1, 17 (1st Cir. 2011) (holding that federal courts are required to "construe the facts of the complaint in the light most favorable to the plaintiffs, and to resolve any ambiguities in their favor."); *Doyle v. Hasbro, Inc.*, 103 F.3d 186, 190 (1st Cir. 1996) (holding that dismissal under Rule 12 (b)(6) is "appropriate if the facts alleged, taken as true, do not justify recovery.").

In judging the sufficiency of a complaint, courts must "differentiate between well-pleaded facts, on the one hand, and 'bald assertions, unsupportable conclusions, periphrastic circumlocution, and the like,' on the other hand; the former must be credited, but the latter can safely be ignored." *LaChapelle v. Berkshire Life Ins.*, 142 F.3d 507, 508 (quoting *Aulson v. Blanchard*, 83 F.3d 1, 3 (1st Cir. 1996)); *Buck v. American Airlines, Inc.*, 476 F.3d 29, 33 (1st Cir. 2007); *see also Rogan v. Menino*, 175 F.3d 75, 77 (1st Cir. 1999). Moreover, "even under the liberal pleading standards of Fed R. Civ. P. 8, the Supreme Court has held that to survive a motion to dismiss, a complaint must allege 'a plausible entitlement to relief.'" *Twombly*, 550 U.S. at 559.

Although complaints do not need detailed factual allegations, the plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. *See id*. at 556.

In *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), the Supreme Court of the United States clarified that two underlying principles must guide a court's assessment of the adequacy of pleadings when evaluating whether a complaint can survive a Rule 12(b)(6) motion. First, the Court explained that it is not compelled to accept legal conclusions. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*. (citing *Twombly*, 550 U.S. at 555). Second, a complaint survives only if it states a plausible claim for relief. *Twombly*, 550 U.S. at 556. Thus, any non-conclusory factual allegations in the complaint, accepted as true, must be sufficient to give the claim facial plausibility. *See id*. A claim has facial plausibility when the pleaded facts allow the court to reasonably infer that the defendant is liable for the specific misconduct alleged. *Iqbal*, 556 U.S. at 678. Such inferences must amount to more than a sheer possibility and be as plausible as any obvious alternative explanation. *Id*. Plausibility is a context-specific determination that requires the court to draw on its judicial experience and common sense. *Id*. at 67.

Based on the arguments that follow and on the lack of plausibly pleaded allegations, Defendant hereby requests the Court to **DISMISS with prejudice** the Amended Complaint (Docket No. 11) because Plaintiffs' allegations fail to set forth a cognizable claim upon which relief can be granted.

IV. DISCUSSION

A. The Executive Order is a valid exercise of the Commonwealth's police powers during the COVID-19 pandemic public health emergency.

The Governor issued the challenged Executive Order pursuant to Section 5.10 of the *Puerto Rico Public Safety Department Act*, Act No. 20-2017, which empowers him to, upon declaring a state of emergency or a disaster, promulgate measures as are necessary to manage said emergency, which shall be in effect for the duration of the emergency to protect the safety, health, and property of all the citizens of Puerto Rico. *See* Act No. 20-2017, Sec. 5.10. Specifically, Act No. 20-2017, Section 5.10 (b), provides that the Governor may prescribe, amend, and revoke any regulations as well as issue, amend, and rescind such orders as deemed convenient which shall be in effect for the duration of the state of emergency or disaster. *Id.*, Sec. 5.10(b). Therefore, the Commonwealth's Legislative Assembly authorized the Governor to issue executive orders in order to address any public emergencies, such as the COVID-19 pandemic, to protect the health and safety of its population.

Consistent with the powers vested to the Governor by Act No. 20-2017, he issued the Executive Order to address an alarming spike in COVID-19 positive cases, hospitalizations, and death tolls because of the ongoing pandemic. *See* Docket 11-1. Essentially, the Executive Order requires that all public employees from the Executive Branch that work in-person be vaccinated against COVID-19. *Id*. However, the Executive Order provides three "opt out" alternatives from the mandatory vaccination requirement: (1) a medical exception (which has to be certified by a physician authorized to practice medicine in the Commonwealth); (2) a religious exception (which has to be certified by the employee's religious leader); and (3) a general "opt out" for public employees that do not fall within the medical or religious exceptions. Additionally, all public employees that opt not to inoculate with the COVID-19 vaccine must provide a weekly

negative qualified SARS-CoV2 test, performed within a maximum of seventy-two (72) hours prior to the beginning of the week.

Since *Jacobson*, 197 U.S. 11, the Supreme Court has upheld the government's exercise of its police powers to promote public safety in times of a public health crisis, such as the COVID-19 pandemic. To that end, the Supreme Court held that "a community has the right to protect itself against an epidemic of disease which threatens the safety of its members." *Id*. at 27. Further, in *Jacobson*, the Supreme Court established that a state's police power "must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety." *Id*. at 25. This police power included the "authority of a state to enact quarantine laws and health laws of every description;" and such power extended to "all laws that relate to matters completely within its territory and which do not by their necessary operation affect the people of other states." *Id*. Consequently, in *Jacobson*, the Supreme Court upheld as constitutional a vaccination requirement that lacked exceptions for adults. *See id*. at 30.

Later, in *Zucht*, the Supreme Court reiterated *Jacobson* and held that "it is within the police power of a state to provide for compulsory vaccination." 260 U.S. 174, 176 (1922). To date, *Jacobson* and *Zucht* are still good law and have not been overruled by the Supreme Court. *See Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S.Ct. 63, 71 (2020) (Gorsuch, J., concurring) (citing *Jacobson* with approval); S. *Bay United Pentecostal Church*, 140 S. Ct. at 1613 (citing *Jacobson* with approval); *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944) (citing *Jacobson* with approval); *Klaassen v. Trustees of Indiana U.*, 7 F.4th 592 (7th Cir. 2021) (citing *Jacobson* with approval); *Workman v. Mingo County Bd. of Educ.*, 419 Fed. Appx. 348, 353 (4th Cir. 2011) (unpublished) (citing *Jacobson* with approval).

Recently, in *Klaassen*, 7 F.4th 592, the U.S. Court of Appeals for the Seventh Circuit ("Seventh Circuit"), addressing a constitutional challenge made by a group of students against a vaccine mandate issued by Indiana University, held that since in *Jacobson* the Supreme Court established that a state may require all members of the public to be vaccinated against smallpox, "there [cannot] be a constitutional problem with vaccination against SARS-CoV-2." 7 F.4th at 592.

Still, a century after *Jacobson* and *Zucht* were decided, and weeks after *Klaassen*, Plaintiffs set forth flawed arguments and erred constitutional challenges that have been consistently rejected by federal courts. *See* ERWIN CHEMERINSKY, MICHELE GOODWIN, *Compulsory Vaccination Laws Are Constitutional*, 110 Nw. U.L. Rev. 589, 608 (2016) (stating that "the cases from courts at all levels and from all jurisdictions are unanimous: state laws requiring compulsory vaccination are constitutional."). Here, Plaintiffs challenge the Governor's Executive Order, which is less restrictive than the vaccine mandates that were upheld by the Supreme Court in *Jacobson* and in *Zucht* requiring compulsory inoculation, and similar to the vaccine mandate upheld by the Seventh Circuit in *Klaassen,* which recognized certain exceptions.

As explained before, the Executive Order provides public employees three alternatives to "opt out" of the mandatory vaccination requirement. *See* Docket No. 11-1 at 10-12. In that sense, where more restrictive compulsory vaccine mandates have been held constitutional, it follows that a lesser restrictive vaccine requirement falls well within the broad limits of the Commonwealth's police powers to protect the health and lives of its citizens. *See Roman Catholic Diocese of Brooklyn*, 141 S.Ct. at 71 (stating that the vaccine requirement in *Jacobson* "easily survived rational basis review, and might even have survived strict scrutiny, given the

opt-outs available to certain objectors."); *see also Gonzales v. Carhart*, 550 U.S. 124, 163 (2007) (recognizing that state and federal governments have wide discretion to act in areas where there is medical and scientific uncertainty) (citing *Kansas v. Hendricks*, 521 U.S. 346, 360, n. 3 (1997). Therefore, it is forceful to conclude that the challenged Executive Order requiring mandatory vaccination or a weekly negative COVID-19 qualified tests to public employees is a valid constitutional exercise of the Commonwealth's police powers. *See* CHEMERINSKY & GOODWIN, 110 Nw. U.L. Rev. at 595 (stating that "the government's interest in protecting [citizens] and preventing the spread of communicable disease justifies mandatory vaccinations for all [citizens] in the United States.").

B. The Executive Order does not violate Plaintiff's Fourteenth Amendment's due process rights.

1. The Executive Order does not violate Plaintiffs' substantive due process rights inasmuch it addresses a compelling government interest through less onerous means.

Plaintiffs' substantive due process allegations are mostly based on their personal interpretation of random data downloaded from the internet to push, through this Court, their own COVID-19 public health policy for the Commonwealth. As previously discussed, Plaintiffs are not in charge of designing the Commonwealth's public health policy, as that matter falls within the sole responsibility and discretion of elected officers and a team of public health experts. *See* S. *Bay United Pentecostal Church*, 140 S. Ct. at 1613 (stating that the Constitution principally entrusts the safety and the health of the people to the politically accountable officials of the States and that they should not be subject to second-guessing by an "unelected federal judiciary," that "lacks the background, competence, and expertise to assess public health and is not accountable to the people."). Defendant will not waste the Court's time by engaging on a never-ending debate regarding statistical conclusions and public policy that is

certainly not appropriate for a court of law. Thus, Defendant will only address the issues of **law** regarding substantive and procedural due process raised in Plaintiffs' Amended Complaint.

a. The Executive Order does not violate Plaintiffs' Fourteenth Amendment substantive due process rights to personal autonomy, bodily integrity or right to reject medical treatment.

Plaintiffs allege that the Executive Order "violates [their] liberty protected by the Fourteenth Amendment to the Constitution, which includes rights of personal autonomy and bodily integrity, and the right to reject medical treatment," Docket No. 11 at 41, ¶116, and their "constitutional right to decisional privacy," *id.*, ¶119. Specifically, Plaintiffs argue that "forcing citizens to have objects inserted up their noses weekly against their will is itself a personal-integrity violation." *Id*. at 47, ¶156.

Plainly, Plaintiffs are wrong and have not provided a single precedent from any federal court that has held that a vaccine requirement or a weekly negative qualified COVID-19 test violates the substantive due process right to bodily integrity or autonomy. Contrarywise, the Supreme Court and other federal courts, as well as state courts, have long validated vaccines mandates, even when not including a single exception to inoculation. *See Jacobson*, 197 U.S. at 27 (upholding a Massachusetts law that required compulsory vaccinations for adults); *Zucht*, 260 U.S. 174 (holding that a city can impose compulsory vaccination, even if there is no immediate threat of an epidemic like there was in *Jacobson*); *Klaassen*, 7 F.4th 592 (holding that State university's requirement that students either be vaccinated against COVID-19 or, if they claimed religious or medical exemption, wear masks and be tested twice a week did not violate Due Process Clause); *Workman v. Mingo County Board of Education*, 419 Fed.Appx. 348 (4th Cir. 2011) (holding that a West Virginia law requiring all school children to be vaccinated, with no exemption for religious reasons, is constitutional); *McCarthy v. Boozman*, 212 F. Supp.

2d 945, 948 (W.D. Ark. 2002) (upholding the Arkansas compulsory vaccination law); *Wright v. DeWitt School District*, 385 S.W.2d 644, 646 (Ark. 1965) (holding that it is within the state's police power "to require that school children be vaccinated and that such requirement does not violate the constitutional rights of anyone, on religious grounds or otherwise."); *Amadeo et al. v. Pierluisi-Urritia et al.*, Civil No. SJ2021CV04779 (P.R. Court of First Inst. 2021) (upholding a vaccine mandate for students and school employees in Puerto Rico). However, even when federal and state case law consistently have refused to strike down vaccine mandates throughout the United Sates, Defendant will demonstrate that Plaintiffs cannot prevail in their challenge to the Executive Order on substantive due process grounds.

The Due Process Clause of the Fourteenth Amendment, which prohibits a state from depriving any person of "life, liberty, or property, without due process of law," U.S. Const. amend. XIV, § 1, has both a substantive and a procedural component. *DePoutot v. Raffaelly*, 424 F.3d 112, 118 (1st Cir.2005). The right to substantive due process is narrow. *See Ramos-Piñero v. Puerto Rico*, 453 F.3d 48, 52 (1st Cir. 2006). "The substantive component of due process protects against 'certain government actions regardless of the fairness of the procedures used to implement them.'" *Souza v. Pina*, 53 F.3d 423, 425–26 (1st Cir. 1995) (quoting *Daniels v. Williams*, 474 U.S. 327, 331 (1986)). Generally, courts are "reluctant to expand the concept of substantive due process because guideposts for responsible decision-making in this unchartered area are scarce and open-ended." *Collins v. City of Harker Heights, Tex.*, 503 U.S. 115, 125 (1992).

Specifically, bodily integrity and autonomy claims are based on the common law "right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891); *see also Ingraham v. Wright*, 430 U.S. 651, 673 (1977) ("Among

the historic liberties so protected [by the Due Process Clause] was a right to be free from and to obtain judicial relief [...] for unjustified intrusions on personal security."). Indeed, "[n]o right is held more sacred." *Union Pac. Ry. Co.*, 141 U.S. at 251. In that sense, the First Circuit has held that a plaintiff must bring a substantive due process claim by demonstrating a deprivation of a "fundamental" interested protected by the Fourteenth Amendment. *See Sever v. City of Salem, Mass.*, 2020 WL 948413, at *1 (1st Cir. 2020). Similarly, individuals have a constitutional liberty interest under the Due Process Clause to refuse medical treatment. *Cruzan v. Dir., Missouri Dep't of Health*, 497 U.S. 261, 278 (1990). For example, the forced administration of antipsychotic drugs, *Washington v. Harper*, 494 U.S. 210, 221–22 (1990), and the transfer to a mental hospital along with mandatory behavior modification treatment, *Vitek v. Jones*, 445 U.S. 480, 487 (1980), implicate this interest. This right is not absolute, however, and can be regulated by the State. *See, Jacobson*, 197 U.S. at 24–30. "[D]etermining that a person has a 'liberty interest' under the Due Process Clause does not end the inquiry; whether [an individual's] constitutional rights have been violated must be determined by balancing his liberty interests against the relevant state interests." *Cruzan*, 497 U.S. at 279 (internal quotation omitted).

In addition to demonstrating a deprivation of a constitutionally protected interest—in this case, a liberty interest in bodily integrity, autonomy and refusal of medical treatment—plaintiff asserting a substantive due process claim must also ultimately show that the defendant's "'acts were so egregious as to shock the conscience.'" *Harron v. Town of Franklin*, 660 F.3d 531, 536 (1st Cir. 2011) (quoting *Pagán v. Calderón*, 448 F.3d 16, 32 (1st Cir. 2006)); *see also Rivera v. Rhode Island*, 402 F.3d 27, 36 (1st Cir. 2005) ("The state actions must be 'so

egregious, so outrageous, that it may fairly be said to shock the contemporary conscience.") (quoting *Cnty. of Sacramento v. Lewis*, 523 U.S. 833, 847 n.8 (1998)).

First, Plaintiffs allege that the Executive Order forces citizens "to have objects inserted up their noses weekly against their will Docket No. 11 at 47, ¶156. Purely, Plaintiffs' argument falls flat because not a single federal court has recognized a fundamental constitutional right to not be tested for a virus before entering a place of public accommodation. *Aviles v. Di Blasio*, 20 CIV. 9829 (PGG), 2021 WL 796033, at *18 (S.D.N.Y. Mar. 2, 2021) (holding that testing regime does not violate substantive due process because it is "reasonably related to a legitimate state objective–curbing the spread of the COVID-19 virus."); *see also Webb v. Johnson*, 2021 WL 2002712 (D. Neb. Mar. 2, 2021) (D. Neb. May 19, 2021) (prisoner had no fundamental right to refuse having his temperature taken); *Wilcox v. Lancour*, 2021 WL 230113 (W.D. Mich. Jan. 22, 2021) (prisoner had no fundamental right to refuse a nasal passage test for COVID-19); *Little Rock Family Planning Servs. v. Rutledge*, 458 F. Supp.3d 1065, 1074 (E.D. Ark. 2020) (applying *Jacobson* to uphold requirement that women obtain negative COVID-19 test before medical procedure).

The Executive Order does not necessarily mandate that Plaintiffs be subjected to weekly testing, as that is merely a requirement for the exceptions or to the "opt out" alternative. Particularly, Plaintiffs can avoid the weekly test if they opt to either: (1) inoculate against COVID-19 or (2) take regular or compensatory time paid leave. *See* Docket No. 11-1. In that sense, the alleged imposition on Plaintiffs claimed right to bodily integrity and autonomy, thus, is avoidable and relatively modest, given the opt-outs available to them. *See Roman Catholic Diocese of Brooklyn*, 141 S. Ct. at 71 (2020) (Gorsuch, J., concurring) (stating that *Jacobson's* constitutional challenge to a vaccine mandate would still not prosper today because the alleged

bodily integrity violation "was avoidable and relatively modest [...] given the opt-outs available to certain objectors.").

Further, the Executive Order's weekly test condition is merely an exception/"opt out" alternative and does not affect the possession and control Plaintiffs' "own person, free from all restraint or interference of others," *Botsford*, 141 U.S. at 251, because it provides an exit to weekly tests and inoculation: regular or compensatory time paid leave. Even so, the weekly test required for the exceptions and "opt out" alternative would still not violate Plaintiffs' bodily integrity and autonomy rights under the substantive due process because it was adopted "by clear and unquestionable authority of law." *Id*. at 251. Simply put, the Executive Order provides multiple alternatives for Plaintiffs to avoid the weekly COVID-19 testing, but if one of the exceptions (medical or religious) or the general "opt out" is chosen by any public employee, "[they] just need to wear masks and be tested, requirements that are not constitutionally problematic." *Klaassen*, 7 F.4th at 592.

Plaintiffs clearly failed to: (1) plausibly plead a bodily integrity or autonomy right violation under the substantive due process as to the Executive Order's vaccine requirement, exceptions or "opt out" alternative, which include the weekly test; and (2) set forth federal case law that supports their theory or that has recognized that a vaccine mandate or a requirement of weekly testing for COVID-19 violates 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 (1997); *see also Klaassen,* 2021 WL 3073926, at *39 (declining plaintiffs' invitation "to expand substantive due process rights to include the rights not to wear a mask or to be tested for a

virus."). Therefore, Plaintiffs' bodily integrity and autonomy substantive due process violation claim must be dismissed with prejudice.

Second, Plaintiffs also challenge the Executive Order under the medical treatment refusal substantive due process right by erroneously asserting that the "government is willing to do anything to force the plaintiffs, and other Puerto Ricans, even by deceit, into getting vaccinated, with little if any regard to their fundamental right to personal autonomy, religious beliefs, and medical choice." Docket No. 11 at 11, ¶29. However, it has been clearly established that the medical treatment refusal right is not absolute and can be regulated by the State. *See Jacobson*, 197 U.S. at 24-30. Plaintiffs' argument, once again, falls flat because this matter was settled by the Supreme Court. That is because *Jacobson* is essentially a substantive due process case concerning medical decisions in which the Supreme Court rejected the claim that the Constitution prevented a state from enforcing its compulsory vaccination law against an individual's will. 197 U.S. at 39; *see also Zucht*, 260 U.S at 176 (noting *Jacobson* settled that it is within the police power of a state to provide for compulsory vaccination). Further, even taking as true that immunization and/or weekly testing infringe Plaintiffs' substantive due process right to refuse medical treatment—which it does not—the Executive Order survives because it provides a non-invasive alternative: regular or compensatory time paid leave. Thus, since *Jacobson* already held that that mandatory vaccination during a public health emergency is a constitutional exercise of a state's police power and because the Executive Order provides a viable alternative to immunization and weekly testing, Plaintiffs' medical treatment challenge cannot prosper and must be dismissed with prejudice. *See Klaassen*, 7 F.4th 592 (holding that requirement to either be vaccinated against COVID-19 or, if they claimed religious or medical exemption, wear masks and be tested twice a week did not violate Due Process Clause); *see also*

Boone v. Boozman, 217 F. Supp. 2d 938, 956 (E.D. Ark. 2002) (holding that a vaccination mandate does not violate the right to refuse medical treatment under the substantive due process).

Finally, the Court must now turn to determine whether the Executive Order's requirements are conscience-shocking. Generally, conscience-shocking is fact-specific, but the Court can take Plaintiffs' well-pleaded allegations as true—for the purpose of the motion—under a Rule 12(b)(6) standard. *Rivera*, 402 F.3d at 36. In the instant case, the Executive Order essentially requires all public employees to either immunize or provide a weekly negative COVID-19 test (whether in an exception or "opt out" context) to work in-person in any of the Executive Branch's public agencies. In that sense, not a single federal court has found that a vaccine mandate or a weekly test requirement is "so egregious, so outrageous, that it may fairly be said to shock the contemporary conscience," which is the standard for a substantive due process violation. *See id*. Furthermore, the Executive Order's only purpose is to protect the health and lives of all the Executive Branch's covered employees, which is far from "conduct intended to injure in some way unjustifiable by any government interest." Lewis, 523 U.S. at 118 (holding that "conduct intended to injure in some way unjustifiable by any government interest is the sort of official action most likely to rise to the conscience-shocking level.").

In that sense, the only egregious, outrageous, and conscience-shocking behavior in this case is the filing of Plaintiffs' Amended Complaint (Docket No. 11), which advocates for the spread of a deadly virus among public employees in lieu of the safety of Commonwealth's citizens. Thus, since the Supreme Court's holdings in *Jacobson* and *Zucht* support the Executive Order's requirements to safeguard public health, Plaintiffs' will never be able to meet the

conscience-shocking standard of a substantive due process claim; hence, the claims must be dismissed with prejudice for failure to plead a plausible substantive due process claim.

b. The Executive Order swiftly passes the applicable rational scrutiny.

Rational basis review is the test that courts *normally* apply 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*, 141 S.Ct. 63, 70 (Gorsuch, J., concurring). It is less stringent than strict scrutiny. Under rational basis review, government action "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 (1985). Indeed, *Jacobson* was decided before tiers of scrutiny, but it effectively endorsed—as a considered precursor—rational basis review of a government's mandate during a health crisis. *See Jacobson*, 197 U.S. at 31, 25 S.Ct. 358; *see also Roman Catholic Diocese of Brooklyn*, 141 S. Ct. at 70 (Gorsuch, J., concurring). In its words, if a mandate purporting to be enacted to protect public health "has no real or substantial relation to [that legitimate aim]" or if the law proves "a plain, palpable invasion of rights secured by the fundamental law," the court's job is to give effect to the Constitution. *Jacobson*, 197 U.S. at 31. Should the court have this melding of history and modernity wrong in faithfully adhering to the Fourteenth Amendment's plain original meaning of "life" and "liberty," comfort should come in knowing that *Jacobson*, whether rational basis review by any other name, leads to the same result today.

Added comfort comes from the consistent use of rational basis review to assess mandatory vaccination measures. *See*, e.g., *Prince*, 321 U.S. at 166-67 (parent "cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds"

and "[t]he right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death"); *Zucht*, 260 U.S. at 176-77; *Jacobson*, 197 U.S. at 30-31; *Phillips v. City of New York*, 775 F.3d 538, 542-43 (2d Cir. 2015);; *Connecticut Citizens Defense League, Inc. v. Lamont*, 465 F. Supp.3d 56, 72 (D. Conn. 2020); *Middleton v. Pan*, 2016 WL 11518596, at *7, 2016 U.S. Dist. LEXIS 197627, 20 (C.D. Cal. Dec. 15, 2016); *George v. Kankakee Cmty. Coll.*, 2014 U.S. Dist. LEXIS 161379, 8-9 (C.D. Ill. Oct. 27, 2014), *recommendation adopted*, 2014 U.S. Dist. LEXIS 160737, 1-2; *Boone v. Boozman*, 217 F. Supp.2d 938, 954 (E.D. Ark. 2002). *Klaassen*, 2021 WL 3073926 at *24.

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 rather a strict constitutional scrutiny." Docket No. 11 at 2, ¶3. However, as discussed in the previous section, 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.").

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.

See S. Bay United Pentecostal Church, 140 S. Ct. 1613, 1613 (2020) (Roberts, C.J., concurring); *Jacobson*, 197 U.S. at 37-38. Having established the Governor had a legitimate interest, Defendant turns to whether the Executive Order is rationally related.

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). It would be difficult to contend with a straight face that a vaccine mandate or a weekly test requirement does not bear a rational relation to protecting people's health and preventing the spread of COVID-19. The Plaintiffs do not point to a single court holding otherwise. *See* CHEMERINSKY & GOODWIN, 110 Nw. U.L. Rev. at 610 (concluding that vaccine mandates generally pass the rational basis test). Some may disagree with the Governor's Executive Order, but federal courts do not sit in a policy-checking capacity to second guess the wisdom of state governments' acts. *F.C.C. v. Beach Commun., Inc.*, 508 U.S. 307, 313 (1993) (clarifying that federal courts do not have "a license [...] to judge the wisdom, fairness, or logic of legislative choices."). So, the Executive Order itself bares a rational relation to the County's interest. Therefore, since the Executive Order swiftly passes a rational basis scrutiny, the instant case must be dismissed with prejudice.

c. The Executive Order would easily pass an inapposite strict scrutiny.

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.

Generally, 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. As such, it can be easily concluded that the only purpose that the Executive Order seeks is to safeguard the lives and health of all public employees and citizens with the only two known alternatives to prevent the spread of the deadly COVID-19 virus and its variants: (1) immunization or (2) weekly tests for public employees that decide not to inoculate. Thus, the Executive Order's aggressive attempt to protect the lives and health of the Executive Branch's employees is undeniably a compelling state interest. *See Roman Catholic Diocese of Brooklyn*, 141 S. Ct. at 67 (holding that "[s]temming the spread of COVID-19 is unquestionably a compelling interest.").

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. In that sense, the Executive Order is narrowly tailored to protect public employees because it is the least restrictive measure available to stop the growing spread of the deadly COVID-19 virus and its variants. That is because, while the Executive Order generally requires public employees to be vaccinated, it provides less restrictive measures like religious and medical exceptions, as well as a general "opt out" for those that decide not to immunize against COVID-19, regardless of the reason, as well as regular or compensatory paid leave for those that decline to inoculate or provide a weekly negative test. Therefore, it is forceful to conclude that—while Defendant vehemently argues that such level of review is inapposite—the Executive Order easily passes a strict scrutiny muster. *See* CHEMERINSKY & GOODWIN, 110 Nw. U.L. Rev. at 615 ("Compulsory vaccination laws are unquestionably constitutional without [religious or conscience] exceptions.").

d. The Executive Order does not infringe Plaintiffs' "economic liberty rights."

Plaintiffs claim that having to get tested for COVID-19 weekly imposes an economic burden upon them. *See* Docket No. 11 at 19, ¶30. Nonetheless, Defendant posits that the Commonwealth's Health Department has dozens of fixed COVID-19 testing facilities throughout the Island, where Plaintiffs and other persons can get tested for COVID-19 free of charge.[4] Further, the Department of Health provides a free of charge PCR-Molecular referral or

[4] *See* El Nuevo Día, *COVID-19 tests: see the places where you can get them for free in Puerto Rico,* https://www.elnuevodia.com/noticias/locales/notas/pruebas-de-covid-19-mira-los-lugares-donde-te-las-puedes-realizar-gratis-en-puerto-rico/ (retrieved on August 29, 2021).

equally valid antigen test to all citizens, including Plaintiffs, that desire to get tested for COVID-19.[5] In that sense, since the requirement of a negative weekly COVID-19 test for public employees that decide not to immunize, for any reason, is rationally related to the Governor's interest of containing the spread of the deadly virus (and its variants) among public employees, added to the fact that the Commonwealth provides various alternatives for free testing, it must follow that the Executive Order does not violate Plaintiffs' Fourteenth Amendment's economic liberty rights. *See Mass. Food Association v. Mass. Alcoholic Beverages Control Commission*, 197 F.3d. 560 (1st Cir., 1999) ("The Sherman Act is a charter of economic liberty, but only against private restraints"); *910 E Main LLC v. Edwards*, 481 F. Supp. 3d 607, 620 (W.D. La. 2020) (holding that economic rights are not fundamental and are subject to rational basis scrutiny and upholding economic restrictions established by the government in light of the COVID-19 pandemic).

e. The Eleventh Amendment bars this Court from ordering state officer to conform their conduct to state law.

Plaintiffs also allege that the Defendant could allow them to work from their homes. *See* Docket No. 11 at 12, ¶32. The *Government of Puerto Rico Remote Work Act*, Act No. 36-2020, provided that all public agencies and public corporations must provide the alternative of remote work for its employees if they meet several parameters. The remote work option is examined by each covered agency or public corporation. Upon request, each covered entity determines the employee's eligibility based to their positions and essential duties. Nonetheless, each agency has the discretion of granting said request, and the employees would not necessarily be granted to work at home the entire week. Indeed, Plaintiffs are free to request

[5] *See*, Department of Health, *PCR COVID-19 Referral*, http://www.salud.gov.pr/Documents/Hazte%20la%20prueba/COVID19%20PCR%20Test%20Referral.pdf (retrieved on August 29, 2021).

remote work in their respective agencies—pursuant to Act No. 36-2020—but must comply with the applicable requirements and regulations of each government entity. It is important to note that remote work does not constitute an open-ended right; thus, the agency has full discretion on whether to grant or not such a request.

Here, Plaintiffs seem to demand that this Court orders the Commonwealth to grant them remote work, pursuant to Act No. 36-2020, to circumvent the Executive Order. However, this Court is barred to do so. In *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 101-02 (1984), the Supreme Court established that a federal suit against state officials is, in fact, a suit against the state and is barred regardless of whether it seeks monetary damages or an injunctive relief. Further, in *Pennhurst*, the Supreme Court held that the Eleventh Amendment prohibited a federal district court from ordering state officials to conform their conduct to state law, even though only prospective injunctive relief was sought, since state was real, substantial party in interest. *Id*. at 106.

In the instant case, there is no doubt that the Commonwealth is the real and substantial party being sued. *See* Docket 11 at 17, ¶52. Moreover, the Plaintiffs filed the instant case, in part, seeking an injunctive relief that orders state officers to conform their conduct to the Commonwealth's Act No. 36-2020. Specifically, Plaintiffs are attempting to obtain an injunctive relief that orders the Governor to grant them remote work so that they can circumvent the Executive Order. In that sense, it is evident that *Pennhurst* is controlling in the instant case since the injunctive relief requested by the Plaintiffs would require this Court to order Commonwealth officers to act pursuant to Act No. 36-2020. Simply put, this Court is barred by the Eleventh Amendment from entertaining Plaintiffs' attempt to obtain an order for remote work pursuant to Commonwealth's Act No. 36-2020; hence, lacks subject matter jurisdiction

regarding that matter because, insofar as an injunctive relief is sought, an error of law by state officers acting in their official capacities will not suffice to override sovereign immunity of state where relief effectively is against it. *Pennhurst*, 465 U.S. 89, 113.

2. The Executive Order does not violate Plaintiffs' procedural due process rights since it does not contemplate the deprivation of a property interest and no such depravation has been alleged.

Protected property interests are created not by the Constitution, but "by existing rules or understandings that stem from an independent source such as state law." *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 577 (1972). To show constructive discharge, a plaintiff must "show that [his] working conditions were so difficult or unpleasant that a reasonable person in [his] shoes would have felt compelled to resign." *Torrech–Hernández v. Gen. Elec. Co.*, 519 F.3d 41, 50 (1st Cir. 2008) (quoting *De La Vega v. San Juan Star, Inc.*, 377 F.3d 111, 117 (1st Cir.2004)). The word "compelled" is key; it is not enough to demonstrate that a reasonable person would have wanted to quit. "[R]ather, an employee must show that, **at the time of his resignation**, his employer did not allow him the opportunity to make a free choice regarding his employment relationship." *Id*. (quoting *Exum v. U.S. Olympic Comm.*, 389 F.3d 1130, 1135 (10th Cir.2004)) (internal quotation marks omitted and emphasis added). "In order for a resignation to constitute a constructive discharge, it effectively must be void of choice or free will." *Id*. (citing *Exum*, 389 F.3d at 1135). Further, a state may not "discharg[e] a public employee who possesses a property interest in continued employment without due process of law." *Santana v. Calderón*, 342 F.3d 18, 23 (1st Cir.2003) (citing *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 538 (1985)). Generally, due process is satisfied if the plaintiff is provided with notice and a meaningful opportunity to be heard. *See Loudermill*, 470 U.S. at 542.

In the instant case, 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.").

On the other hand, Plaintiffs 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.

Defendant, aside from Plaintiff's lack of standing, will briefly discuss—for the Court's benefit—their frivolous argument as to that the unpaid leave contemplated by the Executive Order violates the procedural due process of the Fourteenth Amendment. 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. In that sense, the Executive Order does not impose an unpaid leave for public employees as a disciplinary action or a discharge, but rather as viable alternative to the Executive Order's mandates when employees do not have regular or compensatory time accrued. Further, the clearest proof that the unpaid leave provision is not a depravation of public employees' salaries is that absent regular or compensatory time accrued, they can collect their salaries by simply showing up and providing the employer with a negative COVID-19 test. 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 plausible claim has been plausibly pleaded; hence, such claim must be dismissed with prejudice.[6] *See Bennett v. City of Boston*, 869 F.2d 19 (1st Cir.1989) (holding that a suspension without pay oftentimes does not raise due process concerns).

[6] If the Court were to determine that the unpaid leave provision of the Executive Order constitutes a depravation of a public employees' proprietary interest—which Defendant vehemently denies—a post-depravation hearing could be held after the public health emergency without infringing the procedural due process. *See Boddie v. Connecticut*, 401 U.S. 371, 379 (1971) (pre-deprivation hearing not required "where some valid governmental interest is at stake that justifies postponing the hearing until after the event.").

B. THE EXECUTIVE ORDER DOES NOT INFRINGE THE RELIGIOUS FREEDOM RESTORATION ACT.

1. The Executive Order does not impose a substantial burden in Plaintiffs free exercise of religion under RFRA.

The Religious Freedom Restoration Act ("RFRA"), 42 U.S.C. ¶2000bb-1(a) *et seq*., provides that "Government shall not **substantially** burden a person's exercise of religion even if the burden results from a rule of general applicability, except as provided in subsection (b)" (emphasis added). RFRA's Subsection (b) provides as exceptions that "Government may **substantially** burden a person's exercise of religion only if it demonstrates that application of the burden to the person: (1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest" (emphasis added). In RFRA's Section 2000bb(a)(3), Congress found that "governments should not substantially burden religious exercise without compelling justification," and in subsection (a)(4) it stated that "in *Employment Division v. Smith*, 494 U.S. 872 (1990), the Supreme Court virtually eliminated the requirement that the government justify burdens on religious exercise imposed by laws neutral toward religion." Also, subsection (b)(1) of RFRA sets that Congress' purpose of the statute is to restore the compelling interest test as set forth in *Sherbert v. Verner*, 374 U.S. 398 (1963) and *Wisconsin v. Yoder*, 406 U.S. 205 (1972), and "to guarantee its application in all cases where free exercise of religion is substantially burdened." Under the *Sherbert* test, governmental actions that substantially burden a religious practice must be justified by a compelling governmental interest. However, in *Employment Division v. Smith*, 494 U.S. 872 (1990), the Supreme Court held that the Free Exercise Clause cannot be used to challenge a neutral law of general applicability. In other words, no matter how much a law

burdens religious practices, it is constitutional under *Smith* so long as it does not single out religious behavior for punishment and was not motivated by a desire to interfere with religion.

Plaintiffs invite the Court to apply the strict scrutiny to the alleged violation of their freedom to exercise religion. However, Defendant posits 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 wheregovernor Cuomo—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.

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 the previously discussed in this motion, the Executive Order does not promote a classification between employees based on any factor other than being public employees in the

Executive Branch. The Executive Order clearly states that "all public agencies of the Executive Branch shall require employees who work in-person [...]." Docket No. 11-1 at 10. Further, the Executive Order describes the applicable exceptions from the vaccination mandate: (1) "the employees whose immune system is compromised, are allergic to vaccines, or have a medical contraindication to the receipt of a vaccine shall be exempt from the COVID-19 vaccination requirement," *id*. at 10; and (2) "refusal to be vaccinated **is hereby permitted**—as an exception—on the basis of religious beliefs, provided that the vaccines are against the employee's religious observance," *id*. at 10-11 (emphasis added). Additionally, the Executive Order explains that **all** employees who choose to refuse to be vaccinated based on religious beliefs, in order to comply with said chosen exception, "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." *Id*. (emphasis added). Finally, the Executive Order requires **all** public employees that decide not to immunize, regardless of the reason, pro provide a weekly negative COVID-19 test result. *Id*. at 11-12.

Clearly, the Executive Order does not create classifications among public employees that invoke an exception to work-in person. Quite the contrary, the Executive Order applies neutrally to all public employees that opt not to immunize in the same fashion. In fact, any public employee whose religious dogma prohibits him or her to immunize does not have to invoke the religious exception and can avoid the sworn declaration required by simply showing a weekly negative COVID-19 test. In that sense, the exceptions and "opt out" alternative apply neutrally to every employee that refuses to immunize 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 which of the exceptions or "opt out" alternatives they will select 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."). Thus, since the Executive Order: (1) provides an exception on religious grounds for employees that do not want to immunize; and (2) the test requirement neutrally applies to all public employees that decide not to immunize, regardless of the reason, it cannot be reasonably found that the Defendant is imposing a substantial burden on Plaintiffs' religious practices. *See Smith*, 494 U.S. 872 (holding that the Free Exercise Clause cannot be used to challenge a neutral law of general applicability); *see also* CHEMERINSKY & GOODWIN, 110 Nw. U.L. Rev. at 610 (concluding that "State statutes requiring vaccinations of all [citizens] are neutral laws of general applicability [...] [t]hey are not motivated by a desire to interfere with religion and they apply to everyone [...] [t]herefore, there is no basis for a [free exercise of religion] challenge to compulsory vaccination laws").

2. The Executive Order provides more rights that constitutionally required, as vaccine mandated are not usually required to provide religious exceptions.

Generally, policies requiring vaccination need not exceptions for those who have religious objections to vaccinations. *See Jacobson*, 197 U.S. 11 (upholding a vaccine mandate that did not have a religious exception); *see also Workman*, 419 F. App'x 348 (upholding a vaccine mandate that had no religious exceptions). In terms of free exercise of religion, as explained before, the Supreme Court held in *Smith* that the Constitution does not require exceptions to general laws for religious beliefs. 494 U.S. 872. In said case, the Supreme Court stated that as long as the law is neutral, not motivated by a desire to interfere with religion and of general applicability to all individuals, it cannot be challenged based on free exercise of religion. *Id.*

Recently, in *Fulton v. City of Philadelphia*, the Supreme Court reaffirmed this legal test by reaffirming that "incidentally burdening religion are ordinarily not subject to strict scrutiny under the Free Exercise Clause so long as they are neutral and generally applicable." 141 S.Ct. 1868, 1876 (2021).

If *Smith* were to be applied to a vaccine mandate without a religious exception, the same would have to be upheld because vaccine mandates are the epitome of a neutral law of general applicability. That is, because it is a requirement that applies to everyone and that is not motivated by a desire to interfere with religion but to protect the lives of all citizens. *See Klaassen*, 2021 WL 3073926, at *25 ("The vaccine mandate is a neutral rule of general applicability [because] [i]t applies to all [persons], whether religious or not.").

However, even if the Court does not agree with said application of *Smith*, a vaccine mandate without a religious exception would still be upheld because government can infringe on religious freedom if its action is necessary to achieve a compelling interest and safeguarding the lives and health of **all** citizens is, certainly, a compelling interest. *See Roman Catholic Diocese of Brooklyn*, 141 S. Ct. at 67 (holding that "[s]temming the spread of COVID-19 is unquestionably a compelling interest."); *see also Workman*, 419 F. App'x 348, 353 (holding that State's wish to prevent spread of communicable diseases clearly constituted compelling interest to vaccinate as condition of admission to school, and thus substantial burden on free exercise of religion through mandatory vaccination did not violate First Amendment, even if state required vaccination against diseases that were not very prevalent).

Further, federal employment discrimination laws do not require a religious exception from mandatory vaccination for employees. In *Trans World Airlines vs. Hardison*, 432 U.S. 63 (1977), the Supreme Court stated that employers do not have to bear more than a "de minimus"

cost in accommodating employees' religious beliefs. Clearly, under the *Hardison* holding, it can be concluded that vaccine exemptions could impose a significant cost on employers in terms of illness and, therefore, would not be required. *See* CHEMERINSKY & GOODWIN, 110 Nw. U.L. Rev. at 611 (concluding that "under current law, there is no basis for a religious challenge--either under the Constitution or federal laws--to state laws' mandatory vaccinations for all [citizens].").

As this Court can attest, the challenged Executive Order provides a religious exception, that may not even be constitutionally required, to respect all public employees' free exercise of religion and provide an alternative to those whose religious dogmas prohibit vaccination. In that sense, the Executive Order not only safeguards free exercise of religion but provides more rights than those constitutionally or statutorily required. This Court must conclude that, far from infringing RFRA or free exercise of religion, the Executive Order protects all public employees' religious beliefs by creating a religious exception to the vaccine mandate. Therefore, once again, Plaintiff's arguments fall flat because, even though neither the Constitution or RFRA require a religious exception to vaccine mandates, the Executive Order created a religious exception to protect public employees' free exercise of religion; hence, the RFRA claim must be dismissed with prejudice.

3. The Executive Order easily passes strict scrutiny under RFRA.

Should the Honorable Court find that the Executive Order substantially burdens Plaintiffs' religious practice, which is vehemently denied, it would still pass a strict scrutiny examination because it has compelling interest to do so.

At the outset, the Supreme Court has already recognized that "stemming the spread of COVID-19 is unquestionably a compelling interest." *Roman Catholic Diocese of Brooklyn*, 141

S.Ct. at 67. Clearly, stopping the spread of a deadly communicable disease is obviously a compelling interest and vaccinations are the best way to reach that goal. No one, in practicing his or her religion, has a constitutional right to endanger others. Thus, there is no question that the Executive Order was issued with a compelling interest to protect the lives and health of all employees by avoiding a spread of COVID-19 in covered agencies.

Defendant now turns to establish that the Executive Order is narrowly tailored to promote the compelling government interest. As previously explained in this motion, the Executive Order is narrowly tailored because, while it mandates vaccination, it provides multiple exceptions and "opt outs" for employees that decide not to inoculate. Clearly, the Executive Order is not broader that necessary as it does not obligate public employees to immunize against COVID-19 if they do not desire; be it on religious, medical or any other ground. Specifically, the Executive Order provides an exception for those public employees that cannot inoculate on religious grounds. That religious exception, itself, is the narrowly tailoring required to pass a strict scrutiny since the Executive Order does not place an undue burden on religion, but rather protects public employees free exercise by allowing them to work in-person by providing a negative COVID-19 test result. It follows that that the Executive Order is narrowly tailored to contain the contagion of COVID-19 among public employees that work in-person, which would, in turn, avoid the propagation of the virus to their families, to school children and personnel (thousands of public employees have school-age children) and to the general population.[7] *See Listecki v. Official Comm. of Unsecured Creditors*, 780 F.3d 731, 744 (7th

[7] Plaintiffs recklessly allege that "[t]he logical conclusion is that the Vaccine Mandate is the government's attempt to protect the unvaccinated population, who choose to assume the risk of not getting vaccinated, from themselves." Docket No. 11 at 43, ¶130. However, the Governor is not, simplistically, protecting the voluntarily unvaccinated from themselves. Plaintiffs appear to need to be reminded that there are unvaccinated people who do not choose to assume the risk to remain unvaccinated. These groups are composed of people who simply cannot get vaccinated either because of a medical condition or because they

Cir. 2015) ("A benefit to religion does not disfavor religion in violation of the Free Exercise Clause."); *see also Smith*, 494 U.S. at 888 (Scalia, J.) (no exemption required). Therefore, Plaintiffs' claim of violation of RFRA is misplaced, frivolous, and must be dismissed with prejudice.

C. THE EXECUTIVE ORDER IS NOT AT ODDS WITH THE FDA'S EUA AND THE PREEMPTION CLAIM IS ALSO MOOT IN LIGHT OF THE FDA'S FULL APPROVAL OF THE PFIZER VACCINE.

1. 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.

Article III of the Constitution limits federal-court jurisdiction to "cases" and "controversies." U.S. Const., Art. III, § 2. The Supreme Court has interpreted this requirement to demand that "an actual controversy … be extant at all stages of review, not merely at the time the complaint is filed." *Arizonans for Official English v. Arizona*, 520 U.S. 43, 67 (1997). "If

belong to a group age that cannot get vaccinated still and who are in constant contact with other unvaccinated people, e.g., school aged children. The Governor has the duty to protect all these citizens during this pandemic.

an intervening circumstance deprives the plaintiff of a 'personal stake in the outcome of the lawsuit,' at any point during litigation, the action can no longer proceed and must be dismissed as moot." *Lewis v. Continental Bank Corp.*, 494 U.S. 472, 477–78 (1990). A case becomes moot, however, "only when it is impossible for a court to grant any effectual relief whatever to the prevailing party." *Knox v. Serv. Employees Int'l Union, Local 1000*, 567 U.S. 298, 307 (2012). "As long as the parties have a concrete interest, however small, in the outcome of the litigation, the case is not moot." *Campbell-Ewald Co. v. Gómez*, 577 U.S. 153, 160 (2016). Mootness is a ground which should ordinarily be decided in advance of any determination on the merits. *See Arizonans for Official English v. Arizona,* 520 U.S. 43, 67 (1997). Further, courts are obligated to follow the doctrine of constitutional avoidance, under which federal courts are not to reach constitutional issues where alternative grounds for resolution are available. *See Mills v. Rogers,* 457 U.S. 291, 305 (1982). The case may, nevertheless, be moot if the defendant can demonstrate that "there is no reasonable expectation that the wrong will be repeated." *United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953).

In the case at hand, it is impossible for this Court to grant an effectual relief to Plaintiffs when their cause of action regarding preemption has been completely mooted due to the full approval of the Pfizer vaccine. *See Swift & Co. v. United States*, 276 U.S. 311, 326 (1928) (The purpose of an injunction is to prevent future violations). 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). Therefore, since Plaintiffs' EUA preemption claim has turned moot in light of the Pfizer vaccine approval, this Court has no alternative but to dismiss it with prejudice.

2. The preemption claim is meritless.

When Congress states expressly in its enactment which areas of state authority are to be preempted, a state law will fall if: (1) a direct conflict exists between the state and federal regulation, such that it is impossible to comply with both laws, *Florida Lime and Avocado Growers, Inc. v. Paul,* 373 U.S. 132, (1963); or (2) the state regulation "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz,* 312 U.S. 52, 67, (1941); or (3) when Congress "has occupied the field" in a given area so as to displace all state regulations whether compatible or hostile, *Campbell v. Hussey,* 368 U.S. 297, (1961).

In the unlikely event that this Court does not discard the preemption claims on mootness, the same must be dismiss for failure to state a claim upon which a relief can be granted. For starters, in *Klaassen*, 2021 WL 3073926, the District Court discussed that not all EUAs are created equally. Specifically, the District Court stated that:

> Because of the widespread use of a COVID-19 vaccine, the FDA informed manufacturers that it expected the same level of endpoint efficacy data as required for full approval, enough safety data to justify by clear and compelling evidence the vaccine's safety, and confirmation of the technical procedures and verification steps necessary to support full approval. In short, [...], the FDA promulgated guidance that enhanced the basis on which any COVID-19 vaccine would meet EUA approval. In setting these more stringent standards, the FDA invited EUA applications only for vaccines positioned well to receive full approval.

Klaassen, 2021 WL 3073926, at *8. The Court's reasoning is supported by the recent fully approval of the Pfizer vaccine.

Also, in *Klaassen*, District Court discussed that the EUA only applies to medical providers:

> The students admit that the informed consent requirement under the EUA statute only applies to medical providers. The university isn't directly administering the vaccine to its students; instead, it is requiring students to obtain the vaccine from a medical provider and to attest that they have been vaccinated, save for certain exemptions. The students will be informed of the risks and benefits of the vaccine and of the option to accept or refuse the vaccine by their medical providers. *See id.* Also, the university isn't forcing the students to undergo injections. The situation here is a far cry from past blunders in medical ethics like the Tuskegee Study.

2021 WL 3073926, at *25.

The same reasoning that the District Court applied in *Klaassen* can be applied in the instant case to the challenged Executive Order. The Executive Order mandates that all **agencies** must require that all their employees are vaccinated against COVID-19. However, none of the agencies in which Plaintiffs are employed administer the vaccines to its employees. In that sense, requiring vaccination and administering the vaccines are two different things. This is the same conclusion reached in the Legal Opinion issued by the United States Department of Justice, where it concluded that public and private entities can lawfully mandate that their employees receive one of the vaccines. *See* U.S. Department of Justice, *Memorandum Opinion for the Deputy Counsel to the President, Whether Section 564 of the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization* (July 6, 2021) at 7-13 ("OLC Op.").

Although Plaintiffs claim that the separation of powers dictates that this Court is not bound by the OLC Opinion, Docket No. 11 at 49, ¶ 177, this in no way impedes it from

considering its logical and well-supported legal conclusions. Mainly, that section 564(e)(1)(A)(ii)(III) concerns only the provision of information to potential vaccine recipients and does not prohibit public or private entities from imposing vaccination requirements for vaccines that are subject to EUAs," and that "[b]y its terms, the provision directs only that potential vaccine recipients be "informed" of certain information, including "the option to accept or refuse administration of the product." *See* OLC Op. at 7.

In light of the above, the Executive Order is not contrary to the EUA and is no obstacle to the accomplishment and execution of the full purpose and objectives of Congress. Quite the opposite, there is no need to enjoin Defendant from enforcing the Executive Order because public employees are well informed by their medical providers of the risks and benefits of the vaccine, as well as of the options available to accept or refuse the vaccine. Defendant reiterates that in the case at bar none of the agencies for which Plaintiffs' work is administering COVID-19 vaccines; thus, no duty to inform is required. Therefore, besides Plaintiffs' preemption claim being moot, they failed plausibly plead a valid preemption; hence it must be dismissed with prejudice.

D. PENDENT CLAIMS MUST BE DISMISSED IN ABSENCE OF A COGNIZABLE FEDERAL CLAIM AND PROVEN MERITLESS IN LIGHT OF PR COURT OF FIRST INSTANCE'S RECENT DECISION.

"As a general principle, the unfavorable disposition of a plaintiff's federal claims at the early stages of a suit, well before the commencement of trial, will trigger the dismissal without prejudice of any supplemental state-law claims." *Rodríguez v. Doral Mortg. Corp.*, 57 F. 3d 1168, 1177 (1st Cir. 1995). In those cases where the federal claims are dismissed, "the balance of factors to be considered under the pendent jurisdiction doctrine—judicial economy, convenience, fairness, and comity—will point toward declining to exercise jurisdiction over the remaining

state-law claims". *Id*. The use of supplemental jurisdiction in these circumstances is completely discretionary. The exercise of this jurisdiction will be determined on a case-specific basis. *See Dibbs v. Gonsalves*, 921 F. Supp. 44, 51 (D.P.R. 1996) (restating *Rodríguez*, 57 F. 3d at 1177); *see also Rodríguez Cirilo v. García*, 908 F. Supp. 85, 92 (D.P.R. 1995) ("[t]he assertion of supplemental jurisdiction over state law claims is within a federal court's discretion... [i]f federal law claims are dismissed before trial, however, the state law claims should also be dismissed").

Here, Plaintiffs have invoked the supplemental jurisdiction of this Court to entertain its claims pursuant to the laws of the Commonwealth of Puerto Rico. Plaintiffs, however, have not plausibly pleaded any federal cause of action, which warrants that this Court does not exercise its supplemental jurisdiction. Therefore, since Plaintiffs federal claims are destined to fail, the Court must dismiss all alleged state claims.

Alternatively, in an abundance of caution, should the Court determine to consider Plaintiffs' supplemental claims, the Defendant will proceed to discuss them in order to put it in position to dismiss the on the merits. Essentially, Plaintiffs allege that the "Vaccinate Mandate 'violates the Due Process Clause of the Fourteenth Amendment, it also runs head-on into the plaintiffs' constitutional right to decisional privacy under the Puerto Rico Constitution". Docket No. 11 at 53, ¶193. In addition, Plaintiffs allege that "[t]he Puerto Rico Supreme Court has made it clear that "it is impossible to obtain a voluntary waiver of the right of privacy, particularly if such waiver becomes a requirement for obtaining a job or for staying in it. The risk of losing a job or not getting one, and the worker's position of disadvantage vis-à-vis his employer's, impair the possibility of a really free and voluntary waiver. *Arroyo v. Rattan Specialties, Inc.*, 117 P.R. Dec. 35 (1986)." Docket No. 11 at 53, ¶ 194.

The Constitution of the Commonwealth of Puerto Rico recognizes that "[t]he dignity of the human being is inviolable." P.R. Const. Art. II § 1. Also, section eight safeguards that "[e]very person has the right to the protection of law against abusive attacks on his honor, reputation and private or family life." P.R. Const. Art. II § 8. The Supreme Court of Puerto Rico has interpreted that the right of privacy is fundamental, but not an absolute under the Commonwealth law, and, pressing circumstances of greater weight in the absence of other effective alternatives, could justify that the State contains the necessary safeguards. For example, social public safety before a national emergency may have a more pressing need to protect social interests than the right to public of employees in their place of work. *See Arroyo*, 117 P.R. Dec. at 61. "In an employment scenario, 'the validity of intrusion into an employee's privacy rights will be examined by reference to the employer's particular interests' it is trying to protect." *Rivera-Cartagena v. Wal-Mart Puerto Rico, Inc.*, 767 F. Supp. 2d 310, 322 (D.P.R. 2011). Also, in *García Santiago v. Acosta*, 104 P.R. Dec. 321, 324 (1975), the Puerto Rico Supreme Court held that: "the intrusion into private life must only be tolerated when so required by factors that exceed public health and safety […]." *See Arroyo*, 117 P.R. Dec. at 59.

Here, Plaintiffs' reference to the Supreme Court of Puerto Rico's *Arroyo* is out of context, but it gives to this Court a basis of Puerto Rico courts' interpretation regarding the privacy claims raised. In *Arroyo*, the Supreme Court of Puerto Rico discussed the violation of constitutional rights within the context of a private employment relationship and the discipline standards of the employer regarding the refusal of an employee to take a polygraph exam as a condition of employment. *See Arroyo*, 117 P.R. Dec. at 65. Contrary to the facts in *Arroyo*, the instant case has "special circumstances of a real threat to our national security, or a serious danger to social order, or any other compelling interest of the State have been demonstrated

that justify the restriction of this important and fundamental right [privacy right]". *See id*. at 61.

In the case at bar, Defendant has a compelling interest because of the quicky rising COVID-19 pandemic. This emergency has created the need for the Commonwealth to enforce policies in aid of the public health, lives, and safety of all its public employees. One of these policies is the vaccination requirement established in the Executive Order for all covered public employees to detain the spiking COVID-19 contagion. Although these requirements could be taken by some as an interference to the right to privacy of public employees, there is no question that the Defendant's compelling interest to protect the lives and health of public employees constitutes a compelling interest to act upon said right. Further, even though the Supreme Court of Puerto Rico has recognized a constitutional privacy right under the Constitution of Puerto Rico in the context of the decision making of a medical treatment, this right is not absolute. *See Lozada Tirado v. Testigos de Jehová*, 177 P.R. Dec. 893, 900 (2010) ("[W]e recognize that the right to refuse medical treatment is not absolute and may be limited in the presence of certain interests of the State.").

In Puerto Rico "this right is recognized, not only as part of the doctrine of informed consent, but also as part of the right to privacy expressly guaranteed in our Constitution as a fundamental right." *Id.* at 930. In *Lozada*, the Supreme Court of Puerto Rico emphasized that, "like all constitutional rights, the right to refuse medical treatment is not absolute" and recognized that "in *Cruzan v. Director, Missouri Dept. of Health*, [497 U.S. 261 (1990),] the Federal Supreme Court ruled that, when faced with the refusal of a patient to certain medical treatment, the courts must balance that right with certain interests of the State. In the case it was recognized, based on what was decided by state jurisprudence, that the State may have an

interest in the preservation of life, the prevention of suicide, protecting innocent third parties and maintaining the integrity of the medical profession." *Lozada Tirado*, 177 P.R. Dec. at 916. This interest is the one most often invoked in court in the context of refusal of medical treatment cases. The protection of innocent third parties take—in most cases—two aspects, namely: the State's interest in protecting minors who may be abandoned by the death of their parents and in which citizens undergo certain treatment doctor during a public health crisis. *See id*; *see also Warner Lambert Co. v. Tribunal Superior*, 101 P.R. Dec. 378, 393 (1973) (holding that the state's "broad powers to approve reasonable measures for the purpose of safeguarding the fundamental interests of the people and promoting the common good.").

Recently, the Puerto Rico Court of First Instance of San Juan addressed a similar controversy as the one raised by Plaintiffs. In *Amadeo et al. v. Pierluisi-Urritia et al.*, Civil No. SJ2021CV04779 (P.R. Court of First Inst. 2021) ("Exhibit B"), where it dismissed a challenge Commonwealth's vaccine mandates for schools and universities by concluding that the existence of a compelling interest in protecting the public health created by the COVID-19 pandemic passed strict scrutiny under the Constitution of Puerto Rico.[8] *See* **Exhibit B** at31-32. In addition, the Court of First Instance held that the Commonwealth had shown that the vaccine mandates questioned were necessary and were the less onerous way to promote the governmental interest. *See* **Exhibit B** at 32. Accordingly, the Court decided that the Vaccinate Requirement does not violate the Due Process Clause of the Fourteenth Amendment and does not interfere with the constitutional right to privacy under the Constitution of Puerto Rico. *See* **Exhibit B** at 30-34.

[8] A certified English translation of *Amadeo et al.* is being filed with the instant motion as Exhibit B, so that the Court can take into consideration the Puerto Rico Court of First Instance's grounds to upheld vaccine mandated in schools and universities pursuant to the Constitution of Puerto Rico.

Therefore, it is pellucidly clear that, in light of the Commonwealth's compelling interest to mitigate the effects of a public health crisis provoked by the pandemic of COVID-19, the Executive Order would pass a strict scrutiny for alleged violation to privacy under the Constitution of Puerto Rico. *See* **Exhibit B**. In that sense, even if this Court decides to exercise it supplemental jurisdiction, the result must be that the Executive Order is a constitutional exercise of Defendant's police powers under the Constitution of Puerto Rico. Therefore, all supplemental claims raised by Plaintiffs must be dismissed with prejudice.

III. CONCLUSION

For all the above discussed, Defendant has clearly established that the Executive Order is a constitutional exercise of its as police powers granted to prevent and stop the spread of the deadly COVID-19 virus throughout the population of Puerto Rico. The U.S. Supreme Court has consistently upheld vaccine mandates. *See Jacobson*, 197 U.S. 11; *see also Zucht*, 260 U.S. 17. Further, the fact that the Executive Order is of general application among all public employees of the Executive Branch that work in-person, trumps any due process or RFRA arguments raised by Plaintiffs. Also, the Executive Order passes the applicable rational basis test, as well as the inapposite strict scrutiny under the U.S. Constitution and the Constitution of Puerto Rico. Finally, the Executive Order is not preempted by any federal law, much less by the EUA statute. Therefore, since Defendant has established that the Executive Order is well within the confinements of the Constitution and does not violate any federal statute, the instant case must be **DISMISSED with prejudice**.

WHEREFORE, based on the preceding arguments, Defendant respectfully requests that the instant case be **DISMISSED with prejudice** pursuant to Rule 12(b)(6) of the Rules of Federal Civil Procedure for failing to state a claim upon which relief can be granted.

In San Juan, Puerto Rico, this 31st day of August 2021.

RESPECTFULLY SUBMITTED.

I HEREBY CERTIFY that the undersigned attorney electronically filed the foregoing with the Clerk of the Court, which will send notification of such filing to the parties subscribing to the CM/ECF System.

DOMINGO EMANUELLI-HERNÁNDEZ
Secretary of Justice

SUSANA PEÑAGARÍCANO-BROWN, ESQ.
Deputy Secretary in Charge of Litigation

s/Juan C. Ramírez-Ortiz
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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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COMMONWEALTH OF PUERTO RICO
GENERAL COURT OF JUSTICE
COURT OF FIRST INSTANCE
SAN JUAN PART

LOURDES AMADEO OCASIO; MIGUEL MARRERO, both personally and on behalf of their children A.M.A., M.M.A; and others **PLAINTIFFS** v. PEDRO PIERLUISI-URRUTIA, in his capacity of Governor of the COMMONWEALTH OF PUERTO RICO; DEPARTMENT OF HEALTH, through its Secretary, DR. CARLOS MELLADO LOPEZ **DEFENDANTS**	**CIVIL NO.:** SJ2021CV04779 **COURTROOM:** 907 **RE:** Declaratory Judgment; Injunction; Torts

JUDGMENT

On this occasion, we will address a complaint filed by more than 300 individuals to challenge the constitutionality of certain administrative orders issued by the Secretary of Health thar require, among other things, the COVID-19 vaccination of students older than 12 years old in all schools and universities of Puerto Rico and of their employees, as well as the use of masks in certain specific circumstances. After carefully examining the arguments of both parties, it is forceful to conclude that the State has a compelling interest in safeguarding public health and taking all the measures necessary to effectively battle a pandemic that has affected the life of all people on this planet and that simply has no precedent in our contemporary history. Without a doubt, these measures include requiring the vaccination against that illness and the use of masks in places that susceptible to crowds of people in closed spaces, such as schools and universities.

As we understand that the executive and administrative orders in controversy are based in accurate and verifiable scientific facts and that, also, are carefully designed to grant reasonable accommodation to those persons that qualify and need it, we conclude that these are valid, and they completely adjust to the applicable constitutional parameters. In contrast, the allegations and the evidence presented by the plaintiffs to question the scientific basis of this public policy in the battle against COVID-19 are based in speculative theories and in the interpretation of sources that, at best, lack reliability and are not admissible in a court of

law. Also, their arguments on this matter about the applicable law in Puerto Rico and in the federal field are incorrect. Consequently, and given that the plaintiffs have not certified that they have suffered a constitutional damage that justifies the granting of any remedy in their favor, we state ahead that the dismissal of this case is appropriate.

I.

On July 29, 2021, Mrs. Lourdes Amadeo Ocasio and Mr. Miguel Marrero, both personally and on behalf of their children A.M.A. and M.M.A. and hundreds of other adults and minors ("plaintiffs")[1] filed the captioned complaint against the Hon. Pedro Pierluisi Urrutia, in his official capacity as Governor of the Commonwealth of Puerto Rico, and the Department of Health, through its Secretary, the Hon. Carlos Mellado-Lopez ("defendants"). In sum, the plaintiffs alleged that the Governor violated their constitutional rights by delegating to the Secretary of the Department of Health a broad faculty to require, all school and university students of Puerto Rico older than 12 years old, and the teachers and other employees to be vaccinated against COVID-19, among other things. Particularly, they argued that the delegation of powers via executive order violated the separation of powers; that was contrary to the federal law FDCA, which they believe is preemptive; and also, violated other fundamental constitutionally protected rights like dignity, body integrity, self-determination, the right to formulate informed decisions to provide consent or not, the enjoyment of life without being subject to governmental coercion, the due process of law and the equal protection of the laws.

As the main argument of their constitutional claims, some of the plaintiffs alleged that they are persons and parents of minors that have been "object of discrimination, marginalization and prosecution by the Government of Puerto Rico, for having decided not to participate in the experiment underway that the pharmaceuticals are carrying out with its assistance, control and distribution, contrary version [sic] to what is clearly established by the Federal Act FD&CA 21 U.S.C. §360bbb-3(e)(1)(a)(ii)(I-III) that is preemptive, and that only made the products available to the population, under a restrictive Emergency Use Authorization, (EUA)". *Docket Entry no. 1* pgs. 4-5. They added that "[t]he evaluation underway of these products is exclusive of the Food and Drug Administration (FDA). First, the indiscriminate use of these vaccine products is being compelled, without their having an approval and market license, distribution and "F.D.A. Approved" seal. Phase 3 of the current study in the population is projected to end at the end of the year 2023, time in which, the majority of the F.D.A. panel will be in condition to resolve whether to officially approve or withdraw them. By forcing to advance [sic] this step, in violation of the federal law

[1] For a complete list of all the plaintiffs in this case, see caption and paragraphs 1 to 126 of the complaint, *Docket Entry no. 1*, pgs. 7-26; as revised by the list provided in the motion in compliance with order about standing of each one of them. *Docket Entry no. 21*.

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itself, the State is violating the necessary consent, and the section of the law that gives the individual the option to accept or reject the product". *Id*, pg. 5.

With regard to these allegations, the plaintiffs asked the Court to issue a declaratory judgment in order to declare unconstitutional and invalidate Executive Order EO 2021-054 issued by the Governor to delegate these faculties to the Secretary of the Department of Health, and also Administrative Orders AO 2021-508, OA 2021-508A and AO 2021-509 of that civil servant to implement compulsory vaccination in the school context and order the use of masks and quarantine or temporary isolation of persons potentially infected with COVID-19.

Also, a compensation of at least $50,000.00 was requested for each plaintiff for violation to civil rights, $20,000.00 to each plaintiff for moral damages and mental anguish, and $75,000.00 for attorney's fees. *Id*., pg. 61. Lastly, and regarding the allegations of the complaint, affidavits and other documents filed by the plaintiffs, they requested the Court to issue a preliminary injunction, and a preliminary and permanent injunction, "against compulsory vaccination imposed by the A.O. to preserve the fundamental rights of the plaintiffs intact". *Docket Entry no. 4,* pg. 20.

After evaluating the complaint, the Court issued an Order and Summons by which it scheduled the injunction hearing for August 3, 2021 and requested the execution of the summons and the filing of a responsive pleading in reduced terms due prior to the holding of the hearing. *Docket Entry no. 3*. At the same time, we denied the petition for preliminary injunction filed by the plaintiffs as we deemed it lacked facts certified under oath clearly showing the requesting party would suffer immediate and irreparable harm, losses, or damages if such remedy was not issued before notifying and listening to the opposing party, especially when the preliminary injunction hearing was scheduled for the near future. *Docket Entry no. 7.* Lastly, we asked the plaintiffs to clarify and specify the standing of each one of the plaintiffs, as there were certain doubts as to this matter in the way the complaint was drafted. *Id*, pgs. 1-2.

After some procedural incidents, on August 2, 2021 the Colegio de Medicos Cirujanos de Puerto Rico appeared via an *Amicus Curiae Petition*. *Docket Entry no. 15*. It held that it requested to participate in the case according to the public policy that designates this entity as the consulting organization of the government in public health expertise to protect the wellbeing of the people. It recognized that its participation in the case was not a right, "but an allowable intervention, according to the discretion of the court, with the objective of illustrating the court". *Id*., pg. 4.

After examining that special appearance, the Court issued an order providing that that petition would be addressed in the hearing on the next day. *Docket Entry no. 17*.

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On August 2, 2021, the plaintiffs filed a motion in compliance with order to clarify the standing of each one of the plaintiffs, as required by the Court. *Docket Entry no. 21*. In it, they emphasized that the main argument of the standing of many of the plaintiffs was that the administrative order of the Department of Health "directly impacts and affects the here appearing plaintiffs because it has ordered that all children or students 12 years of age and older have to be vaccinated against COVID-19 as a requirement to be admitted in person in any school in Puerto Rico and, in turn, orders the parents to comply with this requirement of compulsory vaccination on or before August 9, 2021". *Id*, pg. 2.

On August 3, 3021 the defendants filed a *Motion to Dismiss*. *Docket Entry no. 40*. In sum, they argued that "[f]irst of all, as an initial matter, the three hundred twenty (320) plaintiffs have no standing which-to begin with-the case is not justiciable. Secondly, the claims contained in the Complaint do not meet the requirements established by the Rules of Civil Procedure and the interpretative case law to issue a preliminary or permanent injunction and do not meet the requirements for entering declaratory judgment. Much less is a claim for torts appropriate as the plaintiffs have not suffered any damage and there is no violation to any civil rights given that [sic] the measures taken by the State have been made to safeguard the health and life of the population, including that of the plaintiffs themselves". *Id.,* pg. 3. The Court provided that this motion would be addressed in the hearing. *Docket Entry no. 44*.

On August 3, 2021, the injunction hearing took place via videoconference, in which the parties appeared through their legal representatives. As a preliminary matter, the Court authorized the participation of the Colegio de Medicos Cirujanos de Puerto Rico as an allowable intervention. Also, the Court defined the scope of the matters before its consideration in that hearing, which was aimed at resolving both the preliminary injunction filed by the plaintiffs and the motion to dismiss filed by the defendants.

As to the matter of standing, it was provided that although the standing of each one of the 320 plaintiffs[2] was not clearly shown in the complaint and the motion in compliance with order filed afterwards

[2] Among the plaintiffs that clearly have no standing in this case are-for example-those that merely alleged the following: "Chiropractor doctor in Guaynabo. Knows of other less invasive alternatives. The requirement by the Government has caused a reaction in all the sectors, which are requiring vaccination. The limitation to places such as supermarkets, doctors, hospitals and public places, who are segregating because the orders of the Governor and the Secretary of the Health Department, affects our integrity because it is inciting all places to request compulsory vaccination and the Government is causing and inciting segregation". Other plaintiffs just alleged that: "[t]he limitation to supermarkets, doctors, hospitals and public places, who are segregating due to the orders of the Governor and the Secretary of the Department of Health, affect our integrity because they are inciting all places to request compulsory vaccination and the Government is provoking and inciting segregation*". Docket Entry no. 29,* pg. 22, 25. Also the standing is not clear-and indispensable parties are missing-as to those plaintiffs that question the measures imposed *motu proprio* by third parties and their employers such as the use of masks, test requirements and other measures to mitigate the propagation of the virus. As to these plaintiffs it is not clearly established that each one of them (i) has suffered a clear and palpable damage; (ii) that the referenced damage is "real, immediate and precise, and not abstract and hypothetical"; (iii) there is a "connection between the damage suffered and the cause of action

by the plaintiffs, those documents and affidavits showed that at least some of the plaintiffs in this case potentially had standing in constitutional terms, namely: 1) those students of schools and universities, both public and private, for whom vaccination against COVID-19 was being required as a condition to attend the classrooms in-person pursuant to the challenged orders, despite their opposition or that of their parents; 2) those teaching and non-teaching employees of the educational institutions for whom this vaccine was required as an employment condition and who refused to comply with that requirement imposed by the State.

Also, the Court explained that the controversies related to the validity of the executive and administrative orders issued by the Governor and the Secretary of the Health Department in accordance with the doctrine of separation of powers, and that regarding the alleged preemption of the FDA were matters of law that did not require the presentation of evidence. However, the Court provided that, as to the claim of individual rights to refuse the vaccine by virtue of several constitutional provisions, the Court would have to consider the interests involved, which required the consideration of the evidence offered by each party. Although in the preliminary injunction stage it would suffice to decide based on the affidavits and other documents, we accepted the request of the plaintiffs for the parties to be able to present that pertinent witness evidence to assess the governmental and individual interests involved according to the applicable constitutional test.

Given the foregoing, Dr. Maria Carrascal (pediatric infectious diseases doctor) and Dr. Rafael Iriarte (family doctor) testified at the hearing for plaintiffs, Dr. Iris Cardona for defendants (pediatrician specialist in infectious diseases and chief medical official of the Department of Health) and Dr. Lemuel Martínez for the intervenor Colegio de Medicos (President of the Associacion de Enfermedades Infecciosas de Puerto Rico and member of the Coalicion Cientifica de Puerto Rico). Both at the beginning of the hearing and at the end of the presentation of witness evidence, the parties had ample opportunity to state their arguments about the appropriateness of the preliminary injunction in accordance with the criteria established in Rule 57 of Civil Procedure, 32 LPRA Ap. V, and about the appropriateness of the arguments to dismiss filed by the defendants.

Although we had said in open court that we would deem the injunction petition and the motion to dismiss submitted based on the evidence and the arguments at the hearing, on August 4, 2021, the plaintiffs filed a motion for reconsideration about this particular and asked that we grant them a brief term to reply to the motion to dismiss. *Docket Entry no. 46*. In consideration of the request and the extraordinary nature

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exercised", and (iv) that the cause of action arises "under the Constitution or a law". *Fund Surfrider v. ARPe*, 178 DPR 563, ,572 (2010); *Col Peritos Elec v. AEE*, 150 DPR 327, 331 (2000).

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of the matters before our consideration, we granted the plaintiffs a final term for that purpose due on August 6, 2021 at 12:00 p.m. *Docket Entry no. 47*.

In compliance with the foregoing, on August 6, 2021 the plaintiffs filed an *Opposition to Motion to Dismiss*. *Docket Entry no. 49*. Essentially, it held that the plaintiffs have standing to litigate the controversies of this case; that the complaint states plausible claims in accordance with Rules 6.1 and 10.2 of Civil Procedure; and that in this case there are the necessary elements for the Court to issue the injunction remedy requested. For that, they reiterated and expanded the arguments that they had already provided in its previous documents and the injunction hearing.

The plaintiffs emphasized that the challenged administrative orders "requiring that students older than 12 years old, and teaching and non-teaching employees of the educational system, to provide evidence of vaccination against COVID-19 at the beginning of the school semester is an imminent threat to the right of informed consent" by virtue of the federal law "and that entails a damage that is concrete and real, not speculative". *Id,* pg. 2. They stated that "[i]f the State were allowed to go over a product with EUA (Emergency Use Authorization) classification it would destine the Puerto Ricans to be laboratory rats, which in addition to being illegal it would be a disastrous precedent". *Id.,* pg. 9. In their opinion, "a state cannot make an EUA in hands of the FDA its own. The state must wait for the approval of the FDA". *Id*., pg. 20.

They added that the exceptions recognized in the challenged orders are invalid and are deemed not there. As to the medical exception, they explained that it would force the plaintiffs to "have to show, disclose and publish they have health conditions, to identify and specify them". *Id.,* pg. 10. Also, as to the exception for religious reasons it held that it is null and inexistent as it would force them to "reveal their religious creed, they believe in God and have a close and spiritual relationship with him, but they do not actively or regularly participate in a religious entity as if religious ideas were not protected by our Constitution". *Id.*

At this point, we deem the motion for preliminary injunction filed by plaintiffs and the motion to dismiss filed by defendants submitted.

II.

After carefully evaluating the witness and documental evidence presented and believed by the Court in the referenced hearing, as well as the complaint, affidavits, motions filed by the parties and other documents in the docket, as well as considering the matters of which we can take judicial notice, we make the following fact-findings:

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1) For the past 18 months, Puerto Rico and the whole world have gone through a pandemic caused by the propagation of COVID-19 that has affected the public health system, as well as the daily, social, and economic life of all persons.

2) On March 12, 2020, the then Governor issued Executive Order EO 2020-20 in which a state of emergency was decreed due to COVID-19 that continues today. In its text, the Executive Order states that it was promulgated to safeguard the public order and protect the life and safety of citizens.

3) The state of emergency caused by the pandemic is reflected in the official statistics available. Presently, in Puerto Rico a total of 129,011 positive cases have been confirmed; 21,353 probable cases; and 2,598 persons dead because of this virus. Among the deceased, four have been minors.[3]

4) The daily count of confirmed cases and hospitalized persons in Puerto Rico because of COVID-19 has fluctuated in several ways during the past 18 months. For example, around a year ago in August 2020 close to 400 confirmed cases daily were reported and a moving average of over 300, numbers that continued increasing until November and December of 2020 when the cases reached over 1,000 a day and a greater moving average of even more than 800 cases. After that, and after the implementation of the first vaccination phases in Puerto Rico, the confirmed cases began to gradually decrease until March 2021, when they reached the average of around 120. However, these numbers began to drastically increase again at the beginning of spring. By mid-April of 2021 the moving average exceeded 800 while the daily cases exceeded 1000 confirmed cases again. However, in the subsequent months another drastic reduction occurred in the confirmed cases, to a point that by mid-June and beginning of July 2021 both the moving average and the confirmed cases were close to 20 daily. Lastly, these numbers increased again in the past

[3] That is evident from both the testimony of Dr. Cardona, which the Court gave entire credibility to, and of the official site of statistics of the Department of Health (over which we anticipated in the injunction hearing that we could take judicial notice): https://covid19datos.salud.gov.pr/ (last hearing of August 6, 2021). See, for persuasive purposes, several cases that the courts have taken judicial notice of the official statistics published by the government, even over matters regarding public health. *Immigrant Legal Res. Ctr. V. City of McFarland*, 472 F. Supp. 3d 779, 785 n. 2 (E.D. Cal. 2020); *Lee v. Virginia State Bd. Of Elections*, 188 F. Supp. 3d 577, 606 n. 16 (E.D. Va.); *Gent v. CUNA Mut. Ins. Soc'y*, 611 F. 3d 79, 84 n. 5 (1st Cir. 2010); *Victoria Cruises, Inc. v. Changjiang Cruise Overseas Travel Co*., 640 F. Supp. 2d 255, 263 n. 3 (E.D.N.Y. 2008); *United States v. Esquivel*, 88 F. 3d 711, 726-27 (9th Cir. 1996); *City Bank Farmers' Trust Co. v. United States,* 5 F. Supp. 871, 873 (S.D.N.Y. 1934).
On the other hand we bear in mind that the plaintiffs tried to controvert Dr. Cardona in their line of questions and in their *Motion in Opposition to the Motion to Dismiss* the scope of some of the official statistics of the government ("As the positive results that the PCR-Test show are not indicative of the presence of SARS-CoV-2 RNA, there must be a clinical correlation with the history of the patient and other diagnostic information to determine the status of infection of that patient. These positive results do not rule out bacterial infections or coinfections with other viruses". *Docket Entry no. 49,* pg. 13). However, the plaintiffs did not present expert witness or documental evidence that allows us to reach the conclusion that the official statistics published by the government as to COVID-19 are not susceptible to immediate and exact corroboration by sources which accuracy cannot be reasonably questioned". Rule 201 of Evidence, 32 LPRA Ap. V.

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month of July and beginning of August 2021, which is mainly attributed to the Delta variant, to the point that the moving average of confirmed cases today exceeds the 280 confirmed cases daily.[4]

5) Now, the statistics as to the daily hospitalizations because of COVID-19 have also fluctuated, but not in a way that is entirely parallel to the cases confirmed. For example, even when in August 2020 the moving average of confirmed cases was similar to the one reported today (between 250 to 300 daily cases approximately) the hospitalizations for COVID-19 a year ago exceeded 400 and even 500 in December 2020, **while presently in August 2021-a year after-the patients infected with the virus that require hospitalization are about hal**f (226 adult patients hospitalized with 54 in intensive care and 28 pediatric patients, of which three are in intensive care).[5]

6) The same happens with the statistics related to deaths because of COVID-19. While in August 2020, the moving average reached the number of 10 deaths a day, which increased in December 2020 to 16 deaths a day, the average number of daily deaths significantly decreased until reaching 1 to 3 deaths a day. Although recently this number increased again after the arrival of the Delta variant, it continues being exponentially lower than the average of daily deaths occurred in August 2020, even when the average of confirmed cases is statistically similar.[6]

7) The younger the person, the possibility of infection with COVID-19 and to suffer severe symptoms caused by the illness is lower. However, minors can be infected and become severely ill, to the point of requiring hospitalization and use of ventilators, and even die because of the illness, as in fact has occurred in Puerto Rico and the United States.

8) Also, the minors can also spread COVID-19, as statistically also asymptomatic and/or vaccinated people can do to different degrees.

9) In our legal and administrative system, the scientific procedures to develop, investigate, experiment, and provide medication for human use usually consist of five stages:

a. Discovery/Concept.
b. Pre-clinical studies (evaluation in non-humans).
c. Clinical Studies (Phase 0, Phase 1, Phase 2, Phase 3).
d. Evaluation by the Federal Drug Administration ("FDA").
e. Post-approval monitoring.

10) As to the phases of the clinical studies (evaluation in humans), these are characterized in the following way:

a. Phase 0 (expose humans to low doses to understand how it behaves in the human body).
b. Phase 1 (evaluation of different doses to determine safety of the doses).
c. Phase 2 (evaluation of effectiveness and low scale secondary effects, 100-300 patients).
d. Phase 3 (evaluation of great scale clinical study measuring effectiveness and safety, 300-3,000 patients).

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[4] *Id.*
[5] *Id.*
[6] *Id.*

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e. Phase 4 (monitoring after ending the study and/or approval).

11) In the ordinary course, the pharmaceuticals submit to the FDA their studies from Phase 0 until Phase 3, so the FDA approves the sale and distribution of any medication or medical device. Also, they must submit another series of documents explaining the manufacturing and logistics system.

12) Now, in accordance with the applicable federal schedule, the FDA also has an alternative to expeditiously facilitate access to medications and instruments to be able to swiftly respond to threats of great magnitude to society, such as chemical, biological, radiation, and nuclear threats, which undoubtedly includes pandemics as the one we are going through now. This administrative procedure is known as the Emergency Use Authorization (EUA)".

13) Although it is an expedited administrative procedure for which it is not even necessary to have complete animal or clinical studies, every EUA must rigorously comply with multiple guarantees of safety, effectiveness, and manufacturing criteria. Also, the legal and administrative system requires that the medical providers inform the patients of the status of the EUA, as well as of the known risks and potential benefits and those that are still unknown. Lastly, the medical providers must inform the individuals of the option of rejecting the use of the product and the possible consequences of that decision. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I)-(III).

14) Now, **it is necessary for any authorization through an EUA for the pharmaceutical to submit facts and evidence that shows that the product may be effective, but above all, that its potential benefits are greater than the potential risks**. 21 U.S.C. §360bbb(c)(2)(A).

15) At the beginning of the COVID-19 pandemic, the federal Department of Health declared a public health emergency and authorized the FDA to grant emergency authorizations (EUA) for those products and interventions to battle the pandemic. 85 Fed. Reg. 7316, 7316-7317; 85 Fed. Reg. 18250, 18250-18251.

16) From December 2020, through the process of EUA, the FDA authorized as emergency three vaccines against COVID-19, namely: PfizerBioNTech, Moderna and Janssen/Johnson & Johnson.

17) The testimony of doctors Cardona and Martínez, which merited complete credibility from the Court, revealed that all these vaccines exceeded the requirements to be granted an emergency authorization. In fact, these completed their clinical Phase 3 studies with a total of more than 100,000 participants between the three. Their results were published in scientific magazines and were properly submitted to the FDA. Without a doubt, the experimental phases of these three vaccines were completed and it was indubitably shown before that federal agency that their potential benefits outweigh their potential risks, therefore are not considered "experimental".

18) The referenced studies performed in a great number of patients had the following results regarding their effectiveness:

a. Moderna-initial study:30,420 participants-Prevention of illness 94.1%
b. Pfizer/BioNTech-initial study:43,548 participants-Prevention of illness 95%
c. Janssen/J&J-initial study: 39,321 participants-Prevention of critical illness 14 days post vaccination 76.7% Prevention of critical illness 28 days post vaccination 85.4%[7]

19) Although the Pfizer and Moderna vaccines use relatively new technology of mRNA, it has been developing for decades according to studies and investigations that have already acquired a general acceptance from the scientific community.[8]

20) After the authorization of these three vaccines through the EUA process, their use and distribution-that per legal provision corresponds to the government-was not immediate. At this time, their instructions for use provide that the Moderna and Janssen vaccines can be given to persons older than 18 years of age, while the Pfizer vaccine can be given to those older than 12 years of age.

21) As every scientific method and process, the vaccines authorized through EUA continue being evaluated regarding their final and ordinary approval by the FDA. In fact, there was a second evaluation by the Advisory Committee on Immunization Practices ("ACIP"). Even so, as a judicial and scientific matter their authorized use clearly is not indiscriminate but based on completed studies. Also, their use is continued to be studied for other ranges of ages.[9]

22) From December 2020 until today, in Puerto Rico 2,168,500 persons have been vaccinated against COVID-19 in Puerto Rico with at least one dose; and 1,901,249 with the series of doses completed (or 66.8% of the eligible persons older than 12 years old). Also, the official statistics show that the amount of vaccinated persons began to exponentially increase in January of 2021 until April 2021, when the moving average of persons that were vaccinated daily began to reduce drastically, tendency that continues to today.[10]

23) **The three vaccines against COVID-19 have resulted to be greatly effective to battle the severe impact of this virus in Puerto Rico and the world. Its effectiveness has been scientifically shown both to reduce the number of infections in general terms and to mitigate successfully and significantly the most severe symptomatic effects of the illness, including hospitalization and possible death of the infected persons.**

24) In fact, the scientific evidence itself presented by the plaintiffs shows that, at least, these vaccines have a high short-term efficacy ("Vaccines based on the spike glycoprotein of SARS-CoV-2 are being rolled out globally to control transmission and limit morbidity and mortality due to COVID-19. **Current evidence indicates strong immunogenicity and high short-term efficacy for BNT162b2**

[7] *Docket Entry* no. 15 and testimony of Dr. Martínez.
[8] *Id.*
[9] *Id.*
[10] See, *supra*, note 3.

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(Pfizer-BioNTech)) […]").[11] In its own context, this study suggests that the efficacy of certain vaccines could be decreasing with time, particularly in view of the new variants of SARS-CoV-2 like the Delta variant. Even so, we take into consideration that this same study is aimed at examining the hypothesis about the convenience of a third dose of the vaccine, and not to discredit in any way the efficacy and convenience of being vaccinated against COVID-19. ("**Higher antibody levels are possibly associated with greater protection against variants that can partially evade immunity, which could explain the observed higher efficacy (partly preliminary) of BNT162b2 [Pfizer]** compared to ChAdOx1 [Oxford-AstraZeneca] against the Delta variant").[12]

25) In another study presented by the plaintiffs, published recently by the Center for Disease Control and Prevention, it is indicated that in July 2021 in a town in Massachusetts 469 cases of COVID-19 associated with public events where many persons participated were confirmed of which 346 (or 74%) were completely vaccinated (the called "breakthrough infections"). However, in this study it is also emphasized that of this high number of infected persons (almost all by the Delta variant), only four were hospitalized and there was no death reported. Also, another statistic reality is emphasized: as vaccination coverage reaches a greater percentage of the population, it is inevitable that persons vaccinated will represent a larger proportion of COVID-19 cases. ("As population-level coverage increases, vaccinated persons are likely to represent a larger proportion of COVID-19 cases").[13]

26) The testimonies believed by the Court show that the immunity percentage required for the population to reach herd-immunity has been revised with the time and is currently estimated in around 75% of the population, but it is clear that Puerto Rico still has not reached that objective.

27) Presently in the United States around 350 million doses of the COVID-19 vaccines have been administered, therefore there is plenty experience as to possible adverse effects caused by the administration of the COVID-19 vaccines.

28) The verifiable reports of severe adverse effects reflect that they have occurred in extremely low percentages (for example, 0.0005% thrombus with the Janssen/J&J vaccine), just like it could happen with any other medication.

29) It must be emphasized that in case that a person has doubts with the administration of any vaccine specifically, they have the availability to choose between the three vaccines authorized by the emergency process of EUA that are accessible in the market.

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[11] *Spike-antibody waning after second dose of BNT162b2 or ChAdOx1*, Institute of Health Informatics, University College London, WC1E6BT London, UK (July 15, 2021) (Emphasis provided).
[12] *Spike-antibody waning after second dose of BNT162b2 or ChAdOx1*, Institute of Health Informatics, University College London, WC1E6BT London, UK (July 15, 2021) (Emphasis provided).
[13] *Id.*

30) The plaintiffs reference certain facts published in the Vaccine Adverse Event Reporting System ("VAERS")-administered by the FDA and the Center for Disease Control ("CDC") about the adverse effects and the number of deaths reported as a result of the administration of these vaccines.[14] However, the testimony of doctor Cardona, which was believed by the Court, shows that this system has a very limited scope and really is not reliable to reach accurate conclusions about the amount and causality of the possible adverse effects, because any person can enter data into this system and it is not corroborated. In other words, the data gathered in the VAERS can contain incomplete, imprecise, anecdotal, and unreliable information, that in no way would be admissible in a court of law. Also, they do not necessarily reflect a scientific causality between the death reported and the administration of the vaccine. In contrast, doctor Cardona explained that there have been very few serious adverse effects officially detected in Puerto Rico and the United States regarding the administration of these vaccines.

31) The CDC recommends that all persons older than 12 years old vaccinate against COVID-19 as soon as possible to be protected from both the illness and the severe complications that could occur.

32) Both the FDA and the CDC are continuously monitoring the safety of the vaccines authorized through EUA.

33) **The known benefits of being vaccinated against COVID-19 greatly exceed the possible risks for all persons older than 12 years old**. By mandate of law, the FDA so determined by authorizing as an emergency the use of these vaccines and that should be shown in the respective informative fact sheets for each one of those products. Section 564 of the FDCA, *supra.*

34) The academic semester of the public and private schools and universities is soon to begin in August 2021.

35) During the past year and a half, school and university education-as well as other social and economic sectors-has been severely affected by the COVID-19 pandemic, requiring the suspension of classes and the adoption of remote education programs.

36) On July 1, 2021, the Governor issued Executive Order EO 2021-054 through which he delegated-from July 5, 2021- to the "Secretary of the Department of Health the power to establish the guides, guidelines, protocols and recommendations to address-in a particularized way for each service, business, activity or area, as is necessary pursuant to the risk of infection-the COVID-19 emergency" and provided that "[t]he measures adopted by the Secretary of the Health Department will apply to the population in general, and to the employers and entities in the public and private sector". See, Executive Order No. 2021-054 (July 1, 2021).

[14] However, note that the original source of the fact referenced is not the official site of the federal Health Department (https://vaers.hhs.gov/) but a cybernetic portal (https://openvaers.com) evidently managed by other persons.

37) This Executive Order states, among other things that: "[t]he scientific studies state that the vaccines against COVID-19 are effective to avoid contracting the illness. Therefore, it is encouraging that today more than 1,759,206 adults have been vaccinated, that is, close to sixty-four percent (64%) and 1,933,163 persons older than eighteen (18) years old have received at least one (1) dose of the vaccine, which, in turn, represents close to seventy-four percent (74%) of that population. This last number is consistent with the goal set forth by the President of the United States of America, Joseph R. Biden Jr., for July 4, 2021. Such statistics increase daily. It is clear that with the vaccination process we have managed to reach significant advances in the fight against this virus and that it is necessary to continue with that process." Id. Pg. 2.

38) On July 1, 2021, the Secretary of the Health Department issued Administrative Order AO 2021-508. This order was amended on July 8, 2021 by that civil servant through Administrative Order AO 2021-508A.

39) Administrative Order AO 2021-508A states that the Department of Health issued multiple previous orders during the COVID-19 pandemic through which it implemented "strategies as to the logistics and administration []both of the tests to detect the virus [] and the vaccination process", that such agency "has implemented an aggressive vaccination program throughout the whole Island, with the purpose of reaching herd immunity among our citizens and, thus prevent and control the propagation of COVID-19" and that "[t]he epidemiologic reports show that these orders-along with the vaccination-were effective and met their purpose...because, the infection levels of COVID-19 have drastically decreased". Id. Pg. 2.

40) AO 2021-508A also establishes that "[t]he scientific studies show that the vaccines against COVID-19 are effective to avoid being infected with the illness", which is why "it is encouraging that today in Puerto Rico more than 50% of the eligible population has been completely vaccinated and close to 70% has received at least one dose of it". Id.

41) Also, this order affirms that

> The scientific facts and statistics show that the measures taken by the Government of Puerto Rico and the Department of Health have been effective, because the levels of Covid-19 infections have dramatically decreased; therefore it is viable to take new affirmative steps to continue to increase the flexibility of the measures of containment and mitigation to battle the pandemic [] responsibly"; but that, "[e]ven so, it is necessary to continue with the vaccination campaigns until achieving herd immunity….for the individual and collective protection, as there is still a segment of the population that is not eligible for vaccination" and that, "[i]n the same way, we must continue taking prevention measures as hand hygiene, physical distancing and the use of masks of the unvaccinated population [] that is susceptible to the illness". *Id.* Pg. 3.

42) Administrative Order AO 2021-508A provides that every person not completely vaccinated that has been exposed to COVID-19 will have to be in quarantine for a period of 14 days and

requires physical isolation for a period of 10 days for every person infected with COVID-19. *Id.* pgs. 5-6. Also, this order establishes the mandatory use of masks to persons that personally go to health services institutions, to the persons that are not completely vaccinated and minors between ages 2 and 11. *Id*. pgs. 6-7. Administrative Order AO 2021-508A also ordered the use of masks during events that receive simultaneously 500 persons or more. *Id.*

43) On July 22, 2021, the Secretary of Health issued Administrative Order AO 2021-509. This order reiterates that "the scientific facts and statistics show that the measures taken by the Government of Puerto Rico and the Department of Health have been effective"; but that, "[e]ven so, it is necessary to continue with the vaccination campaigns until achieving herd immunity….for the individual and collective protection, as there is still a segment of the population that is not eligible for vaccination" and that, "[i]n the same way, we must continue taking prevention measures as hand hygiene, physical distancing and the use of masks of the unvaccinated population [] that is susceptible to the illness". Id. Pg. 3.

44) Also, AO 2021-509 states that:

> The start of classes, on pre-university and university levels, brings new challenges and opportunities, because the COVID-19 vaccines have been allowed for the population of 12 years and older. Having the greatest amount of students will allow having a safer environment in the school community and will provide more guarantees to the student population that still cannot get vaccinated. This measure will be part of the protocol that the Department of Health and the Department of Education will announce, but it must be stated in advance in this Administrative Order so that the fathers and mothers, and students of legal age can make the pertinent arrangements in preparation for the beginning of classes. *Id.* pgs. 3-4.

45) In pertinent part to the present case, AO 2021-509 provides that no student or child 12 years or older may be admitted personally in a school, unless he/she is duly vaccinated against COVID-19 with the vaccines authorized by the federal agencies. *Id.* pg. 4.

46) Compliance with the vaccination requirement of the students must be within the first 30 calendar day following the start of classes; therefore all "the schools, education centers and public and private universities, must adjust their protocols to the following instruction for the beginning of classes in August 2021". *Id.* pgs. 6-7.

47) Also, AO 2021-509 explains and justifies this vaccine mandate in the following way:

> Mandatory vaccination, as a requirement for personal admission to schools and universities will have an indispensable role in the control of the pandemic and will allow to provide a safer environment in our educational environment…The Health Department of Puerto Rico, in its duty to guarantee public health, has the obligation to safeguard the health of all students, teachers and personnel that works in both public and private teaching institutions. One of the keys to eradicate the pandemic caused by COVID-19 is minimizing the propagation of the virus. The teaching centers by design are places where the cautionary measures of distancing, use of masks and washing hands do not necessarily guarantee that the levels of propagation decrease. It is important to

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> mention that, in the case of the minors population, the majority of those infected have been asymptomatic and the virus as a general rule has not caused severe symptoms that cause hospitalization. However, vaccinating this sector of the population is key to decrease the propagation of COVID-19 and obtaining the herd immunity to achieve the goal of protecting all sectors of the population. Also, the propagation of this virus in this sector does not rule out severe cases and deaths in minors and young people. The fundamental rights protected by the Constitution of Puerto Rico and the United States do not represent an absolute right of every person, as there are circumstances in which the State can order their restriction for the collective wellbeing. The Fourteenth Amendment of the Constitution of the United States allows that, through the Due Process of Law, a balance is made between the interest of the state of safeguarding public health and the right of the citizens to not receive medical treatment. This order is demarcated in this constitutional precept and in the power of safety of the State. Id. pgs. 5-6.

48) At the same time, AO 2021-509 applies to the fathers, mothers, or tutors of those older than 12 years old, and to public and private employers and educational institutions. *Id.,* pg. 4. However, it exempts from the vaccine requirement those students whose immune systems are compromised, which must be certified by medical certificate, and those students whose religion (or that of their parents) is against vaccination, which must be certified by affidavit of the parents signed by them and the minister of the religion. *Id*., pg. 6.

49) AO 2021-509 also establishes the mandatory vaccination for the teaching and non-teaching personnel of the schools, educational centers and universities, regardless if these entities or institutions are public or private. *Id*. Also, this mandatory vaccination also applies to the contractors that have contact with the educational community. *Id.*

50) At least some of the plaintiffs in this case are students older than 12 years old (represented by their parents) that have opted not to be vaccinated against COVID-19 and that are enrolled in public and private schools or universities. Other plaintiffs are also employees of those educational institutions, to whom Administrative Orders 2021-508 and 509 of the Department of Health are applicable. Therefore, if they do not get vaccinated and do not qualify for any of the exceptions by reason of health or religious objection, they cannot attend the school in person, either to work or receive education in person.

51) The Commonwealth has a compelling interest to safeguard the public health in face of the emergency caused by the COVID-19 pandemic and protect innocent third parties, and to effectively guarantee the education of the students of the whole educational system in Puerto Rico.

52) As a matter of fact, the mandate established by the government to require vaccination against COVID-19 for all persons that qualify-used jointly with other health measures such as the use of masks, washing hands, social distancing in those scenarios susceptible to grouping of people in closed spaces like schools and universities-constitutes a necessary measure to advance this compelling interest of the State. Also, there are no other measures that are less onerous to advance that compelling governmental interest.

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53) The vaccination requirement against COVID-19 is less onerous than other alternatives theoretically available in these historic times, as would be the fully remote education, the curfews, the social distancing or going back to a type of lockdown as the one that characterized the first months of the pandemic. See, for example, EO-2020-033.

Based on the foregoing fact-findings, we proceed to examine the law applicable to the matters before the consideration of the Court.

III.

A. The authority of the Governor and the Secretary of the Health Department to issue, respectively, executive orders and administrative orders to address the state of emergency caused by the COVID-19 pandemic.

To begin with, we must evaluate the argument in law of the plaintiffs that the Governor and the Secretary of the Health Department lack legal authority to issue Executive Order OE 2021-054 and Administrative Orders AO 2021-508, AO 2021-508A and AO 2021-509, respectively. In their understanding, the delegation of powers by the Governor to the Secretary of Health to regulate certain matters related to the COVID-19 pandemic-including the vaccination requirement in certain social and economic contexts like schools and universities-was excessively broad and contravenes the separation of powers. As they argue, a delegation like that could only be approved by the Legislative Assembly because that is required by section 19 of Article II of the Constitution of the Commonwealth of Puerto Rico, by recognizing "the faculty of the Legislative Assembly to approve laws in protection of the life, health and wellbeing of the people". Const. Commonwealth, LPRA Tome 1.

In essence, the thesis of the plaintiffs is based on that the only legal source that gives the Secretary of the Health Department authority to issue those administrative orders is Executive Order EO 2021-054 issued by the Governor. However, they are not correct. The authority of the Secretary of the Department of Health to approve those administrative orders emanates from legislation duly approved by the constitutional powers of the Commonwealth of Puerto Rico and not merely from the EO 2021-054 issued at the start of July 2021, by the First Executive.

Firstly, it is evident that the Governor of Puerto Rico has legal authority to delegate to the Secretary of the Health Department the power to establish guides, guidelines, protocols, and recommendations to address the COVID-19 emergency. Certainly, pursuant to what is provided in Section 4 of Article IV of the Constitution, the First Executive has the faculty and constitutional duty to "comply and enforce the laws" and "exercise the other faculties and responsibilities and comply with the other duties that are stated in this Constitution or in law". It is because of that, that in our horizontal division of powers system, the Governor has constitutional authority to issue executive orders, if they are promulgated based on the faculties inherent

to the position or of a law. *Hernández, Romero v. Pol. De P.R.,* 177 DPR 121, 138 (2009). Also, see, William Vázquez Irizarry*, Los poderes del Gobernador de Puerto Rico y el uso de Ordenes Ejecutivas*, 76 Rev. Jur. UPR 951, 953 (2007).

In what is relevant to this case, Article 6.10 of the Puerto Rico Public Safety Department Act, Act No. 20-207, constitutes a clear example in which the Legislative Assembly conferred to the Governor ample faculties to act in protection of public interest in cases of emergency. To begin with, this article states that "[i]n emergency or disaster situations, the Governor of Puerto Rico may decree, by proclamation that there is a state of emergency or disaster, as the case may be, in all the territory of Puerto Rico or in part of it". 25 LPRA sec. 3650. Also, the statute contains a non-exhaustive list of faculties that the Governor will have, clarifying that these faculties are in addition "to any other powers conferred by other laws". *Id.* In fact, the Legislative Assembly also authorized the Governor through this provision to carry out the following acts for the duration of the disaster or state of emergency: "enter, amend and revoke those regulations and **issue, amend and rescind those orders he deems convenient to rule during the state of emergency or disaster. The regulations issued or orders issued during a state of emergency or disaster will be binding like law for the duration of the state of emergency or disaster."** *Id*. (emphasis provided).

Notice that Article 6.10 of Act No. 20-2017 is not the only statutory provision that shows the Governor's authority to manage an emergency like the one caused by the COVID-19 pandemic. In fact, **Act No. 157 of May 10, 1938 expressly recognizes the authority of the Governor to act in an epidemic through executive orders and specifically appoints the Secretary of the Health Department as the civil servant of the executive power who will have in his charge the governmental response upon the declaration of epidemic decreed by the First Executive.** Particularly, that law establishes that, "[w]hen an epidemic is declared in one or several municipalities, by proclamation of the Governor of Puerto Rico, immediately upon the declaration of the epidemic the Secretary of the Health Department will take charge of the health of the affected municipality or municipalities. 24 LPRA sec. 354.

Therefore, it is evident that the Governor of Puerto Rico has the constitutional and statutory authority to delegate to the Secretary of the Health Department the faculty to establish the guides, guidelines, protocols, and recommendations to address the COVID-19 emergency. That in accordance with Section 4 of Article IV of the Constitution of the Commonwealth, the Puerto Rico Public Safety Department Act and Act No. 157 of May 10, 1938.

However, we stress that Executive Order EO 2021-054 and the referenced laws are not the exclusive legal sources from which the legal authority of the Secretary of the Health Department in controversy to issue administrative orders is derived. The legal authority of the Secretary of the Health

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Department to demand the use of masks and impose the vaccination requirement on students and employees through administrative orders is also reflected in what is established in the provisions of Act No. 81 of March 14, 1912, as amended, known as the Originating Act of the Department of Health, and in Act No. 25 of September 25, 1983.

On one hand, in accordance with what is provided in Article 1 of the Originating Act of the Department of Health and Sections 5 and 6 of Article IV of the Constitution of Puerto Rico, the Secretary of the Department of Health is the Chief of the Department of Health and has in his charge all the matters that are appointed to him by law regarding health, salubriousness, and public wellbeing, except those that are related to the maritime quarantine service. 3 LPRA sec. 171. In the part that is pertinent to this case, **Article 5 of Act No. 81 of 1912 expressly grants authority to the Secretary of the Health Department to take the measures he deems necessary to battle any epidemic that poses risk to public health.** *Id.* Sec. 175.

Notice that **the Originating Law of the Department of Health itself recognizes vaccination as a crucial tool to fight epidemics, and the authority of the Secretary of Health to implement vaccination programs to carry out his legal responsibility of guaranteeing the public health upon epidemics that affect the country.** See, 24 LPRA sec. 353 ("The inoculation of the vaccine virus is hereby declared mandatory for all the habitants of the Commonwealth, in the time, way and term determined by the Secretary of the Department of Health; being also mandatory in cases of epidemic, the inoculation of any other organic prophylactic or therapeutic product").

On the other hand, Article 12 of Act No. 91 of 1912 expressly recognizes the authority and the powers of the Secretary of the Health Department to enter, reverse and amend regulations to prevent and suppress infectious, contagious, epidemic illnesses and to protect the public health in any service, business, activity, or case that could affect it. 3 LPRA sec. 178. The importance of the exercise of the authority recognized to the Secretary of the Health Department in the context of epidemics and emergencies of public health is such that Article 15 of that law requires the courts to take judicial notice of the adoption of the rules and regulations to address this type of emergency situations.[15] Id. Sec. 180.

Additionally, regarding the vaccination requirements for students of public or private schools, **Act No. 25 of September 25, 1983, provides a requirement of compulsory vaccination for all students of educational institutions of the country.** Also, it expressly delegates to the Secretary of the Health

[15] See, Dept. of Health, Isolation and Quarantine Regulation, No. 7380 (July 5, 2007), http://app.estado.gobierno.pr/ReglamentosOnLine/Reglamentos/7380.pdf. This regulation establishes the norms and procedures for isolation and quarantine of persons that have been exposed to transmittable diseases that represent a threat to public health.

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Department the authority and the duty to establish the illnesses for which the immunization of the students will be required. Moreover, Act No. 25 clearly establishes that **the students that are not duly vaccinated against the illnesses identified by the Secretary of the Health Department will not be admitted to in-person classes**. 24 LPRA sec. 182a ("no student or child of preschool may be admitted or enrolled in a school, day care center or social treatment center if they are not duly vaccinated"). The vaccinations required will be those identified by the Secretary of the Health Department, pursuant to Article 10 of the referenced Act No. 25-1983. Id. Sec. 182i ("The Secretary of the Department of Health will be obligated to publish annually, three months before the beginning of each school course the illnesses against which the students must be vaccinated, among others diphtheria, tetanus, whooping cough, poliomyelitis, German measles, common measles, mumps, and any other that the Secretary of the Health Department requires. The vaccinations required and the form and frequency to administer them must be in accordance with the medical practices recognized in the Commonwealth of Puerto Rico.").

At the same time, Article 5 of Act No. 25-like Administrative Order AO-2021-509-excempts from compulsory vaccination those students that present an affidavit that him/her or his/her parents belong to a religious organization which dogmas conflict with vaccination. *Id.* Sec. 182d; cf. Dept. of Health, Administrative Number No. 2021-509 (July 22, 2021). This affidavit must state the name of the religion or sect and must be signed by the student, or his/her parents, and by the minister of the religion or sect. *Id.* On the other hand, Article 5 also exempts from compulsory vaccination the students that present a certification signed by a doctor authorized to practice the profession in Puerto Rico to the effect that one or more of the vaccines required by the Secretary of the Health Department could be prejudicial to the health of the student. This certificate must indicate the specific reason and possible duration of the contraindicated conditions or circumstances of the immunization. *Id.* However, one must bear in mind that this same Article establishes that "[t]he exemptions for religious reasons will be null in any epidemic declared by the Secretary of Health" and that "[t]he students or preschool children exempt of the provisions of this law may be vaccinated during an emergency, as determined by an authorized representative of the Department of Health." *Id.*[16] Also see, *Lozada Tirado v. Testigos Jehova,* 177 DPR 893, 918 (2010).

In this case, the plaintiffs allege that AO 2021-509 is contrary to Act No. 25, inasmuch as Article 10 of this Law provides that "[t]he Secretary of Health will be compelled to publish annually, three months prior to the beginning of each school course the illnesses against which the students must be vaccinated […] The required immunizations and the way and frequency of administering them must be in accordance

[16] Note, however, that Administrative Order AO-2021-509 of the Department of Health challenged by the plaintiffs in this case does not require the vaccination of exempt students, even when it was promulgated to address the emergency caused by the COVID-19 pandemic.

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with the medical practices recognized in the Commonwealth of Puerto Rico." 24 LPRA sec. 182i. While it is true that the requirement of vaccination against COVID-19 was imposed in a term shorter than three months, it is evident that the particular provision is not contemplated for a pandemic scenario. This in contrast to Article 5, which even authorizes statutorily the Secretary of the Health Department to order-in times of pandemic-the immunization of exempt students.

Also, no provision of Act 25 prevents the Secretary of the Health Department to establish a vaccination mandate upon a pandemic by virtue of the duties granted to him by the other special laws stated above. A restrictive interpretation of these faculties would significantly injure the power of reason of the State to manage expeditiously and effectively the matters of public health, particularly upon an emergency caused by a pandemic.

In the context of a broad delegation of authority to the Executive Power to manage a state of emergency that puts at risk public health and wellbeing, it is pertinent to highlight that the Supreme Court has affirmed that "**nothing prevents the Legislature to establish general norms that are broad and that leave the administrator an adequate margin of freedom to complement the legislative norms by the use of a specialized judgment, that can be developed in accordance with an analysis, appreciation and administrative discretion that has a reasonableness basis**." *Dominguez Castro v. ELA*, 178 DPR 1, 94 (2010) (emphasis provided).

In short, the first executive and the administrative agencies under his supervision are the governmental entities in charge of processing the governmental response upon de uncertain, dynamic, and constantly changing scenario created by the COVID-19 pandemic, which caused a state of emergency to be decreed by virtue of the applicable legislation. The above-mentioned statutory provisions constitute a clear sample of the faculties of the Governor and the Secretary of the Health Department, as delegated by the Legislative Assembly, to issue those orders directed towards addressing and mitigating the current state of emergency.

Against this background, the Court concludes that EO 2021-054 issued by the Governor of Puerto Rico and AO 2021-508, AO 2021-508A and AO 2021-5 issued by the Secretary of the Health Department constitute a valid exercise of the authority delegated to those civil servants pursuant to the constitution of the Commonwealth of Puerto Rico; the Originating Act of the Department of Health, Act No. 81 of March 14, 1912; Act No. 157 of May 10, 1938; Act No. 25 of September 25, 1983 and the Puerto Rico Public Safety Department Act, Act No. 20 of April 10, 2017.

B. Preemption and the scope of the pertinent federal laws

Secondly, we examine the argument reiterated in multiple occasions by the plaintiffs that the administrative orders in controversy that require or promote the vaccination against COVID-19 are invalid by virtue of the supremacy of the federal Constitution and the preemption doctrine. Per their argument, these orders "are in conflict with the federal law FD&CA, supreme law of the Nation as to the products, and therefore the Orders must be declared as unconstitutional […]". *Docket Entry no. 1,* pg. 5. It is their belief that federal law prevents a state or territory from requiring the use of "those vaccine products" which authorization was only granted as emergency ("Emergency Use Authorization" or "EUA") and in an "experimental" way, because the Federal Drug Administration still has not given them an approval and market license, distribution and "F.D.A. Approved" seal to the three vaccines in the market.

In particular, plaintiffs allege that Section 564 of the FDCA, 21 U.S.C. sec. 360bbb-3(e)(1)(A)(ii)(I-III), establishes that this type of vaccines which use has been restrictively authorized by a EUA can only be provided if the person provides an informed and voluntary consent. In view of this, the plaintiffs understand that the administrative orders issued by the Department of Health to mandate or require the COVID-19 vaccine in any context surpass and conflict with the limitations established by that federal law. However, after carefully evaluating that argument and the referenced provision of the FDCA, **we conclude-like all the courts that have addressed this specific controversy to date have done and like the federal government itself-that these arguments are not appropriate in law.**

Undoubtedly, when there is a conflict between a federal law and a state law or regulation, the latter is preempted by virtue of the Supremacy Clause of the Constitution of the United States. Const. US art. VI, sec. 2. This displacement may occur because there is a direct and express conflict between both legislations or when the intention of Congress to preempt about a certain matter is clear and evident. See *Mun. de Penuelas v. Ecosystems, Inc.*, 197 DPR 5, 16 (2016). [17] All in all, this federalism doctrine requires the

[17] As the Puerto Rico Supreme Court has explained, the preemption doctrine has the purpose

> of avoiding regulatory conflicts between two governments, promoting a uniform policy. Therefore, it is understood there is exclusive jurisdiction of the federal Government over the matters of federal law in those instances in which the Congress has expressly provided it or when the clear intention of the law is to deprive the state courts from jurisdiction in a federal matter. As it can be concluded, determining what has been the intention of Congress when legislating will be fundamental.
>
> Also, it is understood there is preemption in those circumstances in that "certain federal interest or purpose is so dominant there should be no state regulation or when the state norm could produce a result that is incompatible with the federal objectives in certain area". Pursuant to this doctrine, any state law that contravenes a federal law is null. *Mun. de Penuelas v. Ecosystems, Inc*., 197 DPR 5, 16 (2016) (citations omitted).

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establishment with clarity of the intention of the Congress to preempt. As the federal Supreme Court explained in a case that also involved the FDA and the scope of the FDCA "[w]e start with the assumption that the historic police power of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress". *Wyeth v. Levine*, 555 US 555, (2009).

In the part pertinent to this case, Section 564 of the Federal Drugs and Cosmetics Act (or "FDCA") provides the following about the conditions that the FDA must require for a product which use was authorized by emergency (through an EUA):

> With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:
>
> (i) Appropriate conditions designed to ensure that health care professionals administering the product are informed-
> (I) That the Secretary has authorized the emergency use of the product;
> (II) Of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and
> (III) Of the alternatives to the product that are available, and of their benefits and risks.
>
> **(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed-**
> **(I) That the Secretary has authorized the emergency use of the product;**
> **(II) Of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and**
> **(III) Of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.**
> 21 U.S.C. sec. 360bbb-3(e)(1)(A) (Emphasis provided).

As you can appreciate, the cited federal law requires the health providers that administer a product authorized via an EUA *to inform* the person certain matters, including the benefits and risks of the product, whether known or unknown up to the moment. Also, they are *required to inform* the patient that they have the option to accept or reject the administration of the product and the consequences, if any, of refusing its administration, as the available alternatives and risks and benefits.

Now, the **text of this federal provision does not show-either expressly or implicitly-that the Congress had decided to preempt or forbidden the states and territories to establish their own**

requirements as to the administration of a product which use was authorized by emergency through an EUA (like it occurred with the three vaccines against COVID-19 authorized in the United States since December 2020). If the Congress had had the intention of forbidding other entities-like the government of Puerto Rico and its Department of Health-from imposing as a requirement the use of a vaccine authorized by emergency, it only had to textually provide that no entity could require the use of a EUA product. It would be that simple. However, Section 564 of the FDCA or any other federal law or regulation does not say that the Congress has placed that limitation to other entities, including the Puerto Rico Department of Health. By virtue of the norms applicable to the preemption doctrines, it is not possible to interpret its scope otherwise.

After all, the Puerto Rico Supreme Court recently provided that in the interpretation norms in our jurisdiction the courts shall not supply omissions when interpreting the laws and that "[w]hen the language of the law is simple and absolute we must not brush it off and attempt to provide something that the legislator did not attempt to approve. […] This because the judge is an interpreter, and not a creator". *Universidad de Puerto Rico v. Union Bonafide de Seguridad de la Universidad de Puerto Rico*, 2021 TSPR 11, res February 2, 2021, pgs. 13-16 ('[i]t simply is incompatible with a democratic government to determine the meaning of a law based on what we think the legislator meant to say, instead of on what the legislator in fact promulgated." *Id*, citing A. Scalia, *The Essential Scalia: On the Constitution, the Courts, and the Rule of Law* (J.S. Sutton and E. Whelan, Eds.), New York, Crown Forum, 2020, pg. 26). Also see, Art. 19 of the Civil Code of 2020, Act No. 55-2020.

Again, when evaluating the text of Section 564 of the FDCA it is evident that the only thing that the Congress did through this provision was to require to provide certain information about the people about the product EUA at the time of administering it, including information about the possible consequences that the persons that accept or reject the product would have. For persuasive purposes, **the federal Justice Department and the FDA itself reached this same conclusion about the strictly informative nature of this provision:**

> This reading of the "option to accept or refuse" condition to be informational follows not only from the plain text of the provision, but also from the surrounding requirements in section 564(e)(1)(A)(ii) […] Indeed, if Congress had intended to restrict entities from imposing EUA vaccination requirements, it chose a strangely oblique way to do so, embedding the restriction in a provision that on its face requires only that individuals be provided with certain information (and grouping that requirement with other conditions that are likewise informational in nature)". See *Memorandum Opinion for the Deputy Counsel to the President*, 45 Op. O.L.C. __ (July 6, 2021), pg. 9.

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In fact and even when the federal government and the FDA-by authorizing these vaccines against COVID-19-also imposed as a condition to inform the person about the option to accept or refuse these products, **not even the FDA itself interprets this informative condition as an impediment for public or private entities by their own initiative to require these vaccines as a condition for the people to attend in-person to the schools, universities or other events; receive certain services; or even as an employment condition.** *Id.,* pg. 13.[18]

By virtue of the administrative orders challenged in this case, the Department of Health requires that all students older than 12 years old and the teaching and non-teaching personnel in public and private educational entities-except those that qualify for reasonable accommodation for medical due to duly documented medical or religious reasons receive one of the three vaccines authorized by the FDA by the process of EUA. However, one must bear in mind that every person continues having the *option* to reject the vaccine, because there is not a direct legal requirement to receive it under penalty of some criminal

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[18] In a motion to take judicial knowledge, certain plaintiffs reference a document of the FDA titled "Emergency Use of Medical Products and Related Authorities". *Docket Entry no. 32*. This document informs the following:

> FDA believes that the terms and conditions of an EUA issued under section 564 preempt state or local law, both legislative requirements and common-law duties, **that impose different or additional requirements on the medical product** for which the EUA was issued in the context of the emergency declared under section 564 […] To the extent state or local law may impose requirements different from or in addition to those imposed by the EUA **for a particular medical product within the scope of the declared emergency or threat of emergency (e.g. requirements on prescribing, dispensing, administering, or labeling of the medical product),** such law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," and conflicts with the exercise of Federal authority under [§564]." …Affected state laws may include, but are not limited to, laws governing the administration of investigational medical products, such as informed consent laws and laws requiring Institutional Review Board approval, and laws governing the prescribing or dispensing of medical products, such as laws limiting who may prescribe or dispense medical products and under what circumstances. **(**Emphasis provided).

However, we are of the criterion that said document does not have the scope proposed by the plaintiffs, because it refers rather to the requirements related with the regulation and issuance of the medical product itself, like those of prescribing, dispensing, and placing the label to the product. In that sense, it does not refer to a limitation as to the requirements that other entities could impose as an employment condition or to receive certain services, like education. In fact, in the Memorandum of the federal Justice Department about this matter that is after the referenced document, it is **formally informed that the FDA agrees with its legal interpretation about the scope of Section 564 of the FDCA as to the strictly informative character of the provision in controversy**. Also, it is specifically stated that the FDA concludes the following: **"FDA further informs us that, wholly apart from FDA's own authority to change the Fact Sheet, nothing in the FDCA would prohibit an administrator of the vaccine who also has a relationship with the individuals to whom the vaccine is offered (e.g. students in a university that offers the vaccine) from supplementing the FDA Fact Sheet at the point of administration with factually accurate information about the possible nonmedical consequences of the person choosing not to use the product (e.g. that she might not be permit-ted to enroll)".** See the *Memorandum Opinion for the Deputy Counsel to the President*, 45 Op. O.L.C. __ (July 6, 2021), pg. 13. (emphasis provided).

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consequence, or much less be arrested by the State and be given that product under coercion and involuntarily.

Instead, the *consequences* of not getting the vaccine in accordance with what is established in the administrative orders of the Department of Health are of secondary nature, since they only imply that the student older than 12 years old "may not be admitted in-person in a school", subject to certain exceptions for reasons of health or religious objections. See AO No. 2021-509, pg. 4. Also, it does not prevent the student from attending classes remotely or requesting another alternative available. The Federal Court of the District of North Indiana recently reached this same conclusion, in which it validated a compulsory COVID-19 vaccination for university students and even concluded that the requirement of informed consent of EUA products under the FDCA only applies to medical providers. *Klaassen v. The Trustees of Indiana University*, No. 1:21-CV-238 DRL, (N.D. Ind. July 18, 2021), pgs. 53-54.[19]

In the case of the teaching and non-teaching personnel that opts to reject vaccination and does not qualify for any of the exceptions recognized in the administrative order of the Department of Health, the consequences would be of labor in nature (as the expiration of a leave or that measure that the employer may take in accordance with the applicable law). The District Court of the South of Texas reached this same conclusion when validating a requirement of COVID-19 vaccination as to employees of a private hospital. See, for illustrative purposes, *Bridges v. Houston Methodist Hosp*., No. 4:21-cv-01774, 2021 (S.D. Tex. June 12, 2021), pg. 2 (which emphasized that the requirement of compulsory vaccination against COVID-19 as an employment condition was not considered coercive, since the employee "can freely choose to accept or refuse a COVID-19 vaccine; however, if she refuses, she will simply need to work someplace else").[20]

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[19] For persuasive purposes, that federal court also stated the following:
The university isn't directly administering the vaccine to its students; instead, it is requiring students to obtain the vaccine from a medical provider and to attest that they have been vaccinated, save for certain exemptions. The students will be informed of the risks and benefits of the vaccine and of the option to accept or refuse the vaccine by their medical providers. See id. The university isn't forcing the students to undergo injections. The situation here is a far cry from past blunders in medical ethics like the Tuskegee Study. The university is presenting the students with a difficult choice-get the vaccine or else apply for an exemption or deferral, transfer to a different school, or forego school for the semester or altogether. But this hard choice doesn't amount to coercion. The students taking the vaccine are choosing it among other options, and before the shot reaches their arms, they are made aware of the risks and the option to refuse. Id.

[20] The plaintiffs argue that another federal case is more relevant to this controversy, namely, *Doe v. Rumsfeld,* 341 F. Supp. 2d 1 (D.D.C. 2004), in which a federal district court granted an injunction to cancel the mandate of a vaccine that still was in an investigative stage against anthrax applicable to the members of the armed forces of United States. *Docket Entry no. 49*, pgs. 18-19. However, in this case the Court did not interpret or apply in any way section 564 of the FDCA about informative requirements imposed to the medical providers we discuss here. Rather, that decision was based in another federal law (totally inapplicable to the EUA and the facts of this case) that forbids experimenting as to the members of the armed forces. See 10 U.S.C. sec. 1107) Also, and different to what this Court concluded after

With this background, **we conclude that Section 564(e)(1)(A)(ii)(III) of the FDCA is limited to providing about matters related to the information that must be provided to potential recipients of the vaccines and does not prohibit in any way other public or private entities -such as the Puerto Rico Department of Health-from imposing the compulsory vaccination requirement to receive certain services or as an employment condition, even when these vaccines have been authorized as emergency by an EUA**. According to its own text and the interpretation by the FDA as a federal agency tasked with its implementation, this legal provision only requires informing the persons of certain matters, including the option to accept or reject the administration of the product and its possible consequences. We reiterate that "[i]t is the meaning of the text and not the content of anyone's expectations or intentions, what is binding as law. In sum, when the law is clear, the courts shall not evaluate its wisdom […] Not recognizing this, places us in the illegitimate position to legislate through the courts. That is a task that the Constitution reserves for the civil servants chosen by the People" and not to the courts. *Universidad de Puerto Rico v. Union Bonafide de Seguridad de la Universidad de Puerto Rico, supra*, citing Laurence H. Tribe, "*Comment",* in Antonin Scalia, *A Matter of Interpretation: Federal Courts and the Law* 65 (1997).

C. *Substantive Due Process, equal protection of the laws and individual rights upon a claim against a vaccination mandate*.

Compulsory vaccination is not a new matter in our society or in the democratic constitutional system that reigns in Puerto Rico and United States. For more than a century, the states and territories have used their powers and faculties to approve measures directed towards safeguarding public health within the applicable constitutional parameters, including requiring the vaccination of persons and minors in certain contexts, as the classroom would be. See *Barnes v. Glen Theatre*, 501 U.S. 560, 569 (1991); *Zucht v. King*, 260 U.S. 174, 176-77 (1922); *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 24-25 (1905). Also see, Nat'l Conf. of State Legislatures, *States with Religious and Philosophical Exemptions from School Immunization Requirements* (April 30, 2021), https://www.ncsl.org/research/health/school-immunization-exemption-laws.aspx, cited in *Klaassen v. The Trustees of Indiana University*, pg. 40. Just like the then Associate Judge Scalia of the United States Supreme Court stated, "**the elimination of communicable diseases through vaccination [is] one of the greatest achievements of public health in the 20th century**," *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 226 (2011) (emphasis provided).

The normative case about this matter is *Jacobson v. Commonwealth of Massachusetts, supra* in which the federal Supreme Court validated a state law that would allow the local governments to require the vaccination of their residents if it was found that was necessary for public health or safety. The only

examining the evidence as to the COVID-19 vaccines authorized through EUA, in that case the Court concluded that that vaccine against anthrax was in a preliminary investigative stage.

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exception recognized by the statute was for minors that had a health condition that would prevent them from getting vaccinated and for that to be certified by a doctor. In view of the propagation of smallpox at the beginning of the twentieth century, the city of Cambridge required its citizens to be vaccinated against that illness. However, Mr. Henning Jacobson rejected the vaccine and a jury sentenced him to jail until he paid the fine of $5.00 imposed on him. Mr. Jacobson appealed and argued that the legal mandate that required his vaccination was contrary to his rights under the Fourteenth Amendment of the Constitution of the United States.

However, the Supreme Court rejected that argument and concluded that the power of reason of the state "must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety." *Id,* pg. 25. This faculty undoubtedly included the authority of the state to promulgate quarantine laws and to safeguard public health. According to the highest federal court, the Constitution recognized broad deference to the states, so the courts only should intervene if the governmental measure that sought to protect public health and safety had no real or substantial relation to its objectives, or if it was concluded that it constituted a clear and palpable invasion of fundamental rights. *Id*, pg. 31. In other words, for a challenge of a measure directed towards procuring public health in a pandemic to be successful, it would have to be concluded that it is so arbitrary and oppressive to justify the intervention of the courts to prevent that violation. *Id.*, pg. 38.

The plaintiffs in this case argue that the scope of the *Johnson* case is limited to its times and that it has become obsolete because it was decided in 1905, before the creation of the FDA and the promulgation of the FDCA. However, the fact is that the United States Supreme Court and other federal courts have reiterated what was decided in *Jacobson* on multiple occasions. For example, and in pertinent part to this case, in *Zucht v. King, supra,* the Court validated a municipal ordinance that excluded minors that did not have the vaccine certificate from the public schools. In other words, in this case compulsory vaccination was validated in the context of school using *Jacobson* as basis and the power of reason of the state to promulgate reasonable measures directed towards safeguarding public health. Also see, in another context, *Hamilton v. Regents of the University of California*, 293 U.S. 245, 264 (1934). Analogously as to the power of reason of State in Puerto Rico, the Supreme Court has explained that the State has "ample powers to approve reasonable measures with the purpose of safeguarding the fundamental interests of the people and promoting the common good". *Warner Lambert Co. v. Tribunal Superior*, 101 DPR 378, 394 (1973). However, that "power of regulation, as broad as it is, is not limited", because "[i]ts exercise can never be arbitrary or unreasonable". *Id.*

Now, we recognize that *Jacobson* was decided prior to our courts defining more certainly the tests applicable to the contemporaneous constitutional litigation both in Puerto Rico and in the United States. In

view of this, and when deeming as true the well-plead allegations in the complaint, we must determine if we must apply a strict test or rational test or traditional minimum test to the controversy like the one in this case. Even so, we keep in mind that *Jacobson* would appear to endorse a rational test to review the governmental decisions in the context of a health crisis, like a pandemic. See *Roman Catholic Diocese of Brooklyn v. Cuomo,* 141 S. Ct. 63, 70 (2020) (Concurrent Op., J. Gorsuch).

Analogously the Fourteenth Amendment of the federal Constitution, the Constitution of the Commonwealth of Puerto Rico establishes that "[n]o person will be deprived of their liberty or property without due process of law, nor any person in Puerto Rico will be denied the equal protection of the laws" and that "[n]o laws that diminish contractual obligations shall be approved". CONST. PR art. II §7, LPRA Tome 1. As to the scope of these constitutional provisions, the Puerto Rico Supreme Court repeatedly has held that "[w]hen one law regulates a right or a liberty that affects citizens in general equally, it submits it to the **substantive due process of law test**; when the law establishes classifications that regulate the exercise of a certain right or liberty differently to different groups or persons, then the test applicable is the one **of equal protection of the laws".** *Dominguez Castro v. ELA*, 178 DPR 1, 41 (2010). Under this analysis, when a **socioeconomic measure or legislation** is challenged, the courts must examine the validity of such statutes **through a rationality or rational test.** In this sense, "the due process of law guarantee demands that a statute of socioeconomic nature not be unreasonable, arbitrary, capricious and that the means chosen has a rational relationship with the interest sought*". Id.,* 44-45; cf *Marina Ind., Inc. v. Brown Boveri Corp*., 114 DPR 64, 80 (1983).

At the same time, in the cases which controversy is related to the equal protection of the laws, "the rational test is employed in cases where the *economic and social regulation* is challenged". *Domingez Castro v. ELA, supra*, pgs. 71-72. In these cases, the constitutionality of the classification is presumed and the court must give deference to the challenged governmental action. *Id*. Even "[a]lthough the classification does not appear to be the most correct, adequate, wise and efficient way of advancing the legislative purpose, the court must maintain its constitutionality once it is shown there is a rational relationship between it and the purpose set forth". *Id,* pg. 72. In fact, in pertinent part to this case, the Supreme Court has affirmed that the "prevailing doctrine in Puerto Rico about equal protection of laws recognizes to the State a broad breadth in reference to the establishment of relative classifications to social and economic matters", reason for which the applicable test in these cases is the traditional minimum or rational. *López v. ELA*, 165 DPR 280, 298 (2005); *Domínguez Castro v. ELA, supra*, pgs. 72-73.

In that sense, it must be emphasized that "[t]he analysis and criteria under the due process clause and the equal protection of laws are similar **except when fundamental rights are affected or there are suspicious classifications**". *Marina Ind., Inc. v. Brown Boveri Corp., supra,* pg. 81. If fundamental rights

are affected or there are suspicious classifications, the courts would have to apply a **strict test**. In those cases, the unconstitutionality of the challenged measure is presumed and the State has the burden of proof to show that it has a compelling state interest and that is necessary to promote that interest. In other words, it must be shown that "there is no less onerous mean to advance that interest". *Domínguez Castro v. ELA, supra,* pgs. 73-74; *Soto v. Adm. Inst. Juveniles*, 148 DPR 810, 831 (1999); *Calo Morales v. Cartagena Calo*, 129 DPR 102, 133 (1991).

As to the claims against legal schemes of compulsory vaccination, **the courts in the United States have consistently rejected there is a fundamental right *per se* to reject vaccines in social and economic contexts (like education and employment), which is why they have applied a rationality test**.[21] This even in cases where other fundamental rights are invoked such as freedom of worship and parental rights. In fact, recently when denying an injunction in appeal upon a similar controversy in the university context, the Federal Seventh Circuit, through Judge Easterbrook and based mostly in *Jacobson,* stated that that right did not exist in the North American constitutional system. *Klaassen v. The Trustees of Indiana University*, No. 21-2326 (7th Cir. Fed. August 2, 2021). Also it is not appropriate to talk about suspicious classifications in the distinctions that the government could do between vaccinated and unvaccinated persons. In fact, in *Prince v. Massachusetts*, 321 U.S. 158, 166-67 (1944), the federal Supreme Court decided that freedom of worship and right to raise children does not include the liberty to expose the community or the child to communicable disease ("parents…cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds" and "[t]he right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death").

In the context of Puerto Rico our Supreme Court has not had the opportunity so far of deciding a controversy of this nature. However, it has recognized

> the right of every patient to make decisions regarding medical intervention they will be subjected to. **That includes their right to consent or refuse medical treatment, after their doctor has provided the necessary information to make a decision of this nature. This doctrine, known as the informed consent doctrine, is based in the fundamental right that establishes the inviolability of the human body as an inalienable right of people.**
>
> Also, the informed consent doctrine imposes on the health professional the duty of informing their patient all that is related to the nature and the risks of a medical treatment, so that they can make an intelligent and informed decision. In fact, based on the intimacy right and in accordance with the referenced informed consent doctrine, we have decided that a medical

[21] See the multiple cases cited in *Klaassen v. The Trustees of Indiana University, supra*, pgs. 51-52.

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> intervention performed without having the prior consent of the patient is a tortious and illegal act. *Lozada Tirado v. Testigos Jehova*, 177 DPR 893, 911 (2010) (citations omitted) (emphasis provided).

So, while in the United States it has only been "presumed" or "inferred" from the North American common law the existence of a right to reject medical treatment, **in Puerto Rico "that right is recognized, not only as part of the doctrine of informed consent, but as part of the right to intimacy expressly guaranteed in our Constitution as a fundamental right".** *Lozada Tirado, supra*, pg. 930 (emphasis provided); cf. *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997); *Cruzan v. Director, Missouri Dept. of Health,* 497 U.S. 261, 278 (1990). After all, the Constitution of the Commonwealth of Puerto Rico is more bcomprehensive ("de factura más ancha"), and different from the federal Constitution, its Bill of Rights expressly protects the right to intimacy, the dignity of the human being and the private or family life. Art. II, Secs. 1 and 8, Constitution of the Commonwealth, LPRA Tome 1.

Now, in *Lozada Tirado* the Supreme Court emphasized that "as every constitutional right, the right to reject medical treatment is not absolute. In that sense, in *Cruzan v. Director, Missouri Dept. of Health, supra*, the Federal Supreme Court provided that, when faced with the rejection of a patient to certain medical treatment, the courts must balance that right and certain interests of the State. In particular, in the referenced precedent, it was recognized, based on what was decided by the state case law, that the Court can have interest in the preservation of life, the prevention of suicide, the protection of innocent third parties and in keeping the integrity of the medical profession". *Lozada Tirado v. Testigos Jehova, supra*, pgs. 915-16. As **to the interest of the State in protecting innocent third parties**, it has two aspects: the interest of the State in protecting minors under its power of *parens patriae* and the interest "**in the citizens to submit to certain medical treatment during a public health crisis"**. *Id.,* pg. 918 (Emphasis provided). In fact, in this case the highest court emphasized that

> [t]he courts have stated that the interest of the State in protecting innocent third parties can be invoked in cases of emergency of public health. **It has been recognized that the State can approve laws that require certain vaccines compulsorily upon the threat of an epidemic**. *See: Fosmire v. Nicoleau,* 551 N.Y.S. 2d 876, 880 (Ct. App. 1990); *Jacobson v. Massachusetts* 197 U.S. 11 (1905); J.A. Cohan, *Judicial Enforcement of Lifesaving Treatment for Unwilling Patients,* 39 (No. 4) Creighton L. Rev. 849, 895 (2006). In Puerto Rico, for example, **Act No. 25 of September 25, 1983 regulates what concerns immunization of students and children of preschool age and allows to exempt from this requirement those children that show that themselves or their parents belong to a religion that does not allow the immunization. 24 LPRA sec. 182d. However, that exemption will be cancelled in case of an epidemic declared by the Department of Health**. *Id.,* note 13 (emphasis provided).

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In view of the applicable norm, we proceed to decide.

IV.

In this case, we conclude that-in view of the greater scope of the Constitution of the Commonwealth of Puerto Rico and the case law previously outlined-**we should apply the strict test** when evaluating the constitutionality of Administrative Order AO 2021-509 of the Department of Health.[22] This Administrative Order requires COVID-19 vaccination for all students in Puerto Rico older than 12 years old as a previous condition for them to receive the education (which also constitutes a constitutional right),[23] even when those students or their parents reject this medical treatment. Also, it also requires COVID-19 vaccination for those teaching and non-teaching employees of all educational institutions as an employment condition, even when they want to exercise their right to reject vaccination.

Faced with this reality, the Commonwealth of Puerto Rico has the burden to show the constitutionality of the referenced administrative order, which requires the identification of a compelling interest, to show that these orders are necessary and, also, that there is no less onerous means to promote this governmental interest. *Dominguez Castro v. ELA, supra*, pgs. 73074. To meet this judicial crucible, the defendants first invoke the arguments stated in the executive and administrative orders in controversy themselves.[24] In this context, we emphasize that the objective expressly articulated in these orders to mitigate the effect of a public health crisis caused by the COVID-19 pandemic and protect innocent third parties through measures like the ones challenged in this case undoubtedly constitute a compelling governmental interest that both the Executive Order and the administrative orders in controversy certify satisfactorily. See *Lozada Tirado v. Testigos Jehova, supra*, pg. 918; *Pueblo v. Santiago Cruz*, 2020 TSPR 99 (res. on September 8, 2020).

But beyond what is textually provided in these orders, the fact-findings of this Court after the presentation of evidence in the injunction hearing show that the **Commonwealth has a compelling interest of: 1) protecting the public health of the People upon the emergency caused by the COVID-19 pandemic, 2) finally reaching herd immunity and 3) effectively guaranteeing the education of the**

[22] See, for persuasive purposes, Sylvianette Luna Anavitate, *Vacunacion de Menores en Puerto Rico: Poder de razón de estado v. El derecho de los padres y las madres sobre sus hijos e hijas*, 54 Rev. Jur. UIPR 355, 381-383 (2020).
[23] See Art. II, sec. 5, Const. ELA, LPRA Tome 1.
[24] As to this appreciation on what is the interest of the State based on the exposition in the governmental orders or measures, it is pertinent to highlight that in *Velez v. Srio. De Justicia*, the Supreme Court used the statement of motives of the statute in controversy there to identify the legitimate interest of the government in that case. *Velez v. Srio. De Justicia*, 115 DPR 533, 538-39 (1984) ("The statement of motives of the referenced Act No. 45 constitutes an excellent summary of the prevailing situation and the "social malady" that our legislator correctly wanted to correct or regulate by approving that legislation."); *cf. Dominguez Castro v. ELA, supra*, pgs. 77-78, n. 139 ("It should be noted that in *Velez v. Srio de Justicia*,…this Court recognized the intrinsic value of the Statement of Motives of a law at the time of determining the interest of the State under the analysis of equal protection of the laws").

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students of the entire educational system of Puerto Rico. In addition, the evidence presented by the parties about scientific matters pertinent to this controversy reflects that the vaccines authorized by the federal government against COVID-19 have been and continue being extremely effective in mitigating the individual and collective impact of this disease. The facts admitted in evidence show that since more people are vaccinated, less people are severely ill and even less people die as a result of this disease, even upon the arrival to our Island of new variants like the Delta variant.

Consequently, we conclude that the mandate established by the State to require vaccination against COVID-19 in our schools and universities-along with other public health measures like the use of masks, washing hands, tests for the non-vaccinated and physical distancing in those scenarios susceptible to grouping of people in closed spaces-constitutes a necessary measure to advance this compelling State interest. Also, we are of the opinion that in these times there are no other more effective or less onerous alternatives to reach those objectives.

Now, we bear in mind the concerns expressed by the plaintiffs about the possible risks that could entail the use of the COVID-19 vaccines, which certainly were authorized as emergency by the federal government barely eight months ago. However, **when evaluating and assessing the scientific evidence presented by the parties to the Court, we coincide with the conclusion of both the CDC and the FDA itself when authorizing the emergency use of these vaccines-after performing a rigorous scientific and regulatory process- that their use is generally safe and entails much more benefits than potential risks**. Although the witnesses of the plaintiffs stated their opinion that the risks of the vaccine exceeded their potential benefits, all the scientific evidence that was presented at the hearing-including some of the scientific studies presented by the plaintiffs themselves-indicate precisely the opposite. **Also, the evidence and the applicable federal law show that the experimental phases of these three vaccines were already successfully completed, therefore it is a factual and legal error to characterize these vaccines as experimental"**.[25]

On the other hand, we must emphasize that **the plaintiffs have not certified that they have suffered or will suffer imminently a particular and irreparable damage because of the administrative orders challenged**. Also, notice that their intention of not vaccinating does not exceed or destroy the

[25] However, we recognize that "medicine is not an exact science and absolute certainty is rarely possible". *Saez v. Mun. de Ponce,* 84 DPR 535, 544 (1962). Also, it is known that the methods and procedures of science are developed and evolve over time based on human knowledge. In that sense, the evidence shows that upon new challenges like the Delta variant, the scientists continue evaluating, investigating, and even always re-examining the strategies to effectively mitigate the impact of the pandemic, whether as to how to optimize the effectiveness of these vaccines in the real world or other health measures such as the use of masks.

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compelling interest that the State clearly showed to justify the vaccination requirement in schools and universities upon the COVID-19 pandemic. Also, in the challenged orders exceptions or reasonable accommodations were established for those students or employees that cannot get vaccinated for some medical reason or some religious objection duly documented.[26] In any case, the challenged orders are not coercive, because they do not rule out the possibility that the students that reject the vaccine receive educational services at a distance, or that the teaching and non-teaching employees that refuse to vaccinate take a leave or another alternative provided by their workplace, which would be adequate remedies in law.[27]

All in all, the requirement of COVID-19 vaccination for students and employees of the educational institutions is a necessary measure to achieve the compelling interest of guaranteeing the education and public health, mitigating the harmful effects of the pandemic, and finally reaching herd-immunity in the Country. Although the power of the government is not unrestricted not even in a state of emergency like the one we currently face, we reiterate that the vaccination mandate in these moments is an even less onerous mean to reach these governmental objectives in comparison with other possible alternatives. For example, as it would be to require that all the students return to totally remote education or to put in place again other restriction of social isolation, such as curfews or social and economic lockdowns. As a result, when considering in the scales the alleged damages, the interests involved of all the parties and the collective good of our society, it is appropriate to deny the remedies requested by the plaintiffs.

V.

Wherefore, this Court enters this **Judgment Denying** the injunction requested by the plaintiffs pursuant to what is provided in Rule 57 of Civil Procedure, *supra.* Also, in accordance with what is provided in Rules 10.2 and 42.2 of Civil Procedure, *supra*, the motion to dismiss filed by the defendants is evaluated and Granted. This because the plaintiffs have not been able to certify that they have suffered an irreparable

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[26] We emphasize that the allegations of the complaint do not show that some plaintiff has been denied any reasonable accommodation due to religious beliefs. In view of this, standing has not been certified as to the controversy invoked by the plaintiffs about the particular reasonability and in its application of the exceptions in the orders or if these establish an onerous burden as to the practice of some specific religion. However, we reiterate that the Puerto Rico Supreme Court recognized in *Lozada Tirado* that "Act No. 25 of September 25, 1983 regulates that concerning the immunization of students and preschool children and allows children that show that themselves or their parents belong to a religion that does not allow immunization to be exempt from that requirement. 24 LPRA sec. 182d". Also, the vaccine requirement in controversy clearly is a neutral norm of general application to all the students and employees, whether religious or not. See *Employment Division v. Smith*, 494 U.S. 872, 879 (1992). Faced with similar scenarios, other courts have decided that an exception of this type equals a permissible, but not required, concession, for the freedom of worship that emanates from the First Amendment of the Federal Constitution. *Klaassen v. The Trustees of Indiana University, supra.*

[27] See Rule 57 of Civil Procedure, *supra*.

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damage or that the damages that they could suffer from the effectiveness of Administrative Order 2021-509 were real, immediate, and precise, therefore the other causes of action included in the complaint are simply not justiciable. In view of those fact-findings and conclusions of law, this Court lacks jurisdiction to continue overseeing this case. Consequently**, the dismissal and closing of this captioned case is ordered.**

REGISTER AND NOTIFY.

In San Juan, Puerto Rico, on August 6, 2021.

s/ALFONSO S. MARTÍNEZ-PIOVANETTI
SUPERIOR JUDGE

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