

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

TROPICAL CHILL CORP. *et al.*

Plaintiffs,

v.

HON. PEDRO R. PIERLUISI URRUTIA *et*

al.

Defendants.

Civil No. 21-1411 (RAM)

Jury Trial Demanded

MOTION TO DISMISS

TO THE DISTRICT COURT:

COME NOW, Hon. Pedro R. Pierluisi-Urrutia, in his official capacity as Governor of Puerto Rico, and **Dr. Carlos R. Mellado-López**, in his official capacity as Secretary of the Department of Health, without waiving any right or defense arising from Title III of Puerto Rico Oversight, Management, and Economic Stability Act (“PROMESA”), 48 U.S.C. 20 *et seq.*, and the Commonwealth of Puerto Rico’s (“Commonwealth”) Petition under said Title or under this case, represented by the undersigned counsel, and respectfully **STATES** and **PRAYS** as follows:

I. INTRODUCTION

On August 27, 2021, Tropical Chill Corp., Ms. Alexandra Irizarry, Ms. Yasmin Vega, and Mr. René Matos (altogether, “Plaintiffs”), a Puerto Rico corporation which operates ice cream stores in three municipalities, a pharmacy worker, a supermarket stock clerk and the owner and operator of a short-term lodging business, respectively, filed the instant case and requested a declaratory and injunctive relief against Hon. Pedro R. Pierluisi-Urrutia, in his official capacity as Governor of Puerto Rico (“Governor”), and Dr. Carlos R. Mellado-López, in his official capacity as Secretary of the Department of Health (“Secretary” or “Secretary of Health”) (altogether, “Defendants”). Plaintiffs are challenging the

constitutionality of Executive Orders Nos. 2021-062 through 2021-064 (altogether “Executive Orders”) and Secretary of Health’s Regulation No. 138-A.

The Executive Orders and Regulation No. 138-A were part of the official policy response of the Government of Puerto Rico to the COVID-19 epidemic and were meant to attack or curtail the spread of the deadly virus by establishing additional vaccination and verification requirements, mostly directed to the private sector, since “[v]accination should be treated as a primary means for providing protection against severe illness or death, especially for persons at high risk [...]” Docket No. 1 at 2, ¶4. Plaintiffs posit that these additional mandates are “particularly unreasonable” (Docket No. 1 at 3, ¶8), because they view the rates of infection, hospitalization, and mortality as low and not a significant burden to the health care system of the Commonwealth. *See id.* (“...Puerto Rico’s health system was never strained by COVID...”, and the risk of the system being placed in jeopardy by the advent of the Delta variant is “highly unlikely”, Docket No. 1 at 18, ¶89). Simply put, Plaintiffs’ claims are based in their belief that vaccination should be voluntary and grounded on individual risk/benefit assessments, as well as moral considerations. Docket No. 1 at 9, ¶40. However, Plaintiffs are not the elected or appointed officers in charge of designing the Commonwealth’s public health policy, that responsibility falls solely within the powers of the Governor and Secretary of Health. *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.’”).

Specifically, Plaintiffs claim that the existing mandates infringe on their right to earn a living and use their property as they see fit, without sufficient justification for such infringement, in violation of their economic liberty and property rights under the Fourteenth Amendment of the United States Constitution. *See* Docket No. 1 at 26, ¶¶124-34, 140. Also, Plaintiffs claim that the existing mandates violate their rights to personal autonomy, bodily integrity, and the right to reject medical treatment. In the case of plaintiffs Tropical Chill Corp. (“Tropical Chill”) and Ms. Yasmin Vega (“Ms. Vega”), they invoke the constitutional right to privacy of their customers and clients, inasmuch as the mandates require proofs of vaccination,

masking, and other unjustified impositions not narrowly tailored as constitutionally required. *See* Docket No. 1 at 33, ¶¶141-43 & 149-51. Plaintiffs cast doubt on the existence of a compelling government interest to justify the Executive Orders and point to the existence of “...less onerous means to obtain the desired result which would lessen the burden on the plaintiff’s individual liberties and property interest” (Docket No. 1 at 35, ¶161). In Count III of the Complaint, Ms. Vega asserts a claim under the Religious Freedom Restoration Act, 42 U.S.C. 2000bb-2(2) (“RFRA”), because allegedly her religious beliefs compel her not to take the COVID vaccine (Docket No. 1 at 35, ¶166) and that the mandate infringes on her “free exercise of religion as an unalienable right” by forcing her to participate and condone forced vaccination even though least restrictive alternatives exist (Docket No. 1 at 35-36, ¶¶163 & 167-70). Finally, Plaintiffs assert pendent claims against the Executive Orders, claiming these lack appropriate legal basis and violate the separation of powers under Puerto Rico’s Constitution (Docket No. 1 at 37, ¶175) and the *Puerto Rico Department of Public Safety Act*, Act No. 20-2017 (Docket No. 1 at 38-39, ¶¶179-86), as well as the rulemaking process established in the *Uniform Administrative Procedure Act of the Government of Puerto Rico* (“UAPA”), Act No. 38-2017 (Docket No. 1 at 39-40, ¶¶187-89).

Finally, Plaintiffs assert pendent claims against the Executive Orders, claiming these lack appropriate legal basis and violate the separation of powers under Puerto Rico’s Constitution (Docket No. 1 at 37, ¶175) and the *Puerto Rico Department of Public Safety Act*, Act No. 20-2017 (Docket No. 1 at 38-39, ¶¶179-86), as well as the rulemaking process established in the *Uniform Administrative Procedure Act of the Government of Puerto Rico* (“UAPA”), Act No. 38-2017 (Docket No. 1 at 39-40, ¶¶187-89).

Defendants will establish that Plaintiffs’ constitutional challenges to the Executive Order and Regulation No. 138-A are a subterfuge to further their own public policy agenda through a federal court and promote constitutional theories which depart from currently prevalent doctrines. The ensuing arguments will demonstrate that the Executive Orders, Regulation No. 138-A and their requirements: (i) do not violate the Fourteenth Amendment’s substantive due process rights, since they meet both 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) do not violate Plaintiffs' freedom to exercise their religious rights under RFRA; and (iii) absent a cognizable federal claim, this Court should abstain from exercising its supplemental jurisdiction as to the claims under the Constitution and the Laws of the Commonwealth of Puerto Rico. Therefore, Defendants request that the instant 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 Orders and Regulation No. 138-A are a constitutional exercise of the Commonwealth's police powers to safeguard the health and lives of Puerto Rico residents and visitors, which complies with any applicable constitutional standard.

II. THE CONTENTS OF THE EXECUTIVE ORDERS AND REGULATION

To put this Court in position to dismiss the instant case, Defendants will summarize for the Court the contents of the Health Department Regulation and the Executive Orders Plaintiffs challenged in this case. **First**, Regulation No. 138-A amends Regulation No. 138, which generally deals with the issuing of health certificates by medical professionals in Puerto Rico, and was issued on August 5, 2021, in an exercise of the Secretary of Health's powers pursuant to the *Organic Law of the Department of Health*, Act No. 81 of March 14, 1912 (3 P.R.L.A. 171 *et seq.*); *Uniform Administrative Procedure Act*, Act 38-2017 (3 PRLA 2101 *et. Seq.*); and *Puerto Rico Health Certification Act*, Act No. 232-2000 (29 P.R.L.A. 411 *et seq.*). The purpose of the amendment is "expressly establishing the requirement to present the vaccination card against COVID-19 of the 'COVID-19 Vaccination Record Card' as an essential document for a doctor to issue a health certificate." Docket No. 1-1 at 2, Art. 2. To comply with the new requirement, medical doctors that issue health certificates must attest that the individual requesting it has shown evidence of vaccination against COVID-19, specifically the Vaccination Record Card issued by the CDC, showing completion of the inoculation. The evidence to be required is the original Vaccination Record Card.

Also, Regulation 138-A provides exemptions to compliance with this requirement. A doctor may issue a health certificate “in those cases where the patient has a compromised immune system or there is a medical contraindication that prevents inoculation.” Docket No. 1-1 at 3, Art. 2. This condition must be certified by a licensed medical doctor in Puerto Rico, or by the doctor issuing the certificate, who must then additionally certify the duration of the medical contraindication and whether it is permanent or temporary. In cases in which it is temporary, the patient must eventually comply with the vaccination requirement. The challenged regulation also provides an exemption on religious grounds, which allows the doctor to issue the certificate being requested by people “not inoculated for religious reasons, as long as the vaccine goes against the dogmas of the patient’s religion.” Docket No. 1-1 at 3, Art. 2. On those instances, “the doctor must certify that he was shown the sworn statement required by the Department of Health for these cases, in accordance with the Executive Orders in force.” (Docket No. 1-1 at 3, Article 2).

Second, Executive Order 2021-062, issued on August 5, 2021, established a general vaccination requirement for Executive Branch contractors in the Government of Puerto Rico, as well as in the health and lodgings industries. Specifically, Executive Order 2021-062 requires that all government contractors and their employees—who work or regularly visit government offices—provide evidence of vaccination by means of showing their CDC Vaccination Record Card and sets specific deadlines to comply with this requirement (Docket 1-1, at 8 Section 1). For **healthcare workers and employees**, Executive Order 2021-062 requires that all workers in health facilities be vaccinated by September 30, 2021, imposing on employers the duty to verify compliance with this requirement by requiring the employee’s Vaccination Record Card. This requisite applies to hospitals, clinical laboratories, emergency rooms, medical service clinics, health centers, medical offices (both primary physicians and specialists), therapy centers, blood banks, drug stores, care facilities for the elderly, and medical cannabis facilities (Docket 1-1 at 8-9, Section

2).¹ For the **lodging industry**, Executive Order 2021-062 requires vaccination for all employees of hotels, hostels (“*paradores*” in Spanish) and lodging facilities in general. Managers of these facilities are required to verify compliance with these requisites by requiring the Vaccination Record Card (Docket 1-1 at 9, Section 3).² Section 4 of the Executive Order 2021-062 extends this requisite to guests of these facilities, as well as guests of short-term rental facilities, whether they operate independently or through a digital platform.

Also, Section 5 of Executive Order 2021-062 established exemptions from compliance with these requirements. The first one is the medical grounds exception, which applies to all individuals otherwise required to comply but whose immune system is compromised to the extent that the vaccine may be harmful to their health. Individuals with any other kind of medical reason to justify not being vaccinated are also exempted. Medical exemptions require a certification by a medical doctor licensed to practice in Puerto Rico, who must then certify the duration of the medical condition which justifies non-compliance with the requisite and whether it is permanent or temporary. In cases in which it is temporary the patient must eventually comply with the vaccination requirement.³

The second exemption contained in the Order is for religious grounds. If getting the vaccine goes against the religious beliefs or dogmas of the contractor, employee or guest, the individual may avail himself of the benefits of this exemption by furnishing a sworn statement by both the individual and the minister or leader of his religious congregation. Both would have to state in the document, under penalty of perjury, that because of their religious beliefs the individual cannot receive the COVID-19 vaccine. If the individual has no minister or congregation leader, the sworn statement will have to make specific reference to his religious convictions and beliefs. All individuals covered by Executive Order 2021-062

¹ The Executive Order 2021-062 clearly indicates that this list is not meant to be exhaustive.

² Franchise operators and licensees within these facilities are recommended to follow these same requirements for their employees.

³ This exception mechanism is like the one established in Regulation No. 138-A.

who invoke the exception described in Section 5 will also have to submit a negative laboratory result of COVID-19 from a qualified viral SARS-CoV2 test issued within the previous seventy-two (72) hours.

Section 6 of the Executive Order 2021-062 deals with the contingency of those individuals who do not present the vaccination certificate and do not invoke, or do not comply with the requisites of any of the exemptions previously referred to. These individuals, to get access to their workplaces or be able to stay in the lodging facilities covered by the Executive Order 2021-062, will need to present a COVID-19 negative result not more than 72 hours old, or a positive result to a COVID-19 test along with documents evidencing recovery from the condition, including a letter from a health care provider or a health government official certifying recovery and readiness to be present at public spaces.

Individuals who do not comply or refuse to comply with any of the requirements or the exemption requisites described above will not be able to be physically present at their workplace, in the case of employees or contractors who render services at government offices. If the services of this contractor or employee cannot be rendered from a distance, supervisors will consider other measures such as cancellation of the contract, or having the employee take a leave of absence. In the case of guests at lodging facilities, they will not be able to stay at them until they fully comply with the applicable requisites previously described.

Section 7 of Executive Order 2021-062 empowers the Department of Health, the Department of Labor and Human Resources, the Tourism Company, the Department of Commerce and Economic Development and the Office of Administration and Human Resources Transformation of the Government of Puerto Rico to enact and issue all necessary guides and regulations to ensure compliance with these requisites. Section 8 provides that failure to comply with the requisites and prohibitions of the Order will carry penalties and criminal sanctions as provided in Article 5.14 of Act No. 20-2017, including but not limited to a reclusion for a term not to exceed six months or penalties not to exceed \$5,000.

Invoking the same statutory grounds and general description in its WHEREAS sections of the justifications for these emergency measures and restrictions, Executive Order 2021-063 makes applicable

to all public locations where food and drink are prepared and sold the same restrictions, requirements and exemption requisites established in Order 2021-062. These apply to employees and guests at restaurants, theaters, cinemas, stadiums, activity centers, rural native food spots (“*chinchorros*” in Spanish), as well as the same consequences for failure to comply. The management of these locations is charged with ensuring compliance with these restrictions for guests and visitors to access their facilities. In the case of guests and visitors, the requirement applies to those above the age of twelve. Those venues who choose not to accept the verification requirements to ensure their guests comply with the vaccination mandate will have to limit the number of guests at their facilities at any given time to 50% of their maximum capacity. *See* Docket No. 1-1 at 10-11, Sections 4 and 5.

Finally, Executive Order 2021-064 establishes the same restrictions, requirements and exemption requisites provided in Orders 2021-062 and 2021-063 to gyms, beauty salons, barber shops, spas, childcare centers, casinos, grocery stores, convenience stores, gas stations, and others. The management of these locations is charged with ensuring compliance with these restrictions for employees, guests, and visitors to access their facilities. In the case of guests and visitors, the requirement applies to those above the age of twelve, and mandatory mask usage is an additional requirement. Those venues who choose not to accept the verification requirements to ensure their guests comply with the vaccination mandate will have to limit the number of guests at their facilities at any given time to 50% of their maximum capacity. Nevertheless, visitors may not access any of these establishments if they refuse to comply with what the Order requires. *See* Docket No. 1-6, at 11-13, Sections 4-6.

III. STANDARD FOR DISMISSAL UNDER RULE 12(b)(6)

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 “constru[e] 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.

IV. MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS

On the legal grounds to be set forth in this motion, Defendants respectfully request that Plaintiffs' causes of action be dismissed, under Rule 12(b)(6) of the Federal Rules of Civil Procedure, for failing to state a claim for which relief may be granted by this Court. Specifically, (a) Plaintiffs failed to state a claim for violations of their substantive due process rights under the Fourteenth Amendment of the United States Constitution, since no fundamental rights and liberties are infringed by the challenged executive orders; (b) even if taking as true that the mandates of the Executive Orders infringe on Plaintiffs' fundamental rights and liberties, which it does not, a compelling state interest fully justifies these restrictions because they are narrowly tailored to achieve and promote their public policy objectives; (c) plaintiff Vega fails to state a claim under RFRA, since the mandates and restrictions of the challenged executive orders are neutral requirements which do not infringe on her fundamental rights to freedom of worship; and (d) under the applicable legal standards, Plaintiffs' pendent claims should be dismissed absent a cognizable federal claim and for failure to state a claim on the merits.⁴

In summary, Plaintiffs' venturous 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*, 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**

⁴ These legal arguments bear substantial similarity to the arguments invoked in support of the Commonwealth's Motion to Dismiss in the case *Rodríguez Vélez v. Pierluisi Urrutia*, 21-cv-01366 (PAD), currently pending before this Court. Plaintiffs' claims in that case and the legal theories in support thereof also bear substantial similarity to the claims set forth in this case. Counsel for Plaintiffs are the same on both cases.

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, Defendants 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 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).

A. The challenged legal precepts do not violate Plaintiff’s substantive due process rights.

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)).

Plaintiffs’ substantive due process allegations are mostly based on their personal interpretation of random data to promote, through this Court, their own COVID-19 public health policy for the

Commonwealth. Plaintiffs have not been electorally entrusted with 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."). Thus, Defendants will only address legal issues regarding substantive and procedural due process raised in the Complaint.

Plaintiffs allege that the vaccination requirements and mandates of the challenged Executive Orders, whose specific details were discussed at some length in a prior section of this motion, are unconstitutional restrictions on individual liberties, and ineffective tools to deal with the crisis (Docket No. 1 at 3, ¶¶6-7). Specifically, they claim the existing mandates infringe on their right to earn a living and use their property as they see fit, without sufficient justification for such infringement, in violation of their economic liberty and property rights under the Fourteenth Amendment of the United States Constitution. *See* Docket No. 1 at 28-29, 31, 32, ¶¶124, 128, 134 & 140).

As to Department of Health's Regulation 138-A, Plaintiffs Tropical Chill and Vega did not attack the legality or constitutionality of its requirements in their pleadings. *See* Docket No. 1 at 26-28, ¶¶115-125, 130-31, 135-40. As to Plaintiffs Irizarry and Matos, their argument against Regulation 138-A is grounded on an alleged property interest in their health certificates, a legal proposition for which no authority was cited, even though this is the foundation of the constitutional attack against the regulation on Fourteenth Amendment grounds. *See* Docket No. 1 at 29, ¶¶128; 130 & 134. Irizarry claims her employer requires the certificate as a condition for employment, but that she does not qualify for any of the exceptions (Docket No. 1 at 28, ¶126). However, the Secretary of Health, in the valid exercise of his authority under Regulation No. 138-A, determines when and under what circumstances and exceptions are health certificates to be issued. *See Great A. & Pac. Tea Co., Inc. v. Cottrell*, 424 U.S. 366, 371 (1976)

(holding that the states retain “broad power” to legislate protection for their citizens in matters of local concern such as public health). As to Plaintiff Matos, even under the existing regulation he was able to obtain the health certificate required by his employer, a grocery store, “but he fears that Regulation 138-A will be used to deprive him of that certificate or prevent him from renewing it” (Docket No. 1 at 29-30, ¶ 133). Matos has not alleged an expiration date on the Certificate he already obtained.

Plaintiffs also claim the existing mandates violate their rights to personal autonomy, bodily integrity, and the right to reject medical treatment. In the case of plaintiffs Tropical Chill and Vega, they invoke the constitutional right to privacy of their customers and clients, since the mandates require proofs of vaccination, masking, and other unjustified impositions not narrowly tailored as constitutionally required. Docket No. 1 at 31 and 32, ¶¶ 141-143, and 149-151. Plaintiffs cast doubt on the existence of a compelling government interest to justify the Executive Orders and point to the existence of “...less onerous means to obtain the desired result which would lessen the burden on the plaintiff’s individual liberties and property interest.” (Docket 1, at 35, ¶ 161)).

Plaintiffs have failed to direct this Court to a single precedent from any federal court in support of the proposition 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 v. Trustees of Indiana U.*, 7 F.4th 592 (7th Cir. 2021) (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). See **Exhibit I** - CFI *Amadeo* Judgment. Since federal and state case law have consistently refused to strike down vaccine mandates throughout the United States, Plaintiffs cannot prevail in their challenge to the Executive Order on substantive due process grounds. Current doctrine as espoused by applicable precedents referred to in this motion is just not on their side.

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 v. King*, 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*, 7 F.4th 592 (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.”

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 like the vaccine mandate upheld by the Seventh Circuit in *Klaassen*, which recognized certain exceptions.

As explained in a prior section of this motion, the Executive Orders provide covered individuals (employees and guests) and subject to its requisite’s alternatives to “opt out” of the mandatory vaccination requirement. 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, the challenged orders requiring mandatory vaccination or a weekly negative COVID-19 qualified tests to employees and guests of the facilities within their scope are 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.").

Plaintiffs have alleged that the challenged vaccine mandates and regulation also violate the economic liberty protected by the Fourteenth Amendment. *See* Docket 1 at 26. Plaintiffs' pleadings contain no specific definition nor legal standards associated with that elusive concept, nor any reference to legal authorities in support thereof. The Supreme Court of the United States has never acknowledged economic liberty as a substantial component of the individual liberties afforded protection against governmental intrusion under the Fourteenth Amendment to the United States Constitution. The liberties protected by substantive due process do not include economic liberties. *Savage v. Mills*, 478 F.Supp.3d 16 (D. Me. 2020). Such protection exists, but its origin is statutory, not constitutional, and it is limited to private restraints. *See*, for example, *Mass. Food Association v. Mass. Alcoholic Beverages Control Commission*, 197 F.3d. 560 (1st Cir., 1999) (holding that "[t]he Sherman Act is a charter of economic liberty, but only against private restraints"). The notion of a higher level of constitutional protection for economic liberty has been debated in scholar circles, but so far, no broad recognition of such right, which would subject to strict judicial scrutiny and "less onerous means" analysis any legislation or regulatory scheme over commerce and economic activity in general, has been forthcoming from the Court. *See* GEORGE THOMAS, *Economic Liberty and the Courts*, National Affairs (Summer 2010); RANDY E. BARNETT, *Does the Constitution Protect Economic Liberty?* 35 Harv. J.L. & Pub. Pol'y 1 (March 2012). The notion of an economic liberty interest finds no explicit support in the text of the Constitution, but its advocates rely on a broad interpretation, allegedly grounded on historical precedents, of the Privileges or Immunities, Due Process and Equal Protection Clauses of the Fourteenth Amendment, and the way they

wish these clauses were construed. *See* BARNETT, 35 Harv. J.L. & Pub. Pol’y at 11-12. In this mindset, *Jacobson* and the rational basis scrutiny it validated for public health vaccine requirements has become a doctrinal target for derision. Advocates of “economic liberty” support stricter limitations on governmental regulatory powers to carry out public policy objectives, even in areas as sensitive as public health threats like the ones the world is currently facing. *See* BARNETT, 35 Harv. J.L. & Pub. Pol’y 1.

“If a precedent of the Supreme Court has direct application in a case yet appears to rest on reasons rejected in some other line of decisions, the court of Appeals should follow the case which directly controls, leaving the Supreme Court the prerogative of overruling its own decisions”, *Rodriguez de Quijas v. Shearson/American Express*, 490 U.S. 477, 484 (1989); *U.S. v. McIvery*, 806 F.2d. 645, 653 (1st Cir., 2015). “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**”, *U.S. v. Moore-Bush*, 963 F.3d. 29, 31 (1st Cir., 2020) (emphasis added). As recently as early this month the Court of Appeals for the Seventh Circuit, when ruling upon the substantive due process challenge of a vaccination regime enacted to fight the current COVID-19 epidemic, validated the continuing applicability and binding nature of *Jacobson* and its sanctioning of vaccination requirements. *See Klaassen*, 7 F.4th 592. This is the standard by which Plaintiff’s substantive due process claims must be evaluated, notwithstanding doctrinal calls for alternative interpretations.

Having failed to identify a federally protected right breached by the Executive Orders at issue and having failed to even plea or develop in some meaningful way that Defendants’ conduct is “shocking to the conscience”, as required by the substantive due process standard, Plaintiffs’ 1983 claims must be dismissed with prejudice at this stage of the proceedings.

B. The Executive Orders and the Regulation do not breach any Fourteenth Amendment substantive due process interest under any standard of review

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.

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 (The state legislature proceeded upon the theory which recognized vaccination as at least an effective, if not the best-known, way in which to meet and suppress the evils of a smallpox epidemic that imperiled an entire population); *Phillips v. City of New York*, 775 F.3d 538, 542-43 (2d Cir. 2015) (“Plaintiffs' substantive due process challenge to the mandatory vaccination regime is therefore no more compelling than *Jacobson's* was more than a century ago”); *Connecticut Citizens Defense League, Inc. v. Lamont*, 465 F. Supp.3d 56, 72 (D. Conn. 2020) (“in every well-ordered society charged with the duty of conserving the safety of its members the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand”) (quoting *Jacobson*, 197 U.S. at 29); *Middleton v. Pan*, 2016 WL 11518596, at *7 (C.D. Cal. Dec. 15, 2016) (quoting *Prince*); *George v.*

Kankakee Cmty. Coll., 2014 U.S. Dist. LEXIS 161379, 8-9 (C.D. Ill. Oct. 27, 2014) (“the right of free exercise does not relieve an individual of the obligation to comply with a ‘valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his religion prescribes (or proscribes)’”) (quoting *United States v. Lee*, 455 U.S. 252, 263, n. 3 (1982)) (Stevens, J., concurring in judgment), *recommendation adopted*, 2014 U.S. Dist. LEXIS 160737, 1-2); *Boone v. Boozman*, 217 F. Supp.2d 938, 954 (E.D. Ark. 2002) (“It is well established that the State may enact reasonable regulations to protect the public health and the public safety, and it cannot be questioned that compulsory immunization is a permissible exercise of the State's police power”) (quoting *Zucht*, 260 U.S. at 176); *Klaassen*, 2021 WL 3073926 at *24 (“Given over a century's worth of rulings saying there is no greater right to refuse a vaccination than what the Constitution recognizes as a significant liberty, the court declines the students’ invitation to extend substantive due process to recognize more than what already and historically exists”).

In the instant case, the Executive Orders, and the Department of Health’s Regulation, as amended, did not violate any of Plaintiffs’ substantive due process rights. Moreover, Plaintiffs did not refer in their pleadings to any binding or persuasive case law declining to follow *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.”).

The Executive Orders spelled out 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. 1 at 2, ¶¶ 3-4). This is an undeniably legitimate governmental interest. *See S. Bay United Pentecostal Church*, 140

S. Ct. at 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 Orders are rationally related.

As a general matter, the Executive Orders' 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. Plaintiffs do not point to a single court holding otherwise. *See Am. Cruise Ferries, Inc.*, 2020 WL 7786939 at *16 (upholding governmental economic restrictions and stating that in the wake of the COVID-19 pandemic, across the nation, federal courts have reaffirmed state or local government decisions as to orders regarding to quarantines, the closing of businesses and other restrictions in their exercise of police power to control the deadly spread of the virus); *see also* 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 Orders, 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."). Accordingly, since the Executive Orders bear a rational relation to the Government's interest, they swiftly pass a rational basis scrutiny under current constitutional standards; thus, the instant case must be dismissed with prejudice.

As to Regulation 138-A, only two of the Plaintiffs have alleged that its requirements constitute infringements on their substantive due process rights, claiming to have a property interest in their health certificates for which no legal authority is invoked. One of the plaintiffs admitted that he has already obtained a health certificate, for which no expiration date was proffered. Assuming the existence of a property interest, a legal proposition for which no authority has been cited by Plaintiffs, the requirements established in Regulation 138-A for the issuance of health certificates—among them, evidence of vaccination against COVID-19, unless health or religious exceptions apply—on its face are substantially

less intrusive and onerous than the ones contained in the Executive Orders, which comply with applicable scrutiny standards, as we have already discussed. The same level of scrutiny should lead the Court to a similar conclusion as to the validity of this requirement as a rational measure to promote a compelling public interest.

Should the Court understand that the Executive Orders should be examined under a strict scrutiny—which Defendant vehemently denies—they would easily pass said test since they are narrowly tailored to serve a compelling state interest: the health and lives of all public employees and citizens who visit and sponsor public facilities of all kinds during this crisis period.

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 Orders 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. Their only purpose is to safeguard the lives and health of all public employees and individuals visiting government and public facilities 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 individuals that decide not to inoculate. Thus, the Executive Orders’ aggressive attempt to protect the lives and health of the individuals and citizens 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 Orders are narrowly tailored because: (1) do not create suspect classifications, as they are of general application to employees and individuals in the covered facilities that work in-person, and visitors; (2) mandate vaccination to all employees that work in-person, but has exceptions (religious and medical) and general “opt-outs” that equally apply to employees that do not want to be immunized against COVID-19, and contractors who visit the locations regularly; (3) requires that **all** 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) create 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, or possibly an unpaid leave. In that sense, the Executive Orders are narrowly tailored to protect 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 Orders generally require 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, the Court must conclude that—while Defendant vehemently argues that such level of review is inapposite—the Executive Orders easily pass 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”).

In short, the Executive Orders do not violate Plaintiffs’ Fourteenth Amendment’s economic liberty rights, because no unequivocal recognition has come from the Supreme Court as to the existence of such rights. *See Mass. Food Association v. Mass. Alcoholic Beverages Control Commission, supra* (“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). While Plaintiffs may put their economic interests before

the health of all citizens, the Government's duty to protect the lives of its citizens cannot give during a deadly pandemic. *See Am. Cruise Ferries, Inc.*, 2020 WL 7786939, at *17 (“Although everybody is profoundly concerned with the negative effects that the determinations taken by state and local governments nationwide have had, and will continue to have, in the economy, the weighting of the factors in the context of the pandemic lead the Court to find [economic restrictions] must be upheld as a valid constitutional exercise of the Commonwealth's police power.”).

C. Plaintiff Vega failed to state a plausible claim 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 *Smith*, 494 U.S. 872, 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 RFRA's strict scrutiny to the alleged violation of their freedom to exercise religion. However, the Executive Orders do not violate Plaintiffs' freedom to exercise their religion of choice. The Supreme Court applied the strict scrutiny in a recent case, in a Free Exercise Clause context, questioning an Executive Order dealing with the COVID-19 pandemic, where plaintiffs alleged a violation to their First Amendment right of freedom to exercise their religion. Specifically, in *Roman Catholic Diocese of Brooklyn*, 141 S.Ct. at 63, the Supreme Court was faced with a case where the state governor—in response 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 Orders are to be generally applied to all contractors, employees and guests who work in-person or visit the facilities within the scope of the Orders.

Plaintiffs claim that the vaccine mandate in EO 062 “burdens Plaintiff Vega's religious beliefs—by compelling her to become the government's vaccination or COVID-19 test verifier—as it obligates her to participate in and condone forced vaccination, which go against her religious belief”, by means of alternatives that are neither the least restrictive nor the narrowly tailored to achieve the Government's interest. (Docket No. 1 at 36, ¶¶ 169-170). However, Plaintiff Vega ignores that, generally, policies requiring vaccination need not have 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). That is because these exemptions make it possible for anyone to circumvent the vaccine mandate.

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 if 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).

As this Court can attest, the challenged Executive Orders provide a medical and religious exemption, that may not even be constitutionally required, in which case Plaintiff Vega has the option to require a COVID-19 negative test result to respect to the individual’s free exercise of religion and provide

an alternative to those whose religious dogmas prohibit vaccination. In that sense, the Executive Orders not only safeguard free exercise of religion but provides more rights than those constitutionally or statutorily required. Far from infringing RFRA or free exercise of religion, the Executive Orders protect religious beliefs by creating a religious exception to the vaccine mandate. The alternative provided to Plaintiff Vega of requiring a negative COVID-19 test result to all guests is the less restrictive means that the Government can provide to safeguard the public health. 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 Orders still created an alternative to short-term rental business persons like Plaintiff Vega—requiring a negative COVID-19 test result in lieu of a Vaccination Record Card—that constitute a less restrictive mean and that is narrowly tailored to advance the compelling government interest of containing the COVID-19 deadly virus from spreading. The RFRA claim must be dismissed with prejudice.

Nevertheless, even if, *arguendo*, the Court finds that the Executive Orders 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 Orders were issued with a compelling interest to protect the lives and health of all employees by avoiding a spread of COVID-19 in covered workplaces.

The next step of the RFRA compelling interest test is to determine if the Government implemented the least restrictive means to achieve its compelling interest. In that sense, to establish that a government employed the least restrictive means in advancing a compelling government interest, the government is required to establish that no alternative, less restrictive, means exists. *Sherbet*, 374 U.S. at

407. See *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 728 (2014) (requiring government to show “that it lacks other means of achieving its desired goal without imposing a substantial burden on the exercise of religion on the objecting parties”). Recognizing the tests within difficulty of proving a negative, courts that have addressed this issue have held that “the government should not be required ‘to refute every conceivable option in order to satisfy the least restrictive means prong of RFRA.’” *Armstrong v. Jewell*, 151 F.Supp.3d 242, 249 (citing *United States v. Wilgus*, 638 F.3d 1274, 1289 (10th Cir.2011) (listing concurring cases from other jurisdictions); *United States v. Lafley*, 656 F.3d 936, 942 (9th Cir. 2011) (rejecting alternative restrictive means that would be “as impractical as they are insufficient”); *Olsen v. Drug Enforcement Agency*, 878 F.2d 1458 (D.C.C.1989) (rejecting proposal for restrictive use of marijuana during religious services, which required “burdensome and constant official supervision and management”).

In the instant case, the Government has complied with the “least restrictive means” requirement of RFRA, being that the Executive Order provides alternatives for Airbnb owners compliance with its dispositions by conforming with Sections 5 and 6. Specifically, Section 5 of EO 2021-62 allows for an exception to be inoculated for religious beliefs, for owners, employees, and guests. To apply for the exception based on religion, they must obtain a sworn statement along with their religious leader stating that inoculation goes against their religious beliefs. If they do not have a religious leader to sign the sworn statement, then they must furnish a sworn statement where they sustain their specific and sincere religious convictions. Furthermore, Section 5(3) allows for guests to provide a negative COVID-19 test result of at least 72 hours to be able to check in the Airbnb if they do not get inoculated based on religious beliefs. On the other hand, Section 6 of EO 2021-62, allows for Airbnb guests to stay by providing a negative result of the COVID-19 test taken within 72 hours of their arrival, should they refuse to be inoculated. These opt-outs are the least restrictive means by which the Defendants can achieve the purposes of the Executive Orders: contain the spread of a deadly virus.

Unquestionably, the Executive Orders are narrowly tailored to promote the compelling government interest. As previously explained in this motion, the Executive Orders are narrowly tailored because, while they mandate vaccination, they provide multiple exceptions and “opt outs” for owners of Airbnb short-term rental properties that do not wish to require a Vaccination Record Card for their guests, like Plaintiff Vega. In that sense, the Executive Orders are not broader than necessary as they do not obligate covered individuals to immunize against COVID-19 if they do not desire; be it on religious, medical or any other ground. The Executive Orders provide an exception for those who cannot inoculate on religious grounds and that, itself, is the less restrictive mean—subsumed within the narrowly tailoring—required to pass a RFRA strict scrutiny. Simply put, the Executive Orders do not place an undue burden on religion, but rather protect the individual’s free exercise by allowing them to simply require a negative COVID-19 test result. Therefore, since the Executive Orders are narrowly tailored to contain the contagion of COVID-19 among all guests in Airbnb rentals, which would, in turn, avoid the propagation of the virus to their families, to school children and personnel (thousands of employees, contractors and visitors have school-age children) and to the general population, Plaintiffs’ claim of violation of RFRA is misplaced, frivolous, and must be dismissed with prejudice. *See Listecki v. Official Comm. of Unsecured Creditors*, 780 F.3d 731, 744 (7th 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 religious exemption required).

D. Pendent claims must be dismissed absent a cognizable federal claim and for failure to state a claim on the merits.

Plaintiffs have invoked the supplemental jurisdiction of this Court to entertain its claims pursuant to the laws of the Commonwealth of Puerto Rico. “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”).

Plaintiffs have not plausibly pleaded any federal cause of action warranting the exercise of this Court’s supplemental jurisdiction. Since Plaintiffs’ federal claims are destined to fail, the Court must dismiss all alleged state claims.

Nevertheless, in an abundance of caution and without waiving the absence of a cognizable federal claim argument, should the Court determine to consider Plaintiffs’ supplemental claims, Defendants will proceed to discuss the basis for the dismissal of the same on the merits. Essentially, Plaintiffs allege that the Rolling EOs (EO 2021 062-064) constitute a violation of the separation of powers doctrine by being an exercise of non-delegated legislative powers, grounded in that Article 5.10 of Act No. 20-2017 does not bestow upon the Governor the authority to issue these types of executive orders, despite the COVID-19 emergency declaration. In the alternative, Plaintiffs allege that if Article 5.10 delegates such authority, then, it constitutes an unconstitutional delegation of power under the non-delegation doctrine. Lastly, Plaintiffs allege that the Rolling EOs should be declared null and void because they encompass unlawful criminal threats not contemplated in Article 5.14 of Act No. 20-2017 nor Article 33 of Act No. 81 of March 14, 1912, as amended (Act No. 81-1912). (Docket No. 1 at 36-42). The ensuing discussion will show that Plaintiffs are wrong in all three pendent claims arguments.

1. Plaintiffs lack standing to bring a claim under the separation of powers doctrine.

At the threshold, to gain access to federal courts, a plaintiff has the burden of establishing that he or she has standing. *Clapper v. Amnesty Int. USA*, 568 U.S. 398, 411-12 (2013); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). A federal court must satisfy itself as to its jurisdiction, which requires it to primarily evaluate if a plaintiff has Article III standing to sue, before addressing specific claims. *See Orr v. Orr*, 440 U.S. 268, 271 (1979); *Juidice v. Vail*, 430 U.S. 327, 331 (1977); *see also Warth v. Seldin*, 422 U.S. 490, 498 (1975) (explaining that standing is a threshold issue in every federal case). The standing inquiry is both plaintiff-specific and claim-specific and its requirement “is founded in concern about the proper—and properly limited—role of the courts in a democratic society.” *Summers v. Earth Island Inst.*, 555 U.S. 488, 492–93 (2009); *Warth v. Seldin*, 422 U.S. 490 (1975); *Pagán v. Calderón*, 448 F.3d 16, 26 (1st Cir. 2006). Only if a particular plaintiff has standing to pursue a particular claim will the court proceed to assess them. *See Pagán*, 448 F.3d at 26. Thus, a court must determine whether each plaintiff is entitled to have a federal court adjudicate each particular claim that he or she asserts as the standing issue is tied to its jurisdiction. *Allen v. Wright*, 468 U.S. 737, 752 (1984); *Donahue v. City of Boston*, 304 F.3d 110, 116 (1st Cir. 2002). To have Article III standing, Plaintiffs’ alleged injury must be “concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling.” *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010); *Lujan*, 504 U.S. at 560–61.

Importantly, here, no case challenging the Executive Orders 2021-062 to 064 has been filed by the Commonwealth’s Legislative Branch, in state or federal court, claiming a violation of the separation of powers. Clearly, the Legislative Branch is the only party that has standing to set forth such a challenge, if any. That is because if there is a violation to the separation of powers, the party that suffers a cognizable harm for such violation is the government’s branch that is entitled to the power that the other branch is usurping. Thus, since there is no controversy between the Executive and the Legislative branches on this matter, the Judicial branch is not required to intervene in the matter and serve as a mediator. *See Goldwater*

v. Carter, 444 U.S. 996 (1979) (Powell, J., concurring) (“The Judicial Branch should not decide issues affecting the allocation of power between the [Executive Branch] and [Legislative Branch] until the political branches reach a constitutional impasse.”). Here, the Court is not faced with a dispute between two branches of the Commonwealth’s Government regarding the allocation of power, but merely against an allegation of individual citizens that attempt to step into the Commonwealth Legislative Branch’s shoes. That simply cannot be.

In the instant case, the Executive Orders 2021-062 to 064 did not usurp the Legislative Assembly’s constitutional power to legislate, and that branch has not expressed itself challenging the authority of the Governor in adopting COVID-19 public policy. *See* W. Vázquez Irizarry, *Los poderes del Gobernador de Puerto Rico y el uso de Ordenes Ejecutivas*, 76 Rev. Jur. UPR 951, 1047 (2007) (explaining that the legislative silence in the face of a repeated practice by the first executive to issue executive orders on a certain issue may be an element to consider in favor of the existence of a constitutional understanding between the two branches). It should be noted that the Judicial Branch should only intervene between the political branches when there is a conflict between their constitutional powers. In other words, only when the political branches reach an impasse, should the courts intervene to define their limits. *See Goldwater*, 444 U.S. at 996. The Governor has stayed within his boundaries and has not seized the legislative role by issuing executive orders 2021-062 to 064. If the Legislative Assembly believed that the Governor’s executive orders overstepped his constitutional boundaries, they would have already filed a complaint. But they have not. In such a scenario, Plaintiffs do not have standing to raise a separation of powers violation because, in this scenario, the Legislative Assembly would be the only part that would have standing to do so.

2. The Executive Orders are a valid exercise of the Governor’s constitutional duties that do not violate the separation of powers doctrine.

Defendants have established that Plaintiffs do not have standing to raise a separation of powers claim, but—in an abundance of caution—they will discuss the merits of the arguments to put this Court

is position to dismiss them on the merits. In *Patchak v. Zinke*, 138 S. Ct. 897, 904 (2018), the Supreme Court of the United States examined the constitutional doctrine of separation of powers. First, “the Constitution creates three branches of Government and vests each branch with a different type of power” and “[b]y vesting each branch with an exclusive form of power, the Framers kept those powers separate. *Id.* Each branch “exercise[s] ... the powers appropriate to its own department,” and no branch can “encroach upon the powers confided to the others.” This system prevents “[t]he accumulation of all powers, legislative, executive, and judiciary, in the same hands,” *Id.* at 904-905 (citing *Kilbourn v. Thompson*, 103 U.S. 168, 191 (1881)).

Under the separation of powers doctrine, even when a branch does not arrogate power to itself, it must not impair another in the performance of its constitutional duties. *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 500 (2010) (citing *Loving v. United States*, 517 U.S. 748, 757 (1996)). Note, however, that “[t]he Constitution does not establish three branches with precisely defined boundaries.” *I.N.S. v. Chadha*, 462 U.S. 919, 962, (1983). Consequently, “[s]eparation-of-powers principles are vindicated, not disserved, by measured cooperation between the two political branches of the Government, each contributing to a lawful objective through its own processes.” *Loving v. United States* at 773. “When any Branch acts, it is presumptively exercising the power the Constitution has delegated to it.” *Chadha*, 462 U.S. at 951 (1983) (citing *Hampton & Co. v. United States*, 276 U.S. 394, 406 (1928)). The Supreme Court of the United States “has been mindful that the boundaries between each branch should be fixed ‘according to common sense and the inherent necessities of the governmental co-ordination.’” *Chadha*, 462 U.S. at 962 (1983) (citing *J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394, 406 (1928)).

It should be noted that federal jurisprudence on the separation of powers is not mandatory to resolve Puerto Rico separation of powers controversies. See *Noriega v. Hernández Colón*, 135 P.R. Dec. 406, 473-74 (1994). “The separation of powers in Puerto Rico is expressly enshrined in Art. I, Sec. 2 of the Constitution of the Commonwealth of Puerto Rico.” *Colón-Cortés v. Pesquera*, 150 P.R. Dec. 724, 2000 P.R.-Eng. 424,713, P.R. Offic. Trans. (2000). Article I, Section 2, of our Constitution states that

“[t]he government of the Commonwealth of Puerto Rico shall be republican in form and its legislative, judicial and executive branches as established by this Constitution shall be equally subordinate to the sovereignty of the people of Puerto Rico.” Puerto Rico Const. Art. I, § 2. In *Rivera Schatz v. ELA y C. Abo. PR II*, 191 P.R. Dec. 791, 802 (2014), the Supreme Court of Puerto Rico (“P.R. Supreme Court”) explains that the doctrine of separation of powers aspires to establish the responsibilities of the constitutional branches of government and to frame their scope of action. See *Rivera Schatz v. ELA y C. Abo. PR II*, 191 P.R. Dec. 791, 802 (2014). However, the model of the division of powers into three (3) branches, Legislative, Executive and Judicial, does not intend to define in an absolute and inflexible way the scope of power that corresponds to each of these branches. *Id.*

In addressing Plaintiffs’ separation of powers claim, the Court must consider that Puerto Rico, as well as worldwide, is still under a public health emergency, thus the Governor has to use all his constitutional powers to face the everchanging pandemic. Both, the President of the United States, Joseph R. Biden, and the Governor of Puerto Rico, Pedro R. Pierluisi, have continued to label COVID-19 as a public health emergency.⁵ Moreover, since the instant complaint was filed on August 27, 2021, the number of COVID-19 cases has risen. On August 30, 2021, seven destinations, including our jurisdiction, moved up from the Level 3: COVID-19 High list to Level 4: Azerbaijan, Estonia, Guam, North Macedonia, Puerto Rico, Saint Lucia and Switzerland. See *CDC adds 7 destinations to ‘very high’ Covid-19 travel risk list, including Puerto Rico and Switzerland*, <https://edition.cnn.com/travel/article/cdc-very-high-risk-travel-destinations-august-30/index.html> (last accessed September 15, 2021). The CDC’s

⁵ See *A Letter on the Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID-19) Pandemic*, <https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/24/a-letter-on-the-continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic/> (last accessed September 15, 2021); see also the Governor’s EO 2021 062-064, declaring state of emergency.

evolving list of travel notices ranges from Level 1 (“low”) to Level 4 (“very high”)⁶. *Id.* Thus, the Governor is more than entitled to use his powers to deal with the emergency.

Plaintiffs allege that because Puerto Rico’s constitutional structure emulates the federal design, including a government that is organized pursuant to the doctrine of separation of powers, the power to enact laws for the protection of the life, health, and the general welfare of the people rests with the Legislative Branch. Docket No. 1 at 36, ¶173. Specifically, Plaintiffs argue that “[a]n executive order of general application constitutes a state act of a legislative nature which, without an appropriate legal basis, constitute a violation of the separation of powers.” *Id.* at ¶175. Moreover, they argue that “the Governor does not possess the power to issue executive orders abridging fundamental rights or that contravene an act of the Legislature.” *Id.* at ¶176. However, Plaintiffs’ claim lack merit altogether because aside from lacking standing, the Rolling EOs are a valid exercise of the Governor’s constitutional authority. Plaintiffs also argue that Article 5.10 of the *Puerto Rico Department of Public Safety Act*, Act 20-2017, P.R. Laws Ann., tit. 25, § 3550, et seq., cannot be construed to authorize the Governor to declare an emergency of a completely different nature (that is not a hurricane or an earthquake) such as learning how to grapple with COVID. Docket No. 1 at 38-39, ¶¶181-183.

It should be noted that the Puerto Rico Department of Public Safety unlike public instrumentalities or corporations, is an “arm of” the Commonwealth of Puerto Rico. *Puerto Rico Dep’t of Pub. Safety v. Tracfone Wireless, Inc.*, 514 F. Supp. 3d 400, 402 (D.P.R. 2021). Regarding the use of executive orders to deal with the current state of emergency, Defendants bring to the attention of this Court, the August 6, 2021, Judgment by the Puerto Rico Court of First Instance (“CFI”) in *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. *See* Exhibit I - CFI *Amadeo* Judgment. The complaint questioned the authority of the Governor and the Secretary of the Health Department to issue, respectively,

⁶ The referenced CNN article explains that “Destinations that fall into the ‘Covid-19 Very High’ Level 4 category have had more than 500 cases per 100,000 residents in the past 28 days, according to CDC criteria.”

executive orders and administrative orders to address the state of emergency. Importantly, the CFI explained that Article 5.10⁷ of the Puerto Rico Public Safety Department Act, Act No. 20-2017, “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.” *Id.* at 17.

According to Plaintiffs “[t]he Puerto Rico Legislative Assembly has enacted specific laws for the protection of life and health against the threat of an epidemic or infectious disease, *none* of which include rulemaking delegation to the governor by way of executive order.” Docket No. 1 at 36, ¶174 (citing Proclamation of Epidemics Act, P.R. Laws Ann. tit. 24, § 354 and Act No. 81-1912, which delegates to the Secretary of Health the power to quarantine sick individuals during times of pandemic.). However, Plaintiffs omit that Act No. 157 of May 10, 1938, expressly recognizes the authority of the Governor to act in an epidemic through executive orders. “Whereby proclamation of the Governor of Puerto Rico an epidemic shall be declared to exist in one or several municipalities, the Secretary of Health, immediately upon such declaration of an epidemic, shall take charge of the municipal sanitation of such municipality or municipalities so affected.” 24 L.P.R.A. § 354. In *Amadeo*, the CFI clarified that article 5.10 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.

Exhibit I - CFI *Amadeo* Judgment at 17. (Emphasis in original).⁸

⁷ Note that article 6.10 of Act No. 20-207 was amended by Act 135 of September 1, 2020, and renumbered as article 5.10. When the CFI mentions article 6.10, it is referring to article 5.10.

⁸ Note that article 6.10 of Act No. 20-207 was amended by Act 135 of September 1, 2020 and renumbered as article 5.10. When the CFI mentions article 6.10, it refers to article 5.10. The quoted paragraph of the Judgment said article 6.10.

It is preposterous that, as part of their anti-vaccine claim, Plaintiffs attempt to undermine the use of executive orders by arguing that, instead of using them, the Department of Health should adopt legislation to address the health emergency that complies “with the rulemaking process established by the Puerto Rico Uniform Administrative Procedure Act (LPAU), Act. 38-2017, P.R. Laws Ann., tit. 3, §§ 9601-9713, which provides for citizen participation through a written comments period and in the case of the Department of Health, even a public hearing” Docket No. 1 at 39-40, ¶187. The COVID-19 pandemic has proven to be difficult for governments, including Puerto Rico, because new challenges appear daily. These changes require agility from the Governor and his executive branch, which includes the Health Department. The idea that citizen participation, through written comments and public hearings, would have to be incorporated to try to tackle the COVID-19 pandemic is unrealistic. Particularly, with the surge in the pandemic because of the spread of the Delta variant. “Delta is currently the predominant strain of the virus in the United States. *See Delta Variant: What We Know About the Science*, <https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html> (last accessed September 15, 2021). As expected by the increasing number of cases, the ‘Delta variant is highly contagious, more than 2x as contagious as previous variants.’” *Id. United States of America, v. Parker H. Petit*, No. 19-CR-850 (JSR), 2021 WL 4060361, at *2 (S.D.N.Y. Sept. 7, 2021).

3. The nondelegation doctrine is inapposite because article 5.10 provides an intelligible principle to guide the Governor’s use of discretion.

In *Mistretta v. United States*, 488 U.S. 361, 371 (1989), the Supreme Court explained that “[t]he nondelegation doctrine is rooted in the principle of separation of powers that underlies our tripartite system of Government.” The Court has long “insisted that the integrity and maintenance of the system of government ordained by the Constitution mandate that Congress generally cannot delegate its legislative power to another Branch.” *Mistretta*, 488 U.S. 361, 372 (1989) (internal quotations and citations omitted). However, the Supreme Court has also recognized “that the separation-of-powers principle, and the nondelegation doctrine in particular, do not prevent Congress from obtaining the assistance of its

coordinate Branches.” *Id.* Importantly, *Mistretta* clarifies that “[s]o long as Congress shall lay down by legislative act an intelligible principle to which the person or body authorized to exercise the delegated authority is directed to conform, such legislative action is not a forbidden delegation of legislative power.” *Id.* at 372 (internal quotations, alterations, and citations omitted).

In determining whether a statutory delegation of authority by Congress violates the Constitution’s assignment of all legislative power to Congress, the nondelegation inquiry always begins and often almost ends with statutory interpretation, because the constitutional question is whether Congress has supplied an intelligible principle to guide the delegee’s use of discretion, and the answer requires construing the challenged statute to figure out what task it delegates and what instructions it provides. *Gundy v. United States*, 139 S. Ct. 2116, 2123, *reh’g denied*, 140 S. Ct. 579 (2019). However, it should be highlighted, that since 1935 the Supreme Court “has uniformly rejected nondelegation arguments and has upheld provisions that authorized agencies to adopt important rules pursuant to extraordinarily capacious standards.” *Gundy*, 139 S. Ct. at 2130–31, *reh’g denied*, 140 S. Ct. 579, (2019) (Alito, J. concurring in the judgment).

The reason why the Supreme Court has rejected nondelegation arguments since 1935 gives weight to the argument of legal scholars like Eric A. Posner and Adrian Vermeule, who affirm that “Courts shouldn’t enforce a nondelegation doctrine for the simple reason that there is no constitutional warrant for that doctrine.” ERIC A. POSNER & ADRIAN VERMEULE, *Interring the Nondelegation Doctrine*, 69 U. Chi. L. Rev. 1721, 1723 (2002). In *Interring the Nondelegation Doctrine*, Posner and Vermeule argue that “there is no such nondelegation doctrine: A statutory grant of authority to the executive branch or other agents never effects a delegation of legislative power. Agents acting within the terms of such a statutory grant are exercising executive power, not legislative power.” *Id.* at 1721. “Nondelegation is nothing more than a controversial theory that floated around the margins of nineteenth-century constitutionalism—a theory that wasn’t clearly adopted by the Supreme Court until 1892, and even then only in dictum.” *Id.* at 1722 (citing *Marshall Field & Co. v. Clark*, 143 US 649, 692 (1892), claiming that Congress cannot

delegate legislative power to the president, but stating that the act in question “is not inconsistent with that principle”).

Here, Plaintiffs allege that article 5.10 of the *Puerto Rico Department of Public Safety Act*, Act No. 20-2017’s “delegation of power is excessively vague and overbroad and should be declared unconstitutional.” Docket No. 1 at 41, ¶199. Article 5.10 of Act No. 20-2017 provides, in pertinent part, that the Governor:

(b) 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. Regulations prescribed or orders issued during a state of emergency or disaster shall have force of law for the duration of the state of emergency or disaster.

(c) May render effective any state regulations, orders, plans, or measures for emergency or disaster situations or modify them at his discretion.

P.R. Laws Ann. tit. 25, § 3650. Since Act No. 20-2017 is a local statute, it should be noted that “territorial legislators may exercise the legislative power of the Territories without violating the nondelegation doctrine”. *Fin. Oversight & Mgmt. Bd. For Puerto Rico v. Aurelius Inv., LLC*, 140 S. Ct. 1649, 1659, 207 L. Ed. 2d 18 (2020). The plain language of the challenged statute, Article 5.10 of Act No. 20-2017, clearly allows the Governor to: (1) **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, and (2) **to render effective any state regulations, orders, plans, or measures for emergency or disaster situations** or modify them at his discretion. P.R. Laws Ann. tit. 25, § 3650. The Legislative Assembly supplied an intelligible principle to guide the Governor’s use of discretion. In fact, Article 5.10 itself sets forth the boundaries of the authority delegated by the Legislative Assembly to the Governor by enumerating the Governor’s powers and the events during which he can take those actions: emergencies and disasters.

Plaintiffs cite the P.R. Supreme Court opinion of *Domínguez Castro v. ELA*, 178 P.R. Dec. 1, 92-94 (2010), when they assert that “[t]he non-delegation doctrine equally applies to separation-of-powers controversies under Puerto Rico law.” Docket No. 1 at 41, ¶194. “In *Domínguez Castro*, the

constitutionality of Act No. 7 was challenged by the government employees that were terminated by the implementation of Act No. 7, which was geared to reduce the size of the government, as an emergency fiscal measure under Act No. 7.” *Vaquería Tres Monjitas, Inc. v. Comas*, 980 F. Supp. 2d 65, 81 (D.P.R. 2013). It should be noted that *Domínguez Castro* clarifies that nothing prevents the Legislature from establishing general norms that are broad and that leave the administrator an adequate margin of freedom to complement the legislative norms using a specialized judgment, which can be developed according to an administrative analysis, appreciation and discretion that has a reasonableness basis. *Domínguez Castro v. E.L.A.*, 178 P.R. Dec. 1, 94, 2010 TSPR 11 (2010). Therefore, it is forceful to conclude that Plaintiffs do not adequately allege a violation of the non-delegation doctrine, since Article 5.10 Act No. 20-2017 is not vague and overbroad, and it includes an intelligible principle to guide the Governor’s use of discretion.

4. Article 5.14 of Act 20-2017 provide for penalties, and they are correctly applied in the executive orders 2021 062-064 and that the population has been warned about the penalties included in the executive orders.

Plaintiffs also allege that “each Rolling EOs include a direct threat of criminal sanctions for failing to comply with its provisions” (Docket No. 1 at 42, ¶200), that “[t]his threat of criminal penalties lacks a legal basis and should be declared null and void by the Court” (Docket No. 1 at 42, ¶201), and that “[n]either Art. 5.14 of Act 20-2017 nor Art. 33 of the Health Department Act (Act 81) provides for such penalty”. Docket No. 1 at 42, ¶202. On the contrary, Article 5.14 of Act 20-2017, as amended,⁹ does provide for penalties and they are correctly applied in the executive orders 2021 062-064. Specifically, Article 5.14 provides, in pertinent part, that any person who persists on carrying out any activity that endangers his life or the lives of other persons, after having been warned by the authorities while a state of emergency declared by the Governor of Puerto Rico through an Executive Order is in effect, shall be punished by imprisonment for a term not to exceed six (6) months or a fine not to exceed five thousand

⁹ Note that articles 6.10 and 6.14 of Act No. 20-207 were amended by Act 135 of September 1, 2020 and renumbered as articles 5.10 and 5.14, respectively.

dollars (\$5,000), or both penalties at the discretion of the court. 25 L.P.R.A. § 3654. There should be no question that we are in a state of emergency and that the population has been warned about the penalties included in the executive orders. When the executive orders are issued, they are well publicized in newspapers, radio, television, and social media. They are also made public on the website of the Department of State.¹⁰ Thus, the challenged Executive Orders 2021-062 to 064 are a valid exercise of the Governor's constitutional duties that do not violate the separation of powers. Thus, the Plaintiffs' pendent claims should be dismissed with prejudice.

V. CONCLUSION AND PRAYER FOR RELIEF

The COVID-19 pandemic is a high-risk threat to general populations and health care systems around the world. No amount of theoretical tinkering with vaccination statistics, infection, mortality, and hospital utilization rates will seriously undermine this proposition. Vaccination is and should be treated as a primary means for providing protection against severe illness and death, especially for persons at high risk. The vaccination requirements have been given constitutional approval, under the most lenient standards of scrutiny, and would comply with even the more rigorous ones. Plaintiffs have not articulated a plausible RFRA claim the standards required by the statute. No one, in practicing his or her religion, has a constitutional right to endanger others and no belief can trump the health and lives of the citizens of Puerto Rico. Further, no economic interest disguised as an "economic liberty" can deviate the Government's compelling interest of saving the lives of its citizens. On all these grounds, this motion should be granted, and Plaintiffs' case should be dismissed with prejudice at this stage of the proceedings. Granting the remedies that Plaintiffs pray for would tie the Commonwealth's hands in facing this public health crisis in ways impossible to determine—even costing lives. Plaintiffs' invitation to the Court to travel down the road full of unforeseen consequences should be declined as too risky for Puerto Rico's population.

¹⁰ The executive orders 20021 062-064 were all published on the Puerto Rico Department of State's website and are available at: <https://www.estado.pr.gov/en/executive-orders/>

WHEREFORE, it is respectfully requested from this Court that this Motion be granted, and that Plaintiffs' claims be dismissed with prejudice.

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed a digital copy of this document with the Clerk of the Court, who will automatically notify of such filing to all parties officially registered in the CM/ECF System.

In San Juan, Puerto Rico, this 16th day of September 2021.

DOMINGO EMANUELLI-HERNÁNDEZ
Secretary of Justice

SUSANA PEÑAGARÍCANO-BROWN
Secretary in Charge of Litigation

IDZA DÍAZ-RIVERA
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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 that 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

pep

I, Juan E. Segarra, USCCI #06-067/translator, certify that the foregoing is a true and accurate translation, to the best of my abilities, of the document in Spanish which I have seen.

CERTIFIED TRANSLATION

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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, 2021 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 plaintiffs² 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



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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 Asociacion 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

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 half** (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).

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:

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- 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.

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.*



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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.

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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

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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

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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, salubrity, 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 L.P.R.A. 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-exempts 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



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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**

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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

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

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

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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

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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”. *Dominguez 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); *Dominguez 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

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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, LPRC 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 LPRC 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 Anavitae, *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

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 LPR 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*.



I, Juan E. Segarra, USCCI #06-067/translator, certify that the foregoing is a true and accurate translation, to the best of my abilities, of the document in Spanish which I have seen.

CERTIFIED TRANSLATION

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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**



I, Juan E. Segarra, USCCI #06-067/translator, certify that the foregoing is a true and accurate translation, to the best of my abilities, of the document in Spanish which I have seen.