

# APPENDIX

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**APPENDIX A**

**FILED**  
DEC 19 2025  
MOLLY C. DWYER, CLERK  
U.S. COURT OF APPEALS

**UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT**

MELANIE CRITES-BACHERT, Plaintiff-Appellant,  v. PROVIDENCE HEALTH & SERVICES – OREGON, Defendant-Appellee.
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No. 24-6664  
D.C. Case No.  
3:23-CV-01510-YY

**ORDER**

Before: M. SMITH, NGUYEN, and H.A. THOMAS,  
Circuit Judges.

The panel unanimously votes to deny the petition for panel rehearing and petition for rehearing en banc. The full court has been advised of the petition for rehearing en banc, and no judge of the court has requested a vote on it. Fed. R. App. P. 40.

The petition for panel rehearing and the petition for rehearing en banc are **DENIED**.

**APPENDIX B**

**FILED**  
NOV 10 2025  
MOLLY C. DWYER, CLERK  
U.S. COURT OF APPEALS

**NOT FOR PUBLICATION**

**UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT**

MELANIE CRITES-BACHERT, Plaintiff-Appellant,  v. PROVIDENCE HEALTH & SERVICES – OREGON, Defendant-Appellee.
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No. 24-6664

D.C. No.  
3:23-CV-01510-YY

MEMORANDUM\*

Appeal from the United States District Court  
for the District of Oregon  
Michael H. Simon, District Judge, Presiding  
Submitted November 6, 2025\*\*

Before: M. SMITH, NGUYEN, and H.A. THOMAS,  
Circuit Judges.

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

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

Plaintiff Melanie Crites-Bachert appeals from the district court’s dismissal of her complaint alleging that Defendant Providence Health & Services – Oregon (“Providence”) violated her rights by implementing state and federal regulations requiring healthcare personnel to receive COVID-19 vaccinations.<sup>1</sup> With jurisdiction under 28 U.S.C. § 1291, we review the district court’s dismissal for failure to state a claim de novo, *Hunley v. Instagram, LLC*, 73 F.4th 1060, 1068 (9th Cir. 2023), and now affirm.

The parties are familiar with the facts, so we do not recount them here except as necessary for context.

Crites-Bachert contends the district court erred in dismissing each of her eleven claims. We disagree. Her first through fourth, sixth, seventh, and eleventh causes of action are all constitutional claims brought under 42 U.S.C. § 1983. These claims fail as a matter of law because Providence is a private company, not a government actor. A private entity can only be held liable under § 1983 for conduct “fairly attributable to the State.” *Rendell-Baker v. Kohn*, 457 U.S. 830, 838 (1982) (quoting *Lunar v. Edmondson Oil Co.*, 457 U.S. 922, 937 (1982)) Here, Providence’s conduct is not. The company’s “compliance with generally applicable laws,” such as state and federal vaccine mandates, is not “sufficient to convert private

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<sup>1</sup> See Or. Admin. R. 333-019-0010 (June 29, 2021), Medicare and Medicaid Programs, Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61555 (Nov. 5, 2021). Oregon’s rule has since been repealed, Or. Admin. R. 333-019-0010 (Oct. 26, 2023), and the Centers for Medicare and Medicaid Services’ regulation has been withdrawn, Medicare and Medicaid Programs, Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements, 88 Fed. Reg. 36485 (June 5, 2023).

conduct into state action,” even where noncompliance poses a risk of “penalties.” *Heineke v. Santa Clara Univ.*, 965 F.3d 1009, 1013-14 (9th Cir. 2020).

Relying on *Adickes v. S.H. Kress & Co.*, 398 U.S. 144 (1970), Crites-Bachert responds that Providence “knew six ways from Sunday” that the vaccine policies were “invalid.” In *Adickes*, the Supreme Court found triable disputes on plaintiff’s constitutional claim against a private restaurant because she offered evidence that the state compelled the restaurant to “refuse[] her service” in furtherance of a “state-enforced custom of segregating the races.” *Id.* at 170-71. But unlike in *Adickes*, where it was “virtually inconceivable” that the restaurant “could have acted [with] the innocent belief” that the state’s segregation policies “were presumptively valid,” *Sutton v. Providence St. Joseph Med. Ctr.*, 192 F.3d 826, 841 (9th Cir. 1999) (quoting *Lunar*, 457 U.S. at 954-55 (Powell, J., dissenting)), Crites-Bachert pleads no facts showing that Providence must have harbored such doubts about the vaccine policies as to compel Providence to ignore them. Instead, she discusses various off-point materials involving “nonconsensual medical experimentation” and the right to “refuse experimental medical products.” These allegations do not support an inference that Providence knew that state and federal vaccine mandates, which conditioned privileges like employment on the receipt of a COVID-19 vaccine, were in fact “invalid” such that Providence was obliged to disregard them.<sup>2</sup>

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<sup>2</sup> That is particularly so in view of this country’s long history of enforcing narrow vaccine mandates during a pandemic. *See, e.g., Jacobson v. Massachusetts*, 197 U.S. 11, 12-14, 27, 39 (1905) (upholding municipal vaccine mandate during smallpox “epidemic,” which imposed financial penalties on violators and

Equally meritless is Crites-Bachert’s fifth claim for an alleged violation of her alleged right to “informed consent” under the Food, Drug and Cosmetic Act (“FDCA”). This claim assumes the FDCA’s Emergency Use Authorization (“EUA”) provision, 21 U.S.C. § 360bbb-3, created an “implied private right of action.” But as the district court correctly held, it did not. The FDCA’s plain text disclaims private remedies and instead directs that “enforcement ... of this chapter,” which includes the EUA, “shall be by and in the name of the United States.” 21 U.S.C. § 337(a). This statute offers “clear evidence that Congress intended” for the FDCA to “be enforced exclusively by the Federal Government.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 352 (2001).

Crites-Bachert counters that the EUA postdates *Buckman* and provides no means for enforcing its “informed consent” term. But neither contention changes the calculus. If Congress wished to empower private citizens to enforce the EUA, when nestling that provision into a broad statute that explicitly disavowed private remedies, it was incumbent upon Congress to announce its departure. Yet Crites-Bachert offers no evidence that it did.

The district court also correctly dismissed her eighth claim for breach of contract, as Crites-Bachert’s complaint fails to identify any term that

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was deemed “necessary for [] public health or safety”), *Biden v. Missouri*, 595 U.S. 87, 89-92 (2022) (upholding federal regulation requiring covered healthcare facilities to vaccinate employees against COVID-19), *Health Freedom Def Fund, Inc. v. Carvalho*, 148 F.4th 1020, 1023, 1029, 1031 (9th Cir. 2025) (en banc) (applying *Jacobson* to uphold school district’s policy, “which essentially required all of its employees to be fully vaccinated” against COVID-19, and explaining that such policies will be upheld so long as they have a “rational basis”).

Providence supposedly breached. Rather, the complaint hyperlinks Providence’s website, which contains multiple hyperlinks of its own to various lengthy sets of “Bylaws” and “Policies and Procedures,” and then asserts in sweeping terms that Providence “breached” an unspecified “contract with Crites-Bachert by terminating her privileges at Providence.” We decline to “scour the record in search” of whatever contract term, if any, Crites-Bachert had in mind. *Keenan v. Allan*, 91 F.3d 1275, 1279 (9th Cir. 1996) (quoting *Richards v. Combined Ins. Co. of Am.*, 55 F.3d 247, 251 (7th Cir. 1995)).

Nor does her theory that Providence “unilaterally modif[ied]” the parties’ contract, without more, support a viable claim. As Providence points out, “unilateral changes are permissible” under Oregon law “when the contract allows [such] changes.” *Associated Oregon Veterans v. Dep’t of Veterans’ Affs.*, 712 P.2d 103, 107 (Or. 1985). And in this case, one set of “Bylaws” that Crites-Bachert apparently concedes applies required professional staff to comply with all “qualifications, standards, requirements and responsibilities set forth in ... policies and rules governing the Hospital.”<sup>3</sup> Crites-Bachert fails to explain how the vaccine mandates at issue are not qualifying “policies” or “rules.”

Her ninth claim for breach of contract as a third-party beneficiary also falls short. Crites-Bachert did not demonstrate that Providence’s “COVID-19 Vaccination Program Provider Agreement” with the Centers for Disease Control and Prevention

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<sup>3</sup> We may consider these terms under the incorporation-by-reference doctrine, as they “form[] the basis of [Crites-Bachert’s] claim.” *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1002 (9th Cir. 2018) (quoting *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003)).

conferred upon her an enforceable right as a third-party beneficiary. Even taking at face value her contention that she stood to benefit from this agreement, “[p]arties that benefit from a government contract are generally assumed to be incidental beneficiaries” who cannot “enforce the contract absent a clear intent to the contrary.” *Klamath Water Users Protective Ass’n v. Patterson*, 204 F.3d 1206, 1211 (9th Cir. 1999). Crites-Bachert alleges no facts supporting such “clear intent.”

Her tenth claim for tortious interference fares no better. Her complaint alleges no facts suggesting that Providence’s compliance with presumptively valid state and federal vaccine policies was “improper” for purposes of Oregon’s tortious-interference doctrine. *See McGanty v. Staudenraus*, 901 P.2d 841, 844 (Or. 1995) (stating elements of tortious interference). Nor does her appellate briefing offer any legal support for this theory.

**AFFIRMED.**

**APPENDIX C**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF OREGON**

MELANIE CRITES-BACHERT,  
Plaintiff,

v.

PROVIDENCE HEALTH &  
SERVICES – OREGON,  
Defendant.

Case No.  
3:23-cv-1510-YY

**ORDER**

**Michael H. Simon, District Judge.**

United States Magistrate Judge Youlee Yim You issued Findings and Recommendation in this case on September 9, 2024. Judge You recommended that this Court grant Defendant’s motion to dismiss and dismiss this case with prejudice. No party has filed objections.

Under the Federal Magistrates Act (Act), the court may “accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate.” 28 U.S.C. § 636(b)(1). If a party objects to a magistrate judge’s findings and recommendations, “the court shall make a de novo determination of those portions of the report or specified proposed findings or recommendations to which objection is made.” *Id.*; Fed. R. Civ. P. 72(b)(3).

If no party objects, the Act does not prescribe any standard of review. *See Thomas v. Arn*, 474 U.S. 140,

152 (1985) (“There is no indication that Congress, in enacting [the Act], intended to require a district judge to review a magistrate’s report to which no objections are filed.”); *United States. v. Reyna-Tapia*, 328 F.3d 1114, 1121 (9th Cir. 2003) (en banc) (holding that the court must review *de novo* magistrate judge’s findings and recommendations if objection is made, “but not otherwise”).

Although review is not required in the absence of objections, the Act “does not preclude further review by the district judge[] *sua sponte* ... under a *de novo* or any other standard.” *Thomas*, 474 U.S. at 154. Indeed, the Advisory Committee Notes to Rule 72(b) of the Federal Rules of Civil Procedure recommend that “[w]hen no timely objection is filed,” the court review the magistrate judge’s findings and recommendations for “clear error on the face of the record.”

No party having made objections, this Court follows the recommendation of the Advisory Committee and reviews Judge You’s Findings and Recommendation for clear error on the face of the record. No such error is apparent.

The Court ADOPTS Judge You’s Findings and Recommendation, ECF 19. The Court GRANTS Defendant’s Motion to Dismiss Amended Complaint, ECF 15. The Court dismisses this case with prejudice.

**IT IS SO ORDERED.**

DATED this 27th day of September, 2024.

/s/ Michael H. Simon

Michael H. Simon

United States District Judge

**APPENDIX D**

**UNITED STATES DISTRICT COURT  
DISTRICT OF OREGON  
PORTLAND DIVISION**

MELANIE CRITES-  
BACHERT,

Plaintiff,

v.

PROVIDENCE HEALTH &  
SERVICES – OREGON,

Defendant.

Case No.

3:23-cv-1510-YY

**FINDINGS AND  
RECOMMENDATIONS**

YOU, Magistrate Judge.

**FINDINGS**

Plaintiff Melanie Crites-Bachert brings this action against defendant Providence Health & Services, where plaintiff previously worked as a Professional Staff Member,<sup>1</sup> and from whom plaintiff received operating privileges at several hospitals in Oregon. Plaintiff asserts eleven claims for relief, including violations of the First Amendment, Eighth Amendment, Fourteenth Amendment, and Food, Drug, and Cosmetic Act (“FDCA”), and common law

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<sup>1</sup> The parties do not dispute that plaintiff was not defendant’s employee.

claims for breach of contract and tortious interference.

Plaintiff alleges that defendant discriminated against her on the basis of her religion when it denied her request for a religious exception from defendant's COVID-19 vaccination mandate and later revoked her hospital privileges after she refused to vaccinate against COVID-19.

Defendant has filed a motion to dismiss all of plaintiff's claims for failure to state a plausible claim for relief under Federal Rule of Civil Procedure 12(b)(6). ECF 15. Defendant's motion should be GRANTED for the reasons discussed below

## **I. Motion to Dismiss Standard**

To survive a motion to dismiss under Rule 12(b)(6), the complaint must contain facts that “state a claim to relief that is plausible on its face,” such that the court can reasonably infer the defendant is liable for the misconduct alleged. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The court must assume the veracity of the plaintiff's factual allegations and draw all reasonable inferences in favor of the nonmoving party. *Id.*; *Retail Prop. Tr. v. United Bhd. of Carpenters & Joiners of Am.*, 768 F.3d 938, 945 (9th Cir. 2014). However, mere legal conclusions couched as factual allegations are not entitled to an assumption of truth. *Iqbal*, 556 U.S. at 678–79. Dismissal of a complaint for failure to state a claim is appropriate if it “appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.” *Zimmerman v. City of Oakland*, 255 F.3d 734, 737 (9th Cir. 2001).

## II. 42 U.S.C. § 1983 Claims

Plaintiff’s first, second, third, fourth, sixth, seventh, and eleventh claims arise under 42 U.S.C. § 1983. Am. Compl. ¶¶ 240–57, 261–67, 278–81, ECF 11. Under § 1983, a private party can be held liable for the deprivation of a federal right where its conduct “is fairly attributable to the State.” *Lugar v. Edmondson Oil Co.*, 457 U.S. 922, 937 (1982). Conduct is “fairly attributable” where “the private party engaged in state action under color of law” and “thereby deprived a plaintiff of some right, privilege, or immunity protected by the Constitution or the laws of the United States.” *Brunette v. Humane Soc’y of Ventura Cnty.*, 294 F.3d 1205, 1209 (9th Cir. 2002), *as amended on denial of reh’g and reh’g en banc* (Aug. 23, 2002). “The Supreme Court has articulated four tests for determining whether a private [party’s] actions amount to state action: (1) the public function test; (2) the joint action test; (3) the state compulsion test; and (4) the governmental nexus test.” *Tsao v. Desert Palace, Inc.*, 698 F.3d 1128, 1140 (9th Cir. 2012).<sup>2</sup> “As a matter of substantive constitutional law the state-action requirement reflects judicial recognition of the fact that most rights secured by the Constitution are protected only against infringement by governments.” *Lugar*, 457 U.S. at 936 (internal quotation marks omitted). The “presumption [is] that conduct by private actors is not state action.” *Florer v. Congregation Pidyon Shevuyim, N.A.*, 639 F.3d 916, 922 (9th Cir. 2011). The plaintiff bears the burden of establishing that the defendant was a state actor. *Id.*

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<sup>2</sup> Plaintiff does not advance a theory of liability under the public function test.

Plaintiff argues that defendant is properly characterized as a state actor under the compulsion test. Opp. 6, ECF 16. Under the compulsion test, state action may be found “where the state has ‘exercised coercive power or has provided such significant encouragement, either overt or covert, that the [private actor’s] choice must in law be deemed to be that of the State.’” *Johnson v. Knowles*, 113 F.3d 1114, 1119 (9th Cir. 1997) (quoting *Blum v. Yaretsky*, 457 U.S. 991, 1004 (1982)). However, where the defendant is a private actor, “governmental compulsion in the form of a generally applicable law, without more,” is insufficient. *Sutton v. Providence St. Joseph Med. Ctr.*, 192 F.3d 826, 841 (9th Cir. 1999). The plaintiff must allege another nexus such that the private entity may be fairly held liable for the state action. *Id.* Courts have, for example, found a sufficient nexus in cases where the state has participated in the actions of a private entity “through conspiratorial agreement, official cooperation with the private entity to achieve the private entity’s goal, or enforcement and ratification of the private entity’s chosen action.” *Id.* (internal citations omitted).

Plaintiff alleges that defendant “was subject to massive government compulsion” due to Oregon’s administrative order mandating that medical workers receive COVID-19 vaccinations, subject to a \$500 per day penalty per violation, and the Centers for Medicare & Medicaid Services (“CMS”) rule requiring employees of healthcare facilities to receive COVID-19 vaccinations, subject to a reduction of reimbursement. Opp. 6, ECF 16. Plaintiff argues that she has alleged a nexus between defendant and the government in that defendant “knew that the vaccine

mandates by Oregon and CMS were invalid.” *Id.* at 8–9.

Plaintiff relies on the Supreme Court’s opinion in *Adickes v. S.H. Kress & Co.*, 398 U.S. 144 (1970), and *Sutton v. Providence St. Joseph Med. Ctr.*, a Ninth Circuit opinion analyzing the *Adickes* decision. In *Adickes*, a private restaurant refused to serve a White teacher who sought to dine with six Black students. 398 U.S. at 149. The teacher and students left the restaurant and, upon exiting the store, the teacher was arrested for vagrancy. *Id.* The Supreme Court held that the restaurant had jointly participated “with a state official in a conspiracy to discriminate,” had taken state action in violation of the Fourteenth Amendment, and was liable under § 1983. *Lugar*, 457 U.S. at 931 (citing *Adickes*, 398 U.S. at 150). Notably, the conduct at issue occurred ten years after *Brown v. Board of Education*, 347 U.S. 483 (1954), and “a decade of publicized litigation that followed in its wake,” and in the context of “intense national focus on issues of racial discrimination.” *Sutton*, 192 F.3d at 841 (quoting *Lugar*, 457 U.S. at 955–56 (Powell, J., dissenting)). Under those circumstances, it was “virtually inconceivable” that the restaurant could have acted with the innocent belief that the laws involved were presumptively valid. *Id.* “In such a context, the private party could be characterized as hiding behind the authority of law and as engaging in ‘joint participation’ with the State in the deprivation of constitutional rights.” *Id.*

*Adickes* is patently distinguishable from the instant case. In *Adickes*, “substantial evidence” existed to demonstrate the restaurant’s knowing violation of discrimination laws. *Sutton*, 192 F.3d at 841; see also *id.* (“[W]e do not read *Adickes* as a case

in which a private defendant was held responsible merely for complying with a presumptively valid state law.”).

Unlike the conduct at issue in *Adickes*, here the allegedly infringing conduct was novel and largely untested in the courts—no body of law existed as to the constitutionality of COVID-19 vaccination requirements. These significant factual differences render *Adickes* inapplicable. Thus, neither *Adickes* nor *Sutton* provides a basis upon which to hold that defendant’s actions in this case were conducted jointly with the government.

The actions alleged in the amended complaint otherwise do not rise to the level of state participation that would fairly render defendant liable for state action. Plaintiff essentially alleges that a private entity’s mere implementation of a government mandate exposes the entity to liability as a state actor. That argument leads to the unworkable result that entities are exposed to liability for acting in compliance with legal requirements. Thus, defendant’s implementation of state and federal vaccine mandates does not satisfy the compulsion test. *See also Kiss v. Best Buy Stores*, No. 3:22-CV-00281-SB, 2022 WL 17480936, at \*5 (D. Or. Dec. 6, 2022), *aff’d sub nom. Kiss v. Best Buy Stores, Ltd. P’ship*, No. 23-35004, 2023 WL 8621972 (9th Cir. Dec. 13, 2023) (holding that an Oregon statute imposing a \$500 fine on businesses that failed to require masks did not satisfy the compulsion test); *Edtl v. Best Buy Stores, L.P.*, No. 3:22-CV-00003-6-AR, 2022 WL 11436434, at \*6 n.6 (D. Or. Oct. 13, 2022), *appeal dismissed*, No. 22-35929, 2023 WL 3475436 (9th Cir. Feb. 27, 2023) (same).

Plaintiff’s reliance on *Carlin Communications*,

*Inc. v. Mountain States*, 827 F.2d 1291, 1295 (9th Cir. 1987), is also misplaced. Opp. 6, ECF 16. Plaintiff cites that case for the proposition that a private party may be considered a state actor when threatened “with adverse action if the private party did not comply with a demand to perform a specific act.” *Id.* In *Carlin Communications*, the court determined that a deputy county attorney’s instruction to a telephone company to terminate service to an entity, under the threat of criminal prosecution, “converted its otherwise private conduct into state action for purposes of § 1983.” *Id.* at 1295. Here, plaintiff has not alleged that defendant acted pursuant to direct instruction by a governmental authority under the threat of criminal prosecution. Thus, *Carlin Communications* is inapposite.

To the extent that plaintiff is asserting that defendant may be held liable as a state actor under the governmental nexus or joint action tests, plaintiff has not articulated how her allegations satisfy the elements of those tests, or presented the standards for those tests, or cited to relevant legal authority interpreting those tests. Mere conclusory statements that defendant is a state actor are insufficient to allege a claim for relief.

Because plaintiff has not plausibly alleged that defendant is a state actor, defendant cannot be held liable under § 1983. The court need not proceed to the second step of the analysis, i.e., whether plaintiff has pled that defendant violated a federal right. *Brunette*, 294 F.3d at 1209. All of plaintiff’s claims arising under § 1983 fail as a matter of law.

### III. Section 564

Plaintiff's fifth claim is premised upon § 564 of the FDCA, codified at 21 U.S.C. § 360bbb-3, which pertains to Emergency Use Authorizations. Am. Compl. ¶¶ 258–60, ECF 11. Plaintiff asserts that the FDCA implies a private cause of action. Opp. 28–29, ECF 16.

It is well-established that the FDCA does not provide a private cause of action. In express terms, the FDCA states that all proceedings for its enforcement “shall be by and in the name of the United States.” 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 (2001) (“The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions ... .”); *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1049 (9th Cir. 2022) (“Because the FDCA forbids private rights of action under [§ 337], a private action brought under [other laws] may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation.”). Because the FDCA unequivocally disclaims a private right of action under the statute, plaintiff's claim under § 564 fails..

### IV. Breach of Contract

Plaintiff's eighth claim is for breach of contract. Am. Compl. ¶¶ 268–71, ECF 11. Plaintiff alleges that defendant breached its contract with plaintiff by unilaterally modifying the contract to require

plaintiff to “take an experimental drug” and subsequently terminating her hospital privileges. *Id.* ¶¶ 270–71. Plaintiff identifies two documents as providing the relevant contract language: defendant’s “Professional Staff Bylaws” and “Professional Staff Policies and Procedures.” *Id.* ¶ 269 (citing Providence, “Medical Staff Services – Oregon,” <https://www.providence.org/locations/or/medical-staff-services>).

“To state a claim for breach of contract under Oregon law, a plaintiff must allege the existence of a contract, its relevant terms, plaintiff’s full performance and lack of breach and defendant’s breach resulting in damage to plaintiff.” *Arnett v. Bank of Am., N.A.*, 874 F. Supp. 2d 1021, 1029 (D. Or. 2012) (quoting *Slover v. Oregon State Bd. of Clinical Soc. Workers*, 144 Or. App. 565, 570 (1996)).

Plaintiff cursorily argues that she has “alleged all the relevant contract terms” to support her breach of contract claim. Opp. 33, ECF 16. However, conspicuously absent from plaintiff’s amended complaint and briefing in response to the motion to dismiss is any allegation as to the substance of the terms that defendant purportedly violated. As defendant points out, the documents that plaintiff cites are extensive, and plaintiff does not indicate which portion of the policy defendant allegedly breached. Mot. Dismiss 31, ECF 15. Plaintiff has not identified a basis for her assertion that the contract prohibited defendant from requiring professional staff to be vaccinated or from terminating staff members who did not comply with the requirement. Thus, plaintiff has not adequately pleaded a breach of contract claim. *See Austin v. Univ. of Oregon*, 205 F. Supp. 3d 1214, 1232 (D. Or. 2016), *aff’d*, 925 F.3d 1133 (9th Cir. 2019) (dismissing contract claim where the plaintiffs “failed to identify an actual breach,”

“pointed to no promise regarding renewal,” and “asserted no contractual basis for their alleged expectation of renewal, save for the mere inclusion of a renewability provision in the terms of the contract”); *Com. & Indus. Ins. Co. v. HR Staffing, Inc.*, No. 3:14-CV-00559-HZ, 2014 WL 4983671, at \*2 (D. Or. Oct. 1, 2014) (dismissing breach of contract claim where the plaintiff “failed to identify the relevant contractual provisions” that the defendant allegedly breached); *Khamnaye v. Schnitzer Steel Indus., Inc.*, No. 3:22-CV-00391-AR, 2024 WL 3275549, at \*4 (D. Or. May 8, 2024) (“Schnitzer’s counterclaim does not identify the relevant contract provision or how Khamnaye is supposed to have breached it. Accordingly, Schnitzer’s counterclaim for breach of contract should be dismissed for failure to state a claim.”).

## **V. Breach of Contract — Third-Party Beneficiary**

Plaintiff’s ninth claim is for breach of contract as a third-party beneficiary. Am. Compl. ¶¶ 272–74, ECF 11. Plaintiff alleges that the “[Center for Disease Control’s] COVID Vaccination Program Provider Agreement, and the implementing statutes and regulations found at 45 CFR 46, 21 U.S.C. §360bbb-3, Title 21 of the US Code, the EUA Scope of Authorization letter,” and a Federal Wide Assurance (“FWA”) agreement create a third-party right to informed consent. *Id.* ¶¶ 91–109, 273. Plaintiff asserts that defendant violated her right to informed consent when it required her to “take an experimental drug.” Opp. 33, ECF 16.

“Parties that benefit from a government contract are generally assumed to be incidental beneficiaries,

and may not enforce the contract absent a clear intent to the contrary.” *Klamath Water Users Protective Ass’n v. Patterson*, 204 F.3d 1206, 1211 (9th Cir. 1999), *opinion amended on denial of reh’g*, 203 F.3d 1175 (9th Cir. 2000). The mere fact that a member of the public derives benefit from a government contract does not give that individual enforceable rights under the contract—“Government contracts often benefit the public, but individual members of the public are treated as incidental beneficiaries unless a different intention is manifested.” *Id.* Here, plaintiff has not plausibly alleged that the parties to the aforementioned contracts evinced an intent to confer an enforceable right to members of the public.

Additionally, the Vaccination Program Provider Agreement is, plainly, not applicable here. The Agreement imposes requirements for the administration of COVID vaccines. Am. Compl., Ex. 1 at 2–3, ECF 11-1. Plaintiff acknowledges that she has not received the COVID-19 vaccine. Am. Compl. ¶ 9, ECF 11. Thus, defendant did not administer the vaccine to plaintiff, and the Agreement does not confer any rights to plaintiff. Because plaintiff has not alleged that she is entitled to enforce any of the agreements that she lists in her amended complaint, her third-party beneficiary claim fails.

## **VI. Tortious Interference**

Lastly, plaintiff’s tenth claim is for intentional interference with a business relationship. Am. Compl. ¶¶ 275–77, ECF 11. Plaintiff argues that by imposing a vaccine requirement, refusing to provide her with a religious exemption, and subsequently revoking her hospital privileges, defendant interfered

with plaintiff's ability to perform surgeries for current and prospective patients. *Id.*; Opp. 34–35, ECF 16.

“To state a claim for intentional interference with economic relations, a plaintiff must allege each of the following elements: (1) the existence of a professional or business relationship (which could include, e.g., a contract or a prospective economic advantage), (2) intentional interference with that relationship, (3) by a third party, (4) accomplished through improper means or for an improper purpose, (5) a causal effect between the interference and damage to the economic relationship, and (6) damages.” *McGanty v. Staudenraus*, 321 Or. 532, 535 (1995). If liability is based on “improper means,” the plaintiff must show that the defendant violated an “objective, identifiable standard, such as a statute or other regulation, or a recognized rule of common law, or perhaps, an established standard of a trade or profession.” *Nw. Nat. Gas Co. v. Chase Gardens, Inc.*, 328 Or. 487, 498 (1999). If liability is based on “improper purpose,” the plaintiff must show that the defendant acted with the intent to “inflict injury on the plaintiff.” *Id.*

Plaintiff maintains that defendant's “vaccine mandate and its refusal to provide a religious exemption each constitute improper means as explained throughout the Amended Complaint.” Opp. 35, ECF 16. Plaintiff appears to be arguing that defendant's improper means are the constitutional and statutory violations asserted in plaintiff's amended complaint. As noted above, because plaintiff has not shown that defendant violated any statute in enacting its vaccine mandate and denying plaintiff's exemption request, the violations alleged in the complaint cannot furnish the improper means

for an intentional interference claim. *Noel v. Hall*, No. CIV. 99-649-AC, 2012 WL 3241858, at \*15 (D. Or. Apr. 27, 2012), *report and recommendation adopted*, No. 3:99-CV-649-AC, 2012 WL 3241814 (D. Or. Aug. 7, 2012), *aff'd*, 525 F. App'x 633 (9th Cir. 2013) (dismissing intentional interference claim premised upon the improper means of violations of wiretap laws where “wiretap claims fail[ed] as a matter of law”); *McIntire v. Sage Software, Inc.*, No. 3:15-CV-00769-JE, 2015 WL 9274301, at \*3 (D. Or. Sept. 28, 2015), *report and recommendation adopted*, No. 3:15-CV-00769-JE, 2015 WL 9272884 (D. Or. Dec. 17, 2015) (dismissing intentional interference claim premised upon labor law violations where the plaintiff failed to show that the defendant could be held liable under those statutes); *Witt Co. v. RISO, Inc.*, 948 F. Supp. 2d 1227, 1245 (D. Or. 2013) (dismissing intentional interference claim based on the improper means of antitrust violations where the antitrust claim was dismissed). Thus, plaintiff's intentional interference claim also fails.

## V. Leave to Amend

Federal Rule of Civil Procedure 15(a)(2) provides that “[t]he court should freely give leave when justice so requires.” “In general, a court should liberally allow a party to amend its pleading.” *Sonoma Cty. Ass'n of Retired Employees v. Sonoma Cty.*, 708 F.3d 1109, 1117 (9th Cir. 2013) (citing FED. R. CIV. P. 15(a)). However, leave to amend “is not to be granted automatically.” *Jackson v. Bank of Hawaii*, 902 F.2d 1385, 1387 (9th Cir. 1990). The court “may exercise its discretion to deny leave to amend due to ‘undue delay, bad faith or dilatory motive on part of the movant, repeated failure to cure deficiencies by

amendments previously allowed, undue prejudice to the opposing party, and futility of amendment.” *Carvalho v. Equifax Info. Servs., LLC*, 629 F.3d 876, 892–93 (9th Cir. 2010) (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)) (alterations omitted).

In her response to the motion to dismiss, plaintiff does not seek leave to amend or explain how she would amend her complaint to allege a viable claim for relief. Moreover, this is defendant’s second motion to dismiss, and plaintiff has already amended her complaint once. Therefore, dismissal with prejudice is appropriate.

### **RECOMMENDATIONS**

Defendant’s motion to dismiss, ECF 15, should be granted and this case should be dismissed with prejudice.

### **SCHEDULING ORDER**

These Findings and Recommendations will be referred to a district judge. Objections, if any, are due Monday, September 23, 2024. If no objections are filed, then the Findings and Recommendations will go under advisement on that date.

If objections are filed, then a response is due within 14 days after being served with a copy of the objections. When the response is due or filed, whichever date is earlier, the Findings and Recommendations will go under advisement.

### **NOTICE**

These Findings and Recommendations are not an order that is immediately appealable to the Ninth

Circuit Court of Appeals. Any Notice of Appeal pursuant to Rule 4(a)(1), Federal Rules of Appellate Procedure, should not be filed until entry of a judgment.

DATED September 9, 2024.

/s/ Youlee Yim You

Youlee Yim You

United States Magistrate Judge

## APPENDIX E

### THE NUREMBERG CODE

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

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

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

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

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

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

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

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

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

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

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

## APPENDIX F

### FEDERAL STATUTORY PROVISIONS AND REGULATIONS

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

##### (a) Waiver by the President.

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

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

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

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

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

### **21 U.S.C. § 331. Prohibited acts**

The following acts and the causing thereof are hereby prohibited:

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

tobacco product, or cosmetic that is adulterated or misbranded.

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

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

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

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

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

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

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

**(i)**

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

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

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

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

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

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

**(l)** [Deleted]

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

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

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

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

**(q)**

**(1)** The failure or refusal—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**(z)** [Terminated]

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

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

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

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

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

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

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

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

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

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

**(jj)**

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

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

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

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

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

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

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

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

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

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

- (B)** a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;
  - (C)** the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier’s determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;
  - (D)** a food contact substance notification that is effective under section 409(h) [21 USCS § 348(h)]; or
  - (E)** such drug or biological product had been marketed for smoking cessation prior to the date of the enactment of the Food and Drug Administration Amendments Act of 2007 [enacted Sept. 27, 2007]; or
- (4)** the drug is a new animal drug whose use is not unsafe under section 512 [21 USCS § 360b].
- (mm)** The failure to submit a report or provide a notification required under section 417(d) [21 USCS § 350f(d)].
- (nn)** The falsification of a report or notification required under section 417(d) [21 USCS § 350f(d)].
- (oo)** The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f) [21 USCS § 333(f)].
- (pp)** The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911 [21 USCS § 387k].

**(qq)**

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

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

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

**(rr)** The charitable distribution of tobacco products.

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

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

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

- (2)** the Food and Drug Administration deems the product to be safe for use by consumers;
- (3)** the product is endorsed by the Food and Drug Administration for use by consumers; or
- (4)** the product is safe or less harmful by virtue of—

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

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

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

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

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

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

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

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

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

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

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

**(ccc)**

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

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

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

**(ddd)**

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

(2) In this paragraph—

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

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

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

**(fff)**

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

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

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

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

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

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

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

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

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

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this Act [21 USCS §§ 301 et seq.] shall be by and in the name of the United States.

Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

**(b)**

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

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

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

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

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

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

**21 U.S.C. § 360bbb-3 (excerpts)**

**(a) In general.**

**(1)** Emergency uses. Notwithstanding any provision of this Act and section 351 of the Public

Health Service Act, and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an “emergency use”).

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

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

...

**(4)** Definitions. For purposes of this section:

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

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

**(C)** The term “product” means a drug, device, or biological product.

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

...

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

**(1)** In general. The Secretary may make a declaration that the circumstances exist

justifying the authorization under this subsection for a product on the basis of— ...

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

...

**(e) Conditions of authorization.**

**(1)** Unapproved product.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- (1)** A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- (2)** A description of any reasonably foreseeable risks or discomforts to the subject.
- (3)** A description of any benefits to the subject or to others which may reasonably be expected from the research.
- (4)** A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- (5)** A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.
- (6)** For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- (7)** An explanation of whom to contact for answers to pertinent questions about the

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

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

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

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

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

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

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

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

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

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

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

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