APPENDIX

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APPENDIX A

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MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 25-1070

D.C. No. 2:24-cv-00850-BJR

MEMORANDUM*

MICHAEL BROCK; MATTHEW LEROY ALLBAUGH; CRAIG BREWER; KELLY GAMBINI; ROBERT VINCENT GLORIOSO; JASON HAGIN; DANIELLARSEN; BRIAN LONG; SHAWN CURTIS MANTHEY; PAUL PLUSCHAKOV; CALEB RODRIGUEZ; HANNAH SNAVELY; ANGELA TERRY; DION TERRY; TAWSHA KATHLEEN THOMPSON; WILLIAM TRAVIS TRUEMAN; TIMOTHY VAN DYKE; TIM VANDERMEY; ELISABETH OAKES; GALINA D'AMELIO; JOEL DOUGLAS; BRENNAN JACOBY; JEREMIAH LELAND DAVID LITTLE; NEAL LUNDE; REBEKAH ROYEV,

Plaintiffs—Appellants,

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

v.

CITY OF BELLINGHAM; SETH FLEETWOOD, Mayor, City of Bellingham, Washington,

Defendants—Appellees.

Appeal from the United States District Court for the Western District of Washington

Barbara Jacobs Rothstein, District Judge, Presiding

Submitted May 20, 2026**
Seattle, Washington

Before: TALLMAN, CLIFTON, and R. NELSON, Circuit Judges.

This case arises from a COVID-19 vaccine mandate imposed by Seth Fleetwood, the Mayor of the City of Bellingham. Plaintiffs-Appellants, former City employees, were fired after they refused to comply with the mandate. They now appeal from the district court's order dismissing their Second Amended Complaint (SAC) with prejudice and without leave to amend. We affirm.

We have jurisdiction under 28 U.S.C. § 1291. We review de novo the grant of a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). *Saloojas, Inc. v. Aetna Health of Cal., Inc.*, 80 F.4th 1011, 1014 (9th Cir. 2023). Denial

**The panel unanimously concludes this case is suitable for decision without oral argument. See Fed. R. App. P. 34(a)(2).

of leave to amend is reviewed for abuse of discretion. *Curtis v. Inslee*, 154 F.4th 678, 695 (9th Cir. 2025), *petition for cert. filed*, No. 25-1119 (U.S. Mar. 5, 2026).

1. The district court did not err in dismissing the SAC for failure to state a claim. Plaintiffs-Appellants presented nine causes of action under 42 U.S.C. § 1983 and two causes of action under Washington common law.

Plaintiffs-Appellants failed to state a claim that they were deprived of the option to accept or refuse without consequence administration of drugs authorized for emergency use because their first cause of action relies on sources that do not create rights enforceable under § 1983. *See Curtis*, 154 F.4th at 687–91.

Plaintiffs-Appellants failed to state a claim for violations of equal protection or substantive due process under the Fourteenth Amendment. Their claims under both doctrines are subject to rational basis review. *Id.* at 691–94; *Health Freedom Def. Fund v. Carvalho*, 148 F.4th 1020, 1025, 1029–33 (9th Cir. 2025) (en banc). Accepting as true the factual allegations in the SAC and its attachments, the information available to Mayor Fleetwood showed: (1) that the Food and Drug Administration (FDA) had found, and Pfizer's data confirmed, that the Pfizer-BioNTech COVID-19 Vaccine provided protection against COVID-19 to at least 84% of recipients, with protection levels decreasing over time; (2) that COMIRNATY, which was FDA-licensed, had the same formulation as the Pfizer-BioNTech COVID-19 Vaccine; and (3) that the two products could be used interchangeably to provide the vaccination series without presenting any safety

or effectiveness concerns. In addition, the Pfizer-BioNTech COVID-19 Vaccine posed a significant risk of serious adverse effects and did not prevent transmission of or infection with COVID-19—it only lessened the severity of symptoms. The FDA concluded that the Pfizer-BioNTech COVID-19 Vaccine's known and potential benefits outweighed its known and potential risks.

We have already concluded that substantially similar mandates, which were imposed for substantially similar reasons, survive rational basis review. *Curtis*, 154 F.4th at 691–95; *Carvalho*, 148 F.4th at 1029–33. Plaintiffs-Appellants allege no facts that materially distinguish their case from *Curtis* or *Carvalho*.

To the extent Plaintiffs-Appellants rely on the PREP Act, 42 U.S.C. § 247d-6d, -6e, to support a substantive due process claim, the claim is foreclosed by *Curtis*, 154 F.4th at 692.

Plaintiffs-Appellants fail to state a claim for deprivation of procedural due process under the Fourteenth Amendment. We assume without deciding that Plaintiffs-Appellants alleged deprivation of a constitutionally protected interest. We have already held that employees received sufficient process related to a vaccine mandate if they received "notice of the vaccination requirements and of the consequence of termination for failure to comply," and "opportunities to be heard for the purpose of religious and medical exemptions." *Id*. at 693. Here, the mandate provided for individualized religious and medical exemptions, which at least some Plaintiffs-Appellants applied for. While Plaintiffs-Appellants allege that their requests should have been accepted but were not, they fail to allege any

other facts concerning the adequacy of their requests or the exemption process. This is insufficient to state a plausible claim for a procedural due process violation. *See id*.

We do not consider Plaintiffs-Appellants' causes of action for alleged deprivation of their right to informational privacy under federal law, for liability under *Monell v. Department of Social Services*, 426 U.S. 658 (1978), or for their state law claims. Plaintiffs-Appellants abandoned these claims on appeal, as they fail to cite or discuss any relevant authority, or make any argument concerning the application of relevant law to these claims. See *Indep. Towers of Wash. v. Washington*, 350 F.3d 925, 929 (9th Cir. 2003) ("A bare assertion of an issue does not preserve a claim," and this Court "will not consider any claims that were not actually argued … specifically and distinctly in a party's opening brief.").

Plaintiffs-Appellants' cause of action for alleged violation of the unconstitutional conditions doctrine necessarily fails because they have failed to state a claim that the vaccine mandate violated any of their constitutional rights. Thus, they have failed to state a claim that the Defendants "den[ied] a benefit to [them] on a basis that infringes [their] constitutionally protected interests." *Perry v. Sindermann*, 408 U.S. 593, 597 (1972).

2. We need not address whether the Pfizer-BioNTech COVID-19 Vaccine was classified as an "investigational drug" at the relevant time because its status does not affect our analysis. *See Curtis*, 154 F.4th at 691.

3. The district court did not abuse its discretion in denying leave to 6 25-1070 amend the SAC. Plaintiffs-Appellants filed their SAC with the district court's leave after the motion to dismiss was fully briefed and before the district court issued its order. Despite being on notice of the potential deficiencies in their First Amended Complaint, Plaintiffs-Appellants made no substantive amendments in the SAC to address those potential deficiencies. Moreover, they have never identified (either below or on appeal) what amendments they might make and how those amendments might cure the SAC's deficiencies. Given that our precedent forecloses Plaintiffs-Appellants' claims and they have failed to identify how they could cure the SAC's deficiencies, the district court did not err in concluding that amendment would be futile. *See Eminence Cap., LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1051–52 (setting forth the factors to consider when deciding whether to grant leave to amend).

AFFIRMED.[1]

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[1] The parties' respective motions for judicial notice, which were made in the opening and answering briefs, are denied. The motion for leave to file an amicus brief, Dkt. No. 16, is granted.

APPENDIX B

The Honorable Barbara J. Rothstein

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

MICHAEL BROCK, *et al.*, Plaintiffs, v. CITY OF BELLINGHAM AND MAYOR SETH FLEETWOOD, Defendants.	No. 2:24-CV-850 **ORDER GRANTING DEFENDANTS' MOTION TO DISMISS**

I. INTRODUCTION

This matter comes before the Court on a Motion to Dismiss filed by Defendants City of Bellingham ("City") and former City Mayor Seth Fleetwood (collectively "Defendants"). Dkt. No. 17.[1] Defendants seek dismissal, with prejudice, of each of the eleven claims asserted by Plaintiffs Michael Brock and 25 other individuals ("Plaintiffs"), all former employees of the City who refused to comply with Defendants' COVID-19 vaccine mandate. Having reviewed the Second Amended Complaint and exhibits thereto; the Motion to Dismiss and the briefs and exhibits filed in

[1] Being unopposed, the Motion for Leave to File Sur-reply, Dkt. No. 22, is granted.

support of and in opposition thereto; and the relevant caselaw, the Court finds and rules as follows.

II. BACKGROUND

In early 2020, the COVID-19 virus emerged in the U.S. and around the world as one of the most significant and acute public health crises in at least a generation. COVID–19 was widely acknowledged to be a "highly contagious, dangerous, and ... deadly disease." *Biden v. Missouri*, 595 U.S. 87, 93 (2022). In the years that followed, the COVID-19 pandemic would wreak havoc on the public health of countries around the world and, to date, is responsible for the death of an estimated 1.2 million people in the U.S. alone. *See* https://covid.cdc.gov/covid-data-tracker/#maps_deaths-total (last visited 1/13/2025).

In response to this crisis, Washington Governor Jay Inslee declared a State of Emergency on February 29, 2020, and "[g]overnments at all levels instituted restrictions to curb the transmission of the virus," including mask mandates and limitations on public gatherings. *Slidewaters LLC v. Washington State Dep't of Lab. & Indus.*, 4 F.4th 747, 752 (9th Cir. 2021) (citing *S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613 (2020) (Roberts, C.J., concurring in denial of application for injunctive relief)). By late 2020, scientists had developed vaccines that would prove effective in slowing the spread of COVID-19 and reducing the risk of serious illness and death caused by the virus. *See* August 23, 2021 letter from FDA Chief Scientist Denise M. Hinton ("FDA Approval Letter"), Attached as Ex. E to Sec. Am. Compl., ("SAC") (granting full FDA approval of the Pfizer vaccine, and noting that based on available data, "the vaccine was 95% effective …

in preventing COVID-19 occurring at least 7 days after the second dose.").[2] In December of 2020, FDA exercised its authority to issue "emergency use

[2] The Court takes judicial notice of the August 23, 2021 letter from Chief Scientist Hinton, attached as Exhibit E to the Second Amended Complaint, and of the assertions in that letter, including the statement that "[b]ased on the totality of scientific evidence available to FDA, *it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19*, and that, when used under the conditions described in this authorization the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks." SAC, Ex. E (emphasis added). For purposes of this motion to dismiss, as outlined *infra* Section III.A., while the Court will accept as true the well-pleaded facts as alleged in Plaintiffs' Second Amended Complaint, the Court does not, and is not required to, accept as true those allegations that are contradicted by judicially noticeable facts. *See Health Freedom Def. Fund, Inc. v. Carvalho*, 104 F.4th 715, 725 (9th Cir. 2024) ("It is true that we need not accept as true allegations that contradict matters properly subject to judicial notice.") (cleaned up, citing *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001)). In this case, for instance, Plaintiffs have repeatedly alleged that the COVID-19 vaccines "did not prevent transmission or infection." *See, e.g.,* SAC, ¶ 141. Critically, Plaintiffs do not actually dispute the facts contained in the FDA Approval Letter, as they do not allege that the vaccines *never* prevent transmission or infection. Furthermore, the CDC has provided data establishing that, to the contrary "[t]he incidence of SARS-CoV-2 infection … is higher in unvaccinated than vaccinated persons." *See* H. Scobie, *et al., Morbidity and Mortality Weekly Report (MMWR), Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status* (Sept. 17, 2021) (asserting that after Delta became the most common variant, the risk of infection was five times greater in unvaccinated than vaccinated people). These statements are not "subject to reasonable dispute" and, as noted above, are not specifically disputed by Plaintiffs in any event. Fed. R. Evid. 201(b). The Court therefore takes judicial notice of these data as well.

authorization" ("EUA") for one of those vaccines, the Pfizer-BioNTech ("Pfizer") two-dose mRNA vaccine (the "Pfizer vaccine") for individuals 16 and older.[3] *See* FDA, *Comirnaty and Pfizer-BioNTech COVID-19 Vaccine*, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine; 21 U.S.C. § 360bbb-3(a)(1) (FDA may issue EUA for FDA-regulated products "intended for use" in responding to actual or potential emergency before such products receive full FDA approval.).

On August 23, 2021, FDA granted full approval to that Pfizer vaccine, labeled and marketed under the name "COMIRNATY®," for "the prevention of COVID-19 disease in individuals 16 years of age and older." *Church v. Biden*, 2022 WL 1491100, at *2 (D.D.C. May 11, 2022); *see* FDA Approval Letter (August 23, 2021), SAC, Ex. E; *see also* C*urtis v. Inslee*, 709 F. Supp. 3d 1257, 1263–65 (W.D. Wash. 2023) (taking judicial notice that the Pfizer-BioNTech vaccine was approved on August 23, 2021 as a fact that is "accurately and readily determined" from the FDA's approval and CDC's explanation, citing Fed. R. Evid. 201(b); *We The Patriots USA, Inc. v. Hochul*, 17 F.4th 266, 283 (2d Cir. 2021)).

In early fall 2021, following a surge of reported COVID cases related to the emergent Delta strain of the virus and the FDA's full approval of the Pfizer vaccine, federal, state, and local government entities

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[3] FDA also later issued EUA for vaccines developed by Moderna and Johnson and Johnson. *See* FDA, *Moderna COVID-19 Vaccine*, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine; FDA, *Janssen COVID-19 Vaccine*, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine.

around the country issued mandates requiring vaccination of certain groups, including healthcare workers and public employees. *See, e.g., Church*, 2022 WL 1491100, at *3 ("On September 9, 2021, President Joseph R. Biden issued Executive Order 14043, Requiring Coronavirus Disease 2019 Vaccination for Federal Employees.") (citing Exec. Order 14043, 86 Fed. Reg. 50,989 (Sept. 9, 2021)). Relevant to the instant case, on September 21, 2021, the City of Bellingham issued Executive Order 2021-01 (the "Order"), which required all City employees, volunteers, and on-site indoor contractors to be fully vaccinated against COVID-19 no later than December 3, 2021 as a condition of continuing to work with the City. *See* Order, SAC, Ex. A. The Order explicitly defined "fully vaccinated" to mean "two weeks after the second dose of the Pfizer or Moderna vaccine or two weeks after the single dose of Johnson & Johnson's Janssen vaccine." Order at 4. The Order provided exemptions for "legitimate medical reasons or sincerely held religious beliefs." *Id*.

Plaintiffs in this case were employees, contractors, and volunteers working for the City of Bellingham who were subject to and refused to comply with the Order, and were relieved of their duties as a consequence.[4] SAC, ¶¶ 2, 12. Plaintiffs filed the instant action on June 13, 2024. As discussed in detail below, their Second Amended Complaint asserts 11 causes of action, under 42 U.S.C. § 1983 and the Due Process and Equal Protection clauses to the U.S. Constitution, and for violations of federal and state statutory and common

[4] For simplicity, the Court will refer to this group as city "employees" and to their work with the City as "employment," though the group also includes contractors and volunteers.

law. By this motion, Defendants seek dismissal, with prejudice, of all of Plaintiffs' claims.

III. DISCUSSION

A. Standard on Motion to Dismiss

Federal Rule of Civil Procedure 12(b)(6) permits dismissal for "failure to state a claim upon which relief can be granted." To survive a Rule 12(b)(6) motion to dismiss, a complaint must "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). This is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. Dismissal is appropriate where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory. *See Johnson v. Riverside Healthcare Sys., LP,* 534 F.3d 1116, 1121 (9th Cir. 2008).

The court is required to presume that all well-pleaded allegations are true, to resolve all reasonable doubts and inferences in the pleader's favor, and to view the pleading in the light most favorable to the non-moving party. *See Fitzgerald v. Barnstable Sch. Comm.*, 555 U.S. 246, 249 (2009). However, a court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555). Additionally, the Court is not "required to accept as true allegations that contradict exhibits attached to the

Complaint or matters properly subject to judicial notice, or allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998 (9th Cir. 2010); Fed. R. Evid. 201(b). Matters properly subject to judicial notice include those that are "not subject to reasonable dispute," that are "generally known," or that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(1)–(2); *see Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999 (9th Cir. 2018). In opposing a motion to dismiss, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678.

B. First Cause of Action: § 1983 – Deprivation of the Option to Refuse

Plaintiffs' First Cause of Action is labeled "Deprivation of the Option to Refuse." SAC, ¶¶ 171–84. The claim is predicated on an allegation that the Pfizer vaccine was an "investigational drug." Plaintiffs contend, for example, that Defendants violated the law when "they issued a Policy mandating that Plaintiffs be injected with investigational drugs to keep their employment with the City," and "required Plaintiffs to use federally funded investigational drugs outside of their free consent." *Id.*, ¶¶ 170, 175. The First Cause of Action is brought under 42 U.S.C. § 1983, and claims violations of various federal statutes and regulations, including the Public Readiness and Emergency Preparedness Act, 42 U.S.C § 247d-6d *et seq*. ("PREP Act") and the Emergency Use Authorization Act, 21

U.S.C. § 360bbb-3 ("EUA Act"), in addition to violations of Plaintiffs' unspecified "Constitutional rights." *Id.*, ¶ 184. As discussed further below, the Court concludes that the First Cause of Action is both factually and legally insufficient, and should be dismissed for two independent reasons: (1) because, based upon judicially noticeable facts and facts established in documents attached to the Second Amended Complaint, the Pfizer vaccine was not an "investigational drug" at any time Plaintiffs were subject to the Order; and (2) because Plaintiffs have failed to demonstrate that the federal authorities on which they rely create any rights enforceable under § 1983.

1. Whether Pfizer Vaccine Available to Plaintiffs Was an "Investigational Drug"

As noted, Plaintiffs' First Cause of Action maintains that Defendants denied Plaintiffs the "option to refuse," and violated their federal statutory and constitutional rights when they required that Plaintiffs "be injected with investigational drugs to keep their employment with the City." SAC, ¶ 170. Although the Court is unable to discern from the Complaint an explicit legal or scientific definition of the phrase "investigational drug," it understands Plaintiffs to mean "an investigational vaccine not licensed for any indication" and "without a legal indication to treat, cure, or prevent any known disease." SAC, ¶¶ 49, 50 (alleging that the EUA Pfizer vaccine "is an investigational vaccine not licensed for any indication."). Plaintiffs cite a December 11, 2020 Letter to Pfizer from Denise Hinton, FDA Chief Scientist, for the proposition that Plaintiffs were

obligated to take an "investigational drug." SAC, Ex. D at 1-2 (issuing FDA's EUA for Pfizer vaccine "for the prevention of COVID-19" in individuals 16 years and older, noting "[i]t is an investigational vaccine not licensed for any indication").[5]

Plaintiffs' reliance on the December 11, 2020 letter for the proposition that the Pfizer vaccine was an "investigational drug" is misplaced. As outlined above, Defendants issued the Order over nine months later, on September 21, 2021, and gave Plaintiffs (and other city employees) until December 3, 2021 to become fully vaccinated. By that time—indeed, on August 23, 2021, a full month before the City issued the Order—FDA had "approved the biologics license application (BLA) submitted by BioNTech Manufacturing GmbH for COMIRNATY (COVID-19 Vaccine, mRNA) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older." FDA Approval Letter, SAC, Ex. E. In doing so, FDA emphasized that "COMIRNATY (COVID-19 Vaccine, mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide the COVID-19 vaccination series." *Id*. In other words, by the time Defendants issued the Order mandating vaccination of City employees, the Pfizer vaccine was no longer (if it had been before) an "investigational drug." Multiple courts have reached this same conclusion, rejecting the same argument that Plaintiffs make here. *See, e.g., Curtis v. Inslee*, 709 F. Supp. 3d at 1264 ("On August 23, 2021, the Pfizer-BioNTech vaccine, COMIRNATY®, received

[5] The Court takes judicial notice of the December 11, 2020 letter, which is attached to the Second Amended Complaint at Ex. D. See Fed. R. Evid. 201(b).

full approval for individuals 16 and older.") (citing, *inter alia*, FDA Approval Letter); *Church v. Biden*, 2022 WL 1491100, at *2 (D.D.C. May 11, 2022) ("On August 23, 2021, the FDA approved the vaccine created by Pfizer BioNTech, which would be marketed as "Comirnaty," for "the prevention of COVID-19 disease in individuals 16 years of age and older.") (citing FDA News Release, FDA Approves First COVID-19 Vaccine (Aug. 23, 2021)); *Burcham v. City of Los Angeles*, 562 F. Supp. 3d 694, 707 (C.D. Cal. 2022) ("The Pfizer vaccine has received full FDA approval, and is no longer merely authorized under the EUA statute. Therefore, the informed consent requirements of the EUA statute do not apply to the Pfizer vaccine.") (citation omitted). Plaintiffs have not cited, and the Court has been unable to identify, authority to the contrary.

Indeed, Plaintiffs essentially concede that FDA granted the Pfizer vaccine labeled COMIRNATY® full approval well before the December 3, 2021 deadline provided in the Order. SAC, ¶ 77. Plaintiffs nevertheless allege that "[t]he only drugs available to Plaintiffs for complying with Defendants Policy were FDA-classified as investigational," *id.*, ¶ 230, apparently implying that they were obligated to take Pfizer's pre-approval EUA vaccine, presumably because the drug bearing the COMIRNATY® label was not available.[6] Plaintiffs assert that the

[6] Defendants argue that Plaintiffs "fail to explain why they could not have complied with the Order by receiving the Comirnaty vaccine." Defs.' Rep. at 3. This failure would be fatal to Plaintiffs' First Cause of Action as well. However, at this motion to dismiss stage the Court must "construe[s] the pleadings in the light most favorable to the nonmoving party," *Manzarek v. St. Paul Fire & Marine Ins. Co.,* 519 F.3d 1025, 1031 (9th Cir. 2008), and therefore reasonably infers from the

COMIRNATY® formulation is somehow materially distinct from the formulation approved for EUA use. Plaintiffs fail, however, to cite any facts supporting this claim which, being conclusory, is one the Court is not obligated to accept as true. *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir.), opinion amended on denial of reh'g, 275 F.3d 1187 (9th Cir. 2001). This is particularly so given that the only available evidence is to the contrary. While FDA acknowledged in its approval letter that Pfizer's COMIRNATY® and EUA "products are legally distinct," it went on to emphasize that any "differences [] do not impact safety or effectiveness." Ex. E to SAC, at n. 8. As clearly stated in the FDA Approval Letter, "[t]he licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns." *Id.* The FDA elsewhere in that letter repeated, as noted above, that "COMIRNATY (COVID-19 Vaccine, mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide the COVID-19 vaccination series." *Id.* at 2. Plaintiffs have failed to allege facts disputing these statements, or supporting their conclusory assertion that there are differences in the formulations or the labeling of the drugs that are significant, either medically or legally. Multiple courts have concluded there are not. *See, e.g., Roberts v. Inslee*, 2024 WL 1160895, at *4 (E.D. Wash. Mar. 18, 2024) ("[T]he Pfizer-BioNTech and Comirnaty vaccines were

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ambiguous allegation at SAC ¶ 230 that the COMIRNATY® vaccine was somehow not available to Plaintiffs, and for purposes of this motion accepts this implicit allegation as true.

identical in all but name."); *Johnson v. Brown*, 567 F. Supp. 3d 1230, 1247 (D. Or. 2021) ("On December 11, 2020, Pfizer-BioNTech received an EUA for that vaccine in the United States under the name 'Pfizer-BioNTech COVID-19 Vaccine.' … The FDA approval [of the same vaccine, under the name COMIRNATY®] on August 23, 2021 was for the *physically, chemically, and biologically identical vaccine*.") (emphasis in original); *Navy Seal 1 v. Biden*, 574 F. Supp. 3d 1124, 1131 (M.D. Fla. 2021) ("Pfizer has produced vaccines bearing the 'emergency use authorization' label but nonetheless complying with the technical, scientific, compositional, manufacturing, and other requirements of the FDA license. Comirnaty comprises 'the same formulation as' Pfizer's emergency vaccine and can be used interchangeably ... to provide [the two-dose] vaccination series[.]' The plaintiffs identify no factual distinction between Pfizer's vaccine bearing the emergency label but produced in compliance with the FDA license and Pfizer's 'interchangeable' vaccine bearing the Comirnaty label.").

Similarly here, Plaintiffs have failed to demonstrate that any purported distinction bears a factual or legal significance. They have also failed to cite any authority for the novel and implausible proposition that a licensed drug somehow becomes "investigational" based upon nothing more than a difference in the name under which it is marketed, despite FDA's repeated statements that the formulations are the same. Given the judicially noticeable facts referenced above, and the overwhelming weight of legal authority, the Court concludes that the Pfizer vaccine available to Plaintiffs was not an "investigational drug" at any time relevant to Plaintiffs' claims. For this reason

alone, Plaintiffs' First Cause of Action, predicated on the assertion that only "investigational drugs" were available to them, must be dismissed.

2. Whether Federal Laws on Which Plaintiffs Rely Support § 1983 Cause of Action

Defendants also seek dismissal of the First Cause of Action because Plaintiffs have failed to invoke a federal right that may be enforced under § 1983. Section 1983 "provide[s] an express cause of action to any person deprived (by someone acting under color of state law) of 'any rights ... secured by the Constitution and laws'" of the United States. *Health & Hosp. Corp. of Marion Cnty. v. Talevski*, 599 U.S. 166, 171 (2023). The Supreme Court has interpreted this to mean that the provision "can presumptively be used to enforce unambiguously conferred federal individual rights, unless a private right of action under § 1983 would thwart any enforcement mechanism that the rights-creating statute contains for protection of the rights it has created." *Id*. at 172 (citing *Fitzgerald v. Barnstable School Comm.*, 555 U.S. 246, 253–255 (2009); *Gonzaga Univ. v. Doe*, 536 U.S. 273, 284, and n. 4 (2002)). It is Plaintiffs' position that "rights-creating language … exists in both the EUA statute (the option to accept [or] refuse) and the PREP Act (the right to be informed of the voluntary nature of the program)." Pls.' Op. at 7. Plaintiffs' First Cause of Action also refers to the "Provider Agreement," which is attached as Exhibit C to the Second Amended Complaint, as a source of rights enforceable under § 1983. SAC, ¶ 184.

Not every federal law creates rights that may be enforced under § 1983. Indeed, as reaffirmed in *Talevski*, in evaluating whether a statute creates rights enforceable under § 1983, "precedent sets a demanding bar." 599 U.S. at 180 (citing *Gonzaga Univ.*, 536 U.S. at 280). Courts "must employ traditional tools of statutory construction to assess whether Congress has 'unambiguously conferred' 'individual rights upon a class of beneficiaries' to which the plaintiff belongs." *Talevski*, 599 U.S. at 183 (quoting *Gonzaga*, 536 U.S. at 283, 285–86). A statute unambiguously confers individual rights if it is "phrased in terms of the persons benefited" and "contains 'rights-creating,' individual-centric language with an 'unmistakable focus on the benefited class.'" *Id*. (quoting *Gonzaga*, 536 U.S. at 284, 287). Moreover, even if "a statutory provision unambiguously secures rights, a defendant may defeat the presumption by demonstrating that Congress did not intend that § 1983 be available to enforce those rights." *Id*. at 186 (cleaned up). The Court reviews each of the authorities on which Plaintiffs' First Cause of Action relies in turn.

a. The Emergency Use Authorization Act

Plaintiffs attempt to bring their § 1983 claim under, among other authorities discussed below, the informed-consent provisions of the Emergency Use Authorization statute. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(II). That section provides, in relevant part, that "[w]ith respect to the emergency use of an unapproved product, the Secretary … shall … establish … [a]ppropriate conditions designed to ensure that individuals to whom the product is administered are informed … of the option to accept

or refuse administration of the product, [and] of the consequences, if any, of refusing administration of the product." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(II).

The Court concludes, as several courts have already concluded (unanimously, as far as the Court has been able to determine), that this provision does not create rights privately enforceable under § 1983 (or otherwise[7]). *See, e.g., Curtis v. Inslee*, 2024 WL 810503, at *5 (W.D. Wash. Feb. 27, 2024) (in relying on the EUA provision, "Plaintiffs' proposed second

[7] As the Supreme Court has observed, the initial inquiry as to whether a right is "unambiguously" conferred, whether for enforcement as a private right of action implied by the statute itself, or under § 1983, is essentially the same. This is true even though the next step (whether that right may be enforced as an implied right of action through a mechanism created by the statute itself, or through § 1983) may differ. *See Gonzaga Univ. v. Doe*, 536 U.S. 273, 285 (2002) ("A court's role in discerning whether personal rights exist in the § 1983 context should therefore not differ from its role in discerning whether personal rights exist in the implied right of action context."). Myriad courts have concluded at the first step that the statute at issue here does not create rights that are enforceable in a private right of action implied in the statute itself. *See, e.g., PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010) ("Section 337(a) of the FDCA [of which the EUA is a part] bars private enforcement of the statute, stating that "all such proceedings for the enforcement, or to restrain violations, of this [Act] shall be by and in the name of the United States."); *see also Navy Seal 1 v. Biden*, 574 F. Supp. 3d 1124, 1130 (M.D. Fla. 2021) (21 U.S.C. § 360bbb-3(e)(1)(A)'s "'option to accept or refuse' an emergency vaccine confers no private right of action, creates no 'opportunity to sue the government[,]' and permits enforcement by the United States and by the states in specific circumstances only.") (citing *Doe v. Franklin Square Union Free Sch. Dst.*, 568 F.Supp.3d 270, 292 (E.D.N.Y. 2021), *Bridges v. Houston Methodist Hosp.*, 543 F.Supp.3d 525, 527–28 (S.D. Tex. 2021)). For this reason as well, Plaintiffs' attempt to bootstrap an "option to refuse" claim through § 1983 is without merit.

amended complaint again fails to point to federal law … that 'unambiguously confer[s]' individual federal rights enforceable under § 1983 which would entitle them to relief here."); *Peralta v. New York City Dep't of Educ.*, 2023 WL 6201507, at *6 (E.D.N.Y. Sept. 22, 2023) ("Section 360bbb-3 does not provide an individual right. … [Plaintiff] has failed to identify any right conferred by Section 360bbb-3 that she can vindicate in a Section 1983 cause of action."). The provision that Plaintiffs cite merely directs the Secretary of Health and Human Services to "establish … appropriate conditions" to "ensure" that individuals under certain circumstances are properly informed about emergency use medications. It is not "phrased in terms of the persons benefited" and contains no "rights-creating" or "individual-centric" language. *Talevski,* 599 U.S. at 183 (quoting *Gonzaga*, 536 U.S. at 284, 287).

Even if the EUA provision did create presumptively enforceable rights, it is nevertheless evident that "Congress did not intend that § 1983 be available to enforce those rights." *Talevski* at 186. The federal Food, Drug, and Cosmetic Act ("FDCA"), which contains the EUA provision, includes an express provision limiting enforcement actions to those brought by "a State in its own name" or by the United States. *See Standley on behalf of B.M.S. v. Nelms*, 2024 WL 1793667, at *3 (9th Cir. Apr. 25, 2024) (rejecting § 1983 claim brought under § 360bbb-3(e)(1)(A)(ii)(III) because the statute "expressly states that (subject to exceptions not relevant here) all proceedings to enforce that statute 'shall be by and in the name of the United States.'") (citing 21 U.S.C. § 337(a)); *Curtis*, 2024 WL 810503, at *5 ("[E]ven if 21 U.S.C. § 360bbb-3(e) unambiguously conferred individual federal rights which were

presumptively enforceable under § 1983, Congress evinced an express intention that § 1983 was not available to enforce those rights – only a State or the United States may sue under the statute.") (citing *Talevski* at 186).

Plaintiffs' reliance on the EUA provision additionally fails because, even setting aside the fatal flaws in a claim based on the statute as outlined above, Plaintiffs' allegations fall outside of the scope of that provision. As discussed *supra* § III.B.1., the Pfizer vaccine in question was not, during the relevant time period, an "unapproved product," an element of the statute. *See* § 360bbb-3(e)(1)(A)(ii)(II) (referencing "the emergency use of an unapproved product"). Moreover, the EUA concerns "the interaction between the medical provider and the person receiving the vaccine, not the interaction between an employer and an employee receiving a vaccine." *Norris v. Stanley*, 73 F.4th 431, 438 (6th Cir. 2023). "[A]s other courts have held, those conditions of informed consent only relate to those who 'carr[y] out any activity for which the authorization is issued,' which are the medical providers who administer the vaccine, not those who issue vaccine mandates." *Johnson v. Brown*, 567 F. Supp. 3d 1230, 1256 (D. Or. 2021); *see also Bridges v. Methodist Hosp.*, 2024 WL 4354816, at *4 (S.D. Tex. Sept. 30, 2024) ("Plaintiffs do not allege that any Defendant in this case directly administered the vaccine to them, so their claims against Defendants fall outside of the reach of the informed-consent provisions of 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(II)—even assuming, again, that Plaintiffs could root a Section 1983 action in the informed-consent provisions in the first place."); *Valdez v. Grisham*, 559 F. Supp. 3d 1161, 1171–72 (D.N.M. 2021), *aff'd*,

2022 WL 2129071 (10th Cir. June 14, 2022) ("[The informed-consent] provisions nowhere prevent the state, or any other entity, from requiring certain individuals to be vaccinated against COVID-19 ... This informed consent requirement only applies to medical providers [who are] directly administering the vaccine[.]"); *Norris*, 73 F.4th at 438 ("The statute is meant to ensure patients' consent to the pharmaceutical they are receiving, but this does not mean that [defendant Michigan State University] cannot require vaccination as a term of employment.").

Furthermore, Plaintiffs do not allege that Defendants failed to inform Plaintiffs of the "option to accept or refuse administration of the product" or "of the consequences … of refusing," the only rights even arguably created by the statute. To the contrary, Plaintiffs were obviously aware of their option to refuse the vaccine, as they allege they in fact refused it; and the Order itself explicitly outlines the consequences of such refusal. SAC, Ex. A. (mandating vaccination "as a condition of employment"). For all of the reasons outlined herein, the EUA Act does not create rights Plaintiffs may enforce under § 1983, and to the extent the First Cause of Action is based on that provision it is dismissed.

b. The Public Readiness and Emergency Preparedness Act

Plaintiffs also cite the PREP Act as a source of federal rights they claim are enforceable under § 1983. SAC, ¶¶ 171-84. "Congress passed the PREP Act to encourage the development and deployment of medical countermeasures (such as diagnostics, treatments, and vaccines) by limiting legal liability

relating to their administration during times of crisis." *Curtis*, 2024 WL 810503 at *6 (citing *Maney v. Brown*, 91 F.4th 1296, 1298 (9th Cir. 2024)). The statute provides immunity for a "covered person" from "all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure," such as a vaccine. 42 U.S.C.A. § 247d-6d(a)(1). A "covered person" includes "persons who make policy-level decisions regarding administration or use of covered countermeasures." *Maney*, 91 F.4th at 1301. Suits against a covered person are limited to claims involving "death or serious physical injury proximately caused by willful misconduct." 42 U.S.C.A. § 247d-6d.

Under the *Talevski* test outlined above, § III.B.2., the PREP Act does not "unambiguously" create rights Plaintiffs might enforce under § 1983, and Plaintiffs fail even to attempt to apply the *Talevski* test to their PREP Act claims. *See Sweeney v. Univ. of Colorado Hosp. Auth.*, 2024 WL 3713835, at *8 (D. Colo. July 12, 2024) and cases cited therein ("[T]he PREP Act does not create an individual right enforceable under § 1983."). Far from creating such rights, the PREP Act in fact limits lawsuits based on administration of EUA drugs to claims involving only "death or serious physical injury," and provides a narrowly circumscribed procedure by which such claims might even be brought. *See, e.g.*, 42 U.S.C. § 247d-6d(e)(1) (providing that claims under the PREP Act must "be filed and maintained only in the United States District Court for the District of Columbia"). The sum of Plaintiffs' response is that "the rights creating language under the EUA Statute has been retained under the PREP Act," essentially conceding that their PREP Act-based claims rise and fall with

their EUA-based claims. Pls.' Opp. at 11. Even if the EUA statute provided a basis for a § 1983 lawsuit, which it does not, for the reasons outlined above, Plaintiffs' claims purportedly brought under the PREP would fail. Such claims are accordingly dismissed.

c. The Provider Agreement

Plaintiffs also rely on the "Provider Agreement," attached as Exhibit C to the Second Amended Complaint, as a source of rights enforceable under § 1983. The Provider Agreement at Exhibit C is essentially a form agreement, issued by the Centers for Disease Control and Prevention ("CDC"), to be signed by a provider administering the COVID vaccine (e.g. a pharmacy, medical practice, school, etc.), setting forth the provider's obligations. SAC, ¶ 3 ("The CDC Program created the 'CDC COVID-19 Vaccination Program Provider Agreement' [] to be signed by persons and entities participating in the CDC Program to ensure the State and the State's recruited parties complied with their legal obligations."). Plaintiffs argue that the Provider Agreement "requires strict adherence to the requirement of the EUA Statute and 'any EUA letter' to inform individuals of their right to accept or refuse any product authorized under the statute." *Id.* ¶ 38.

To the extent that Plaintiffs are attempting to rely on the Provider Agreement as an independent source of rights enforceable under § 1983, they fail not least because the agreement is intended to be between the CDC and vaccine providers who sign the agreement, and there is no allegation that either Defendant was a party to that agreement. Plaintiffs fail to argue, let alone demonstrate, that the Provider

Agreement meets the "demanding bar" set by *Talevski* and *Gonzaga* by containing "rights-creating language" enforceable under § 1983. 599 U.S. at 180; *see also Curtis*, 709 F. Supp. 3d at 1269 (dismissing "investigational drug use" claim brought against Gov. Inslee pursuant to the Provider Agreement because "there [was] no allegation that Gov. Inslee signed this agreement"). Indeed, because § 1983 protects rights secured only "by the Constitution and laws" of the United States, agency actions on their own do not create enforceable rights under § 1983. *Id.*, 709 F. Supp. 3d at 1268–69 ("Agency regulations … cannot provide a private right of action where the authorizing statute has not so provided.") (citing *Alexander v. Sandoval*, 532 U.S. 275, 291 (2001) ("Language in a regulation may invoke a private right of action that Congress through statutory text created, but it may not create a right that Congress has not.")). The Provider Agreement does not create rights enforceable under § 1983, and to the extent Plaintiffs' First Cause of Action is an attempt to claim as much, it is dismissed.

In sum, for the reasons outlined above, Plaintiffs' First Cause of Action is dismissed.

C. Fourth, Fifth and Sixth Causes of Action: Substantive Due Process

1. Plaintiffs' Substantive Due Process Claims

Defendants seek dismissal of Plaintiffs' Fourth, Fifth, and Sixth Causes of Action, all brought under 42 U.S.C. § 1983 as purported Substantive Due Process Clause claims. Plaintiffs' Fourth Cause of Action is labeled "Substantive Due Process -

Investigational Drug"; their Fifth Cause of Action is labeled "Substantive Due Process - PREP ACT"; and their Sixth Cause of Action is for "Substantive Due Process - Unwanted Medical Treatment." SAC, ¶¶ 217–32; 233–43; 243–49.

Under the Due Process Clause, a state may not "deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1. The threshold question in a substantive due process challenge to a state action is the proper standard of review. Strict scrutiny applies where the plaintiff has identified a fundamental interest at stake, and "substantive due process forbids the infringement of that right 'at all, no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest.'" *Witt v. Dep't of Air Force*, 527 F.3d 806, 817 (9th Cir. 2008) (quoting *Reno v. Flores*, 507 U.S. 292, 302 (1993)). When the action does not infringe a fundamental right, "the statute need only bear a 'reasonable relation to a legitimate state interest to justify the action.'" *United States v. Juvenile Male*, 670 F.3d 999, 1012 (9th Cir. 2012) (quoting *Washington v. Glucksberg*, 521 U.S. 702, 722 (1997)).

To state a fundamental right, the plaintiff must identify a right that is "deeply rooted in this Nation's history and tradition, and implicit in the concept of ordered liberty." *Glucksberg*, 521 U.S. at 720–21. In the absence of such a right, the less stringent rational basis review applies. *Id.*

In their Fourth Cause of Action, the purported right Plaintiffs assert is "a fundamental right to refuse an investigational drug without penalty or pressure." *Id.*, ¶ 221. In their Fifth Cause of Action, Plaintiffs again claim a violation of the PREP Act, 42 U.S.C. §§247d-6d,6e, which they assert "unam-

biguously create[s] rights enforceable pursuant to 42 U.S.C. § 1983." *Id.*, ¶ 235. In their Sixth Cause of Action, Plaintiffs assert a "fundamental right to refuse unwanted medical treatment." *Id.*, ¶ 247. The Court first examines in turn whether each claim identifies a "fundamental right" triggering strict scrutiny review.

2. Whether Fourth, Fifth, Sixth Causes of Action Articulate a "Fundamental Right" That May Be Vindicated in a Due Process Claim

Each of these three causes of action fails to articulate a fundamental right at issue under the facts alleged in this case, and is therefore subject to rational basis review. As to the Fourth Cause of Action, the Court has already discussed at length the factual deficiencies in Plaintiffs' assertion that the Pfizer vaccine was an "investigational drug." *See supra*, § III.B.1. Because the vaccine available to Plaintiffs at the time was not "investigational," even assuming a fundamental liberty interest exists as Plaintiffs have articulated, that interest was not implicated under the facts alleged in this case. Similarly, regarding the Fifth Cause of Action, the Court has already discussed the flaws in Plaintiffs' claims regarding the PREP Act. *See supra*, § III.B.2.b. That statute does not create rights enforceable under § 1983, let alone articulate a "fundamental liberty interest" so "deeply rooted in this Nation's history and tradition, and implicit in the concept of ordered liberty" as to support a substantive due process claim. *Glucksberg*, 521 U.S. at 720–21.

Plaintiffs' Sixth Cause of Action, in which Plaintiffs claim a "fundamental right to refuse unwanted medical treatment," also fails to articulate a fundamental liberty interest. *See Boysen v. PeaceHealth*, 2024 WL 3888682, at *9 (D. Or. Aug. 19, 2024) ("[T]he Covid-19 vaccine mandates do not implicate a fundamental right.") (citing *Kheriaty v. Regents of the Univ. of California*, 2022 WL 17175070, at *1 (9th Cir. Nov. 23, 2022) (California educator's challenge of the University of California's COVID-19 vaccination policy as a violation of his due process rights did not implicate a fundamental constitutional right.); *Klaassen v. Trs. of Ind. Univ.*, 7 F.4th 592, 593 (7th Cir. 2021) (a substantive due process claim "depends on the existence of a fundamental right ingrained in the American legal tradition. … [P]laintiffs lack such a right. To the contrary, vaccination requirements, like other public-health measures, have been common in this nation.")).

Perhaps recognizing this country's long tradition of upholding vaccine requirements,[8] Plaintiffs

[8] In the seminal case of *Jacobson v. Commonwealth of Massachusetts* decided over a hundred years ago, the Supreme Court upheld a state-issued smallpox vaccine mandate. 197 U.S. 11 (1905). As Justice Harlan wrote, "[i]t must be conceded that some laymen, both learned and unlearned, and some physicians of great skill and repute, do not believe that vaccination is a preventive of smallpox. The common belief, however, is that it has a decided tendency to prevent the spread of this fearful disease, and to render it less dangerous to those who contract it. While not accepted by all, it is accepted by the mass of the people, as well as by most members of the medical profession. It has been general in our state, and in most civilized nations for generations. It is generally accepted in theory, and generally applied in practice, both by the voluntary action of the people, and in obedience to the command of law.

attempt to frame the interest in their Sixth Cause of Action as the "right to refuse unwanted medical treatment." SAC, ¶ 247. But none of the Plaintiffs allege that they were denied that right and were vaccinated against their will; to the contrary, they allege they in fact exercised that right. *See, e.g.,* SAC ¶ 191 ("Plaintiffs exercised their … fundamental rights … to refuse unwanted medical treatment."). Instead, the right that Plaintiffs are asserting, based upon the facts alleged, is "the right to continued employment … without receiving the COVID-19 vaccine." *Sweeney*, 2024 WL 3713835, at *14; SAC, ¶ 2 ("When Plaintiffs exercised their fundamental rights … to refuse unwanted medical treatment and, thus, refused to comply with the Order, they were terminated from employment."). An innumerable number of federal courts have determined that conditioning continued employment on receiving a COVID-19 vaccine does not implicate a fundamental liberty interest. *See id.*; *Aleman v. Cnty. of Los Angeles*, 2024 WL 5257028, at *6 (C.D. Cal. Sept. 23, 2024) ("[H]ere the Policy requires vaccination as a condition of Plaintiff's employment, and 'there is no fundamental right to governmental employment' under the Fourteenth Amendment.") (citing *Canfield*

Nearly every state in the Union has statutes to encourage, or directly or indirectly to require, vaccination; and this is true of most nations of Europe. … A common belief, like common knowledge, does not require evidence to establish its existence, but may be acted upon without proof by the legislature and the courts. … The fact that the belief is not universal is not controlling, for there is scarcely any belief that is accepted by everyone. The possibility that the belief may be wrong, and that science may yet show it to be wrong, is not conclusive; for the legislature has the right to pass laws which, according to the common belief of the people, are adapted to prevent the spread of contagious diseases." 197 U.S. at 34–35.

v. Sullivan, 774 F.2d 1466, 1469 (9th Cir. 1985)); *see also cases cited in Wilkins v. Herron*, 2024 WL 5200177, at *3, fn. 1 (9th Cir. Dec. 23, 2024) ("[S]ince the onset of the COVID-19 pandemic, numerous courts have rejected claims that COVID-19 vaccine mandates … violate individuals' substantive due process rights."); *We The Patriots USA, Inc. v. Hochul*, 17 F.4th 266, 293–94 (2d Cir. 2021) ("Plaintiffs provide no basis for concluding that the vaccination requirement here ... violates a fundamental constitutional right. Vaccination is a condition of employment in the healthcare field; the State is not forcibly vaccinating healthcare workers."), *opinion clarified*, 17 F.4th 368 (2d Cir. 2021); *Burcham v. City of Los Angeles*, 562 F. Supp. 3d 694, 706 (C.D. Cal. 2022) (rejecting Los Angeles Police Department employees' argument that City COVID-19 vaccine mandate was subject to strict scrutiny in part because there is "no fundamental right to continued governmental employment"); *Andre-Rodney v. Hochul*, 569 F. Supp. 3d 128, 139 (N.D.N.Y. 2021) ("[T]he Vaccine Mandate conditions Plaintiffs' right to be employed at a covered entity on their vaccination against COVID-19. Thus, the right that is being burdened is the right to employment at a covered healthcare entity in New York."); *Bauer v. Summey*, 568 F. Supp. 3d 573, 592 (D.S.C. 2021) ("Plaintiffs' overly general characterization of the rights at issue as 'bodily integrity' or 'privacy' falls short of the required 'careful description' of the liberty interest. Rather, a more appropriate description is plaintiffs' interest in employment with defendants while unvaccinated for COVID-19.") (citation and footnote omitted)). Even taking as accurate Plaintiffs' characterization of the Pfizer vaccine as an "unwanted medical treatment," the

only interest Plaintiffs have articulated at their Sixth Cause of Action is the right to continued employment without receiving that "treatment."[9]

[9] Plaintiffs argue that the Ninth Circuit's recent decision in *Health Freedom v. Carvalho* establishes that the Court must take as true Plaintiffs' allegation that the Pfizer vaccine is not truly a "vaccine" because it does not provide 100% immunity, but is instead a "medical treatment" that merely reduces the severity of the disease's symptoms. 104 F.4th 715 (9th Cir. 2024) (reversing district court's dismissal of plaintiffs' challenge to vaccine mandate because allegation that vaccine did not prevent spread of COVID-19 had to be accepted as true at motion-to-dismiss stage, and therefore *Jacobson*, Supreme Court precedent upholding smallpox vaccine mandate, *see supra* n.8, did not necessarily apply). However, the record before the *Carvalho* court differed significantly from the record before this Court. In *Carvalho*, the defendant school district had failed to proffer any judicially noticeable evidence contradicting the plaintiffs' allegation that the vaccines did not prevent the spread of the disease. 104 F.4th at 725 ("It is true that we need not accept as true allegations that contradict matters properly subject to judicial notice. But even if the materials offered by [defendant] LAUSD are subject to judicial notice, they do not support rejecting Plaintiffs' allegations. LAUSD only provides a CDC publication that says "COVID-19 vaccines are safe and effective." But "safe and effective" for what? LAUSD implies that it is for preventing transmission of COVID-19 but does not adduce judicially noticeable facts that prove this.") (cleaned up). Here, Defendants *have* provided judicially noticeable evidence (including documents attached to the Second Amended Complaint) contradicting Plaintiffs' allegation that the Pfizer vaccine did not reduce the spread of COVID-19. *See supra* n. 2 and authority cited therein. This Court therefore is not obligated to take Plaintiffs' allegations as true, and *Carvalho* is thus distinguishable. *See Boysen v. PeaceHealth*, 2024 WL 3888682, at *5 (D. Or. Aug. 19, 2024) (distinguishing *Carvalho* and dismissing challenge to COVID-19 vaccine mandate, noting that in *Carvalho*, "[t]he Ninth Circuit agreed with the plaintiffs that, when uncontradicted by judicially noticeable facts, their allegations must be taken as true. … Here, the record is replete with judicially noticeable facts that Pfizer-BioNTech COVID-19

Plaintiffs have failed to provide any authority for their contention that this interest is so fundamental as to require strict judicial scrutiny in a due process challenge.

3. Whether Defendants' Order Survives Rational Basis Review

Because Plaintiffs have failed to identify a fundamental liberty interest underlying any of their three substantive due process claims, these claims are subject only to rational basis review. *See Williams v. Brown*, 567 F. Supp. 3d 1213, 1226 (D. Or. 2021) ("Courts have also consistently held that … challenges to vaccination mandates are properly considered under rational basis review.") and cases cited therein. Under rational basis review, state conduct is presumed valid and will be upheld so long as it is "rationally related to a legitimate state interest." *City of Cleburne v. Cleburne Living Ctr.,* 473 U.S. 432, 440 (1985).

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vaccine is a vaccine—as that term is used in *Jacobson*—'as a preventative' of Covid-19.").

Moreover, *Carvalho* is simply inapposite to the instant case, because unlike the district court in *Carvalho*, this Court has not relied on *Jacobson* in determining that rational basis review applies to Plaintiffs' due process claims. As discussed above, the asserted liberty interest in this case is the right to public employment without receiving the vaccine, not the "right to refuse unwanted medical treatment." As the District Court of Colorado recently observed under materially identical circumstances, "*Carvalho* does not change this Court's analysis, which does not rely on *Jacobson*, because even taking Plaintiffs' allegations as true, they have not alleged that they were forcibly vaccinated or forcibly given medical treatment, [and] have not identified an articulable fundamental right at issue in this case."). *Sweeney v. Univ. of Colorado Hosp. Auth.*, 2024 WL 3713835, at *14.

The preamble to the Order lays out extensive legitimate state interests to which the mandate is rationally related:

> COVID-19 is a threat to life and public health. … the WHO has raised the health emergency to the highest level requiring dramatic interventions to disrupt the spread of this disease; … COVID-19 vaccines are effective in reducing serious disease and hospitalizations, and widespread vaccination is the primary means available to the City to protect its employees and the public, including persons who cannot be vaccinated for medical reasons, youth who are not eligible to receive a vaccine, immune-compromised individuals, and vulnerable persons. SAC, Ex. 1.

In their Motion, Defendants also assert that "vaccines are a safe and effective way to prevent the spread of COVID-19." Defs.' MTD at 10 (citing *Smith v. Biden*, 2021 WL 5195688, at *6 (D.N.J. Nov. 8, 2021); Mass. Corr. Officers Federated Union v. Baker, 567 F. Supp. 3d 315, 319–20 (D. Mass. 2021)). Defendants also cite the CDC's September 17, 2021 Morbidity and Mortality Weekly Report (MMWR) to refute Plaintiffs' assertion that the vaccines did not slow the spread of COVID-19. See Defs.' MTD at 10, n. 9.

The Court takes judicial notice of the CDC data, which were available to Defendants at the time the Order was issued, "showing that people who were fully vaccinated against COVID-19 when the Delta variant was prominent were five times less likely to become infected with the disease, and ten times less

likely to die or be hospitalized due to the disease than the unvaccinated." *White v. Univ. of Washington*, 2024 WL 1241063, at *7 (W.D. Wash. Mar. 22, 2024) (taking judicial notice of same document, citing Fed. R. Evid. 201 (allowing courts to take judicial notice of facts that are "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned")); *United States v. Lomeli*, No. CR12-2791, 2022 WL 16752979, at *3, n.3 (S.D. Cal. Nov. 7, 2022) (explaining that the CDC website's accuracy cannot reasonably be questioned). However, the Court need not resolve a dispute over the degree of the vaccines' efficacy in slowing the spread of the virus to conclude, as the Court does, that Defendants' actions were rationally related to a legitimate state interest. *See Halgren v. City of Naperville*, 577 F. Supp. 3d 700, 738–39 (N.D. Ill. 2021), *aff'd sub nom. Lukaszczyk v. Cook Cnty.*, 47 F.4th 587 (7th Cir. 2022) ("Because the legislative act may be based on rational speculation unsupported by evidence or empirical data, the state need not produce evidence to sustain its decision. Instead, despite any initial fact-finding by the court, the rational basis test commands deference to legislative choice in the end. … Courts must, therefore, accept a legislature's generalizations even when there is an imperfect fit between means and ends because a law can pass muster even if it is not made with mathematical nicety.") (cleaned up, citations omitted).

As nearly all of the cases cited in this Order have concluded, COVID-19 vaccine mandates, adopted under materially identical circumstances, pass this lowest level of judicial scrutiny. *See, e.g., Boysen*, 2024 WL 3888682 at *9 ("Plaintiffs have not alleged sufficient facts from which to conclude that state

Defendants do not have a rational basis for the vaccination orders."); *Sweeney*, 2024 WL 3713835, at *14 (referring to "the numerous courts concluding that similar employer-mandated vaccination requirements satisfy the rational basis test" and citing *Legaretta v. Macias*, 603 F.Supp.3d 1050, 1065 (D.N.M. 2022); *Bauer*, 568 F. Supp. 3d at 595) ("As explained above, stemming the spread of COVID-19 is a compelling government interest, and requiring hospital employees to take measures against the spread is rationally related to that interest."); *Johnson*, 2021 WL 4846060, at *14 (Oregon's vaccine mandates "are rationally related to Defendants' interests in slowing the spread of COVID-19, protecting Oregon's citizens, protecting children and teachers in schools, and preserving healthcare resources and protecting patients."); *Williams*, 567 F. Supp. 3d at 1227 ("[T]he vaccine mandates easily survive rational basis review."); *Halgren v. City of Naperville*, 577 F. Supp. 3d 700, 746 (N.D. Ill. 2021), *aff'd sub nom. Lukaszczyk v. Cook Cnty.*, 47 F.4th 587 (7th Cir. 2022) (Plaintiffs' substantive due process challenge to vaccine mandate fails "because this Court has found, as discussed above, 'conceivable' grounds for the mandate, and therefore on the present record, this Court cannot say that the relationship between the government's legitimate ends (i.e., decreasing the possible degree of viral transmission …) is 'so attenuated' from the chosen means (i.e., compelling healthcare workers to either submit to vaccination …) as to be arbitrary, irrational, or otherwise beyond the bounds of reasonable speculation."). Plaintiffs have cited no authority to the contrary. Their Substantive Due Process Clause claims at the Fourth, Fifth, and Sixth Causes of Action are, accordingly, dismissed.

D. Eighth Cause of Action: Deprivation of Right of Privacy

Plaintiffs' Eighth Cause of Action, brought under 42 U.S.C. § 1983, claims a "Deprivation of Right of Privacy." SAC, ¶¶ 255-61. In support of this claim, Plaintiffs allege that they were required "to involuntarily surrender their Private Health Information to the City's human resources department if and when one of the investigational drugs was injected into their bodies." *Id.*, ¶ 258. They claim this requirement was a violation of their "Fourteenth Amendment right to privacy." *Id.*, ¶ 261.[10]

The parties agree that this claim purports to vindicate a "constitutionally protected privacy interest in avoiding disclosure of personal matters." Pls.' Opp. at 15 (citing *Norman-Bloodsaw v. Lawrence Berkeley Lab*, 135 F.3d 1260, 1269 (9th Cir. 1998)); Defs.' MTD at 11 (citing *A.C. ex rel. Park v. Cortez*, 34 F.4th 783, 787 (9th Cir. 2022)). In the Ninth Circuit, this "informational privacy" right "is not absolute; rather, it is a conditional right which may be infringed upon a showing of proper governmental interest." *Coons v. Lew*, 762 F.3d 891, 900 (9th Cir. 2014).

Courts apply a balancing test, weighing: "(1) the type of information requested, (2) the potential for harm in any subsequent non-consensual disclosure, (3) the adequacy of safeguards to prevent unauthorized disclosure, (4) the degree of need for access, and (5) whether there is an express statutory

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[10] The Eighth Cause of Action does not explicitly invoke the Due Process Clause, but in opposition to Defendants' Motion to Dismiss, Plaintiffs argue in support of their Right of Privacy under the heading "Substantive Due Process."

mandate, articulated public policy, or other recognizable public interest militating toward access." *Cortez*, 34 F.4th at 787.

Related to the first and second considerations, Plaintiffs argue that the "type of information requested" was of a highly sensitive nature, and that the "potential for harm" included being "constantly subjected to injury, embarrassment, stigma, harassment, ridicule, scorn, and financial penalties." Pls.' Opp. at 16. Plaintiffs have not alleged any facts supporting this claimed embarrassment, stigma, or ridicule which, in the total absence of such allegations, the Court finds overstated and implausible. *See Schmidt v. City of Pasadena*, 2024 WL 1640913, at *14 (C.D. Cal. Mar. 21, 2024) (citing In re Crawford, 194 F.3d 954, 960 (9th Cir. 1999)) ("There is no basis to accept an allegation that an individual's [COVID-19] vaccination status is 'sensitive or intimate' under this standard, and the alleged circumstances surrounding the disclosure of Plaintiff's vaccination status do not support the inference that it was likely to cause 'injury, embarrassment, or stigma.'"). The only claimed injury that is supported by Plaintiffs' allegations is the loss of employment with the City, which is attributable not to any violation of their "informational privacy" rights (*i.e.*, disclosure of their vaccination status), but to their refusal to receive the vaccine.

Plaintiffs fail to allege any facts at all that would support their claim as to the third consideration, the adequacy of safeguards to prevent unauthorized disclosure, and do not claim that any unauthorized disclosure in fact occurred. As to the fourth and fifth factors—the degree of need for access to the information, and whether there was a "recognizable

public interest" supporting that need—the Court makes reference to the discussion, *supra*, concerning Plaintiffs' substantive due process claims. The Order was based upon at least a "recognizable public interest"—that is, "to slow the spread of COVID-19" and in particular, to protect "high risk populations such as people with underlying medical conditions and the elderly," which was clearly articulated in the Order itself. Order, SAC, Ex. A; *see Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020) ("Stemming the spread of COVID-19 is unquestionably a compelling interest."). Although Plaintiffs dispute that the vaccines served this interest, as discussed at length above, the Court concludes that Defendants' actions were based upon judicially noticeable data and thus were, at a minimum, rationally related to that interest.

Taking the foregoing considerations into account, the Court concludes that "the alleged disclosure of Plaintiff[s'] vaccination status does not sufficiently state an impermissible invasion of the right to informational privacy." *Schmidt*, 2024 WL 1640913, at *14; *see also Miller v. Farris*, 2023 WL 4680370, at *5 (C.D. Cal. June 14, 2023), report and recommendation adopted sub nom. *Miller v. Ferris*, 2023 WL 4850749 (C.D. Cal. July 28, 2023) (dismissing informational privacy challenge to COVID-19 vaccine mandate; citing *Kheriaty v. Regents of Univ. of California*, 2021 WL 4714664, at *6, 9 (C.D. Cal. Sept. 29, 2021) (policy requiring the disclosure of employee's vaccination status did not violate plaintiff's fundamental right to informational privacy because his employers demonstrated a legitimate governmental interest in receiving the information)). Because, as discussed above, the Order

survives a rational basis review, Plaintiffs' Eighth Cause of Action is dismissed.

E. Third Cause of Action: Procedural Due Process

Defendants seek dismissal of Plaintiffs' Third Cause of Action, for "Deprivation of Procedural Due Process Rights." SAC, ¶¶ 200-16. In that claim, Plaintiffs again invoke the PREP Act, the "EUA Statute, the Provider Agreement, 10 U.S.C. § 980, and the State's FWA," which laws they claim "provide Plaintiffs with statutory and federal program entitlements to give their legally effective informed consent before being injected with federally funded investigational drugs, which they were deprived of by Defendants' Policy." SAC, ¶ 207. Plaintiffs contend that "Defendants owed Fourteenth Amendment obligations to Plaintiffs and could not deprive them of their statutory entitlements and terminate their property interest to public employment without 'some form of hearing.'" *Id.*, ¶ 210 (citing *Wolff v. McDonnell*, 418 U.S. 539 (1974)).

This Court has already observed, in upholding a similar COVID-19 vaccine mandate issued to certain state agency employees, that the "essential requirements of due process … are notice and an opportunity to respond." *Pilz v. Inslee*, 2022 WL 1719172, at *7 (W.D. Wash. May 27, 2022), *aff'd,* 2023 WL 8866565 (9th Cir. Dec. 22, 2023) (citing *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 546 (1985)). As in *Pilz*, Plaintiffs here "cannot seriously maintain that they did not have written notice of the vaccine requirement." *Pilz*, 2022 WL 1719172, at *7.

There is no allegation that Plaintiffs were unaware of Defendants' Order, which clearly articulated the vaccine requirements, set reasonable deadlines, and outlined the consequences of failure to comply. *See* SAC, Ex. A. The Order also explicitly provided an opportunity to be heard, providing that "[e]mployees seeking reasonable accommodations for legitimate medical reasons or sincerely held religious beliefs may apply for an accommodation," and that "[r]equests for reasonable accommodations will be evaluated on an individualized basis." *Id*., p. 3. In fact, Plaintiffs allege they "submitted religious and medical exemption requests," but were simply dissatisfied that those requests were denied. SAC, ¶ 126.

As the Ninth Circuit recently noted in discussing (and upholding) another COVID-19 vaccine mandate, this one issued to firefighters in Washington state, "with respect to a categorical challenge to the substance of a generally applicable law impacting property rights—such as 'continued employment in a state job'—we have held that no procedural due process is required beyond the proper promulgation of the new substantive rule." *Bacon v. Woodward*, 2024 WL 3041850, at *2 (9th Cir. June 18, 2024) (citing *Rea v. Matteucci*, 121 F.3d 483, 484–85 (9th Cir. 1997)) ("As the district court recognized, the firefighters had 'advance notice of the vaccination requirement,' were 'offered ... the opportunity to participate in *Loudermill* hearings,' and were 'communicated the results of those hearings along with proposed alternative accommodations.'

The firefighters did not like the substance of the City's construction of the Proclamation in their individual cases, but that is not a procedural due process objection."). Plaintiffs here have not claimed

that the Order was not "properly promulgated"—the only procedural process they were due—and "the Court joins other district courts around the country that have rejected procedural due process challenges to employer-issued vaccine mandates during the COVID-19 pandemic, finding employees are not entitled to greater service than what is provided by enactment of the mandates themselves.'" *Pilz*, 2022 WL 1719172, at *7 (cleaned up, citing *Wise v. Inslee*, 2022 WL 1243662, at *5 (E.D. Wash. Apr. 27, 2022)); *Bacon v. Woodward*, 2021 WL 5183059, at *3 (E.D. Wash. Nov. 8, 2021); *Harris v. Univ. of Massachusetts, Lowell*, 557 F. Supp. 3d 304, 312 (D. Mass. 2021); *Valdez*, 559 F.Supp.3d 1161; *Bauer*, 568 F.Supp.3d 573). Because no procedural due process violation has occurred, Plaintiffs' Third Cause of Action is dismissed.

F. Second Cause of Action: Deprivation of Equal Protection Rights

Defendants seek dismissal of Plaintiffs' Second Cause of Action, brought under 42 U.S.C. § 1983, for a claimed "Deprivation of Equal Protection Rights." SAC, ¶¶ 185–99. This claim explicitly invokes the "class of one" doctrine, alleging that "Plaintiffs were public employees and were discriminated against by Defendants when Defendants issued and enforced their unlawful Policy." *Id.*, ¶ 192. Plaintiffs claim "Defendants only discriminated against those who chose the option to refuse and not those who chose the option to accept under the EUA Statute and PREP Act," and "Defendants' Policy treated a class of public employees who refused an EUA product differently than those who accepted it." *Id.*, ¶¶ 193–94.

Under the Fourteenth Amendment to the U.S. Constitution, "no state shall 'deny to any person within its jurisdiction the equal protection of the laws,' which is essentially a direction that all persons similarly situated should be treated alike." *Cleburne*, 473 U.S. at 439 (quoting *Plyler v. Doe*, 457 U.S. 202, 216 (1982)). As with challenges under the Due Process Clause, "[c]ourts have routinely rejected the argument that vaccine mandates will trigger heightened scrutiny under the Equal Protection Clause and have instead applied rational basis review." *Williams*, 567 F. Supp. 3d at 1227–28 (citations omitted). Plaintiffs have not argued, and based upon their allegations would not be able to establish, that they are members of a suspect class. *See Boysen*, 2024 WL 3888682, at *8 ("[U]nvaccinated individuals do not constitute a suspect class.") (quoting *George v. Grossmont Cuyamaca Cmty. Coll. Dist. Bd. of Governors*, 2022 WL 16722357, at *10 (S.D. Cal. Nov. 4, 2022)); *Schmidt*, 2023 WL 4291440, at *11 ("Plaintiff has not shown that distinguishing between vaccinated and unvaccinated individuals reflects a suspect classification."). Furthermore, as discussed elsewhere in this Order, Plaintiffs have not articulated a fundamental right at stake. *See, e.g.*, *supra*, § III.C.2. Accordingly, Plaintiffs' Equal Protection claim is subject to rational basis review. *Armour v. City of Indianapolis, Ind.*, 566 U.S. 673, 680 (2012) (quoting Heller v. Doe, 509 U.S. 312, 319–20 (1993) ("[A] classification neither involving fundamental rights nor proceeding along suspect lines ... cannot run afoul of the Equal Protection Clause if there is a rational relationship between the disparity of treatment and some legitimate governmental purpose.").

As discussed above with respect to Plaintiffs' substantive due process claims, Section III.C.3, Defendants' Order passes rational basis review. *See Williams*, 567 F. Supp. 3d at 1228 ("The rational basis review test is functionally the same under substantive due process and the Equal Protection Clause.") (citing *Gamble v. City of Escondido*, 104 F.3d 300, 307 (9th Cir. 1997)). "Stemming the spread of COVID-19 is unquestionably a compelling interest," *Roman Catholic Diocese of Brooklyn*, 141 S. Ct. at 67, and in issuing the Order, Defendants rationally relied upon judicially noticeable data supporting their actions. *See supra*, § III.C.3. Plaintiffs have again cited no authority holding to the contrary. Plaintiffs' Second Cause of Action is dismissed.

G. Seventh Cause of Action: Unconstitutional Conditions

Plaintiffs bring their Seventh Cause of Action, for "Unconstitutional Conditions," under 42 U.S.C. § 1983. *See* SAC, ¶¶ 250–54. As Plaintiffs correctly assert, the state cannot condition the granting of a privilege on the relinquishment of one's constitutional rights. *Id.*, ¶ 251.

Plaintiffs claim Defendants violated this doctrine by conditioning continued public employment on the surrender of Plaintiffs' rights: to wit, their "due process, privacy, equal protection, public employment, [and] property interests." *Id.* ¶ 252. As outlined above, however, the Order does not violate these enumerated rights. Plaintiffs' Seventh Cause of Action therefore necessarily also fails. *See Legaretta*, 603 F. Supp. 3d at 1070–71 (vaccine mandate "does not violate any of Plaintiffs' fundamental rights[, and

w]ithout identifying a fundamental right, Plaintiffs' challenge to the Vaccine Mandate as an unconstitutional condition necessarily fails."); *Smith*, 2021 WL 5195688, at *8 (rejecting Unconstitutional Conditions Claim because plaintiffs are "presented with a choice and are not being coerced to give up a fundamental right since there is no fundamental right to refuse vaccination."). Plaintiffs' Seventh Cause of Action is dismissed.

H. Ninth Cause of Action: 42 U.S.C. § 1983 – Monell Liability

In their Ninth Cause of Action, Plaintiffs assert under 42 U.S.C. § 1983 a claim against the municipal defendant, the City of Bellingham, for "*Monell* Liability." SAC, ¶¶ 262-88. The claim again makes reference to the PREP Act, the EUA Act, the Equal Protection and Due Process Clauses, and the Supremacy Clause, and asserts that Defendant City of Bellingham is liable for violations of these various federal provisions. In responding to Defendants' Motion to Dismiss this claim, Plaintiffs fail to argue or demonstrate that the City has any liability that is not predicated on at least one of the claims reviewed—and dismissed—above. Because the Court has dismissed all of Plaintiffs' federal constitutional and statutory causes of action on their merits, Plaintiffs are unable to state a claim for liability against the City under *Monell* as well. Plaintiffs' Ninth Cause of Action is therefore dismissed.

I. State Law Claims

1. Tenth Cause of Action "Against Defendant City of Bellingham,

Wrongful Termination"

Plaintiffs' state-law claims include their Tenth Cause of Action, against Defendant City of Bellingham, for "Wrongful Termination." SAC, ¶¶ 289-94. Plaintiffs assert that the City violated state common law that authorizes individuals "to exercise a federal or legal right without losing employment when doing so." *Id*., ¶ 292 (citing, *inter alia*, *Becker v. Cmty. Health Sys., Inc.*, 184 Wn. 2d 252 (2015)). The "federal or legal rights" Plaintiffs invoke are those already discussed above: the right "to refuse products under each statute"—that is, the PREP Act and the EUA Act—"without penalty or pressure, . . . and the rights to refuse investigational drugs and to refuse unwanted medical treatment." *Id*., ¶ 293. Defendants seek dismissal of this cause of action as well.

In Washington, the tort of wrongful discharge "is a narrow exception to the doctrine of at-will employment." *Becker*, 184 Wn. 2d at 258. "To state a cause of action, the plaintiff must plead and prove that his or her termination was motivated by reasons that contravene an important mandate of public policy." *Id*. Wrongful termination claims are limited to a narrow set of scenarios, including most relevantly here, "where employees are fired for exercising a legal right or privilege." *Id*. As repeatedly noted above, Plaintiffs have failed to demonstrate that they were exercising a "legal right or privilege," under either state or federal constitutional or statutory law. The Tenth Cause of Action is, accordingly, dismissed as well.

2. Eleventh Cause of Action: Intentional Infliction of Emotional Distress

Plaintiffs' Eleventh Cause of Action is for Intentional Infliction of Emotional Distress ("IIED," also known as the tort of outrage). SAC, ¶¶ 295-97. To establish a claim for IIED, a plaintiff must show "(1) extreme and outrageous conduct, (2) intentional or reckless infliction of emotional distress, and (3) an actual result of severe emotional distress." *Kloepfel v. Bokor*, 149 Wn. 2d 192, 195 (2003) (citations omitted). An IIED claim must be predicated on behavior "so outrageous in character, and so extreme in degree, as to go beyond all possible bounds of decency, and to be regarded as atrocious, and utterly intolerable in a civilized community." *Id*.

In support of this claim, Plaintiffs aver that "Defendants engaged in a scorched-earth policy and inflicted, with malicious intent, emotional distress to the fullest extent that one in their positions of authority and power could inflict, all to the detriment of Plaintiffs' emotional well-being." SAC, ¶ 296. This Court has already held that a materially identical COVID-19 vaccine mandate did not meet the level of "extreme and outrageous conduct" necessary to support a claim under Washington state law for intentional infliction of emotional distress. *Curtis v. Inslee*, 709 F. Supp. 3d 1257, 1271 (W.D. Wash. 2023) ("The Plaintiffs' outrage claim should be dismissed. The properly credited allegations in the Amended Complaint are insufficient from which to conclude that the Proclamation was 'beyond all possible bounds of decency' considering the circumstances at the time."). Plaintiffs have not attempted to distinguish or discredit Curtis, which the Court finds persuasive in any event, and have failed to cite any

authority in support of their contention that Defendants' actions were outrageous. As discussed above, Plaintiffs' Second Amended Complaint fails to state any federal constitutional or statutory violations, or violations of state law, let alone allege facts supporting their claim that Defendants' behavior was "extreme and outrageous" or "beyond the bounds of decency." Accordingly, Plaintiffs have failed to state a claim for intentional infliction of emotional distress, and their Eleventh Cause of Action is dismissed.

J. Leave to Amend Second Amended Complaint

Federal Rule of Civil Procedure 15(a) provides in relevant part that after a party has amended a pleading once as a matter of course, it may amend further only after obtaining leave of the court. In general, "[t]he court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). In determining the propriety of granting leave to amend, Courts are required to balance the following factors: (1) undue delay; (2) bad faith or dilatory motive of the moving party; (3) repeated failure to cure deficiencies by amendments previously allowed; (4) undue prejudice to the non-moving party by virtue of allowance of the amendment; and (5) futility of amendment. *Eminence Cap., LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

Having considered these factors, the Court concludes that Plaintiffs are not entitled to amend, and the Second Amended Complaint should be dismissed with prejudice. Plaintiffs have twice amended their original Complaint, neither time

attempting to cure the deficiencies outlined above. In opposing Defendants' Motion to Dismiss, Plaintiffs repeatedly failed to cite any on-point authority—within this Ninth Circuit or beyond—tending to support their position. Perhaps most critically of all, Plaintiffs have not requested leave to amend or dismissal without prejudice.

They have failed to call into question or distinguish cases around the country that have, nearly unanimously, rejected COVID-19 vaccine mandate claims materially identical to theirs, and have not suggested any additional allegations on which they might rely if granted leave to amend. For all of the reasons articulated herein, the Court finds that amendment of the Second Amended Complaint or any of the dismissed causes of action putatively stated therein would be futile, and denies Plaintiffs leave to amend. This matter is dismissed with prejudice in its entirety.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss is GRANTED. This matter is dismissed with prejudice.

DATED this 21st day of January, 2025.

s/*Barbara J. Rothstein*
Barbara Jacobs Rothstein
U.S. District Court Judge

APPENDIX C

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 24-1869

D.C. No. 3:23-cv-05741-RJB

OPINION

AILA CURTIS; CIERA AGEE; ALISON ARCHER; SHANNON LEE ADAMS; BECKY BARCENAS; HANNAH BERNHARDT; KATHY BORDEAUX; CHRISTINE AMBER BRUCE; SUSAN BUCHANAN; KIRSTEN CLARKE; DIANE CLEMANS; JEFF COFFEY; DEREK COINER; SHEILA CRAIG; RAE LY CROCKER; LISA DALUZ; CHRISTINA DAWSON; MARGARITA DEMCHENKO; MONICA DICKINSON; HAYLEY DIXON; JASON DONG; SHANTA GERVICKAS; EDUARD GONCHARUK; AMY HASEROT; BETHEN HAYDEN; RHONDA HOLMES; MIKAYLA HOLSINGER SUMIKO KUBA; NADEZHDA LITVINENKO; LILIYA LOPATIN; MISTY LYONS; SHEILA LYONS; IRINA MAKSIMENKO; LYUBOV MELNYCHUK; ASHLEY MENDOZA; MONICA MILLER; CHERYL MITCHELL; DAMARIS MOCAN; KATHRYN MORGAN; NICK MORZHOV; DWAIN NASH; LYSANDER NERIDA; KATHRYN ORTEGA; YVONNE QUASHIE; LESLIE QUINTANA; EMMA RANSON; SHANNON RINGNALDA; MALLORY SCHLANG; MELISSA SMITHDEAL; LORI SOUDERS; BROOKE TANNER; TRACIE THOMAS; DENA THORP; JENNIFER TORRES; LYUBOV

TSHUPRIN; OLGA TSYTSYNA; ROXANA VOLYNETS; HANNAH WAGER; VERA YADLOVSKIY; ALLA KUTSA ZABOLOTSKA; DINA ZABOLOTSKA; NELYA ZABOLOTSKA; KRISTINE ZAMUDIO; DANIEL BRICKERT; AMY JAMES; BRITNEY BROWN; NELLI ANTONOV; DAVID BENNETT; AMBER TAYLOR; TAMARA KOPP; WHITNEY KONRADY; JOSEY KOLBO; LINDSEY LAMB; KATERINA EROKHINA; IGOR SHAPOVAL; WHITNEY ONOFREY; AMY TALLBUT; VIOLETTA ROBERTS; LINDA VEATCH; ANGELA RIPP; KRISTIN ELLISON; STACI GRAY,

Plaintiffs—Appellants,

v.

JAY ROBERT INSLEE; PEACEHEALTH, INC.; LIZ DUNNE; DOUG KOEKKOEK,

Defendants—Appellees.

Appeal from the United States District Court
for the Western District of Washington
Robert J. Bryan, District Judge, Presiding

Argued and Submitted July 9, 2025
Seattle, Washington

Filed October 6, 2025

Before: M. Margaret McKeown, Richard A. Paez, and Gabriel P. Sanchez, Circuit Judges.

Opinion by Judge McKeown

SUMMARY*

Employment/COVID-19

The panel affirmed the district court's dismissal for failure to state a claim of an action brought by former at-will employees of a nonprofit health care system (Employees) alleging various statutory, constitutional, and state law claims arising from then-Governor Jay Inslee's August 2021 proclamation requiring healthcare workers in Washington to be vaccinated against COVID-19.

The panel first held that none of the Employees' statutory and non-constitutional claims alleged specific and definite rights enforceable under 42 U.S.C. § 1983. The panel therefore rejected Employees' claims based on 21 U.S.C. § 360bbb-3, 10 U.S.C. § 980, 42 U.S.C. § 247d-6, Article VII of the International Covenant on Civil and Political Rights, 45 C.F.R. Part 46, the Belmont Report, the Federal Wide Assurance Agreement, the COVID-19 Vaccination Program Provider Agreement, and Emergency Use Authorizations.

Addressing the Employees' constitutional claims, the panel held that neither the Spending Clause nor the Supremacy Clause provided Employees with a federal right enforceable under § 1983. Employees' claims under the Fourteenth Amendment Due Process Clause failed. The substantive due process claim alleging the right to refuse unwanted investigational drugs was foreclosed by *Jacobson v.*

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

Massachusetts, 197 U.S. 11 (1905), and *Health Freedom Def. Fund, Inc. v. Carvalho*, 148 F.4th 1020 (9th Cir. 2025) (en banc). The procedural due process claim failed because, among other things, the Employees' at-will employment was not a constitutionally protected property interest. Employees' Equal Protection Clause claim, asserting a claim of discrimination against a non-suspect class, failed because the mandate here survived rational-basis review.

Because amendment of the federal claims would be futile, the panel held that the district court did not abuse its discretion in denying leave to amend the complaint. The panel affirmed the dismissal of the state law claims alleging breach of contract, employment tort, outrage, and invasion of privacy against the Governor. As for the state-law claims against PeaceHealth, the panel upheld the district court's discretion to decline to exercise supplemental jurisdiction.

COUNSEL

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OPINION

McKEOWN, Circuit Judge:

We have considered a spate of appeals related to vaccination orders spawned by COVID-19. This case arises from then-Governor Jay Inslee's August 2021 proclamation requiring healthcare workers in Washington to be vaccinated against COVID-19. Aila Curtis and more than 80 other former at-will employees of the nonprofit health care system PeaceHealth ("Employees") were terminated after they refused to comply with PeaceHealth's COVID-19 vaccination policy. Employees' claims against PeaceHealth and Governor Inslee range from statutory and constitutional claims under 42 U.S.C. § 1983 to state-law contract and tort claims. The district court dismissed all claims with prejudice. Although Employees throw the kitchen sink at the Proclamation, none of their wide-ranging sources of purported rights supports their federal claims. As for the state-law claims, the district court correctly dismissed with prejudice the claims against the Governor and left the merits of the claims against PeaceHealth for state courts to adjudicate. The district court acted within its discretion in denying leave to amend.

Because we affirm on the basis of Employees' failure to state a claim, we do not decide the questions of state action and qualified immunity addressed by the district court. We also note that our analysis holds even if the drug in question was deemed "investigational," as Employees assert; any claimed error by the district court in its view of the facts pertaining to this issue is harmless. We affirm.

Background

On August 20, 2021, then-Governor of Washington State Jay Inslee ("the Governor") issued Proclamation 21-14 ("the Proclamation"), which, absent an exemption, required healthcare workers to be vaccinated against COVID-19 before October 18, 2021. In accord with this directive, on August 30, PeaceHealth adopted a vaccination mandate for its employees, with a deadline of October 15. Because Employees refused to be vaccinated, PeaceHealth terminated their employment.

Employees sued PeaceHealth and its executives (collectively, "PeaceHealth"), as well as the Governor, seeking damages. Employees allege that, leading up to the vaccination deadline, the sole available vaccine to satisfy the vaccination mandate was an "investigational drug," authorized only for emergency use.[1] Despite the fact that the Pfizer vaccine authorized for emergency use and the Pfizer vaccine fully approved by the Food and Drug Administration undisputedly had the same "medical formulation,"

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[1] The Food and Drug Administration ("FDA") issued an Emergency Use Authorization ("EUA") for Pfizer's COVID-19 vaccine in January 2021. Authorizations of Emergency Use of Two Biological Products During the COVID–19 Pandemic; Availability, 86 Fed. Reg. 5200 (January 19, 2021). By August 2021, Pfizer's EUA-authorized COVID-19 vaccines had been manufactured and made available for many months.

As the district court noted, on August 23, 2021, the FDA approved Pfizer's COVID-19 vaccine, marketed as COMIRNATY. *See We The Patriots USA, Inc. v. Hochul*, 17 F.4th 266, 283 (2d Cir. 2021) ("[T]he FDA gave full approval to the Pfizer-BioNTech vaccine for individuals 16 years of age and older."). We take as true Employees' factual assertion that Pfizer's COVID-19 vaccines manufactured under FDA approval were not available before the relevant vaccination deadlines.

Employees claim that their rights were violated when they were penalized for refusing a vaccine that was only EUA-authorized and not yet FDA-approved. Employees also claim they were not adequately informed of their option to refuse administration of the vaccine. Employees contend that these rights are enforceable through a variety of sources—ranging from multiple federal statutes to the Fourteenth Amendment to the terms of the agreements under which COVID-19 vaccines (or "investigational drugs") were administered.

The district court first dismissed all of the claims against the Governor, then dismissed the federal claims against PeaceHealth, and finally denied Employees' motions for leave to amend and reconsideration and declined to exercise supplemental jurisdiction over their state-law claims against PeaceHealth.

Analysis

I. Statutory and Other Non-Constitutional Claims

Section 1983 authorizes private parties to sue for violations of their constitutional rights and certain federal statutory rights. 42 U.S.C. § 1983. Because a statutory right enforceable under Section 1983 is not created "as a matter of course," *Health & Hosp. Corp. of Marion Cnty. v. Talevski*, 599 U.S. 166, 183 (2023), Employees must "prove that a statute secures an enforceable right, privilege, or immunity, and does not just provide a benefit or protect an interest." *Medina v. Planned Parenthood S. Atl.*, 145 S. Ct.

2219, 2229 (2025).[2] Provisions that place a "merely precatory obligation" on the government do not create enforceable rights. *Ball v. Rodgers*, 492 F.3d 1094, 1103 (9th Cir. 2007).

Although the existence of an "unambiguously conferred," "sufficiently specific and definite" statutory right establishes a presumption of enforceability under Section 1983, *Gonzaga Univ. v. Doe*, 536 U.S. 273, 280, 283 (2002) (citation omitted), that presumption can be overcome. A Section 1983 claim will not be available where there is "incompatibility between enforcement under § 1983 and the enforcement scheme that Congress has enacted." *Talevski*, 599 U.S. at 187.

Employees' non-constitutional claims under Section 1983—styled as "subjected to investigational drug use," "unconstitutional conditions doctrine," equal protection, due process, and "spending clause doctrine"—are based on an eclectic collection of statutes, an international treaty, a regulation, two agreements, a report, and constitutional doctrines and provisions. After considering each in turn, our conclusion is unequivocal: None of these claims alleges a specific and definite right enforceable by Employees under Section 1983.

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[2] "Plaintiffs suing under § 1983 do not have the burden of showing an intent to create a private remedy because § 1983 generally supplies a remedy for the vindication of rights secured by federal statutes. … Once a plaintiff demonstrates that a statute confers an individual right, the right is presumptively enforceable by § 1983." *Gonzaga Univ. v. Doe*, 536 U.S. 273, 280, 284 (2002).

A. 21 U.S.C. § 360bbb-3 – "EUA Statute"

The statutory provision referred to by Employees as "the EUA Statute" or 21 U.S.C. § 360bbb-3, a section of the Food, Drug, and Cosmetic Act ("FDCA"), empowers the FDA to authorize the use of a drug in certain circumstances. Under this statute, the Secretary of Health and Human Services is obliged to design "[a]ppropriate conditions … to ensure that individuals to whom the product is administered are informed … of the option to accept or refuse administration of the product." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii). Employees argue that Defendants did not adequately inform them of their option to refuse the COVID-19 vaccine, thereby violating the statute.

Even assuming this language applies to Defendants and their conduct, Congress has limited the enforcement of the FDCA to public actions. *Id.* § 337(a) (requiring that enforcement be brought "by and in the name of the United States"). Contrary to Employees' wishes, we cannot "judicially creat[e] an implied private right of action." Instead, our role is to interpret Congress's intent in creating a private right. "In the absence of clear evidence of congressional intent, we may not usurp the legislative power by unilaterally creating a cause of action." *In re Digimarc Corp. Derivative Litig.*, 549 F.3d 1223, 1230–31 (9th Cir. 2008). By providing only for public enforcement, Congress has made its intent to "shut the door to private enforcement" evident. *Gonzaga Univ.*, 536 U.S. at 284 n.4. Employees have not provided evidence of any contrary Congressional intent or even a colorable interpretation of the statute that would enable their

suit. We conclude that Section 360bbb-3 does not create a private right that is enforceable under Section 1983.

B. 10 U.S.C. § 980 – "Funds Appropriated for Human Subjects"

This statute, 10 U.S.C. § 980, provides that "[f]unds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject." Spending-power statutes, like this one, are "especially unlikely" to confer an enforceable right. *Medina*, 145 S. Ct. at 2230. This statute contains no language "phrased in … explicit rights-creating terms." *Gonzaga*, 536 U.S. at 284. Nor does it "manifest[] an 'unambiguous' intent to confer individual rights" and so is not enforceable under Section 1983. *Id.* at 280 (citation omitted).

C. 42 U.S.C. § 247d-6 – "Public Readiness and Emergency Preparedness Act"

The Public Readiness and Emergency Preparedness Act ("PREP Act"), 42 U.S.C. § 247d-6, requires the Secretary of Health and Human Services to "ensure that … potential participants [in the administration or use of a covered counter-measure] are educated with respect to … the voluntary nature of the program." *Id.* § 247d-6e(c). Employees extrapolate from this statute a "right" to be so educated and thus hang their hat on this statute as a basis for their Section 1983 claims. The PREP Act, however, lacks the requisite "rights-creating language" and "individual[] focus" to create

rights enforceable under Section 1983. *Gonzaga,* 536 U.S. at 290. Further, the statute, at most, imposes an educational obligation on a federal agency, not Defendants. Plaintiffs' PREP Act claim therefore fails.

D. Article VII of the International Covenant on Civil and Political Rights

The International Covenant on Civil and Political Rights ("ICCPR") is a treaty that protects certain human rights. Some treaties—those that are either self-executing or legislatively implemented—can confer enforceable rights under Section 1983. *See, e.g., Olympic Airways v. Husain*, 540 U.S. 644, 646 (2004) (upholding the imposition of liability under Article 17 of the Warsaw Convention); *Missouri v. Holland*, 252 U.S. 416, 431 (1920) (discussing the Migratory Bird Treaty Act of 1918 as legislative implementation that "g[a]ve effect" to a 1916 treaty between the United States and Great Britain); *see also Medellín v. Texas*, 552 U.S. 491, 568–69 (2008) (appendix listing "Supreme Court decisions considering a treaty provision to be self-executing").

However, the ICCPR was ratified by the United States "on the express understanding that it was not self-executing and so did not itself create obligations enforceable in the federal courts." *Sosa v. Alvarez-Machain*, 542 U.S. 692, 735 (2004). Because the ICCPR is not self-executing, and Congress has not acted to enable private lawsuits for violations of rights enshrined in that treaty, it is not "susceptible to judicial enforcement." *Serra v. Lappin*, 600 F.3d 1191, 1196 (9th Cir. 2010) (citation omitted). Article

VII of the ICCPR thus cannot serve as the basis for a Section 1983 action. *See Medellín*, 552 U.S. at 505 (concluding that absent self-executing status or implementing statutes, such treaties' commitments are "not domestic law"); *Frolova v. Union of Soviet Socialist Republics*, 761 F.2d 370, 373 (7th Cir. 1985) (holding that a treaty "do[es] not provide the basis for a private lawsuit" if it is neither self-executing nor implemented by legislation).

E. 45 C.F.R. Part 46 – "Human Subjects in Research"

Employees contend that Defendants, in administering "investigational drugs," were "bound to comply" with 45 C.F.R. Part 46, which concerns the protection of human subjects in research. 45 C.F.R. §§ 46.101, *et seq*. But even if these regulations applied to the conduct at issue here, a regulation "may not create a right that Congress has not." *Alexander v. Sandoval*, 532 U.S. 275, 291 (2001); *see also Save Our Valley v. Sound Transit*, 335 F.3d 932, 936 (9th Cir. 2003). Employees do not argue that any authorizing statutes create any right enforceable under Section 1983.[3] The regulation, standing alone, cannot support Employees' claims.

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[3] If a "statute itself confers a specific right upon the plaintiff, and a valid regulation merely further defines or fleshes out the content of that right, then the statute—in conjunction with the regulation—may create a federal right as further defined by the regulation." *Save our Valley*, 335 F.3d at 941 (quoting *Harris v. James*, 127 F.3d 993, 1009 (11th Cir. 1997)).

F. The Belmont Report

The Belmont Report outlines "basic ethical principles" and their application in the conduct of research on human subjects. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report (April 18, 1979), https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html, accessed May 9, 2025. The Belmont Report is neither a statute nor a regulation. It does not carry the force of law. It contains no hint of a legal right or remedy enforceable in U.S. courts. Employees' claims based on the Belmont Report also fail.

G. The Federal Wide Assurance Agreement

Like the Belmont Report, the Federal Wide Assurance agreement ("FWA") is far afield from any potential rights- creating source. The FWA is an agreement between the U.S. Department of Health and Human Services and any institution involved in federally funded research, under which the institution commits to complying with requirements in 45 C.F.R. Part 46 and the Belmont Report. Employees argue that the FWA created a duty to obtain "legally effective informed consent" from them and "to ensure that at no time is an individual under 'coercion,' 'undue influence,' 'unjustifiable pressures' or a sanction to participate" in the administration of an investigational drug. Notably, the language regarding "coercion" and similar phrases comes from the Belmont Report, not the FWA. Even if the FWA created such a duty, and such a duty applied to Defendants, the FWA does not create rights

enforceable under Section 1983. *See Save Our Valley*, 335 F.3d at 941–42. Employees, who bear the burden of proving the existence of a right enforceable under Section 1983, have failed to point to any "explicit rights-creating terms" in the FWA itself. *Gonzaga*, 536 U.S. at 284. Their sole citation is to a federal government website that explains the general nature of the FWA. This basis for Employees' Section 1983 claim too fails.

H. The COVID-19 Vaccination Program Provider Agreement

The COVID-19 Vaccination Program Provider Agreement ("Provider Agreement") is "a form contract between the [Center for Disease Control] and medical providers that plan to administer COVID-19 vaccines." As relevant, medical providers are to "provide a[] … fact sheet … to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative." The contract also incorporates "all applicable requirements as set forth by the U.S. Food and Drug Administration." Employees contend that the Provider Agreement, by incorporating all federal requirements, required the medical providers to "accept[] the Appellants' freely chosen option" to refuse the administration of the drug at issue. Once more, such an agreement cannot create enforceable rights under Section 1983. *Id.*

Nor do Employees meet the requirements for bringing suit as direct third-party beneficiaries to a government contract. Employees bear the burden of demonstrating that they individually can enforce any right created by the contract and seek damages. *See Indep. Living Ctr. of S. Cal., Inc. v. Kent*, 909 F.3d

272, 280 (9th Cir. 2018). Where, as here, third-party beneficiaries seek consequential damages for failure to perform under a government contract, that burden has two requirements: 1) that "the terms of the promise provide for such liability," Restatement (Second) of Contracts § 313(2)(a); and 2) that the plaintiffs "fall within a class clearly intended by the parties to benefit from the contract." *Orff v. United States*, 358 F.3d 1137, 1145 (9th Cir. 2004) (citation omitted).

Employees meet neither requirement. The Provider Agreement contemplates fines and imprisonment as penalties but does not address private enforcement. *Cf. Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 190 (1994) ("We have been quite reluctant to infer a private right of action from a criminal prohibition alone."). Nothing in the Provider Agreement even hints at the option for a damages claim. As for the second requirement, if there are any direct beneficiaries to the Provider Agreement, those would be "vaccine recipient[s]." As the district court pointed out, Employees are not vaccine recipients but rather vaccine refusers. Once again, Employees have not demonstrated that they have a right to sue under this type of agreement.

I. Emergency Use Authorizations

Emergency use authorizations ("EUAs") are letters from the Chief Scientist of the FDA to drug manufacturers. These letters contain conditions of authorization, including the requirement of distribution of "authorized labeling" to "vaccination providers, recipients, and caregivers." Yet again,

these letters do not confer rights enforceable under Section 1983. Nor are the Employees direct beneficiaries of these letters such that they could possibly sue in contract—they are neither the senders nor the recipients of these letters, and they have not alleged that they are "vaccination providers, recipients, [or] caregivers."

II. Constitutional Provisions

A. Spending Clause

Employees style one of their Section 1983 claims under the "Spending Clause Doctrine," presumably referring 10 U.S.C. § 980, governing the use of Department of Defense funds. While statutes enacted pursuant to the Spending Clause "can create § 1983-enforceable rights," the operative question is whether they "actually do so." *Talevski*, 599 U.S. at 180. That question is answered by our discussion of the statutes above. The invocation of the Spending Clause does not change the analysis.

B. Supremacy Clause

When discussing the PREP Act and the "EUA Statute," Employees invoke "preemption" in their complaint and briefs. To the extent Employees rely on the Supremacy Clause as a basis for their Section 1983 claims, this argument fails. The Supremacy Clause itself "is not a source of any federal rights" enforceable under Section 1983. *Golden State Transit*, 493 U.S. at 107 (citation omitted). The "availability of the § 1983 remedy turns on whether the statute[s]" that Employees argue preempt state

action create enforceable rights. We already concluded they do not.

C. Fourteenth Amendment Due Process

a. Substantive Due Process

Employees' efforts to situate their claims under the Fourteenth Amendment Due Process Clause also fail. Employees claim Defendants violated their substantive due process right "to refuse unwanted investigational drugs." The "substantive protection of the Due Process Clause" extends to "[o]nly those aspects of liberty that we as a society traditionally have protected as fundamental." *Mullins v. Oregon*, 57 F.3d 789, 793 (9th Cir. 1995). Because fundamental rights are highly circumscribed, courts are "reluctant to expand the concept of substantive due process." *Regino v. Staley*, 133 F.4th 951, 962 (9th Cir. 2025) (citation omitted). Employees must therefore articulate a "careful description" of a fundamental right. *Stormans, Inc. v. Wiesman*, 794 F.3d 1064, 1085 (9th Cir. 2015) (quoting *Washington v. Glucksberg*, 521 U.S. 702, 728 (1997)). If a fundamental right is implicated, we apply strict scrutiny. *Witt v. Dep't of Air Force*, 527 F.3d 806, 817 (9th Cir. 2006)). If a fundamental liberty interest is not implicated, we apply rational basis review, which is "highly deferential to the government, allowing any conceivable rational basis to suffice." *Health Freedom Def. Fund, Inc. v. Carvalho*, 148 F.4th 1020, 1029 (9th Cir. 2025) (en banc) (quotation omitted).[4]

[4] We recently rejected a similar challenge to a COVID-19 vaccine mandate. In *Carvalho*, we held that the "constitutionality of a vaccine mandate … turns on what reasonable

Employees' clearest articulation of the right they assert is the "right to refuse an investigational drug without penalty or pressure." It is undisputed that the "investigational drug" is a COVID-19 vaccine and that the Governor and PeaceHealth believed compulsory vaccination for healthcare workers would protect public health. In fact, the vaccine even has the same "medical formulation" as a vaccine that was FDA-approved before the issuance of PeaceHealth's vaccination policy and thus prior to Employees' refusals. On this record, for the purposes of this analysis, there is no material distinction between the refusal of a vaccine and Employees' refusal of administration of an investigational drug that is clinically identical to a vaccine.

Under longstanding Supreme Court precedent, the right to refuse a vaccine is not inviolate. Penalties for refusing vaccination are plainly permissible. The Supreme Court in *Jacobson v. Massachusetts* upheld a vaccination-refusal penalty of "commit[ment] until [a] fine was paid" and indicated the permissibility of "manifold restraints," including quarantine. 197 U.S. 11, 21, 26 (1905); see also *Zucht v. King*, 260 U.S. 174, 175 (1922) (upholding the exclusion of a student from school for refusing vaccination). When we consider "substantive due process challenges to COVID-19 vaccine mandates," our analysis is controlled by *Jacobson*. *Carvalho*, 148 F.4th at 1029.

Specifically, under *Jacobson*, penalties justified by public health concerns are legitimate. The court in *Jacobson* was crystal clear that, because "a

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legislative and executive decisionmakers could have rationally concluded about whether a vaccine protects the public's health and safety." *Id.* at 1031.

community has the right to protect itself against an epidemic of disease which threatens the safety of its members," a vaccine mandate that has a "real or substantial relation to the protection of public health" is not "in palpable conflict with the Constitution." 197 U.S. at 27, 31. Thus, the Court in *Jacobson* "essentially applied rational basis review" to the smallpox vaccine mandate and found it survived such deferential review. *Carvalho*, 148 F.4th at 1030. In *Carvalho*, applying *Jacobson*, we reached the same conclusion with respect to a vaccination policy imposed for closely analogous reasons, at nearly the same time, as the vaccine mandates at issue here. In that case, applying rational basis review, we upheld the vaccine policy because it was "more than reasonable for the [state actors] to conclude that COVID-19 vaccines would protect the health and safety of [the relevant populations]." *Id.*

Jacobson and *Carvalho* foreclose Employees' substantive due process claim regarding the purported "right to refuse an investigational drug without penalty or pressure." The penalties imposed on Employees were amply justified by public health concerns, as explained elsewhere in this opinion. Employees have failed to plausibly allege that the state action in this case was an exercise of "arbitrary power" rather than merely "that broad discretion required for the protection of the public health." *Zucht*, 260 U.S. at 177. We therefore conclude that Employees have not stated a substantive due process claim based on the right to refuse the COVID-19 vaccine at issue.

Employees' substantive due process claim regarding the PREP Act's grant of immunity also

fails. Even if there exists some constitutional limit on the Congressional power to grant immunity, Employees have pointed to no authority suggesting that the PREP Act exceeds that limit. Employees cannot allege a deprivation of their ability to bring suit, as they have had an opportunity to be heard in this action. And, of course, Employees are not entitled to damages in the absence of a meritorious claim. As for any right to "educat[ion] with respect to the voluntary nature of the program," Employees have not shown a deprivation of that right. Materials provided to recipients and caregivers made clear that "it is [their] choice to receive or not receive any of these vaccines," and consent forms acknowledged their right to refuse.

b. Procedural Due Process

Employees' procedural due process claim fares no better. Employees' at-will employment with PeaceHealth is not a constitutionally protected property interest under the Fourteenth Amendment. *Portman v. Cnty. of Santa Clara*, 995 F.2d 898, 904 (9th Cir. 1993) (holding that at-will employees "ha[ve] no property interest in the[ir] job[s]"). In the absence of a deprivation of a protected interest, Employees cannot make out a procedural due process claim. *See Reed v. Goertz*, 598 U.S. 230, 236 (2023).

Employees also allege a deprivation of a protected liberty interest in the refusal of unwanted administration of a drug and a protected property interest in the use of their medical licenses (asserted in the Second Amended Complaint). Assuming without deciding that Employees have adequately alleged a deprivation, they have not plausibly alleged

that they have not received all the process that was due.

Unlike their prior pleadings, Employees' Second Amended Complaint claims that the Governor gave Employees no "date, time, place, or procedure to defend their right to refuse injection … before depriving them of their liberty and property."[5] However, the Proclamation provided notice of the vaccination requirements and of the consequence of termination for failure to comply. The Proclamation also required that healthcare workers be given opportunities to be heard for the purpose of religious and medical exemptions and that assessments for qualification for such exemptions be "individualized." Employees do not contend that they sought and were deprived of an exemption without due process.

Indeed, it is difficult to characterize Employees' complaint in the usual framework of a procedural due process challenge. A typical challenge concerns a plaintiff who, subjected to a permissible standard by the state, seeks to show that "there is no [non-discriminatory] basis for their finding that he fails to meet these standards." *Schware v. Bd. of Bar Exam. of State of N.M.*, 353 U.S. 232, 239 (1957). The ordinary purpose of the due process inquiry is to fulfill "the public interest in correct eligibility determinations," and thus the ordinary question is one of factual "eligibility." *Goldberg v. Kelly*, 397 U.S. 254, 266 (1970).

Here, by contrast, Employees seek to challenge the standards themselves: either the breadth of the mandate or the narrowness of the exemptions. But

[5] The Second Amended Complaint does not make any assertions on this point as to PeaceHealth.

the legitimacy of a standard—as opposed to the process by which the state determines whether the Employee meets that standard—is not a question to be answered by procedural due process. The Supreme Court long ago held that "legislation is not open to the charge of depriving one of his rights without due process of law, if it be general in its operation upon the subjects to which it relates." *Dent v. West Virginia*, 129 U.S. 114, 124 (1889). The Governor was under no obligation to hold a town hall for Employees to make known their various complaints regarding the Proclamation. The process the state created for granting exemptions "fulfilled the purpose of the requisite pretermination hearing": to "provide a meaningful hedge against erroneous action." *Clements v. Airport Auth. of Washoe Cnty.*, 69 F.3d 321, 332 & n.13 (9th Cir. 1995) (quoting *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 543 n.8 (1985)).

Employees' procedural due process challenge better construed as a bid to alter the state's policies, rather than its procedures—fails.

D. Equal Protection

Employees assert a claim of discrimination against a non-suspect class, *cf. New York City Transit Auth. v. Beazer*, 440 U.S. 568, 592–93 (1979), namely, a class of "healthcare workers … choosing the option to refuse." However, the Proclamation "appl[ied] evenhandedly" to all healthcare workers in Washington State, except for its religious and medical exemptions. *Beazer*, 440 U.S. at 587. The presence of the exemptions splits Employees' articulated class in two: those workers who refused

and had exemptions (and so were not penalized), and those workers who refused and did not have exemptions (and so were penalized). The "exclusionary line" of vaccination status challenged by Employees simply does not reflect the reality of the policy, which allows exemptions for medical and religious reasons. *Id*. at 592. We are hard-pressed to conclude that they have "confronted [us] with the question whether the rule reflects an impermissible bias against a special class." *Id*. at 588.

Even if the vaccine mandates classify such that the Equal Protection Clause applies, our "only inquiry" is whether Employees' treatment is "rationally related to the State's objective." *Harrah Indep. Sch. Dist. v. Martin*, 440 U.S. 194, 199 (1979) (quoting *Mass. Bd. of Ret. v. Murgia*, 427 U.S. 307 315 (1976)); *see also Carvalho*, 148 F.4th at 1033. We conclude that the state action here easily survives rational-basis review.

Rational-basis review affords government actions a "strong presumption of validity." *Aleman v. Glickman*, 217 F.3d 1191, 1200 (9th Cir. 2000) (citation omitted). It is satisfied where the state decisionmaker "could rationally have decided" that its action would further a legitimate state interest. *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 466 (1981) (emphasis omitted). "Under rational basis review, the state actor has no obligation to produce evidence to sustain the rationality of a … classification; rather, the burden is on the one attacking the … arrangement to negative every conceivable basis which might support it." *Johnson v. Rancho Santiago Cmty. Coll. Dist.*, 623 F.3d 1011, 1031 (9th Cir. 2010) (internal quotations and citation omitted).

Early in the pandemic, we reiterated that "[s]temming the spread of COVID-19" is not merely a legitimate state interest; it is "unquestionably a compelling" one. *Slidewaters LLC v. Wash. State Dep't of Lab. & Indus.*, 4 F.4th 747, 758 (9th Cir. 2021) (quoting *Roman Cath. Diocese of Brooklyn v. Cuomo*, 592 U.S. 14, 18 (2020)). In *Biden v. Missouri*, the Supreme Court recently articulated the public-health rationale underlying vaccine mandates for healthcare workers:

> COVID–19 is a highly contagious, dangerous, and—especially for Medicare and Medicaid patients—deadly disease. The Secretary of Health and Human Services determined that a COVID-19 vaccine mandate will substantially reduce the likelihood that healthcare workers will contract the virus and transmit it to their patients. … He accordingly concluded that a vaccine mandate is "necessary to promote and protect patient health and safety" in the face of the ongoing pandemic.

595 U.S. 87, 93 (2022).

That decision plainly demonstrates that a state decisionmaker "could rationally have decided" that a vaccine mandate for healthcare workers would further the legitimate state interest of stemming the spread of COVID-19. Thus, the mandate here survives rational-basis review. *Clover Leaf Creamery*, 449 U.S. at 466.

Employees provide no factually supported argument to undermine this conclusion. Employees only note that "[a]n investigational drug does not

have a legal indication to treat, cure, or prevent any known disease or virus." But the absence of a legal indication does not negate the obvious inference that the available COVID-19 vaccine would be rationally related to the protection of public health. *See Rancho Santiago Cmty. Coll. Dist.*, 623 F.3d at 1031. For example, the Proclamation recognized that based on "clinical trials involving tens of thousands of participants" and "the [FDA's] rigorous scientific standards" for emergency use authorization, the available COVID-19 vaccines are "safe and effective." *See also Carvalho*, 148 F.4th at 1033 (concluding that an August 2021 COVID-19 vaccination mandate for public school teachers easily survived rational basis review). And, in this case, Employees even concede that the vaccine available to them had the same medical formulation and effectiveness as an FDA-approved COVID-19 vaccine. If there were any state action constituting differential treatment of Employees as a class, that action had a rational basis. Employees' equal protection challenge fails.

III. Denial of Leave to Amend

We review for abuse of discretion the district court's denial of leave to amend. *Herring Networks, Inc. v. Maddow*, 8 F.4th 1148, 1155 (9th Cir. 2021). Employees appeal that denial only with respect to their federal claims. Denial of leave to amend was proper because amendment of those claims would be futile. *Cervantes v. Countrywide Home Loans, Inc.*, 656 F.3d 1034, 1041 (9th Cir. 2011). No amendment to Employees' existing claims could change the absence of a source of law conferring on them a right enforceable under Section 1983. Employees' one

novel claim in the Second Amended Complaint, an invocation of 21 U.S.C. § 355(a), another provision of the FDCA, fails for the same reasons as did their claim under 21 U.S.C. § 360bbb-3. Nor do Employees' proposed amendments alter our analysis with respect to the constitutional claims. The Second Amended Complaint reiterates that the EUA-authorized and FDA-approved vaccines "can be used interchangeably to provide the vaccination series." In light of that continued allegation, an inference in favor of Employees' inconsistent new assertion that the EUA-authorized vaccine does not "stop infection or transmission" of COVID-19 would be unreasonable. On review of a motion to dismiss, we need draw only those reasonable inferences in the Employees' favor, not all potential inferences. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009).

Employees' attempt to distinguish Jacobson by comparing fatality rates from smallpox to fatality rates from COVID-19 does not change the equal protection analysis under rational-basis review, particularly given that stemming the spread of COVID-19 is a "compelling" interest. *Roman Cath. Diocese of Brooklyn*, 592 U.S. at 18. Nor does this new assertion disturb our conclusion that *Jacobson* forecloses Employees' substantive due process claim. *See Carvalho*, 148 F.4th at 1029–31. Further, Employees' attempt to distinguish *Jacobson* on this ground fails under *Carvalho*, which rejected attempts to distinguish *Jacobson* on similar grounds. *Id.* at 1033. Employees' proposed amendment regarding procedural due process "fail[s] to cure the pleading deficiencies." *Cervantes*, 656 F.3d at 1041.

Because amendment would be futile, the district court did not abuse its discretion in denying leave to amend the complaint.

IV. Dismissal of State Law Claims

Employees brought four claims under Washington state law: "breach of contract," "employment tort," "outrage," and "invasion of privacy." We review de novo the district court's dismissal of the state-law claims as to the Governor. *Laws. for Fair Reciprocal Admission v. United States*, 141 F.4th 1056, 1063 (9th Cir. 2025). We review for abuse of discretion the district court's decision not to exercise supplemental jurisdiction over the state-law claims as to PeaceHealth and thus to dismiss them without prejudice. *Bryant v. Adventist Health Sys./W.*, 289 F.3d 1162, 1165 (9th Cir. 2002).

The breach-of-contract claim was properly dismissed because the Governor was not a signatory to the Provider Agreement, the contract at issue, and therefore had no duty that could have been breached. The employment-tort claim was dismissed because Employees did not allege that the Governor was acting as their employer. The invasion-of-privacy claim was dismissed because Employees' allegations did not relate to any actions taken by the Governor. Employees do not specifically dispute any of these determinations on appeal.

As to the outrage claim against the Governor, the district court concluded that "[t]he properly credited allegations in the Amended Complaint are insufficient from which to conclude that the Proclamation was 'beyond all possible bounds of

decency' considering the circumstances at the time," and therefore could not meet an element of outrage under Washington state law. On de novo review, even assuming that the drugs were "investigational," we are unpersuaded that Employees have alleged facts sufficient to "state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678. As the Supreme Court noted with respect to a similar federal vaccine mandate, "[v]accination requirements are a common feature of the provision of healthcare in America: Healthcare workers around the country are ordinarily required to be vaccinated for diseases such as hepatitis B, influenza, and measles, mumps, and rubella." *Biden*, 595 U.S. at 95. At the time of the Proclamation, the drug in question was already authorized for emergency use to prevent COVID-19. The record shows that the CDC had concluded months earlier that the drug had a 92% efficacy and that taking the EUA-authorized drug was associated with "reduced risk for … severe outcomes" of infection with COVID-19. Within three days of the Proclamation's issuance, a vaccine with an identical medical formulation was fully approved by the FDA. Given the backdrop of common vaccination requirements for healthcare workers, the Proclamation does not remotely constitute conduct "utterly intolerable in a civilized community." *Kloepfel v. Bokor*, 66 P.3d 630, 632 (Wash. 2003) (emphasis omitted). We affirm the district court's dismissal of the outrage claim as to the Governor.

As for the state-law claims against PeaceHealth, we uphold the district court's discretion to decline to exercise supplemental jurisdiction. The district court concluded that it had "dismissed all claims over which it ha[d] original jurisdiction," and that the

remaining state-law claims "raise[] novel or complex issues of state law," two of the important factors that trigger a court's discretion to decline supplemental jurisdiction. *Acri v. Varian Assocs., Inc.*, 114 F.3d 999, 1000 n.2 (9th Cir. 1997) (en banc) (citing 28 U.S.C. § 1367(c)). In exercising that discretion, the court appropriately noted that the decision served the value of comity and possibly also the values of economy, convenience, and fairness. The district court did not pass judgment on whether the Employees had failed to state a claim under state law or failed to assert rights protected under state law. The court left those issues to the state courts and was within its discretion in doing so.

AFFIRMED.

APPENDIX D

CONSTITUTIONAL AND STATUTORY PROVISIONS

U.S. Constitution

Fourteenth Amendment, § 1

… No state shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any state deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

U.S. Constitution, Art. VI, Cl. 2

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Statutes

42 U.S.C. § 1983

Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress, except that in any action brought against a judicial officer for an act or omission taken in such officer's judicial capacity, injunctive relief shall not be granted unless a declaratory decree was violated or declaratory relief was unavailable.

21 U.S.C. § 355

(a) [n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug. …

(i)(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings 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 and will obtain the consent of such human beings or their representtatives …

21 U.S.C. § 360bbb

(a) The Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

(b) Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may, after complying with the provisions of this subsection, provide to such physician an investigational drug or investigational device for the diagnosis, monitoring, or treatment of a serious disease or condition if—

> (1) the licensed physician determines that the person has no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved, and that the probable risk to the person from the investigational drug or investigational device is not greater than the probable risk from the disease or condition;
>
> (2) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug or investigational device in the case described in

paragraph (1); …

(4) the sponsor, or clinical investigator, of the investigational drug or investigational device submits to the Secretary a clinical protocol consistent with the provisions of section 355(i) or 360j(g) of this title, including any regulations promulgated under section 355(i) or 360j(g) of this title, describing the use of the investigational drug or investigational device in a single patient or a small group of patients.

21 U.S.C. § 360bbb-3

(e) Conditions of authorization

(1) Unapproved product

(A) Required conditions

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

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

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

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

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

(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—

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

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

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

(iii) Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product ….

(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, and no person is required to inform the Secretary that the person will not be carrying out such activity …

42 U.S.C. § 247d-6d(a)(1)

Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

42 U.S.C. § 247d-6d(b)(8)

During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—

(A) is different from, or is in conflict with, any requirement applicable under this section; and

(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 *et seq*.].

42 U.S.C. § 247d-6e(c)

(c) The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure is consistent with any declaration under 247d–6d of this title and any applicable guidelines of the Centers for Disease Control and Prevention and that potential participants are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part.

42 U.S.C. § 289

The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this chapter for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.