UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

TROPICAL CHILL CORP., ET AL., Plaintiffs, v. HON. PEDRO R. PIERLUISI URRUTIA, IN HIS OFFICIAL CAPACITY AS GOVERNOR OF THE COMMONWEALTH OF PUERTO RICO, ET AL., Defendants.	Civil No. 21-1411 (RAM-MEL)

Plaintiffs' Objections to Report & Recommendation

To the Hon. Raul Arias-Marxuach, U.S. Chief District Judge:

The plaintiffs, Tropical Chill Corp. (Tropic Chill), Eliza Llenza, Yasmin Vega, and Rene Matos (collectively, "Plaintiffs") respectfully object to the magistrate judge's report of proposed findings and recommendations (R&R) at ECF No. 103.

Introduction

This is a case about burdens and justifications. The executive orders challenged in this lawsuit burden the Plaintiffs in various ways, and must be justified by some evidentiary basis, beyond the circular assertion that "we must do something; this is something, so we must do it." Plaintiffs acknowledge that the COVID-19 vaccines, developed so rapidly and becoming available more than a year ago, have been a godsend. They generally reduce the severity of the illness and thus prevent much needless human suffering. It is a good thing that Puerto Rico quickly achieved such a high rate of vaccination, which is one of the reasons why our medical system was never threatened with being overcapacity or otherwise incapable of meeting the population's needs. But that doesn't mean that the territorial government is justified in imposing a set of ever-expanding

executive orders that make it harder and harder to live and work on the island, just to cajole and coerce the remaining holdouts—who at this point are largely those with valid religious or medical objections, and largely concentrated among younger populations who we know are (thankfully) less harmed by COVID-19.

In assuming that the Puerto Rico Legislature properly delegated to the governor the power to impose rolling executive orders, the R&R acknowledged that "[t]he grant of power to the Governor must be closely tied to the scientific and factual evidence triggering the state of emergency." R&R at 54. But then, relying on Chief Justice John Roberts's concurrence in *Bay United Pentecostal Church*, it suggested a ruling for the government because "[w]here 'local officials are actively shaping their response to changing facts on the ground' and '[w]hen those officials undertake[] to act in areas fraught with medical and scientific uncertainties, their latitude must be especially broad.'" *Id.* (quoting *S. Bay United Pentecostal Church*, 140 S. Ct. at 1613 (Roberts, C.J., concurring). That reliance was misplaced. Although the able magistrate judge acknowledged that "[w]e now know much more about COVID-19 and the virus that causes it than when *S. Bay Pentecostal Church* was decided in May 2020," R&R at 54, he ignored the significant statistical evidence in the record. He also omitted discussion of subsequent Supreme Court decisions on COVID restrictions, ranging from *Roman Catholic Diocese of Brooklyn v. Cuomo,* 141 S. Ct. 63, 65 (2020), to *Nat'l Fed. of Indep. Bus. v. Dept. of Labor*, 142 S. Ct. 661 (2022). These cases show that jurisprudence must evolve as our understandings evolve; pandemic policies that could be justified in April 2020 may no longer be in August 2021—or now.

The R&R, after all, acknowledged that "a[s] more knowledge is gained about the pandemic, scientific uncertainty may become less of a justification for expansive government powers and the curtailing of rights." R&R at 54. But the incorrect application of that correct premise appears to

have informed the lion's share of the R&R's analysis. For one thing, the R&R neither mentions nor analyzes the implications of Puerto Rico's being the most vaccinated jurisdiction—number one as a percentage of the population—in the U.S. For another, the R&R barely alluded to the collection of scientific studies (including peer-reviewed ones) that Plaintiffs presented—Defendants presented zero studies—demonstrating that vaccines were ineffective in stopping the spread and that natural immunity both lasts longer and provides stronger protection. And although "stopping the spread of the pandemic," *id*. at 40, may be a legitimate and compelling interest Plaintiffs presented abundant evidence showing that compulsory vaccination under pains of losing civil liberties does little, if anything, to stop the spread. The magistrate judge nonetheless agreed—despite copious evidence to the contrary—with the government's unsupported assertions.

If vaccination prevented viral transmission, this Court may wonder, how could the jurisdiction with the most people vaccinated go from the lowest number of cases to the greatest number in just three weeks? [1] The short of it is that COVID variants and mutations are known to evade antibody protection—leading to mass outbreaks in heavily vaccinated populations, including Puerto Rico's—so vaccines cannot really stop the spread. But mandating a vaccine to stop the *spread* of a disease requires evidence that the vaccines will prevent infection or transmission—and not just severe health outcomes, which is certainly a good reason for an individual to choose to get vaccinated if he doesn't already have natural immunity. Not only the empirical data from Puerto

[1] When Regulation 138-A and EO No. 75 were enacted, the Delta variant represented almost all Covid cases. And the vaccines remained effective against hospitalization and death from Delta. But, as explained later, those findings lack force in the wake of Omicron, which, as of January 15, Omicron represented more than 99% of U.S. Covid total cases. CDC, *Variant Proportions*, https://covid.cdc.gov/covid-data-tracker/#variant-proportions (last seen Jan. 20, 2022). On December 13, Puerto Rico confirmed its first case. *See* El Nuevo Día, *Salud confirma el primer caso de ómicron en Puerto Rico (*Dec. 13, 2021*)*,https://www.elnuevodia.com/noticias/locales/notas/salud-confirma-el-primer-caso-de-omicron-en-puerto-rico/. Back then, Puerto Rico was the U.S. jurisdiction with the lowest number of cases per 100k (21.9). *See* CDC, *Data Table for Cumulative Cases per 100k in Last 7 Days*, https://web.archive.org/web/20211214160757/https://covid.cdc.gov/covid-data tracker/#cases_casesper100klast7days; Appendix 1A. But in three weeks, from December 14 to January 4, Puerto Rico became the jurisdiction with the highest number of cases per 100K with 2,192. *See id*. and Appendix 1B.

Rico, but the scientific studies introduced by the Plaintiffs demonstrate that those vaccinated with breakthrough infections are highly contagious and, as explained in Section I-A(1), preliminary data from all over the world indicate that this conclusion is even stronger for Omicron.

At bottom, because vaccination does little to nothing to prevent transmission, the decision of whether to get vaccinated should be personal. And the government simply cannot mandate that all individuals do something to improve their health if that thing has no implications for others' health. In other words, there is no more *public* health justification for a Covid vaccine mandate than for a directive that every Puerto Rican exercise for an hour daily or consume healthy foods. This case, then, is not about whether people should get vaccinated. Nor is it even about the territorial government's power, exercised properly, to mandate vaccination; it is instead about whether the governor can—with the stroke of a pen and without the legislature's input—impose significant burdens that violate religious, economic, and other rights, requiring hundreds of thousands of Americans to undergo a medical procedure as a condition of residing in Puerto Rico. Every burden requires a commensurate justification; Defendants here have not established a justification for the burdens they are imposing.

Standard of Review

Local Rule 72(d) provides that "[a]ny party may object to the magistrate judge's report of proposed findings and recommendations." The objecting party must file "written objections which shall specifically identify the portions of the proposed findings and recommendations to which objection is made and the basis for the objection." For its part, Federal Rule of Civil Procedure 59(a) provides that this Court "must consider timely objections and modify or set aside any part of the order that is contrary to law or clearly erroneous." And Local Rule 72(d) makes it clear that

this Court "shall make a *de novo* determination of those portions to which objection is made and may accept, reject or modify, in whole or in part, the findings or recommendations." *Id.*

This Court "need not normally conduct a new hearing and may consider the record developed before the magistrate judge, making his or her own determination on the basis of that record." *Id.* It, however, "may also receive additional evidence, recall witnesses or remand the matter to the magistrate judge with instructions." *Id.* Although Plaintiffs have introduced all the evidence necessary for this Court to rule in their favor, they are ready to help it in any way to resolve disputed findings of fact or conclusions of law.

I. Objections to Findings of Fact

A. Scientific Evidence and Statistics

1. Vaccine Effectiveness in preventing transmission

Common sense dictates that mandating a vaccine to stop the *spread* of a disease requires *scientific and factual* evidence (R&R at 54) that it will *prevent* infection or transmission, *see id.* at 59-60. As the World Health Organization has said, "if mandatory vaccination is considered necessary to interrupt transmission chains and prevent harm to others, there should be sufficient evidence that the vaccine is efficacious in preventing serious infection and/or transmission." WHO, *COVID-19 and mandatory vaccination: Ethical considerations and caveats* (Apr. 13, 2021), https://apps.who.int/iris/handle/10665/340841. No such evidence exists for the Delta variant, let alone Omicron.

Ironically, the R&R, when referring to "compelling interest in preventing increasing spread of the COVID-19 virus" (R&R at 39) made no mention of the unfortunate fact—of which the Court could have taken judicial knowledge, *see* note 2, below and ECF No. 83 at 2 (citing caselaw on that point)— that, in the wake of Omicron, the vaccine's effectiveness against symptomatic disease

has plummeted even more than with Delta. With Omicron, the spread of Covid in Puerto Rico, the most vaccinated U.S. jurisdiction, was the most significant of any State. Puerto Rico went from the least number of cases per 100,000 to the most in just three weeks. *See* note 1, above.[2] Repeated exposure to the virus—which, as per Dr. Fauci, "virtually everybody is going to wind up getting exposed and likely get infected"—is inevitable. The Hill, *Fauci: Omicron will infect 'just about everybody'* (Jan. 12, 2022), https://thehill.com/policy/healthcare/589344-fauci-omicron-will-infect-just-about-everybody. Over time and as new variants develop, and with vaccine efficacy this low and dwindling, infection is virtually guaranteed. The foregoing lends credence to Dr. Hay's testimony that "Omicron which just popped up all over the world in a matter of days, despite masks, despite vaccination, despite social distancing, despite lockdowns… because as the FDA says, the vaccines don't stop it." ECF No. 106 at 74: 2-6. Indeed, during the apogee of Delta's spread, the CDC had already reported, through its August 6, 2021 Barnstable County study, that 74% of cases had "occurred in fully vaccinated persons." ECF No. 7 at 15 (citing https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm). Vaccination, then, while reducing the risk of death, does little to slow onward transmission. The moment vaccine-related immunity plunges like this, the government's theory of justification for its mandates and accompanying burdens collapses.[3]

[2]"Although the COVID-19 vaccines remain effective at preventing severe illness, they provide comparatively little protection against Omicron infection. *United States v. Brunetti*, 2022 WL 92753, at *4 (S.D.N.Y. Jan. 10, 2022) (collecting sources). Thus, Omicron's "ability to evade vaccine-related immunity has resulted in an exponential increase in "breakthrough" infections in vaccinated individuals." *Id.* (citation omitted); *United States v. Hernando Rodriguez*, 2022 WL 158685, at *3 (S.D.N.Y. Jan. 18, 2022) ("Rodriguez received both doses of a COVID vaccine . . . and his vaccination status surely reduces his risk of extreme illness from COVID. However, as the new variant has demonstrated, being vaccinated does not guarantee protection against COVID.").

[3] This conclusion has an added force with Omicron variant, as it "contains more changes in the spike protein than have been observed in other variants, . . . which may indicate reduced protection from infection, are anticipated." CDC, *Science Brief: Omicron (B.1.1.529) Variant* (Dec. 2, 2021), https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/scientific-brief-omicron-variant.html. The African Health Research Institute showed how with Omicron, there was "much more extensive escape" from vaccine-related immunity than the already "3-fold

It bears repeating that Defendants introduced no evidence and no data—other than conclusory testimony without any scientific studies to support it—to show that the vaccinated are at a substantially lower risk of spreading the disease. Ignoring this backdrop, the R&R states in a conclusory fashion that "[b]ecause unvaccinated persons pose a heightened risk of infection, the government of Puerto Rico has an interest in preventing unvaccinated individuals from entering high-risk locations without proof of a negative test or a COVID-19 infection within the last three months." R&R at 38-39. But again, Defendants' experts failed to marshal any scientific studies to support that. But they did provide evidence that contradicted the R&R's finding. During Dr. Irizarry's testimony, Defendants introduced Exhibit H, which is a graph "showing us the seven-day moving average for detected cases" in Puerto Rico. ECF No. 108 at 22: 17-18. Dr. Irizarry addressed the Delta-driven surge by saying that "the final wave starting on July – end of June 2021 and then the exponential growth ending around August 15th." What he failed to mention is that, during that period, Puerto Rico was sixth among the States with approximately "69.6% of eligible recipients . . . fully vaccinated and 78.4% . . . [with] at least one dose." ECF No. 1 at 4.

The upshot is that Dr. Irizarry's testimony lends credence and provided empirical data to the inescapable conclusion drawn from the multiple scientific studies presented by Plaintiffs and their experts: "vaccination is not sufficient to prevent transmission of the delta variant" ECF No. 103-1 at 385 and "vaccinated persons who become infected with SARS-CoV-2 [are] no less infectious than unvaccinated persons." *Id.* at 309: 56-57. This belies the statement that a "vaccinated person's viral load decreases more rapidly after they contract the virus, making them less likely to spread

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reduction" in vaccine-related immunity with Beta (Dec. 29, 2020), AHRI, *SARS-CoV-2 Omicron has extensive but incomplete escape of Pfizer BNT162b2 elicited neutralization and requires ACE2 for infection* (Dec. 17, 2021), https://www.ahri.org/wp-content/uploads/2021/12/MEDRXIV-2021-267417v1-Sigal.pdf. Put differently, "the omicron variant shows an unprecedented degree of neutralizing antibody escape." NEJM, *Plasma Neutralization of the SARS-CoV-2 Omicron Variant* (Dec. 20, 2021), https://www.nejm.org/doi/full/10.1056/NEJMc2119641

the virus," R&R at 38, as well as Defendants' claim that "unvaccinated persons pose a heightened risk of infection." *Id.* at 38-39. Thus, the R&R's finding that "the specific policies being questioned in this case are rationally related to the compelling government interest of stopping the spread of the pandemic…," *Id.* at 40, was a mistake.

More to the point, Plaintiffs' expert testimony from Dr. Hay established that "the vaccines do not stop transmission," so they "will not and they're not FDA approved to reduce the transmission, particularly Delta or Omicron." ECF No. 106 at 64: 7-9. Dr. Hay further testified that "the FDA is correct when they labeled those vaccines as reducing hospitalizations and deaths." *Id.* at 82:3-5. Even before Omicron, which the CDC now recognizes as creating a heightened risk of infection among vaccinated people, Plaintiffs provided multiple studies supporting Dr. Hay's testimony that were not even mentioned in the R&R.[4] Plaintiffs showed precisely how "arbitrary and far beyond reasonably required" the government's mandates are. As recent data in Puerto Rico reveals, Dr. Marzan herself, Puerto Rico's chief epidemiologist, testified that "thanks to the multiple strategies that are being implemented for prevention, we've come back down to a moderate level of transmission over the past two and half months and when you look at other jurisdictions where the Delta variant is also predominant, there has been a high or a substantial level of community transmission levels." ECF No. 113 at 47: 29-24. But with Omicron and including "the multiple strategies" that had been implemented, by January 4, 2022—two weeks before the R&R—Puerto

[4] A study published *after* the evidentiary hearing but *before* the R&R concluded that, "[a]mong 70,983 infected individuals (age ≥ 12 years)", there was a "a 30-40-fold reduction in the neutralization of the Omicron variant with convalescent sera or sera of fully vaccinated individuals." It added that the "results suggest a large reduction in protection against SARS-CoV-2 infection with the Omicron variant compared to the Delta variant after full vaccination." medRxiv, *Increased risk of infection with SARS-CoV-2 Omicron compared to Delta in vaccinated and previously infected individuals, the Netherlands, 22 November to 19 December 2021* (Dec. 21, 2021), https://www.medrxiv.org/content/10.1101/2021.12.20.21268121v1.full.pdf

Rico had become higher in cumulative cases per 100K than any State.[5] The high rate of vaccination, let alone the ever-stricter vaccination mandates imposed by the executive order, didn't help stop the spread at all.

It thus follows that the R&R incorrectly concluded that "at this point, the threat of COVID-19 presents an unacceptable risk to human life and presents a risk of overwhelming the health system in Puerto Rico." *Id.* The facts are that "at this point" there are two years of knowledge, with 94.4% of the 5+ years-old population in Puerto Rico with one vaccine dose and an astounding 84.3% fully vaccinated. Moreover, 87.5% of the 65+ years-old population (the most vulnerable group) is fully vaccinated, plus an estimated 5% of the population cannot be vaccinated for medical or religious reasons (ECF No. 113 at 58: 14-22), and an estimated 30%-50% of the total population has natural immunity (ECF No. 106 at 159: 13-16). And in addition to vaccines' preventing of hospitalizations and deaths, we now have FDA-approved treatments, such as monoclonal antibodies and oral antivirals, not to mention free FDA-authorized at-home tests. We're in a very different situation than we were in a year ago, or even half a year ago when the first executive orders went into effect. And as explained in Subsection 5 below, the hospital capacity—as Exhibit 11 shows, even when the cases with Omicron have quadrupled what they were with the previous highest surge—has never exceeded 60% (Appendix 2).[6] As fully discussed later, contrary to the

[5] *See* CDC, *Data Table for Cumulative Cases per 100k in Last 7 Days* (Jan. 4, 2022), https://web.archive.org/web/20220105150126/https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days and Appendix 1B.

[6] COVID-19 Dashboard, *Vacunación*, https://covid19datos.salud.gov.pr/#vacunacion, CDC, *Data Table for COVID-19 Vaccinations in the United States*, https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-fully-percent-pop65, FDA, *Know Your Treatment Options for COVID-19* (Jan. 21, 2022), https://www.fda.gov/consumers/consumer-updates/know-your-treatment-options-covid-19, FDA, *FDA Takes Actions to Expand Use of Treatment for Outpatients with Mild-to-Moderate COVID-19* (Jan. 21, 2022), https://www.fda.gov/news-events/press-announcements/fda-takes-actions-expand-use-treatment-outpatients-mild-moderate-covid-19, The White House, *Fact Sheet: The Biden Administration to Begin Distributing At-Home, Rapid COVID-19 Tests to Americans for Free* (Jan.14, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/14/fact-sheet-the-biden-administration-to-begin-distributing-at-home-rapid-covid-19-tests-to-

R&R's conclusion, there is neither "an unacceptable risk to human life" nor "a risk of overwhelming the health system in Puerto Rico." R&R at 61

The R&R of course had to concede the obvious: that "over time, the SARS-CoV-2 virus may become less lethal, especially as vaccination increases, new treatments are developed, and the virus mutates." *Id.* "As the virus becomes less likely to overwhelm the capacities of public health, whether that be from natural evolution, vaccination, or natural immunity, or new treatments," the magistrate judge reasoned, "the lines balancing the equities and supporting the public interest may have to be redrawn." *Id.* "Such a future," it argued, "is what science, public health, and the patience of residents of Puerto Rico have striven to achieve." *Id*. But Puerto Rico Health Department data—in alignment with what the WHO, CDC, FDA, and the scientific community have already said—demonstrates that "such a future" is already here.

The R&R bought the government's unsupported argument that the "correlation between positive cases and adverse health outcomes" has remained. R&R at 36. And that "continued growth of positive cases will result in more hospitalizations, ICU referrals, and deaths." R&R at 60. But that is not what the evidence shows. Exhibit 59 shows lower levels in hospitalization with every new surge trigger, ECF 103-1 at 373, even without considering the total amount of cases per surge, as shown in Exhibit 53 and Exhibit H. ECF 103-1 at 361, ECF No. 103-2 at 35.

With Omicron, the fourth variant of concern creating a surge in cases, Puerto Rico has had significantly fewer hospitalizations and mortality relative to total cases. This is evidence of the high levels of vaccination, the FDA treatments authorized, and less-deadly mutations (*see* discussion of Farr's Law, below). Looking at the data, the Omicron surge, which has already

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americans-for-free/, COVID-19 Dashboard, *Sistema de Salud (Historico)*, https://covid19datos.salud.gov.pr/#sistemas_salud.

vanished, had approximately 264,138 cases from December 14, 2021, through January 28, 2022. *See* COVID-19 Dashboard *(Casos, Acumulado)*, https://covid19datos.salud.gov.pr/#casos. That represents 5,869 cases per day, which is nine or ten times more cases per day than in any of the previous three surges as shown in Exhibit 53 (Beta (607/day), Alpha (658/day), or Delta (578/day)). ECF No. 103-1 at 361. And there have been a total of 2,810 hospitalizations (most of which were hospitalized for other reasons) for that same period, meaning the hospitalization rate for Omicron is 1.0%. *See* CDC, *New Admissions of Patients with Confirmed COVID-19, Puerto Rico* (Aug 01, 2020 – Jan 28, 2021), https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions. With Omicron, and as Plaintiffs' Exhibit 59 makes clear, there are three to thirteen times fewer hospitalizations than in any of the previous three surges (Beta (13.1%), Alpha (4.8%), or Delta (3.6%)). *Id.* at 373. The same dynamics play out as to the mortality rate, with Omicron, the mortality rate is at 0.2%. *See* COVID-19 Dashboard, *(Defunciones, Acumulado)*, https://covid19datos.salud.gov.pr/#defunciones. That is four to nine times less than in any of the previous three surges (Beta (1.7%), Alpha (0.8%), or Delta (1.5%)), as shown in Exhibit 13. *Id.* at 25.[7] And this data does not consider that, as demonstrated in sub-section 5, with Omicron, most of the hospitalizations reported as "for Covid" are actually hospitalizations of patients that were admitted for other reasons and just happened to test positive after admission, with no COVID symptoms ("with COVID"). In short, the evidence in the record shows that vaccinated people can not only contract COVID-19 but also spread the virus, so a government focusing on vaccination to slow the spread is indeed "arbitrary and far beyond reasonably required." R&R at 40.

[7]Beta variant surge was from Oct. 1, 2020 to Jan. 1, 2021 (92 days), in that period it has a total of 55,843 cases, a total of 7,314 new admissions of patients with confirmed COVID-19, and 967 deaths related to Covid. Alpha variant surge was from March 20 to May 5, 2021 (46 days), in that period it has a total of 30,285 cases, a total of 1,444 new admissions, and 262 deaths related to Covid. Delta variant surge was from July 20 to Sept. 25, 2021 (45 days), in that period it has a total of 38,740 cases, a total of 1,390 new admissions of patients with confirmed COVID-19, and 581 deaths related to Covid. *See* sources just discussed.

2. Covid transmission rates as between vaccinated and unvaccinated are indistinguishable.

Omitting any mention of the scientific studies that Plaintiffs introduced, the R&R credited Dr. Marzan's statement—using a chart created from raw and unexplained data collected from the Puerto Rico Health Department database—that "showed that unvaccinated persons were 2.49 times more likely to contract COVID-19 than an unvaccinated person in August 2021—at the height of the Delta variant spike." *Id.* at 34 (citing Exhibit D at 1). And according to Dr. Irizarry, "the risk for unvaccinated people to contract COVID-19 is more than 10 times higher compared to a person who was vaccinated." *Id.* Thus, the argument goes, "unvaccinated people are much more likely to be infected and hospitalized because of COVID-19." *Id* at 35. But neither Dr. Marzan nor Dr. Irizarry presented any observational or scientific studies to that effect. The only data presented by the Defendants, Exhibit D, is that chart that includes cases per 100,000 per month (July through November) in Puerto Rico between the groups of unvaccinated and vaccinated. ECF No. 103-2 at 19. But chance is not correlation and correlation is not causation. To graph raw data (cases per 100,000) from two cohorts (unvaccinated and vaccinated) and compare it without factoring in that multiple EOs specifically require the unvaccinated to be tested—which obviously increases the probability of having more cases within that cohort—is bad statistical analysis. To determine if one cohort is "more likely to be infected" than the other, aside from controlling confounding variables and other externalities, you need to look at the positivity rate (total positive cases divided by total tests performed) per cohort. The total number of people that were tested within each cohort must be considered—to weed out the fact that one cohort was forced by several EOs to be tested significantly more frequent than the other.

The magistrate judge acknowledged the Plaintiffs' argument that the "unvaccinated and vaccinated persons transmit COVID-19 equally because the viral load of vaccinated and

unvaccinated people infected with COVID-19 is similar and 'viral load is the most significant factor' in the ability for a person to infect." R&R at 33 (quoting ECF No. 7 at 15). That conclusion was clearly echoed by the CDC Director last summer: "Delta infection resulted in similarly high SARS-CoV-2 viral loads in vaccinated and unvaccinated people. High viral loads suggest an increased risk of transmission and raised concern that, unlike with other variants, vaccinated people infected with Delta can transmit the virus."[8] The R&R grapples with this logical problem by questioning one of the studies the Plaintiffs presented (Exhibit 52) showing that vaccinated and unvaccinated people transmit the virus equally for the same period. It questioned "the utility of the study for society as a whole," because, as Dr. Carrascal explained, it examined "a contained place that is closed and the people are very together, like in a prison." *Id.* (citation omitted). But Dr. Carrascal when referring to this study, Exhibit 52, was answering the question from Plaintiffs' counsel about whether vaccinated individuals transmit less Covid-19 than the unvaccinated, to which she then replied, "in my clinical experience when I see the patients, they are the same". Tr. Carrascal, ECF No. 133 at 89: 2-11. She explained that the prison study describes that "the population that is vaccinated and comparing with the population that is not vaccinated, they are both transmissible, and if they mention that is usually like thirteen days of transmission. So, you have to [have] the same caution with everyone in the population." *Id*. at 90: 4-8. The study, which concluded that "vaccinated persons who become infected with SARS-CoV-2 to be no less infectious than unvaccinated persons," ECF No. 103-1 at 309: 56-57, looked at "RT-PCR positivity and viral culture positivity," which is not dependent on the location or context of the

[8]CDC, *Statement from CDC Director Rochelle P. Walensky, MD, MPH on Today's MMWR* (July 30, 2021), https://www.cdc.gov/media/releases/2021/s0730-mmwr-covid-19.html. If more were needed, Director Walensky said that the viral load in the noses and throats of vaccinated people infected with Delta is "indistinguishable" from that of unvaccinated people, and "what [the vaccines] can't do anymore is prevent transmission." CNN, *Fully vaccinated people who get a Covid-19 breakthrough infection can transmit the virus, CDC chief says,* (Aug. 6, 2021), https://edition.cnn.com/2021/08/05/health/us-coronavirus-thursday/index.html (last seen Jan. 20, 2022).

individual. That is perhaps why nowhere in this study did the CDC COVID-19 Response Team, who performed it, mentioned anything about limitations to the study due to being conducted in a "contained place." The R&R on its own reached an unscientific conclusion by relying on a mischaracterization and a selected portion of testimony from Dr. Carrascal.[9] At any rate, the R&R also failed to consider that people in a restaurant are also in a "contained place."

To support its findings, the R&R also relied on Dr. Bostom's testimony that those "vaccinated may have a short period of time at peak vaccination where their ability to spread the COVID-19 virus may be less than an unvaccinated person." R&R at 33. But Dr. Bostom was referring to an early study before knowledge of the vaccine waning and the Delta variant—i.e., the Pfizer and Moderna MRA trials.[10] Still, he clarified that any vaccination advantage regarding transmission was for a "short period of time at peak vaccination," *id.*, which later Dr. Marzan confirmed that the "difference in declines rate would be less than two days" between the vaccinated and unvaccinated. ECF No. 113 at 84: 25, 85: 1-2 and that "there are studies that reflect that there's actually no difference in the time." *Id.* at 86: 15-19. In other words, if there is a rational basis for any government action, it is to require testing for both the vaccinated and non-vaccinated. But the government's aim is to coerce people to get vaccinated by restricting civil liberties upon a minority of individuals by not letting them participate in normal daily activities such as eating at restaurants. The EOs, as Defendant Pierluisi act "as a deterrent, because I know it's not easy to get proof, I admit that. They may have to stand in line for quite a while and on the other hand, they may have to pay for it." Telemundo, *"Es un disuasivo": Dice Pierluisi sobre prueba negativa para eventos*

[9] This study, which is discussed below, was conducted by the CDC COVID-19 Response Team and assessed "[d]uring a SARS-CoV-2 Delta variant outbreak", the "viral shedding in vaccinated and unvaccinated persons." ECF No. 103-1 at 309: 39-41. By measuring the "[d]uration of RT-PCR positivity and viral culture positivity" in "persons with confirmed SARS-CoV-2 infection". *Id.* at 309: 46-47.

[10] Available at https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.full-text.

multitudinarios: (Jan. 5, 2022), https://www.telemundopr.com/noticias/puerto-rico/es-un-disuasivo-dice-pierluisi-sobre-prueba-negativa-para-eventos-multitudinarios/2294560/ (last seen Feb. 10, 2022) (translation added).

The R&R also failed to consider Dr. Marzan's testimony on viral load. When questioned whether "studies show that, at least with Delta, unvaccinated and vaccinated individuals have a similar peak of viral load," she replied that "Yes, the difference being that . . . the viral load in the vaccinated individuals goes down after seven or eight days, while in the unvaccinated individuals it takes more days to decrease." ECF No. 113 at 81: 14-17,25–82: 1-2. When she was asked for support for that statement, she referred to "data from Puerto Rico and I've already presented the different perspectives with data that is reported from Puerto Rico and the attack rate." *Id.* at 82: 8-11. But no such data was presented as an exhibit, nor did she offer any explanations. And when asked for any "study published in Puerto Rico studying viral loads between vaccinated individuals and unvaccinated individuals," Dr. Marzan answered, "of viral load, no." *Id.* at 82: 12-15. Plaintiffs' counsel then presented to Dr. Marzan an October 28, 2021 peer-reviewed study (Exhibit 62) regarding transmission in viral load kinetics of the Delta variant, ECF No. 103-1 at 383, and asked if she agreed that "if what the study is saying is true, then the difference in declines rate would be less than two days" between the vaccinated and unvaccinated. She responded in the affirmative. ECF No. 113 at 84: 24-25, 85: 1-2. She further recognized that "there are studies that reflect that there's actually no difference in the time, in the decline rates of viral shedding between vaccinated and unvaccinated people"—and went on to testify that "this occurs very frequently in science and data is received and is evaluated in accordance with the limitations of the designer of each study." *Id.* at 86: 15-22. But of course, the CDC has recognized what the scientific studies have said since the beginning of the pandemic: that the virus is "most infectious a few days before

and after symptom onset." ECF. No. 65-1 at 9-10.[11] If in fact viral load in "the vaccinated individuals goes down after seven or eight days," as Dr. Marzan testified, ECF No. 113 at 81: 14-17,25; 82: 1-2, and "transmission occurs early in the course of illness, generally in the 1-2 days prior to onset of symptoms and the 2-3 days after," *id.,* as the CDC has confirmed, then there is no significant difference in the transmissibility of vaccinated and unvaccinated people, *regardless of when viral load starts decreasing*. The R&R missed this point.

Nor did the R&R mention that Dr. Bostom testified about the CDC COVID-19 Response Team study, Exhibit 52, and how that study shows that "prevention and mitigation measures should be applied without regard to vaccination status for persons in high-risk settings or those with significant exposures" ECF No. 103-1 at 333. The R&R ultimately relies on the wrong premise, that "a vaccinated person's viral load decreases more rapidly after they contract the virus," R&R at 38, even though Dr. Marzan confirmed that the "difference in declines rate would be less than two days," ECF No. 113 at 84: 25, 86: 1-2, and that "there are studies that reflect that there's actually no difference in the time" *Id.* at 86: 15-19. On the contrary, the CDC COVID-19 Response Team study presented "one of the first longitudinal investigations of viral shedding from vaccinated persons infected with the Delta variant." ECF No. 103-1 at 311-312. The study states that when assessing "the markers of viral shedding in vaccinated and unvaccinated persons" there was "[n]o significant differences in time to last RT-PCR positive test was found." It continued

[11] On April 15, 2020, one of the first peer-reviewed study published regarding the transmissibility of COVID-19, concluded that viral shedding of patients with COVID-19 "peaked on or before symptom onset". Nature Medicine, *Temporal dynamics in viral shedding and transmissibility of COVID-19* (Apr. 15, 2020), https://www.nature.com/articles/s41591-020-0869-5. On August 23, 2021, a peer-reviewed study from the Journal of the American Medical Association concluded that "contacts were at highest risk of COVID-19 if they were exposed between 2 days before and 3 days after the index patient's symptom onset, peaking at day 0". ECF No. 63-1 at 9-10. And the CDC has said that "the majority of SARS-CoV-2 transmission occurs early in the course of illness, generally in the 1-2 days prior to onset of symptoms and the 2-3 days after." "*CDC Updates and Shortens Recommended Isolation and Quarantine Period for General Population*" (Dec. 27, 2021), https://www.cdc.gov/media/releases/2021/s1227-isolation-quarantine-guidance.html.

saying that "no significant differences were detected in duration of RT-PCR positivity among fully vaccinated participants versus those not fully vaccinated, or in duration of culture positivity." *Id.* at 309. The R&R is thus wrong to conclude that a vaccinated person is "less likely to spread the virus" and as such "provide[ed] some heightened level of protection, albeit temporarily, against spreading the COVID-19 virus." RR at 38. Indeed, the study just discussed (Exhibit 52) contradicts it: "clinicians and public health practitioners should consider vaccinated persons who become infected with SARS-CoV-2 to be no less infectious than unvaccinated persons." ECF No. 103-1 at 309: 56-57. Moreover, as to the claims of Mr. Matos and Ms. Llenza, the CDC study indicates that "prevention and mitigation measures should be applied without regard to vaccination status for persons in high-risk settings or those with significant exposures." *Id.* at 333. Again, not only does the R&R's conclusion lack any evidence—other than conclusory testimony from the defendants' representatives unsupported by any scientific study—but the evidence on the record directly contradicts its premise.

The R&R also omitted any discussion of the October 28, 2021 prospective, longitudinal, cohort study out of the UK, Exhibit 62, which "aimed to investigate transmission and viral load kinetics in vaccinated and unvaccinated individuals with mild delta variant infection in the community." ECF No. 103-1 at 383. That study found that "SAR among household contacts exposed to fully vaccinated index cases was similar to household contacts exposed to unvaccinated index cases," that "peak viral load did not differ by vaccination status or variant type," and that vaccinated individuals "can efficiently transmit infection in household settings, including to fully vaccinated contacts." *Id.*

Ignoring these studies, the R&R nonetheless credited Dr. Cardona's statement that "after the first four days, the viral load decreases faster in vaccinated individuals, which means that the

unvaccinated can transmit the virus for a longer period of time." R&R at 34. Of course, Dr. Cardona did not support that statement with any scientific study. The R&R similarly credited Dr. Marzán's unsupported statement that "viral load is the most important factor in transmitting the COVID-19 virus, but that the viral load in vaccinated people decreases more quickly than those who are not vaccinated." *Id.* Like Dr. Cardona, however, Dr. Marzan invoked no scientific study to support her *ipse dixit*. Indeed, Defendants introduced no published observational studies or any other sort of scientifically sound study with their experts. Accordingly, this Court should reject Dr. Marzan's conclusions, which may have been true as to the variants *before* Delta, but which are now obsolete regardless of their applicability to the two previous variants of concerns.

In an effort to soften the bite of this reasoning, the R&R attempts to undermine Dr. Carrascal's testimony, because she "went so far as to suggest that immunity for COVID-19, like immunity for measles and chickenpox, lasts for the entirety of a person's life after they were infected." R&R at 41. "Such an assertion," the R&R reasoned, "lacks credibility in light of the other evidence, and Dr. Carrascal herself admitted that antibodies for COVID-19 decrease in a person over time." *Id.* But Dr. Carrascal was referring to "immunity for COVID-19" obtained from being infected with the virus (natural immunity), not COVID-19 vaccine-induced antibodies. Her testimony was taken out of context. In fact, as the peer-reviewed study from the *New England Journal of Medicine* (Exhibit 49) says, "published work about many vaccines, such as those against measles, mumps, and rubella, has shown a small decrease each year of 5 to 10% in the neutralizing antibody levels." ECF No. 103-1 at 285. But that "antibody levels decrease only modestly at 8 to 10 months after the infection. This striking difference in antibody kinetics between convalescent persons and vaccinated persons may be the reason for the substantially lower incidence of breakthrough infection among previously infected persons than among vaccinated persons." *Id.* In other words,

natural immunity provides stronger protection against reinfection than vaccination. And in fact, vaccine-induced immunity does decrease as the study said, "[w]e found that a significant and rapid decrease in humoral response to the BNT162b2 vaccine was observed within months after vaccination." *Id.* The study presented during Dr. Carrascal's testimony (Exhibit 51) showed that "long-lived bone marrow plasma cells (BMPCs) are a persistent and essential source of protective antibodies." *Id.* at 291.

Defendants' experts relied on their own raw data with no accompanying documented observational analysis or methodology used —let alone any other published study related to it— to support their analysis. They failed to demonstrate that their opinions were based on fundamental observational or scientific analysis practices, such as type of trials performed (randomized or not), cofounding variables considered, characteristics of each cohort (age groups, comorbidities, natural immunity), and methods used (including under variants of concern).

In sum, Defendants presented not a single scientific study to support their experts' conclusions. Plaintiffs, by contrast, presented a vast number of published scientific studies from reliable sources, including the CDC, with some already peer reviewed. The R&R nevertheless managed to conclude that "unvaccinated persons pose a heightened risk of infection." R&R at 38-39. But because the record is barren of any proof for that assertion, it erred in doing so.[12]

3. Natural Immunity

The R&R acknowledges that "Plaintiffs continually sought to introduce evidence that natural immunity is as robust and long lasting as vaccine induced immunity or better." R&R at 41. Indeed,

[12] Ironically, several concerts, super-spreader events for the vaccinated—the unvaccinated couldn't attend—were the catalyst for the dramatic Omicron surge that began in Puerto Rico right after the evidentiary hearing, such as the Bad Bunny Concert, which was available only for the vaccinated population and triggered thousands of cases across the island. Even the CDC has said that because "the Omicron variant likely will spread more easily than the original SARS-CoV-2 virus . . . [it] expects that anyone with Omicron infection can spread the virus to others, even if they are vaccinated or don't have symptoms." CDC, *Omicron Variant: What You Need to Know (Spread, We Have The Tools to Fight Omicron)* (Dec. 20, 2021), https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html.

Plaintiffs' experts introduced five recent scientific studies, two of them including the Delta variant, demonstrating that natural immunity provides longer and more robust protection than the vaccine. The R&R ignores those studies. By contrast, when the magistrate judge asked Dr. Cardona if "the scientific or medical data make a distinction among those who are unvaccinated but already had Covid-19 and those who have not had Covid-19," she responded, "There are some publications which make the distinction, I don't recall any at this time." ECF No. 109 at 20: 5-10. Dr. Marzan, the chief epidemiologist of Puerto Rico, when asked by Plaintiffs' counsel about studies concluding that the Covid vaccination is stronger and longer lasting than natural immunity, said that "I've seen both. I've seen some that say yes and others say it's the same as having had the infection." But then, when asked if she could "identify one [natural immunity study] that's saying that the vaccine is stronger and longer lasting," Dr. Marzan replied that she was "not able to provide . . . a particular name or article." ECF No. 113 at 86: 24-25, 87: 1-7.

Instead, Dr. Cardona, who is not an epidemiologist, upon further questions from the magistrate judge, alluded to a single CDC study,[13] "Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May-June 2021." ECF No. 109 at 131: 19-20. But that study does not weaken the Plaintiffs' position, which is why they introduced it (as Exhibit 63) during Dr. Marzan's cross. Dr. Marzan confirmed that the study is making a comparison "between people who already had a Covid infection and within that pool, people who got vaccinated and who did not get vaccinated." ECF No. 113 at 87: 22-25, 88: 1; *see also* ECF No. 103-1 at 409 (same). At any rate, that study looked at "persons previously infected with SARS-CoV-2 in 2020," *id.*, that is, pre-Delta infections.

[13]Dr. Cardona also cited the following study which does not even mention natural immunity: Reduced Incidence of Long-COVID Symptoms Related to Administration of COVID-19 Vaccines Both Before COVID-19 Diagnosis and Up to 12 Weeks After | medRxiv. ECF No 109 at 131; 21-22.

The R&R also acknowledges that Dr. Cardona "testified that it is not yet clear how long natural immunity from COVID-19 infection actually lasts, and that it could last as long as 13 months." R&R at 41. But then it credited the testimonies of Doctors Cardona, Marzán, and Irizarry "that there are documented cases of persons who contracted COVID-19 becoming reinfected with COVID-19 after 90 days." *Id.* at 42. But then again, their experts failed to provide any evidence on that front. Nor did they furnish any published scientific studies or any data they may have, as evidence, properly documented and analyzed where a cohort is defined, a description of the methods used is included, and so forth. Dr. Marzan, testified that "based on the data [she] daily evaluate[s]," the unvaccinated were at greater risk of infection than the vaccinated. Then, when the magistrate judge asked her whether "an unvaccinated person who has had Covid-19 in the past is at a higher risk of contagion than somebody who has never had Covid but is vaccinated," she answered that "when we perform the analysis, we refer to a person who has not been infected with Covid-19 in the past 90 days and who does not have a history of vaccination" ECF No. 113 at 26: 3-19. Further, in the context of death rates, the magistrate judge asked Dr. Marzan whether the Health Department has ever analyzed the difference between those who have had COVID-19 but remain unvaccinated and those who are vaccinated. And she replied in the negative: "because for us an unvaccinated person is a person who has received no dose of vaccine regardless of whether the person had the infection or not." *Id.* at 32:15-21.

The R&R also added that "the testifying experts agreed that a vaccinated person's protection wanes six months after being vaccinated. However, Dr. Cardona clarified that although vaccine protection from infection wanes after six months, the protection against hospitalization and death remained high." R&R at 35. But she failed to provide any scientific evidence to that effect, not least because that statement is scientifically incorrect. The waning of the vaccines'

immunity, as explained by Dr. Bostom, "tends to wane over time particularly when the wane is fairly acutely with the vaccines, they confer a fairly narrow spectrum of immunity." ECF No. 106 at 145: 12-14. He explained that the study (Exhibit 46) showed that "in those who were vaccinated versus those who were not vaccinated but had a prior infection[,] there was an eight-fold increase risk for hospitalization." *Id.* at 146: 20-24; *see also* ECF No. 103-1 at 174-175 (same).

The foregoing colloquy demonstrates that the Defendants lack any data collected or analyzed regarding the strength of natural immunity. As Dr. Bostom emphasized multiple times in his testimony, "if you're simply trying to compare the vaccinated and the unvaccinated or the fully vaccinated and the partially vaccinated plus the unvaccinated pool, you're missing a lot of information, critical information without knowing whether they had a history of prior infection." ECF No. 106 at 153: 23-25, 154: 1-2.

In contrast to the Defendants' experts' complete discounting of natural immunity, Plaintiffs' expert witnesses testified about five different scientific studies. The first one (Exhibit 17) was the most recent study. According to the authors, this study "reports the longest real-world follow-up time from primary infection to date" and evaluates the "vaccine effectiveness (VE) (up to 10-months after first dose) and infection-acquired immunity by comparing time to PCR-confirmed infection in vaccinated and unvaccinated individuals." ECF No. 103-1 at 55, 37. "There's more recent data from healthcare workers in the UK." ECF No. 106 at 147: 19-20. As Dr. Bostom testified, that means that "having a previous infection and not being vaccinated, if you're a healthcare worker . . . . There was really no benefit to vaccinating those people that they could demonstrate and certainly compared to vaccinated but infection naive people, they did at least as well." *Id.* at 147: 23-25, 148: 1-4. The study recognizes that it "remains unclear how long immune

protection will last after previous infection due to the limited length of follow-up period, however modelling has suggested that protection could last for up to 61 months." ECF No. 103-1 at 55.[14]

The second study (Exhibit 46) is the "largest real-world observational study comparing natural immunity, gained through previous SARS-CoV-2 infection, to vaccine-induced immunity, afforded by the BNT162b2 mRNA vaccine." ECF No. 103-1 at 187. Dr. Bostom testified that this study showed a "thirteen-fold increase risk for asymptomatic infection, just testing positive again in or testing positive period in those who were vaccinated versus those who were not vaccinated but had a prior infection and there was a twenty-seven fold increase risk for clinical or symptomatic infection and an eight fold increase risk for hospitalization." ECF No. 106 at 146: 18-24; *see also* ECF No. 103-1 at 174-175 (same). The study concludes by saying that "natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity." ECF No. 103-1 at 175.

The third study, Exhibit 47, is the most direct scientific study investigating whether those previously infected with COVID-19 should still get vaccinated. It concludes that "those previously infected who did not receive the vaccine did not have higher rates of SARS-CoV-2 infection than those previously infected who did, thereby providing direct evidence that vaccination does not add protection to those who were previously infected." ECF No. 103-1 at 225.The fourth study, Exhibit

[14] Coincidentally, that study happens to now be referenced by the recent CDC MMW Report published January 19, 2022, which presents new data showing that during the Delta wave, prior infection offered five times stronger protection against infection and three times stronger protection against hospitalization from Covid-19 than vaccination". This new report actually recognized many of the studies presented: "the understanding and epidemiology of COVID-19 has shifted substantially over time with the emergence and circulation of new SARS-CoV-2 variants, introduction of vaccines, and changing immunity as a result…As was observed in the present study after July, recent international studies have also demonstrated increased protection in persons with previous infection, with or without vaccination, relative to vaccination alone. This might be due to differential stimulation of the immune response by either exposure type." CDC, MMWR, *COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis — California and New York, May–November 2021* (Jan. 19, 2022), https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm.

48, first published on September 27, 2021, is a peer-reviewed study discussed by Dr. Carrascal in her testimony. It found that antibodies persist "up to 14 months after natural SARS-CoV-2 infection." ECF No. 103-1 at 245. Fifth and finally, Exhibit 51 is a peer-reviewed study regarding natural immunity, which addresses how "SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans." ECF No. 103-1 at 292. The study concludes that "mild infection with SARS-CoV-2 induces robust antigen-specific, long-lived humoral immune memory in humans." *Id.* at 291. Dr. Bostom summarized the above data by saying that "there is one seventh the rate of hospitalization and one tenth the rate of death. Comparing those with natural immunity to Covid 19, regardless of vaccination status to those who are fully vaccinated." ECF No. 106 at 151: 21-25. Yet neither that testimony nor the studies' findings made it into the R&R. The R&R wrongly states that "the Plaintiffs failed to clarify with any certainty how long natural immunity may last, while Defendants produced evidence that it may only last as long as 90 days." R&R at 53. But the R&R does not even say what is the evidence that Defendants produced. So the R&R discounted the abundant scientific studies presented by Plaintiff showing that natural immunity is stronger and longer lasting than vaccination, while presumptively crediting some declarations by Defendants' expert witnesses who failed to produce a single evidence supporting their conclusory assertions. Indeed, the only study that Defendants mentioned, which was later introduced *by Plaintiffs* as Exhibit 63, ECF No. 109 at 131, because it does not support Defendants' conclusory assertions, which were inexplicably adopted by the magistrate judge.

The R&R found that "the evidence is unclear how long natural immunity lasts, and it may last for as little as 90 days," which "refutes any claim of arbitrariness on the part of the government." R&R at 44. But Plaintiffs provided precise and indisputable evidence, as shown in expert testimony and the five studies referenced above, that it is irrational for the government of Puerto

Rico to create a policy that declines to accept natural immunity in lieu of vaccination. And now, the CDC (see note 12, above) also disagrees with the R&R, ironically using some of the same studies the Plaintiffs used.[15] Indeed, Defendants failed to provide any other evidence about natural immunity. And as demonstrated above, Plaintiffs' experts presented multiple reputable scientific studies, thorough and some peer-reviewed, that now the CDC, on their recent MMWR Report just discussed (see note 14, above), not only makes references to but also concludes what Plaintiffs had demonstrated in court: Prior infection offers longer and stronger protection from COVID-19 than vaccination.

4. Farr's Law

The R&R says that "Dr. Hay asserted that Farr's law is a "theme with most infectious agents. Over time, the virus, or the infectious agent . . . adapts to the host [and] becomes less lethal over time." Therefore "through the natural process of, you might even call it evolution, the virus changes and becomes less lethal and more infectious." R&R at 36 (citation omitted). But the R&R goes on to minimize Farr's law by crediting Dr. Cardona's testimony that "[v]iruses . . . can mutate to become both more infectious and more severe, [such as] the H1N1 swine flu in 2009." *id.*, Dr. Marzan's testimony that "it can be the behavior of certain infectious agents to become less lethal and more transmissible over time," *id.,* and Dr. Irizarry's testimony "express[ing] doubt that Farr's

[15] A recently published study from Israel's Health Ministry found that natural immunity among those unvaccinated but previously infected a year ago is three times stronger—and twice as strong for the first 6 months—than vaccinated previously uninfected individuals. It concludes that for recovered individuals, or those with only natural immunity, the protection level was higher than those who were infection-naïve and only received two doses of the mRNA vaccines, agreeing with earlier studies: "previously infected individuals with or without one vaccination dose have better protection than uninfected doubly-vaccinated individuals 3 to 8 months after the last immunity-conferring event." medRxiv, *Protection and waning of natural and hybrid COVID-19 immunity* (December 05, 2021), https://www.medrxiv.org/content/10.1101/2021.12.04.21267114v1. And now, in *JAMA*, the medical journal published by the American Medical Association, a study just published (February 3) by doctors at Johns Hopkins on the prevalence and durability of COVID-19 antibodies among unvaccinated adults found that "antibodies were detected in 99% of individuals who reported a positive COVID-19 test result" up to 20 months earlier, "extending previous 6-month durability data." JAMA Network, *Prevalence and Durability of SARS-CoV-2 Antibodies Among Unvaccinated US Adults by History of COVID-19* (Feb. 3, 2022), https://jamanetwork.com/journals/jama/fullarticle/2788894.

law has manifested itself in Puerto Rico's COVID-19 outbreak." *Id.* But again, as with natural immunity, all three failed to provide any published scientific study or observational analysis study in this regard. Scientifically speaking, using data from the Puerto Rico Health Department and reaching such a conclusion without a defined cohort, a description of the methods used, testing definition (randomized control trial), confounding parameters, discussion of such analysis, and an established conclusion, all properly documented, should be considered just an opinion.

The R&R gave credence to the opinions of Drs. Marzan and Irizarry that "the Delta wave, which was the second-to-last wave experienced in Puerto Rico before December 2021, was substantially more deadly than the wave that preceded it." R&R at 36. But, *first*, Drs. Marzan and Irizarry failed to recognize that the two scientific studies presented by the Plaintiffs had demonstrated that "the period of [vaccine immunity] waning coincided with the Delta variant being the predominant circulating strain." ECF No. 103-1 at 53:227-228. The same issue came up with Exhibit 46, which stated that "the Delta variant was the dominant strain in Israel during the outcome period [first 6 months], [coinciding with] the decreased long-term protection of the vaccine." *Id.* at 188. In Puerto Rico, as can be seen on Exhibit 53, the Delta variant peak was on August 14, 2021, precisely seven months after vaccination had started. *Id.* at 361.

Second, Dr. Irizarry recognized in his testimony that what he has "been asked to do at this hearing is to analyze and comment on government data with respect to vaccinations, cases, deaths, hospitalizations regarding Covid" not to analyze scientifically the mortality of a variant. Tr. Irizarry, ECF No. 108 at 54: 14-17. *Third*, the fact that vaccine-induced immunity had waned, but people behaved as if they were immune, potentially caused vulnerable people to get infected, causing more deaths than usual. *Finally,* to conclude that a variant of concern is more lethal than others, a scientific expert would need to consider not only the number of total COVID-19 cases—

which is affected by the availability of testing—but also the number of cases per age group, the percentage of individuals with comorbidities infected, the number of people admitted to the hospital with COVID-19 as between the vaccinated and unvaccinated and those "with COVID" versus "for COVID," among others. None of these factors were taken into taken by the Defendants' experts, as can be easily demonstrated through Exhibit 59, which shows that the "new admissions of patients with confirmed COVID-19" in Puerto Rico is lower with every new surge trigger. ECF No. 103-1 at 373. In other words, the increased deaths caused during the Delta surge were not driven by Delta's increased lethality, but by having more people admitted with comorbidities or other vulnerabilities (*e.g.*, older age) than the cohort that was infected with previous variants. Taking these other factors into account—which the Defendants introduced no evidence to contradict—the Delta variant does, in fact, conform to Farr's law.

Moreover, now with Omicron, even without considering the important factors mentioned above to evaluate lethality and infectiousness, comparing total cases to total new admissions and deaths, we see nine or ten times more cases per day than in any of the previous three surges but three to thirteen times fewer hospitalizations and a four to nine times lower mortality rate. *Id.* at 11. The Omicron variant, like the Delta variant before it, thus conforms to Farr's law. In addition, the scientific experts are concluding, in accord with Dr. Hay's testimony, that the principles of Farr's law are in place. Dr. Fauci himself said on December 29, 2021, "all indications point to a lesser severity of Omicron versus Delta" citing preliminary data during a White House COVID-19 briefing." Dr. Fauci "cited a working paper from the University of Edinburgh that suggests Omicron is associated with a two-thirds reduction in the risk of COVID-19 hospitalization compared to Delta, among other research." Axios, *Fauci: Data suggests Omicron less severe than Delta*, https://www.axios.com/fauci-covid-pandemic-omicron-delta-white-house-cef5a788-e50e-

48c9-a9ca-21542b38658a.html. Yet the R&R completely discredits the Plaintiffs' now-proven claims regarding Farr's law.

5. Hospitalizations

Defendants claim that regardless of any disputes over natural immunity, Farr's law, or any other scientific moving targets, COVID-19's unique ability to inundate health care systems justifies ever-stronger vaccination mandates—because regardless of transmissibility or other *public* health issues, vaccines lessen disease severity. But by this logic, when hospital admissions increase (in the northern winters on the mainland, perhaps), the government can mandate that people cease activities that could lead to hospitalization. No skiing or snowboarding. No consuming alcohol either: we can't overburden the hospital with extra cases of hepatitis, alcohol-related accidents, or other injuries and illnesses. All contact sports and "risky" activities should be halted.

Exhibit 11 presents the data from the Puerto Rico Health Department as evidence of low hospital utilization related to COVID-19, as well as the pandemic's overall impact on hospitalization. The R&R noted Dr. Hay's testimony that "since the beginning of the pandemic in August 2020, whenever there was a 'spike' in COVID-19 hospitalizations there was a 'one-for-one decline in hospitalization for other reasons' so that 'hospitals have stayed at 60 percent occupancy.'" R&R at 37 (citing Hearing, Dec. 6, at 11:17 AM, Exhibit 11). That is, there has always been about 40% of hospital capability available since the pandemic started.

Nonetheless, the R&R notes that Dr. Cardona "opined that there was the 'possibility' that the health system in Puerto Rico would have collapsed without greater restrictions. She testified that 'the risk of putting the system in danger is established when [hospital] occupancy is greater than 70 percent.'" R&R at 103 (citation omitted). But Dr. Cardona failed to provide any evidence

supporting her claim. The magistrate judge asked Dr. Marzan if she was "aware of any hospital in Puerto Rico since November 15 of this current year that has informed that it's unable to receive patients because of the Covid-19 pandemic." Dr Marzan answered "[n]o, that is not the current situation right now." ECF No. 113 at 73: 9-14. Therefore, when the R&R concluded that "as the evidence demonstrated, collectively Puerto Rico's hospitals may have only had a 10-percentage point margin of occupancy before a risk of collapse might have become reality," there was no evidence beyond Dr. Cardona's unsupported statement. R&R at 39. And there was no evidence introduced that less than 10-percentage point margin of occupancy represents a significant risk on health capacity in PR. Indeed, upon questioning from Plaintiffs' counsel, Dr. Cardona explained that the "historical average of bed availability" was "fifty, sixty percent." ECF No. 109 at 84: 22-24. So, if 70% occupancy equates to being "at risk of collapse," then hospitals in Puerto always operate on the verge of collapsing, regardless of COVID. But Dr. Cardona admitted that she was "not a specialist in that subject," *id*. at 21, and thus couldn't form an opinion about a statement from the president of the Puerto Rico Hospital Association that: "The normal average was between 77% and 82% occupancy." ECF No. 51 at 27; ECF No. 109 at 85: 15-16 ("I can't answer that"), or the recent expressions by Governor Pierluisi, "fifty-eight percent occupancy rate in hospitals is not high.… the optimal capacity, the optimal utilization rate for hospitals is precisely around 75 percent. There have been times when it has been higher, but *75 is optimal*." Exhibit (a) at 1: 4-8 (Metro, *Conferencia de prensa de Pedro Pierluisi y el Dr. Carlos Mellado* (Video, minute 41:57-42:20) (Jan. 13, 2022), https://www.facebook.com/MetroPR/videos/689812938819363) (certified translation and emphasis supplied). This same topic was brought by Plaintiffs' counsel to Dr. Marzan. She answered that, before the pandemic, the hospital bed occupancy rate was "about 60, 70 percent." ECF No. 113 at 71: 16-23. So, if 60-70 percent is the norm, how can hospitals be at

"risk of collapse" at 70 percent utilization? Tellingly, when Dr. Marzan was asked by Plaintiffs' counsel how she knew those percentages, she replied "it's just in general terms", she admitted that she was "not in charge of certifying or receiving such information." *Id.* at 71: 25, 72: 1-6.

The fact is that the head of the Hospitals Association said that "[t]he reality is that hospitals have not been able to recover and return to the censuses they had prior to the pandemic. Before, hospitals could be 100% and others had less. Now they are still at 60%, about 20% less." *Id.* at 72:7-15. So, the hospital association, far from sending up alarms at being overwhelmed, is concerned about *under*utilization. More to the point, Drs. Cardona and Marzan provided no evidence as to how vaccine mandates would prevent a risk of collapse in the health system when, at the time of their testimony, 89.3% of the eligible population in Puerto Rico had received at least one COVID-19 vaccine dose. *See* COVID-19 Dashboard, *Vacunación*, https://covid19datos.salud.gov.pr/#vacunacion.

Even the governor of Puerto Rico and the Secretary of the Puerto Rico Department of Health, contradicted the R&R's claim crediting Dr. Cardona, that "there was a possibility that 600 to 700 COVID-19 hospitalizations in Puerto Rico would not allow for the treatment of other patients requiring immediate attention." R&R at 38. Recently, through the Omicron surge at its peak, while we had 750 hospitalizations related (not due to) to COVID, Gov. Pierluisi said in a press conference, "our hospitals are not at the point of collapse, and no one should be thinking that. Incoming patients are being treated." Dr. Mellado, alongside the governor in that press conference, said, "it is important to note that hospital occupancy is currently 54% in general, including other conditions. Hospital centers in Puerto Rico are far from a collapse of the system. They have the beds, they have the equipment, and they have enough staff to offer medical assistance." *See*, Primera Hora, *Gobernador y Mellado aseguran que los hospitales están "muy lejos de un colapso"*

(Jan. 9, 2022), https://www.primerahora.com/noticias/gobierno-politica/notas/gobernador-y-mellado-aseguran-que-los-hospitales-estan-muy-lejos-de-un-colapso/ (translation supplied).

Moreover, even beyond the impact of COVID-19 on hospitalizations, which rate has again stayed at 60% during the Omicron surge, this Court should consider "for COVID" versus "with COVID" issue. As Dr. Fauci recently noted, "that many children are hospitalized with COVID as opposed to because of COVID." Axios, *Fauci: Data suggests Omicron less severe than Delta* (Dec. 29, 2021), https://www.axios.com/fauci-covid-pandemic-omicron-delta-white-house-cef5a788-e50e-48c9-a9ca-21542b38658a.html. The *Washington Post* has called this phenomenon "incidental COVID: instances in which people are admitted for other reasons—gastrointestinal bleeding, say, or cancer surgery—but then test positive for the virus, usually as part of a routine screening." *Is a patient hospitalized 'with' covid or 'for' covid? It can be hard to tell,* Wash. Post (Jan. 7, 2022). *https://www.washingtonpost.com/outlook/2022/01/07/hospitalization-covid-statistics-incidental/*. New York has been the first to release figures on how many hospitalizations are of "incidental covid", where some "hospitals that reported that 50 to 65 percent of their hospitalized covid patients actually had incidental covid." *In Omicron Hot Spots, Hospitals Fill Up, but I.C.U.s May Not,* N.Y. Times (Jan. 4, 2022), https://www.nytimes.com/2022/01/04/health/covid-omicron-hospitalizations.html.

The same rings true in Puerto Rico. On an interview during the Omicron surge, Dr. Cardona said, "hospital occupancy is not maxed out, it's not at maximum [capacity]." Exhibit (b) at 3: 4-5 (Jugando Pelota Dura, *Jugando Pelota Dura - 01-10-2022* (Video, minute 7:08-7:38, 8:32-11:48) (Jan. 10, 2022), https://fb.watch/b6eziUy334/ (certified translation and emphasis supplied). Jorge Matta of the Puerto Rico Medical Center then said that he "had around 23 patients who tested positive for COVID, not necessarily because they came to the hospital saying that they had

COVID, but mostly . . . because they had some kind of accident." *Id.* at 3: 4-17. Mr. Matta went on to say, "that, possibly, over 90% of our patients at the Medical Center didn't come in because of COVID. They came in, well, walking or because of some situation they had, other than COVID. Afterwards, when the tests are done, because of the protocol we have at hospitals, then, it turns out that they have COVID." *Id.* at 4: 1-6. "And, in the case of those people, COVID-19 is not necessarily a threat to them in the sense of the clinical picture. They're not about to die. . . . Many of them are completely asymptomatic." *Id.* at 4: 8-13. Then, when the reporter moved into the subject of beds, he asked the administrator of the Ashford, "in terms of . . . of available beds, how many beds do you still have available?", and he responded, "the hospital is at 46%." *Id.* at 7: 15-18. Mr. Matta, for his part, responded that "the Christmas season is the most complicated time of the year for us. In other words, basically, we, well, can be at 80%," but that "[i]t's not COVID. It's what we usually have at... at this time of the year." *Id.* at 7: 20-25, 8:1-13.

By February 10, 2022, only 5.9% of the total Puerto Rico population had not been vaccinated, and 95 percent of the population 5 years or older had received at least one COVID-19 vaccine dose. *See* CDC, *Data Table for COVID-19 Vaccinations in the United States* (View: People, Show: At Least One Dose, Metric: % of the Population, Population: Total Population), https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-onedose-percent-total. The government has not shown that enjoining vaccine mandates here will have any serious detrimental effect in the hospitalizations or the risk of collapse of the public system.

B. Objections to Facts Related to Plaintiffs

1. **Tropical Chill**

The R&R, in describing the reasons that "Mr. Vega decided that Tropical Chill would only operate at 50 percent capacity rather than check the vaccination status of its customers," R&R at

8, choosing between "the lesser of two evils," *id.* at 9, did not mention Mr. Vega's testimony that "I am a strong believer in vaccines but I am not a strong believer in government overreach. I believe that everyone should get vaccinated but I don't believe that we should force people to put things inside their bodies that they don't want to." Tr. Mr. Vega, ECF No. 106 at 7: 22-25, 8: 1. He also mentioned that he thought that the EOs were "arbitrary, not solely based on scientific data," and he didn't "think they're fair and just to people who don't want to get vaccinated." *Id.* at 8: 7-11. Then, during cross-examination, Mr. Vega again stated "Customers have turned away when there is a line outside." *Id.* at 43: 9.

Mr. Vega also mentioned that they "are a family focused company. So, our main target are families and children. Children age one through 17 and adult ages 18 through 80." ECF No. 106 at 12: 3-5. So, if not doing the 50%, he will "have to verify if the children were younger than 12." *Id.* at 12: 15-16. If not choosing the 50% option, children younger than 5 could not go into his stores, meaning families with children younger than 5 will not be going into his stores either. When asked if he was "making a moral and economic decision or both in deciding to operate at fifty percent," he replied "it's difficult, it's difficult. Of course, it's moral because I don't feel comfortable asking and making my clients uncomfortable. I don't feel it's right but it has affected my economical level." *Id.* at 20: 19-24. He continued: "I can't continue operating at a loss but it's between, it's like being between a rock and a hard place because I don't want to bend my beliefs to get more customers but and I don't want, of 6 course, to lay off any of my employees but I have to –- the purpose of business is to turn a profit. So, it's a difficult judgement call right now." *Id.* at 21: 2-8.[16]

[16] The magistrate judge mentioned that the reason he "has not attempted" to "hire an extra employee dedicated to check the vaccination status of patrons or to take orders outside the store" is because "bend [his] beliefs to get more customers." R&R at 7. But he failed to credit Mr. Vega's testimony, multiple times, that it would not be financially

Finally, the magistrate judge concluded that the "type of harm" that Tropical Chill "is suffering . . . is traditionally remedied through compensatory damages, not prospective injunctive relief." R&R at 57. But even if this were true, Tropical Chill is not requesting any compensatory damages. This action is not about money; it's about vindicating civil rights.

2. **Yasmín Vega González**

The R&R acknowledges that Ms. Vega is opposed, on account of her faith," due to "[h]er "personal and religious interpretation is that we are reaching the last days," and the EO75 requirements, she explained, are part of the "mark of the Beast." R&R at 11. But the R&R failed to mention that Ms. Vega also testified that "everything that is happening with the government where we are being forced to get vaccinated. We can't go to restaurants or movie theaters, those of us who are not vaccinated. Just with that, the word of God is being complied with." Tr. at Vega, ECF No. 112 at 73: 1-8.

It then questions her 33% drop in revenues monthly, from "a fully booked occupancy for "two or three months in a row." But the R&R failed to mention that Ms. Vega testified about the "large decrease in guests who stay at our place ever since the Executive Order began." ECF No. 112 at 75: 21-23. Moreover, the fact that Ms. Vega "has only operated Hillside Cabin since December 2020" is not enough to conclude that the 33% drop in monthly revenues is due to "seasonality," R&R at 10, especially when the drop in revenue came immediately after the EO went into effect Ms. Vega, when asked if it "makes sense for the government to require you to request proof of vaccination or Covid tests to your guests," she thought "it's absurd because my property is so private." ECF No. 112 at 75: 8-12. Ms. Vega also mentioned that she also feels discriminated

feasible to "take the order from the customer outside," because "the order is taken on a POS system and the POS system is within the store." *Id.* at 40: 8-12." And that would mean "having additional employees going outside to take orders." *Id.* at 42: 18-19.

trying to go to restaurants and open-air activities, adding "recently in recent days there was the lighting of the Christmas lights there at the Mayaguez Town Square and it was an open air activity and there were check points and you had to present proof of vaccination and if you didn't have that, you couldn't go in." *Id.* 76: 2, 77: 1-4.

The R&R acknowledged Ms. Vega's religious beliefs but missed the central point: that requiring *either* proof of vaccination or negative COVID test violates her religious beliefs. As the R&R correctly pointed out, Ms. Vega testified "that because of her Christian faith she is particularly opposed to the COVID-19 vaccination, explaining that she believes that the vaccine mandates are a fulfillment of 'Apocalypse 13' whereby all people will be 'marked' in the end times." R&R at 46. Perhaps more importantly, she declared that her "personal and religious interpretation is that we are reaching the last days, and with *all of these impositions* [her] interpretation is that this is the mark of the Beast." *Id.* (emphasis added) (quoting Hearing, Dec. 7, at 2:27 PM). As a result, as the R&R correctly acknowledged, "she is religiously opposed to all mandates requiring her to check for proof of vaccination or to ask for a negative COVID-19 test *because such requirements are all part of the aforementioned marking process and her compliance makes her an "accomplice of everything*." R&R at 46 (emphasis added).

The magistrate judge, however, did not believe Ms. Vega, because she mentioned that she did not know what was in the COVID tests and that she had never asked a physician about the content of a COVID swab. R&R at 47. Again, this misses the point. When asked why she was specifically against the COVID vaccine, as opposed to vaccines in general, she answered: "because of everything that is happening with the government where *we are being forced* to get vaccinated…" ECF No. 112 at 73: 1-2 (emphasis added). Later, in response to a question as to why checking the vaccination status of her guests goes against her religion, she replied: as I explained earlier,

regarding a chapter of Apocalypses with everything that's going on *with these impositions*, … we are reaching the last days and *with all these impositions*, my interpretation is that this is the mark of the beast." *Id*. at 84: 4-20.

The point is that for Ms. Vega, participating in the government's imposition of restrictions for those who are not vaccinated—those who do not bear the mark of the beast according to her religious beliefs—is, in and of itself, a sin. R&R at 9. As the R&R correctly noted but ignored, for Ms. Vega, it is all part of the same "marking process and her compliance makes her an 'accomplice of everything.'" R&R at 46. Still, the R&R says that EO75 does not unduly burden her exercise of religion because "[s]he can instead only require evidence of a negative COVID-19 test or evidence of a positive COVID-19 infection and proof of recovery in the last three months." *Id.* But that also misses the point. She would still have to comply with the government's impositions which are related to forcing the population—according to her interpretation of the Bible—to wear the mark of the beast. The R&R's suggestion, moreover, presumes that obtaining a negative Covid test and the proof required to demonstrate a prior COVID infection, would be relatively easy for her guests. But of course, with some luck, it takes hours to secure free testing in Puerto Rico.

3. **René Matos Ruiz**

The R&R failed to credit Mr. Matos's testimony about the significant long lines and wait times for getting a free test, which means that one of his two days off each week is dedicated to getting that test—a significant burden. But the magistrate judge brushed this off, saying that Plaintiffs may secure free testing by investing a few hours each week. Plaintiffs submit that waiting in line for one or two hours under the sun to get tested just because the government wants to make it difficult for people to refuse vaccination is a significant burden.

On another front, the magistrate judge correctly pointed out that Mr. Matos had not requested the government subsidized health insurance—Plan Vital. R&R at 31. But Mr. Matos is a healthy hard-working man who rarely gets sick, so he has never been in real need of having health insurance, and who is not used to depending on the government. Yes, he has received unemployment benefits a few times in his life, the longest being for a period between three to four months after he lost his job due to a reduction in force during the 2008 financial crisis. A few other times he received the benefits for even shorter periods of time when he was between contracts while working in construction. But he has never requested nutritional assistance "coupons" and he is a proud man who has never been fired from a job, who does not like to depend on government assistance. Instead, Mr. Matos drives one and half hours, each way, for the "last three years" to go to and from work from his "town of San German" to "Econo Supermarkets in Mayaguez", where he is a "warehouse assistant and a shelf attendant." Tr. Matos, ECF No. 112, 93: 23-25, 94: 1. As Exhibit 31 shows, Mr. Matos earns "eight dollars an hour," which translates into "a gross of $280 odd dollars net" and after the "deduction from paycheck" due to "child support" comes out to approximately "$104 weekly" *Id.* at 96: 10-22.

Not depending on government assistance used to be something that all Americans admired, not something to be used in court against someone whose civil and economic rights were being put in jeopardy by the very same government that is supposed to protect him.

The R&R correctly notes that "Mr. Matos is not required to be vaccinated by Econo Supermarkets as long as he gets a weekly COVID-19 test." R&R at 13. But it fails to include Mr. Matos's testimony that he has "loss of work days and, therefore, of income also" as a result of the "vaccine mandates." ECF No. 112 at 101: 23-25, 102: 1. Mr. Matos added that "[a]t the beginning of the mandate, I lost approximately close to two weeks until I was able to achieve the exams

[Covid tests] that were required until I was able to return to my work duties because I was separated from my duties." *Id.* at 102: 2-9.

4. **Eliza Llenza**

The R&R says, "To arrive at the lab, Ms. Llenza must leave early in the morning, drive 25 to 30 minutes, and then drive home for an hour in rush-hour traffic," R&R at 32, but fails to specify that Ms. Llenza testified that "early in the morning" means "at 5:30 in the morning to be there because they open around 6:00." Tr. Llenza, ECF No. 113 at 31: 14-15. So. Ms. Llenza needs to wake up well before 5:00 in the morning which is the time she leaves her house. These burdens add up.

The R&R says that "Ms. Llenza believes these antibodies give her natural immunity from the COVID-19 virus, and so has declined to be vaccinated. However, Ms. Llenza acknowledged that she has not consulted with a doctor about whether she should be vaccinated, nor has any doctor advised her not to be vaccinated." R&R 10-11. But the R&R failed to mention the two antibody tests Ms. Llenza did were "nine months" apart. ECF No. 113 at 21: 1-2. And that in the second antibody tests she scored "[a]t a minimum of 10, I scored 46.59". *Id.* at 21: 5.

Ms. Llenza also responded, when asked "[w]hy do you want to get a job right now", that "I need an income. I have bills to pay. Besides, you know, I'm in the empty nest stage, you know, where my kids are gone, I don't have anybody – when you raise children without a husband, basically all your money goes to educate your children." *Id.* at 28: 5-11.

II. Objections to Conclusions of Law

A. Mr. Matos's claim is ripe because he will endure similar restrictions whenever he needs to renew his health certificate.

The R&R concludes that Mr. Matos's claim is "not ripe," R&R at 18 n.6, because it "requires the hypothesis that the COVID-19 pandemic and pandemic related restrictions will not improve

before August 2022," *id*. at 19. But Regulation 138-A contains no expiration date—and indeed the executive orders only keep expanding—so it's entirely reasonable for Mr. Matos to expect to be subject to it in August 2022, a mere six months from now, when he next needs to renew his health certificate. Puerto Rico's circumstance is simply not the same as in other jurisdictions on the mainland, which are loosening restrictions. *Cf. Spell. v. Edwards*, 2022 WL 131249, at *9 (M.D. La. Jan. 12, 2022) ("Louisiana has endured a deadly fourth wave of COVID-19 driven by the more contagious Delta variant, and has recently entered into a fifth wave . . . yet no additional crowd-size limits have been imposed on religious assemblies. Rather, time and experience have reinforced that '[t]he trend in Louisiana has been to reopen the state, not to close it down,' making it even more speculative now to suggest that Plaintiffs might endure similar restrictions in the future.") (cleaned up).

Moreover, the vaccination requirement for obtaining a health certificate Puerto Rico is being implemented through a regulation, not through an executive order under "emergency powers" as the rest of Puerto Rico's restrictions upon the population. That it's being implemented through regulation suggests that it may last longer than any executive order, and likely permanently. Indeed, nothing in Reg. 138-A suggest that it is of a temporary application. *See* ECF No. 103-3 at 37-39, and the record is barren of any proof.

B. The R&R Applied an Incorrect RFRA Standard to Ms. Vega's claims

The R&R applied an incorrect standard to Ms. Vega's RFRA claims. RFRA imposes a burden on the government to prove not only that the means are narrowly tailored to achieve the government's alleged compelling interest, but also that the government is using "*the least restrictive means* of furthering that compelling governmental interest." 42 U.S.C. § 200bb(a)(3) (emphasis added). The R&R appears to have implicitly adopted Defendants' argument that they

need not refute every conceivable alternative to satisfy RFRA's least restrictive means prong. *See* ECF No. 103 at 47. For that proposition, however, Defendants invoked *Armstrong v. Jewell*, 151 F.Supp.3d 242, 249 (D.R.I 2015)). But *Armstrong* relied on a test announced in *United States v. Wilgus*, 638 F.3d 1274, 1289 (10th Cir.2011), which is non-binding and predates *Burwell v. Hobby Lobby Stores, Inc.*, 573 U. S. 682 (2014), *Zubik v. Burwell*, 578 U. S. 403 (2016) (per curiam), and *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*, 140 S. Ct. 2367 (2020). And the *Wilgus* test likely runs afoul RFRA since it "effectively exempts the Government from being required to prove what the statute requires, *i.e.*, that it has employed 'the least restrictive means of furthering [its] compelling governmental interest.'" *Legatus v. Sebelius*, 988 F. Supp. 2d 794, 811 (E.D. Mich. 2013) (quoting 42 U.S.C. § 2000bb–1). In any event, that test has not been adopted by the First Circuit and has been effectively set aside by the Supreme Court.

More critically, "to meet the least restrictive means test, [the government] generally ought to explore at least some alternatives, and their rejection should generally be accompanied by some measure of explanation. *A blanket statement* that *all alternatives* have been *considered and rejected*, such as the one here, *will ordinarily be insufficient*." *Spratt v. R.I. Dept. of Corrections*, 482 F.3d 33, 42 n. 11 (1st Cir. 2007) (emphasis added). But a blanket statement is precisely what EO75 proffered here. It thus follows that Defendants have not even asserted that "at least some alternatives" have been explored, and thus *cannot* offer "some measure of explanation" for their rejection of unidentified alternatives. *Spratt*, 482 F.3d at 42 n. 11.

The proper way to evaluate a RFRA claim begins by asking, "would the mandate substantially burden [Plaintiff Vega's] exercise of Religion? Second, if the mandate would impose such a burden, would it nevertheless serve a 'compelling interest'? And third, if it serves such an interest, would it represent 'the least restrictive means of furthering' that interest?" *Little Sisters of the*

Poor, 140 S. Ct. at 2389 (Alito, J., concurring). Here, the mandate imposes a substantial burden on Ms. Vega's religious beliefs. The R&R conceded that requiring proof of vaccination goes against her religious beliefs and, as explained below, Ms. Vega's religious objections extend to the testing regime because—as the R&R correctly acknowledged but ignored—"she is religiously opposed to all mandates requiring her to check for proof of vaccination or to ask for a negative COVID-19 test *because such requirements are all part of the aforementioned marking process and her compliance makes her an "accomplice of everything*." R&R at 46 (emphasis added). And recall that "it is not for [courts] to say that [a plaintiff's] religious belief are mistaken or insubstantial." *Hobby Lobby*, 573 U.S. at 725.

It thus stands to reason that EO75 imposes a substantial burden because non-compliance could subject Ms. Vega to a $10,000 fine and 12 months' imprisonment. *Cf. Hobby Lobby*, 573 U.S. at 691 ("[if] the owners comply with the HHS mandate, they believe they will be facilitating abortions, and if they do not comply, they will pay a very heavy price."). The R&R brushes off Ms. Vega's RFRA claim, alleging that her religious beliefs are being burdened because "[s]he can instead only require evidence of a negative COVID-19 test or evidence of a positive COVID-19 infection and proof of recovery in the last three months." *Id.* But that ignores that she would still have to comply with the government's impositions which are related to forcing the population—according to her interpretation of the Bible—to wear the mark of the beast, and incorrectly presumes that presumes that obtaining a negative Covid test and the proof required to demonstrate a prior COVID infection, would be relatively easy for her guests, or that the occupation of her Airbnb would not decrease by implementing such a requirement.

The second question, whether the Government has a "compelling interest" that justifies compelling Ms. Vega to betray her faith, is dubious at this stage of the pandemic. To show that it

has a "compelling interest" under RFRA, Defendants must clear a high bar. Under *Sherbert v. Verner*, 374 U. S. 398 (1963), the decision that provides the foundation for the rule codified in RFRA, "'[o]nly the gravest abuses, endangering paramount interest'" could "'give occasion for [a] permissible limitation'" on the free exercise of religion. *Id.*, at 406. But the statistical figures and scientific studies discussed in Section I-A, above, coupled with the fact that Puerto Rico has the highest vaccination rate in the U.S, cast serious doubts on whether the government's professed interest—"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," MTD at 19—should be deemed "compelling" in this context, in 2022, not March 2020. As of February 7, 2022, the percent of total able population fully vaccinated in Puerto Rico was 80% and of the population 65 and older was 87.4%. *See* CDC, *Data Table for COVID-19 Vaccinations in the United States* (View: People, Show: Fully Vaccinated, Metric: % of the Population, Population: ≥ 65 Years of Age), https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-fully-percent-pop65.

Does the government truly have a compelling interest in achieving an even higher vaccination rate? The R&R seems to assume it does, but at what level of vaccination does the compelling interest wane? And does the government have to show that vaccination prevents transmission, or that moving from, say, an 80% to an 85% vaccinated rate achieves that effect, or even that mandates can achieve that increase? The R&R is silent on those counts because the government has not introduced any evidence supporting its assertions.

Does 1-6 v. Mills, 16 F.4th 20 (1st Cir. 2021) shows why the Rolling EOs and Regulation 138-A are unreasonable in the context of the actions challenged here. *Mills* was a Free Exercise case, not one under RFRA, which is essential to the analysis. Of critical importance to the pendent claims, Maine's *legislature*—not its governor through executive orders—responded "to declining

vaccination rates by amending its law to allow for only the medical exemption" for its healthcare workers. *Id.* at 24. And Maine concluded that its mandatory vaccination was necessary because, according to the First Circuit's opinion, "vaccination rates among healthcare workers [were] too low to prevent community transmission." *Id*. But Maine, contrary to Puerto Rico, "determined that at least 90% of a population must be vaccinated to prevent community transmission of the delta variant." *Id.* at 27. In Puerto Rico, to the contrary, neither EO75 nor the Regulation 138-A, which are indefinite, speak of any such goalposts. The court also took pains to emphasize that Maine's law applied only to healthcare workers, who, according to the court, were directly exposed to the immunocompromised. Indeed, it found that Maine's law was not overinclusive because it limited itself to only to healthcare workers. The challenged government actions here, by contrast, apply to virtually all Puerto Ricans who reject vaccination, and even to those who do not reject it but refuse to participate as the government police in its implementation. And contrary to Maine's situation, the R&R acknowledges (at page 39) that Puerto Rico "faced a severe crisis in its healthcare facilities when the delta variant hit the state." *Id.* at 26.[17]

But even if the government's interest could still be deemed as "compelling," it is passing strange how requiring proof of vaccination or a negative COVID test from Airbnb guests—contrary, to say, healthcare workers—could further that interest. Indeed, the R&R stated that it was not irrational to center restrictions "on places like restaurants, bars, movie theaters, and stadiums where people may congregate together and remove their masks to eat and drink." R&R at 39. While Plaintiffs' do not agree with that conclusion, notably, neither the R&R nor Defendants

[17] *See also See Does 1-3 v. Mills*, No. 21A90, 2021 WL 5027177, at *6 (U.S. Oct. 29, 2021) (Gorsuch, J., dissenting) (questioning whether Maine's professed interest was still "compelling" noting that "[b]ack when we decided *Roman Catholic Diocese*, there were no widely distributed vaccines. Today there are three. At that time, the country had comparably few treatments for those suffering with the disease. Today we have additional treatments and more appear near."). The indefiniteness of the mandate is also problematic. *Id.* at *6-7 ("I would acknowledge that this interest cannot qualify as such forever… If human nature and history teach anything, it is that civil liberties face grave risks when governments proclaim indefinite states of emergency.").

have stated a rational basis for requiring proof of vaccination or negative Covid tests to Airbnb guests.

And that is precisely why the generality of the Government's asserted interest is a problem. "At some great height, after all, almost any state action might be said to touch on '. . . public health and safety' . . . and measuring a highly particularized and individual interest' in the exercise of a civil right 'directly against . . . these rarified values inevitably makes the individual interest appear the less significant." *Yellowbear v. Lampert*, 741 F. 3d 48, 57 (10th Cir. 2014) (cleaned up). On this point, the government has not even alleged that people staying at Airbnbs are significantly contributing to the spread of COVID. Much less in an Airbnb such as the one operated by Plaintiff Vega, which, as R&R correctly pointed out, is a cabin "located on a mountain in the countryside," "is located 200 feet from the entrance," "and the closest neighbor to the structure is 220 feet away. R&R at 9. So, the government has not even articulated how EO75, as applied to Ms. Vega's Airbnb operation, serves to further its asserted interest.

In any event, there are other less restrictive ways to curb the spread of COVID than compelling Ms. Vega to be complicit in enforcing the government's mandate, which she sincerely believes betrays her faith. The use of masks and social distancing are less intrusive ways—though again, with Ms. Vega's particular business, it's unclear what these measures would accomplish. But the government could enforce the vaccine requirement itself by, say, establishing a platform for Airbnb guests to send their vaccination or testing information directly to the government, thus enforcing the mandate on guests, not proprietors. After all, all who fly into Puerto Rico already need to provide proof of vaccination or a negative test result upon arriving at the airport. Instead of a blanket mandate, the government could also set reasonable parameters for when proof of vaccination or negative COVID tests would be required: *e.g.,* only when the Airbnb is in a complex

akin to a hotel, or when guests are not members of the same household. The government could also require that all guests, regardless of vaccination status, take a COVID test before staying at an Airbnb. Of course, this last alternative could be implemented only if the government provided readily available COVID tests free of charge for the vaccinated and unvaccinated as is the case in all jurisdictions with comparable mandates. Or perhaps it could at least allow the use of over-the-counter Covid tests, which the government has failed to explain why it refuses to do so. Moreover, the government has not even attempted to explain why Puerto Rico ranks at the bottom (last[18]) among U.S. jurisdictions in COVID testing per capita, and why testing is so expensive and burdensome here when compared to testing regimens on the mainland. *See, e.g.,* ECF No. 35, ¶¶ 19, 97 (f). Is the government's interest truly to contain the spread of COVID? Or is it to force vaccination without regard to its citizens' religious beliefs and other civil liberties? These goals may appear similar, but they aren't the same.

At bottom, Defendants have the burden to support their choice of regulation and refute alternative schemes "*through the evidence presented in the record*." *U.S. v. Wilgus*, 638 F.3d 1274, 1289 (10th Cir. 2011) (emphasis added). Under a *de novo* review of the record, this Court should conclude that they fell short of meeting that burden.

A. Substantive Due Process

The R&R lacks empirical, statistical, or scientific evidence, as if such information weren't relevant to evaluating the justifications for government actions that burden constitutional rights, here or generally. Plaintiffs, by contrast, have gone to great lengths to include all data available to them—precisely to place this Court in a position to gauge whether, considering Puerto Rico's COVID metrics, health system capacity, and related statistics, Regulation 138-A and the Rolling

[18] CDC, *Data Table for Cumulative COVID-19 Nucleic Acid Amplification Tests (NAATs) Performed per 100k by State/Territory*, https://covid.cdc.gov/covid-data-tracker/#cases_testsper100k

EOs are proportional (or even rational) to the infringement of Plaintiffs' constitutional rights. Like Defendants' filings, the R&R brushes off the studies, data, and statistics furnished by Plaintiffs. But the whole reason that Plaintiffs have painstakingly presented scholarly studies, data, and *the government's own statistics* is because the actions that the Defendants take must have adequate legal justification. But Plaintiffs' data-driven claims are not based on their own subjective policy preferences, but on arguments that the Defendants aren't objectively justified in taking the measures they have. Plaintiffs have explained why the *Jacobson* standard, which predates modern jurisprudence, should not apply here, arguing instead for some form of heightened scrutiny.[19] They fully accept that the Puerto Rican government has certain police powers to act for the public health and safety, but that doesn't mean it gets to do whatever it wants, without meaningful judicial scrutiny.

That's where the scientific data comes in. When taken seriously, the science shows that Defendants aren't justified in imposing the burdens that EO75 and Regulation 138-A impose. Indeed, even if *Jacobson* applied directly, with no intervening jurisprudence to add nuance, perspective, and doctrine, all it would mean is that, with a contagious disease *as deadly as smallpox* (which COVID-19 thankfully isn't), someone can choose between getting vaccinated and paying $140. Just because certain vaccine mandates, as applied to certain classes of people, pass judicial muster (*Jacobson, Klaassen*), doesn't mean that all do. Different mandates are structured differently and impose different burdens. If Puerto Rico gave Plaintiffs a choice of getting vaccinated (or checking their clients' vaccination status) or paying $140, we would likely not be here. Instead, with Defendants' mandate backed by a $5,000 fine or six-months' jail time, not to mention a costly testing scheme that's uniquely burdensome in the Puerto Rico context, are far

[19] *Jacobson* has been thoughtfully criticized by legal scholars across the ideological spectrum for lacking in limiting principles characteristics of legal standards. *See* ECF No. 27, p. 7 n. 1 (collecting such secondary sources).

worse than *Jacobson*'s modest one-time fine. No reported cases have dealt with such draconian measures.

More to the initial point, in *Jacobson* itself, the Supreme Court used statistics to justify its holding. *See Jacobson*, 197 U.S. at 33, n.†. ("Nothing proves this utility more clearly than the statistics obtained."). The Court noted, among other things, that "[o]f those vaccinated 953, or 1.77 per cent, became affected with smallpox, and off the uninoculated 2,643, or 46.3 per cent, had the disease." *Id*. And according to the statistics referenced in *Jacobson*, the smallpox vaccine was far deadlier than COVID. Unlike the evidence furnished by Plaintiffs, however, what Mr. Jacobson offered in his defense, and which was rejected by the trial court, did not challenge the statistics supporting the smallpox vaccine mandate. Indeed, the Court noted that according to the recitals in the regulation, smallpox was increasing and "nothing [was] asserted or appear[ed] in the record to the contrary." *Jacobson*, 197 U.S. at 27–28. The evidence Mr. Jacobson introduced was instead aimed to challenge the efficacy and potential dangers of the smallpox vaccine. *See id.* at 30. In rejecting Jacobson's proffer, the Court noted "that not only the medical profession and the people generally ha[d] *for a long time* entertained these opinions, but legislatures and courts have acted upon them with general unanimity." *Id.* at 24 (emphasis added).

That is certainly not the case here. "A long time" in *Jacobson* meant that the first compulsory act in England was passed in 1853, even though state-supported facilities for vaccinations had begun there since 1808. *Id.* at n. †. That is, it took over 40 years for England to impose a compulsory vaccination regime for a disease that was far deadlier than COVID. Here, in contrast, compulsory vaccination was implemented—with far more burdens for citizens like Plaintiffs—before a single year had passed since the vaccine was made available to the public. And recall that Plaintiffs are not challenging the efficacy of the vaccine in preventing COVID-related

hospitalizations and deaths. Instead, they are questioning whether the statistics presented, *which raw data has been provided by the government itself*, support a vaccine mandate that is: (1) more stringent than the one in *Jacobson,* when (2) the underlying disease is less deadly than in *Jacobson,* (3) the available data shows that the vaccine is not effective in preventing the *spread* (as opposed to individual harm) of COVID, which is different than the smallpox vaccine addressed in *Jacobson,* and (4) vaccination rates are already high, higher than any other U.S. state or territory—all facts that the R&R ignored or waved away. Indeed, the R&R at one point curiously states that "Plaintiffs make no allegation, nor did they produce any evidence, that the challenged measures . . . have no real or substantial relation to public health." R&R at 21 n.8. But Plaintiffs have introduced studies supporting, the argument that vaccination is a good thing for many or most individuals but that it does not stop the spread and so cannot be justified on communitarian (as opposed to paternalistic) grounds. All along, Plaintiffs have accepted that vaccines are good for public health—just as exercise and diet are—but that vaccine mandates, unlike other actions taken during this pandemic, are not strictly speaking an effective *public* health measure.

The critical point is that, with the Rolling EOs, the punishment is far more severe than in *Jacobson*. For the Rolling EOs are more restrictive and punitive than the *Jacobson* mandate. Indeed, the punishment for noncompliance in *Jacobson* was relatively modest: a "$5 fine (about $140 today)." *Roman Cath. Diocese of Brooklyn*, 141 S. Ct. at 70 (Gorsuch, J., concurring). An unvaccinated person who paid the one-time $5 fine was then free to roam the streets—and if infected spread *smallpox*—while being fully compliant. That is precisely what Mr. Jacobson and others did. *See* Josh Blackman, *The Irrepressible Myth of Jacobson v. Massachusetts* (Aug. 17, 2021), https://tinyurl.com/28ts4t6e, at 16-17.

The R&R does not grapple with any of these nuances nor with the way that each particular plaintiff is deprived of substantive due process. For example, Plaintiff Matos runs the risk of losing his livelihood unless he submits to a weekly COVID test, which is neither free nor readily available as in the mainland United States. Even worse, the tests require a medical referral to have insurance pay for it. The *indefinite nature* of the costs and burdens of weekly testing, then, is more punitive than *Jacobson*'s nominal fine—and that's before we even get to fines or imprisonment. *Id*. ¶ 73.

Both the R&R and Defendants have asserted that Plaintiff's substantive due process claims must be evaluated under a low standard, such as *Klaassen v. Trustees of Indiana U.*, 7 F.4th 592 (7th Cir. 2021)." R&R at 25; ECF No. 20 at 8. But *Klassen* involved a different mandate and different facts, being based in the education sector. And, at the time *Klaassen* was decided, only 49.6 % of eligible Indiana citizens had been fully vaccinated. *Klaassen v. Trustees of Indiana U*. 2021 WL 3073926, at *10 (N.D. Ind. July 18, 2021). Today, in Puerto Rico, the rate of fully vaccinated eligible citizens is 84.3%, better than all U.S. states (with one dose is 94.4%). COVID-19 Dashboard, *Vacunacion*, https://covid19datos.salud.gov.pr/ (last seen on Feb. 11, 2022). More to the point, the *students* in *Klaasen* were given the option of studying remotely or submitting to *free* COVID swab tests that were scheduled and administered on campus. Here, in contrast, free testing is scarce and burdensome. The consequences here are different as well: Plaintiff Llenza, for example, can't secure a health certificate, which in turn makes it impossible for her to gain meaningful employment. ECF No. 113 at 13: 15-16: 10.

Plaintiffs readily concede that there is no precedent superseding *Jacobson*, but there simply hasn't been a widespread pandemic in the modern era, at least not one that touches American law. Still, as explained above, the facts in *Jacobson* differ significantly from the facts presented here. And modern jurisprudence has applied intermediate scrutiny when the government compels a

criminal defendant to take medication. *See, e.g.*, *Riggins v. Nevada*, 504 U.S. 127, 135 (1992). Even in that situation, the government must show that it considered less burdensome alternatives. *Sell v. United States*, 539 U.S. 166, 181 (2003) ("The court must find that any alternative, less intrusive treatments are unlikely to achieve substantially the same results"). At the very least the government here should be required to show that its asserted interests supersede the plaintiffs' liberty interest, *Cruzan by Cruzan v. Dir., Missouri Dept. of Health*, 497 U.S. 261, 262 (1990) ("[W]hether respondent's constitutional rights have been violated must be determined by balancing his liberty interests against the relevant state interests."), which involves more than merely referencing "the safety of the public." R&R at 24. Yet the R&R, citing *Jacobson* and *Klassen*, simply assumes that "vaccination against COVID-19 does not violate a fundamental right to bodily integrity and medical choice," R&R at 25, and accordingly defers to government action.

The government here has not asserted concrete and specific interests to justify the different prohibitions and burdens contained in each of its rolling and EOs. Instead, it asserted an abstract interest to justify them all: curbing the spread of COVID. This is probably because "[t]he more abstract the level of inquiry, often the better the governmental interest will look." *Yellowbear*, 741 F. 3d at 57. Indeed, "almost any state action might be said to touch on 'public health and safety' and measuring a highly particularized and individual interest' in the exercise of a civil right 'directly against these rarified values inevitably makes the individual interest appear the less significant." *Id*. (cleaned up). On this point, it bears noting that all the Rolling EOs are of indefinite duration, and none of them include parameters or specific objectives—*e.g.*, certain rates of vaccination, cases, hospitalizations, or deaths—that could hint when the government's overreaches will stop. And "civil liberties face grave risks when governments proclaim indefinite states of emergency." *Mills*, 2021 WL 5027177, at *3 (Gorsuch, J. dissenting).

Moreover, the government is employing a process—mandatory testing—whose means to further the stated end is questionable. This is because the government lacks a sufficient supply of free and readily available tests to impose its draconian measures. And Defendants' inability to explain the low amount of COVID testing in Puerto Rico and the substantial burdens imposed on citizens trying to obtain a free COIVD test undermines its asserted interest of decreasing the spread of COVID through the vaccine mandate. *See* ECF No. 35 at 96. Frequent testing among the whole population is indispensable to properly track the spread of COVID and respond to outbreaks. Readily available and easily accessible free COVID testing, as in all jurisdictions with similar mandates, would certainly further the government's professed interest—or at least it would have until the Omicron wave, when rates of hospitalization and death seem to have decoupled from overall case rates. But regardless, the government has been mum on that subject—which means that the vaccine mandate is being implemented in an "arbitrary, oppressive, unreasonable manner," R&R at 24, to compel citizens to succumb to vaccination and forego their substantive due process rights. By mandating and at the same time making it extremely difficult to obtain a COVID test, the government is purposely cornering citizens, or as the governor said, "closing the fence" on those like the Plaintiffs who choose to exercise their constitutionally protected rights to bodily integrity and medical informed consent. *See* Primera Hora, *Gobernador sigue "cerrando el cerco" para combatir el COVID-19* (Video, minute 1:33-52) (Aug. 19, 2021), https://www.primerahora.com/noticias/gobierno-politica/videos/gobernador-sigue-cerrando-el-cerco-para-combatir-el-covid-19-273899/ (last seen Feb. 7, 2022).

The same holds true with the government's failure to recognize natural immunity after 90 days (or at all in the case of Regulation 138-A) as an alternative to vaccination. As discussed above, natural immunity provides more robust and longer-lasting protection than two doses of any

available vaccine. So, there is no rational basis to decline to exempt from vaccine mandates those citizens who have recovered from COVID. And this is relevant not only to Ms. Llenza's claims, but also to the substantive due process claims of all Plaintiffs. If the government has an unidentified goal—*e.g.,* a certain percentage of people immunized to achieve herd immunity—that needs to be reached before it rescinds its mandates, natural immunity should be considered in determining whether the government has reached its goal. Otherwise, E075 is the epitome of arbitrary and oppressive, "going far beyond what was reasonably required for the safety of the public. R&R at 24, 28 (citing *Jacobson*, 197 U.S. at 28, 31).

Here, the government must prove at the very least that the already-high and still-increasing vaccination and natural-immunity rates, plus the low rate of COVID-caused hospitalizations and deaths, are insufficient (and remain so more than six months after the mandates) to achieve its asserted objective. Otherwise, the government's infringement on the Plaintiffs' rights isn't warranted—or no longer is if it once was.

B. Regulation 138-A

The R&R concludes that Regulation 138-A is neither arbitrary nor capricious, and that "the Puerto Rico government has a rational basis in requiring testing for people who work in industries like Mr. Matos and for the fields in which Ms. Llenza has training." *Id.* at 30, 32. But requiring proof of vaccination to obtain a health certificate (which entitles them to work) is wholly irrational. One, after all, can be vaccinated and still get and spread Covid. *See Mulero-Carrillo v. Roman-Hernandez*, 790 F.3d 99, 107 (1st Cir. 2015) ("[W]hen plaintiffs do not allege that a fundamental right is affected, they are required to show that the governmental infringement is not rationally related to a legitimate government purpose"). As a result, if anything, a negative Covid test would make more sense. The R&R conveniently ignores Plaintiffs' argument that the vaccination

mandate has become one of the "tests" needed to obtain a health certificate, further suggesting the irrationality of Regulation 138-A. Contrast this arbitrary rule to Maine's emergency rule—discussed in *Mills*—adding the Covid vaccine to vaccine *law* related to healthcare workers. After all, proof of COVID vaccination is "not a test." ECF No. 109 at 101: 13-15 To cinch matters, there are no exceptions for natural immunity.

The R&R takes pains to state that "there is a rational and reasonable need for persons to have a health certificate to avoid spreading illness to others," R&R at 43, but elides the central question of whether it's rational to require a Covid vaccine as part of that process, particularly for those with natural immunity. As described above, it's not—and the R&R concedes that "[p]erhaps the implication of this evidence is that Regulation 138-A should provide some sort of exemption to obtain a health certificate for someone who has contracted and recovered from COVID-19." R&R at 42-43.

Moreover, the Defendants have said that "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." MTD at 11. But, as the R&R noted, Dr. Cardona admitted that there was a lack of clarity from the government about the process for obtaining a health certificate. R&R at 44, n.15. The government's actions seem to be ad hoc, the very definition of arbitrariness. In the context of the health certificate, Regulation 138-A is, simply put, irrational. Even worse, neither Regulation 138-A nor the R&R attempted to explain why all employees who are required by law to obtain a health certificate are more likely to spread COVID than employees or individuals for whom the health certificate is not required.

Dr. Bostom said it best, "we're applying these broad strategies without stratifying, without narrowing down to the particular populations where the risk is highest and, therefore, the risk of

Covid, serious Covid is highest and, therefore, any adverse effects of the vaccine would be likely to be outweighed." ECF No. 106 at 163: 7-12. In short, because Defendants marshalled no rejoinder on how Regulation 138-A could "rationally advance its legitimate interests," *Gonzalez-Droz v. Gonzalez-Colon*, 660 F.3d 1, 10 (1st Cir. 2011), and because Defendants impermissibly withdrew a public benefit on account of the exercise of a right otherwise guaranteed by the Constitution, Regulation 138-A fails even under rational basis review.

C. Economic Liberties

The nub of the R&R on this front was that "[i]t was also not irrational, arbitrary, and beyond what is reasonably required for the government of Puerto Rico to center these restrictions on places like restaurants, bars, movie theaters, and stadiums where people may congregate together and remove their masks to eat and drink." R&R at 39.[20]

And it's unclear how imposing a mandate on each of the plaintiffs—especially an Airbnb owner who never meets customers—stops viral spread and is thus rationally related to any governmental interest. As detailed in other briefing, the Rolling EOs severely restrict the economic liberties of all Plaintiffs. The evidentiary hearing corroborated that Tropical Chill's sales have tanked by almost 20%, when compared to the month before the Rolling EOs went into effect. Tr. Tropical Chill at 13: 9-16. Mr. Matos has a legitimate fear of not being able to work once his current health certificate expires.

[20] The R&R correctly notes that economic regulations are subject to rational basis review. *See United States v. Carolene Products*, 304 U.S. 144, 153 n.4 (1938). But that doesn't mean that economic rights don't exist at all or aren't protected under the Fourteenth Amendment. And there have been plenty of modern cases upholding economic-liberty claims. *See, e.g., Merrifield v. Lockyer,* 547 F. 3d 978 (9th Cir. 2008) (licensing requirement for pest control workers lacked a rational basis); *Craigmiles v. Giles*, 312 F. 3d 220 (6th Cir. 2002) (finding licensing requirement for coffin-makers lacked a rational basis); *Bruner v. Zawacki*, 997 F. Supp. 2d 691 (E.D. Ky. 2014) (certificate of necessity law for moving companies unconstitutionally excluded competition). As in any area of contested law, the scope of those protections and what counts as a rational basis for regulation is much in dispute, of course, *compare Merrifield*, 547 F.3d 991 n.15 (using licensing solely to protect existing firms against competition is unconstitutionally irrational) *with Powers v. Harris*, 379 F.3d 1208, 1221 (10th Cir. 2004) (using licensing for protectionism is constitutional).

Even under rational basis review, the government can't act in an arbitrary manner, waving its hands in the general direction of coercive actions that somehow approximate good public policy. *Cf. Windsor v. United States*, 699 F.3d 169, 180 (2d Cir.2012) ("While rational basis review is indulgent and respectful, it is not meant to be 'toothless.'") (Cleaned up). For example, EO75 nowhere explains why a 50% capacity occupancy is the only way to ensure that social distancing measures can be implemented in closed enclosures when there is no screening of vaccination or negative tests. But a 50% capacity limit on ice cream shops or other culinary establishments is arbitrary. After all, previous EOs have imposed different thresholds, OE-2021-032, on May 6, 2021, imposed 30% occupancy on businesses and OE-2021-043, on June 3, 2021, imposed 75% occupancy on businesses. As the magistrate judge asked Dr. Cardona, "why fifty and not, for example, forty or eighty or one hundred or twenty five." ECF No. 109 at 75: 25 – 76: 1. Dr. Cardona responded: "I think that came out after an order from the President where the number was one hundred employees and here since we're more strict, so it was lowered to fifty." ECF No. 109 at 76: 3-6. This seems to be a number chosen at random because it "feels right." More is required, considering the disastrous economic impact that this is having on Tropical Chill. On the government's logic, vaccine mandates (and any other measures) that burden economic liberties are always and forever justified, just by invoking the magic words "public health." That can't be right—and fails even the laxest application of rational basis review.

D. Supplemental Claims

It bears mentioning at the outset that the R&R fails to address the true scope of the pendent claims under which EO75 is being challenged. Take, for instance, the issue whether Act 20-2017, "Puerto Rico Public Safety Department Act" can be constructed to authorize the almost unlimited and broad powers exercised by the governor. On this matter, the magistrate judge merely quotes

the Act, purporting to establish that a simple reading of the plain language of the statute supports the Governor's authority to issue *any* type of regulations and orders during *any* state of emergency. Indeed, the R&R states at page 50 that this "delegation is made directly to the Governor, and not to the Secretary of Health." This explanation errs in failing to even mention Plaintiffs' arguments regarding the statutory landscape in Puerto Rico regarding health safety police powers.

The issue is not simply whether the "Puerto Rico Public Safety Department Act" includes a delegation of power to the Secretary of Health. The real issue, unaddressed by the R&R, is the *existence of specific legislation*, Act 81-1912, granting the Secretary of Health the power to adopt rules and regulations in relation to health safety matters. In fact, Defendant Mellado used that authority to issue Regulation 9210 of August 21, 2021, establishing a rule for mandatory use of masks and establishing administrative fines for non-compliance.

The authority that Act 20-2017 vests in Defendant Pierluisi to adopt regulations during emergencies needs to be reconciled with the existence of a more specific grant of authority to the Secretary of Health in health safety situations. Indeed, contrary to the generic assertions of authority made by the governor, Section 5 of Act 81 of March 14, 1912 establishes that "[i]n case an epidemic threatens the health of the Commonwealth, the Secretary of Health shall take such measures as he may deem necessary to combat same, and shall, with the approval of the Governor, incur such expenses as may be necessary." P.R. Laws Ann tit. 3, §175So, while the governor issues the proclamation, the measures must be taken by the Health Secretary. This conclusion is reinforced by Section 4 of Act 81, which specifically contemplates the power of the Secretary of Health, not the Governor, to quarantine sick individuals during times of pandemic. *See* P.R. Laws Ann tit. 3, § 351.

Thus, although the Puerto Rico Legislature has enacted specific laws for the protection of life and health against the threat of an epidemic or infectious disease, *none* include rulemaking delegation to the governor by way of executive order. And the R&R cannot ignore this legal framework by just taking refuge in a plain language canon. Inasmuch as the R&R fails to address the statutory design explained, the construction placed upon Act 20-2017 should be dismissed as incomplete and mistaken. Instead, a more reasonable reading is that Act 81-1912 operates as a delegation of a more specific genre in comparison to Act 20-2017. In other words, in Puerto Rico, for health safety issues, the Legislature has assigned duties to the Secretary of Health and for other general matters usually related to natural disaster such as hurricanes, the authority to act has been vested in the Governor. Under that more reasonable construction, EO75 is an illegal use of power by the governor. The R&R, however, avoids that logical conclusion by simply ignoring the statutory powers of the Secretary of Health.

The R&R's confusion is compounded when it states at page 50 that "the plain language [of Act 20] makes no mention of the Puerto Rico Uniform Administrative Procedure Act. It is therefore a reasonable construction of the statute that under a state of emergency, the Governor does not have to act through the Uniform Administrative Procedure Act to promulgate regulations pertaining to the emergency at issue." But Plaintiffs never argued that the governor must act through the Puerto Rico Uniform Administrative Procedure Act in a health safety scenario as the one related to Covid-19. Rather, Plaintiffs alleged that the public officer with a statutory delegation to act upon this situation is the Secretary of Health. We addressed the Puerto Rico Uniform Administrative Procedure Act simply to counter the Defendants' position that the procedures for administrative rulemaking were inadequate in case of emergencies. Administrative Procedure Act, after all, provides for an emergency rulemaking procedure. P.R. Laws Ann. tit. 3, § 9623. Thus,

there was no need to force upon Act 20-2017 a statutory construction in which the governor ends seizing the powers so carefully located by the Legislative Power in the hands of the Secretary of Health.

The R&R's discussion of EO75's criminal penalties also fails to provide an adequate and sound construction of the statutory texts in dispute. The Executive Order threatens non-compliance with criminal penalties under Act 20-2017 and Act 81-1912—but Plaintiffs argue that neither statute really apply as pretended.

As to Act 20-2017, the R&R refers to Subsection (d) of 25 L.P.R.A. § 3654, providing in pertinent part that:

> Any person who commits any of the following acts shall be punished by imprisonment for a term not to exceed six (6) months or a fine not to exceed five thousand dollars ($5,000), or both penalties at the discretion of the court:
>
> ...
>
> (d) Persisting in carrying out any activity that endangers his life or the lives of other persons, after having been warned by the authorities once a hurricane warning has been issued or a state of emergency has been declared by the pertinent authorities, or while a state of emergency declared by the Governor of Puerto Rico through an Executive Order is in effect.

The R&R reacts to this text with an overly simplistic and conclusory reading: "On the basis of this statute alone, it is clear that the Legislature did provide for criminal penalties when a person acts to endanger his life or the lives of other persons while a state of emergency has been declared by the Governor of Puerto Rico through an Executive Order." R&R at 50. The elements of the crime established in this penal statute require a persistent conduct from the subject, "after having been warned." While a simple reading would suggest that the text refers to an individual warning, the R&R seems to construe that the issuance of EO75 by itself is the warning contemplated by Act 20-2017.

The R&R then states that "Plaintiffs seem to argue that 25 L.P.R.A. § 3654 is inapplicable because 'noncompliance with an [executive order] is not included among these.'" R&R at 51. Again, this is a misconstruction of Plaintiffs' argument. As explained in previous filings, *see, e.g.*, ECF No. 29 at 22–23, by enacting Act 20-2017, the Puerto Rico Legislature consolidated pre-existing administrative agencies under the umbrella of the new Public Safety Department. Among those agencies was the Emergency Management and Disaster Administration Agency, which, before that, had been regulated by its own enabling law, Act No. 211-1999, the "Commonwealth of Puerto Rico Emergency Management and Disaster Administration Agency Act". Act No. 211-1999 was rearticulated as Chapter 5 of the new Act 20-2017 and what we refer now as Article 5.14 of Act 20-2017 is the substitute of Section 20 of Act 211-1999, which provided in pertinent part:

> Section 20. — Violations and Penalties. (25 L.P.R.A. § 172r)
>
> Any person who commits any of the following acts shall be sanctioned with a penalty of imprisonment not to exceed six (6) months or a fine not to exceed five thousand dollars ($5,000), or both penalties at the discretion of the court:
>
> (a) Violating any provision of this Act or any regulation drafted or order issued thereunder.
>
> (b) Raising a false alarm with respect to the imminent occurrence of a catastrophe in Puerto Rico, or spreading rumors or raising a false alarm regarding nonexisting abnormalities under a state of emergency or disaster.
>
> (c) Failing to observe civilian population evacuation orders issued by the Commonwealth Agency as part of the enforcement of its plan in cases of emergency or disaster. . . .
>
> (d) Hindering the evacuation, search, reconstruction or assessment and investigation of damages conducted by federal, Commonwealth or municipal agencies, endangering his life or the lives of other persons, or persisting in carrying out any activity, including those of a recreational nature that endanger his life or the lives of other persons, after having been alerted by the authorities once a hurricane watch has been issued by the pertinent authorities or while a state of emergency declared by the Governor of Puerto Rico through an Executive Order is in effect. . . .

Note that former subsection (d) provides a clear understanding of what the current statute means when it makes it a crime to commit actions that endanger a person's own life or those of others. The "warnings" made by authorities refer to those actions taken by civil authorities empowered to perform duties related to the protection of persons from endangered themselves by conducting actions like those of a recreational nature. The classic example would be a beach lifeguard that has warned a surfer against practicing her sport during dangerous conditions and the person keeps engaging in such conduct.

When the R&R refers to the "non-compliance," R&R at 20, it is unknowingly addressing subsection (a) of Section 20 of Act 211-1999. That provision stated a simple and clear description of the conduct to be punished: the violation of any order or regulation adopted pursuant to Act 211-1999. But the R&R fails to address the clear significance of that provision: nowadays Article 5.14 is the current version of Section 20 and *does not include* subsection (a). In other words, when the Puerto Rico Legislature reenacted the penal provisions of the statute, a simply and straight disobedience to an executive order is no longer a crime. Defendants cannot now place upon current subsection (d) a forced reading by which the conduct prohibited not only encompass failure to respond to an individual warning but resurrects old subsection (a) and sanctions simple conduct of non-compliance. By pursuing that interpretation, the R&R fails to acknowledge basic principles applicable to criminal law. And, perhaps more importantly, it ignores that under Article 2 of the Penal Code of Puerto Rico, the legality principal prohibits the prosecution of any person based on a conduct that it not expressly defined as a crime under any Puerto Rico statute. The provision also forbids the application of crimes by analogy as well. In essence, conduct will not be punished, or a penalty will be imposed, if the prohibitions and penalties are not previously established by law.

See, e.g., Pueblo v. Plaza Plaza, 199 D.P.R. 276, 281-83 (2017). The R&R appears to show a lack of concern about these bedrock legal principles.

In addition, although the R&R mentions that Plaintiffs are challenging EO75 for making an illegal threat of criminal sanctions based on Act 81-1912, there is no discussion at all of this claim. Our claim was that Art. 33 of Act 81-1912 contemplates criminal punishment by failing to comply with Health Department *regulations*. It provides no such power against noncompliance with *Executive Orders* like the Rolling EOs. Unsurprisingly, Defendants failed to make any argument at all to support the inclusion of that legal reference in the rolling EOs. It is surprising, however, to note the R&R's same absence of discussion on this front. Plaintiffs' argument, although uncontested, was simply ignored.

Finally, it is remarkable that the magistrate judge recognizes the nondelegation problem posed by Act 20-2017, since the statute grants the governor the power to issue regulations and orders just he deems "convenient" and can "modify them at his discretion." In a candid way, he states that "[p]erhaps in normal times such guidelines would violate an 'intelligible principle.'" R&R at 53. But constitutional problems cannot be simply dismissed simply by pointing to the fact that this is an "emergency." *Id*.

Regardless of how much we can refer to federal case law on this subject, Plaintiffs' claim is based on the Puerto Rico Constitution. And the applicable doctrine has been clearly explained by the Puerto Rico Supreme Court in *Dominguez Castro* v. *ELA*, 178 P.R. Dec. 1, 92-94 (2010). A delegation of legislative powers is only valid if it provides both intelligible principles and sufficient procedural and substantive guidelines that limit the use of the delegated power. Under Puerto Rico law, there is no such thing as a distinct nondelegation for times of emergency. In fact, what we

would expect from the judicial branch is the opposite: to enforce constitutional limitations precisely in times when protections are more fragile.

E. Irreparable Harm, Balancing the Equities, and the Public Interest

As another court recently noted, "[w]hile vaccines are undoubtedly the best way to avoid serious illness from COVID-19, there is no reason to believe that the public interest cannot be served via less restrictive measures than the mandate, such as masking, social distancing, or part- or full-time remote work." *Feds for Med. Freedom v. Biden*, 2022 WL 188329, at *7 (S.D. Tex. Jan. 21, 2022). So "[s]topping the spread of COVID-19 will not be achieved by overbroad policies." *Id.* And "the public interest is also served by maintaining our constitutional structure and maintaining the liberty of individuals to make intensely personal decisions according to their own convictions." *BST Holdings, L.L.C. v. Occupational Safety and Health Administration, U.S. Dept. of Lab.*, 17 F.4th 604, 618–19 (5th Cir. 2021).

But the magistrate judge concluded that "on balance, the scientific evidence presented at the evidentiary hearing shows that the hardship to the Defendants is greater if a preliminary injunction were issued." R&R at 59. That is so, he reasoned, because "[a] collapse of the public health system would be catastrophic for Puerto Rico and a great risk to human life, and the weight of the hardship at this time outweighs the burden on the Plaintiffs' liberty or property interests." *Id.* at 60. But, as described above, that conclusion ignores the "incidental COVID" phenomenon regarding hospitalizations. Both Doctors, Cardona and Marzan, confirmed that a significant number of patients admitted to hospitals are "with COVID" and not "for COVID"—and in any event, and as explained above, there is no evidence that the public health system has, at any point during the pandemic, let alone now, ever been close to collapse.

R&R reached an incorrect conclusion of the evidence shown to support its rationale when saying, "At this time, evidence shows that continued growth of positive cases will result in more

hospitalizations, ICU referrals, and deaths in Puerto Rico." R&R at 60. That statement contradicts the statistical and empirical data introduced in this case. Exhibit 59 shows the "new admissions of patients with confirmed COVID-19" in Puerto Rico is lower with every new surge trigger. ECF 103-1 at 373. This without considering the total amount of cases per surge (hospitalization rate), as shown in Exhibit 53 and Exhibit H. ECF 103-1 at 361, ECF No. 103-2 at 35. Now with Omicron, comparing total cases to total new admissions and deaths, although having many times more cases than in previous surges, there are significantly fewer hospitalizations and a much lower mortality rate. *Id.* at 11.

The upshot is that any harm to the public interest by allowing a very limited number of the people of Puerto Rico to remain unvaccinated must be balanced against the harm sure to come by forcing termination of work in unvaccinated people who provide vital services to the island and limiting commercial activity by businesses to only vaccinated people. While vaccines are undoubtedly the best way to avoid serious illness from COVID-19, they have little to no effect on reducing transmissibility, particularly against the variants now dominant. As Dr. Hay testified, the impact of mandates on the rate of vaccination in Puerto Rico "it's between [0].4 and [0].7 percent". ECF No. 106 at 53: 20. More importantly, he noted that since "around eighty three percent" are already vaccinated, "it would have gone up I would think by [0].4 to [0].7 percent even without a mandate. I'm sure there's enough people out there that are concerned about the Delta variant and the Omicron variant." *Id.* at 53: 25, 54: 3-7.

Dr. Hay also testified as how "increasingly difficult and burdensome" mandates have become: "you've already achieved such a high saturated rate of vaccine," *id.* at 56: 19-20, and that it is already evident from the data, as illustrated by Exhibits 1–3. Dr. Hay further stated that "there's no evidence that increasing the vaccine rate as has been done since September and marginally

since November 15, has done anything at all to the hospitalization rates [or] death rates." *Id.* at 56: 25, 57: 1-3. Explaining Exhibit 4, he demonstrated how, when "look[ing] at the second graph," "the vaccine trend as we've already said is very, very slow and has not been impacted by the mandate at all". *Id.* at 62: 1-3. "The number of people newly getting vaccinated hasn't changed before or after the mandate . . . . there's no impact at all or negligible impact of mandates on vaccine coverage in Puerto Rico for those five and older." *Id.* at 62: 5-6, 20-22.[21]

Defendants' expert Dr. Marzan was asked directly about the effect of the mandate on vaccination rates, and whether she had "any evidence of how was the increase in vaccination or any evidence to suggest that the mandate is what is driving vaccination up except for children 5 to 11 years old?." She responded that she didn't "have any evidence here with . . . [her]." *Id.* at 62:11-25, 63:1-5. Indeed, there is no evidence in the record that mandates are increasing the vaccination rate at this saturated point.

Dr. Irizarry's testimony on Exhibit I, "a plot for vaccinations given per day," Tr. Irizarry at 27: 1-9, further undermines Defendants' position. Dr. Irizarry testified that mandates are correlated to a "big increase in vaccination," because, as can be seen on the graph, "it starts dropping, dropping, dropping until August and then sometime around the end of August, it shoots up to ten thousand per day and there's a period where we see a lot of vaccinations given per day, and this

[21]When asked if she would agree "that [Exhibit 4] represents what the rate of acceleration or deceleration of vaccination is," Dr. Marzan answered that "it does speak of how vaccination has behaved in terms of percentages, yes." ECF No. 113 at 57: 22-25. Dr. Marzan also confirmed in her testimony the "slight increase from November to December" of vaccination rate. When asked if "great part of that increase was because vaccines became available to children from 5 to 11 years old.", she responded "yes, a new age group started now, yes.". *Id.* at 58: 1-8. When asked "when did Puerto Rico start vaccinating children from 5 to 11 years old", Dr. Marzan replied: "during the first week of November this year." *Id.* 52 at 52: 20-23. And she confirmed what Exhibit 56 shows: Between November 3, when the vaccine was made available to 5–11-year-olds in Puerto Rico, and December 10, 2021, "the total number of people vaccinated during that time period was 140,488" and that "79,132 people from ages 5 to 11 were vaccinated during that time period". *Id.* at 54: 21-25. When she was asked if "over fifty percent of the people who got vaccinated between November 3 and December 10, were children from 5 to 11 years old", she answered that "for the first dose, yes". *Id.* at 56:11-14. In other words, of that slight and relatively minor increase during that period (Exhibit 4), over 56% of it was caused by a new group's eligibility for vaccination.

coincides with the vaccine mandates." *Id.* at 27: 12-17. Dr. Irizarry then concludes that "the way I interpret this graph is that the mandates were effective at increasing the rate of vaccination." *Id.* at 30: 20-22. But there are five multiple statistical, analytical, and observational issues with Dr. Irizarry's plot.

First, to measure the impact of vaccine mandates, you need to look at new people, which has not been vaccinated, getting their first dose. *Second*, to measure the rate of change within the vaccination rate, you take the first derivative of people able to be vaccinated getting their first dose. That is what Dr. Hay did with Exhibit 4. Common sense dictates that one needs to compare the newly vaccinated throughout time in relation to the eligible vaccine population. The rate of change of people getting vaccinated through different points in time is the appropriate benchmark—not how many people are getting their second dose at any given time. *Third*, the first vaccine mandate was announced on July 28, 2021, and one can see how through the first weeks, second-dose administrations continued to decline. Then, as observed in the plot, through all of August 2021 it remained flat. This is clear evidence that mandates did not cause the surge. *Fourth*, as Dr. Irizarry admitted in cross-examination, when confronted with "how do you know that the increase in vaccinated people that we see in mid-September . . . is due to the mandate," he responded, "I don't know for sure. Again, correlation is not causation." *Id.* at 68:12-16. When confronted with that fact that when vaccination "shoots up to ten thousand per day "coincide with the FDA's final approval of either Pfizer or Moderna or both," he responded "I can't recall. I don't even – I would – as a statistician I really can't answer that question." *Id.* at 68:21-22. But he somehow managed to answer the question regarding how mandates increased vaccination rates. *Finally*, when questioned about the fact that "even if the mandate had its effect, the one that went into effect originally in August, had its effect in creating this increase in vaccinations, doesn't your

graph show that that effect is now over." Tr. Irizarry at 69: 12-13. Dr. Irizarry responded that "yeah, that effect seems to have subsided, yes." *Id.* at 69:10-14. He alluded to the fact that Exhibit I demonstrates how since mid-September 2021, even with the vaccine mandates in place, the rate of second doses declined tremendously and, by the beginning of November 2021, was at its lowest levels ever. ECF No. 103-2 at 37. He was then asked: "can this graph be used to justify the November 15th mandate or the continuing enforcement of vaccine mandates in Puerto Rico." Tr. Irizarry at 69: 15-17. He agreed that an "argument could be that without the mandates it would be an even larger drop than what you're seeing here," but "that is speculation." *Id.* at 69: 15-24.

Dr. Marzan similarly testified that vaccine mandates don't add much value when asked about "an estimate of how many children from the age of from 5 to 11 are eligible to be vaccinated", she responded that "approximately about 220,000". ECF No. 113 at 56: 16-20. When she was asked if "out of the 79,132 children that got vaccinated between November 3 and December 10, would you[she] agree that most of them would have gotten vaccinated regardless of the mandates," she responded that "most of the population does support vaccination." *Id.* at 56: 21-25. When asked once again by Plaintiff's counsel if "can I interpret your answer as a yes, that most of them would have gotten vaccinated regardless of whether there was a mandate," she answered "Yes, but there is no mandate right now for children age 5 to 11." *Id.* at 57: 3-7.[22]

[22]Dr. Marzan also confirmed Dr. Hay's explanation as to how insignificant and burdensome is trying to increase vaccination rates through mandates on such a highly vaccinated population. Apart from confirming the high vaccination levels for the 5-11 year-old population in the overall population within the period of November 3 and December 10, she also confirmed that "as of November 15," when EO75 became effective, "the percentage of the population that was vaccinated was 74.2 percent of the whole population", that "the total number of people vaccinated that were only 12 plus years old" was closed to "83.2 percent", and that for "the people that are 65 years old", "it must be close" to say that "their vaccination rate would be 84.7 percent". *Id.* at 50:6-18. She also corroborated that as of December 10, "the total population of vaccinated people", "must be close to 75 percent" and that it "must be close to the estimate" that for "the population 12 years old plus, 83.5 percent of that population would be correct that were vaccinated" and "for people 65 years plus,…their vaccination rate was 85.2 percent". *Id.* at 51:2-22. So, with a mandate enacted and effective on November 15, by December 10, almost a month later—even when a new age group (5-11 years old) was for the first time being allowed to be vaccinated and represented over 50% of the total population vaccinated during that period—the increase for the whole population was 0.8 percent.

So, for all practical purposes, the vaccine mandates have provided no material benefit to society in Puerto Rico—let alone when compared with the negative impacts to businesses and individual liberties. As the R&R recognized, the legitimacy of vaccine mandates is that there is a broader benefit to society because of the "unacceptable risk to human life and presents a risk of overwhelming the health system in Puerto Rico," warranting the loss of individual bodily autonomy. R&R at 61. But because the record contains no data demonstrating the vaccine's effectiveness in preventing transmission (let alone for Omicron), and that in any event over 94% of the eligible population have received one dose (and over 87% of the vulnerable population, 65+ years old, is fully vaccinated), plus the advent of FDA-approved antiviral drugs and FDA-authorized monoclonal treatments, there is no such "unacceptable risk." And because there is significant proof that the health system in Puerto Rico is nowhere near being overwhelmed, the challenged actions cannot be justified on that basis either. "Defendants have not shown, then, that such harm is likely." *Missouri v. Biden*, 2021 WL 5631736, at *1 (E.D. Mo. Dec. 1, 2021). That conclusion has an added force when, as here, EO 75 is broad rather being narrowly tailored. R&R at 54 (so recognizing).

Excessive prevention is more costly to society than the damage done by the illness here. Unfortunately, the magistrate judge did not even allude to Dr. McDonald's testimony, which explained the phycological and social rife created by vaccine mandates. As Dr. McDonald puts it, "those who are poor, lesser educated and perhaps not in the best physical health are more likely, not less but more likely to suffer from psychological harm due to being forced to give up an entrenched position regarding a vaccine mandate." Tr. McDonald, ECF No. 107 at 12:24-25, 13:1-4; *see also id*. at 29 (explaining how "holdouts" commit desperate or criminal acts to "maintain

work or to maintain the ability to interact"). This type of physiological harm, coupled with the harms recounted in Section I-B, no doubt constitute irreparable harm.

We don't close highways or set speed limits at 10 miles per hour to minimize accidental deaths. Yet this is exactly what we're doing when the government intervenes to limit the spread of communicable diseases by mandating vaccines that don't prevent transmission. Defendants have proved incapable of quantitatively assessing trade-offs between the harms of prevention and the harms of disease. This has unjustly harmed hundreds of thousands of Puerto Ricans. "The equities do not justify withholding interim relief." *Natl. Fed.. of Indep. Bus. v. Dept. of Labor*, 142 S. Ct. 661, 666 (2022).

Conclusion

For the reasons stated, this Court should decline to accept the R&R and grant Plaintiffs' motion for preliminary injunction.

Dated: February 11, 2022 Respectfully submitted,

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Counsel for Plaintiffs

Appendix 1A

Data Table for Cumulative Cases per 100k in Last 7 Days

CDC | Data as of: December 13, 2021 2:23 PM ET. Posted: December 13, 2021 4:47 PM ET

Download Data

State/Territory	7-Day Case Rate per 100,000
Northern Mariana Islands	1,550.6
New Hampshire	653.2
Rhode Island	605.7
Minnesota	529.3
Maine	511.8
Vermont	503.7
Michigan	503.2
Massachusetts	489.6
Indiana	483.7
Pennsylvania	457.7
Wisconsin	453.5
New York*	446.3
Delaware	443
New Mexico	441.5
Ohio	431.2
Nebraska	410
Kansas	399.2
Connecticut	396.8
Illinois	392
West Virginia	377.9
Iowa	369.7
New York (Level of Community Transmission)*	360
New Jersey	345.8
South Dakota	336.5
Arizona	331.6
North Dakota	320.8
Missouri	314.8
Utah	272.3
Colorado	269.1
Kentucky	268.7
New York City*	246.4
North Carolina	207.1
Alaska	193.7
Virginia	191.5
Wyoming	181.4
District of Columbia	180.2
Oklahoma	172.8
Arkansas	168
Nevada	160.1
Idaho	158
Tennessee	140.4
Montana	138.7
Oregon	133.2
Washington	125.8
California	122.3
Mississippi	121.3
Texas	100.3
South Carolina	96.6
Georgia	93
Alabama	83.4
Florida	72
Louisiana	67.7
Hawaii	63.2
Virgin Islands	62.1
Guam	32.6
Puerto Rico	21.9
Maryland	0
Palau	0
Republic of Marshall Islands	0
American Samoa	N/A
Federated States of Micronesia	N/A

Footnotes

CDC, *United States COVID-19 Cases, Deaths, and Laboratory Testing (NAATs) by State, Territory, and Jurisdiction* (View: Cases, Time period: Last 7 Days, Metric: Rate per 100,00), *Data Table for Cumulative Cases per 100k in Last 7 Days* (December 13, 2021), https://web.archive.org/web/20211214160757/https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days

Appendix 1B

Data Table for Cumulative Cases per 100k in Last 7 Days

CDC | Data as of: January 4, 2022 1:51 PM ET. Posted: January 4, 2022 3:19 PM ET

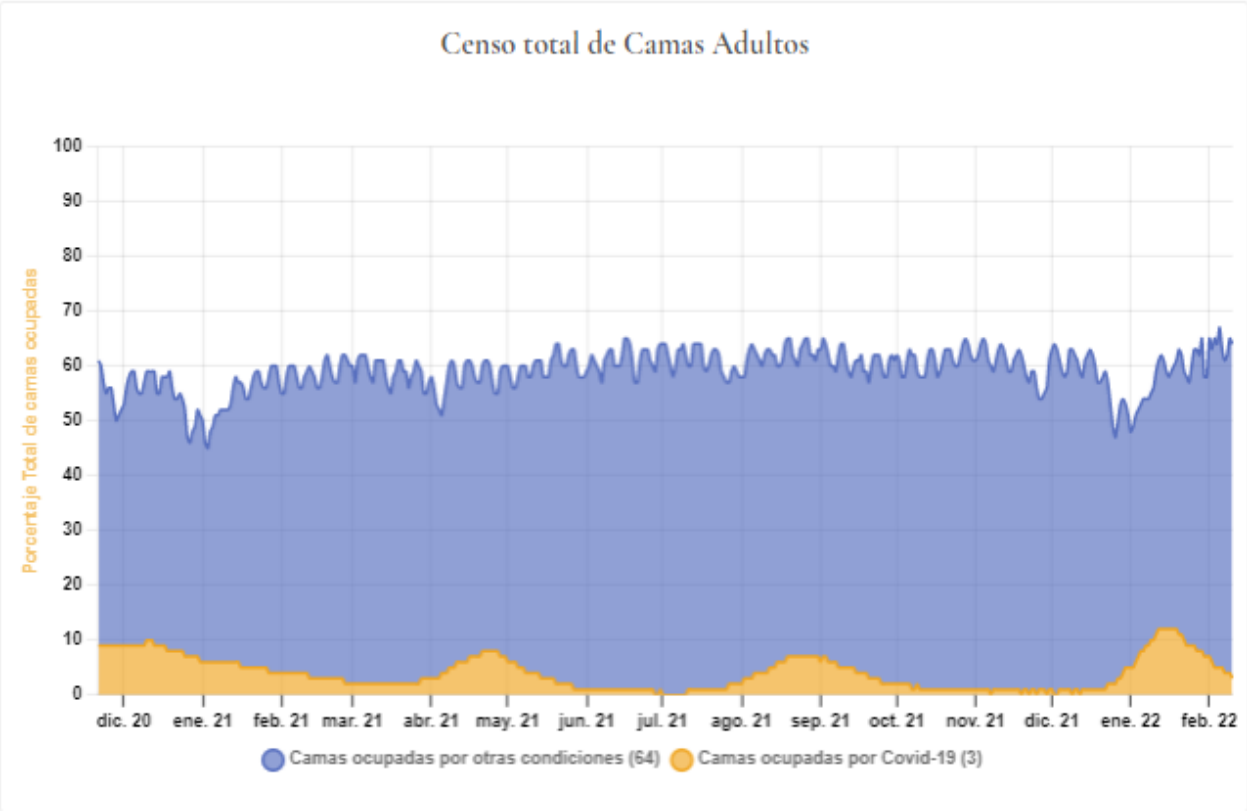
Download Data

State/Territory	7-Day Case Rate per 100,000
New York City*	3,215.1
New York (Level of Community Transmission)*	2,360.8
Puerto Rico	2,192
New Jersey	2,152.5
District of Columbia	2,086
Virgin Islands	1,954.1
Florida	1,772.8
New York*	1,711.7
Delaware	1,655.8
Massachusetts	1,514.6
Maryland	1,498.3
Illinois	1,274.4
Hawaii	1,255.1
Connecticut	1,252.5
Louisiana	1,233
Virginia	1,181.8
Ohio	1,134.9
Tennessee	1,056.4
Vermont	1,054
Pennsylvania	1,012.5
Colorado	1,008.8
Mississippi	964.4
Michigan	950
Alabama	939.2
North Carolina	904.2
Rhode Island	895.8
Indiana	846.5
West Virginia	828.1
Northern Mariana Islands	827.4
Texas	789
Missouri	777.6
Arkansas	768
Georgia	753.5
Kansas	753
Wisconsin	744.9
Kentucky	731.4
Utah	731
New Hampshire	682.4
Nevada	680.7
Washington	629.2
Arizona	575.8
North Dakota	572.5
New Mexico	563.6
California	540
Iowa	536.2
Oklahoma	528.9
Alaska	509.3
Minnesota	507.6
Nebraska	498.8
South Dakota	429.2
Oregon	398.1
South Carolina	387
Maine	372.5
Wyoming	348.9
Guam	236.2
Montana	231.7
Idaho	228.6
Palau	13.9
Republic of Marshall Islands	0
American Samoa	N/A
Federated States of Micronesia	N/A

Footnotes

CDC, *United States COVID-19 Cases, Deaths, and Laboratory Testing (NAATs) by State, Territory, and Jurisdiction (View: Cases*, Time period: Last 7 Days, Metric: Rate per 100,00), *Data Table for Cumulative Cases per 100k in Last 7 Days* (January 4, 2021), https://web.archive.org/web/20220105195812/https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days

Appendix 2



Puerto Rico Health Department COVID-19 Dashboard, *Sistema de Salud (Historico)*, https://covid19datos.salud.gov.pr/#sistemas_salud

[CERTIFIED TRANSLATION]

41:57

GOVERNOR PEDRO PIERLUISI:

A fifty-eight percent occupancy rate in hospitals is not high. Hospitals have been as high as at 75 percent capacity.

In fact, the optimal capacity, the optimal utilization rate for hospitals is precisely around 75 percent. There have been times when it has been higher, but 75 is optimal. They're at 58.

42:20

I hereby certify that this is a true and accurate translation to the best of my abilities.

Miriam R. García
Federally Certified Court Interpreter
Certificate No. 03-051

REPORTER'S CERTIFICATION

I, Sonia Negrón, court reporter, with offices in Toa Baja, Puerto Rico, hereby CERTIFY:

The foregoing is the true and accurate transcript of the audio of minutes 41:57-42:20 of a press conference with Pedro Pierluisi and Dr. Carlos Mellado, posted on January 13, 2022, on the Facebook page of the Metro newspaper: https://www.facebook.com/MetroPR/, and with the specific link to the video: https://www.facebook.com/MetroPR/videos/689812938819363.

I am not related to any party in this lawsuit nor am I interested in the final outcome thereof.

Therefore, I am issuing this certification in Toa Baja, Puerto Rico, today, February 9, 2022.

s/Sonia Negrón

I hereby certify that this is a true and accurate translation to the best of my abilities.

Miriam R. García
Federally Certified Court Interpreter
Certificate No. 03-051

[CERTIFIED TRANSLATION]

(7:08)

UNIDENTIFIED MALE VOICE:

Here with us is Doctor Iris Cardona, the chief medical officer of the Department of Health.

Welcome, Doctor. How are you? Hello.

DR. IRIS CARDONA:

Thank you. Good evening.

UNIDENTIFIED MALE VOICE:

Great.

We also have Doctor Melissa Marzán, who is the epidemiologist for Puerto Rico.

Hello, Doctor.

MS. MELISSA MARZÁN:

Hello.

UNIDENTIFIED MALE VOICE:

And we also have with us Mr. Héctor Ortiz, the administrator of the Ashford Hospital in Condado.

Hello, Mr. Ortiz.

MR. HÉCTOR ORTIZ:

How are you?

UNIDENTIFIED MALE VOICE:

Hello, Mr. Ortiz.

And also with us is Jorge Matta, who is the director of the Puerto Rico Medical Center.

Mr. Matta, how are you?

I hereby certify that this is a true and accurate translation to the best of my abilities.

Miriam R. García
Federally Certified Court Interpreter
Certificate No. 03-051

[CERTIFIED TRANSLATION]

MR. JORGE MATTA:

Good evening. Happy New Year (unintelligible).

UNIDENTIFIED MALE VOICE:

Hello to all four of you.

(7:38)

I hereby certify that this is a true and accurate translation to the best of my abilities.

Miriam R. García
Federally Certified Court Interpreter
Certificate No. 03-051

[CERTIFIED TRANSLATION]

(8:32)

DR. IRIS CARDONA:

I don't have that number, but I can look it up. But, certainly, hospital occupancy is not maxed out, it's not at maximum [capacity].

UNIDENTIFIED MALE VOICE:

It's not maxed out. I'm going to ask the Medical Center, for example, what...? It's, I don't know, the face of the country's hospital system. How is the hospital doing today? Are you concerned about the increase in hospitalizations or not?

MR. JORGE MATTA:

Well, basically, we've seen a high... an increase in hospitalizations, but we're addressing the... the situation.

To give you an idea, today we had around 23 patients who tested positive for COVID, not necessarily because they came to the hospital saying that they had COVID, but mostly... because they had some kind of accident.

UNIDENTIFIED MALE VOICE:

That's what I wanted to get to. And I'm sorry for interrupting you. The 750 people hospitalized with COVID didn't necessarily go [to the hospital] because they have COVID--they twisted a knee or... or they had an accident and went there, they had the test done and it turned out they have COVID?

MR. JORGE MATTA:

I hereby certify that this is a true and accurate translation to the best of my abilities.

Miriam R. García
Federally Certified Court Interpreter
Certificate No. 03-051

Yes, clearly, I would like to say that, possibly, over 90% of our patients at the Medical Center didn't come in because of COVID. They came in, well, walking or because of some situation they had, other than COVID. Afterwards, when the tests are done, because of the protocol we have at hospitals, then, it turns out that they have COVID. In other words...

UNIDENTIFIED MALE VOICE:

And, in the case of those people, COVID-19 is not necessarily a threat to them in the sense of the clinical picture. They're not about to die.

MR. JORGE MATTA:

No, not necessarily. Many of them are completely asymptomatic.

UNIDENTIFIED FEMALE VOICE:

(Unintelligible – overlapping voices)

MR. JORGE MATTA:

...(unintelligible – overlapping voices) COVID.

MS. CYD MARIE FLEMING:

Why are they... why are they hospitalized?

MR. JORGE MATTA:

Well, because... For example, in the case of the Medical Center, well, they mostly come in because of trauma. Because they come in with... with... They fell down at home, now... painting their house and the roof, they were in a car crash, and it's mostly traumas.

I hereby certify that this is a true and accurate translation to the best of my abilities.

Miriam R. García
Federally Certified Court Interpreter
Certificate No. 03-051

[CERTIFIED TRANSLATION]

MS. CYD MARIE FLEMING:

They're not hospitalized for COVID?

MR. JORGE MATTA:

No, no.

MS. CYD MARIE FLEMING:

(unintelligible – overlapping voices) COVID.

MR. JORGE MATTA:

No.

UNIDENTIFIED MALE VOICE:

Cardona or Marzán, when you say "750 people hospitalized for COVID," are you including those people who didn't come in with symptoms?

DR. MELISSA MARZÁN:

Yes, they're people who have (unintelligible – audio error).

UNIDENTIFIED MALE VOICE:

In other words, the... Well, then, there's no... there aren't necessarily 750 people hospitalized for COVID, it's for other conditions that... right? It later turned out that, yes, they had COVID.

DR. IRIS CARDONA:

That's right. But the analysis, right?, of confirmed or probable cases reported by hospitals, they're under the obligation to report every person hospitalized who tests positive for COVID.

I hereby certify that this is a true and accurate translation to the best of my abilities.

Miriam R. García
Federally Certified Court Interpreter
Certificate No. 03-051

[CERTIFIED TRANSLATION]

UNIDENTIFIED MALE VOICE:

Let me rephrase the question.

DR. IRIS CARDONA:

I can give you another example. We have a girl who came in to an intensive care area because of her primary illness.

UNIDENTIFIED MALE VOICE:

Uh-huh.

DR. IRIS CARDONA:

She was *admi* [incomplete]... she was admitted because of her primary illness.

UNIDENTIFIED MALE VOICE:

Uh-huh.

DR. IRIS CARDONA:

During the evaluation, we tested for COVID, the molecular test, and it came back positive.

UNIDENTIFIED MALE VOICE:

Mr. Ortiz, and in the case of you all, at the hospital over there--which is also a very well-known hospital--the Ashford in Condado, how are you doing there in terms of... of... of... of available beds?

MR. HÉCTOR ORTIZ:

Well, just like my colleague, Mr. Matta, said, we've seen an increase in hospitalized COVID patients, but we do have to differentiate whether it's a patient [hospitalized] for COVID or a patient with COVID, right?

I hereby certify that this is a true and accurate translation to the best of my abilities.

Miriam R. García
Federally Certified Court Interpreter
Certificate No. 03-051

UNIDENTIFIED MALE VOICE:

Uh-huh.

MR. HÉCTOR ORTIZ:

From...

UNIDENTIFIED MALE VOICE:

For... Differentiate from “for COVID”?

MR. HÉCTOR ORTIZ:

For COVID, we’ve had the same percentage of hospitalized patients. We’ve been seeing it all through 2021. Currently, there is a... an increase in people hospitalized with COVID, which is not necessarily the chief reason for their hospitalization.

UNIDENTIFIED MALE VOICE:

One... one more question to see... to continue... so that my colleagues can continue asking questions, in terms of... of available beds, how many beds do you still have available?

MR. HÉCTOR ORTIZ:

Currently, the hospital is at 46%.

UNIDENTIFIED MALE VOICE:

Forty-six. And in the case of the Medical Center?

MR. JORGE MATTA:

In the case of the Medical Center, remember that, at the Medical Center, the Christmas season is the most complicated time of the year for us.

UNIDENTIFIED MALE VOICE:

I hereby certify that this is a true and accurate translation to the best of my abilities.

Miriam R. García
Federally Certified Court Interpreter
Certificate No. 03-051

Yes.

MR. JORGE MATTA:

In other words, basically, we, well, can be at 80% occupancy.

UNIDENTIFIED MALE VOICE:

Eighty percent.

MR. JORGE MATTA:

But...

UNIDENTIFIED MALE VOICE:

It's not COVID?

MR. JORGE MATTA:

It's not COVID. It's what we usually have at... at this time of the year.

* * *

(End of recording)

* * *

I hereby certify that this is a true and accurate translation to the best of my abilities.

Miriam R. García
Federally Certified Court Interpreter
Certificate No. 03-051

[CERTIFIED TRANSLATION]

REPORTER'S CERTIFICATION

I, Sonia Negrón, court reporter, with offices in Toa Baja, Puerto Rico, hereby CERTIFY:

The foregoing is the true and accurate transcript of the audio of the Jugando Pelota Dura television program, minutes 7:08-7:38, 8:32-11:48, posted on January 10, 2022, on the Facebook page of the program: https://www.facebook.com/watch/JugandoPelotaPR/, and with the specific link to the video: https://fb.watch/aNfhD_ewZz/.

I am not related to any party in this lawsuit nor am I interested in the final outcome thereof.

Therefore, I am issuing this certification in Toa Baja, Puerto Rico, today, February 3, 2022.

s/Sonia Negrón

I hereby certify that this is a true and accurate translation to the best of my abilities.

Miriam R. García
Federally Certified Court Interpreter
Certificate No. 03-051