# IN THE COURT OF APPEALS OF THE STATE OF OREGON

FREE OREGON, INC., MANDATE FREE OREGON, INC., Oregon nonprofit corporations, and DOCTORS FOR FREEDOM, an unincorporated association, HEALTH FREEDOM DEFENSE FUND, and TAMARA DIMMICK, RASA SIDAGYTE, MICHELLE DAVIS, LISA NAVE, CHARLOTTE PERSINGER, CHRYSTAL GERVAIS, AARON HARRIS, ROY McGRATH, GLENN CAMPBELL, JESSICA COX, BRITTANY WILSON, JOSHUA WILLIAMS, and MOLLY VALDEZ individuals,

Petitioners,

v.

**STATE OF OREGON**, acting by and through the **OREGON HEALTH AUTHORITY**; **KATE BROWN**, in her official capacity as Governor of Oregon and as Chief Executive of the Oregon Health Authority; **PATRICK ALLEN**, in his official capacity as Director of the Oregon Health Authority, CA A176977

#### PETITIONERS EMERGENCY MOTION TO STAY ENFORCEMENT OF RULE PENDING REVIEW

EMERGENCY MOTION UNDER ORAP 7.35

Respondents.

### PETITIONERS' EMERGENCY MOTION TO STAY ENFORCEMENT OF

#### **RULE PENDING REVIEW (ORAP 7.35)**

#### INDEX

# Page

Indexii
Index of Authorities iv
Cases Citediv
Rules Citedv
I. BACKGROUND
II. PETITIONERS
III. POINTS AND AUTHORITIES
<b>A.</b> The Petitioners have a high likelihood of prevailing on merits8
1. OHA's Rules are in direct conflict with ORS 431.1809
<ol> <li>COVID-19 vaccines cannot be mandated under Section 564 of the Federal Food, Drug and Cosmetic Act (21 USC § 360bbb-3</li></ol>
a. Legal background; federal requirement of informed consent, as a condition precedent to administration of EUA medical products, is inviolable and cannot be waived by state authority
<b>b.</b> The State of Oregon and the OHA must comply with Section 564 of the FD&C Act
c. There is a right to informed consent under EUA 17
d. The definition of "fully vaccinated" under the OHA Rules include vaccines that cannot be mandated under federal EUC law
e. COMIRNATY (FDA-approved vaccine to prevent COVID-19)
f. Federal Preemption under the Supremacy Clause 36
g. CDC COVID-19 Vaccination Program and Provider Agreement

h. CDC COVID-19 Vaccination Program and Provider Agreement	43
3. The Rules are Unconstitutional Because They Violate the Contracts Clause of the Oregon and United State Constitutions	45
a. The Rules unlawfully impair the contracts of the employers and employees.	45
b. The Rules unlawfully impair the contracts of the CDC and the providers	49
c. The Rules must be enjoined because they repudiate and breach the terms of the State of Oregon's cooperative agreement with the CDC.	49
4. The Rules are invalid because they fail to comply with ORS 183.335	50
a. OHA's Rules are substantively permanent rules, but only followed temporary rule making procedures	50
b. OHA's Rules violate ORS 183.335(5)	50
5. OHA's rule us unconstitutional because it is overboard, vague and class-based deprivation of civil rights of certain person in violation of 42 USC § 1983	55
a. Balancing of the Harms if Stay is not Granted	
IV. Conclusion	61

# **INDEX OF AUTHORITIES**

# **Cases Cited**

Aluminum Cooking Utongil Co. y. N. Pand		
<i>Aluminum Cooking Utensil Co. v. N. Bend</i> , 210 Or 412, 428, 311 P2d 464, 472 (1957)		
Black's Law Dictionary 203, 210 (6th ed 1991) 24, 25		
Blantz v. Cal. Dep't of Corr. & Rehab., 727 F3d 917 (9th Cir 2013) 57		
<i>Bridges v. Houston Methodist Hosp.</i> , No. 4:21-cv-01774, 2021 WL 2399994, 2021 US Dist LEXIS 110382 (SD Tex June 12, 2021)		
<i>Cf. Waterwatch of Oregon, Inc. v. Oregon Water Resources Commission,</i> 97 Or App 1, 774 P2d 1118 (1989)		
Comcast of Ore. II, Inc. v. City of Eugene, 211 Or App 573, 586 25		
Cruzan v. Dir., Mo. Dep't of Health, 497 US 261 (1990) 12, 13, 23, 28		
Dent v. West Virginia, 129 US 114, 121 (1889) 56		
Doe v. Rumsfeld, 297 F Supp 2d 119 (D DC 2003) 20, 21, 25		
<i>Dunn v. Reynolds Sch. Dist. No. 7</i> , 2010 US Dist LEXIS 121401 (D Or 2010)		
<i>Eckles v. State of Oregon</i> , 306 Or 380, 390, 760 P2d 846 (1988) 45, 46		
Engquist v. Or. Dep't of Agric., 478 F3d 985, 998 (9th Cir 2007) 57, 58		
<i>Franklin v. Biggs</i> , 14 Or App 450, 461 (1973) 25		
Gibbons v. Ogden, 9 Wheat 1, 211 (1824)		
Illustrated Stedman's Medical Dictionary 1526–27 (24th ed 1982) 10, 11		
Jacobson v. Massachusetts, 197 U.S. 11, 24-30, 49 L. Ed. 643, 25 S. Ct. 358 (1905) 11, 13, 44, 47		
Johnson v. Crook Cnty., 53 Or 329, 334–35 (1909)		
<i>Lane v. Marion County</i> , No 6:19-CV-287-MC, 2020 US Dist LEXIS 170515, 2020 WL 5579820, at *3 (D Or Sept 17, 2020) 58		
Lewis v. Oregon Beauty Supply Co., 302 Ore 616, 620–21, 733 P2d 430 45		
Mabry v. Johnson, 467 US 504, 508 (1984) 22		
Metro. Hospitals, Inc. v. State Health Planning & Dev. Agency,		

52 Or App 621, 628 P2d 783 (1981) 53
Nunez v. City of Los Angeles, 147 F3d 867, 873 (9th Cir 1998) 57
Porter v. Oba, Inc., 180 Or App 207, 213–14, 42 P3d 931, 935 (2002) 45
<i>Powell Grove Cem. v. Multnomah Co.</i> , 228 Or 597, 600, 365 P2d 1058 (1961) 47
<i>R.R. Co. v. Husen</i> , 95 US 465 (1877) 40
<i>Schloendorff v. Society of N.Y. Hosp.</i> , 211 NY 125, 129–130, 105 NE. 92, 93 (1914) 22
Schmidt v. Masters, 7 Or App 421, 434, 490 P2d 1029 (1971) 47
Smith v. Texas, 233 US 630, 638 (1914) 57
State v. Gable, 127 Or App 320, 324, 873 P2d 351 (1994) 22
State v. Wright, 53 Or 344, 348, 100 P 296 (1909) 55
Thoren v. Builders Board, 21 Or App 148, 533 P2d 1388 (1975) 47
Tofsrud v. Spokane Police Dep't, 2021 US Dist LEXIS 103715, at *20 57
<i>Truax</i> v. <i>Raich</i> , 239 US 33, 60 L Ed 131, 36 S Ct 7 (1915) 45
United States v. Calise, 217 F Supp 705, 708 (SD NY 1962) 40
Washington v. Glucksberg, 521 US 702, 725 (1997) 12, 24
<i>Washington v. Harper</i> , 494 US 210, 229 (1990)
Wilkinson v. Carpenter, 277 Or 557, 564, 561 P2d 607 (1977) 48

# **Rules** Cited

# Oregon Revised Statutes

ORS 19.350	7
ORS 183.310	1
ORS 183.332	42

ORS 183.530 51
ORS 183.534 51
ORS 183.335 50, 51, 52, 55
ORS 183.400
ORS 431.001
ORS 431.180
ORS 431.550
ORS 431.9909
ORS 433.040 10
ORS 433.407
ORS 433.416 24, 43, 58
ORS 441.181 24
ORS 659A 61
ORS 677.010 10, 15
ORS 677.097 19, 24, 27
Oregon Administrative Rules
OAR 333-019-1010 1, 3, 4, 6, 8, 9, 10, 11, 29, 31, 59, 61
OAR 333-019-1030 1, 3, 30, 31, 61
United States Code
10 USC § 1107 20, 23, 29
EMERGENCY MOTION UNDER ORAP 7.35 TYLER SMITH & ASSOCIATES, P.C. 181 N. Grant St. STE 212, Canby, Oregon 97013 503-266-5590; Fax 503-212-6392

vi

18 USC § 35	01
21 USC §§ 3	01-399
21 USC § 32	1
21 USC § 35.	5
21 USC § 36	013, 15, 16, 17, 18, 20, 21, 23, 27, 33, 34, 35, 36, 37, 38, 41
21 USC § 39	3
42 USC § 26	2
42 USC § 19	83

# Code of Federal Regulations

45 CFR § 46.116	
21 CFR § 50.20	
21 CFR § 312.3	

Oregon Constitution	
Article I, section 21	8, 45, 46
Article VI, section 2	

# PETITIONERS' EMERGENCY MOTION TO STAY ENFORCEMENT OF RULE PENDING REVIEW (ORAP 7.35)

Petitioners request that the court grant an emergency temporary stay of OAR 333-019-1010, attached as Exhibit 1, and OAR 333-019-1030, attached as Exhibit 2 (collectively the "Rules"). Counsel has conferred with the Solicitor General who would not stipulate to this stay. This emergency stay is necessary because on or after October 18, 2021 all Petitioners and those like them will be terminated. If hospitals, doctors offices, emergency responders have a drastic reduction in workforce between October 1 and October 18, the innocent public will suffer the avoidable consequences. We request the court stay these two agency "orders," which by law are "rules" as defined in ORS 183.310(9), until this court as a whole has an opportunity to substantively review these Rules, but at a minimum 21 days from any decision on this motion, or until a full adjudication of this matter so that Petitioners and others to whom the rule arguably applies can preserve their rights until this court rules on whether OHA's actions are legal. If this court does not grant this emergency stay, it will be too late for Petitioners as by then they will be terminated, or have been successfully coerced into a treatment against their will. The rules themselves expire on or about February 7, 2022 so immediate and full legal review and an emergency stay is necessary now, or else the Plaintiffs will be irreparably injured

before this court is able to rule on the substantive invalidity of these rules.

The issues presented in this case turn on what are arguably some of the most impactful and harmful temporary administrative rules that have ever been adopted by an agency because they force potentially hundreds of thousands of individuals to undergo a medical treatment against their wishes or else be deprived by a state actor of their job, their income, and their very means of livelihood. A failure to stay these Rules will leave Petitioners and those individuals without the ability to provide for their families. The Petitioners have filed an emergency motion because Petitioners, together with hundreds if not tens of thousands of other Oregonians, will be imminently terminated from their public and private employment in their chosen professions unless they subject themselves to the false choice of succumbing to an unwanted, intrinsically coercive, unreasonable medical intervention with unknown long-term risks, that is likely in violation of state and federal law, the Oregon Constitution, and the United States Constitution. The United States Supreme Court has ruled that a "forcible injection ... into a nonconsenting person's body represents a substantial interference with that person's liberty[.]" Washington v. Harper, 494 US 210, 229 (1990). Petitioners should have their day in court before they are compelled to be subject to such substantial interference with their liberty.

Petitioners also point out that their fire departments, health providers and other places of employment will be ravaged by these Rules and left short-handed and incapable of serving those who do contract the virus – both vaccinated and unvaccinated.

As detailed below, OHA's rules (the Rules hereafter) not only compel the Petitioners to accept the State's preferred medical treatment at the risk of physical injury with only immediate short-term (and short-sighted) benefits (terminating February 7<sup>th</sup>), but also endanger otherwise healthy Oregonians. This violates state law, is pre-empted by federal law, and is unconstitutional. The Rules effectively create a second class of citizens-viz., the unvaccinated-who the State of Oregon, by and through the OHA, apparently regards as a "separate but equal" class of citizens, who cannot be employed. The Rules establish as a matter of law that certain individuals cannot work in certain industries. As such, the OHA has deemed it appropriate to exclude Petitioners and others similarly situated from pursing their chosen vocations, professions, and careers in order to temporarily curb the spread of an endemic illness that OHA admits can neither be stopped nor eradicated by these Rules.

#### I. BACKGROUND

On August 4, 2021, the Oregon Health Authority (OHA) adopted a temporary rule (codified at OAR 333-019-1010) mandating, with some exceptions, either COVID-19 vaccination or weekly testing of all healthcare providers and healthcare staff no later than September 30, 2021.

On August 25, 2021, the OHA adopted an amended temporary rule that superseded the prior rule. Among other substantive changes, the amended rule extended the date of compliance to October 18, 2021 and removed the option of weekly testing. On the same date, the OHA adopted a similar vaccination requirement as applied to schools and school-based programs (codified at OAR 333-019-1030).

On September 1, 2021, the OHA again amended OAR 333-019-1010, to include changes that are not relevant for purposes of this case.

#### **II. PETITIONERS**

Petitioner Free Oregon Inc. (Free Oregon) is an Oregon nonprofit corporation dedicated to the preservation of civil rights and civil liberties in Oregon. Free Oregon has members such as many of the Petitioners shown in its sworn declaration who have been threatened with termination from their employment if they do not get vaccinated. Decl. Free Oregon ¶ 2. Free Oregon members cannot exercise their statutory right to choose their own medical treatment in prevention of COVID-19 and are being deprived of the right to elect not to receive one of the authorized vaccine treatments.

Petitioner Mandate Free Oregon, Inc. is an Oregon nonprofit corporation formed by firefighters, first responders, and other professionals in response and objection to being forced to receive the vaccine or be terminated from employment. Mandate Free Oregon already has over 2,500 members like Petitioners Wilson and Davis who it represents to protect its members civil and constitutional rights against unlawful mandates.

Doctors for Freedom is an unincorporated association and group of Oregon medical providers that stand for and have taken an oath to protect the people's individual medical autonomy in the communities we serve. Doctors from across the medical industry have banned together to fight and stand against extreme governmental overreach that has been forced upon our communities through mandatory COVID-19 vaccination. We steadfastly believe the power to freely choose any medical treatment lies solely with the individual. It is our duty as medical practitioners to inform our patients of all risks, benefits, and alternatives to any treatment that they freely choose to undergo. That is not what is happening with the COVID-19 vaccine in Oregon. Doctors for Freedom has asked the court to allow them to participate by and through legal representation for fear of professional retaliation against them by the State and regulatory agencies of the state.

Health Freedom Defense Fund (HFDF) seeks to rectify health injustice through education, advocacy and legal challenges to unjust mandates, laws and policies that undermine our health freedoms and human rights. They are working around the clock to implement a strategy to remove the unethical and unlawful mask, testing, and vaccine mandates being rolled out nationwide by government, businesses and educational institutions.

Petitioner Rasa Sidagyte works for Providence Newberg and has worked over nine years with Providence and two years at Providence Newberg. The harm to her caused by the Rules means the loss of her only source of income to care for herself and her pets. Moreover, besides the loss of all her income to support herself, she will also be unable to visit and support her family who resides in various European countries. *See* Declaration of Rasa Sidagyte.

Petitioner Chrystal Gervais, a Providence Willamette Falls employee, has been an employee for 24 years. For her, it means she will lose her only source of income. She has a well-paying professional career that she will lose and will be unable to support her horses which she has owned her entire life, and she will be unable to afford her current house payments and car payments. *See* Declaration of Chrystal Gervais.

Petitioner Tamara Dimmick does not provide direct medical service to anyone. She is an office specialist who has been an employee for the Oregon State Police Department for eight years, yet she too will be terminated under OAR 333-019-1010 on or before October 18th. The injury to her if this rule stays in place would be the erroneous deprivation of her job—it not only means she will be unable to support her 15-year-old granddaughter whom she has custody over, but

she will also lose her retirement benefits and likely be unable to find new employment due to her age. Petitioner Dimmick has a formal contract via a collective-bargaining agreement that will be breached and unilaterally altered by the interference created by the Rules. *See* Declaration of Tamara Dimmick.

Petitioner and registered nurse Lisa Nave, who has been an employee of Providence Willamette Falls for 10 years, has also been threatened with being terminated, and for her it means the loss of not only her income, but the only source of income for her family of five, including three teenagers who are all in school. *See* Declaration of Lisa Nave.

Petitioner Charlotte Persinger is a communications disease nurse who has been an employee of the State of Oregon Department of Corrections for over 18 years. Application of this temporary rule to her means she will lose her insurance that supports her husband who has congestive heart failure. It also means she will lose the only source of income that supports her household. *See* Declaration of Charlotte Persinger.

Petitioner and medical receptionist Michelle Davis has been an employee of OHSU Hillsboro Medical Center for one year. She too has been threatened with termination which, if allowed to take place, means she will no longer be able to support her daughter in graduate school. Not only will she be unable to provide benefits to her family, she will also be unable to financially support her mother

who is in a nursing home. See Declaration of Michelle Davis.

#### **III. POINTS AND AUTHORITIES**

The legal standard for the Court of Appeals granting a stay is similar to that of a preliminary injunction. Pursuant to ORS 19.350(5), the court will normally consider the following:

(a) the likelihood of the appellant prevailing on appeal;

(b) whether the appeal is taken in good faith and not for the purpose of delay;

(c) whether there is any support in fact or in law for the appeal; and

(d) the nature of the harm to the appellant, to other parties, to other persons, and to the public that will likely result from the grant or denial of a stay.

#### (A) The Petitioners have a high likelihood of prevailing on appeal.

The Rules are invalid under ORS 183.400 for the following reasons and the legal merits in this case are so strong they warrant and immediate stay:

First, the Rules are in direct and express conflict with ORS 431.180 by mandating a particular medical treatment under color of law or face government mandated sanctions.

Second, the Rules are preempted by federal law that requires recipients of emergency use authorization biologics be told that the unapproved product is optional.

Third, the Rules directly violate Article I, section 21, of the Oregon

Constitution by impairing the contracts between Petitioners and their employers who have no choice but to terminate their respective contractual relationships unless Petitioners are compelled, against their will, to receive an undesired, investigational form of medical treatment.

Fourth, OAR 333-019-1010 is unconstitutionally overbroad, vague, and arbitrary as applied to police and firefighters and must be narrowed by this court to avoid irrational and unfounded terminations of employees.

Fifth, the Rules do not follow the applicable rulemaking processes required by the Oregon Administrative Procedures Act.

Sixth, the Rules are unconstitutional because they violate Petitioners' federal civil rights under 42 USC § 1983 by depriving Plaintiffs of liberty and property interest without due process of law.

### 1. OHA's Rules are in direct conflict with ORS 431.180.

ORS chapter 431 governs the use and enforcement of public health laws. ORS

431.180 specifically limits the enforcement of public health laws as follows:

Nothing in ORS 431.001 to 431.550 and 431.990 or any other public health law of this state shall be construed as authorizing the Oregon Health Authority or its representatives, or any local public health authority or its representatives, to interfere in any manner with an individual's right to select the physician, physician assistant, naturopathic physician or nurse practitioner of the individual's choice or the individual's choice of mode of treatment....

ORS 431.180(1) (emphasis added).

Unlike common childhood vaccines, which give lasting if not lifelong

immunity to disease, the current crop of COVID-19 vaccines, two of which utilize novel mechanisms of action, have admittedly unknown durability. They are similar to vaccinations for seasonal influenza<sup>1</sup> and thus should be regarded as a *prophylactic treatment option*, particularly for certain at-risk populations.

There is no Oregon statute that defines "vaccine" for purposes of public vaccine mandates, but nonetheless, all vaccines in generally qualify as drugs for purposes of Oregon law. ORS 677.010(7); *cf.* ORS 433.040 (defining "vaccine" for purposes of Oregon Vaccine Education and Prioritization Plan as "vaccines, immune products and chemoprophylactic medications"). The etymology of the word comes from *vaccinus*, the Latin word relating to a cow and the term first given to the vaccinia virus, which caused a contagious disease in cattle. *Illustrated Stedman's Medical Dictionary* 1526–27 (24th ed 1982) (hereinafter *Stedman's*). "Usage has extended the meaning to include essentially any preparation intended for active immunological prophylaxis — preparations of killed microbes of virulent strains or living microbes of attenuated (variant or mutant) strains; or microbial, fungal, plant, protozoal, or metazoan derivatives or products." *Id.* 

With respect to the COVID-19 vaccines, in all three FDA fact sheets for recipients, it is expressly stated that the vaccine "may not protect everyone," and

<sup>&</sup>lt;sup>1</sup> Like influenza, "COVID-19 undergoes frequent mutations as it replicates." OAR 333-019-1010(1).

that the "duration of protection against COVID-19 is currently unknown." Exhibits 3-5. Indeed, the OHA admits in its own rule that there "is emerging evidence that people infected with the Delta variant have similar viral loads regardless of vaccination status suggesting that even vaccine breakthrough cases may transmit this variant effectively." OAR 333-019-1010(1). Admitting that being vaccinated does not create immunity, prevent infection, or stop transmission, and that "Delta was the variant making up more than 98 percent of sequenced specimens in Oregon," the OHA concludes nonetheless that "[b]eing vaccinated, is therefore critical to prevent spread of Delta." OAR 333-019-1010(1).

Even if the COVID-19 vaccines are effective at mitigating symptoms only, it cannot therefore be said that the vaccines render one immune from infection and thus may be the subject of a state mandate. *See Stedman's* at 694 (defining "immune" as "[f]ree from the possibility of acquiring a given infections disease; resistant to an infectious disease"). Not all vaccines are created equal, and these particular vaccines are better understood as a form (mode) of *prophylactic treatment* that can only benefit the person if administered prior to infection and the onset of symptoms, similar to, for example, drugs to prevent malaria or sea sickness. Indeed, the principle articulated by the Supreme Court in *Jacobson v. Massachusetts* as justifying the power of the state to mandate vaccination is the natural right to self-defense, the assumption of course being that a given vaccine prevents transmission

of infectious disease and provides personal immunity. *See Jacobson*, 197 US at 27 ("Upon the principle of self-defense, of paramount necessary, a community has the right to protect itself against an epidemic disease which threatens the safety of its members.").

On the other hand, a drug (however administered) taken as a mere prophylactic for the management of future symptoms, if any, cannot be reasonably regarded as the fitting subject of a public health mandate. As with all other drugs and treatments, the decision whether to receive a COVID-19 vaccine as a prophylactic therapy must remain a personal choice, subject only to the doctorpatient relationship and state laws and rules of ethics that govern that relationship.

The Rules clearly and directly interfere with an individual's right to select the choice or mode of treatment in relation to prevention and mitigation related to COVID-19 because the Rules mandate vaccination or the State will force your employer to fire you. This is textbook coercion aka "interference with the individuals choice or mode of treatment." That violates state statute directly, and the U.S. Constitution as explained below. The United States Supreme Court has explained that "the Fourteenth Amendment provides that no State shall "deprive any person of life, liberty, or property, without due process of law." *Cruzan v. Dir., Mo. Dep't of Health*, 497 US 261, 278, 110 S Ct 2841, 2851 (1990). The principle that a competent person has a constitutionally protected liberty interest in refusing

unwanted medical treatment may be inferred from our prior decisions. *Washington* v. *Glucksberg*, 521 U.S. 702, 722-23, 117 S. Ct. 2258, 2269, 117 S. Ct. 2302, 2269 (1997) (*Cruzan* recognized "the more specific interest in making decisions about how to confront an imminent death"), we were, in fact, more precise: we assumed that the Constitution granted competent persons a "constitutionally protected right to refuse lifesaving hydration and nutrition." *Id*, citing *Cruzan*, 497 US at 279. In *Jacobson* v. *Massachusetts*, 197 US 11, 24-30, 49 L Ed 643, 25 S Ct 358 (1905), for instance, the Court balanced an individual's liberty interest in declining an unwanted smallpox vaccine against the State's interest in preventing disease.

Thus, OHA's Rules clearly and expressly violate 431.180, which giving Oregonians the right to select their own treatment and therefore pursuant to ORS 183.400(4) OHA's rules exceed the OHA's statutory authority and violate the Oregon Constitution.

# 2. COVID-19 vaccines cannot be mandated under Section 564 of the Federal Food, Drug, and Cosmetic Act (21 USC § 360bbb-3)

As discussed below, the OHA Rules are void and unenforceable because they exceed the statutory authority of the agency and violate federal law and the Supremacy Clause of the Federal Constitution. By adopting rules which require vaccination with unlicensed investigational drugs without the option to refuse, the OHA has failed to comply with paramount federal laws, has exceeded the scope of its authority, and has created an insurmountable obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

# (a) Legal background; federal requirement of informed consent, as a condition precedent to administration of EUA medical products, is inviolable and cannot be waived by state authority.

The regulation and licensing of biological products used in interstate commerce is governed by provisions of the Public Health Service Act of 1944 (PHS Act), 78 Pub L 410, 58 Stat 682 (codified as amended at 42 USC ch 6A). As defined in the PHS Act, a *biological product* includes, among other things, vaccines. 42 USC § 262(i)(1).

Biological products must be federally licensed and properly packaged before they can be "introduce[d] or deliver[ed] for introduction into interstate commerce." 42 USC § 262(a). This requirement is generally known as premarket approval. Since 1972, the federal agency responsible for evaluating and approving a biologics license is the U.S. Food and Drug Administration (FDA), by delegated authority of the Secretary of Health and Human Services (HHS Secretary). *See* 21 USC § 393(a); 42 USC § 262(a)(2); 21 CFR pt 601 (biologics licensing); Statement of Organization, Functions, and Delegations of Authority, 37 Fed Reg 12,865 (June 19, 1972); *see also* 86 Fed Reg 49,337 (Sept 2, 2021) (HHS Secretary's delegation of rulemaking authority). Accordingly, the federal laws governing these biologics apply to Oregon and pre-empt any Oregon laws in conflict and in this entire field.

The PHS Act is intended to operate in tandem with the Federal Food, Drug, and Cosmetic Act (FD&C Act), 75 Pub L 717, 52 Stat 1040 (codified as amended at 21 USC §§ 301–399i), under which the FDA was reorganized in 1988 as part of the Department of Health and Human Services. See 42 USC § 262(g) ("Nothing in this [PHS Act] shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act . . . ."); Food and Drug Administration Act of 1988, 100 Pub L 607, § 903, 102 Stat 3048 (codified at 21 USC § 393). Hence, a biological product subject to the PHS Act is also a "drug" subject to the FD&C Act. See 42 USC § 262(j); 21 USC § 321(g) (defining "drug" to mean *inter alia* "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man"); accord ORS 677.010(7) (defining "drug" as "all medicines and preparations for internal or external use of humans, intended to be used for the cure, mitigation or prevention of diseases or abnormalities of humans"). Thus, COVID-19 products have to be licensed unless they fit into an exception.

#### (b) Emergency use authorizations

An important exception to the licensing requirement for biological products under 42 USC section 262 is the conditional authorization under the FD&C Act of drugs, devices, and biological products for use in an actual or potential emergency. 21 USC § 360bbb-3(a). Under this extraordinary regulatory framework, medical products given emergency use authorization (EUA) are legally classified as either an "unapproved product" or an "unapproved use of an approved product." 21 USC § 360bbb-3(a)(2). The approval status of a drug, device, or biological product basically refers to the normal statutory requirements and procedures for obtaining premarket approval by the FDA, either under the PHS Act (e.g., for biological products) or under the FD&C Act (e.g., for new drugs or devices). *See* 21 USC § 360bbb-3(a)(2), (4).

Because unlicensed biological products are actually experimental drugs undergoing investigation,<sup>2</sup> their emergency authorization is subject to strict statutory criteria, including, for instance, that "there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating" a serious or lifethreatening disease or condition. 21 USC § 360bbb-3(c)(3). For unapproved products, a required condition of authorization is to

ensure that individuals to whom the product is administered are informed... of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; <u>and of the option to accept or refuse administration of</u> <u>the product</u>, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and

<sup>&</sup>lt;sup>2</sup> See 42 USC § 262(a)(3); 21 USC § 355(i); 21 CFR § 312.3 (defining "clinical investigation" as "any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects"). See generally 21 CFR Part 312 (investigational new drugs).

of their benefits and risks.

21 USC § 360bbb-3(e)(1)(ii) (emphasis added). This requirement applies to the biologic producer and the treatment providers. 21 USC § 360bbb-3(e)(1)(A); *see* 21 USC § 321 (see subsection (b) below).

As explained in below, this language does not merely refer to the traditional right to informed consent between a doctor and patient. Rather, it includes that traditional understanding and superadds important federal guarantees intended to protect human beings who choose to participate in clinical investigations of new, experimental drugs. By ignoring or failing to appreciate this crucial provision under federal law, the OHA Rules effectively remove the federally-enlarged right to informed consent, strip all of the currently available COVID-19 vaccines of their EUA status, and thus purport to mandate investigational drugs as a condition of continued employment. OHA cannot violate nor exempt providers from the federal requirements.

# (c) The State of Oregon and the OHA must comply with Section 564 of the FD&C Act.

All of the currently available COVID-19 vaccines administered in this state are EUA medical products. *See* Part 2(e), *infra*. Consequently, any "person who carries out any activity for which the authorization is issued" is subject to and must comply with the terms and conditions of the EUA. 21 USC § 360bbb-3(e)(1)(A); *see*  21 USC § 321 (the term *person* "includes individual, partnership, corporation, and association"). Such persons include the vaccine manufacturer, as well as "emergency response stakeholders" and "vaccination providers" as those terms are defined in the published terms and conditions of the EUA (see Part 2(e), *infra*). OHA's Rules mandate the taking of the vaccine, under penalty of being deprived of your employment by a decree from a "state actor".

Importantly, it should be noted that the mere availability of an EUA medical product does not constitute a federal mandate for its use; participation is voluntary. *See* 21 USC § 360bbb-3(*l*) ("Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section  $\ldots$ . This section only has legal effect on a person who carries out an activity for which an authorization under this section is issued."). Yet, OHA is mandating the vaccine under penalty of law and deprivation of rights.

According to the scope of authorization issued by the FDA, discussed in detail in Part 2(e), *infra*, the State of Oregon and the OHA are participating emergency stakeholders and therefore carry out EUA activities subject to federal law. In so doing, the OHA must strictly adhere to the federally required terms and conditions of authorization and in no way derogate from them. That is because, in reality, a person's participation in such activity amounts to participation in the administration of experimental drugs under the cloak of strict federal limitations designed to ensure the informed consent of the human subject. *See* 45 CFR § 46.116(b)(8) (defining the basic elements of informed consent as a "statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled"); 21 CFR § 50.20 (clinical investigations seeking informed consent must "minimize the possibility of coercion or undue influence"); ORS 677.097 (procedure for obtaining informed consent).

All EUA participants, whether state or private actors, are bound by precisely the same scope of authorization and federal limitations. Had the OHA written the "option to accept or refuse" language into its COVID-19 vaccination Rules there would be no mandate to speak of. Indeed, the OHA cannot comply with its duties under federal law and at the same time mandate EUA vaccines, nor can it do so indirectly, by creating the social conditions under which employers are forced to terminate nonconsenting employees as a matter of legal compliance. *See* Part 2(d), *infra*. Compelled acceptance of the vaccine under penalty of being deprived of your employment, is not an "option", it is coercion and state deprivation of a property right. Both the OHA Rules and the employment actions and policies created in response to them impose coercive penalties and loss of benefits if a person refuses to being vaccinated with an EUA medical product.

#### (d) There is a right to informed consent under EUA.

It is telling that Congress provided a single narrow exception to mandate EUA medical products, and that is in the interest of national security and only as applied to members of the armed forces. In such times, only the President of the United States may waive the option to refuse administration of EUA medical products, and "only if the President determines, in writing, that complying with such requirement is not in the interests of national security." 10 USC § 1107a(a)(1) (note the phrase "complying with such requirement"). There is no similar provision in 21 USC section 360bbb-3a or any other federal law that allows a state or local government to waive the option to refuse, which this Court should construe as an inviolable right to informed consent, the exercise of which may not lawfully be burdened by coercive state mandates that threaten the imminent loss of employment and even wholesale exclusion from certain professions. See 10 USC § 1107a (describing the "condition ... designed to ensure that individuals are informed of an option to accept or refuse administration" as a "required" condition, which, as applied to the armed forces, can be waived only by the President) (emphasis added); cf. 10 USC § 1107(f) (requiring "prior consent" to administer investigational new drugs to members of the armed forces under 21 USC § 355, subject to presidential waiver); Doe v. Rumsfeld, 297 F Supp 2d 119 (D DC 2003) ("This provision [10 USC § 1107] prohibits the

administration of investigational new drugs, or drugs unapproved for their intended use, to service members without their informed consent.").

*Rumsfeld* was an action brought by members of the military under the federal APA challenging a mass inoculation program administered by the Department of Defense. Having concluded that an anthrax vaccine was not licensed for its intended use, the court held that it was an investigational new drug that could not be administered without informed consent unless the federal requirement is waived by the president; to do otherwise would amount to "arbitrary action," the court held. *Rumsfeld*, 297 F Supp 2d at 134. Likewise, the arbitrary actions taken by the OHA to mandate unlicensed EUA vaccines in disregard of federal law and the right to informed consent cannot be sustained under the Oregon APA.

As explained above, the "option to refuse" administration of an EUA medical product guaranteed under 21 section 360bbb-3(e) codifies a federal requirement of informed consent, or what the *Rumsfeld* court described as "fundamental precepts of drug law." *Rumsfeld*, 297 F Supp 2d at 133. Nevertheless, it has been argued elsewhere that the option to refuse—despite being a required condition—is strictly informational and does not confer a substantive privilege on the recipient nor therefore prohibit public or private vaccine mandates. *See, e.g., Bridges v. Houston Methodist Hosp.*, No. 4:21-cv-01774, 2021 WL 2399994, 2021 US Dist LEXIS 110382 (SD Tex June 12, 2021) (holding that this provision "neither expands nor

restricts the responsibilities of private employers like the hospital in this case"). Tersely put, choices have consequences. Here we are not dealing with choices of private employers. We are dealing with a mandate by a state actor, depriving individuals of important liberty and property rights.

The Bridges reading of the law would be mistaken when a state actor is depriving the person of their rights, and this Court is already exercised in the discernment of similar cases. The dutiful communication of specific information, required by federal or state law, presupposes the existence of a legally protected interest in the person to whom the information is communicated. Human beings do not need laws to inform them they are free moral agents and may choose between one action or another, especially when it comes to one's bodily integrity and personal healthcare decisions. A "forcible injection ... into a nonconsenting person's body represents a substantial interference with that person's liberty[.]" Washington v. Harper, 494 U.S. 210, 229 (1990). "Every human being of adult years and sound mind has a right to determine what shall be done with his own body[.]" Schloendorff v. Society of N.Y. Hosp., 211 NY 125, 129–130, 105 NE. 92, 93 (1914) (Cardozo, J.). Choices protected by law, however, very often are the subject of a legal duty to communicate information for the benefit (and not to the detriment) of the person. See, e.g., State v. Gable, 127 Or App 320, 324, 873 P2d 351 (1994) ("A defendant's admissions may be suppressed as involuntary either because they were the product

of coercion or because the defendant's *Miranda* rights were violated."); *United States v. Dickerson*, 166 F3d 667, 671 (opining that Congress enacted 18 USC § 3501 "with the clear intent of restoring voluntariness as the test for admitting confessions in federal court"); *Mabry v. Johnson*, 467 US 504, 508 (1984) ("a voluntary and intelligent plea of guilty made by an accused person, who has been advised by competent counsel, may not be collaterally attacked").

Similarly, the principle of voluntary informed consent is clearly demonstrated by analogous provisions which govern EUAs under declarations of emergency by the Secretary of Defense. If an EUA is given under these circumstances, then subsections (a) through (f) of 10 USC section 1107—including the prior consent requirement—are not applicable. 10 USC § 1107a(c). Evidently, that is because the substantive protections under section 1107 are already included and required as a condition of authorization for emergency use. 21 USC § 360bbb-3(e). The EUA statute does not use the term "informed consent," but states, arguably in even stronger terms, that administration of an EUA medical product must be conditioned upon "the option to accept or refuse," and that this option is "*designed to ensure* that individuals are *informed*" of their right in this regard. 21 USC § 360bbb-3(e)(1)(ii) (emphasis added).

"The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment." *Cruzan v*.

Dir., Mo. Dep't of Health, 497 US 261, 270 (1990). It would be anomalous if this Court were to recognize that basic principle but construe the federally guaranteed option to refuse administration of investigational drugs under EUA as merely affording a personally informed choice, come what may. In principle, whenever a law mandates that a person must be informed, it is to protect some vital interest which is favored as a matter of public policy, not merely to foster prudent personal decisions. Thus, for example, as between patient and physician, informed consent simultaneously protects the patient from medical battery and, when validly obtained, is a legal defense to an action for malpractice. See ORS 677.097; Washington v. Glucksberg, 521 US 702, 725 (1997). Under federal EUA law, however, the right to informed consent was given a wider scope of application by Congress given the inherent risks to individual human life and to the public health. In fact, the EUA itself cannot be granted unconditionally; the conditions are what make the EUA possible in the first place. See Black's Law Dictionary 203 (6th ed 1991) (defining *conditional* as "[t]hat which is dependent upon or granted subject to a condition").

If the required condition fails, however, the EUA evaporates, and what remains then is an unlicensed, unapproved medical product that cannot be mandated, cannot be lawfully introduced or delivered for introduction into interstate commerce, and cannot be required as a condition of employment.<sup>3</sup> *See* 42 USC § 262(a), (f); ORS 433.416 (exempting certain workers from immunization); ORS 441.181 (prohibiting hospital retaliation against nursing staff for believed violations of federal law).

Accordingly, a person's right to accept or refuse administration of an EUA medical product on the basis of informed consent necessarily includes the corollary right, or liberty, of being free of any element of coercion including under color of state law or agency rule, as the holding in *Rumsfeld* clearly suggests. The status of the vaccine being optional is a pre-condition to it being authorized to be even used and issued as an EUA.

Quoting the *Belmont Report*,<sup>4</sup> the FDA explains that "[c]oercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance."<sup>5</sup> Indeed, this accords with fundamental principles of law, whereby the right to informed consent includes certain attendant rights which guarantee the former, including the prerequisite of willingness or voluntariness.

<sup>&</sup>lt;sup>3</sup> With respect to public and nonprofit employers, any disciplinary action taken against an employee who refuses an EUA COVID-19 vaccine may also constitute an unlawful employment practice under the Oregon Whistleblower Law (ORS 659A.200–659A.224). ORS 659A.203; *see also* ORS 659A.199 (whistleblowers in private employment). <sup>4</sup> HHS, Dep't of Health, Education, and Welfare, *The Belmont Report* (April 18,

<sup>1979),</sup> available at https://www.hhs.gov/ohrp/sites/default/files/the-belmontreport-508c\_FINAL.pdf

<sup>&</sup>lt;sup>5</sup> https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent#coercion

Consent "supposes a physical power to act, a moral power of acting, and a serious, determined, *and free use* of these powers. . . . It is an act unclouded by fraud, duress, or sometimes even mistake." *Black's Law Dictionary* 210 (6th ed 1991) (defining "consent"); *cf. Franklin v. Biggs*, 14 Or App 450, 461 (1973) (the payment of \$200 to birth mother vitiated consent to adoption); *Comcast of Ore. II, Inc. v. City of Eugene*, 211 Or App 573, 586 (citing the rule that where government fees or taxes are paid "under duress, it is not deemed voluntary and, thus, recovery may be had") (citing *Johnson v. Crook Cntv.*, 53 Or 329, 334–35 (1909)).

Furthermore, federal law expressly provides that an EUA vaccine that is not used "within the scope of the authorization" constitutes a clinical investigation of a new drug for purposes of 21 USC section 355(i), which codifies the doctrine of informed consent in the following terms:

[E]xperts using such drugs for investigational purposes [must] certify to such manufacturer or sponsor that they will <u>inform any</u> <u>human beings</u> to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes <u>and will obtain the consent of such human beings or their representatives</u>, except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings.

21 USC § 355(i)(4) (emphasis added).

As authorized for emergency use by the FDA, each of the currently available

EUA vaccines to prevent COVID-19 set forth the scope of authorization in which the FDA has expressly required "use consistent with the terms and conditions of this EUA." Exhibits 3-5 (emphasis added). Thus, any person who attempts to mandate an EUA vaccine is not acting within the scope of the FDA's authorization. Plainly stated, a mandate deprives the vaccine of its EUA status. Deprived of its EUA status, the use of the vaccine constitutes a clinical investigation of a new drug for purposes of 21 USC section 355(i), which requires drug manufacturers and sponsors to seek an exemption to the standard licensing requirements for "drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." Only the FDA, under authority originally granted by Congress, may specify the terms and conditions under which any unapproved medical product—or unapproved use of an approved medical product—may be prescribed or administered to United States citizens. OHA is pre-empted from ignoring these federal law requirements.

At most, the OHA may require that available EUA COVID-19 vaccines are offered to individuals for whom the EUA is indicated, subject to established conditions for emergency use as authorized under federal law, including the requirement of informed consent. *See* 21 USC § 360bbb-3(e); *cf.* ORS 677.097.

In a recent memorandum opinion, the Office of Legal Counsel (OLC) in the United States Department of Justice conceded the distinction that legal mandates would be unlawful. *See* 45 Op OLC \_\_\_\_, at 11 (July 6, 2021) (concluding that "virtually all such persons continue to have the 'option' of refusing the vaccine *in the sense that there is no direct legal requirement that they receive it*") (emphasis added) (citing *Bridges*, 2021 WL 2399994, at \*2).<sup>6</sup>

Unlike in *Bridges*, in which the state of Texas did not mandate vaccination but a private employer did, the OHA has adopted a "direct legal requirement" to be vaccinated. *Cf. Klaassen v. Trustees of Indiana Univ.*, No. 1:21-CV-238 DRL, \_\_\_\_\_ F Supp 3d \_\_\_\_, 2021 US Dist LEXIS 133300, at \*64–65, 2021 WL 3073926 (ND Ind 2021) (suggesting that the "informed consent requirement under the EUA statute only applies to medical providers"). In *Klaassen*, the district court reasoned that a public university was not subject to the "informed consent requirement" under the EUA statute because the university was not directly administering the vaccine, but rather third-party medical providers, suggesting that a direct legal requirement would be a step too far, one that would convert what the *Klaassen* court perceived as a "difficult choice" to what Petitioners here contend is both unconstitutional and illegal under federal EUA law. *See Cruzan v. Dir., Mo. Dep't of Health*, 497 US 261

<sup>&</sup>lt;sup>6</sup> Nevertheless, the OLC takes the incoherent position that, as applied to the armed forces, who ordinarily have fewer liberties than civilians, service members have a real right to refuse administration of an EUA vaccine but individuals in the civilian population may be deprived of that right, and "effectively lack such an option," because of a state or agency mandate.

(1990) (recognizing that the constitutional guarantee of "liberty" embraces a "general liberty interest in refusing medical treatment").

To pretend to give recipients the option of refusing administration, even while informing them of the real risks and benefits, or else be terminated from employment is an illusory choice. That degree of coercion vitiates consent and is clearly at odds with the purpose of the federal EUA law, especially as expressed in the fact sheets that must be provided to recipients and communicated by vaccine providers. Thus, for example, in the analogous context of the armed forces, the OLC opined:

As for DOD's [Department of Defense] concern about service members who would lack a meaningful option to refuse EUA products because of the prospect of sanction, including possible prosecution, we note that any difference between our view and the assumption reflected in the conference report should have limited practical significance. Given that FDA has imposed the 'option to accept or refuse' condition for the COVID-19 vaccines by requiring distribution of its Fact Sheet containing the '[i]t is your choice to receive or not receive' language, DOD is required to provide service members with the specified notification unless the President waives the condition pursuant to 10 U.S.C. § 1107a. And because DOD has informed us that it understandably does not want to convey inaccurate or confusing information to service members—that is, telling them that they have the 'option' to refuse the COVID-19 vaccine if they effectively lack such an option because of a military order—DOD should seek a presidential waiver before it imposes a vaccination requirement.

45 Op OLC \_\_\_\_, at 18.

Likewise, the OHA Rules provide no meaningful option to refuse vaccination;

the federally guaranteed option is merely illusory. After October 18, 2021, any
healthcare provider or staff person who refuses vaccination and does not provide documentation of a medical or religious exception "may not work, learn, study, assist, observe, or volunteer in a healthcare setting." OAR 333-019-1010(3)(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," and schools may not employ, contract with, or accept the volunteer services of such persons. OAR 333-019-1030(3). There can be no legal reason for informing a person of an option (i.e., right) to refuse if his or her choice may be superseded by government mandates, which are intrinsically coercive. *See* I21-007 Op Atty Gen at 13–14 (Ariz Aug 20, 2021) ("OLC later acknowledges . . . that certain secondary effects can be so severe as to render the option to accept or reject illusory.").

In summary, any interpretation that would uphold a person's right to refuse administration of an EUA vaccine yet suffer adverse legal or employment consequences for exercising that right, fails to appreciate the scope of the federallyenlarged right to informed consent and the fundamental liberties at stake, and the very concept of a denial of due process<sup>7</sup>. The "option to refuse" language crafted by

<sup>&</sup>lt;sup>7</sup> Compelled vaccination for employment is materially different from compelled vaccination based upon compulsory education as the state is forcing individuals to attend school.

Congress was not intended to be superfluous given that the law of informed consent (not to mention codes of medical ethics) is ubiquitous in the states, nor can it seriously be maintained that this language is intended only to prohibit forcible injections. *Cf. Washington v. Harper*, 494 US 210, 110 S Ct 1028, 108 L Ed 2d 178 (1990) ("The forcible injection of medication [i.e., drugs] into a nonconsenting person's body represents a substantial interference with that person's liberty."). With the exception of a presidential mandate for the armed forces, federal law prohibits states from mandating the administration of EUA medical products. If that were possible, the "option to accept or refuse administration" proviso would not be a meaningful option, and may as well be stricken from the law.

# (e) The definition of "fully vaccinated" under the OHA Rules include vaccines that cannot be mandated under federal EUA law.

The Rules define "fully vaccinated" as "having received both doses of a twodose 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." OAR 333-019-1010(2)(c); OAR 333-019-1030(2)(b).

There are currently three EUA COVID-19 vaccines available for use in Oregon: (1) Pfizer-BioNTech COVID-19 Vaccine (the "Pfizer EUA vaccine"); (2) Moderna COVID-19 Vaccine (the "Moderna EUA vaccine"); and (3) Janssen COVID-19 Vaccine (the "J&J EUA vaccine"). The J&J EUA vaccine is administered as a single dose, while the Pfizer and Moderna EUA vaccines are administered as a two-dose series. As relevant to this case, a discussion of the FDAapproved Pfizer vaccine is treated separately in Part 2(f), *infra*.

The federally required criteria, scope of authorization, and conditions of emergency use authorization are set forth in the FDA's letters of authorization (as amended) to each vaccine manufacturer, in conjunction with any referenced materials. *See* Renner Decl., exhibits 6–8.

As pertinent here, the scope of authorization is limited to, among other things, distribution of the vaccine to "emergency response stakeholders" and authorized "vaccination providers." Those terms are defined as follows:

For purposes of this letter, 'emergency response stakeholder' refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction's COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among 'emergency response stakeholders' and 'vaccination providers' (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

For purposes of this letter, 'vaccination provider' refers to the facility, organization, or healthcare provider licensed or otherwise

**EMERGENCY MOTION UNDER ORAP 7.35** 

authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. . . . For purposes of this letter, 'healthcare provider' also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist).

Renner Decl., exhibits 6–8 (emphasis added; citation omitted).

Accordingly, as discussed in Part 2(c), the foregoing persons and entities constitute persons who carry out an EUA activity and, therefore, are subject to 21 USC § 360bbb-3(*l*) ("This section only has legal effect on a person who carries out an activity for which an authorization under this section is issued."); *accord* Secretary of Health and Human Services, *Secretarial Directive on Eligibility to Receive COVID-19 Vaccines* (March 17, 2021) (directing that all COVID-19 vaccination providers are "required to make available and administer COVID-19 vaccine to all persons eligible to receive the COVID-19 vaccine *consistent with the applicable Emergency Use Authorizations for such products*") (emphasis added). Accordingly the only authorized administration of the vaccines must be consistent with the FDA's terms and conditions. Compelled and coerced administration is a violation.

Additionally, the FDA's letters of authorization require that the "vial label and carton labels are clearly marked for 'Emergency Use Authorization," and that product-specific information is "required to be made available to vaccination providers and recipients." Renner Decl., exhibits 6-8. This information comprises (1) a fact sheet for healthcare providers and (2) a fact sheet for recipients and caregivers, and together constitute "authorized labeling" for purposes of the EUA. In Part III of the EUA (conditions of authorization), the FDA expressly requires that "the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter." Renner Decl., exhibits 6–8. Thus, the conditions of authorization stated in the FDA's letters of authorization, together with the authorized labeling, set forth the federally required conditions under 21 USC section 360bbb-3(e) that the HHS Secretary, by and through the FDA, "finds necessary or appropriate to protect the public health."

As required by federal law, the fact sheets for all of the currently available EUA COVID-19 vaccines uniformly state that vaccination is optional. "As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the 'Fact Sheet for Recipients and Caregivers' . . . prior to the individual receiving the [EUA] COVID-19 Vaccine," including the fact that the "recipient or their caregiver has the option to accept or refuse" the vaccine. Renner Decl., exhibit 14 (Janssen EUA). There is identical language in the *Fact* 

Sheet for Healthcare Providers Administering Vaccine for the Moderna EUA vaccine and the Pfizer EUA vaccine. Renner Decl., exhibits 12–13.

In addition to mandatory reporting of adverse events, the voluntary and informed consent of the recipient is an express condition of EUA as stated in all of the FDA's letters of authorization. Under the bold heading "MANDATORY REQUIREMENTS FOR [EUA] COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION," the FDA stipulates:

In order to mitigate the risk of using this unapproved product under EUA and to optimize the potential benefit of the [EUA] COVID-19 Vaccine, the following items are required. Use of unapproved [...] COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements <u>must</u> be met):

. . . .

2. The vaccination provider must communicate to the individual receiving the [EUA] COVID-19 Vaccine or their caregiver information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving the [EUA] COVID-19 Vaccine.

Renner Decl., exhibits 12–14 (emphasis in original).

In turn, the fact sheets for recipients and caregivers all provide, in pertinent

part: "It is your choice to receive or not receive the [EUA] COVID-19 Vaccine.

Should you decide not to receive it, it will not change your standard medical care."

Renner Decl., exhibits 3–5. In other words, the FDA established no consequence,

medical or otherwise, "of refusing administration of the product." 21 USC § 360bbb-

EMERGENCY MOTION UNDER ORAP 7.35

3(e)(1)(A)(ii)(III). Obviously, this clause of the statute must be limited to its context, that is, primarily medical consequences and any others that are within the FDA's authority to determine at the time the EUA is granted; thus, what it cannot mean is any *legal* or *civil consequences*, such as termination from employment.

Because emergency response stakeholders and vaccination providers carry out an EUA activity, such persons must comply with federal law in the provision of vaccination services. Thus, any and all such persons are not only precluded from mandating an EUA vaccine, but are obligated to inform recipients of the choice to refuse administration and to obtain the informed consent of those choosing to be vaccinated. 21 USC § 360bbb-3(e)(1)(A)(ii).

#### (f) COMIRNATY (FDA-approved vaccine to prevent COVID-19)

In a letter dated August 23, 2021, the FDA approved the biologics license and draft package insert for a vaccine manufactured by Pfizer-BioNTech under the proprietary name COMIRNATY. *See* Renner Decl., exhibits 9–10. "Under this license," the letter reads, "you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older." Renner Decl., exhibit 9.

In accordance with the PHS Act, the manufacturer is required to label the

product with the proprietary name, COMIRNATY. 42 USC § 262(a)(1)(B) (requiring *inter alia* that each package of the biological product is plainly marked with the "proper name of the biological product contained in the package"). A biological product that is not marked with its "proper name" shall not be introduced or delivered for introduction into interstate commerce notwithstanding its formal approval by the FDA. 42 USC § 262(a)(1); *see* 42 USC § 262(f) (violations of the PHS Act constitute a criminal offense subject to a \$500 fine, imprisonment for one year, or both). Biological products labeled COMIRNATY are not available in Oregon.

On the same date, the FDA reissued the existing EUA for the Pfizer EUA vaccine with certain revisions pursuant to 21 USC section 360bbb-3(g). Renner Decl., exhibit 6. The revised EUA now includes, in addition to the previously authorized indications and uses (i.e., ages 16+ and a third dose to certain immunocompromised individuals), the "unapproved use of an approved product" (viz., COMIRNATY) to "provide a two-dose regimen for individuals aged 12 through 15, or to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise." *Id.* 

However, the reissued EUA clarifies in a footnote that while the licensed vaccine has the same formulation as the EUA-authorized vaccine and the products

may be used interchangeably, the "*products are legally distinct* with certain differences that do not impact safety or effectiveness." *Id.* (emphasis added). This note is repeated verbatim in footnotes in the accompanying EUA fact sheet. See Renner Decl., exhibit 3 at 1–2. Therefore, insofar as the approved Pfizer vaccine is actually being used to carry out an EUA activity, the product—and persons administering the product—remain subject to the same terms and conditions as the Pfizer EUA vaccine, including the option to refuse administration. See 21 USC § 360bbb-3(e)(2) (required conditions of authorization for unapproved uses of an approved product).

Importantly, the FDA justified reissuing the EUA because, as required by federal law, there "is no adequate, approved, **and available** alternative to the emergency use of Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19." Renner Decl., exhibit 6 (emphasis added; footnotes omitted). In a footnote, the FDA explains: "Although COMIRNATY . . . is approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA." *Id*.

Consequently, the EUA for either COMIRNATY or the unapproved Pfizer EUA vaccine remains in effect until the HHS Secretary terminates the declaration of a public health emergency or the EUA is revoked. 21 USC § 360bbb-3(g)(2); *see* 

U.S. Dep't of Health & Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.* § 360bbb-3, 85 Fed Reg 18,250 (April 1, 2020).

Like the fact sheets for the Moderna and J&J EUA vaccines, the combined fact sheet for the Pfizer EUA vaccine and COMIRNATY under EUA clearly states that its purpose is "to help you understand the risks and benefits of COMIRNATY . . . and the [Pfizer EUA vaccine], which you may receive because there is currently a pandemic of COVID-19. Talk to your vaccination provider if you have questions." Renner Decl., exhibit 3. The fact sheet also states: "Under the EUA, it is your choice to receive or not receive the vaccine. Should you decide not to receive it, it will not change your standard medical care." *Id*.

### (g) Federal Preemption under the Supremacy Clause

The Supremacy Clause of the United States Constitution, art. VI, cl. 2, invalidates state laws that "interfere with, or are contrary to," federal law. *Gibbons v. Ogden*, 9 Wheat 1, 211 (1824) (Marshall, C.J.). In the absence of express preemptive language in a federal statue or regulation, courts have recognized the doctrine of conflict preemption. To the extent that state law actually conflicts with federal law, the former must yield to the latter. As explained by the United States Supreme Court, "[s]uch a conflict arises when 'compliance with both federal and state regulation is a physical impossibility' or when state law 'stands as an obstacle

to the accomplishment and execution of the full purposes and objectives of Congress[.]" *Hillsborough County v. Automated Medical Labs.*, 471 US 707 (1985) (citations omitted).

As discussed in Part 2(a), the FDA-authorized emergency use of medical products, including vaccines, is an exception to the regulation and licensing requirements under the PHS Act and the FD&C Act. While the state's police power is constitutionally broad with respect to public health mandates, it is not unlimited. See, e.g., R.R. Co. v. Husen, 95 US 465 (1877) (holding that Missouri sanitary law prohibiting transportation of certain cattle was unconstitutional exercise of the police power in violation of the Commerce Clause). Logically, the subject of any state mandate, viz., a vaccine product, must be (1) in existence and (2) authorized by applicable law for distribution to the public. It is this second element that Congress has chosen to regulate exclusively for biological products introduced into interstate commerce. See, e.g., United States v. Calise, 217 F Supp 705, 708 (SD NY 1962) (concluding that 42 USC § 262(b) is not restricted "exclusively to products moving in interstate commerce" because that would be "inconsistent with the general purpose of the [PHS] Act as a whole"); *Husen*, 95 US at ("Whatever may be the power of a State over commerce that is completely internal, it can no more prohibit or regulate that which is inter-state than it can that which is with foreign nations.").

By attempting to mandate an unapproved medical product that is the subject

of strict federal regulation under an EUA, the OHA has unlawfully interfered with the liberty of choice legislated by Congress for the benefit of U.S. citizens. Were that allowed, the OHA could substitute its own judgment for that of Congress and, in effect, introduce via mandates EUA drugs and biological products in violation of federal licensing requirements. *See, e.g.*, 42 USC § 262(a) (biologics licensing); 21 USC § 355 (new drugs). *But cf. Bridges v. Houston Methodist Hosp.*, No. 4:21-cv-01774, 2021 WL 2399994, 2021 US Dist LEXIS 110382 (SD Tex June 12, 2021) (summarily rejecting Plaintiffs' argument on the basis of 21 USC § 360bbb-3), *appeal docketed*, No. 21-20311 (5th Cir June 14, 2021).

Moreover, the state or its agencies could rewrite or circumvent the conditions of authorization required by federal law and the FDA as "appropriate to protect the public health." 21 USC § 360bbb-3(e)(1)(A). As currently written, the Rules are in direct conflict with federal law because they tacitly override the terms and conditions of the EUA and mandate an outcome that is expressly prohibited by federal law.

Consider, for example, an OHA rule that required vaccination providers to merely offer the Moderna EUA vaccine to individuals 16 years of age or older. As applied to individuals between the ages of 16 and 17, the rule would be in violation of the terms and conditions of the EUA, which applies to individuals 18 years of age or older. A rule that mandated additional doses or boosters, not otherwise authorized, would be similarly unlawful, and so too with all other terms and conditions of use under an EUA that conflict with and supersede state law. *See* 21 USC § 360bbb-3(k). The OHA has no authority to ignore, delete, or modify any required conditions on the use of EUA medical products; only the FDA is given authority to impose conditions in addition to those that are statutorily required, as may be found "necessary or appropriate to protect the public health." 21 USC § 360bbb-3(e)(1)(B).

Insofar as the Rules purport to require vaccine providers to violate federal law and ignore the express terms and conditions of the EUA, the Rules are ultra vires, void, and unenforceable. Moreover, the Rules are plainly inconsistent with the legislative policy of the Oregon APA, under which agencies must attempt to adopt rules that correspond with equivalent federal laws unless:

(1) There is specific statutory direction to the agency that authorizes the adoption of the rule;

(2) A federal waiver has been granted that authorizes the adoption of the rule;

(3) Local or special conditions exist in this state that warrant a different rule;

(4) The state rule has the effect of clarifying the federal rules, standards, procedures or requirements;

(5) The state rule achieves the goals of the federal and state law with the least impact on public and private resources; or

(6) There is no corresponding federal regulation.

ORS 183.332.

Here, the legislature has not specifically directed the OHA to mandate EUA vaccines, nor has a federal waiver been granted. With respect to the pandemic, local conditions in this state appear to be no better or worse than any other state, but in

any event the OHA made no special findings in this regard. Far from clarifying federal requirements and achieving the goals of federal law, the Rules expressly undermine and contradict them.

For the foregoing reasons, the OHA Rules are unconstitutional and void because preempted by federal law, and the persons subject to them must be accorded the option of freely choosing if they want to be vaccinated, without coercion by any public or private entities. *See* ORS 433.416(3) (exempting some classes of workers from immunization as a condition of employment); ORS 433.407(3) (defining "workers").

### (h) CDC COVID-19 Vaccination Program and Provider Agreement

Regardless of approval status, all currently available COVID-19 vaccines are property of the federal government until administered to the vaccination recipient. *See CDC COVID-19 Vaccination Program Provider Requirements and Support*, <https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html> (last accessed Sept 7, 2021). As noted in Part 2(c), administration of COVID-19 vaccines is carried out by vaccination providers through the CDC COVID-19 Vaccination Program and Provider Agreement, which must be signed by vaccination providers and responsible officers (the "CDC Vaccination Provider Agreement"). *See* Renner Decl., exhibit 11. The CDC Vaccination Provider Agreement stipulates the following: "Before administering COVID-19 Vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative."

. . . .

"a) Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine."

"b) Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws."

*Id.* (emphasis added).

Thus, individual vaccination providers—who are also employers subject to the Rules—are contractually required to "comply" with federal EUA requirements and with "applicable" (i.e., nonconflicting) state immunization laws. But compliance with federal law and with the terms of the CDC Vaccination Provider Agreement would constitute a violation of the OHA Rules. Because compliance with both federal law and the Rules is impossible, the Rules are superseded by federal law and unenforceable. As the Supreme Court explained in *Jacobson v. Massachusetts*, "A local enactment or regulation, even if based on the acknowledged police power of a State, must always yield in case of conflict with the exercise by the General Government of any power it possesses under the Constitution, or with any right which that instrument gives or secures." *Jacobson*, 197 US at 25. Petitioners' contention is simple: given federal preemption, no state may lawfully mandate that its people be vaccinated with unlicensed biological products. The limited conditions under which investigational drugs may be offered and administered to the public under EUA cannot justify state mandates. Mandates such as OHA's Rules are invalid.

# 3. The Rules are Unconstitutional Because They Violate the Contracts Clause of the Oregon and United States Constitutions

# (a) The Rules unlawfully impair the contracts between employers and employees.

Article I, section 21, of the Oregon Constitution provides in part: "No . . . law impairing the obligation of contracts shall ever be passed . . . ." In *Eckles v. State of Oregon*, 306 Or 380, 390, 760 P2d 846 (1988), *appeal dismissed*, 490 US 1032 (1989), the Oregon Supreme Court concluded that Article I, section 21, applies to contracts made by the state as well as to contracts between private parties. *Hughes v. State*, 314 Or 1, 12–14, 838 P2d 1018, 1024–25 (1992).

This Court has held that "the parties to an at-will employment relationship have no less of an interest in the integrity and security of their contract than do any other contracting parties and, until such a contract is terminated[,] [the] contract is valid and subsisting, and the defendant may not improperly interfere with it." *Porter v. Oba, Inc.*, 180 Or App 207, 213–14, 42 P3d 931, 935 (2002) (internal quotation marks omitted; alterations in original) (quoting Lewis v. Oregon Beauty Supply Co.,

302 Ore 616, 620–21, 733 P2d 430).

The United States Supreme Court recognized in *Truax* v. *Raich*, 239 US 33, 60 L Ed 131, 36 S Ct 7 (1915):

The fact that the employment is at the will of the parties, respectively, does not make it one at the will of others. The employee has manifest interest in the freedom of the employer to exercise his judgment without illegal interference or compulsion and, by the weight of authority, the unjustified interference of third persons is actionable although the employment is **at will**.

Id. at 38 (emphasis added) (citing cases); see also Haddle v. Garrison, 525 US 121,

126, 119 S Ct 489, 492 (1998).

Here, OHA, a state actor, is forcibly and under color of law compelling individuals to breach their contracts, and in fact terminate them in relation to employment contracts between Petitioners and their employers, and provider contracts between the State of Oregon, the service providers, and the federal government via their CDC Vaccination Provider Agreement.

The proper analysis to determine whether a state law violates the Contract Clause of Article I, section 21, requires two steps: First, it must be determined whether a contract exists to which the person asserting an impairment is a party; and second, it must be determined whether a law of this state has impaired an obligation of that contract. General principles of contract law normally will govern both inquiries, even where the state is alleged to be a party to the contract at issue. *Eckles*, 306 Or at 396–97; *Hughes*, 314 Or at 12–14.

Here, Petitioners each have a contract of employment with their respective employers regardless of whether it is for a term, subject to special terms and conditions like a collective bargaining agreement or at-will. OHA's Rules call for the employers to terminate those respective employment contracts for reasons, and on a basis, that was not bargained for by the parties, and does not comply with the terms and conditions of the contracts the parties entered into. Therefore, the Rules clearly impair the obligations of the contracts, and that constitutes a direct violation of the Contract Clause. As recently as September 22, it was announced that Governor Kate Brown re-negotiated her 'contract' with the SEIU and gave them all an extra month before they have to get vaccinated, but Plaintiffs are not afforded the opportunity to re-negotiate their employment contracts. They are to be terminated by Order of the OHA.

The State's expected response is that it can violate contracts by legislative acts exercising the "police powers" of the State of Oregon. However, that argument is simply inapplicable here because we are dealing with temporary administrative rules—not legislation. The 100 years of case law,<sup>8</sup> even since *Jacobson*, which

<sup>&</sup>lt;sup>8</sup> For instance, "All "\* \* \* contracts [are] necessarily subject to being modified by requirements of laws enacted in pursuance of the police power. *See Powell Grove* 

explains that legislation, exercising the police power can potentially legally terminate contracts, but that is not the case here where we have only a temporary administrative rule.

Thus, under the applicable standard, the legal test is "whether the legislation is addressed to a legitimate end and the measures taken are reasonable and appropriate to that end." *Wilkinson v. Carpenter*, 277 Or 557, 564, 561 P2d 607 (1977) (quoting *Home Building & Loan Ass 'n v. Blaisdell*, 290 US 398, 438 (1934)). Here we have no legislation; instead we had only a haphazard agency temporary rule that has already been changed a number of times. As the Oregon Supreme Court explained in *Wilkinson*:

[W]hatever is reserved of state power must be consistent with the fair intent of the constitutional limitation of that power [prohibition on impairment of contracts]. The reserved power cannot be construed so as to destroy the limitation, nor is the limitation to be construed to destroy the reserved power in its essential aspects. They must be construed in harmony with each other. This principle precludes a construction which would permit the State to adopt as its policy the repudiation of debts or the destruction of contracts or the denial of means to enforce them . . . .

*Cem. v. Multnomah Co.*, 228 Or 597, 600, 365 P2d 1058 (1961), and *Highway Com. v. Clackamas W. Dist.*, 247 Or 216, 220, 428 P2d 395 (1967)." *Schmidt v. Masters*, 7 Or App 421, 434, 490 P2d 1029 (1971); *see also Thoren v. Builders Board*, 21 Or App 148, 533 P2d 1388 (1975); *Marcus Brown Co. v. Feldman, supra*. [S]tate legislation which reflects 'the use of reasonable means to safeguard the economic structure upon which the good of all depends,' does not violate the contract clause for 'the reservation of the reasonable exercise of the protective power of the state is read into all contracts.' *Home Building & Loan Ass'n. v. Blaisdell, supra*, 290 U.S. at 442, 444.

Wilkinson, 277 Or at 563–64 (emphasis in original) (citing Home Building & Loan Ass 'n, 290 US at 439).

As a state actor, OHA's temporary rules directly require the termination of contracts that have terms and conditions contrary to OHA's desires. This is an unconstitutional violation of Article 1, section 21.

# (b) The Rules unlawfully impair the contracts of the CDC and the providers.

Petitioners are third-party (donee) beneficiaries of their respective employers' CDC Vaccination Provider Agreements, under which vaccination services must be provided at no charge to eligible recipients. As applied to them, the OHA Rules are void because they impair the obligations in these contracts requiring strict adherence to federal law and the terms and conditions established for each of the EUA vaccines. *See Hughes v. State*, 314 Or 1, 31 (1992). Thus, Petitioners request that this Court enjoin enforcement of the Rules until Defendant can demonstrate that it will allow Oregon employers to follow their CDC Vaccination Provider Agreements, which, among other things, require the provider to notify the recipient that the vaccine is optional, and the state is powerless to mandate that a person be vaccinated with an EUA biologic or else be terminated.

(c) The Rules must be enjoined because they repudiate and breach the terms of the State of Oregon's cooperative agreement with the CDC.

Upon information and belief, the State of Oregon and the OHA, like other states have been required to do, in their capacity as "emergency stakeholders" under federal law (see Part 2(c), *supra*), have entered into a cooperative agreement with the CDC for administration of COVID-19 vaccines. Upon information and belief, that agreement requires strict compliance with federal law and the terms and required conditions of EUA vaccines established by the FDA. As third-party (donee) beneficiaries, Petitioners request that this Court enjoin enforcement of the Rules until OHA can demonstrate that it is allowing Providers and recipients to fully comply with the terms and conditions for EUA usage.

#### 4. The Rules are invalid because they fail to comply with ORS 183.335

# (a) OHA's Rules are substantively permanent rules, but the agency only followed temporary rulemaking procedures.

ORS 183.335(6)(a) dictates that a temporary rule can only be effective for 180 days. For a person coerced into obtaining a vaccine against their will, the effect is permanent. The person will either be permanently terminated from employment, or if the person gets vaccinated will have received a permanent and irreversible medical treatment. Both such effects are longer than 180 days and cause the Rules to violate ORS 183.335(6)(a) wherein the rule can only be effective for 180 days.

### (b) OHA's Rules violate ORS 183.335(5).

ORS 183.335(5) sets forth the rulemaking procedures by which the OHA may

adopt an emergency temporary rule. That subsection reads as follows:

Notwithstanding subsections (1) to (4) of this section, an agency may adopt, amend or suspend a rule without prior notice or hearing or upon any abbreviated notice and hearing that it finds practicable, if the agency prepares:

(a) A statement of its findings that its failure to act promptly will result in serious prejudice to the public interest or the interest of the parties concerned and the specific reasons for its findings of prejudice;

(b) A citation of the statutory or other legal authority relied upon and bearing upon the promulgation of the rule;

(c) A statement of the need for the rule and a statement of how the rule is intended to meet the need;

(d) A list of the principal documents, reports or studies, if any, prepared by or relied upon by the agency in considering the need for and in preparing the rule, and a statement of the location at which those documents are available for public inspection; and

(e) For an agency specified in ORS 183.530, a housing cost impact statement as defined in ORS 183.534.

ORS 183.335(5).

OHA's rationale, statement of need, and showing of prejudice is woefully inadequate for such a draconian and damaging administrative rule. In its temporary administrative order ("PH 42-2021") dated September 1, 2021, the OHA gives considerable space to noting the prevalence of the Delta variant of SARS-CoV-2, which, among other features of this variant, has "decreased vaccine effectiveness." "There is emerging evidence," the OHA explains, "that people infected with the Delta variant have similar viral loads regardless of vaccination status suggesting that even vaccine breakthrough cases may transmit this variant effectively." Thus, the OHA observes that the "Delta variant is causing a surge in unvaccinated cases and vaccine breakthrough cases" and concludes that mandatory vaccination is "necessary to help control COVID-19, protect patients, and to protect the state's healthcare workforce." This is actually a showing *against* the need for everyone to get vaccinated.

In other words, the OHA intends to mandate vaccination with a product that the agency admits does not provide immunity let alone stop transmission of the Delta variant, which, due to its mutability, infects individuals regardless of vaccination status. Without logic, and without acknowledging OHA's own statement that even the vaccinated can be infected with COVID-19 and transmit COVID-19, the agency goes on to conclude that, "Being vaccinated, is therefore critical to prevent spread of Delta" and to protect patients and healthcare workers, especially when the Delta variant "accounted for more than 98% of the COVID-19 infections in Oregon."

Given the OHA's own findings, the rationale for this emergency temporary rule conflicts with itself and admittedly cannot meet the purported need. The rule therefore is irrational and arbitrary on its face. OHA admits that vaccinated people can still contract COVID-19 and can still spread COVID-19 and yet insists that an emergency temporary order mandating those vaccinations is critical to prevent the spread of Delta.

Moreover, the OHA failed to state the "specific reasons for its findings of prejudice," ORS 183.335(5)(a), essentially relying on its conclusory findings to do double duty as the need and the basis for prejudice. Thus, the OHA conflates the alleged need for the rule with the specific reasons that are required to support its

**EMERGENCY MOTION UNDER ORAP 7.35** 

findings of serious prejudice. A *reason*, however, is a coherent assertion or argument from certain premises; a finding is not a reason to itself.

To adopt a valid temporary rule, the OHA is required to provide a reasoned opinion, much like a court would, explaining its findings, in particular, that its failure to act promptly will result in serious prejudice to the public interest with specific reasons for its findings of prejudice (i.e., without relying on tacit assumptions). But the OHA's rationale, if any is given, is incomprehensible and it gives no indication or reason why its findings are seriously prejudicial to the "public interest or the interest of the parties concerned." ORS 183.335(5)(a). Thus, the OHA' bald statement is insufficient; the agency provides no relevant, comparative data from which the purported *seriousness* can be ascertained (e.g., when compared to previous years), nor does it specify the nature of the prejudice or explain why ordinary rulemaking procedures (or actual legislation or executive orders) are inadequate under the circumstances. Cf. Waterwatch of Oregon, Inc. v. Oregon Water Resources Commission, 97 Or App 1, 774 P2d 1118 (1989) (invalidating temporary rule where agency's "proffered justifications for the temporary rule presuppose[d] a nonexistent ambiguity"); Metro. Hospitals, Inc. v. State Health Planning & Dev. Agency, 52 Or App 621, 628 P2d 783 (1981) (invalidating rule where agency's statement of justification "in no way demonstrates (or really even suggests) that 'serious prejudice' to the parties involved will result unless the rules are adopted").

**EMERGENCY MOTION UNDER ORAP 7.35** 

To the contrary, the social and economic consequences of enforcing this temporary rule *are* seriously prejudicial to the Petitioners, the public interest, and to the parties involved, facts that would have been disclosed had the OHA followed ordinary procedures for rulemaking. The Governor herself has already waived the vaccination requirement for her executive branch employees for at least 30 days.

If this court were to excise the particular findings that cannot reasonably justify the need for mandatory vaccinations, what would be left, essentially, is an arbitrary policy decision based on a vague statement about the Delta variant; that an unstated number of Oregonians are presently infected, with or without symptoms, the severity of which one can only guess; and that some individuals being cared for in healthcare settings are "at risk for [unstated] complications of COVID-19." PH 42-2021 at 1 (emphasis added). It may be tempting to read into these lines more than what is really there, due to the abstract fear of COVID-19 and genuine understanding that either way people will continue to contract COVID-19 and transmit COVID-19 as perhaps the OHA has done in this instance, but state law dictates that the agency justify such a severe and broad sweeping temporary rule that will forever change the lives of hundreds of thousands of people who have already gone more than a year and a half without being vaccinated for COVID-19. It is not the court's role to do the agency's work for it by connecting the dots and providing a coherent reason why, absent prompt and mandatory vaccinations, serious prejudice will be unavoidable.

On the contrary, vaccinations against COVID-19 have been authorized and available since December 2020. Alternative treatments have been available since before that time. If anything, the OHA has created its own state of emergency by delaying its intention to adopt vaccine mandates until now, requiring termination some 48 days after creation of these rules. Nevertheless, the Rules cannot be justified on an emergency basis because the OHA has failed to comply with ORS 183.335(5)(a), and where it has complied, the purported need for the rule is belied by the facts. *Cf. Waterwatch of Oregon, Inc.*, 97 Or App at 5 (concluding that "what the rule does instead is 'change policy' without any showing of an 'emergency' need to do so").

# 5. OHA's Rules are unconstitutional because they are overbroad, vague, and impose class-based deprivation of civil rights of certain persons in violation of 42 USC § 1983.

OHA's Rules have not been narrowly tailored, nor do they use the least restrictive means available, yet they arbitrarily create classes of people and deprive others of important civil rights in violation of 42 USC § 1983.

"A statute which ... imposes special burdens upon persons engaged in substantially the same business, under the same conditions, cannot be sound, because it is class legislation, and an infringement of the equal rights guaranteed to all." *Aluminum Cooking Utensil Co. v. N. Bend*, 210 Or 412, 428, 311 P2d 464, 472

**EMERGENCY MOTION UNDER ORAP 7.35** 

(1957) (quoting *State v. Wright*, 53 Or 344, 348, 100 P 296 (1909)). OHA's rules are merely temporary agency rules entitled to far less deference than actual legislation. However, for many individuals such as Petitioners, OHA has not given a need or a justification for such a rule for that class. Some police officers such as Petitioner Tamara Dimmick do not go into a healthcare setting during the course of their role, but are being told they will be terminated due to this rule. Firefighters who may provide direct medical care as part of their role, but may rarely do so in a "healthcare setting" as defined in the rule, are being terminated. As explained below, deprivation of an employment interest by a state actor implicates the due process protections of the United States Constitution.

For example, in *Dent v. West Virginia*, 129 US 114, 121 (1889), the United States Supreme Court explained:

It is undoubtedly the right of every citizen of the United States to follow any lawful calling, business, or profession he may choose, subject only to such restrictions as are imposed upon all persons of like age, sex and condition. This right may in many respects be considered as a distinguishing feature of our republican institutions. Here all vocations are open to every one on like conditions. All may be pursued as sources of livelihood, some requiring years of study and great learning for their successful prosecution. The interest, or, as it is sometimes termed, the estate acquired in them, that is, the right to continue their prosecution, is often of great value to the possessors, and cannot be arbitrarily taken from them, any more than their real or personal property can be thus taken. But there is no arbitrary deprivation of such right where its exercise is not permitted because of a failure to comply with conditions imposed by the State for the protection of society. The power of the State to provide for the general welfare of its people authorizes it to prescribe all such regulations as, in its judgment, will secure or tend to secure them against the consequences of ignorance and incapacity as well as of deception and fraud.

The same United States Supreme Court that decided Jacobson also ruled:

None of the cases sustains the proposition that, under the power to secure the public safety, a privileged class can be created and be then given a monopoly of the right to work in a special or favored position. Such a statute would shut the door, without a hearing, upon many persons and classes of persons who were competent to serve and would deprive them of the liberty to work in a calling they were qualified to fill with safety to the public and benefit to themselves.

#### Smith v. Texas, 233 US 630, 638 (1914).

Numerous controlling cases stand for the proposition that deprivation of an employment interest by a state actor implicates the due process protections of the United States Constitution. Blantz v. Cal. Dep't of Corr. & Rehab., 727 F3d 917 (9th Cir 2013) (in case involving a nurse employed by prison medical care system, the court recognized that denial of liberty interest without due process is cognizable where there is *permanent* exclusion from chosen profession); *Dunn v. Reynolds Sch.* Dist. No. 7, 2010 US Dist LEXIS 121401 (D Or 2010) (applying Oregon law) (must show entitlement or reasonable expectation of continued employment to allege violation of due process); Nunez v. City of Los Angeles, 147 F3d 867, 873 (9th Cir 1998) ("As long as employment options within the profession remain, no due process interests have been implicated."); Engquist v. Or. Dep't of Agric., 478 F3d 985, 998 (9th Cir 2007) ("Therefore, we hold that there is substantive due process protection against government employer actions that foreclose access to a particular

profession to the same degree as government regulation."); Tofsrud v. Spokane Police Dep't, 2021 US Dist LEXIS 103715, at \*20 ("However, substantive due process claims in the public employment context are limited to extreme cases, such as a "government blacklist," which when circulated or otherwise publicized to prospective employers effectively excludes the blacklisted individual from his occupation, much as if the government had yanked the license of an individual in an occupation that requires licensure. ... Stated differently, one does not have a constitutional right to a specific job or position, but only to a liberty interest in pursuing an occupation of one's choice.") (internal quotation marks omitted) (quoting Engquist, 478 F3d at 997–98, and Lane v. Marion County, No 6:19-CV-287-MC, 2020 US Dist LEXIS 170515, 2020 WL 5579820, at \*3 (D Or Sept 17, 2020). The coercive demand to obtain an emergency use vaccine treatment, or else be terminated by order of the Oregon Health Authority, violates the due process clause of the United States Constitution and must be enjoined.

#### (a) Balancing of the Harms if Stay is not Granted

The harm to the Petitioners and other parties if relief is not granted is direct, devastating, and imminent. In contrast, the harm to the public is conjecture, speculation, and at best a fraction of the population. All of the relevant public specifically the employees in question—can already get vaccinated if they so choose. All of the relevant employees who have been vaccinated can also stay home if they

so choose, or even seek employment in a less risky profession. They are allowed their freedom, and until now, that was the controlling legislative policy of this state. See ORS 433.416(3). OHA has already admitted in its own rule that there "is emerging evidence that people infected with the Delta variant have similar viral loads regardless of vaccination status suggesting that even vaccine breakthrough cases may transmit this variant effectively." OAR 333-019-1010(1). Thus, the benefit to the specific individuals covered by the OHA Rules is basically that if they contract COVID-19, they may not have as severe a case as they otherwise might have. Further, to the extent that a subset of any of the individuals covered by the Rules do contract COVID-19, and to the extent that some fraction of those do need hospitalization, there may be a small increase in the overall statewide hospitalization. However, that increase will be offset by the healthcare workers being able to stay on the job. This rule probably creates more of a shortage of healthcare workers than it prevents. We know for sure that healthcare workers like Petitioners will no longer be able to provide services. It is only speculation that some of them might get sick.

For purposes of comparison, the harm to the general public, that some extra persons might contract COVID-19, even hypothetically if the State enacted the most severe restrictions possible, are only educated guesses, and all potential harm to the public is conjecture and theoretical at best. The reality is that most of the states in the United States do not have vaccine mandates. The facts are that Petitioners comprise a tiny fraction of the overall Oregon population. The truth is that by now every eligible person has had the opportunity to obtain the free vaccine that is now being mandated. The State is compelling a medical treatment that is already available and has been declined. Those seeking any benefit from the vaccine already have that option, so the harm is almost exclusively to those who choose not to be vaccinated. Thus, the harm to Petitioners and those like them greatly outweighs the harm to others in the general public who already have the option to obtain the vaccine treatment or decline it. The harm to Petitioners from these particular Rules greatly outweighs the general risk to the public created by the unvaccinated that has now existed since spring of 2020.

Specifically, on October 19th, the Petitioners' lives will be shattered, including the more than 2,500 members of Mandate Free Oregon and 3,000 Member of Free Oregon. Petitioners' declarations are merely a representative sample. Petitioners, Petitioners' members, and thousands upon thousands of other productive Oregonians in the vital service industries of teaching, health care, fire services, and police will suddenly be without jobs, left without a source of income, and will have their entire careers eliminated based upon a temporary rule. Their employers will be left without anyone filling the important teaching, fire services, police or healthcare role during the middle of a pandemic. The Rules will create an entire class of persons who will have to change careers, and a shortage of vital service workers.

The employers will have to terminate employees, evaluated hundreds of thousands of exception requests and spring into life an astonishing amount of litigation over the contours of the religious exceptions and medical exceptions required to be available under ORS 659A and Title VII of the Civil Rights Act.

## **IV. CONCLUSION**

For these reasons, OAR 333-019-1010 and OAR 333-019-1030 are unconstitutional, violate state law and should be stayed pending the outcome of this case.

DATED: September 28, 2021

## Tyler Smith & Associates, P.C.

/s/Tyler Smith Tyler D. Smith, OSB# 075287 Yasha Renner, OSB# 134681 181 N. Grant St. Suite 212, Canby, OR 97013 Phone: 503-266-5590 Tyler@RuralBusinessAttorneys.com Of Attorneys for Petitioners

George R. Wentz, Jr. (Louisiana Bar #2180)\* Davillier Law Group, LLC 935 Gravier Street, Suite 1702 New Orleans, LA 70112 Phone: (504) 582-6998 Fax: (504) 582-6985 gwentz@davillierlawgroup.com \*pro hac vice motion to be filed when case number assigned

#### **CERTIFICATE OF FILING AND SERVICE**

I certify that on the 27th day of September, 2021, I caused a true copy of the EMERGENCY MOTION UNDER ORAP 7.35, and PETITION FOR JUDICIAL REVIEW, EXHBITS 1 and 2 and the DECLARTIONS OF FREE OREGON, MANDATE FREE OREGON, TAMARA DIMMICK, RASA SIDAGYTE, MICHELLE DAVIS, LISA NAVE, CHARLOTTE PERSINGER, CHRYSTAL GERVAIS, AARON HARRIS, ROY McGRATH, GLENN CAMPBELL, JESSICA COX, BRITTANY WILSON, and JOSHUA WILLIAMS to be filed with the Appellate Court Administrator by electronic filing.

I further certify that on the 28th day of September, 2021, I caused a true copy of the EMERGENCY MOTION UNDER ORAP 7.35 and PETITION FOR JUDICIAL REVIEW, EXHBITS 1 and 2 and the DECLARTIONS OF FREE OREGON, MANDATE FREE OREGON, TAMARA DIMMICK, RASA SIDAGYTE, MICHELLE DAVIS, LISA NAVE, CHARLOTTE PERSINGER, CHRYSTAL GERVAIS, AARON HARRIS, ROY McGRATH, GLENN CAMPBELL, JESSICA COX, BRITTANY WILSON, and JOSHUA WILLIAMS to be served on the following parties at the addresses set forth below:

Oregon Health Authority, Public Health Division 800 NE Oregon Street Portland, OR 97232

Attorney General of the State of Oregon

EMERGENCY MOTION UNDER ORAP 7.35

1162 Court Street NE Salem, Oregon 97301-4096

Ben Gutman Solicitor General 1162 Court Street NE Salem, Oregon 97301-4096 Benjamin.Gutman@doj.state.or.us

Service was made by eFiling and by first class mail.

DATED this 28th day of September, 2021

### Tyler Smith & Associates, P.C.

/s/Tyler Smith Tyler D. Smith, OSB# 075287 181 N. Grant St. Suite 212, Canby, OR 97013 Phone: 503-266-5590 Tyler@RuralBusinessAttorneys.com Attorneys for Petitioners