Nos. 23-2038, 23-2039, 23-2040, 23-2042, 23-2043, 23-2044, and 23-2045

IN THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

TODD LOPEZ, as personal representative of the wrongful death estates of Clara Mae Cook, Don Begay, Raymond Gabehart, Eva Hunt, Gladys Pioche, Clara Mae Cook, and Nellie Hardwood,

Plaintiff-Appellee,

v.

CANTEX HEALTH CARE CENTERS II, LLC, et al.,

Defendants-Appellants.

DENNIS MURPHY, as personal representative of the wrongful death estate of Joe A. James,

Plaintiff-Appellee,

v.

CANTEX HEALTH CARE CENTERS II, LLC, et al.,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of New Mexico

Case Nos. 1:22-CV-00825; 1:22-CV-00822; 1:22-CV-00826; 1:22-CV-00831; 1:22-CV-00824; 1:22-CV-00834; 1:22-CV-00827; 1:22-CV-00832
Hon. Kea W. Riggs

BRIEF OF AMICUS CURIAE PUBLIC CITIZEN IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

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August 2, 2023

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 & 29(a)(4), amicus curiae Public Citizen, Inc. states that it has no parent corporation and that no publicly held corporation has an ownership interest in it.

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GLOSSARY

ATSSA	Air Transportation Safety and System Stabilization Act of 2001
ERISA	Employee Retirement Income Security Act of 1974
HHS	United States Department of Health and Human Services
LMRA	Labor Management Relations Act
PREP Act	Public Readiness and Emergency Preparedness Act

INTEREST OF AMICUS CURIAE[1]

Amicus Curiae Public Citizen is a non-profit consumer advocacy organization with members in all 50 states. Appearing before Congress, agencies, and courts on a wide range of issues, Public Citizen works for the enactment and enforcement of laws to protect consumers, workers, and the public. Public Citizen has a longstanding interest in patient safety and in holding health care providers accountable for protecting patients, including by supporting individuals' ability to access the civil justice system. It often appears as amicus curiae to address issues such as federal-court jurisdiction, statutory interpretation, and preemption. Public Citizen has appeared as amicus curiae in several cases in the courts of appeals involving nursing homes' attempts to remove cases involving COVID-19 infection control to federal court on the basis of the Public Readiness and Emergency Preparedness (PREP) Act. *See*, *e.g.*,

[1] The parties have consented to the filing of this brief. No party's counsel authored this brief in whole or part, no party or party's counsel contributed money intended to fund the brief's preparation or submission, and no person other than amicus curiae, its members, or its counsel contributed money intended to fund the brief's preparation or submission.

Martin v. Petersen Health Operations, LLC, 37 F.4th 1210 (7th Cir. 2022); *Maglioli v. Alliance HC Holdings LLC*, 16 F.4th 393 (3d Cir. 2021).

Public Citizen submits this brief because it believes that, if accepted, Appellants' erroneous arguments regarding jurisdiction and the scope of the PREP Act would pose a substantial risk of wrongfully depriving injured plaintiffs of access to meaningful remedies and their choice of forum.

STATUTORY BACKGROUND

Initially enacted in 2005 "[t]o 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." Cong. Res. Serv., *The PREP Act and COVID-19, Part 1: Statutory Authority to Limit Liability for Medical Countermeasures* 1 (updated April 13, 2022).[2]

The Secretary triggers the PREP Act by issuing a declaration determining that a public health emergency exists and "recommending"

[2] https://crsreports.congress.gov/product/pdf/LSB/LSB10443.

the "manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures," under certain conditions. 42 U.S.C. § 247d-6d(b)(1). The Secretary may designate only certain drugs, biological products, and devices authorized or approved for use by the Food and Drug Administration or the National Institute for Occupational Safety and Health as "covered countermeasures." 42 U.S.C. § 247d-6d(i)(1)(A)–(D).

Subsection (a) of the PREP Act provides "covered persons" with immunity from liability under state or federal law for "any claim for loss that has a causal relationship with the administration to or use by an individual of a [designated] covered countermeasure." *Id.* §§ 247d-6d(a)(1), (a)(2)(B). Subsection (d) creates an "exception" to such immunity for suits brought against covered persons "for death or serious physical injury proximately caused by willful misconduct." *Id.* § 247d-6d(d)(1). The statute defines "willful misconduct" as:

> an act or omission that is taken—
>
> (i) intentionally to achieve a wrongful purpose;
> (ii) knowingly without legal or factual justification; and
> (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

Id. § 247d-6d(c)(1)(A). Congress also included a "[r]ule of construction," specifying that these elements "establish[] a standard for liability that is more stringent than a standard of negligence in any form or recklessness." *Id.* § 247d-6d(c)(1)(B). Critically, however, the statute provides this exclusive cause of action only for claims that otherwise would fall within the immunity provision. *See id.* § 247d-6d(d)(1). Unless a claim would be otherwise barred by subsection (a), it cannot be brought as a subsection (d) claim.

For claims within the carve-out, the statute creates an "exclusive Federal cause of action," *id.*, and provides special adjudicatory procedures and exclusive jurisdiction in a three-judge court of the U.S. District Court for the District of Columbia, *id.* § 247d-6d(e). Among these procedural requirements, the statute requires plaintiffs to "plead with particularity each element" of their claim, including "each act or omission, by each covered person sued, that is alleged to constitute willful misconduct relating to the covered countermeasure administered to or used by the person on whose behalf the complaint was filed," and "facts supporting the allegation that such alleged willful misconduct proximately caused the injury claimed." *Id.* § 247d-6d(e)(3).

The PREP Act also creates an administrative compensation scheme, which, like subsection (d), is available only to those who suffered injuries "directly caused by the administration or use of a covered countermeasure" subject to a PREP Act declaration. 42 U.S.C. § 247d-6e(a). HHS regulations specify that eligibility for compensation is limited to "injured countermeasure recipients" and their survivors, 42 C.F.R. § 110.10(a), and define "covered injuries" as excluding "injur[ies] sustained as the direct result of the covered condition or disease for which the countermeasure was administered or used … (e.g., if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease)," *id.* § 110.20(d).

On March 10, 2020, then-HHS Secretary Alex Azar issued a Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. 85 Fed. Reg. 15,198 (published Mar. 17, 2020). The Declaration recommended the "manufacture, testing, development, distribution, administration, and use" of certain countermeasures to combat COVID-19: "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the

transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product." *Id*. at 15,202.

The Secretary amended the initial Declaration several times. The First Amendment expanded covered countermeasures to include certain respiratory protective equipment. *See* 85 Fed. Reg. 21,012, 21,013–14 (Apr. 15, 2020). In the Fourth Amendment, the Secretary amended the definition of the term "administration of the covered countermeasure," specifying that "[w]here there are limited Covered Countermeasures, not administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute 'relating to … the administration to … an individual' under 42 U.S.C. 247d-6d," to the extent such non-administration reflects "prioritization or purposeful allocation … particularly if done in accordance with a public health authority's directive." 85 Fed. Reg. 79,190, 79,197 (Dec. 9, 2020). He gave as an example the decision to vaccinate a more-vulnerable individual instead of a less-vulnerable individual given a supply shortage. *Id.*

The Fourth Amendment also incorporated by reference four advisory opinions previously issued by HHS's General Counsel. *Id.* at

79,191 & n.5. In one of those opinions, the General Counsel had opined that PREP Act immunity was available to persons "using a covered countermeasure in accordance with" guidance from public health authorities, including guidance on how to prioritize scarce countermeasures like vaccines. HHS General Counsel, Advisory Opinion 20-04 at 4 (Oct. 22, 2020, as modified on Oct. 23, 2020), App. Vol. 1 at 107. The General Counsel provided "examples of program planners using covered countermeasures according to the guidance of" a public health authority that would, in his view, trigger PREP Act immunity, including the vaccination prioritization example given in the Fourth Amendment. *Id.* at 5–6, App. Vol. 1 at 108–09.

In January 2021, the General Counsel issued a fifth advisory opinion. HHS General Counsel, Advisory Opinion 21-01 (Jan. 8, 2021), App. Vol. 1 at 113. That opinion stated his view that "the PREP Act is a [c]omplete [p]reemption statute" and that it applies to situations where a covered person makes a decision regarding allocation of covered countermeasures that "results in non-use by some individuals," but *not* where non-use was the result of "nonfeasance." *Id.* at 2–4, App. Vol. 1 at 114–16. Like the previous advisory opinions, Opinion 21-01 states that it

"sets forth the current views" of the General Counsel, is "not a final agency action or a final order," and "does not have the force or effect of law." *Id.* at 5, App. Vol. 1 at 117.

SUMMARY OF ARGUMENT

In arguing that the PREP Act completely preempts the state-law claims brought by the plaintiffs in these consolidated appeals, Cantex ignores this Court's complete preemption jurisprudence and mischaracterizes the holdings of the six courts of appeals that have rejected similar arguments. *None* of those courts of appeals have found *any* claims completely preempted by the PREP Act. And while those courts have given a range of reasons for rejecting the complete preemption arguments presented to them, applying the reasoning of any of those courts to this case would require affirmance of the decisions below and remand to the state court. That same outcome is dictated by this Court's "two-step" framework for complete preemption, under which complete preemption provides a basis for federal jurisdiction only where (1) federal law preempts the state law invoked by the plaintiff and (2) Congress has manifested an intent to permit removal by transforming

state-law claims into federal ones. *Bd. of Cty. Comm'rs of Boulder Cty. v. Suncor Energy (U.S.A.) Inc.*, 25 F.4th 1238, 1256 (10th Cir. 2022).[3]

This Court generally addresses the "second" of these steps first, *see id.*, and Cantex's argument fails at that step: Congress did not manifest an intent to permit removal of state-law claims by completely "transmogrifying" them into federal ones. *Felix v. Lucent Techs., Inc.*, 387 F.3d 1146, 1157 (10th Cir. 2004) (citation omitted). As the Seventh and Ninth Circuits have recognized, the PREP Act does not reflect the requisite intent because it does not completely displace state law and replace it with comprehensive federal regulation. Where the PREP Act applies, it does one of two things: (1) provides an ordinary immunity defense that can be raised in state court, or (2) provides a federal cause of action that is governed by *state* substantive law. In neither scenario does the Act prescribe rights or duties that bind covered entities. The PREP Act is thus unlike those statutes that the Supreme Court has found to possess complete preemptive effect, each of which imposes nationwide,

[3] The courts of appeals have also unanimously rejected federal-officer removal arguments like Cantex's. For the reasons stated in those cases and by the district court below, the federal-officer argument raised here is "frivolous." App. Vol. 1 at 293–96.

uniform substantive federal-law duties. As this Court has held, a federal cause of action that incorporates state substantive law is not a completely preemptive one. Additionally, Congress's creation of federal jurisdiction only where plaintiffs have pleaded claims under the "willful misconduct" exception to PREP Act immunity strongly suggests that Congress did not intend for federal courts to adjudicate the applicability of that immunity more generally. As five courts of appeals have held with respect to indistinguishable allegations, the plaintiffs have not pleaded such willful misconduct claims here.

Cantex's complete preemption argument also fails at the "first" step of the inquiry, because the claims alleged are not subject to ordinary preemption under the PREP Act. The statute provides immunity only for claims based on injuries caused by the "administration to or use by an individual" of a covered countermeasure. As recognized by the Fifth, Sixth, and Seventh Circuits, claims that nursing home residents died due to failures to adopt and implement adequate infection control measures to fight the spread of COVID-19 are not claims for injuries caused by the administration to or the use by an individual of a covered countermeasure.

ARGUMENT

"A subspecies of field preemption, complete preemption arises when Congress affords defendants not only an affirmative defense against state law claims, but also the right to remove the dispute to federal court—ensuring that the preemption question itself is decided in a federal (rather than a state) forum." *Cook v. Rockwell Int'l Corp.*, 790 F.3d 1088, 1097 (10th Cir. 2015). "Complete preemption should not be lightly implied." *Devon Energy Prod. Co., L.P. v. Mosaic Potash Carlsbad, Inc.*, 693 F.3d 1195, 1205 (10th Cir. 2012) (quotation marks and citation omitted).

This Court applies a two-step analysis "[t]o determine whether a state-law claim is completely preempted by federal law." *Suncor*, 25 F.4th at 1256. The Court "asks whether the federal question at issue preempts the state law relied on by the plaintiff," and "whether Congress intended to allow removal in such a case, as manifested by the provision of a federal cause of action." *Id.* (quoting *Dutcher v. Matheson*, 733 F.3d 980, 986 (10th Cir. 2013)). Generally, "courts should begin their inquiry with the second prong" to "avoid addressing needlessly the first prong, which will frequently require a discussion of the merits of the preemption

defense." *Devon Energy*, 693 F.3d at 1206 (citation omitted). Cantex's argument that the PREP Act completely preempts the Estates' claims fails at both steps.

I. The PREP Act is not a complete preemption statute.

A. "For the complete-preemption doctrine to apply, the challenged claims must 'fall within the scope of federal statutes intended by Congress completely to displace all state law on the given issue and comprehensively to regulate the area.'" *Devon Energy*, 693 F.3d at 1205 (quoting *Hansen v. Harper Excavating, Inc.*, 641 F.3d 1216, 1221 (10th Cir. 2011)). Thus, to satisfy the second prong of this Court's complete preemption analysis, a statute "must 'so pervasively regulate [its] respective area[ ]' that it leaves no room for state-law claims." *Id.* (quoting *Hansen*, 641 F.3d at 1221 (alterations omitted)).

This standard is rarely met. The Supreme Court has recognized only three statutes with the requisite force to give rise to complete preemption: section 301 of the Labor Management Relations Act (LMRA), section 502(a) of the Employee Retirement Income Security Act (ERISA), and sections 85 and 86 of the National Bank Act. *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 6–8, 11 (2003); *see Suncor*, 25 F.4th at 1257. Each

of these statutes provides both a federal cause of action and uniform substantive federal law that creates the legal duties that the cause of action enforces. A claim that necessarily implicates those federal duties, even if denominated a state-law claim, is thus transformed into one for a violation of federal substantive law. *See Giles v. NYLCare Health Plans, Inc.*, 172 F.3d 332, 337 (5th Cir. 1999)*, quoted in Felix,* 387 F.3d at 1157 (noting that complete preemption "transmogrif[ies] a state cause of action into a federal one").

For example, the LMRA completely preempts only state-law claims that are "controlled by [the] federal substantive law" of contract interpretation that exclusively governs covered collective bargaining agreements. *Avco Corp. v. Aero Lodge No. 735, Int'l Ass'n of Machinists & Aerospace Workers*, 390 U.S. 557, 560 (1968). Where "[s]tate law—not the CBA is the source of the rights asserted by plaintiffs," on the other hand, there is no complete preemption. *Felix*, 387 F.3d at 1164 (citation omitted). Similarly, ERISA section 502(a) completely preempts only state-law claims that are governed by federal substantive duties—specifically, those imposed by ERISA or an ERISA plan—and not those that seek to vindicate independent legal duties. *See Aetna Health Inc. v.*

Davila, 542 U.S. 200, 210 (2004); *Salzer v. SSM Health Care of Okla. Inc.*, 762 F.3d 1130, 1135–37 (10th Cir. 2014). And sections 85 and 86 of the National Bank Act completely preempt only claims that are governed by the federal "substantive limits on the rates of interest that national banks may charge." *Beneficial*, 539 U.S. at 9.

As the Seventh and Ninth Circuits have recognized, the PREP Act does not displace state law in that way. *See Martin*, 37 F.4th at 1213); *Saldana v. Glenhaven Healthcare LLC,* 27 F.4th 679, 688 (9th Cir.), *cert. denied*, 143 S. Ct. 444 (2022). "The PREP Act is, at its core, an immunity statute; it creates no rights, duties, or obligations." *Khalek v. S. Denver Rehab., LLC*, 543 F. Supp. 3d 1019, 1025 (D. Colo. 2021) (citation omitted). Thus, no federal substantive duties are at issue in claims implicating the PREP Act that can be adjudicated independent of state law. And without prescribing any federal uniform standards, a federal law cannot be said to "so pervasively regulate its respective area that it leaves no room for state-law claims," as is required for complete preemption under this Court's precedent. *Devon Energy*, 693 F.3d at 1205 (quoting *Hansen*, 641 F.3d at 1221); *see Martin*, 37 F.4th at 1213 (holding

that the PREP Act does not completely preempt state-law claims because it does not "occupy the field of health safety").

When a state-law claim meets the requirements of subsection (a) of the PREP Act, one of two things happens. *First*, where a plaintiff pleads that the three criteria for willful misconduct have been satisfied, the statute expressly preserves, not displaces, state law and provides a federal forum for adjudicating state-law claims. *See* 42 U.S.C. § 247d-6d(e)(2) (providing that *state* law is the source of "[t]he substantive law for decision" in a subsection (d) action). *Second*, for other claims based on injuries caused by the administration to or use by an individual of a covered countermeasure, the statute "does not transform the plaintiff's state-law claims into federal claims but rather extinguishes them altogether." *Rivet v. Regions Bank of La.*, 522 U.S. 470, 476 (1998). In neither set of circumstances does the PREP Act transform state-law claims into purely federal ones.

A transformation from state-law to federal-law claims is necessary for complete preemption, which is based on the idea that state law has been wholly displaced in favor of uniform, federal substantive and procedural law. *See Beneficial*, 539 U.S. at 10. As this Court has held, a

statute that "preserve[s] state rules of decision" while providing a federal forum "is not a true complete preemption statute." *Cook*, 790 F.3d at 1097; *see also Matthews v. Centrus Energy Corp.*, 15 F.4th 714, 721 (6th Cir. 2021) (holding that a statute that "incorporate[es] state law into the federal action … does not entirely displace state law," and thus does not create complete preemption). "A statute that goes so far out of its way to preserve state prerogatives cannot be said to be an expression of Congress's extraordinary pre-emptive power to convert state-law into federal-law claims." *Suncor Energy*, 25 F.4th at 1263–64 (10th Cir. 2022) (internal quotation marks and citation omitted). The express congressional direction that state law continue to apply, even if limited by a federal defense, evidences the opposite of the required complete displacement of state law.

In *Cook*, this Court held that the Price-Anderson Act does not completely preempt any state-law claims for exactly this reason. The relevant language of that statute parallels that of the PREP Act: It provides that "[t]he substantive rules for decision" in a "public liability action" brought in federal court pursuant to 42 U.S.C. § 40101(n) "shall be derived from the law of the State in which the nuclear incident

involved occurs, unless such law is inconsistent with the provisions of [42 U.S.C. § 2210]." 42 U.S.C. § 2014(hh). The PREP Act, 42 U.S.C. § 247d-6d(e)(2), likewise provides that "the substantive law for decision" for cases brought in the U.S. District Court for the District of Columbia pursuant to 42 U.S.C. § 247d-6d(d) "shall be derived from the law … of the State in which the alleged willful misconduct occurred, unless such law is inconsistent with" federal law, including the immunity protections of the statute. Given these similar clauses, this Court should construe the PREP Act not to be a complete preemption statute, as it has the Price-Anderson Act.[4]

Further, "[t]he provision of one specifically defined, exclusive federal cause of action" available only when a plaintiff alleges willful misconduct under the statutory definition—and not available in any other situations where the applicability of PREP Act immunity is to be adjudicated—"undermines [the] argument that Congress intended the Act to completely preempt all state-law claims related to the pandemic."

[4] Although not a complete preemption statute, the Price-Anderson Act includes a provision providing for federal jurisdiction over "public liability actions" and expressly making such cases removable. 42 U.S.C. § 2210(n)(2). The PREP Act does not.

Saldana, 27 F.4th at 688. To the contrary, the PREP Act differs from other statutes where Congress has expressed its "inten[t] to allow removal"—the relevant inquiry under this Court's precedent. *See Suncor* 25 F.4th at 1256. Congress could also have taken the same tack it took, for example, in the Air Transportation Safety and System Stabilization Act of 2001 (ATSSSA), Pub. L. No. 107-42, 115 Stat. 230 (2001), *codified as amended at* 49 U.S.C. § 40101 note. There, Congress created a broad federal cause of action for *any* damages claims arising out of the September 11, 2001, attacks, and conferred "exclusive and original jurisdiction" over such claims in the Southern District of New York—providing that court with jurisdiction to determine whether the statute's accompanying limitations on liability applied to a given claim. The PREP Act, though, does not give any federal court jurisdiction over negligence or other claims that might be subject to the statute's immunity provisions—only willful misconduct claims that are *carved out* from that immunity provision. *See Mitchell v. Advanced HCS, LLC*, 28 F.4th 580, 588 (5th Cir. 2022) (reasoning that the differences between ATSSSA and PREP Act "cut decisively against complete preemption").

B. Cantex contends that "the Second, Third, Fifth, and Seventh Circuits appear to agree that state-law claims for 'willful misconduct' are [completely] preempted under the Act." Appellants' Br. 53. None of those courts, however, have held *any* claim is completely preempted by the PREP Act. The Fifth Circuit, in two separate published opinions, explicitly declined to reach the question whether claims alleging "willful misconduct" are completely preempted. *See Manyweather v. Woodlawn Manor, Inc.*, 40 F.4th 237, 245 n.6 (5th Cir. 2022) ("We reserved that question in *Mitchell*, and again reserve it here." (citing 28 F.4th at 587)). And the Seventh Circuit held that the willful misconduct cause of action does *not* evince any completely preemptive effect as that cause of action does not "occupy the field of health safety." *Martin*, 37 F.4th at 1213.

At most, dicta in Second and Third Circuit opinions suggest complete preemption might apply where a plaintiff expressly brings a claim for willful misconduct in the administration or use of a covered countermeasure. The Third Circuit recognized in "a note on the limits of [its] holding" that "[c]onceivably" some state-law claims could be completely preempted by the PREP Act. *Maglioli*, 16 F.4th at 413. However, it also noted that claims that could be brought under the PREP

Act might not be completely preempted if they were supported by "an independent legal duty," an analysis the court found it unnecessary to undertake. *Id.* at 410 n.11 (citations omitted). As explained above, because the PREP Act does not create any federal legal duty *at all*, claims brought under the subsection (d) cause of action will *always* be based on an independent legal duty—typically a state-law duty that has not been displaced. The Third Circuit did not address the point because there was no need to do so in the case before it. Similarly, while the Second Circuit recognized that the PREP Act's willful misconduct cause of action had some features of complete preemption statutes, it did not address those aspects of the PREP Act that differ from those of complete preemption statutes—again, having no need to do so because the plaintiffs did not plead willful misconduct claims. *Solomon v. St. Joseph Hosp.*, 62 F.4th 54, 61 (2d Cir. 2023).

Here, the plaintiffs' claims are not meaningfully different from those at issue in *Maglioli* and *Solomon*, or in any of the many other courts of appeals' decisions finding that similar claims were not "willful misconduct" claims. Thus, even if willful misconduct claims were completely preempted, the claims here would not be. While Cantex

highlights the complaints' allegations of "fraudulent and misleading statements," Appellants' Br. 57–58, none of those allegations relate to the administration or use of a covered countermeasure. And neither those allegations, nor the generic allegations relating to "wanton and/or reckless disregard" in the punitive damages request, *id.* at 59 (quoting App. Vol. 1 at 54–56, 62–66), are enough to convert the claims alleged into willful misconduct claims as that term is defined under the statute. *See Hudak v. Elmcroft of Sagamore Hills*, 58 F.4th 845, 854 (6th Cir. 2023) (holding that a claim labeled as one for "reckless, intentional, willful and wanton misconduct" could not have been brought under the PREP Act's willful misconduct cause of action); *Maglioli*, 16 F.4th at 411 (holding that "standard language for a punitive-damages request" of "grossly reckless, willful, and wanton" conduct does not bring a claim under the willful misconduct cause of action); *see also Friedman v. Montefiore*, 2023 WL 4536084, at *4–5 (6th Cir. July 13, 2023) (same as to allegations that defendant acted "negligently, recklessly, and with malicious intent"); *Rivera-Zayas v. Our Lady of Consolation Geriatric Care Ctr.*, 2023 WL 2926286, at *3 (2d Cir. Apr. 13, 2023) (same as to allegations that conduct was "'willful", "knowing" and "in so careless a

manner as to show complete disregard for the rights and safety of others").

II. The plaintiffs' claims of inadequate infection control are not preempted by the PREP Act.

In light of the foregoing, the Court need not address the other prong of the complete preemption inquiry: whether the claims alleged are within the preemptive scope of the PREP Act. Should it do so, however, it should affirm the district court's conclusion, App. Vol. 2 at 291–92, that the plaintiffs' claims are not claims for losses with "a causal relationship with the administration to or use by an individual of a covered countermeasure," 42 U.S.C. § 247d-6d(a)(2)(B), and, thus, are not preempted by the PREP Act. That conclusion is consistent with the decisions of dozens of courts recognizing the inapplicability of the PREP Act "where a plaintiff's claim is premised on a failure to take preventative measures to stop the spread of COVID-19, as here, and where none of the alleged harm was causally connected to the administration or use of any counter-measure." *Gwilt v. Harvard Sq. Retirement & Assisted Living*, 537 F. Supp. 3d 1231, 1240 (D. Colo. 2021).[5] Such claims "are not even

[5] *Accord*, *e.g.*, *Hudak*, 58 F.4th at 855–57; *Martin*, 37 F.4th at 1213; *Manyweather*, 40 F.4th at 245–46; *Barron v. Benchmark Sr. Living, LLC*,

arguably preempted" by the PREP Act because the only relationship they conceivably have with covered countermeasures is with their *non*-use—contrary to the Secretary's recommendations. *Martin*, 37 F.4th at 1213. Such an allegation thus does not fall within the statutory grant of immunity even under the "expansive reading of the PREP Act" contained in the Fourth Amendment to the Declaration upon which Cantex relies. *Hudak*, 58 F.4th at 857.

2023 WL 1782246 (D.N.H. Feb. 6, 2023); *Walker v. Arbor Mgmt. Servs., LLC*, 2022 WL 18777384, at *4–6 (N.D. Ga. Nov. 17, 2022); *Testa v. Broomall Operating Co.*, 2022 WL 3563616, at *4–5 (E.D. Pa. Aug. 18, 2022); *Yarnell v. Clinton No. 1, Inc.*, 591 F. Supp. 3d 432, 439 (W.D. Mo. 2022); *Morse v. Hacienda Care VI, LP*, 2021 WL 5812064, at *4–6 (S.D. Fla. Oct. 26, 2021), report and recommendation adopted, 2021 WL 5810659 (S.D. Fla. Dec. 7, 2021); *Khalek v. S. Denver Rehab., LLC*, 543 F. Supp. 3d 1019, 1027–28 (D. Colo. 2021); *Lopez v. Life Care Centers of Am., Inc.*, 2021 WL 1121034, at *10–13 (D.N.M. Mar. 24, 2021); *Robertson v. Big Blue Healthcare, Inc.*, 523 F. Supp. 3d 1271, 1284 (D. Kan. 2021); *Lyons v. Cucumber Holdings, LLC*, 520 F. Supp. 3d 1277, 1286 (C.D. Cal. 2021); *Grohmann v. HCP Prairie Vill. KS OPCO LLC*, 516 F. Supp. 3d 1267, 1280–81 (D. Kan. 2021); *Dupervil v. Alliance Health Ops., LCC*, 516 F. Supp. 3d 238, 255–56 (E.D.N.Y. 2021), *vacated as moot*, 2022 WL 3756009 (2d Cir. Aug. 1, 2022); *Hatcher v. HCP Prairie Vill. KS OPCO LLC*, 515 F. Supp. 3d 1152, 1159–62 (D. Kan. 2021); *Arbor Mgmt. Servs., LLC v. Hendrix*, 875 S.E.2d 392, 397 (Ga. Ct. App. 2022); *Hansen v. Brandywine Nursing & Rehab. Ctr., Inc.*, 2023 WL 587950, at *5–8 (Del. Super. Ct. Jan. 23, 2023), *appeal refused*, 294 A.3d 64, 2023 WL 2544241 (Del. Mar. 16, 2023); *Whitehead v. Pine Haven Operating LLC*, 75 Misc. 3d 985, 991–92 (N.Y. Sup. Ct. 2022).

A. The PREP Act applies only to claims alleging that the use or administration of a covered countermeasure caused injury to an individual.

"In ascertaining [a] statute's plain meaning, the proper interpretation of a word depends upon reading the whole statutory text, considering the purpose and context of the statute, and consulting any precedent or authorities that inform the analysis." *United States v. Figueroa-Labrada*, 780 F.3d 1294, 1298 (10th Cir. 2015) (cleaned up). Here, the PREP Act's text, purpose, and context confirm that only claims with a causal relationship to the actual use of covered countermeasures, and not claims based on a negligent failure to use covered countermeasures, fall within the statute's scope.

The immunity provision of the PREP Act applies only to "claim[s] for loss that ha[ve] a causal relationship with the administration to or use by an individual" of a covered countermeasure. 42 U.S.C. § 247d-6d(a)(2)(B). Cantex bases its brief argument that claims about generally negligent infection control measures fall within the scope of the statute on the word "administration," suggesting all decisionmaking related to pandemic control constitutes "administration." *See* Appellants' Br. 60–61. But the presence of the prepositions "to" and "by an individual" makes

Cantex's broad interpretation of the statute untenable. To "administer" can mean "to manage or supervise the execution, use, or conduct of" something, or it can mean "to provide or apply: DISPENSE." Merriam-Webster Online Dictionary.[6] Here, only the latter definition of the word makes sense. When a facility does *not* use a covered countermeasure, it is not administering a covered countermeasure *to an individual*, nor is a countermeasure being used *by an individual*. And when someone dies because a covered countermeasure was not used, their death was not *caused by* the use of a covered countermeasure by an individual, as the statute requires.

Other statutory provisions confirm that the Act cannot sensibly be read to apply where an injury was caused by a countermeasure's *non*-administration or use. For instance, the statute provides for immunity "only if" a countermeasure was "administered or used" during the period of the declaration, for the condition specified in the declaration, and "administered to or used by" an individual within the population or area specified in the declaration. 42 U.S.C. § 247d-6d(a)(3). Similarly,

[6] https://www.merriam-webster.com/dictionary/administer.

healthcare professionals may obtain immunity only if authorized to administer countermeasures "under the law of the State in which the countermeasure was prescribed, administered, or dispensed." *Id.* § 247d-6d(i)(8)(A). These provisions cannot function if the statute applies, as Cantex suggests, where there is no allegation that the injury was caused by the affirmative administration or use of a covered countermeasure to anyone. *See also id.* § 247d-6d(e)(3) (listing elements of a subsection (d) claim that must be pleaded with particularity, including "the covered countermeasure administered to or used by the person on whose behalf the complaint was filed").

If the PREP Act's text left any ambiguity as to its scope, its purpose confirms that it applies only where an injury was caused by actual use—not non-use—of covered countermeasures. The PREP Act was intended to encourage the manufacture, distribution, and use of covered countermeasures. *See Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 3d 518, 529 (D.N.J. 2020) (noting statute's "evident purpose is to embolden caregivers, permitting them to administer certain encouraged forms of care (listed COVID 'countermeasures') with the assurance that they will not face liability for having done so"), *aff'd on other grounds*, 16

F.4th 393. Supporters explained that the bill would ensure that a pandemic flu "vaccine gets developed and [that] doctors are willing to give it." 151 Cong. Rec. H12244-03 (daily ed. Dec. 18, 2005) (statement of Rep. Deal); Assessing the Nat'l Pandemic Flu Preparedness Plan: Hearing Before the H. Comm. on Energy & Commerce, Serial No. 109-59 at 20 (Nov. 8, 2005) (statement of HHS Secretary Leavitt) ("[T]he threat of liability exposure is too often a barrier to willingness to participate in the vaccine business.").[7] Likewise, a 2020 amendment to the PREP Act expanding the scope of potential covered countermeasures to include certain respiratory protective devices, Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, § 3103, 134 Stat. 281, 361, was designed to "boost the availability and supply of critically needed respirator[] [masks]." 166 Cong. Rec. H1675-09 (daily ed. Mar. 13, 2020) (statement of Rep. Walden); *see also* Coronavirus Preparedness and Response: Hearing Before the H. Comm. on Oversight & Reform, Serial No. 116-96 at 43 (Mar. 11, 2020) (testimony of HHS Asst. Secretary

[7] https://www.govinfo.gov/content/pkg/CHRG-109hhrg26891/pdf/CHRG-109hhrg26891.pdf.

Kadlec, urging addition of respiratory protective devices to boost supply).[8] Immunity from suit for injuries resulting from the affirmative administration or use of covered countermeasures encourages production and use of those countermeasures. By contrast, immunity for decisions *not* to administer or use covered countermeasures "would defeat the basic purpose of the statute." *Martin v. Petersen Health Ops., LLC*, 2021 WL 4313604, at *10 (C.D. Ill. Sept. 22, 2021), *aff'd*, 37 F.4th 1210.

Throughout 2020, Congress debated—but did not enact—liability protections for claims like the Estates'. *See*, *e.g.*, 166 Cong. Rec. S2358 (daily ed. May 12, 2020) (statement of Sen. McConnell, discussing legislation to "raise the liability threshold for COVID-related malpractice lawsuits" and to "create a legal safe harbor" for entities "following public health guidelines to the best of their ability"). The debate over whether to immunize entities that failed to take adequate infection control measures indicates that the PREP Act did not already provide immunity.

[8] https://www.govinfo.gov/content/pkg/CHRG-116hhrg40428/pdf/CHRG-116hhrg40428.pdf.

B. Administrative authority does not support Cantex.

Cantex suggests that the Fourth Amendment to the Secretary's PREP Act Declaration somehow expanded the scope of PREP Act immunity to the claims here. *See* Appellants' Br. 60. As the Sixth Circuit recently explained in rejecting a similar argument, it does not even purport to do so.

In the Fourth Amendment, the Secretary modified the definition of the term "Administration of the Covered Countermeasure" as used in his Declaration to refer to:

> physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for the purpose of distributing and dispensing countermeasures.

85 Fed. Reg. at 79,197, *cited in* Appellants' Br. 60. He further specified that "[w]here there are limited Covered Countermeasures, not administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute 'relating to … the administration to … an individual' under 42 U.S.C. 247d-6d," where such non-administration reflects "prioritization or purposeful allocation … particularly if done in accordance with a public health authority's

directive." *Id.* In the accompanying preamble text, the Secretary explained this change was intended "to make explicit that there can be situations where not administering a covered countermeasure to a *particular individual* can fall within the PREP Act and this Declaration's liability protections." *Id.* at 79,194 (emphasis added).

This text does not purport to broaden the applicability of the statutory immunity to injuries other than those with a causal relationship to the administration to or use by an individual of a covered countermeasure, nor could it. As the Sixth Circuit explained, this amended language reflects the Secretary's view that the PREP Act may provide immunity where injuries were caused in the course of distributing and dispensing of covered countermeasures, even if the countermeasure itself is not the direct cause. *Hudak*, 58 F.4th at 856–57. It "does not suggest that the term 'administration' extends to all activities associated with the management or operation of a facility," or "that the statute confers immunity for injuries unrelated to [a facility's] provision of the covered countermeasure solely because it provides countermeasures." *Id.* at 856–57. Thus, contrary to Cantex's suggestion, Appellants' Br. 61 n.17, even under the Fourth Amendment, a facility's

administration of covered countermeasures to someone, somewhere, is irrelevant to PREP Act immunity when the plaintiff does not allege that such "distribution or dispersal of countermeasures" caused the decedent's death. *Hudak*, 58 F.4th at 857.

Accordingly, the Fourth Amendment does not help Cantex here, where, in Cantex's own words, the plaintiffs allege that their loved ones died because of Defendants' "allegedly failing to screen (i.e., diagnose) all residents, staff, vendors, and visitors for COVID-19, and failing to consistently follow and enforce policies and procedures, as well as federal and state guidelines pertaining to the use of personal protective equipment, to mitigate the spread of COVID-19." Appellants' Br. 60 (citing App. Vol. 1 at 54–55). These are not allegations that the decedents died because Cantex purposefully allocated, and "administered to" others, any of the specific drugs and devices deemed covered countermeasures. Nor do they suggest that something Cantex did for the purpose of distributing and dispensing countermeasures to other individuals caused their loved ones to die. They are allegations of general neglect. *See Estate of McCalebb v. AG Lynwood, LLC*, 2021 WL 911951,

at *5 (C.D. Cal. Mar. 1, 2021) (concluding that claims of "general neglect" do not fall within the scope of the statute, even under HHS's view).[9]

For all these reasons, Cantex's reliance on the Fourth Amendment to the Secretary's PREP Act Declaration is misplaced.

[9] In any event, HHS's view is owed no deference because the text and purpose of the PREP Act unambiguously demonstrate that only claims based on injuries caused by the actual administration to or use by an individual of a covered countermeasure fall under the statute. *See Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 175 (2016) (stating "we do not defer to the agency when the statute is unambiguous"). Even were there ambiguity, moreover, there is no evidence "that Congress delegated authority to the agency generally to make rules carrying the force of law." *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001). Rather, Congress delegated to the Secretary authority to issue a declaration "recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended." 42 U.S.C. § 247d-6d(b)(1). Congress did not give HHS the power to define the terms "administration" or "use." *Cf. id.* § 247d-6d(c)(2)(A) (providing rulemaking authority to define "willful misconduct").

CONCLUSION

The decision of the district court should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) and 32(a)(7)(B) because, excluding the parts of the brief exempted by Rule 32(f) and the Rules of this Court, it contains 6,458 words.

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Rule 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word for Microsoft 365 MSO in 14-point Book Antiqua.

August 2, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on August 2, 2023, I electronically filed the forgoing using the court's CM/ECF system which will send notification of such filing to the following:

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