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APPENDIX A

FILED
APR 3, 2024
MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MALCOM JOHNSON; STEPHANIE KAISER; JESSIE CLARK; CHRISTINA CARMICHAEL; TARA JOHNSON; KATHLEEN SANDERS; F., DR; TRAVIS BRENNEMAN; D., MS.; LINDA RISER; CHAD DILLARD; HEIDI HOPKINS; GLENN HOPKINS; LEANN WAGERLE; TERESA LYNN KARN; BOAZ MILLER; CANDY BARNETT; LAINE EWRY; MARGARET HENSON; MELISSA SWANCUTT; B., MS.; WENDY SUMNER; ADRIAN PARK; C., DR.; KIMBERLY SWEGAR; KELLY HICKMAN; MS. E; GAIL GILTNER; G., MS.; JENNIFER BRIER; MELANIE CRITES-BACHERT; D.O.; MARTI LAMB; MARY GABRIELE; M.D.; ELISABETH COATES; KORI DISTEFANO; TERESE LAMPA; JAZMIN GRAFF; M.D.; TERRI KAM; STEPHANIE NYHUS; A., DR.; DAVID WEST; NATE LYONS; MITCHELL MOORE; DEBRA BURDETTE; SUSAN BURDICK; SHANE BAKER; KRISTIN DILL; K., MS.; FREE OREGON;

NO. 22-35624

D.C. NO.
3:21-CV-01494-SI

ORDER

M., MS.; ANDRIELE STODDEN; N., MS.; GREG NIGH; AMANDA GAYKEN; H., MS.; KAREN CARREIRA; DANIEL PAUL PENNA; TAILER HART; CAROLYN BROWN; ALYSSA LAKE; JANIRA BRANNIGAN; AMETHYST WHITE; SERENA BORDES; DEAN JOHNSON; LUCERO TERRAZAS; ELAINE ATKINSON; STACY FLETCHER; J., MS.; CHILDREN'S HEALTH DEFENSE, OREGON; CHRISTINA TRESSEL; L., MS.; CARRIE HOWE; TAMARA MILETICH; TAMMY GOAD; CASSANDRA DYKE;

Plaintiffs-Appellants,

v.

TINA KOTEK, in her official capacity as Governor of the State of Oregon; SEJAL HATHI, in her official capacity as Director of the Oregon Health Authority; KATE BROWN, in her personal capacity; PATRICK ALLEN, in his personal capacity,

Defendants-Appellees.

Before: HAWKINS, R. NELSON, and COLLINS, Circuit Judges.

The panel has unanimously voted to deny the petition for panel rehearing. Judge Nelson and Judge Collins have voted to deny the petition for rehearing en banc, and Judge Hawkins so recommends. The

full court has been advised of the petition for rehearing en banc and no judge has requested a vote on whether to rehear the matter en banc. See FED. R. APP. P. 35. Accordingly, Appellants' petition for panel rehearing and rehearing en banc (Dkt. Entry 41) is DENIED.

APPENDIX B

FILED
Feb 23, 2024
MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MALCOM JOHNSON; STEPHANIE KAISER; JESSIE CLARK; CHRISTINA CARMICHAEL; TARA JOHNSON; KATHLEEN SANDERS; F., DR; TRAVIS BRENNEMAN; D., MS.; LINDA RISER; CHAD DILLARD; HEIDI HOPKINS; GLENN HOPKINS; LEANN WAGERLE; TERESA LYNN KARN; BOAZ MILLER; CANDY BARNETT; LAINE EWRY; MARGARET HENSON; MELISSA SWANCUTT; B., MS.; WENDY SUMNER; ADRIAN PARK; C., DR.; KIMBERLY SWEGAR; KELLY HICKMAN; MS. E; GAIL GILTNER; G., MS.; JENNIFER BRIER; MELANIE CRITES-BACHERT; D.O.; MARTI LAMB; MARY GABRIELE; M.D.; ELISABETH COATES; KORI DISTEFANO; TERESE LAMPA; JAZMIN GRAFF; M.D.; TERRI KAM;	NO. 22-35624 D.C. NO. 3:21-CV-01494-SI MEMORANDUM*

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

STEPHANIE NYHUS; A., DR.; DAVID WEST; NATE LYONS; MITCHELL MOORE; DEBRA BURDETTE; SUSAN BURDICK; SHANE BAKER; KRISTIN DILL; K., MS.; FREE OREGON; M., MS.; ANDRIELE STODDEN; N., MS.; GREG NIGH; AMANDA GAYKEN; H., MS.; KAREN CARREIRA; DANIEL PAUL PENNA; TAILER HART; CAROLYN BROWN; ALYSSA LAKE; JANIRA BRANNIGAN; AMETHYST WHITE; SERENA BORDES; DEAN JOHNSON; LUCERO TERRAZAS; ELAINE ATKINSON; STACY FLETCHER; J., MS.; CHILDREN'S HEALTH DEFENSE, OREGON; CHRISTINA TRESSEL; L., MS.; CARRIE HOWE; TAMARA MILETICH; TAMMY GOAD; CASSANDRA DYKE;

Plaintiffs-Appellants,

v.

TINA KOTEK, in her official capacity as Governor of the State of Oregon; SEJAL HATHI, in her official capacity as Director of the Oregon Health Authority; KATE BROWN, in her personal capacity; PATRICK ALLEN, in his personal capacity,

Defendants-Appellees.

Appeal from the United States District Court for the District of Oregon

Michael H. Simon, District Judge, Presiding

Argued and Submitted September 14, 2023 Seattle, Washington

Before: HAWKINS, R. NELSON, and COLLINS, Circuit Judges.

Plaintiffs appeal the dismissal of their federal claims in this action under 42 U.S.C. § 1983, in which they have challenged three since-repealed orders issued by former Oregon Governor Kate Brown and former Director of the Oregon Health Authority ("OHA") Patrick Allen. We largely affirm the district court's judgment, but we remand with instructions to correct the judgment to state that certain mooted claims are dismissed without prejudice, rather than with prejudice.

In August 2021, then-Governor Brown issued an executive order generally prohibiting any state executive branch employee from continuing to work for the executive branch after October 18, 2021 unless he or she received an approved Covid vaccine. Two OHA orders issued under Director Allen's authority likewise generally forbade healthcare workers and school employees from continuing t work in those capacities after October 18, 2021 unless they received Covid vaccinations. Shortly before the orders were about to take effect, Plaintiffs filed this suit, challenging all three orders on various grounds. Plaintiffs' operative complaint named as Defendants Governor Brown and Director Allen, in their official and personal capacities. Governor Brown, however, rescinded the challenged executive order on April 1, 2022. In July 2022, the district court dismissed all claims against Governor Brown as having been mooted by the rescission of the challenged executive order, and the court dismissed the remaining claims against Director Allen for failure to state a claim.

Plaintiffs timely appealed in August 2022. After Allen resigned as OHA Director in early 2023, the two challenged OHA orders were rescinded by an

interim OHA Director, effective June 30, 2023.[1] We have jurisdiction under 28 U.S.C. § 1291, and we review the district court's decision de novo. *Hunley v. Instagram, LLC*, 73 F.4th 1060, 1068 (9th Cir. 2023).

1. All three challenged orders have been rescinded, and we are persuaded that, on the particular record of this case, "the State has carried its burden of establishing there is no reasonable expectation the challenged conduct will recur." *Brach v. Newsom*, 38 F.4th 6, 15 (9th Cir. 2022) (en banc). Moreover, Plaintiffs' complaint did not seek reinstatement as a remedy for any employee who was terminated as a consequence of the vaccine mandates while they were in effect, and Plaintiffs likewise have not asserted the issue of reinstatement as a basis for rejecting Defendants' mootness arguments. *Cf. Doe v. Lawrence Livermore Nat'l Lab.*, 131 F.3d 836, 840 (9th Cir. 1997) (stating that "reinstatement constitutes prospective injunctive relief"). We therefore deem any contentions based on reinstatement to be forfeited. See *Brownfield v. City of Yakima*, 612 F.3d 1140, 1149 n.4 (9th Cir. 2010). Under these circumstances, Plaintiffs' claims for prospective injunctive relief and declaratory relief are moot. See *Brach*, 38 F.4th at 11. The district court, however, dismissed these claims (even ones that it found to be moot) with prejudice. Under

[1] Moreover, during the course of this appeal, Governor Brown was succeeded by Governor Tina Kotek, and Director Allen was ultimately succeeded by Director Sejal Hathi. Pursuant to Federal Rule of Appellate Procedure 43(c)(2), Governor Kotek and Director Hathi are automatically substituted for their predecessors with respect to the claims asserted below against the Governor and Director in their official capacities. Former Governor Brown and former Director Allen remain the named Defendants with respect to the claims asserted against them below in their personal capacities.

Brach, that was error. We therefore vacate the district court's judgment dismissing with prejudice Plaintiffs' claims for injunctive and declaratory relief and remand with instructions to dismiss these claims without prejudice as moot. See *id*. at 15 (citing *Board of Trs. of Glazing Health & Welfare Tr. v. Chambers,* 941 F.3d 1195, 1200 (9th Cir. 2019) (en banc)).

2. To the extent that Plaintiffs seek damages against the Governor and the Director in their official capacities, those claims are barred by the Eleventh Amendment. *Mitchell v. Washington*, 818 F.3d 436, 442 (9th Cir. 2016).

3. Plaintiffs challenge the dismissal of their three federal claims for monetary damages against former Governor Brown and former Director Allen in their personal capacities.[2] These claims all fail as a matter of law.

a. Plaintiffs assert a § 1983 claim alleging that the challenged orders violated the Constitution's Supremacy Clause. This claim is based on the contention that, by requiring use of a vaccine that was only subject to an emergency authorization for its use, the orders were preempted by § 564 of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360bbb-3. That statute states that, in authorizing "the emergency use of an unapproved product," the FDA must, "to the extent practicable," set "conditions" on such authorization, including "[a]ppropriate conditions designed to ensure that individuals to

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[2] The district court erred in holding that the damages claims against Governor Brown were mooted by the rescission of the challenged executive order. *See Buckhannon Bd. & Care Home, Inc. v. W.V. Dep't of Health & Hum. Servs.*, 532 U.S. 598, 608–09 (2001) ("[S]o long as the plaintiff has a cause of action for damages, a defendant's change in conduct will not moot the case.").

whom the product is administered are informed," inter alia, "of the option to accept or refuse administration of the product." 21 U.S.C. § 360bbb-3(e)(1)(A). However, "the Supremacy Clause, of its own force, does not create rights enforceable under § 1983." *Golden State Transit Corp. v. City of Los Angeles*, 493 U.S. 103, 107 (1989) (footnote omitted). Rather, "the availability of the § 1983 remedy turns on whether the [assertedly pre-empting] statute, by its terms or as interpreted, [1] creates obligations sufficiently specific and definite to be within the competence of the judiciary to enforce, [2] is intended to benefit the putative plaintiff, and [3] is not foreclosed by express provision or other specific evidence from the statute itself." *Id.* at 108 (citations and internal quotation marks omitted). Plaintiffs' claim falters at the third prong of this test, because § 310 of the FDCA expressly states that all proceedings to enforce that statute "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Because Plaintiffs' § 1983 claim on this score is an attempt to use § 1983 to create a federal damages remedy to enforce the requirements of FDCA § 564, it is "foreclosed 'by express provision'" of the FCDA. *Golden State Transit*, 493 U.S. at 108 (citation omitted).

b. Plaintiffs allege a separate § 1983 claim based on the contention that, by violating Plaintiffs' alleged fundamental right to refuse experimental medical treatment, the challenged orders deprived them of the "privileges or immunities of citizens of the United States." U.S. Const. amend. XIV, § 1. Plaintiffs concede that this claim is foreclosed by the narrow construction of the Privileges or Immunities Clause adopted in the *Slaughter-House Cases*, 83 U.S. 36 (1873), and that was left undisturbed by *McDonald v.*

City of Chicago, 561 U.S. 742, 758 (2010) ("We ... decline to disturb the *Slaughter-House* holding."). Consistent with this binding precedent, we conclude that this claim fails as a matter of law.

c. Plaintiffs assert a similar § 1983 claim based on the same asserted underlying fundamental right, but this time based on the doctrine that the Fourteenth Amendment's Due Process Clause provides "substantive" protection for certain "fundamental rights that are not mentioned anywhere in the Constitution." *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 237 (2022). We need not decide whether his theory is viable, because even assuming that it is, Governor Brown and Director Allen are entitled to qualified immunity.

"Qualified immunity attaches when an official's conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would have known." *Rivas-Villegas v. Cortesluna*, 595 U.S. 1, 5 (2021) (citation omitted). For a constitutional right to be clearly established, "existing precedent must have placed the ... constitutional question beyond debate." *Mullenix v. Luna*, 577 U.S. 7, 12 (2015) (emphasis added) (citation omitted). "It is the plaintiff[s] who bear[] the burden of showing that the rights allegedly violated were clearly established." *Shafer v. County of Santa Barbara*, 868 F.3d 1110, 1118 (9th Cir. 2017) (citations and internal quotation marks omitted). Plaintiffs have not carried that burden.

Plaintiffs acknowledge that, in 1905, the Supreme Court rejected a constitutional challenge to a set of provisions that, taken together, imposed a monetary fine on any adult inhabitant of Cambridge, Massachusetts who refused to receive the smallpox vaccination. *Jacobson v. Massachusetts*, 197 U.S. 11,

12–13 (1905). Plaintiffs nonetheless contend that *Jacobson* is distinguishable and that this case is instead clearly governed by subsequent Supreme Court authority that they contend establishes a fundamental right to "refus[e] unwanted medical treatment," *Cruzan v. Director, Mo. Dep't of Health*, 497 U.S. 261, 278 (1990), and to resist the "forcible injection of medication into a nonconsenting person's body," *Washington v. Harper*, 494 U.S. 210, 229 (1990). Plaintiffs assert that *Jacobson* is plainly inapplicable, in their view, for three reasons: (1) smallpox was much more lethal than Covid is; (2) smallpox vaccines had a much more well-documented and superior record of effectiveness in preventing the spread of disease than is true for the Covid vaccines; and (3) the Covid vaccines are associated with a higher rate of adverse side-effects. Plaintiffs also argue that principles of international law recognized at the Nuremberg trials reaffirm the asserted fundamental right invoked by Plaintiffs here.

But even if one assumes *arguendo* that *Jacobson* is distinguishable and that there is arguably some support for the right to refuse forced medication that Plaintiffs posit, Plaintiffs still fall short of carrying their burden here. As we have explained, Plaintiffs' burden is to show that existing precedent at the time of the challenged orders made clear "beyond debate" that those orders' vaccination requirements were invalid. *Mullenix*, 577 U.S. at 12 (emphasis added) (citation omitted). At best, the validity of these vaccine mandates under the principles discussed in *Jacobson, Cruzan*, and related cases is debatable, as reflected by the number of decisions that have rejected Plaintiffs' position. *See, e.g., Lukaszczyk v. Cook County*, 47 F.4th 587, 603 (7th Cir. 2022); *We the Patriots USA, Inc. v. Hochul,* 17 F.4th 266, 293–

94 (2d Cir. 2021). We need go no further to resolve this case. Governor Brown and Director Allen are entitled to qualified immunity.

4. Plaintiffs also challenge the chief district judge's denial of their motion for recusal of the (different) assigned judge who decided their case. Plaintiffs contend that, because the assigned judge had posted a sign outside his courtroom stating, "Do Not Enter Unless You Have Been Fully Vaccinated," his impartiality in this matter "might reasonably be questioned" and his disqualification was therefore mandatory under 28 U.S.C. § 455(a). Reviewing for an abuse of discretion, *United States v. McTiernan*, 695 F.3d 882, 891 (9th Cir. 2012), we affirm the chief judge's denial of this motion.

The apparent premise of Plaintiffs' argument is that this posted notice indicated that the assigned judge had personally adopted a mandatory administrative requirement the validity of which would necessarily turn on the same legal and constitutional issues that he was being asked to decide here. But as the chief judge noted, the factual premise of Plaintiffs' argument is wrong. By its terms, the posted notice, which asked unvaccinated individuals to call the chambers number for assistance, did not mandate anything and did not say what accommodations would or would not be made if and when such individuals inquired of chambers. Indeed, in order to accommodate Plaintiffs in this case, the assigned judge took down the sign and freely permitted any member of the public to attend the hearings. Because the posted sign thus did not reflect a mandatory policy comparable to the challenged orders here and would not necessarily be governed by the same legal principles at issue in this case, the chief judge did not abuse his discretion in

concluding that the assigned judge's impartiality could not reasonably be questioned.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF OREGON

MALCOLM JOHNSON, et al.,
Plaintiffs,
v.
KATE BROWN, in her personal capacity and official capacity of Governor of the State of Oregon; and **PATRICK ALLEN**, in his personal capacity and official capacity as Director of the Oregon Health Authority,
Defendants.

Case No. 3:21-cv-1494-SI

OPINION AND ORDER

Stephen J. Joncus, JONCUS LAW P.C., 13203 SE 172nd Avenue, Suite 166 #344, Happy Valley, OR 97086. Of Attorneys for Plaintiffs.

Ellen F. Rosenblum, Attorney General; Marc Abrams, Assistant Attorney-in-Charge; and Christina L. Beatty-Walters, Senior Assistant Attorney General, OREGON DEPARTMENT OF JUSTICE, 100 SW Market Street, Portland, OR 97201. Of Attorneys for Defendants.

Michael H. Simon, District Judge.

Plaintiffs brought this lawsuit to challenge state-ordered COVID-19 vaccination mandates issued by

Oregon Governor Kate Brown and Oregon Health Authority (OHA) Director Patrick Allen. The Court collectively refers to all vaccination mandates challenged in this lawsuit as the "Vaccine Orders." Under an executive order and related regulations, Oregon required certain employees not otherwise exempt on either medical or religious grounds to be vaccinated against COVID-19 or face the risk of losing their jobs. This Court previously denied Plaintiffs' Motion for Temporary Restraining Order. ECF 20. After the Court's ruling, Plaintiffs filed an Amended Complaint (ECF 37) and then a Corrected Amended Complaint (ECF 38), which is the operative pleading. For simplicity, the Court refers to the Corrected Amended Complaint as the "Amended Complaint."

In their Amended Complaint, Plaintiffs asserted five claims for relief. Plaintiffs' first three claims invoked 42 U.S.C. § 1983 and alleged violations of the Due Process Clause of the Fourteenth Amendment, the Privileges Or Immunities Clause of the Fourteenth Amendment, and the Supremacy Clause. ECF 38. Plaintiffs' fourth claim alleged a violation of state law, and Plaintiffs' fifth claim was titled simply "injunction." *Id.* Defendants have moved to dismiss, arguing that, among other things, Plaintiffs have failed to state a claim upon which relief can be granted. ECF 39. In response to Defendants' motion to dismiss, Plaintiffs explain that they do not oppose dismissal of the latter two claims, including Plaintiffs' state law claim. ECF 42 at 39. For the reasons stated below, the Court grants Defendants' Motion to Dismiss on the grounds that Plaintiffs have failed to state a claim upon which relief can be granted. Because Plaintiffs have already had the opportunity to replead their claims after

receiving the benefit of the Court's analysis denying Plaintiffs' motion for a temporary restraining order (ECF 20), the Court dismisses this action with prejudice.[1]

STANDARDS

A motion to dismiss for failure to state a claim may be granted only when there is no cognizable legal theory to support the claim or when the complaint lacks sufficient factual allegations to state a facially plausible claim for relief. *Shroyer v. New Cingular Wireless Servs., Inc.*, 622 F.3d 1035, 1041 (9th Cir. 2010). In evaluating the sufficiency of a complaint's factual allegations, the court must accept as true all well-pleaded material facts alleged in the complaint and construe them in the light most favorable to the non-moving party. *Wilson v. HewlettPackard Co.*, 668 F.3d 1136, 1140 (9th Cir. 2012); *Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998 (9th Cir. 2010). To be entitled to a presumption of truth, allegations in a complaint "may not simply recite the elements of a cause of action, but must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively." *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011). The court must draw all reasonable inferences from the factual allegations in favor of the plaintiff. *Newcal Indus. v. Ikon Office Sol.*, 513 F.3d 1038, 1043 n.2 (9th Cir. 2008). The court need not, however, credit a

[1] Because the Court concludes that Plaintiffs have failed to state a claim upon which relief may be granted, the Court declines to reach Defendants' argument challenging service of process. Because Plaintiffs agree to the dismissal of their state law claim, there is no need for the Court to address Defendants' jurisdictional argument.

plaintiff's legal conclusions that are couched as factual allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009).

A complaint must contain sufficient factual allegations to "plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation." *Starr*, 652 F.3d at 1216. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). "The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Mashiri v. Epsten Grinnell & Howell*, 845 F.3d 984, 988 (9th Cir. 2017) (quotation marks omitted).

BACKGROUND

In a 55-page Opinion and Order, the Court previously described the background of this dispute, including the COVID-19 pandemic, the FDA licensing process, the surge of COVID-19 cases in Oregon in the summer of 2021, and the State of Oregon's responses. ECF 20. In summary, in the midst of the summer 2021 surge of COVID-19 infections in Oregon, Governor Brown issued Executive Order (EO) 21-29, requiring that State Executive-branch employees be fully vaccinated against COVID-19 either by October 18, 2021, or six weeks after the date that the FDA approves a COVID-19 vaccine, whichever comes later. The OHA adopted a similar rule for teachers, school staff, and school volunteers, and another rule for healthcare

providers and healthcare staff. As of September 22, 2021, the Food and Drug Administration (FDA) had approved the COVID-19 vaccine developed by Pfizer-BioNTech under the brand name COMIRNATY® for use in individuals ages 16 and older.

A. Vaccine Orders

Plaintiffs challenge two orders issued by the OHA regarding COVID-19 vaccinations, ultimately promulgated as Oregon Administrative Rule (OAR) 333-019-1030 (the Education Order) and OAR 333-019-1010 (the Healthcare Order). The Education Order was first adopted on August 25, 2021, and was originally effective through February 20, 2022. OAR 333-019-1030. The Education Order was modified on January 28, 2022, and no longer has an expiration date. *Id.* It states that "[c]hildren are required to attend school, which is a congregate setting where COVID-19 can spread easily if precautions are not taken ... This rule is necessary to help control COVID-19, and to protect students, teachers, school staff, and volunteers." OAR 333-019-1030(1). The Education Order then provides that, after October 18, 2021, "[t]eachers, school staff and volunteers may not teach, work, learn, study, assist, observe, or volunteer at a school unless they are fully vaccinated or have provided documentation of a medical or religious exception and the exception has been approved or accepted." OAR 333-019-1030(3)(a).

The Healthcare Order was originally adopted on August 5, 2021, and was modified several times, with substantive changes made most recently on January 31, 2022. OAR 333-019- 1010. Previous versions of the Healthcare Order expired on January 31, 2022, but the current version has no expiration date. The Healthcare Order explains that:

> It is vital to this state that healthcare providers and healthcare staff be vaccinated against COVID-19. COVID-19 undergoes frequent mutations as it replicates, which over time has resulted in variants that are more transmissible or cause more severe disease. Unvaccinated individuals exposed to COVID-19 are very likely to become infected in the absence of mitigation measures and may then transmit the virus to others. Fully vaccinated people get COVID-19 (known as vaccine breakthrough infections) much less often than unvaccinated people. Being vaccinated is critical to prevent spread of COVID-19. Healthcare providers and healthcare staff have contact with multiple patients over the course of a typical day and week. The CDC recommends vaccination against COVID-19 for all eligible individuals. This rule is necessary to help control COVID-19, protect patients, and to protect the state's healthcare workforce.

OAR 333-019-1010(1). Based on these concerns, the Healthcare Order provides that after October 18, 2021, "[h]ealth care providers and healthcare staff may not work, learn, study, assist, observe, or volunteer in a healthcare setting unless they are fully vaccinated or have provided documentation of a medical or religious exception." OAR 333-019-1010(3)(a).[2]

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[2] The terms "[h]ealthcare providers and healthcare staff" are defined as:

> individuals, paid and unpaid, working, learning, studying, assisting, observing or volunteering in a

Plaintiffs also challenge EO 21-29, issued by Governor Brown on August 13, 2021. EO 21-29 required that Oregon executive branch employees be "fully vaccinated" against COVID-19 by October 18, 2021, or six weeks after the date that the FDA approves a COVID-19 vaccine, whichever comes

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> healthcare setting providing direct patient or resident care or who have the potential for direct or indirect exposure to patients, residents, or infectious materials, and includes but is not limited to any individual licensed by a health regulatory board as that is defined in ORS 676.160, unlicensed caregivers, and any clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, student and volunteer personnel.

OAR 333-019-1010(2)(f)(A). "Healthcare setting" is defined as:

> any place where health care, including physical, dental or behavioral health care is delivered and includes, but is not limited to any health care facility or agency licensed under ORS chapter 441 or 443, such as hospitals, ambulatory surgical centers, birthing centers, special inpatient care facilities, long-term acute care facilities, inpatient rehabilitation facilities, inpatient hospice facilities, nursing facilities, assisted living facilities, residential facilities, residential behavioral health facilities, adult foster homes, group homes, pharmacies, hospice, vehicles or temporary sites where health care is delivered or is related to the provision of health care (for example, mobile clinics, ambulances) outpatient facilities, such as dialysis centers, health care provider offices, dental offices, behavioral health care offices, urgent care centers, counseling offices, offices that provide complementary and alternative medicine such as acupuncture, homeopathy, naturopathy, chiropractic and osteopathic medicine, and other specialty centers.

OAR 333-019-1010(2)(g)(A).

later. EO 21-29 allows for exceptions "for individuals unable to be vaccinated due to disability, qualifying medical condition, or a sincerely held religious belief." By its terms, EO 21-29 was to remain in effect until terminated by the Governor. On March 17, 2022, Governor Brown issued EO 22-03, which terminated the COVID-19 state of emergency and rescinded EO 21-29 as of April 1, 2022.

B. Plaintiffs

Seventy-four Plaintiffs are named in the caption of the Amended Complaint. Two are organizations: (1) Free Oregon, "a domestic non-profit corporation dedicated to restoring and protecting the civil rights of its fellow Oregonians," Am. Compl ¶ 9; and (2) Children's Health Defense, Oregon, a nonprofit whose parent organization, Children's Health Defense, "believes in complete health freedom," *id.* ¶ 10. The remaining 72 named individuals are health-care providers, healthcare staff, teachers, school staff, a school volunteer, five state government employees, and an Oregon State Bar employee, each of whom objects to the Vaccine Orders (collectively, the Named Individual Plaintiffs). *Id.* ¶¶ 11-82. Of the Named Individual Plaintiffs, 27 allege that they have received some kind of exemption from their employers. *Id.* ¶¶ 14, 15, 18, 19, 20, 21-24, 28, 29, 33, 42, 43, 56-59, 62, 64-66, 70, 73, 75, 77, 79. Eight of the Named Individual Plaintiffs allege that they have received at least one dose of the COVID-19 vaccination. *Id.* ¶¶ 25, 31, 55, 60, 67, 69, 76, 81.

DISCUSSION

A. Mootness

Of the 72 Named Individual Plaintiffs, four purport to work for Oregon state executive agencies, such that they are subject to EO 21-29. Am. Compl. ¶¶ 59, 62, 64, 82.[3] As described above, however, EO

[3] Two Named Individual Plaintiffs allege that they are subject to Governor Brown's orders, but that does not appear to be correct. One Plaintiff, Ms. L, alleges that she "works for a branch of the Oregon Judicial Department." Am. Compl. ¶ 75. The Oregon Judicial Department, however, is not an "executive" agency headed by the Governor. Rather, it is overseen by the Chief Justice of the Oregon Supreme Court as part of the Judicial Branch. *See* ORS 174.112 (defining "Executive department"). The challenged Executive Order does not apply to employees of the Judicial Branch. Another Plaintiff, Cassandra Dyke, is an employee of the Oregon State Bar. Am. Compl. ¶ 81. Plaintiffs allege that Ms. Dyke "took a COVID-19 vaccination for her personal family reasons. However, the Oregon State Bar is now mandating a booster shot for its employees. She has learned that the vaccines are ineffective and dangerous, and she is adamantly opposed to the mandate." *Id*. Although employees of the Oregon State Bar are not subject to either the Healthcare or Education Orders, it is unclear whether employees of the Oregon State Bar are "executive" branch state employees subject to EO 21-29. Because, however, the Court finds that the claims against the Governor are moot, the Court need not determine whether the Oregon State Bar employees are "executive" state branch employees, "judicial" branch state employees, employees of a quasi-public entity, or something else.

It is also not apparent which of the Vaccine Orders Plaintiffs believe compels any employer to mandate booster shots. Each of the orders at issue define "fully vaccinated" as "having received both doses of a two-dose COVID-19 vaccine or one dose of a single-dose COVID-19 vaccine and at least 14 days have passed since the individual's final dose of COVID19 vaccine." EO-21-29; OAR 333-019-1010(2)(e); OAR 333-019-1030(2)(d).

21-29 was rescinded as of April 1, 2022, by EO 22-03, which the Governor signed on March 17, 2022. As of March 17, 2022, this Motion to Dismiss (ECF 39) had been filed, as had Plaintiffs' response (ECF 42). In their Reply to the Motion to Dismiss (ECF 45), Defendants state that Plaintiffs' claims against the Governor are moot as of April 1, 2022, and should be dismissed for that additional reason.

A federal court does not have jurisdiction "to give opinions upon moot questions or abstract propositions, or to declare principles or rules of law which cannot affect the matter in issue in the case before it." *Church of Scientology of Cal. v. United States*, 506 U.S. 9, 12 (1992) (quoting *Mills v. Green*, 159 U.S. 651, 653 (1895)). "A claim is moot if it has lost its character as a present, live controversy." *Rosemere Neighborhood Ass'n v. U.S. Env't. Prot. Agency*, 581 F.3d 1169, 1172-73 (9th Cir. 2009) (quoting *Am. Rivers v. Nat'l Marine Fisheries Serv.*, 126 F.3d 1118, 1123 (9th Cir. 1997)). To determine mootness, "the question is not whether the precise relief sought at the time the application for an injunction was filed is still available. The question is whether there can be any effective relief." *Nw. Env't. Def. Ctr. v. Gordon*, 849 F.2d 1241, 1244-45 (9th Cir. 1988) (quoting *Garcia v. Lawn*, 805 F.2d 1400, 1403 (9th Cir. 1986)) (emphasis in original).

If a course of action is mostly complete but modifications still can be made that could alleviate the harm suffered by the plaintiff's injury, the issue is not moot. *Tyler v. Cuomo*, 236 F.3d 1124, 1137 (9th Cir. 2000). A case becomes moot "only when it is impossible for a court to grant any effectual relief whatever to the prevailing party." *Chafin v. Chafin*, 568 U.S. 165, 172 (2013) (citation omitted). The party alleging "mootness bears a 'heavy' burden" to

establish that a court can provide no effective relief. *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1017 (9th Cir. 2012) (quoting *Forest Guardians v. Johanns*, 450 F.3d 455, 461 (9th Cir. 2006)).

The Court agrees with Defendants that it would be impossible to grant the state employee Plaintiffs the relief they request. The Court finds that the Governor's receission of EO 21-29 moots the claims asserted against her. Thus, the Court dismisses as moot all claims alleged against Governor Brown.

B. Due Process Claim

As explained in the Court's earlier Opinion and Order (ECF 20), the applicable standard of review for Plaintiffs' due process claims is rational basis review. *See Jacobson v. Massachusetts*, 197 U.S. 11, 25-29 (1905); *see also Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 70 (2020) (Gorsuch, J., concurring) ("Although *Jacobson* pre-dated the modern tiers of scrutiny, this Court essentially applied rational basis review to Henning Jacobson's challenge to a state law that, in light of an ongoing smallpox pandemic, required individuals to take a vaccine, pay a $5 fine, or establish that they qualified for an exemption."). Under rational basis review, the state conduct is presumed valid and will be upheld so long as it is "rationally related to a legitimate state interest." *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 440 (1985).

Plaintiffs fail plausibly to allege that the Vaccine Orders "shock the conscience" or that the state action is not rationally related to any legitimate state interest. The Vaccine Orders are rationally related to Defendants' interests in slowing the spread of COVID-19, protecting Oregon's citizens, protecting children and teachers in schools, and preserving

healthcare resources and protecting patients. *See Peinhopf v. Leon Guerrero*, 2021 WL 2417150, at *5 (D. Guam June 14, 2021) ("[T]his court finds that 'the notion that restrictions designed to save human lives [from COVID-19] are "conscious shocking" to be absurd and not worthy of serious discussion.'" (quoting *Herrin v. Reeves*, 2020 WL 5748090, at *9 (N.D. Miss. Sept. 25, 2020)) (alterations in *Peinhopf*)).

The decision to require vaccination among critical populations, such as healthcare workers and providers and education workers and volunteers, is a rational way to further the State's interest in protecting everyone's health and safety during the COVID-19 pandemic. *See, e.g., S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613-14 (2020) (Roberts, C.J., concurring) ("When [public] officials undertake to act in areas fraught with medical and scientific uncertainties, their latitude must be especially broad. Where those broad limits are not exceeded, they should not be subject to second-guessing by an unelected federal judiciary, which lacks the background, competence, and expertise to assess public health and is not accountable to the people." (cleaned up)); *see also, Peinhopf,* 2021 WL 2417150, at *5 ("The court finds that Defendants had a legitimate reason for issuing the Executive Orders and Guidance Memos; and that is, to safeguard public health and contain the virus's spread."). Plaintiffs have not plausibly alleged that the Vaccine Orders "shock the conscience." Accordingly, the Vaccine Orders do not violate Plaintiffs' rights under the Due Process Clause of the Fourteenth Amendment, and the Court dismisses that cause of action.

C. Privileges Or Immunities Claim

Plaintiffs allege that the Vaccine Orders also violate the Privileges Or Immunities Clause of the Fourteenth Amendment.[4] Plaintiffs allege that they have a fundamental right "not to be coerced into taking experimental medication." Am. Compl. ¶ 209. Plaintiffs contend that right is "essential to the preservation of liberty," is "inherently possessed by human beings," and "has been explicitly recognized as a fundamental human right since World War II." *Id*. Defendants argue that this claim should be dismissed because, after the Supreme Court's decision in the *Slaughter-House Cases*, 83 U.S. 36 (1872), courts have consistently interpreted the Privileges Or Immunities Clause as a "nugatory," *Paciulan v. George*, 229 F.3d 1226, 1229 (9th Cir. 2000), and that Plaintiffs provide no caselaw to support the application of that clause here. In their response to Defendants' Motion to Dismiss, Plaintiffs do not argue that Defendants are incorrect but assert only that they "are entitled to a seek a change in law, should an appeal get to the Supreme Court." ECF 42 at 31. Because Plaintiffs concede that their legal theories are plainly foreclosed by Supreme Court precedent, the Court dismisses Plaintiffs' claims under the Privileges Or Immunities Clause.

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[4] Plaintiffs refer to the "Privileges And Immunities Clause of the Fourteenth Amendment," and cite "U.S. CONST. amend XIV, § 1." The Court, however, construes the Complaint as referring to the Privileges *Or* Immunities Clause of the Fourteenth Amendment, section 1, rather than the Privileges *And* Immunities Clause of Article IV, section 2 of the Constitution. They are two distinct clauses.

D. Supremacy Clause Claim

Plaintiffs argue that the Vaccine Orders conflict with federal informed consent laws associated with federal Emergency Use Authorization (EUA) medical products and thus violates the Supremacy Clause of the Constitution, U.S. Const. art. VI, cl. 2. The Supremacy Clause, however, does not provide an independent cause of action upon which relief can be granted. *See Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 324–25 (2015) ("It is equally apparent that the Supremacy Clause is not the source of any federal rights, ... and certainly does not create a cause of action." (cleaned up)). In addition, the Vaccine Orders do not violate EUA informed consent laws for the reasons explained in the Court's earlier Opinion and Order. ECF 20 at 35-38. Because Plaintiffs fail plausibly to allege a claim under the Supremacy Clause, the Court dismisses Plaintiffs' claims under the Supremacy Clause.

The Court GRANTS Defendants' Motion to Dismiss (ECF 39) with prejudice and will enter Judgment accordingly.

IT IS SO ORDERED.

Dated this 5th day of July, 2022.

/s/Michael H. Simon
Michael H. Simon
United States District Judge

APPENDIX D

THE NUREMBERG CODE

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted, where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end, if he has reached the physical or mental state, where continuation of the experiment seemed to him to be impossible.

10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

["Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10", Vol. 2, pp. 181–182. Washington, D.C.: U.S. Government Printing Office, 1949.]

APPENDIX E

FEDERAL STATUTORY PROVISIONS AND REGULATIONS

10 U.S. C. § 1107a. Emergency use products

(a) Waiver by the President.

(1) In the case of the administration of a product authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act [21 USCS § 360bbb-3] to members of the armed forces, the condition described in section 564(e)(1)(A)(ii)(III) of such Act [21 USCS § 360bbb-3(e)(1)(A)(ii)(III)] and required under paragraph (1)(A) or (2)(A) of such section 564(e), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security.

(2) The waiver authority provided in paragraph (1) shall not be construed to apply to any case other than a case in which an individual is required to be informed of an option to accept or refuse administration of a particular product by reason of a determination by the Secretary of Health and Human Services that emergency use of such product is authorized under section 564 of the Federal Food, Drug, and Cosmetic Act.

(b) Provision of information. If the President, under subsection (a), waives the condition described in section 564(e)(1)(A)(ii)(III) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 360bbb-3(e)(1)(A)(ii)(III)], and if the Secretary of Defense, in consultation with the Secretary of Health and

Human Services, makes a determination that it is not feasible based on time limitations for the information described in section 564(e)(1)(A)(ii)(I) or (II) of such Act [21 USCS § 360bbb-3(e)(1)(A)(ii)(I) or (II)] and required under paragraph (1)(A) or (2)(A) of such section 564(e), to be provided to a member of the armed forces prior to the administration of the product, such information shall be provided to such member of the armed forces (or next-of-kin in the case of the death of a member) to whom the product was administered as soon as possible, but not later than 30 days, after such administration. The authority provided for in this subsection may not be delegated. Information concerning the administration of the product shall be recorded in the medical record of the member.

(c) Applicability of other provisions. In the case of an authorization by the Secretary of Health and Human Services under section 564(a)(1) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 360bbb-3(a)(1)] based on a determination by the Secretary of Defense under section 564(b)(1)(B) of such Act [21 USCS § 360bbb-3(b)(1)(B)], subsections (a) through (f) of section 1107 [10 USCS § 1107] shall not apply to the use of a product that is the subject of such authorization, within the scope of such authorization and while such authorization is effective.

21 U.S.C. § 331. Prohibited acts

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device,

tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404, 415, 505, 564, or 607 [21 USCS § 344, 350d, 355, 360bbb-3, or 364c].

(e) The refusal to permit access to or copying of any record as required by section 412, 414, 417(j), 416, 504, 564, 605, 703, 704(a), 760, or 761 [21 USCS § 350a, 350c, 350f(j), 350e, 354, 360bbb-3, 364a, 373, 374(a), 379aa, or 379aa-1]; or the failure to establish or maintain any record, or make any report, required under section 412, 414(b), 417, 416, 504, 505(i) or (k), 512(a)(4)(C), 512 (j), (l) or (m), 572(i), 515(f), 519, 564, 605, 611, 760, 761, 909, or 920 [21 USCS § 350a, 350c(b), 350f, 350e, 354, 355(i) or (k), 360b(a)(4)(C), 360b(j), (l), or (m), 360ccc-1(i), 360e(f), 360i, 360bbb-3, 364a, 364g, 379aa, 379aa-1, 387i, or 387t] or the refusal to permit access to or verification or copying of any such required record; or the violation of any recordkeeping requirement under section 204 of the FDA Food Safety Modernization Act [21 USCS § 2223] (except when such violation is committed by a farm).

(f) The refusal to permit entry or inspection as authorized by section 704 [21 USCS § 374].

(g) The manufacture, within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303(c)(2) [21 USCS § 333(c)(2)], which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303(c)(3) [21 USCS § 333(c)(3)], which guaranty or undertaking is false.

(i)

(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404 or 721 [21 USCS § 344 or 379e].

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act [21 USCS §§ 301 et seq.], any information acquired

under authority of section 404, 409, 412, 414, 505, 510, 512, 513, 514, 515, 516, 518, 519, 520, 571, 572, 573, 704, 708, 721, 904, 905, 906, 907, 908, 909, or 920(b) [21 USCS § 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 360eee, 360eee-1, 360eee-2, 374, 379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387t(b)], concerning any method or process which as a trade secret is entitled to protection; or the violating of section 408(i)(2) [21 USCS § 346a(i)(2)] or any regulation issued under that section.[.] This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(l) [Deleted]

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of sections 407(b), or 407(c) [21 USCS § 347(b) or (c)].

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 704 [21 USCS § 374].

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Act [21 USCS §§ 301 et seq.].

(p) The failure to register in accordance with section 510 or 905 [21 USCS § 360 or 387e], the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j) [21 USCS § 360(j), 360(k), 387e(i), or 387e(j)], or the failure to provide a notice required by section 510(j)(2) or 905(i)(3) [21 USCS § 360(j)(2) or 387e(i)(3)].

(q)

(1) The failure or refusal—

(A) to comply with any requirement prescribed under section 518, 520(g), 903(b), 907, 908, or 915 [21 USCS § 360h, 360j(g), 387c(b), 387g, 387h, or 387o];

(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 909, or 920 [21 USCS § 360i, 360j(g), 387d, 387i, or 387t]; or

(C) to comply with a requirement under section 522 or 913 [21 USCS § 360l or 387m].

(2) With respect to any device or tobacco product, the submission of any report that is required by or under this Act [21 USCS §§ 301 et

seq.] that is false or misleading in any material respect.

(3) The failure to comply with any requirement under section 524B(b)(2) [21 USCS § 360n-2(b)(2)] (relating to ensuring device cybersecurity).

(r) The movement of a device, drug, or tobacco product in violation of an order under section 304(g) [21 USCS § 334(g)] or the removal or alteration of any mark or label required by the order to identify the device, drug, or tobacco product as detained.

(s) The failure to provide the notice required by section 412(c) or 412(e) [21 USCS § 350a(c) or (e)], the failure to make the reports required by section 412(f)(1)(B) [21 USCS § 350a(b)(1)(B)], the failure to retain the records required by section 412(b)(4) [21 USCS § 350a(b)(4)], or the failure to meet the requirements prescribed under section 412(f)(3) [21 USCS § 350a(f)(3)].

(t) The importation of a drug in violation of section 801(d)(1) [21 USCS § 381(d)(1)], the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 503(c) [21 USCS § 353(c)], the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 503(c)(2) [21 USCS § 353(c)(2)], the distribution of a drug sample in violation of section 503(d) [21 USCS § 353(d)], or the failure to otherwise comply with the requirements of section 503(d) [21 USCS § 353(d)], the distribution of drugs in violation of section 503(e) [21 USCS § 353(e)], failure to comply with the requirements under section 582 [21 USCS § 360eee-1], the failure to comply with the requirements under section 584 [21 USCS § 360eee-3], as applicable[,], or

the failure to otherwise comply with the requirements of section 503(e) [21 USCS § 353(e)].

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 512(a)(4)(A), 512(a)(4)(D), or 512(a)(5) [21 USCS § 360b(a)(4)(A), (4)(D), or (5)].

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 413 [21 USCS § 350b].

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 801(d)(3) [21 USCS § 381(d)(3)]; the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 801(e) or 802 [21 USCS § 381(e) or 382], or with section 351(h) of the Public Health Service Act [42 USCS § 262(h)]; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under section 514(c) [21 USCS § 360d(c)] or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

(y) In the case of a drug, device, or food—

(1) the submission of a report or recommendation by a person accredited under section 523 [21 USCS § 360m] that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 523 [21 USCS § 360m] of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 523 [21 USCS § 360m] of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act [21 USCS §§ 301 et seq.].

(z) [Terminated]

(aa) The importation of a prescription drug in violation of section 804 [21 USCS § 384], the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

(bb) The transfer of an article of food in violation of an order under section 304(h) [21 USCS § 334(h)], or the removal or alteration of any mark or label required by the order to identify the article as detained.

(cc) The importing or offering for import into the United States of an article of food or a drug by, with the assistance of, or at the direction of, a person debarred from such activity under section 306(b)(3) [21 USCS § 335a(b)(3)].

(dd) The failure to register in accordance with section 415 [21 USCS § 350d].

(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 801(m) [21 USCS § 381(m)].

(ff) The importing or offering for import into the United States of a drug or device with respect to

which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 801(o) [21 USCS § 381(o)].

(gg) The knowing failure to comply with paragraph (7)(E) of section 704(g) [21 USCS § 374(g)]; the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

(hh) The failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by the Secretary under section 416 [21 USCS § 350e].

(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 604, 760, or 761 [21 USCS §§ 364, 379aa, or 379aa-1]) or the falsification of a serious adverse event report (as defined under section 760 or 761 [21 USCS §§ 379aa or 379aa-1] or required under section 605(a) [21 USCS § 364a(a)]) submitted to the Secretary.

(jj)

(1) The failure to submit the certification required by section 402(j)(5)(B) of the Public Health Service Act [42 USCS § 282(j)(5)(B)], or knowingly submitting a false certification under such section.

(2) The failure to submit clinical trial information required under subsection (j) of section 402 of the Public Health Service Act [42 USCS § 282].

(3) The submission of clinical trial information under subsection (j) of section 402 of the Public Health Service Act [42 USCS § 282] that is false

or misleading in any particular under paragraph (5)(D) of such subsection (j).

(kk) The dissemination of a television advertisement without complying with section 503B [21 USCS § 353b].

(ll) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 505 [21 USCS § 355], a biological product licensed under section 351 of the Public Health Service Act [42 USCS § 262], or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless—

(1) such drug or such biological product was marketed in food before any approval of the drug under section 505 [21 USCS § 355], before licensure of the biological product under such section 351 [42 USCS § 262], and before any substantial clinical investigations involving the drug or the biological product have been instituted;

(2) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

(3) the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with—

(A) a regulation issued under section 409 [21 USCS § 348] prescribing conditions of safe use in food;

(B) a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

(D) a food contact substance notification that is effective under section 409(h) [21 USCS § 348(h)]; or

(E) such drug or biological product had been marketed for smoking cessation prior to the date of the enactment of the Food and Drug Administration Amendments Act of 2007 [enacted Sept. 27, 2007]; or

(4) the drug is a new animal drug whose use is not unsafe under section 512 [21 USCS § 360b].

(mm) The failure to submit a report or provide a notification required under section 417(d) [21 USCS § 350f(d)].

(nn) The falsification of a report or notification required under section 417(d) [21 USCS § 350f(d)].

(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f) [21 USCS § 333(f)].

(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911 [21 USCS § 387k].

(qq)

(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

(rr) The charitable distribution of tobacco products.

(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

(tt) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that—

(1) the product is approved by the Food and Drug Administration;

(2) the Food and Drug Administration deems the product to be safe for use by consumers;

(3) the product is endorsed by the Food and Drug Administration for use by consumers; or

(4) the product is safe or less harmful by virtue of—

(A) its regulation or inspection by the Food and Drug Administration; or

(B) its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under section 903 [21 USCS § 387c].

(uu) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 [21 USCS § 350g].

(vv) The failure to comply with the requirements under section 419 [21 USCS § 350h].

(ww) The failure to comply with section 420 [21 USCS § 350i].

(xx) The refusal or failure to follow an order under section 423 [21 USCS § 350l].

(yy) The knowing and willful failure to comply with the notification requirement under section 417(h) [21 USCS § 350f(h)].

(zz) The importation or offering for importation of a food if the importer (as defined in section 805 [21 USCS § 384a]) does not have in place a foreign supplier verification program in compliance with such section 805 [21 USCS § 384a].

(aaa) The failure to register in accordance with section 801(s) [21 USCS § 381(s)].

(bbb) The failure to notify the Secretary in violation of section 568 [21 USCS § 360bbb-7].

(ccc)

(1) The resale of a compounded drug that is labeled "not for resale" in accordance with section 503B [21 USCS § 353B].

(2) With respect to a drug to be compounded pursuant to section 503A or 503B [21 USCS § 353A or 353B], the intentional falsification of a prescription, as applicable.

(3) The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 503B [21 USCS § 353B(b)].

(ddd)

(1) The manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally-added plastic microbeads.

(2) In this paragraph—

(A) the term "plastic microbead" means any solid plastic particle that is less than five millimeters in size and is intended to be used to exfoliate or cleanse the human body or any part thereof; and

(B) the term "rinse-off cosmetic" includes toothpaste.

(eee) The failure to comply with any order issued under section 569D [21 USCS § 360bbb-8d].

(fff)

(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification upon any device or container, packaging, or labeling thereof so as to render such device a counterfeit device.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any

punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark or imprint of another or any likeness of any of the foregoing upon any device or container, packaging, or labeling thereof so as to render such device a counterfeit device.

(3) The doing of any act which causes a device to be a counterfeit device, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit device.

(ggg) The failure of a sponsor of a product approved under accelerated approval pursuant to section 506(c) [21 USCS § 356(c)]—

(1) to conduct with due diligence any postapproval study required under section 506(c) [21 USCS § 356(c)] with respect to such product; or

(2) to submit timely reports with respect to such product in accordance with section 506B(a)(2) [21 USCS § 356b(a)(2)].

(hhh) The failure to register or submit listing information in accordance with section 607 [21 USCS § 364c].

(iii) The refusal or failure to follow an order under section 611 [21 USCS § 364g].

21 U.S. C. § 337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this Act [21 USCS §§ 301 et seq.] shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run

into any other district in any proceeding under this section.

(b)

(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of sections 401, 403(b), 403(c), 403(d), 403(e), 403(f), 403(g), 403(h), 403(i), 403(k), 403(q), or 403(r) [21 USCS § 341, 343(b), (c), (d), (e), (f), (g), (h), (i), (k), (q), or (r)] if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)—

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

21 U.S.C. § 360bbb-3 (excerpts)

(a) In general.

(1) Emergency uses. Notwithstanding any provision of this Act and section 351 of the Public Health Service Act, and subject to the provisions of this section, the Secretary may authorize the

introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an "emergency use").

(2) Approval status of product. An authorization under paragraph (1) may authorize an emergency use of a product that—

(A) is not approved, licensed, or cleared for commercial distribution under section 505, 510(k), 512, or 515 of this Act [21 USCS § 355, 360(k), 360b, or 360e] or section 351 of the Public Health Service Act [42 USCS § 262] or conditionally approved under section 571 of this Act [21 USCS § 360ccc] (referred to in this section as an "unapproved product");

...

(4) Definitions. For purposes of this section:

(A) The term "biological product" has the meaning given such term in section 351 of the Public Health Service Act.

(B) The term "emergency use" has the meaning indicated for such term in paragraph (1).

(C) The term "product" means a drug, device, or biological product.

(D) The term "unapproved product" has the meaning indicated for such term in paragraph (2)(A).

...

(b) Declaration of emergency or threat justifying emergency authorized use.

(1) In general. The Secretary may make a declaration that the circumstances exist justifying the authorization under this subsection for a product on the basis of— ...

(C) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents;

...

(e) Conditions of authorization.

(1) Unapproved product.

(A) Required conditions. With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions designed to ensure that health care professionals administering the product are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

(III) of the alternatives to the product that are available, and of their benefits and risks.

> **(ii)** Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—
>
> **(I)** that the Secretary has authorized the emergency use of the product;
>
> **(II)** of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
>
> **(III)** of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

21 C.F.R. § 50.20 General requirements for informed consent.

Except as provided in §§ 50.22, 50.23, and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to

waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

21 C.F.R. § 50.25 Elements of informed consent.

(a) Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(7) An explanation of whom to contact for answers to pertinent questions about the

research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(3) Any additional costs to the subject that may result from participation in the research.

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

(6) The approximate number of subjects involved in the study.

(c) When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act. The statement is: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

(d) The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.

(e) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.

APPENDIX F

OREGON EXECUTIVE ORDERS AND REGULATIONS

EXECUTIVE ORDER NO. 21-29
Covid-19 Vaccination Requirement for State Executive Branch
(excerpts)

... having implemented a series of incentives aimed at achieving voluntary compliance, and with full FDA approval of the COVID-19 vaccine expected within weeks, the time has come for any remaining state employees and those who work alongside them in state government to get vaccinated.

NOW, THEREFORE, IT IS ORDERED AND DIRECTED:

Pursuant to my authorities under Article V, section 1, of the Oregon Constitution, the emergency invoked in Executive Order 20-03, and ORS 401.168, I hereby order:

1. Definitions ...

   c. "Fully Vaccinated" means having received both doses of a two-dose COVID-19 vaccine or one dose of a single-dose COVID-19 vaccine and at least 14 days have passed since the individual's final dose of COVID-19 vaccine.

   d. "Proof of Vaccination" means documentation provided by a tribal, federal, state or local government, or a health care provider, that includes an individual's name, date of birth, type of COVID-19 vaccination given, date or dates given, depending on whether it is a one- dose or two-dose vaccine, and the name/location of the

health care provider or site where the vaccine was administered. ...

e. "Employee" means any person employed by the Executive Branch, ...

f. "Worker" means an individual who is not an Employee, and is engaged to provide goods or service to the Executive Branch ...

2. Prohibitions. This order prohibits the following:

a. Any Employee or Worker from engaging in work for the Executive Branch after October 18, 2021, or six weeks after the date that the United States Food and Drug Administration approves a vaccination against COVID-19, whichever is later, if the Employee or Worker has not been Fully Vaccinated against COVID-19.

b. The Executive Branch from permitting any Employee or Worker to engage in work for the Executive Branch after October 18, 2021, or six weeks after the date that the United States Food and Drug Administration approves a vaccination against COVID-19, whichever ts later, if the Employee or Worker has not been fully vaccinated against COVID-19 and provided proof or documentation thereof, as required under this Executive Order.

3. Documentation of Vaccination for Employees. On or before October 18, 2021, or six weeks after the date that the United States Food and Drug Administration approves a vaccination against COVID-19, whichever is later, Employees must provide their employer with either:

a. Proof of Vaccination showing they are fully vaccinated; or

b. A written request for an exception if available under paragraph 5 of this Executive Order.

4. Documentation of Vaccination for Workers. On or before October 18, 2021, or six weeks after the date that the United States Food and Drug Administration approves a vaccination against COVID-19, whichever ts later, the Executive Branch contracting agency must have documentation that all Workers subject to this Executive Order are in compliance with paragraph 2 of this Executive Order, or that an exception applies under paragraph 6 of this Executive Order.

5. Compliance with State and Federal Law. The Executive Branch is expected to make reasonable accommodations in order to comply with the Americans with Disabilities Act and Title VII of the Civil Rights Act, and state law equivalents, for individuals unable to be vaccinated due to disability, qualifying medical condition, or a sincerely held religious belief.

6. Exceptions to Prohibition. The prohibitions described in paragraph 2 of this Executive Order do not apply if:

> a. An exception available under paragraph 5 ... has been requested in writing by the Employee or Worker, and the request is pending or has been approved.
>
> b. The director of a contracting agency has determined in writing that there is a critical business need for a Worker to perform work without first coming into compliance ...

7. Enforcement. Employees who fail to comply with this directive will face personnel consequences up to and including separation from employment. Contracting agencies may take any action in contract, at law, or in equity for any noncompliance of Workers and entities for which a Worker is an

employee, contractor, or volunteer. Timelines in this Executive Order may be extended at the Governor's discretion. ...
9. Legal Effect. Pursuant to ORS 401.192(1), the directives set forth in this Executive Order shall have the full force and effect of law, and any existing laws, ordinances, rules and orders shall be inoperative to the extent they are inconsistent with the directives set forth in this Order. ...
12. Effective date. This Executive Order is effective August 13, 2021, and remains in effect until terminated by the Governor.

Done at Salem, Oregon, this 13th day of August, 2021.

Kate Brown
GOVERNOR

OAR 333-019-1010
COVID-19 Vaccination Requirement for Healthcare Providers and Healthcare Staff in Healthcare Settings
(excerpts)

(1) It is vital to this state that healthcare providers and healthcare staff be vaccinated against COVID-19. ...
(2) For purposes of this rule, the following definitions apply:
(a) "Contractor" means a person who has healthcare providers or healthcare staff on contract to provide services in healthcare settings in Oregon. ...

(c) "Fully vaccinated" means having received both doses of a two-dose COVID-19 vaccine or one dose of a single-dose COVID-19 vaccine and at least 14 days have passed since the individual's final dose of COVID-19 vaccine.
(d) "Healthcare providers and healthcare staff":
(A) Means individuals, paid and unpaid, working, learning, studying, assisting, observing or volunteering in a healthcare setting providing direct patient or resident care or who have the potential for direct or indirect exposure to patients, residents, or infectious materials, and includes but is not limited to any individual licensed by a health regulatory board as that is defined in ORS 676.160, unlicensed caregivers, and any clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, student and volunteer personnel. ...
(e) "Healthcare setting":
(A) Means any place where health care, including physical or behavioral health care is delivered and includes, but is not limited to any health care facility or agency licensed under ORS chapter 441 or 443, such as hospitals, ambulatory surgical centers, birthing centers, special inpatient care facilities, long-term acute care facilities, inpatient rehabilitation facilities, inpatient hospice facilities, nursing facilities, assisted living facilities, residential facilities, residential behavioral health facilities, adult foster homes, group homes, pharmacies, hospice, vehicles or temporary sites where health care is delivered (for example, mobile clinics, ambulances), and outpatient facilities, such as dialysis centers, health care provider offices, behavioral health care offices, urgent care centers, counseling offices, offices that provide

complementary and alternative medicine such as acupuncture, homeopathy, naturopathy, chiropractic and osteopathic medicine, and other specialty centers. ...

(f) "Medical exception" means that an individual has a physical or mental impairment that prevents the individual from receiving a COVID-19 vaccination.

(g) "Religious exception" means that an individual has a sincerely held religious belief that prevents the individual from receiving a COVID-19 vaccination.

(h) "Proof of vaccination" means documentation provided by a tribal, federal, state or local government, or a health care provider, that includes an individual's name, date of birth, type of COVID-19 vaccination given, date or dates given, depending on whether it is a one-dose or two-dose vaccine, and the name/location of the health care provider or site where the vaccine was administered. ...

(i) "Responsible party" means a person or persons who have control or responsibility for the activities of healthcare providers or healthcare staff in a healthcare setting.

(3) After October 18, 2021:

(a) A health care provider or healthcare staff person may not work, learn, study, assist, observe, or volunteer in a healthcare setting unless they are fully vaccinated or have provided documentation of a medical or religious exception.

(b) An employer of healthcare providers or healthcare staff, a contractor, or a responsible party may not employ, contract with, or accept the volunteer services of healthcare providers or healthcare staff persons who are working, learning, studying, assisting, observing or volunteering at a healthcare setting unless the healthcare providers or healthcare

staff persons are fully vaccinated against COVID-19 or have a documented medical or religious exception.
(4) On or before October 18, 2021, healthcare providers and healthcare staff must provide their employer, contractor or responsible party with either:
(a) Proof of vaccination showing they are fully vaccinated; or (b) Documentation of a medical or religious exception.
(A) A medical exception must be corroborated by a document signed by a medical provider, who is not the individual seeking the exception, on a form prescribed by the Oregon Health Authority (OHA) or a similar form that contains all of the information required in the OHA form, certifying that the individual has a physical or mental impairment that limits the individual's ability to receive a COVID-19 vaccination based on a specified medical diagnosis, and that specifies whether the impairment is temporary in nature or permanent.
(B) A religious exception must be corroborated by a document, on a form prescribed by the Oregon Health Authority (OHA) or a similar form that contains all of the information required in the OHA form, signed by the individual stating that the individual is requesting an exception from the COVID-19 vaccination requirement on the basis of a sincerely held religious belief and including a statement describing the way in which the vaccination requirement conflicts with the religious observance, practice, or belief of the individual.
(5) Employers of healthcare providers or healthcare staff, contractors and responsible parties who grant an exception to the vaccination requirement under section (4) of this rule must take reasonable steps to ensure that unvaccinated healthcare providers and

healthcare staff are protected from contracting and spreading COVID-19.
(6) On or before October 18, 2021, all employers of healthcare providers or healthcare staff, contractors, and responsible parties must have documentation that all healthcare providers and healthcare staff are in compliance with section (4) of this rule.
(7) Nothing in this rule is intended to prohibit employers of healthcare providers or healthcare staff, contractors and responsible parties from: ...
(c) Imposing these requirements at an earlier date.
(8) The vaccination documentation and documentation of medical and religious exceptions described in section (4) of this rule must be: (a) Maintained in accordance with applicable federal and state laws; (b) Maintained for at least two years; and (c) Provided to the Oregon Health Authority upon request.
(9) Employers of healthcare providers or healthcare staff, contractors and responsible parties who violate any provision of this rule are subject to civil penalties of $ 500 per day per violation.

OAR 333-019-1030
COVID-19 Vaccination Requirements for Teachers and School Staff
(excerpts)

(1) ... This rule is necessary to help control COVID-19, and to protect students, teachers, school staff, and volunteers.
(2) For purposes of this rule, the following definitions apply: ...
(b) "Fully vaccinated" means having received both doses of a two-dose COVID-19 vaccine or one dose of a single-dose COVID-19 vaccine and at least 14 days

have passed since the individual's final dose of COVID-19 vaccine.
(c) "Medical exception" means that an individual has a physical or mental impairment that prevents the individual from receiving a COVID-19 vaccination.
(d) "Religious exception" means that an individual has a sincerely held religious belief that prevents the individual from receiving a COVID-19 vaccination.
(e) "Proof of vaccination" means documentation provided by a tribal, federal, state or local government, or a health care provider, that includes an individual's name, date of birth, type of COVID-19 vaccination given, date or dates given, depending on whether it is a one-dose or two-dose vaccine, and the name/location of the health care provider or site where the vaccine was administered. ...
(f) "School":
(A) Means a public, private, parochial, charter or alternative educational program offering kindergarten through grade 12 or any part thereof.
(B) Does not mean stand-alone preschool program that goes up through kindergarten.
(g) "School-based program" means a program serving children or students that takes place at or in school facilities.
(h) "School-based program staff and volunteers":
(A) Means anyone age 16 and older:
(i) Who is employed by a school-based program or who is not employed but is otherwise engaged to provide goods or services to a school-based program through any formal or informal agreement, whether compensated or uncompensated, and includes but is not limited to teachers, administrative staff, child care staff, cleaning staff, coaches, school-based program drivers, family volunteers; and

(ii) Providing goods or services at or for a school-based program that includes direct or indirect contact with children or students.
(B) Does not mean short-term visitors or individuals making deliveries. (i) "Teachers, school staff and volunteers":
(A) Means anyone age 16 and older:
(i) Who is employed at a school or anyone who is not employed but is otherwise engaged to provide goods or services to or at a school through any formal or informal agreement, whether compensated or uncompensated, and includes but is not limited to teachers, administrative staff, cleaning staff, coaches, school bus drivers, family volunteers and substitute teachers; and
(ii) Providing goods or services at or for a school that includes direct or indirect contact with students.
(B) Does not mean short-term visitors, individuals making deliveries, or school board members unless they are also volunteering in a school.
(3) After October 18, 2021:
(a) Teachers, school staff and volunteers may not teach, work, learn, study, assist, observe, or volunteer at a school unless they are fully vaccinated or have provided documentation of a medical or religious exception.
(b) A school may not employ, contract with, or accept the volunteer services of teachers, school staff or volunteers who are teaching, working, learning, studying, assisting, observing, or volunteering at a school unless the teachers or school staff are fully vaccinated against COVID-19 or have a documented medical or religious exception.
(4) On or before October 18, 2021, teachers, school staff and volunteers must provide their school, employer or contractor with either: (a) Proof of

vaccination showing they are fully vaccinated; or (b) Documentation of a medical or religious exception: ...
(5) Schools that grant an exception to the vaccination requirement under section (4) of this rule must take reasonable steps to ensure that unvaccinated teachers, school staff and volunteers are protected from contracting and spreading COVID-19.
(6) On or before October 18, 2021, schools must have documentation that all teachers, school staff and volunteers are in compliance with section (4) of this rule.
(7) After October 18, 2021:
(a) School-based program staff and volunteers may not teach, work, provide care, learn, study, assist, observe, or volunteer for a school-based program unless they are fully vaccinated or have provided documentation of a medical or religious exception.
(b) A school-based program may not employ, contract with, or accept the volunteer services of school-based program staff or volunteers who are teaching, working, providing care, learning, studying, assisting, observing, or volunteering at a school-based program unless the staff or volunteers are fully vaccinated against COVID-19 or have a documented medical or religious exception.
(8) On or before October 18, 2021, school-based program staff and volunteers must provide their school-based program with either: (a) Proof of vaccination showing they are fully vaccinated; or (b) Documentation of a medical or religious exception. ...
(9) School-based programs that grant an exception to the vaccination requirement under section (8) of this rule must take reasonable steps to ensure that unvaccinated school-based program staff and volunteers are protected from contracting and spreading COVID-19.

(10) On or before October 18, 2021, school-based programs must have documentation that all school-based program staff and volunteers are in compliance with section (8) of this rule. ...
(14) The vaccination documentation and documentation of medical and religious exceptions must be: (a) Maintained in accordance with applicable federal and state laws; (b) Maintained for at least two years; and (c) Provided to the Oregon Health Authority upon request. (15) Schools and school-based programs that violate any provision of this rule are subject to civil penalties of $ 500 per day per violation.