STATE OF MAINE
KENNEBEC, ss.

SUPERIOR COURT
CIVIL ACTION
DOCKET NO. CV-21-158

COALITION FOR HEALTHCARE WORKERS AGAINST MEDICAL MANDATES, et al.,	)	(CONNECTED)
Plaintiffs	)	**ORDER ON PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION**
v.	)	
JEANNE M. LAMBREW and NIRAV D. SHAH,	)	
Defendants	)	

Before the Court is a motion by Plaintiffs seeking a temporary restraining order and/or preliminary injunction directing the Commissioner of Maine Department of Health and Human Services Janet Lambrew and the Director of Maine Center for Disease Control and Prevention Nirav Shah to cease enforcement of an emergency rule mandating COVID-19 vaccinations for healthcare workers in the State.

Oral argument was held on October 8, 2021. Before hearing argument, the Court received testimony from Dr. Peter McCullough for Plaintiffs and Dr. Nirav Shah for Defendants. Attorney Ronald Jenkins represented the Plaintiffs at the hearing, and Maine Deputy Attorney General Thomas Knowlton represented the Defendants. Attorney David Bauer also represents Plaintiffs, and Assistant Attorney General (AAG) Sarah Coleman and AAG Kimberly Patwardhan also represent the Defendants.

Plaintiffs argue the rule is unlawful on six different grounds: the first four claims relate to the methods by which the rule was adopted, the fifth alleges the rule violates federal rights to substantive due process, and the sixth argues the rule is preempted by federal law.[1]

I. Background

Since late 2019, the 2019 Novel Coronavirus, caused by SARS-CoV-2, has spread around the world. The World Health Organization declared a global pandemic in March 2020. Maine has recorded over 86,000 cases of COVID-19 and over 1,000 deaths associated with COVID-19. In late 2020, vaccines emerged as a method to quell the spread of COVID-19.

Maine has required healthcare workers to be vaccinated against certain illnesses since 1989. 22 M.R.S. § 802 (1989). Initially vaccinations were required by statute to prevent and control disease. *Id.* In 2001, the legislature, responding to the changing vaccination field, amended § 802 to grant agency rulemaking power to designate mandatory vaccines for healthcare workers and school children. L.D. 1401, § 1, Summary (120th Legis. 2001); 22 M.R.S. § 802 (2001).

Agency rulemaking began in 2002, when Maine Department of Health and Human Services ("DHHS") adopted a rule requiring vaccination against measles, rubella, hepatitis B, mumps, and chickenpox. 10-144 C.M.R. ch. 264, §§ 1-7 (2002). Plaintiffs challenge a recent amendment to this rule. DHHS and the Maine Center for Disease Control and Prevention (collectively "the Department") promulgated an emergency routine technical rule, effective August 12, 2021, ("the rule" or "the emergency rule"), which modified the vaccination requirements to include a vaccine against COVID-19 and to make the rule apply to dental workers and emergency services

[1] On October 13, 2021, the United States District Court for the District of Maine denied a preliminary injunction requested by another set of plaintiffs opposing the same emergency rule on grounds that differ from those asserted here, including First Amendment and other federal claims. *Jane Does 1-6 v. Janet T. Mills*, No. 1:21-cv-00242-JDL (D. Me. Oct. 13, 2021).

organizations. 10-144 C.M.R. ch. 264 (2021). The emergency rule was promulgated pursuant to 5 M.R.S. § 8054 and 22 M.R.S. § 802(1) and (3).

In its emergency form, the rule lasts ninety days from its inception, until November 10, 2021. The Department initiated rulemaking procedures for a permanent rule of the same substance on September 8, 2021. The notice and comment period for that rule ended on October 7, 2021. Plaintiffs' complaint addresses only the emergency rule, but Plaintiffs argue that the motion properly targets both the emergency and proposed rules, as they contain the same substance. The Court agrees with Defendants that the permanent rule is not ripe for adjudication. However, the Court notes that if the final rule is enacted in substantially similar form, the following analyses for the relevant counts asserted against the emergency rule would likely apply to the final rule.[2]

II. Legal Standard

Injunctive relief is an extraordinary remedy, warranted only when justice urgently demands and remedies at law fall short. *Bar Harbor Banking & Tr. Co. v. Alexander*, 411 A.2d 74, 79 (Me. 1980). A party seeking injunctive relief by a temporary restraining order or a preliminary injunction must demonstrate that the following criteria are met: (1) the moving party will suffer irreparable injury without injunction, (2) the injury outweighs any harm that granting the injunction will cause the nonmoving party, (3) the moving party has at least a substantial possibility that it will succeed on the merits, and (4) injunction will not harm the public interest. M.R. Civ. P. 65; *Bangor Historic Track, Inc. v. Dep't of Agric., Food & Rural Res.*, 2003 ME

[2] The Court was asked by Plaintiffs to expedite this decision if possible. The Court several weeks ago asked the parties to see if they could agree on a Report to the Law Court, but they were unable to reach an agreement on a factual record as required by Rule 24(a) of the Maine Rules of Appellate Procedure if such a Report was to be made.

140, ¶ 9, 837 A.2d 129. Irreparable injury is "injury for which there is no adequate remedy at law...." *Bar Harbor Banking & Tr.*, 411 A.2d at 79.

Of the four factors, "proving likelihood of success on the merits is the 'sine qua non' of a preliminary injunction." *Arborjet, Inc. v. Rainbow Treecare Sci. Advancements*, 794 F.3d 168, 173 (1st Cir. 2015). "Failure to demonstrate that any one of the[] criteria are met requires that injunctive relief be denied." *Bangor Historic Track*, 2003 ME 140, ¶ 10, 837 A.2d 129.

The Maine Administrative Procedure Act governs judicial review of agency rules:

> Judicial review of an agency rule ... may be had by any person who is aggrieved in an action for declaratory judgment in the Superior Court .... Insofar as the court finds that a rule exceeds the rule-making authority of the agency, or is void under section 8057, subsection 1 or 2, it shall declare the rule invalid. In reviewing any other procedural error alleged, the court may invalidate the rule only if it finds the error to be substantial and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if the error had not occurred. If the court finds that the rule is not procedurally invalid and not in excess of the agency's rule-making authority, its substantive review of that rule shall be to determine whether the rule is arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law.

5 M.R.S. § 8058 (2021).

III. Discussion

The first, second, and fourth prongs of the test for whether an injunction should be granted consider the parties' relative injuries and the potential effects on the public. In this case, it is undisputed that Plaintiffs risk job loss if they refuse to comply with the rule. The State, however, alleges that the rule benefits the public interest by preventing the spread of COVID-19, especially in healthcare facilities and secondarily in the community at large. Because the Court concludes that none of the Plaintiffs' claims is likely to succeed on the merits, this opinion does not reach a detailed analysis of the three remaining prongs.

Count I

Count I asserts the rule is invalid under state law because it was promulgated as an emergency rule. This claim is unlikely to succeed on the merits.

The Department may "[e]stablish procedures for the control, detection, prevention and treatment of communicable, environmental and occupational diseases, including public immunization and contact notification programs." 22 M.R.S. § 802(1)(D). The Department "shall adopt rules to carry out its duties as specified in this chapter." § 802(3). When immediate adoption of a rule is "necessary to avoid an immediate threat to public health, safety or general welfare," the Department may "immediate[ly] adopt[] a rule by procedures other than those" prescribed for rulemaking in the normal course. 5 M.R.S. § 8054. In times of a health emergency, the Department "may adopt emergency rules for the protection of public health" and take three categories of actions, none of which encompass the emergency rule at issue. 22 M.R.S. § 802(2).

Plaintiffs make several arguments under the umbrella of Count I. First, they argue that § 802(2) limits the Department's emergency rulemaking authority in times of health emergency to three enumerated categories of permissible actions. The State responds that the § 802(2) emergency rulemaking is a grant of additional authority in health emergencies, and that the plain language of § 802(1) and (3), in conjunction with 5 M.R.S. § 8054(1), authorizes this emergency rule.

"Unless the statute itself discloses a contrary intent, words in a statute must be given their plain, common, and ordinary meaning, such as people of common intelligence would usually ascribe to them." *State v. Brown*, 2014 ME 79, ¶ 13 n.5, 95 A.3d 82. A court will "consider the

whole statutory scheme for the section at issue in seeking to obtain a harmonious result." *Preti Flaherty Beliveau & Pachios LLP v. State Tax Assessor*, 2014 ME 6, ¶ 11, 86 A.3d 30.

The Court finds that the plain reading of 22 M.R.S. § 802(2) does not limit the Department in times of health emergency to emergency rulemaking under the enumerated categories. Section 802 contains two grants of rulemaking authority. First, subsection 3 grants authority to achieve the objectives enumerated in subsection 1.[3] Second, subsection 2 confers additional emergency rulemaking power during health emergencies. No language indicates that the emergency rulemaking power in subsection 2 is exclusive during health emergencies. Read as a whole, the statute allows the Department additional authority during health emergencies, when prompt action may be required. To read subsection 2 as stripping the Department of its broader rulemaking authority, emergency or otherwise, in times of health emergency is in discord with the statute's plain meaning as well as its apparent intent – to allow the Department to act as expeditiously as needed to protect the public from disease and epidemics.

Second, Plaintiffs argue that the § 802(1) and (3) rulemaking authority does not encompass vaccine mandates. This argument, however, ignores the fact that the Legislature has previously acted to mandate vaccinations for certain contagious diseases, and carved out exemptions from such mandates. Plaintiffs' position is that all the existing vaccine mandates in the rule are void. Plaintiffs point to the statutory language, which allows the Department to "establish *procedures* for the control, detection, prevention and treatment of ... diseases" and argue that a mandate is not procedural. § 802(1)(D) (emphasis provided by Plaintiffs). The State responds that the Department does have authority to mandate vaccination, as indicated by the plain language and the statutory history.

[3] The Department can promulgate both emergency and non-emergency rules under the § 802(1) authority. *See* 5 M.R.S. § 8054(1).

Until 2019, the statute contained three exemptions, including for religious and philosophical beliefs. 22 M.R.S.A. § 802(4-B)(A), (B) (2018). In 2019, the Legislature removed two exemptions from subsection 4-B, leaving only medical exemption as a means of avoiding vaccination mandates. L.D. 798, §§ 3-4 (129th Legis. 2019); *see* 22. M.R.S. § 802(4-B)(2020). The Defendants point out that the Legislature made this change before the pandemic. The Court notes that it would not have been necessary for the Legislature to create exemptions from vaccine mandates if such mandates did not have the force of law before, or at the same time, as the exemptions became law. This Court agrees with the Defendants that the recent statutory amendment in conjunction with the reference to public immunization in § 802(1)(D) and, most clearly, the reference to "immunization otherwise required ... by rules adopted by the department pursuant to this section" in § 802(4-B) indicates that the Department does have authority to mandate vaccination under § 802(1) and (3).

Next, Plaintiffs argue that even if the Department had authority to create a vaccine mandate by emergency rulemaking, the rule at issue was illegally promulgated for two reasons. First, they note that the findings of emergency required by 5 M.R.S. § 8054(2) appear in the rule's basis statement and argue that those findings must also be included in the rule itself. The State responds that the plain language of the statute directs the findings to be placed in the rule's basis statement and that the rule is compliant with that reading of the statute.

An "emergency rule must include, with specificity, the agency's findings with respect to the existence of an emergency...." 5 M.R.S. § 8054(2). "Such findings must be included in the basis statement ... in a section labeled 'findings of emergency.'" *Id.*

A plain reading indicates that after directing the findings to be in the rule generally, the Legislature references the basis statement to specify where precisely the findings should exist.

Even if the Legislature does not consider the basis statement a part of the rule, it is unlikely that it intended to require the findings to appear twice. Because the Department did include the findings in the basis statement, the Court concludes that it complied with the statute.

Second, Plaintiffs argue the Department actually caused the emergency by waiting to act until months after COVID-19 vaccines were available. *See* § 8054(2). The Court declines to fault the Department for the timing of this mandate. The Department had no control over when the more aggressive Delta variant arrived in Maine. Since the emergency and final approvals of COVID-19 vaccinations, hundreds of thousands of Mainers have been voluntarily receiving vaccinations. However, some individuals in high-risk settings remain unvaccinated, and Dr. Shah testified credibly about the toll exacted by recurring outbreaks of the virus in congregate settings, including hospitals and especially nursing homes. Obviously, these facilities - particularly nursing homes - are where medically fragile and older Mainers live when they have no other place to go. He testified without contradiction that outbreaks in these settings are still ongoing. The Court finds that the timing of the Department's response was driven by the virus. Given the record before it, the Court finds no basis to infer any bad faith on the part of State actors with regard to the timing of the mandate.

Finally, as the Court has concluded that the Maine Legislature effectively delegated authority to the Department to promulgate this emergency rule, no separation of powers argument is likely to succeed on the merits.

Count II

Count II contends the rule is invalid under state law because it was promulgated as a routine technical rule. This claim is unlikely to succeed on the merits.

"The Legislature shall assign the category and level of review to all rules at the time it enacts the authorizing legislation." 5 M.R.S. § 8071(1). Rules adopted pursuant to 22 M.R.S. § 802(3) "unless otherwise indicated, are routine technical rules...." 22 M.R.S. § 802(3). In deciding whether a rule is major substantive, the judgment of the legislature controls. 5 M.R.S. § 8071(2)(B).

Plaintiffs argue that a vaccine mandate fits the 5 M.R.S. § 8071(2) definition of a "major substantive" rule and therefore cannot be a "routine technical" rule. The State responds that the Legislature holds the power to decide whether rules are major substantive or routine technical, and the Legislature has indicated that rules adopted under 22 M.R.S. § 802(3) will generally be routine technical.

Plaintiffs suggest that the definitions of "major substantive" and "routine technical" in 5 M.R.S. § 8071(2) support their argument that the rule at issue is major substantive rather than routine technical. However, the Court interprets these definitions as guidance for the Legislature in designating the category into which rules promulgated under an authorizing statute fall. If the definitions themselves ultimately controlled the category, the Legislature's designation would be a superfluous and unnecessary task.

More fundamentally, as Defendants point out, the plain language Section 8071 of Title 5 provides that the determination that a rule is "major substantive" is "in the judgment of the Legislature." Given this plain language, the Court must defer to the Legislature's judgment that the rule at issue is routine technical. Plaintiffs' Count II is therefore unlikely to prevail.

Count III

Count III contends the rule is invalid under state law because the Department did not fulfill its obligation to consider all relevant information available to it. This claim is unlikely to succeed on the merits.

In the normal course of rulemaking, the Department must "consider all relevant information available to it, including, but not limited to, economic, environmental, fiscal and social impact analyses and statements and arguments filed, before adopting any rule." 5 M.R.S. § 8052(4).

The Plaintiffs argue that the Department did not meet this threshold. The State counters that the Department did consider all available relevant information, and that the citation of sources the Plaintiffs point to as evidence is not an exhaustive list of all sources the Department considered.

To succeed on their claim, Plaintiffs must prove that the Department did not consider all available relevant information. The list of citations they point to is limited to three sources and is not comprehensive. They also argue that the Department could not have considered all relevant information and rationally decided to promulgate the rule. The Plaintiffs have not carried their burden on this claim, and this argument will likely fail on the merits.

Count IV

Count IV contends the rule is invalid under state law because the Department failed to prepare an economic impact statement. This claim is unlikely to succeed on the merits.

The Department is required to prepare an economic impact statement "[p]rior to the adoption of any proposed rule that may have an adverse impact on small businesses." § 8052 (5-A). A "proposed rule" is a rule "formally proposed for adoption through submission of the rule to the

Secretary of State for publication pursuant to section 8053, subsection 5," the subsection governing public notice of rulemaking. § 8002(8-A).

The Plaintiffs argue that the failure of the Department to create such an impact statement should invalidate the rule. The State responds that the plain language of the statute only applies the requirement to non-emergency rules promulgated in the normal course, before which proposed rules are adopted.

The plain language of the statute supports the State's reading. In the case of an emergency rule such as that at issue, no proposed rule or public hearing predates the rule's official adoption. Because the statute clearly refers to a proposed rule, to construe this requirement to apply to this emergency rule would not comport with a plain reading of the statute. Therefore, Defendants were not obligated to create an economic impact statement under § 8052(5-A).

Count V

Count V alleges the emergency rule violates Plaintiffs' Fourteenth Amendment rights to bodily autonomy and to refuse medical treatment under the substantive due process protections of the United States Constitution. This claim is unlikely to succeed on the merits.

The Plaintiffs contend the rule is subject to strict scrutiny based on its potential infringement on the protected rights. The State argues that *Jacobson* controls, dictating rational basis review, and that regardless, the rule would survive strict scrutiny.

The federal Constitution unquestionably protects an individual's right to bodily integrity and the right to refuse medical treatment. *See Cruzan v. Dir, Mo. Dep't of Health*, 497 U.S. 261, 278 (1990). Determining whether a person's right to refuse medical treatment has been violated, however, requires balancing of individual liberty and state interests. *Id.* at 279. Before the right

to bodily integrity and the right to refuse medical treatment were explicitly recognized, the United States Supreme Court held that public vaccination mandates were valid when weighed against individual liberty interests. *Jacobson v. Mass.*, 197 U.S. 11 (1905).[4]

Neither the Supreme Court nor the Law Court has had an opportunity since *Jacobson* to articulate a precise test for the liberty interests at issue. It is then possible that as the law develops the test will fall somewhere within the bounds of the two tests proffered by the parties in this case: rational basis as applied by *Jacobson,* and strict or heightened scrutiny as applied to many fundamental rights protected by substantive due process. *See Wash. v. Glucksberg*, 521 U.S. 702, 720 (1997). Whether the applicable rule is strict scrutiny, rational basis, or something between the two, has concluded that Plaintiffs' Count V is unlikely to succeed on the merits.

In conducting its analysis under either standard, the Court has been asked to make certain factual determinations based upon a very preliminary record. The parties in this case strongly disagree about the safety and efficacy of COVID-19 vaccination. The Plaintiffs' expert, Dr. Peter McCullough, testified that while the vaccines can prevent an exposed individual from contracting COVID-19, the risks outweigh the benefits. The Plaintiffs' assessment of risk relies in large part on data retrieved from the Vaccine Adverse Event Reporting System ("VAERS"), a database in which anyone can record a negative health event one may believe is associated with a vaccine administration. Reports on VAERS are voluntary and anonymous to the public. According to the testimony of both experts, VAERS may suggest correlation between health events and vaccination, but the data by itself does not establish causation. Plaintiffs make a similar argument with respect to data that shows the number of deaths of Medicare recipients

[4] The Court reasoned that "in every well-ordered society charged with the duty of conserving the safety of its members the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand." *Jacobson v. Mass.*, 197 U.S. 11, 33-34 (1905).

who died after receiving the vaccine. However, Plaintiffs have effectively conceded, as they must, that both the VAERS and Medicare data do not establish causation. It is the Plaintiffs' burden to do that, and the Court is not permitted to speculate about causation. The Court concludes that the Plaintiffs have not proven causation between administration of the vaccine and the harms alleged.

In terms of vaccine efficacy, the parties agree the vaccines may block otherwise likely infection. Dr. McCullough, however, denies that vaccines have demonstrated a reduced risk of hospitalization and death. Aff. of Dr. Peter McCullough ¶ 7. The State pointed to data from Maine hospitals and from FDA trials of the three available vaccines showing otherwise. Based on the record before it, the Court concludes that that the vaccinations likely do ameliorate the risk of hospitalization and death rates among those who contract COVID-19.

Rational Basis

A state action will pass rational basis review when the government has a legitimate interest and the action is rationally related to achieving that interest. *Doe v. Williams*, 2013 ME 24, ¶ 66, 61 A.3d 718. "[W]hen reasonable minds can differ as to the best course of action – for instance, addressing symptomatic versus asymptomatic virus spread or any number or issues here—the court doesn't intervene so long as the [state's] process is rational in trying to achieve public health." *Klaassen v. Trs. of Ind. Univ.*, 2021 U.S. Dist. LEXIS 133300 (N.D. Ind. July 18, 2021) (citing *Phillips v. City of New York*, 775 F.3d 538 (2nd Cir. 2015)); *see also Jacobson*, 197 U.S. at 30 ("It is no part of the function of a court or a jury to determine which ... was likely to be the most effective for the protection of the public against disease.").

In this case, the State has expressed that its interest in promulgating the emergency rule is controlling the spread of COVID-19 by preventing outbreaks, protecting patients, protecting

healthcare workers, and protecting the state healthcare system. The parties seem to agree that COVID-19 presents a risk to the Mainers who work in the medical settings at issue and that the government interests asserted are legitimate. Although the parties disagree as to the extent of the risk, they both agree that vaccination prevents at least some cases of COVID-19. This is enough for the Court to determine that there is a rational basis for the emergency rule. The Court finds further that it is beyond question that prevention of infection, hospitalization and/or death are legitimate state interests. Therefore, the Court concludes that the rule is rationally related to a legitimate government interest, and Plaintiffs' argument under this standard of review is unlikely to succeed on the merits.

Strict Scrutiny

A statute will survive strict scrutiny when it is supported by a "compelling state interest" and is "narrowly tailored to serve" that interest. *Doe*, 2013 ME 24, ¶ 66, 61 A.3d 718. Narrow tailoring exists when a state action is the least restrictive means of achieving the governmental objective. *See Thomas v. Rev. Bd. Of Ind. Emp. Sec. Div.*, 450 U.S. 707, 718 (1981). Still, where scientific and medical uncertainty exists, legislative and agency rulemaking authority receive judicial deference. *Doane v. Dep't of Health & Hum. Servs.*, 2021 ME 28, ¶ 23, 250 A.3d 1101 (recognizing deference to rulemaking authority); *Gonzalez v. Carhart*, 550 U.S. 124, 163 (2007) (recognizing deference to legislation); *Marshall v. United States*, 414 U.S. 417, 427 (1974) (recognizing deference to legislation).

"Stemming the spread of COVID-19 is unquestionably a compelling interest...." *Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020). The question for the court then is whether the emergency rule is narrowly tailored to the asserted government interests. The Plaintiffs argue that other options existed which would have served the same interest without

mandating vaccination. In response, the State argues that less restrictive options were considered but were found to be neither practical nor effective.

The Department expanded those individuals covered by the rule to include dental, emergency medical, and healthcare workers because it determined that their work environments pose higher risks of COVID-19 spread due to the populations served and the type of care provided. For instance, dental patients cannot wear masks or physically distance from their providers while receiving care. Aff. of Dr. Nirav Dinesh Shah ¶ 66. Individuals receiving emergency care tend to be in uncontrolled conditions and are often under considerable distress, with some being on the verge of death. Workers who treat them must be often be in close proximity to them and in direct physical contact with them for extended periods of time. They are therefore at very high risk of being exposed to unmasked individuals at close distance. ¶ 67. Workers in healthcare facilities are likely to interact with many immunocompromised, ill, and elderly patients. ¶ 65. While the Plaintiffs argue that the rule should target only those at high risk of death from COVID-19, the State responds that, because vaccines are not guaranteed to prevent illness, vaccination mandates must also apply to those most likely to spread the disease to vulnerable individuals.

The Court finds the testimony of Dr. Shah to be credible in this regard. The use of personal protective equipment ("PPE"), symptom monitoring, and testing are insufficient to protect against COVID-19 transmission. Even while using PPE and symptom monitoring, healthcare settings in Maine have seen frequent COVID-19 outbreaks. ¶¶ 73-74. Periodic testing is likely to miss quick onsets of the Delta variant, which is the dominant strain of virus throughout Maine and the rest of the country, and this variant can be transmitted within 48 hours after exposure. ¶ 70. Daily testing would require tests that can be processed in short timeframes. Polymerase

Chain Reaction ("PCR") tests may take 24 to 72 hours to process and, if administered daily, would encounter the same issue as periodic testing. ¶ 71. Antigen tests, which can be processed in fifteen minutes, are more likely to show false negative results and are not widely available. *Id.* The Department cites scientific uncertainty regarding whether previous infection with COVID-19 triggers immunity in an individual. ¶ 72. Due to the problems with other methods, the Department found that the least restrictive means to curb COVID-19 spread among vulnerable Mainers was by mandating vaccination for healthcare workers. ¶ 76.[5]

Because the Department provides strong support for its decision by demonstrating how it considered and rejected as ineffective the less restrictive methods proffered by Plaintiffs, as well as other methods it had considered on its own, Plaintiffs are unlikely to succeed on Count V.

Count VI

Count VI seeks a declaratory judgment that federal law, namely the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3 ("FDCA"), preempts the emergency rule. This claim is unlikely to succeed on the merits.

The cited portion of the FDCA requires that patients are informed of the potential benefits and risks of an emergency-authorized product and informed of the option to accept or refuse the product. § 360bbb-3(e)(1)(A)(ii). Plaintiffs argue that the emergency rule does not allow the option to refuse an emergency-approved vaccine. The State first counters that there has been full Food and Drug Administration ("FDA") approval of the Pfizer vaccine and second posits that if

[5] Plaintiffs also suggest several methods of controlling COVID-19 that relate to treatment, such as with "monoclonal antibodies, hydroxychloroquine, ivermectin," etc. Aff. of Dr. Peter McCullough ¶ 7. These methods are not effective at mitigating *spread* of the virus and are targeted instead at increasing survival and decreasing length of illness.

an individual instead chooses a vaccine that has not been fully approved, the rule does not impede the cited protections in the FDCA.

Plaintiffs' argument fails before an assessment of preemption because the rule does not require emergency-authorized vaccines. The Pfizer vaccine against COVID-19 has been approved by the FDA (marketed as "Comirnaty") and is available for injection. Further, the rule does not interfere with the FDCA. Even if covered workers choose to get an emergency-approved vaccine, the rule does not prevent patients from receiving the required information about emergency-authorized products. Workers are also free to accept or reject the emergency treatment in favor of the fully approved Pfizer vaccine. Thus, the rule does not invoke preemption, and Plaintiffs' Count VI is likely to fail.

Maine Administrative Procedure Act Review

Although Plaintiffs did not make the specific claim, after finding no substantive or procedural invalidity, a court reviewing a rule under the Maine Administrative Procedure Act ("MAPA") "shall ... determine whether the rule is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 M.R.S. § 8058.

As outlined above, Defendants have pointed to substantial evidence that links the Department's rule with the valid state interest in protecting the public from COVID-19. As such, Plaintiffs are unlikely to succeed under the above-cited provision of MAPA.

IV. Conclusion

Because none of Plaintiffs' arguments is likely to succeed on the merits, Plaintiffs' motion for a preliminary injunction and/or temporary restraining order is denied.

The clerk is directed to incorporate this order in the docket by reference pursuant to M.R. Civ. P. 79(a).

Dated: October 22, 2021

Justice, Superior Court