No. 20-3287

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

VANESSA SHEROD,
Plaintiff-Appellee,

v.

COMPREHENSIVE HEALTHCARE MANAGEMENT SERVICES, LLC,
Defendant-Appellant.

Appeal from the United States District Court
for the Western District of Pennsylvania
Case No. 2:20-cv-01198
Hon. Arthur J. Schwab

BRIEF OF AMICUS CURIAE PUBLIC CITIZEN IN SUPPORT OF PLAINTIFF-APPELLEE

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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 there is no publicly held corporation that owns 10% or more of Public Citizen.

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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 enactment and enforcement of laws to protect consumers, workers, and the public, including by advocating for policies to improve and protect workplace safety. Among other things, Public Citizen works to support individuals' ability to access the civil justice system to hold corporations and the government accountable for wrongdoing, and it often appears as amicus curiae to address issues such as federal-court jurisdiction, statutory interpretation, and preemption. Public Citizen appeared in this Court as amicus curiae in *Estate of Maglioli v. Alliance HC Holdings LLC*, 16 F.4th 393 (3d Cir. 2021), where this Court considered, and rejected, many of the arguments that Appellant makes here. It has also appeared as amicus curiae in other cases involving nursing homes'

[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.

attempts to remove cases involving COVID-19 infection control to federal court on the basis of the Public Readiness and Emergency Preparedness (PREP) Act and federal-officer removal jurisdiction.

Public Citizen submits this brief because it believes that if accepted, Appellant's 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 [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]

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

The Secretary triggers the PREP Act by issuing a declaration determining that a public health emergency exists and "recommending" 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); *see Maglioli*, 16 F.4th at 400–01 (describing statutory scheme). 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 a carve-out from such immunity for suits brought against covered persons "for death or serious physical injury proximately caused by willful misconduct." *Id.* § 247d-6d(d)(1). 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 District Court for the District of Columbia, *id.* § 247d-6d(e). Critically, however, this exclusive cause of action is available only for claims that otherwise would fall within the immunity provision. Unless a claim would be otherwise barred by subsection (a), it cannot be brought as a subsection (d) claim.

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, HHS Secretary 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). Later, in the Fourth Amendment's preamble, the Secretary opined 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 it reflects "prioritization or purposeful allocation … particularly if done in accordance with a public health authority's directive." 85 Fed. Reg. 79,190, 79,194 (Dec. 9, 2020). He gave as an

example the decision to vaccinate a more-vulnerable individual instead of a less-vulnerable individual. *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) (Appellant's Request for Judicial Notice (RJN), Ex. 27). 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.

In January 2021, the General Counsel issued a fifth advisory opinion. HHS General Counsel, Advisory Opinion 21-01 (Jan. 8, 2021), RJN Ex. 27. 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. He also opined that "substantial federal question" jurisdiction, recognized in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005), applies to any case where a defendant invokes the PREP Act. *Id.* at 4–5. Like the previous advisory opinions, Opinion 21-01 states that it "sets forth the current views" of OGC, is "not a final agency action or a final order," and "does not have the force or effect of law." *Id.* at 5.

SUMMARY OF ARGUMENT

Appellee Vanessa Sherod brought state-law claims against Appellant Comprehensive Healthcare Management Services, LLC, d/b/a Brighton Rehabilitation and Wellness Center (Brighton), alleging that the death of her mother, Elizabeth Wiles, was caused by Brighton's longstanding inadequate staffing, sanitation, and infection-control practices. In arguing for federal jurisdiction over these claims, Brighton largely recycles arguments that its counsel made to this Court in *Maglioli*—arguments that this Court rejected.

As to federal-officer removal and embedded-federal-question (or *Grable*) jurisdiction, Brighton's primary arguments are that *Maglioli* was wrongly decided. *Maglioli*, however, is binding precedent, and its holdings on these questions are correct. Indeed, *Maglioli* has already been approvingly cited in opinions issued by unanimous decisions of other Circuits reaching the same conclusions in similar cases. And there is no relevant distinction between this case and *Maglioli*.

As to complete preemption, Brighton appears to argue both that *Maglioli*'s complete preemption analysis is incorrect and that this action falls into the narrow category of cases that this Court held *could* be completely preempted by the PREP Act: i.e., those that could be brought pursuant to the exclusive cause of action created by the statute. Again, *Maglioli* is both binding precedent and consistent with subsequent decisions of three other courts of appeals holding that the PREP Act does not completely preempt all covered-countermeasure-related claims. Ms. Sherod's claims do not meet the *Maglioli* standard for complete preemption because she could not have brought them pursuant to PREP Act subsection (d). As *Maglioli* held, where a plaintiff, like Ms. Sherod here, does not allege that a defendant acted intentionally to achieve a

wrongful purpose and knowingly without legal or factual justification, a subsection (d) claim is unavailable. Additionally, the subsection (d) cause of action is available only for claims relating to administration to or use by an individual of a covered countermeasure. As the district court held, claims of inadequate infection control like those alleged here do not relate to the administration or use of a covered countermeasure and, therefore, are not completely preempted by the PREP Act. That holding is consistent with recent decisions of two courts of appeals and dozens of district courts,

ARGUMENT

I. Brighton's federal-officer argument is barred by *Maglioli* and wrong.

In *Maglioli*, this Court explained that the pandemic did not convert all of the nation's nursing homes into federal agents. *See Maglioli*, 16 F.4th at 400 ("There is no COVID-19 exception to federalism."). There, the nursing home defendants argued that guidance documents issued by the Centers for Disease Control (CDC) and Centers for Medicare and Medicaid Services (CMS) showed that all of the nation's nursing homes were "acting under" the direction of those agencies. *See* Brief of Appellants, *Maglioli v. Alliance HC Holdings LLC*, Nos. 20-2833/20-2834

(Feb. 8, 2021), at 26–29. This Court disagreed, finding that those documents failed to demonstrate the "'unusually close'" relationship with CMS or CDC" required to trigger federal-officer removal jurisdiction under the Supreme Court's decision in *Watson v. Philip Morris Cos.*, 551 US. 142, 153 (2007). *Maglioli*, 16 F.4th at 405.

Brighton makes the same arguments here, asserting that "*Maglioli* overlooked authority that establishes the term 'guidance' … is viewed by the HHS as interchangeable with the term 'directive.'" Appellant's Br. 49–50. To begin with, even if *Maglioli* "overlooked" something, it remains binding precedent absent en banc reconsideration or intervening Supreme Court decisions. *See Karns v. Shanahan*, 879 F.3d 504, 514 (3d Cir. 2018). Neither criterion is met here. *See* Feb. 7, 2022, Order, *Maglioli v. Alliance HC Holdings*, Nos. 20-2833/20-2844 (denying pet. for rehearing en banc).

Further, *Maglioli*'s holding was not based on the distinction between non-binding guidance and binding directives. Rather, the Court held that "[e]ven assuming the nursing homes are subject to intense regulation, that alone does not mean they were 'acting under' federal officers." 16 F.4th at 405. At most, the documents Brighton points to, like

those addressed in *Maglioli*, constitute "a more specific level of regulation" than the regulation by CMS that had existed before the pandemic. *Id.* at 406. But "[a] 'more specific level of regulation' is simply a difference in the degree of regulatory detail," and insufficient to serve as a basis of federal-officer removal jurisdiction. *Id.*

Brighton also argues that the nation's nursing homes were "deputized" by HHS because HHS guidance indicated that senior living communities could qualify as "program planners," as that term is used in the PREP Act. *See* Appellants Br. 55–56; *but see Maglioli*, 16 F.4th at 405 (holding that nursing homes were "not delegated federal authority, nor do they provide a service that the federal government would otherwise provide").[3] Brighton misunderstands the significance of the term "program planner," which has nothing to do with "deputization." "Program planner" is one of the categories of entities included in the statutory definition of the term "covered person." 42 U.S.C. § 247d-6d(i)(2). That an entity is a program planner simply means that the entity is eligible to invoke the PREP Act immunity defense, when

[3] Brighton states that it was "formally declared" a program planner, Appellant's Br. 55, but the cited material does not show that statement to be correct.

applicable. *Id.* § 247-d-6d(a)(1). The designation, however, does not place the entity into a subservient relationship with the federal government. The broad statutory definition of "program planner"—which includes virtually every state, local, and tribal government and public health employee thereof—itself belies Brighton's theory that a program planner is an HHS deputy.

While *Maglioli* was the first court of appeals decision to reject nursing homes' arguments that they were delegated federal authority by virtue of the federal response to the pandemic, three additional courts of appeals have since reached the same conclusion, explicitly citing this Court's application of *Watson* and rejecting the arguments Brighton repackages here. *See Martin v. Petersen Health Ops., LLC*, 37 F.4th 1210, 1212 (7th Cir. 2022); *Mitchell v. Advanced HCS, LLC*, 28 F.4th 580, 589–91 (5th Cir. 2022); *Perez v. Southeast SNF, LLC*, 2022 WL 987187, at *2 (5th Cir. Mar. 31, 2022); *Saldana v. Glenhaven Healthcare LLC*, 27 F.4th 679, 685 (9th Cir. 2022), *reh'g & reh'g en banc denied* (9th Cir. Apr. 18, 2022); *see also Glenn v. Tyson Foods, Inc.*, --- F.4th ---, 2022 WL 2525724, at *4 (5th Cir. July 7, 2022) (citing *Maglioli* approvingly in rejecting meatpacking company's claim that it was acting under federal officers in

operating during COVID-19 pandemic); *Buljic v. Tyson Foods, Inc.*, 22 F.4th 730, 740 (8th Cir. 2021) (same). Brighton identifies no meritorious basis for this Court to revisit its decision and depart from this consensus. *Cf. Bastardo-Vale v. Att'y Gen. U.S.*, 934 F.3d 255, 267 (3d Cir. 2019) (en banc) (noting unanimity of circuits is relevant in determining whether en banc court should overrule precedent).

II. Brighton's *Grable* argument is barred by *Maglioli* and Supreme Court precedent.

Brighton's *Grable* argument is not meaningfully distinguishable from the argument rejected in *Maglioli*. As in that case, the argument includes citations to inapposite First Circuit authority, heavy reliance on HHS's views about *Grable* jurisdiction, and a suggestion that the PREP Act's scheme somehow creates *Grable* jurisdiction. *Compare* Appellant's Br. 61–65, with *Maglioli* Appellants' Br. 61–65. This Court rejected those arguments in a precedential decision. *See* 16 F.4th at 403–04 (explaining why HHS's views on jurisdiction lack any persuasive value); *id.* at 413 (rejecting arguments that the PREP Act is an essential element of state-law claims).

Brighton briefly argues that this case is distinguishable from *Maglioli* because "the entire thrust of Plaintiff's complaint is that

Brighton should have taken more or different measures than they were mandated to by federal directives, or failed to comply with federal law by allegedly failing to take certain precautions" and because "Plaintiff's claims are inextricably intertwined with Defendants' response to the directives and guidance from CDC and CMS." Appellant's Br. 64. To start, that characterization of Ms. Sherod's claims does not distinguish this case from *Maglioli*: Brighton's counsel said the same thing, using the same words, in its brief in that case. *See Maglioli* Appellants' Br. 63 ("Plaintiffs' claims are inextricably intertwined with Defendants' response to the directives and guidance from CDC and CMS.").

Moreover, Brighton's argument is inconsistent with the Supreme Court's decision in *Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804, 817 (1986). There, the Court held that a complaint alleging a violation of a federal statute as an element of a state cause of action" does not itself state a federal question. The Court expressly reaffirmed that holding in *Grable*, noting that plaintiffs' allegations of violations of federal statutes and regulations as evidence of negligence per se in state-court cases do not convert the state-law claims into federal ones. *Grable*, 545 U.S. at 318–19; *see also Bennett v. Sw. Airlines Co.*, 484 F.3d 907,

912 (7th Cir. 2007) ("That some standards of care used in tort litigation come from federal law does not make the tort claim one 'arising under' federal law."). Because a violation of federal law is not an essential element of any of Ms. Sherod's claims, there is no federal jurisdiction under *Grable*.

III. Brighton's complete preemption argument lacks merit.

Maglioli held that a plaintiff's state-law claims are completely preempted by the PREP Act only when they could have been brought "under the PREP Act's cause of action for willful misconduct." 16 F.4th at 393. Notwithstanding this Court's ruling, Brighton devotes several pages of its brief to arguing that *all* claims involving covered countermeasures are completely preempted by the PREP Act. In so doing, it repeats the arguments advanced and rejected in *Maglioli*—including that the Court owes deference to HHS's views and that the PREP Act's compensation fund completely preempts state-law claims. *Compare* Appellant's Br. 16–26, with *Maglioli*, 16 F.4th at 403–04 (rejecting the deference argument); 412 (rejecting the compensation fund argument as "even less plausible" than other arguments). As with Brighton's federal-officer and *Grable* arguments, this argument too is barred by *Maglioli*,

and has been rejected by every court of appeals to address it. *See Manyweather v. Woodlawn Manor, Inc.*, --- F.4th ---, 2022 WL 2525732, at *3–4 (5th Cir. July 7, 2022); *Martin*, 37 F.4th at 1213–14; *Mitchell*, 28 F.4th at 586–88; *Saldana*, 27 F.4th at 687–88. As these opinions reflect, Brighton's argument is wrong.

Brighton's argument that this action is completely preempted under the standard set out in *Maglioli* also fails. As an "exception to the immunity from suit and liability of covered persons set forth in subsection (a)," 42 U.S.C. § 247d-6d(d)(1), the subsection (d) cause of action is available only for "claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure," *id.* § 247d-6d(a)(1). Where such a claim is "for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c)," the subsection (d) cause of action is available.

Under *Maglioli*, the claims in this case do not meet the "willful misconduct" requirement and thus could not have been brought as subsection (d) claims. And even if Ms. Sherod were seeking to recover for

action and inaction taken with the degree of intent required by the PREP Act, as the Fifth and Seventh Circuits have explained, the claims could not have been brought as subsection (d) claims for the additional reason that they are not ones for loss caused by the administration or use of a covered countermeasure. For both reasons, Ms. Sherod's claims cannot be completely preempted.

A. Ms. Sherod did not plead "willful misconduct" as defined by the PREP Act.

Under the statute, "willful misconduct" is defined as an act or omission 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." 42 U.S.C. § 247d-6d(c)(1)(A). Accordingly, in *Maglioli*, the Court held that only where a plaintiff "allege[s] or impl[ies]" that the act or omission giving rise to the claims met each of these three elements can the claim be completely preempted. 16 F.4th at 411.

Here, the complaint does not contain the required allegations or implications. Arguing otherwise, Brighton points to the allegation that Brighton acted in a "willful, reckless and wanton fashion with a conscious

indifference" to the rights of the public and Ms. Wiles. 2 AA 70, *cited in* Appellant's Br. 25. But *Maglioli* explicitly held that an allegation that a nursing home "engaged in 'conduct that was grossly reckless, willful, and wanton'" was *not* sufficient to demonstrate the subject claims could have been brought pursuant to subsection (d), as such a "fleeting statement" did not allow the Court to infer that the plaintiff alleged "the nursing homes acted with intent 'to achieve a wrongful purpose,' or with knowledge that their actions lacked 'legal or factual justification.'" 16 F.4th at 411 (quoting 42 U.S.C. § 247d-6d(c)(1)(A)). The allegation is not meaningfully different from the allegation addressed by the Court in *Maglioli*.

Nonetheless, Brighton argues that "the standards for willful and wanton misconduct under Pennsylvania law closely track the elements of the PREP Act's cause of action for willful misconduct." Appellant's Br. 15. Brighton is correct that a Pennsylvania willful misconduct claim "requires a culpable mental state involving *intentional* conduct that is *wrongful*." Appellant's Br. 15 (citing *Evans v. Philadelphia Transp. Co.*, 418 Pa. 567, 574 (1995)). Unlike the PREP Act, however, the state-law claim does *not* require an intent to achieve a wrongful *purpose*, much less

that the act have been taken knowingly without legal or factual justification. That is, the allegation of the state-law claim does not meet all elements of the PREP Act cause of action.

B. Because the claims are not related to the use or administration of covered countermeasures, they could not be brought under the PREP Act cause of action.

Ms. Sherod's claim is not a subsection (d) claim for the additional reason that, as the district court held, her "negligence, misrepresentation, wrongful death and survivor claims are not causally connected to Brighton's use of covered countermeasures" and thus "do not fall within the purview of the PREP Act." 1 AA 16; *see also Manyweather*, 2022 WL 2525732, at *5 (holding that, even assuming "plaintiffs did mean to plead a willful-misconduct claim," subsection (d) could not preempt a claim based on the failure to administer or use covered countermeasures).

Ms. Sherod does not allege that her mother died because of "the administration to or the use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(1). Rather, she alleges that her mother died as a result of longstanding staffing, sanitation, and infection-control practices that "regularly exposed residents and workers to

unsanitary and unsafe conditions known to increase the risk of the spread of infectious disease." 2 AA 54. The only relationship such claims conceivably have with covered countermeasures are their *non*-use—contrary to the Secretary's recommendations. As the Seventh Circuit recently held, such claims "are not even arguably preempted" by the PREP Act. *Martin*, 37 F.4th at 1213. The statute is wholly inapplicable "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, which is the focus of the PREP Act." *Gwilt v. Harvard Sq. Ret. & Assisted Living*, 537 F. Supp. 3d 1231, 1240 (D. Colo. 2021).[4]

[4] *Accord, e.g., Cagle v. NHC HealthCare-Maryland Heights, LLC*, 2022 WL 2833986, at *8 (E.D. Mo. July 20, 2022); *In re CIM-SQ Transfer Cases*, 2022 WL 2789808, at *6 (N.D. Cal. July 15, 2022); *Arbor Mgmt. Servs., LLC v. Hendrix*, 2022 WL 2234983, at *4 (Ga. Ct. App. June 22, 2022); *Whitehead v. Pine Haven Operating LLC*, 2022 WL 2071025, at *4 (N.Y. Sup. Ct. June 8, 2022); *Harris v. Allison*, 2022 WL 2232525, at *9–10 (N.D. Cal. May 18, 2022); *Estate of Spring v. Montefiore Home*, 2022 WL 1120381, at *4–5 (N.D. Ohio Apr. 14, 2022); *Hampton v. California*, 2022 WL 838122, at *10–11 (N.D. Cal. Mar. 20, 2022); *Rosen v. Montefiore*, 2022 WL 278106, at *4 (N.D. Ohio Jan. 31, 2022); *Ruiz v. ConAgra Foods Packaged Foods, LLC*, 2021 WL 3056275, at *4 (E.D. Wisc. July 20, 2021); *Roderick v. Life Care Centers of Am.*, 2021 WL 6337496, at *2 (E.D. Tenn. Apr. 30, 2021); *Stone v. Long Beach Healthcare Ctr.*, 2021 WL 1163572, at *4–5 (C.D. Cal. Mar. 26, 2021);

As Judge Easterbrook explained in *Martin*, an allegation of *non*-use "is the opposite of a contention that a covered countermeasure caused harm." 37 F.4th at 1214. And the statutory text and purpose make clear that the PREP Act applies only where a plaintiff claims that *use* of a covered countermeasure caused injury. *See United States v. Smukler*, 991 F.3d 472 (3d Cir. 2021) (holding that, to determine a statute's meaning, this Court "rel[ies] on [its] 'toolkit' containing 'all the standard tools of interpretation' used to 'carefully consider the text, structure, and purpose' of the statute." (quoting *Kisor v. Wilkie*, 138 S. Ct. 2400, 2414–15 (2019)).

1. The statutory text limits its applicability to claims with a causal relationship to the affirmative use of covered countermeasures.

"Statutory interpretation … begins with the text." *Ross v. Blake*, 578 U.S. 632, 638 (2016). Here, the PREP Act's text makes plain that only claims with a causal relationship to actual use of covered

Lopez v. Life Care Ctrs. of Am., 2021 WL 1121034, at *7–15 (D.N.M. Mar. 24, 2021); *Robertson v. Big Blue Healthcare, Inc.*, 523 F. Supp. 3d 1271, 1281–86 (D. Kan. 2021); *Lyons v. Cucumber Holdings, LLC*, 520 F. Supp. 3d 1277, 1286 (C.D. Cal. 2021); *Dupervil v. Alliance Health Ops., LCC*, 516 F. Supp. 3d 238, 255–56 (E.D.N.Y. 2021); *Eaton v. Big Blue Healthcare*, 480 F. Supp. 3d 1184, 1192–95 (D. Kan. 2020).

countermeasures fall within the statute's scope. *See* 42 U.S.C. § 247d-6d(a)(2)(B).

Brighton asserts that the PREP Act applies to any claims that relate to "the administration or use of covered countermeasures to mitigate or prevent a pandemic or to limit the harm such pandemic might otherwise cause." Appellant's Br. 28. This assertion ignores important words in the text—providing immunity only for claims relating to the "administration *to* or use *by an individual*" of a covered countermeasure. 42 U.S.C. §§ 247d-6d(a)(1), (2)(B) (emphasis added). Restoring these words shows that Brighton relies on the incorrect meaning of the word "administration." To "administer" something can mean "to manage or supervise the execution, use, or conduct of," or it can mean "to provide or apply; dispense." Merriam-Webster.com Dictionary.[5] By altering the plain text of the statute, Brighton appears to invoke the former definition. But when the statute is read as written, only the latter definition makes sense, given the use of the prepositions "to" and "by," and the inclusion of the term "an individual." When a facility decides not

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

to use a covered countermeasure, it may be administering its policies, but it is not *administering* a covered countermeasure *to an individual*, nor is a countermeasure being *used by an individual*. And, as the Fifth Circuit has held, although the term "relating to" is broad, it must be construed in accordance with the "scope of claims for loss" provision, § 247d-6d(a)(2)(B), which requires a "causal relationship with the administration to or use by an individual of a covered countermeasure" for the statute to apply. *Manyweather,* 2022 WL 2525732, at *5. A relationship with *non*-use of countermeasures is insufficient. *See id.*

If there were any doubt that a subsection (d) claim is not available for claims based on injuries caused by non-use of covered countermeasures, it would be eliminated by subsection (e), which sets forth requirements for bringing subsection (d) claims. Subsection (e)(3)(A) requires a willful-misconduct plaintiff to plead with particularity, among other things:

> 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.

42 U.S.C. § 247d-6d(e)(3)(A) (emphasis added). And a plaintiff must submit proof that the underlying "injury or death was proximately

caused by the administration or use of a covered countermeasure." *Id.* § 247d-6d(e)(4)(C)(i). Neither of these requirements can be met where the wrong alleged is a *failure* to use a covered countermeasure. *See also* 42 U.S.C. § 247d-6d(a)(3) (limiting immunity to situations where countermeasure was "administered or used" during certain time period and "administered to or used by" individual within specified population); *id.* § 247d-6d(i)(8)(A) (specifying licensed health professionals may invoke statutory protections only if authorized to administer countermeasures "under the law of the State in which the countermeasure was prescribed, administered, or dispensed").

2. Immunity for claims based on use (but not non-use) is consistent with the statutory purpose.

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 that the 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 was designed to ensure that a

pandemic flu "vaccine gets developed and to make sure doctors are willing to give it when the time comes." 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) ("[A]s we seek to build domestic [vaccine] manufacturing capacity, we also know that the threat of liability exposure is too often a barrier to willingness to participate in the vaccine business. … [T]he Administration is proposing limited liability protections for vaccine manufacturers and providers.").[6] 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, § 3101, 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

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

& Reform, Serial No. 116-96 at 43 (2020) (testimony of HHS Asst. Secretary for Preparedness and Response Robert Kadlec, urging addition of respiratory protective devices in order to boost supply).[7]

Providing immunity from suit for injuries resulting from the affirmative administration or use of covered countermeasures encourages production and use of those countermeasures. By contrast, providing 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 (C.D. Ill. Sept. 22, 2021), at *10, *aff'd*, 37 F.4th 1210.[8]

3. HHS interpretations do not establish that the PREP Act applies here.

Brighton relies heavily on documents issued by HHS that it claims support its view that the PREP Act applies to the allegations here. Appellant's Br. 30–33. But HHS has never stated that claims like Ms.

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

[8] HHS regulations regarding the administrative compensation scheme, promulgated pursuant to its rulemaking authority under 42 U.S.C. § 247d-6e(b)(4), reflect a similar understanding by specifying that only "injured countermeasure *recipients*" are eligible for compensation. 42 C.F.R. § 110.10(a) (emphasis added).

Sherod's fall within the scope of the PREP Act. To the contrary, in a Statement of Interest filed in a Tennessee district court, the United States explicitly *declined* to opine whether claims similar to Ms. Sherod's fell within the scope of the PREP Act, limiting its views to the question whether the PREP Act is a "complete preemption" statute generally. *See* Statement of Interest of the United States at 11 n.4, *Bolton v. Gallatin Ctr. for Rehab. & Healing, LLC*, No. 3:20-cv-00683 (M.D. Tenn. Jan. 19, 2021), RJN Ex. 28 (stating that "it may be that the complaint [in *Maglioli*, which alleged negligent infection control measures generally,] raised only claims outside subsection (a)'s ambit (*i.e.*, claims that were not subject to complete preemption) such that it was correct to remand that case"). Brighton's suggestion that HHS had taken the contrary position in earlier statements is unsupported by the documents it cites.[9]

[9] Because nothing HHS has said addresses the allegations in this case, the Court need not address whether HHS's views deserve deference. In any event, because the statutory text and purpose are unambiguous, the agency's views on the scope of the PREP Act are owed no deference. *See Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 175 (2016). In addition, *Chevron* deference would not be applicable because HHS's statements did not purport to be exercises of delegated authority "to make rules carrying the force of law" about the meaning of subsection (a)(1) of the PREP Act. *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001). Finally, whether HHS's statements, which reflect no analysis

Brighton cites Advisory Opinion 20-01 as stating that "'any activity that is part of an authorized emergency response' … [is] protected by PREP Act immunity from liability." Appellant's Br. 30–31 (quoting RJN, Exh. 21 at 2). This assertion is inaccurate. The quoted language is from the Advisory Opinion's discussion of the "Limitations on Distribution" provision of the Secretary's initial declaration. There, pursuant to explicit statutory authority, the Secretary had limited PREP Act immunity to claims relating to covered countermeasures obtained through federal contracts or agreements, or as part of activities authorized by certain "Authorit[ies] Having Jurisdiction." 85 Fed. Reg. at 15,202. In the Advisory Opinion, the General Counsel interpreted those "two conditions broadly to include (1) any arrangement with the federal government, or (2) any activity that is part of an authorized emergency response at the federal, regional, state, or local level." RJN Exh. 21 at 2. This statement was not an interpretation of the statutory immunity provision, but rather of the Secretary's additional *limitations* on that immunity.

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of the statute's text or purpose, even has sufficient persuasive value to merit weight under *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944), must necessarily await a case, unlike this one, in which the facts fit the allocation scenario that the statements address.

Brighton also points to three documents that discuss "purposeful allocation" of covered countermeasures, beginning with a statement in the preamble to the Fourth Amendment to the Declaration that "not administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute [conduct] 'relating to … the administration to … an individual' under 42 U.S.C. 247d-6d." Appellant's Br. 31 (quoting 85 Fed. Reg. at 79,197). This is immaterial, as there is no such allegation in this case.

Next, Brighton points to Advisory Opinion 20-04, stating that it "clarifies" that the term "administration" in the statute "encompasses activities related to the 'management and operation' of COVID-19 countermeasure programs and those facilities that provide countermeasures to recipients." Appellant's Br. 31–32 (quoting RJN Ex. 26 at 7). Again, Brighton overstates what the General Counsel said. The cited language is a quotation from a New York trial court opinion, which held that administration "encompasses 'activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the

countermeasure activities.'" RJN Ex. 26 at 7 (quoting *Casabianca v. Mount Sinai Medical Center*, 2014 WL 10413521, at *3 (N.Y. Sup. Ct. Dec. 12, 2014)). The Advisory Opinion noted it agreed with this principle but disagreed with the New York court's conclusion that it did not apply to the facts of that case; it stated that the statutory immunity applied where a provider was "following CDC directions on who[m] to vaccinate when there are limited doses." *Id.* Here, though, Ms. Sherod's claims are based on Brighton's generally inadequate staffing, sanitation, and infection control policies—not activities that "directly relate" to Brighton's administration of covered countermeasures.

Finally, Brighton points to Advisory Opinion 21-01, in which the General Counsel opined that there are "situations where a conscious decision not to use a covered countermeasure could relate to the administration of the countermeasure." RJN, Ex. 27 at 3. Brighton ignores, though, that the General Counsel specifically distinguished "between allocation which results in non-use by some individuals, on the one hand, and nonfeasance, on the other hand, that also results in non-use," and explained that the latter was *not* within the scope of the statute. *Id.* at 4. It is nonfeasance that is alleged here.

At most, these three documents reflect HHS's opinion that the statute applies to claims based on an injury caused by "a failure to administer a covered countermeasure to one individual because it was administered to another individual." *Lyons*, 520 F. Supp. 3d at 1285. Ms. Sherod has made no such allegations. While Brighton asks the Court to assume that "Brighton's COVID-specific programs included allocation of scarce countermeasures," Appellant's Br. 33, the complaint does not allege that misallocation caused Ms. Wiles's death. Rather, the allegations are that Ms. Wiles died as a result of staffing, sanitation, and infection-control policies that pre-dated the pandemic. Such "cases of general neglect" do not fall under the PREP Act, even under the HHS documents on which Brighton relies. *Estate of McCalebb v. AG Lynwood, LLC*, 2021 WL 911951, at *5 (C.D. Cal. Mar. 1, 2021); *see also Padilla v. Brookfield Healthcare Ctr.*, 2021 WL 1549689, at *5–6 (C.D. Cal. Apr. 19, 2021) (explaining irrelevance of Advisory Opinion 21-01 to analogous claims); *Goldblatt v. HCP Prairie Village KS OpCo LLC*, 516 F. Supp. 3d 1251, 1264 (D. Kan. 2021) (similar). Moreover, no allegation or evidence suggests that Brighton's failures to adopt adequate infection-control

measures was the result of compliance with government recommendations.

CONCLUSION

The decision of the district court should be affirmed.

Respectfully submitted,
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July 27, 2022

/s/ Adam R. Pulver
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I hereby certify that on July 27, 2022, the foregoing brief has been served through this Court's electronic filing system upon counsel of record for all parties.

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