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United States Court of Appeals
Tenth Circuit

PUBLISH

UNITED STATES COURT OF APPEALS

July 23, 2026

FOR THE TENTH CIRCUIT

Christopher M. Wolpert
Clerk of Court

BRIANNE DRESSEN,

Plaintiff - Appellee,

v.

No. 24-4114

ASTRAZENECA AB, a Sweden
corporation; ASTRAZENECA
PHARMACEUTICALS LP, a Delaware
Limited Partnership,

Defendants - Appellants.

**Appeal from the United States District Court
for the District of Utah
(D.C. No. 2:24-CV-00337-RJS-CMR)**

Robert Reeves Anderson of Arnold & Porter Kaye Scholer LLP, Denver, CO (Arthur E. Brown and Alexander Cousins of Arnold & Porter Kaye Scholer LLP, New York, NY; Mathew M. Cannon and Kamie F. Brown of Ray Quinney & Nebeker P.C., Salt Lake City, UT; and Samuel I. Ferenc of Arnold & Porter Kaye Scholer LLP, Washington, DC, with him on the briefs), for Defendants-Appellants.

Michael Connett of Siri & Glimstad LLP, Los Angeles, CA (Jason R. Hull and Anikka T. Hoidal of Marshall Olson & Hull, PC, Salt Lake City, UT; Catherine Cline of Siri & Glimstad LLP, Aventura, FL; and Aaron Siri of Siri & Glimstad LLP, New York, NY, with him on the brief), for Plaintiff-Appellee.

Before **HARTZ**, **TYMKOVICH**, and **BACHARACH**, Circuit Judges.

HARTZ, Circuit Judge.

To encourage the development and use of new preventive and treatment measures during a health emergency declared by the federal government, the Public Readiness and Emergency Preparedness Act (the PREP Act) provides broad immunity from suit and liability to those providing such measures, such as developers of vaccines. This appeal concerns the scope of that immunity.

At the height of the COVID-19 pandemic in 2020, Brianne Dressen participated in one of AstraZeneca’s¹ vaccine trials. Before doing so, she needed to sign an informed-consent form (the ICF). The form said that the company had an insurance policy to cover the costs of injuries caused by the vaccine, tests, or procedures. It also disclosed, however, that federal law may limit her right to sue for vaccine-related injuries. According to the form, the federal government had issued an order that, if applicable, could limit Dressen’s “right to sue [AstraZeneca] if [she is] injured or harmed while participating in [the] COVID-19 related clinical study.” Aplt. App., Vol. I at 62.

Dressen suffered debilitating medical injuries after receiving the experimental vaccine. When AstraZeneca rejected her request for care and compensation, she filed this breach-of-contract suit. AstraZeneca moved to dismiss, claiming that it had immunity under the PREP Act.

The district court denied the motion. It ruled that “[d]espite the [PREP Act’s] seemingly broad scope,” *Dressen v. AstraZeneca AB*, No. 2:24-cv-00337-RJS-CMR,

¹ For convenience, we refer to Appellants collectively as AstraZeneca.

2024 WL 4666577, at *6 (D. Utah Nov. 4, 2024), it shields AstraZeneca only from claims for tortious conduct, not breach of contract, *see id. at* *9.

Our view is different. Exercising jurisdiction under the collateral-order doctrine interpreting 28 U.S.C. § 1291, we reverse the district court and hold that the statute immunizes *all* claims for loss, including breach-of-contract damages. We must remand, however, for the district court to now consider whether AstraZeneca waived its immunity in the ICF.

I. BACKGROUND

A. The Informed-Consent Form

In November 2020 Dressen received AstraZeneca’s experimental COVID-19 vaccine. Velocity Clinical Research, Inc. (Velocity) administered the trial on the company’s behalf. Before receiving the vaccine, Dressen signed AstraZeneca’s ICF, which described “her rights and responsibilities as a trial participant and disclosed possible side effects of the vaccine.” *Dressen*, 2024 WL 4666577, at *1. It provided (1) that AstraZeneca would reimburse Dressen for “time and travel in the amounts of \$125.00 per each completed study visit and \$30.00 for each completed phone call,” and (2) that a “study doctor” would “provide medical treatment or refer [Dressen] for treatment” if she became “ill or injured” during the study. *Dressen*, 2024 WL 4666577, at *1 (internal quotation marks omitted); *see* Aplt. App., Vol. I at 61.

The ICF further told Dressen that AstraZeneca had an insurance policy to “cover the costs of research injuries as long as [she has] followed [the] study doctor’s instructions.” *Id.* at 62. It said that AstraZeneca “will pay the costs of medical

treatment for research injuries, provided that the costs are reasonable, and [Dressen] did not cause the injury [herself].” *Id.* The term *research injuries* was defined as injuries “caused by the vaccine, tests or procedures” but excluded “[i]njuries caused by [a patient’s] usual medical care.” *Id.*

The ICF also disclosed that federal law may limit Dressen’s right to sue for vaccine-related injuries:

Due to the coronavirus public health crisis, *the federal government has issued an order* [strictly speaking, a declaration] *that may limit your right to sue* if you are injured or harmed while participating in this COVID-19-related clinical study.

If the order applies, it limits your right to sue the researchers, healthcare providers, any Sponsor or manufacturer or distributor involved with the Study. *You may be prevented from making claims for injuries that have a causal relationship with the use of the investigational product* in this Study, including, but not limited to, claims for death; physical, mental, or emotional injury, illness, disability, or condition; fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and loss of or damage to property, including business interruption loss.

However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. If funds are appropriated by Congress, compensation for injuries may be available to you under this Countermeasures Injury Compensation Program.

Id. (emphasis added).

B. Statutory Background

Congress passed the PREP Act in 2005 “[t]o encourage the expeditious development and deployment of medical countermeasures during a public health emergency,” such as the COVID-19 pandemic. Kevin J. Hickey, Cong. Rsch. Serv.,

LSB10443, *The PREP Act and COVID-19, Part 1: Statutory Authority to Limit Liability for Medical Countermeasures*, Congressional Research Service 1 (2022), <https://www.congress.gov/crs-product/LSB10443> [<https://perma.cc/D5XE-5DY3>]. It authorizes the Secretary of the United States Department of Health and Human Services (HHS) to issue a declaration to “limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines.” *Id.*; see 42 U.S.C. § 247d-6d(a)(1).

The statute provides immunity for the provision of *covered countermeasures* by *covered persons*. “Covered countermeasures” include any “drug,” “biological product,” or “device,” *id.* § 247d-6d(i)(1), that is “manufactured,” “used,” or “developed” to “diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic[,] or . . . to limit the harm such pandemic or epidemic might otherwise cause,” *id.* § 247d-6d(i)(7)(A)(i). As relevant here, the term *covered person* includes “a manufacturer of [a covered] countermeasure” and “a distributor of such countermeasure.” *Id.* § 247d-6d(i)(2)(B)(i)–(ii). Vaccines, like the COVID-19 vaccine, are “covered countermeasures” under the statute, and AstraZeneca is a “covered person.”

Under the Act, “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 [by the Secretary of HHS] has been issued with respect to such countermeasure.” *Id.* § 247d-6d(a)(1). The statute defines *loss* as

“any type of loss, including . . . (i) death; (ii) physical, mental, or emotional injury, illness, disability, or condition; (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and (iv) loss of or damage to property, including business interruption loss.” *Id.* § 247d-6d(a)(2)(A). The immunity extends to “any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, *clinical testing or investigation*, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, *dispensing*, prescribing, administration, licensing, or use of such countermeasure.” *Id.* § 247d-6d(a)(2)(B) (emphasis added).

The “sole exception” to this immunity is “an exclusive Federal cause of action” available for “*death or serious physical injury* proximately caused by *willful misconduct*” by a “covered person.” *Id.* § 247d-6d(d)(1) (emphasis added). The Act does, however, offer compensation to some injured recipients of covered countermeasures. It provides that an individual who suffers “serious physical injury or death” from the administration of a covered countermeasure may seek compensation from the Covered Countermeasure Process Fund (CCPF), *see id.* § 247d-6e, which is administered by the Countermeasures Injury Compensation Program (CICP), *see Countermeasures Injury Compensation Program*, Health Res. & Servs. Admin. (May 2026), <https://www.hrsa.gov/cicp> [<https://perma.cc/LA4Q-JAE8>].

In sum, for the PREP Act to apply and immunize vaccine manufacturers like AstraZeneca, (1) the Secretary of HHS must first declare a public health emergency (2) the individual or entity seeking immunity must be a “covered person”; (3) the claim against the covered person must be for a “loss”; (4) the manufacturer must manufacture a product that is a “covered countermeasure”; and (5) the loss must bear a “causal relationship” with the administration or use of a covered countermeasure. 42 U.S.C. § 247d-6d(a)(1); *id.* § 247d-6d(a)(2)(B); *see* Hickey, Cong. Rsch. Serv., *supra*, at 1–2. The dispute here turns largely on the meaning of *loss*.

In March 2020 the Secretary of HHS declared COVID-19 a public health emergency under the PREP Act, triggering statutory immunity. *See* Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198, 15201–02 (Mar. 17, 2020). In that declaration the Secretary recommended “the manufacture, testing, development, distribution, administration, and use of” covered countermeasures, including vaccines, “to treat, diagnose, cure, prevent, or mitigate COVID-19.” *Id.* at 15,201. The Secretary also declared that “[l]iability immunity as prescribed in the PREP Act . . . is in effect” for the activities he recommended. *Id.*

C. District-Court Proceedings

Dressen sued AstraZeneca,² alleging claims for breach of contract, including breach of the contractual duty of good faith and fair dealing, by allegedly failing to

² Dressen also sued Velocity, raising the same claims. She later voluntarily dismissed Velocity from the suit. *See Dressen*, 2024 WL 4666577, at *2.

compensate her as promised in the ICF. *See Dressen*, 2024 WL 4666577, at *2. She alleged that AstraZeneca “had a contractual obligation (1) to ‘cover the costs’ of the research injury, including but not limited to medical costs; and (2) to provide medical care and/or refer [her] for medical care.” *Aplts. App.*, Vol. I at 45 (Complaint) (internal quotation marks omitted). And she alleged that AstraZeneca breached its duty by acting with “unconscionable delay,” among other things. *Id.* at 46 (Complaint). She sought damages for the cost of her past and future medical care, lost income, household services, childcare expenses, and attorney fees, as well as emotional distress. AstraZeneca moved to dismiss the complaint for failure to state a claim. *See Dressen*, 2024 WL 4666577, at *1.

The district court denied AstraZeneca’s motion because it determined that the PREP Act does not immunize against contract-based claims. *See id.* at *4–11. It reasoned that the “administration” or “use” of a covered countermeasure “cannot, by itself, *cause* a breach of contract” and the statute requires that a claim for loss be causally related to a covered countermeasure. *Id.* at *7 (internal quotation marks omitted). Dressen had a valid claim, in the district court’s view, because “AstraZeneca made a contractual promise to her that happened to involve the effects of a covered countermeasure,” and the company then breached that independent promise. *Id.* at *8. And for the same reason, the court held that PREP Act immunity did not protect against Dressen’s claim for a breach of the contractual duty of good faith and fair dealing.

The district court reserved ruling on whether the language in AstraZeneca’s ICF promising to cover the costs of participant’s research injuries waived the company’s statutory immunity. *See id.* at *3 n.42 (“Because the court finds the PREP Act does not apply to claims for loss based on breach of contract, the court need not consider whether AstraZeneca waived its immunity”). Finally, the district court rejected the company’s arguments that Dressen’s breach-of-contract claims were time-barred and that she failed to state a claim for a breach of the duty of good faith and fair dealing, *see id.* at *3; neither issue has been raised on appeal.

II. DISCUSSION

We first confirm our jurisdiction under the collateral-order doctrine. We then hold that the PREP Act confers immunity from this suit. But we remand with directions to the district court to consider whether the language in AstraZeneca’s ICF waived that immunity. We do not, however, address Dressen’s alternative argument on appeal invoking equitable estoppel, as she did not preserve that argument in district court.

A. Jurisdiction

Under 28 U.S.C. § 1291, courts of appeals “shall have jurisdiction of appeals from all final decisions of the district courts” Ordinarily a final decision is one that “resolves the entire case—when it ends the litigation (on the merits or otherwise) and leaves nothing for the court to do but execute the judgment.” *GEO Grp., Inc. v. Menocal*, 607 U.S. 438, 443 (2026) (internal quotation marks omitted). But the Supreme Court, applying what is known as the collateral-order doctrine, has allowed

for immediate appeal of a small class of orders not resolving the entire case because they have “practical” finality. *Id.* (internal quotation marks omitted) (collateral-order doctrine gives § 1291’s finality requirement a “practical rather than a technical construction” (internal quotation marks omitted)). Such orders “are said to be too important to be denied review and too independent of the cause itself to justify waiting out the rest of the adjudication.” *Mohamed v. Jones*, 100 F.4th 1214, 1218 (10th Cir. 2024) (internal quotation marks omitted). The Court “identif[ies]” these immediately appealable orders “by category, not case-specific circumstances,” and it has “underscored” that this doctrine is “narrow, stringent, and of modest scope.” *GEO Grp.*, 607 U.S. at 444 (internal quotation marks omitted).

For an order to be appealable under the collateral-order doctrine, the order must satisfy “three non-negotiable conditions”: it must “(1) conclusively determine the disputed question, (2) resolve an important issue completely separate from the merits of the action, and (3) be effectively unreviewable on appeal from a final judgment.” *Id.* (internal quotation marks omitted). For the last condition, “the decisive consideration is whether delaying review until the entry of final judgment would imperil a substantial public interest or some particular value of a high order.” *Mohawk Indus., Inc. v. Carpenter*, 558 U.S. 100, 107 (2009) (internal quotation marks omitted). The appellant (here, AstraZeneca) bears the burden of showing that its appeal satisfies all three of these conditions. *See In re Magic Circle Energy Corp.*, 889 F.2d 950, 954 (10th Cir. 1989) (“Because a party seeking to appeal on this basis

must show that all three requirements of the doctrine are satisfied, we need not address each if any one is not met”).

Beginning with *Digital Equipment Corp. v. Desktop Direct, Inc.*, 511 U.S. 863 (1994), the Supreme Court has expressed concern about inappropriate expansion of the collateral-order doctrine. In particular, the Court has tightened the third requirement. Recognizing that failure to promptly correct (through an interlocutory appeal) an adverse trial-court ruling will virtually always impair some interest, the Court has homed in on the interest at stake and its importance. *See Digital Equip.*, 511 U.S. at 871–81. An insufficiently important interest cannot justify an interlocutory appeal even if that interest cannot be cured by victory in a later appeal. *See id.* at 872 (“[I]f immediate appellate review were available every . . . time [an error in district court could not be fully remedied by an appeal], Congress’s final decision rule would end up a pretty puny one, and so the mere identification of some interest that would be ‘irretrievably lost’ has never sufficed to meet the third . . . requirement”); *see Mohawk Indus.*, 558 U.S. at 107 (“The justification for immediate appeal must . . . be sufficiently strong to overcome the usual benefits of deferring appeal until litigation concludes”).

Still, some interests have been deemed sufficiently important to invoke the doctrine. For example, the Court has long recognized a right to appeal certain orders denying a government official’s claim of immunity, reasoning that such officials should not only be protected from liability but should also be protected from the burdens of litigation. *See Mitchell v. Forsyth*, 472 U.S. 511, 525 (1985) (“[T]he

denial of a substantial claim of absolute immunity is an order appealable before final judgment, for the essence of absolute immunity is its possessor's entitlement not to have to answer for his conduct in a civil damages action"); *id.* at 526 (qualified immunity is an "entitlement [to] an *immunity from suit*" and the entitlement "is effectively lost if a case is erroneously permitted to go to trial"). In qualified-immunity cases, waiting for the end of the litigation to hear the issue on appeal undermines the substantial interest in protecting against the burdens of litigation.

In contrast, the Court has more recently declined to apply the collateral-order doctrine to allow an appeal of an interlocutory order denying a claim of attorney-client privilege, in large part because of the limited need to resolve the issue before final judgment. *See Mohawk Indus.*, 558 U.S. at 108 (acknowledging "the importance of the attorney-client privilege" but noting that "[t]he crucial question . . . is whether deferring review until final judgment so imperils the interest as to justify the cost of allowing immediate appeal of the entire class of relevant orders"). Rather than deciding on a case-by-case basis what interests are worth protecting through interlocutory appeals, the Court has declared that "the preferred means for determining whether and when prejudgment orders should be immediately appealable" is the rulemaking process via the Judicial Conference established by Congress. *Id.* at 113; *see Swint v. Chambers Cnty. Comm'n*, 514 U.S. 35, 48 (1995) (describing the statutory authority and the process for rulemaking).

Considering the Court's present view of the collateral-order doctrine, we must be cautious about applying it. Therefore, even though neither party challenges our

appellate jurisdiction in this case, we explain why we conclude that we do have such jurisdiction here.

The first two requirements of the collateral-order doctrine are certainly satisfied. First, the district court conclusively held that the PREP Act does not immunize Dressen's contract claims because the statute does not cover those claims. Second, the immunity question is important and independent of the merits of Dressen's claim for relief. *See Johnson v. Jones*, 515 U.S. 304, 314 (1995) (an issue is separate from the merits if it is "significantly different from the fact-related legal issues that likely underlie the plaintiff's claim on the merits"). As the Ninth Circuit recently stated, "[A] denial of PREP Act immunity resolves an important question separate from the merits. Whether PREP Act immunity applies turns on whether the claim for which immunity is asserted relates to the defendant's use of certain medical countermeasures, a determination that generally will have no bearing on the merits of the underlying action." *Hampton v. California*, 83 F.4th 754, 762 (9th Cir. 2023) (internal quotation marks omitted).

As for the collateral-order doctrine's third requirement, AstraZeneca claims that it will be irremediably injured if it must proceed to trial, even if later vindicated on liability. But because "virtually every right that could be enforced appropriately by pretrial dismissal might loosely be described as conferring a 'right not to stand trial,'" the Supreme Court requires us "to view claims of a 'right not to be tried' with skepticism, if not a jaundiced eye." *Digital Equip.*, 511 U.S. at 873; *see id.* at 872

(“[T]he jurisdiction of the courts of appeals should not, and cannot, depend on a party’s agility in . . . characterizing the right asserted”).

If, however, the asserted immunity does not spring from the creativity of an advocate but appears in positive law, the jaundice clears: “When a policy is embodied in a constitutional or statutory provision entitling a party to immunity from suit (a rare form of protection), there is little room for the judiciary to gainsay its ‘importance.’” *Id.* at 879. By deferring to Congress (or the Constitution) courts do not abdicate their responsibility to corral the notion of a final judgment. After all, the final-judgment rule is itself a creation of Congress. *See* 28 U.S.C. § 1291. No doubt Congress could explicitly provide for interlocutory appeals from a denial of statutory immunity. That Congress does so implicitly, albeit clearly, by using language conferring immunity from suit, is of no moment.

The Supreme Court has never retreated from the proposition that on the “rare” occasion of “a constitutional or statutory provision entitling a party to immunity from suit,” the judiciary cannot “gainsay” that the asserted right to immunity from suit is sufficiently important to satisfy the third requirement of the collateral-order doctrine. *Digital Equip.*, 511 U.S. at 879. What the Court *has* done, however, is to continue to view with great skepticism claims that an *interest* in avoiding trial (generally based on a statutory or common-law immunity from liability) is sufficiently important to support a *right* to avoid trial. *See Van Cauwenberghe v. Biard*, 486 U.S. 517, 524 (1988) (“The critical question . . . is whether the essence of the claimed right is a right not to stand trial” (internal quotation marks omitted)).

Typical is the opinion in *Will v. Hallock*, 546 U.S. 345 (2006). The defendants in that case were federal employees sued in an action under *Bivens v. Six Unknown Federal Narcotics Agents*, 403 U.S. 388 (1971). They invoked a provision of the Federal Tort Claims Act (FTCA) stating that if the government has prevailed on a suit under that Act, a later suit by the same claimant against government employees regarding the same subject matter is barred. *See Will*, 546 U.S. at 347–48. Following *Digital Equipment*, the Supreme Court examined whether the defendants’ “interest in avoiding trial” was of a sufficiently “high order” to satisfy the third prong of the collateral-order doctrine. *Id.* at 352. Comparing the right provided by the FTCA to the right conferred by res judicata doctrine, the Court rejected the claim of a right not to stand trial. *See id.* at 354–55.

Nor has this court ever disregarded *Digital Equipment*’s directive not to “gainsay” the judgment of Congress by rejecting a statutory provision explicitly recognizing a right not to stand trial as insufficiently “importan[t]” to satisfy the third prong. 511 U.S. at 879. Our decision in *United States ex rel. Fiorisce, LLC v. Colorado Technical University, Inc.*, 130 F.4th 811 (10th Cir. 2025), is not to the contrary. In that case we held that a district-court denial of immunity under the public-disclosure bar in the False Claims Act (FCA) could not be reviewed under the collateral-order doctrine. The FCA does not state that immunity under the public-disclosure bar includes an immunity from suit. And we explicitly rejected the argument “that the public disclosure bar is a right to avoid trial.” *Id.* at 820. Thus, a statutory right to avoid trial was not at issue. We recognize that *Fiorisce* said that

“the Supreme Court clarified that showing a right to avoid trial alone—even immunity—is insufficient to justify expanding the collateral order doctrine,” 130 F.4th at 818 (citing *Will*, 546 U.S. at 352-53). But to the extent that this statement concerns the impact on the collateral-order doctrine of a “right to avoid trial,” the statement is dictum, since the court held that there was no such right in that case. And in any event, our use of the word *right*, rather than *interest*, in that statement was nothing more than an inconsequential (for purposes of that case) slip of the tongue, as shown by the fact that the cited passage in *Will* refers to an *interest* in avoiding trial rather than a *right* to avoid trial.³ Once Congress has declared that an interest in avoiding trial is of sufficient importance to create an immunity from suit, we must defer to that assessment.

The PREP Act has one of those “rare” statutory provisions explicitly providing for immunity from suit. *Digital Equip.*, 511 U.S. at 879. Its text is unambiguous: “[A] covered person *shall be immune from suit* and liability.” 42 U.S.C. § 247d-6d(a)(1) (emphasis added). Hence, delaying review until final

³The relevant paragraph from *Will* states as follows:

In each case [where the Supreme Court has recognized a collateral-order appeal based on an immunity from trial], some particular value of a high order was marshaled in support of the *interest* in avoiding trial: [listing those interests]. That is, it is not mere avoidance of trial, but avoidance of a trial that would imperil a substantial public interest, that counts when asking whether an order is effectively unreviewable if review is to be left until later.

546 U.S. at 352–53 (emphasis added, internal quotation marks omitted).

judgment would offend a congressionally recognized substantial public interest, and the third requirement of the collateral-order doctrine is satisfied. *See Hampton*, 83 F.4th at 762 (“[A]s an immunity from suit, the benefit of PREP Act immunity is effectively lost if a party is erroneously required to face the burdens of litigation” (ellipsis and internal quotation marks omitted)); *Goins v. Saint Elizabeth Med. Ctr.*, No. 22-6070, 2024 WL 229568, at *5 (6th Cir. Jan. 22, 2024) (allowing interlocutory appeal on PREP Act immunity question “because the core point of immunity is its possessor’s entitlement not to have to answer for his conduct in a civil damages action” and “a statutory grant to a private entity of immunity from suit is imbued with a significant public interest” (internal quotation marks omitted)).

B. Construing the PREP Act

1. *The scope of the word loss*

As always, “[s]tatutory interpretation begins with the words in the statute.” *Smith v. Bd. of Governors of the Fed. Rsrv. Sys.*, 73 F.4th 815, 820 (10th Cir. 2023) (internal quotation marks omitted). This court first considers “whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case.” *Id.* (internal quotation marks omitted). We determine “[t]he plainness or ambiguity” of a statute’s text “by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole.” *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997). “If the statute’s text is unambiguous, then its plain meaning controls, and our inquiry ends.” *Smith*, 73 F.4th at 820 (internal quotation marks omitted).

The PREP Act immunizes manufacturers and distributors of COVID-19 vaccines against “*all* claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual” of such a vaccine. 42 U.S.C. § 247d-6d(a)(1) (emphasis added); *see also id.* § 247d-6d(a)(2)(B) (this immunity “applies to *any* claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure” (emphasis added)). The statute defines the term *loss* as “*any* type of loss, including . . . (i) death; (ii) physical, mental, or emotional injury, illness, disability, or condition; (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and (iv) loss of or damage to property, including business interruption loss.” *Id.* § 247d-6d(a)(2)(A) (emphasis added).

i. Text

Dressen argues that AstraZeneca is not entitled to immunity from her claims because her claims are breach-of-contract claims, not tort claims. We are not persuaded. We begin with the language of the statute.

The PREP Act’s immunity provision says nothing about shielding covered persons from specific causes of action. Instead, the statute protects against particular “claims for loss.” 42 U.S.C. § 247d-6d(a)(1). A suit for breach of contract is as much a “claim” as a suit under tort law. To be sure, the term *loss* in the statute is limited. *See id.* § 247d-6d(a)(2)(B) (requiring causation). But Dressen makes no effort to show that the listed losses are recoverable only through tort claims. And there is irony, if notchutzpah, in her argument, since the statutory definition appears to

encompass many of the damages that she seeks through her contract claim in this case. *Compare id.* § 247d-6d(a)(2)(A) (defining *loss* to “include[] . . . (i) death; (ii) physical, mental, or emotional injury, illness, disability, or condition; (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and (iv) loss of or damage to property, including business interruption loss”), *with* Aplt. App., Vol. I at 47–48 (Dressen’s prayer for relief seeking “economic damages, including, but not limited to, past and future medical expenses, past and future loss of household services, childcare expenses, past and future lost income, and past and future transportation costs; . . . non-economic damages, including emotional damages, that [Dressen] foreseeably suffered as a result of [AstraZeneca’s] breaches”; attorney fees; prejudgment interest; and “such other and further relief as the Court deems appropriate”). The very premise of her argument—that the losses enumerated in the statute are recoverable only through tort claims—is therefore contradicted by her own complaint.

We further note that one type of injury listed in the PREP Act’s definition of loss for which Dressen does not seek damages—business-interruption loss—is regularly recovered when there is no claim of any tortious action. *See, e.g., Monarch Casino & Resort, Inc. v. Affiliated FM Ins. Co.*, 85 F.4th 1034, 1036–37 (10th Cir. 2023) (casino operator sued commercial property insurer, alleging breach of contract following denial of coverage for business-interruption losses caused by COVID-19 and government orders); *Goodwill Indus. of Cent. Okla., Inc. v. Phila. Indem. Ins.*, 21 F.4th 704, 709 n.2 (10th Cir. 2021) (similar).

Moreover, the statutory definition of *loss* encompasses “any type of loss.” 42 U.S.C. § 247d-6d(a)(2)(A) (emphasis added). Courts generally interpret the term *any*, and its semantic partner *all*, expansively. *See, e.g., Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 219 (2008) (“read naturally, the word *any* has an expansive meaning, that is, one or some indiscriminately of whatever kind” (brackets and internal quotation marks omitted) (emphasis added)); *Allen v. Env’t Restoration, LLC*, 32 F.4th 1239, 1244 (10th Cir. 2022) (noting “all means all” (internal quotation marks omitted)); *Cohen v. JP Morgan Chase & Co.*, 498 F.3d 111, 117 (2d Cir. 2007) (“As the Supreme Court has frequently observed, use of the word ‘any’ in statutory text generally indicates Congress’s intent to sweep broadly to reach all varieties of the item[s] referenced”).

Illustrative is the Supreme Court opinion in *Norfolk & Western Railway Co. v. American Train Dispatchers’ Ass’n*, 499 U.S. 117 (1991), which considered the scope of the Interstate Commerce Act (ICA), a statute designed to facilitate certain railroad-carrier consolidations. Congress exempted those mergers “from the antitrust laws *and from all other law*, including State and municipal law, as necessary to let that person carry out the transaction [for consolidation].” *Id.* at 127 (emphasis added) (internal quotes omitted) (quoting 49 U.S.C. § 11341(a) (1991)). As the Court observed, the phrase “all other law” was “clear, broad, and unqualified” and “indicates no limitation.” *Id.* at 128–29 (internal quotation marks omitted). The Court rejected the argument “that Congress did not intend the immunity clause to apply to contractual obligations,” such as a collective-bargaining agreement. *Id.* at 128. In

doing so, it explained that the statute “means what it says: A carrier is exempt from *all law* as necessary to carry out an [agency]-approved transaction [that is, a sanctioned merger].” *Id.* at 129. The ICA limited the “all other law” language by qualifying the type of transactions covered by the statute (i.e., mergers approved by a specific regulator), not by limiting the category of law that the modifier “all” could encompass. Likewise, the PREP Act’s phrase “all claims for loss” is limited by the statute’s causation requirement, not by the category of the legal claim.

To be sure, courts should avoid a “literal reading” of the term *any* when it would “dramatically separate the statute from its intended purpose.” *Lewis v. United States*, 523 U.S. 155, 160 (1998) (addressing the purpose of the Assimilated Crimes Act to fill gaps in federal law on federal enclaves); *see Small v. United States*, 544 U.S. 385, 388 (2005) (“convicted in any court” does not encompass foreign courts). But, as we discuss below (see § II.B.1.iv. on absurdity doctrine), Dressen does not (and cannot) show that interpreting the PREP Act to immunize covered persons against certain contract-based claims would do so here.

It is also worth pointing out that if Congress wished to exclude contract claims from PREP Act immunity, it knew how to say so. Less than two months before it passed the PREP Act, Congress excepted contract claims from the immunity provision in the Protection of Lawful Commerce in Arms Act (PLCAA), 15 U.S.C. §§ 7901–7903. *Compare* PLCAA, Pub. L. No. 109-92, 119 Stat. 2095 (Oct. 26, 2005), *with* PREP Act, Pub. L. No. 109-148, div. C, 119 Stat. 2680, 2818–32 (Dec. 30, 2005). Like the PREP Act, the PLCAA is an immunity statute. It states that “[a]

qualified civil liability action may not be brought in any Federal or State court,” § 7902(a), and defines *qualified civil liability action* as “a civil action or proceeding or an administrative proceeding brought by any person against a manufacturer or seller of a qualified product [namely, certain firearms and their components, or ammunition], or a trade association, for damages, punitive damages, injunctive or declaratory relief, abatement, restitution, fines, or penalties, or other relief, resulting from the criminal or unlawful misuse of a qualified product by the person or a third party,” with some exceptions. 15 U.S.C. § 7903(5)(A). But unlike the PREP Act, the PLCAA excluded contract claims. *See id.* § 7903(5)(A)(iv) (the term *qualified civil liability action* does not include any “action for breach of contract or warranty in connection with the purchase of the product”). Dressen argues that the contract exemption was already implicit in the PLCAA. That argument, however, does not diminish the force of the observation that Congress knew how to enact such an exemption and chose not to in the PREP Act. And, in any case, we fail to see how it helps her to say that the contract exemption in the PLCAA was implicit, since she contends that the contract-claim exception to immunity in the PREP Act is also implicit, rendering the two statutes identical in that respect. The “[a]textual judicial supplementation” Dressen seeks here “is particularly inappropriate” as “Congress has shown that it knows how to adopt” a contract-based exception to statutory immunity. *Lackey v. Stinnie*, 604 U.S. 192, 205 (2025) (internal quotation marks omitted).

We conclude that the plain text of the PREP Act’s immunity provision bars Dressen’s contract claims.

ii. *Semantics and Contextual Canons of Statutory Construction*

Dressen attempts to avoid the plain language of the PREP Act by (incorrectly) invoking several canons of statutory construction.

First, Dressen relies on the *ejusdem generis* canon, which states, “Where general words follow specific words in a statutory enumeration, the general words are usually construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words.” *Yates v. United States*, 574 U.S. 528, 545 (2015) (plurality opinion) (brackets and internal quotation marks omitted). She argues that “when the general term ‘loss’ is viewed in context—as part of a definition listing discrete categories of harm that are tort-based in nature—‘loss’ can only reasonably be interpreted to apply to tort-based claims.” Aplee. Br. at 10–11. But Dressen is not attempting to limit the meaning of a general term *at the end of* a list in the statutory provision as *ejusdem generis* requires. See Antonin Scalia & Brian A. Garner, *Reading Law: The Interpretation of Legal Texts* 204 (2012) (explaining that *ejusdem generis* should not be applied when a general term *precedes* specific terms because that structure, especially when the specific terms are preceded by the word *including* or its equivalent (as is true here), may well serve a “belt-and-suspenders function”, “making doubly sure that the broad . . . general term is taken to include the specifics”).

Next, Dressen invokes the negative-implication canon, *expressio unius est exclusio alterius*—the expression of one thing implies the exclusion of others. She

says that the statutory definition of *loss* identifies “only tort-based injuries,” thereby implying (through omission) that there is no immunity for contract-based injuries. Aplee. Br. at 10. This argument repeats her earlier argument that the PREP Act’s immunity protections are limited to tort, which we rejected (see Section II.B.1.i, *supra*). And in any event, the argument is not a proper application of the cited canon. Properly applied, the most that the canon could say in this case is that the only losses for which there is immunity are those that are listed: “(i) death; (ii) physical, mental, or emotional injury, illness, disability, or condition; (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and (iv) loss of or damage to property, including business interruption loss.” 42 U.S.C. § 247d-6d(a)(2)(A). The canon is not used to limit the meaning of what is expressly stated; it is used to exclude what is not stated. That is not the use to which Dressen puts it. It is also worth noting that the *expressio unius* canon “can be overcome by contrary indications that adopting a particular rule or statute was probably not meant to signal any exclusion.” *Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 381 (2013) (internal quotation marks omitted). There could hardly be a stronger contrary indication than, as here, the placement of the phrase “any type of loss, including” immediately before the items expressly stated—an emphatic rejection of the proposition that unmentioned losses are excluded. *See* Scalia & Garner, *supra*, at 132 (“The verb *to include* introduces examples, not an exhaustive list”).

Dressen also tries the word-association canon, *noscitur a sociis*, which posits that “a word is known by the company it keeps.” *Yates*, 574 U.S. at 543. Courts rely on

noscitur a sociis “to avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress.”

Id. (internal quotation marks omitted). For example, “if a statute is said to apply to ‘tacks, staples, nails, brads, screws, and fasteners,’ it is clear from the words with which they are associated that the word *nails* does not denote fingernails and that *staples* does not mean reliable and customary food items.” Scalia & Garner, *supra*, at 196. Again, Dressen misapplies a canon. She does not suggest an accepted definition of the term *death* in the list of included losses that is narrower than the standard meaning of the term (we would be astonished to find a dictionary that provides a definition of *death* as “loss of life caused by tortious conduct but not by a breach of contract”); and the same goes for the other listed losses. Her argument that only tort-related losses are covered by the immunity provision cannot invoke the pedigree of the *noscitur* canon.

Dressen also points to the presumption against surplusage. Under this presumption, courts “will not construe a statute in a way that renders words or phrases meaningless, redundant, or superfluous.” *Bridger Coal Co./Pac. Min., Inc. v. Dir., Off. of Workers’ Comp. Programs, U.S. Dep’t of Labor*, 927 F.2d 1150, 1153 (10th Cir. 1991). She argues that “Congress did not need a four-part definition of ‘loss’ if it meant to immunize parties from every conceivable legal claim.” Aplee. Br. at 12. But she applies this canon too aggressively. The PREP Act’s definition of *loss* states that the term “means any type of loss, including—,” and then identifies examples, such as death and physical, mental, or emotional injury. So, as Dressen sees it, if Congress had wanted to immunize losses from breach of contract, it would

have stopped the definition after “any type of loss,”—without listing examples—since the word *loss* is broad enough to include losses from breach of contract. She concludes that doing otherwise renders all the statutory examples surplusage. But the natural reading of the phrase “any type of loss, including” is that the term *loss* should be read expansively, as shown by the examples following “including,” and that Congress intended *loss* to mean at least the listed losses. This belt-and-suspenders construction is common in statutes. If courts were to accept Dressen’s argument, such a construction would have the opposite of its intended effect—courts would need to construe the listed examples of the meaning of the statutory term narrowly because otherwise all the examples would be surplusage.⁴

iii. Structure

Dressen also makes an argument based on “the structure of the PREP Act’s remedial scheme.” Aplee. Br. at 14. Starting from the propositions that “contract damages are not compensable under the CICP [Countermeasures Injury Compensation Program],” and that the CICP is “the exclusive remedy for claims shielded by PREP Act immunity,” she concludes that “Congress never intended [contract] claims to fall within PREP Act immunity.” *Id.* at 15. “If Congress had

⁴ Dressen also relies on *Happel v. Guilford County Board of Education*, 913 S.E.2d 174 (N.C. 2025), to defend her interpretation of “loss” under the PREP Act. For the reasons already provided in this section, the majority opinion in that case does not persuade us that the immunity provision is inapplicable to Dressen’s contract-based claims.

intended to immunize parties from breach of contract claims,” she argues, “it would have included remedies for such claims in the CICP.” *Id.*

To begin with, we question the predicate of Dressen’s argument—that damages sought in a breach-of-contract claim cannot be compensated under the CICP. (After all, she is seeking similar damages in her CICP claim and her claim in this case.) But setting that aside, we are not persuaded by Dressen’s argument. It simply does not compute. She fails to explain why Congress necessarily wanted to compensate through the CICP all claims shielded by the immunity clause. All indications are to the contrary. For example, the only “covered injur[ies]” compensated by the CICP are “serious physical injury or death.” 42 U.S.C. § 247d-6e(e)(3). By Dressen’s logic there should therefore be no immunity for claims for less significant injury. That, of course, would defeat much of the purpose of the immunity provision, since, say, vaccine manufacturers could be subjected to voluminous claims in which the plaintiffs would, remarkably, allege that their injuries were not “serious” within the meaning of the statute. Dressen presumes that all injuries must be fully compensated, either through the CICP or as an exception to the immunity bar. That presumption is contrary to the public policy of limiting liability of both the healthcare community and the government. The limitation in the CICP to “serious physical injury or death” makes clear that Congress did not want to open the public purse to all manner of loss caused by medical countermeasures.

iv. *Absurdity*

Next, Dressen invokes the absurdity canon. The presumption against absurdity counsels courts to avoid “interpretations of a statute which would produce absurd results . . . if alternative interpretations consistent with the legislative purpose are available.” *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982). Dressen contends that it would be absurd for the immunity provision of the PREP Act to encompass contract claims. We disagree. We begin by reviewing the purpose behind the statutory immunity and then consider whether it is absurd not to exclude contract claims from the immunity.

There can be little doubt about the purpose of PREP Act immunity. Immunity arises only when the HHS Secretary determines that there is a public-health emergency requiring an all-hands-on-deck effort by members of the country’s healthcare sector to unflinchingly work on measures, like the COVID-19 vaccine, to abate the crisis. Nothing could make the members flinch more quickly than the specter of financial ruin from litigation over experimental therapy. As the Congressional Research Service summarized the Act:

To encourage the expeditious development and deployment of medical countermeasures during a public health emergency, the [PREP Act] authorizes the Secretary of Health and Human Services (HHS) to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines. In a declaration effective February 4, 2020 (the HHS Declaration), the Secretary of HHS (Secretary) invoked the PREP Act and declared Coronavirus Disease 2019 (COVID-19) to be a public health emergency warranting liability protections for covered countermeasures. Under the HHS Declaration and its amendments, covered persons are generally immune from legal liability (i.e., they cannot be sued for money damages

in court) for losses relating to the administration or use of covered countermeasures against COVID-19.

Hickey, Cong. Rsch. Serv., *supra*, at 1; *see also* *Maney v. Brown*, 91 F.4th 1298, 1299 (9th Cir. 2024) (Congress enacted the PREP Act to “encourage during times of crisis the development and deployment of medical countermeasures (such as diagnostics, treatments, and vaccines) by limiting legal liability relating to their administration” (internal quotation marks omitted)); *accord Cannon v. Watermark Ret. Cmtys., Inc.*, 45 F.4th 137, 138–39 (D.C. Cir. 2022).

Given the financial risks to those providing countermeasures to alleviate the public-health emergency, one can understand why Congress would enact the broadest possible immunity from liability for *any* losses caused (nonwillfully) by the administration or use of a countermeasure. And it is difficult to see why it would provide an exception to an injured person who could frame a lawsuit as a contract claim. For one thing, it does not take that much imagination to frame a tort suit as one sounding in contract. In the past, medical-malpractice claims were often brought as claims for breach of contract. *See* 1 Gordon L. Ohlsson, *Medical Malpractice* § 8.02 (2026) (“Historically, there was much debate over whether the duty of skill and care was grounded in tort or in contract”). And a common theory supporting product-liability claims was breach of warranty. *See* Restatement (Third) of Torts: Prod. Liab. § 1 cmt. a (A.L.I. 1998) (“Strict products liability is a term of art that reflects the judgment that products liability is a discrete area of tort law which borrows from both negligence and warranty” (internal quotation marks omitted)).

Could a person injured by an experimental vaccine circumvent the immunity provision by claiming the manufacturer breached an implied warranty?

The question thus becomes whether there is something special about contract claims that makes it inappropriate to include them within the statutory immunity. Dressen contends that there is. In her view, providing immunity for contract claims “would erode public trust, disincentivize ethical conduct, and create lawless economic zones around covered countermeasures.” Aplee. Br. at 43. She suggests that “[h]onest businesses and individuals, like Dressen, would avoid dealings with manufacturers, fearing uncompensated risks” in such an environment and Congress could not have intended that result. *Id.*

These assertions are not persuasive. To begin with, Dressen does not explain why eliminating contract immunity would create such distrust, etc., but retaining tort immunity would not. The district court was more forthcoming, suggesting that immunizing a breach of promise is especially offensive:

AstraZeneca’s construction of the PREP Act produces absurd results contrary to the statute’s purpose. For example, under the terms of the ICF, Dressen was entitled to “time and travel” reimbursements in the amount of \$125.00 per study visit during the clinical trial with Velocity. AstraZeneca’s theory of immunity would allow it to shirk this and any other promise made to trial participants merely because the promise ultimately relates to the administration or use of a vaccine. Such a theory would invite rank abuse among covered entities to make illusory promises to unwitting consumers.

Dressen, 2024 WL 4666577, at *11 (footnote omitted). But even assuming that failure to pay the study-visit fee is immunized under the statute, it is not absurd to determine that a public policy in favor of foreclosing litigation can justify refusal to

compensate for clear harm. (For example, a litigant who suffers an adverse judgment cannot sue the trial judge for damages no matter how misguided the rulings.) And the view of Congress on this particular matter is clearly expressed in the statutory provision recognizing “the sole exception to [the Act’s] immunity,” which permits, in limited circumstances, a “cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct.” 42 U.S.C. § 247d-6d(d)(1). Thus, even when the injury is caused by willful misconduct, there can be no recovery for lesser injuries. Perhaps a grant of immunity in such circumstances is bad public policy, but it is congressional policy.

A party “claiming that the plain, unequivocal language of a statute produces an absurd result must surmount a formidable hurdle” and show that “it would have been *unthinkable* for Congress to have intended the result commanded by the words of the statute—that is, when the result would be so bizarre that Congress could not have intended it.” *Robbins v. Chronister*, 435 F.3d 1238, 1241 (10th Cir. 2006) (emphasis added) (internal quotation marks omitted). Dressen has not done so here.

v. Constitutional avoidance

Dressen’s last resort is to urge us to apply the constitutional-avoidance doctrine to narrow the PREP Act’s immunity provisions. That doctrine calls on courts, “if possible, [to] interpret ambiguous statutes to avoid rendering them

unconstitutional.” *See United States v. Davis*, 588 U.S. 445, 463 n.6 (2019).⁵ She contends that “AstraZeneca’s reading” of the PREP Act implicates constitutional concerns because it “would authorize uncompensated takings of contract rights—property protected under the Fifth Amendment.” Aplee. Br. at 42.

To begin with, we do not think that the constitutional-avoidance canon applies here. We invoke the canon “only when, after the application of ordinary textual analysis, the statute is found to be susceptible of more than one construction.” *Hernandez-Carrera v. Carlson*, 547 F.3d 1237, 1245 (10th Cir. 2008) (internal quotation marks omitted). If “Congress’ intent is clear, the canon is inapplicable.” *Id.*; *see Bondi v. VanDerStok*, 604 U.S. 458, 484 (2025) (the constitutional avoidance canon has no role “where text, context, and structure” of a statute “decide the case” (internal quotation marks omitted)). The PREP Act’s language is clear: the statute immunizes “all claims for loss” that satisfy its causation requirement.

In any event, our construction of the PREP Act does not raise a substantial Taking Clause question. “It is by now well established that legislative Acts adjusting the burdens and benefits of economic life come to the Court with a presumption of constitutionality, and that the burden is on [the] one complaining of a due process violation to establish that the legislature has acted in an arbitrary and irrational way.”

⁵ As *Davis* notes, there are “at least two different canons of construction that sometimes go by the name ‘constitutional avoidance.’” 588 U.S. at 463 n.6. The other version, not argued here, is “more modern (and more debated).” *Id.* It counsels that courts “should construe ambiguous statutes to avoid the need even to address serious questions about their constitutionality.” *Id.*

Pension Ben. Guar. Corp. v. R.A. Gray & Co., 467 U.S. 717, 729 (1984) (internal quotation marks omitted) (statute imposing penalties on employer’s withdrawal from multiemployer pension plan could be imposed on employers who withdrew from plan before statute was enacted). In particular, “[i]f the regulatory statute [at issue] is otherwise within the powers of Congress, . . . its application may not be defeated by private contractual provisions.” *Connolly v. Pension Ben. Guar. Corp.*, 475 U.S. 211, 224 (1986). “[T]he fact that legislation disregards or destroys existing contractual rights does not always transform the regulation into an illegal taking.” *Id.* This conclusion is not to suggest “that contractual rights are never property rights or that the Government may always take them for its own benefit without compensation.” *Id.* But when, as here, the government “has taken nothing for its own use and only has nullified a contractual provision” by imposing a statutory obligation “that is otherwise within the power of Congress to impose,” no violation of the Taking Clause has occurred. *Id.*; see *Concrete Pipe & Prods. of Calif. v. Constr. Laborers Pension Tr. for S. Calif.*, 508 U.S. 602, 636–47 (1993) (statute regulating employer pension plans and arbitration agreements is within Congress’s police powers and is not an unconstitutional taking even though it contradicts a private contractual provision within collective-bargaining agreement); *Omnia Com. Co. v. United States*, 261 U.S. 502, 509–10 (1923) (“[I]t is not determinative of the [Taking Clause] question that the commerce act as now construed will render the contract of no value for the purposes for which it was made. . . . [T]he Fifth Amendment . . . has always been understood as referring only to a direct appropriation, and not to consequential

injuries resulting from the exercise of lawful power” (internal quotation marks omitted)); Ronald Rotunda & John Nowak, 2 *Treatise on Const. L.* § 15.12(a)(ii) (2025) (“Because the imposition of liability on employers withdrawing from the pension plans [in *Connolly*] was not a direct government use or taking of property but only the establishment of a program that adjusted the benefits and burdens of economic life to promote the common good, it was not a direct interference with property rights” (internal quotation marks omitted)).

Statutory limits on liability are a commonplace. It would be peculiar if they are invalid takings of private property rights under the Taking Clause when they are rarely, if ever, held to be a deprivation of property under the Due Process Clause of the Fifth Amendment. *See, e.g., Duke Power Co. v. Carolina Env’t Study Grp., Inc.*, 438 U.S. 59, 88 (1978) (“It is not at all clear that the Due Process Clause in fact requires that a legislatively enacted compensation scheme either duplicate the recovery at common law or provide a reasonable substitute remedy”); *see id.* at 88 n.32 (declaring that “[o]ur cases have clearly established that a person has no property, no vested interest, in any rule of the common law,” and that “statutes limiting liability are relatively commonplace and have consistently been enforced by the courts” (brackets and internal quotation marks omitted)).⁶

⁶ We need not dwell on Dressen’s argument that the PREP Act’s legislative history shows that Congress did not intend that the statute’s scope of immunity extended to breach-of-contract claims. She relies on the least reliable legislative history—namely, carefully selected excerpts of statements from a few members of Congress; those statements are far from definitive (indeed, she relies on what those

2. *Causation*

Even though PREP Act immunity extends to breach-of-contract claims, it does not encompass all contract claims against covered persons. There is a causation requirement. The statute immunizes only “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.” 42 U.S.C. § 247d-6d(a)(1), *see also id.* § 247d-6d(a)(2)(B) (immunity “applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure”). This statutory language, not general principles of tort or contract law or other legal sources, is what we must interpret.

The PREP Act provides four choices for the type of causal relationship that must be established: “caused by,” “arising out of,” “relating to,” *or* “resulting from.” The causal relationship is satisfied if any of these four terms applies. We need not parse the meaning of those terms too finely to resolve this case as it is presented to us by the parties. It suffices that the use of the four alternative means of expressing the causation requirement in itself suggests Congress’s intent to be comprehensive.

members did not say); and, as Dressen acknowledges, legislative history should not be invoked when the statute is unambiguous.

We can also summarily reject Dressen’s argument that we must presume that Congress did not intend to preempt state law. We do not “apply such a presumption in express-preemption cases.” *Thornton v. Tyson Foods, Inc.*, 28 F.4th 1016, 1023 (10th Cir. 2022). Insofar as the PREP Act preempts state causes of action, our task is simply standard statutory interpretation.

In this light, we think it safe to say that a causal relationship satisfies the Act when it meets “the simple and traditional standard of but-for causation.” *Bostock v. Clayton County*, 590 U.S. 644, 656 (2020) (internal quotation marks omitted) (construing the meaning of “because of” in an employment-discrimination claim under Title VII). An action or event is a but-for cause of an injury if the injury would not have occurred absent the action or event. *See Comcast Corp. v. Nat’l Ass’n of Afr. Am.-Owned Media*, 589 U.S. 327, 331 (2020) (under the but-for causation standard, “a plaintiff must demonstrate that, but for the defendant’s unlawful conduct, its alleged injury would not have occurred”); *Bostock*, 590 U.S. at 656 (“[A] but-for test directs us to change one thing at a time and see if the outcome changes. If it does, we have found a but-for cause”).

To be sure, sometimes more is required to satisfy causation, such as foreseeability. But Dressen has presented no argument to that effect with respect to the PREP Act.⁷ Rather, she appears to accept that but-for causation suffices, but then she interprets that term contrary to any authority of which we are aware.

Dressen states in bold letters in her opening brief: “**The real but-for cause is the breach (i.e., AstraZeneca’s behavior)—not the Vaccine.**” Aplee. Br. at 19. We are not sure what the word *real* means in that sentence. But what is clear is that she is

⁷ We note that the provision of the PREP Act permitting claims for willful misconduct requires that the injury be *proximately* caused by the misconduct. *See* 42 U.S.C. § 247d-6d(d)(1). The absence of the *proximate* requirement in the immunity provision of the same statutory section is further indication of the sufficiency of satisfying a bare-bones but-for standard for immunity.

focusing on a but-for cause of her injury—AstraZeneca’s refusal to keep its alleged promise “to her to cover the costs if [research injuries] occurred.” *Id.* at 19. Her argument implicitly assumes, however, that there can be no other but-for cause for the injury she suffered. This approach misconceives the meaning of *but-for cause*. AstraZeneca’s breach of a promise could be a but-for cause of Dressen’s alleged damages. But that fact does not undermine the proposition that administration of the vaccine was also a but-for cause. “Often, events have multiple but-for causes.” *Bostock*, 590 U.S. at 656. Although Dressen stakes her claims against AstraZeneca on its failure to honor an alleged promise to provide insurance or medical care in the face of her injuries, she would have no claim against the company absent the injuries from the vaccine. If she had not received an injection, and hence suffered no injury, she would have nothing to recover from a claim against AstraZeneca for breach of contract. Hence, the administration of the vaccine was a but-for cause of the damage for which she seeks recompense.

Finally, Dressen relies on the statement by the district court that “the legal injury is not barred by the PREP Act because the research injury is not a sufficient condition for her claim.” *Dressen*, 2024 WL 4666577, at *9. But that approach is also misconceived. True, the research injury was not in itself sufficient to state the breach-of-contract claim since there also needs to be a broken promise; but likewise the breach of promise is not in itself sufficient to state the claim without the injury from the injection. In determining whether something was a but-for cause, the issue is not whether an action or event was a *sufficient* condition but whether it was a

necessary condition. Here, the vaccination was a necessary condition; it was therefore a but-for cause.

Dressen has failed to persuade us that AstraZeneca cannot invoke statutory immunity.

C. Waiver and AstraZeneca’s Informed Consent

Dressen argues that even if the PREP Act’s immunity shields AstraZeneca, this court may affirm the district court’s decision because the company “waived any such immunity through its conduct and promises.” Aplee. Br. at 49. But the district court expressly reserved this issue. *See Dressen*, 2024 WL 4666577, at *3 n.42. We leave to the district court on remand to determine in the first instance whether PREP Act immunity can be waived and, if so, whether it was waived in this case.

III. CONCLUSION

We **REVERSE** the ruling below that the PREP Act does not provide immunity from contract claims. And we **REMAND** for further proceedings consistent with this opinion.