No. 21-2959

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

ANITA MARTIN, as Independent Administrator of the Estate of MARLENE HILL, Deceased,

Plaintiff-Appellee,

v.

PETERSEN HEALTH OPERATIONS, LLC, an Illinois Limited Liability Company d/b/a BLOOMINGTON REHABILITATION & HEALTH CARE CENTER,

Defendant-Appellant.

Appeal from the U.S. District Court for Central District of Illinois
No. 1:20-cv-01449
Hon. Joe Billy McDade

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

Scott L. Nelson
Michael T. Kirkpatrick
Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
(202) 588-1000

March 7, 2022

Attorneys for Amicus Curiae Public Citizen

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 21-2959

Short Caption: Anita Martin v. Petersen Health Operations, LLC

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statements be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in the front of the table of contents of the party's main brief. **Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.**

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Attorney's Signature: /s/ Scott L. Nelson Date: 3/7/2022

Attorney's Printed Name: Scott L. Nelson

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☑ **No** ☐

Address: 1600 20th St. NW

Washington, DC 20009

Phone Number: (202) 588-1000 Fax Number: (202) 588-7795

E-Mail Address: snelson@citizen.org

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Attorney's Signature: /s/ Michael T. Kirkpatrick Date: 3/7/2022

Attorney's Printed Name: Michael T. Kirkpatrick

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

Address: 1600 20th St. NW

Washington, DC 20009

Phone Number: (202) 588-1000 Fax Number: (202) 588-7795

E-Mail Address: mkirkpatrick@citizen.org

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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. Public Citizen appears before Congress, regulatory agencies, and courts on a wide range of issues, and works for enactment and enforcement of laws to protect consumers, workers, and the public. Among other things, Public Citizen advocates for policies to improve patient safety and hold health care providers and policymakers accountable for protecting patients, including by supporting individuals' ability to access the civil justice system.

Public Citizen submits this brief because it believes the Appellant's arguments regarding the Public Readiness and Emergency Preparedness (PREP) Act misunderstand the Act and, if accepted, would pose a substantial risk of depriving injured plaintiffs of access to meaningful remedies.

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[1] This brief is accompanied by a Motion for Leave to File as required by Federal Rule of Appellate Procedure 29(a)(3). 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.

INTRODUCTION

This action was brought in Illinois state court by Anita Martin, the representative of the Estate of Marlene Hill, alleging claims of negligence and willful misconduct against Petersen Health Operations, LLC, d/b/a Bloomington Rehabilitation & Health Care Center (collectively Bloomington Rehab), the nursing home where Ms. Hill was living until she died of COVID-19. Ms. Martin alleges that Ms. Hill's death was the result of Bloomington Rehab's failure to take precautions to prevent the spread of COVID-19. Bloomington Rehab removed the case to the United States District Court for the Central District of Illinois, asserting as one of its bases for federal-court jurisdiction that the PREP Act completely preempts Ms. Martin's state-law claims. The district court disagreed, held that it lacked subject-matter jurisdiction on that ground or any other, and remanded the case to state court.

In this appeal, Bloomington Rehab again contends as a basis for federal jurisdiction that Ms. Martin's state-law claims are completely preempted under the PREP Act. As the district court held and for the reasons explained by in the Plaintiff-Appellee's Brief, Bloomington Rehab is wrong. Amicus curiae Public Citizen agrees with Appellee that

the district court's decision should be affirmed in its entirety but files this brief to emphasize one basis for rejecting Bloomington Rehab's complete preemption argument: The state-law claims are not completely preempted by the PREP Act because they do not fall within the scope of the Act's immunity provision, and hence are also outside the scope of the narrow exclusive federal cause of action the statute creates. Because Ms. Martin does not allege that Ms. Hill's death was caused by the affirmative administration to or use by an individual of a covered countermeasure, the immunity provided under the PREP Act does not apply to any of Ms. Martin's claims.

BACKGROUND

The PREP Act

The Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. § 247d-6d, was enacted in 2005 "[t]o encourage the expeditious development and deployment of medical countermeasures during a public health emergency" by "authoriz[ing] 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: Limiting Liability for Medical Countermeasures 1 (updated Jan. 13, 2022), https://crsreports.congress.gov/product/pdf/LSB/LSB10443. To trigger the PREP Act, the Secretary issues 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 specific conditions. 42 U.S.C. § 247d-6d(b)(1); *see Maglioli v. All. HC Holdings LLC*, 16 F.4th 393, 400–01 (3d Cir. 2021).

Once the Secretary triggers the PREP Act, section (a) of the Act provides "covered persons" with immunity 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." 42 U.S.C. § 247d-6d(a)(1). Paragraph (2) sets forth the "[s]cope" of this immunity and states that it

> applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a [designated] 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). The term "covered countermeasures" is defined to mean certain drugs, biological products, and devices authorized by HHS for emergency use, *id.* § 247d–6d(i)(1)(A)–(C); *see also id.* § 247d-6d(i)(7), as well as certain respiratory protective devices approved by the National Institute of Occupational Safety and Health (NIOSH), *id.* § 247d–6d(i)(1)(D). The term "covered person," "when used with respect to the administration or use of a covered countermeasure," is defined as:

> (A) the United States; or (B) a person or entity that is—(i) a manufacturer of such countermeasure; (ii) a distributor of such countermeasure; (iii) a program planner of such countermeasure; (iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or (v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

Id. § 247d-6d(i)(2).

An exception to the PREP Act's immunity provision is set forth in subsection (d) of the Act, which provides a narrow carveout from section (a) immunity for certain "willful misconduct" claims, as that term is defined in the statute. *Id.* § 247d-6d(d)(1). For claims within this carveout, the statute creates an "exclusive Federal cause of action," *id.*, and provides special procedures for their adjudication, as well as exclusive jurisdiction in a three-judge court of the United States District

Court for the District of Columbia, *id.* § 247d-6d(e). Critically, though, resort to this exclusive cause of action is necessary only for claims that otherwise would fall within the immunity provision. The subsection (d) cause of action does not displace state causes of action that are outside the scope of the subsection (a) immunity.

The PREP Act also creates an administrative scheme to provide "compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure" subject to a PREP Act declaration. *Id.* § 247d-6e(a). This remedial scheme has no application to cases involving injuries not caused by administration or use of a covered countermeasure.

The COVID-19 PREP Act Declaration, Amendments, and Advisory Opinions

In March 2020, the HHS Secretary 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), A-42.[2] The Declaration recommended the "manufacture, testing, development, distribution, administration, and use" of certain

[2] "A-__" refers to the Appellant's Appendix.

countermeasures to combat COVID-19, *id.* at 15,201, A-45: "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, A-46.

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, 21,014 (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, 79,197 (Dec. 9, 2020), A-75. The Secretary gave as an example

the decision to vaccinate a more-vulnerable individual instead of a less-vulnerable individual. *Id.*

The HHS General Counsel's office has issued multiple advisory opinions relating to the PREP Act. Each advisory opinion specifies that it "sets forth the current views" of the office, is "not a final agency action or a final order," does not "bind HHS or the federal courts," and "does not have the force or effect of law." *E.g.*, Advisory Op. 21-01 at 5, A-81.

ARGUMENT

Ms. Martin's claims are not completely preempted by the PREP Act because they do not fall within the scope of the Act's central immunity provision. Because the alleged claims are outside the scope of the immunity provided under subsection (a) of the Act, they also necessarily fall outside the realm of subsection (d)'s exclusive federal cause of action, cited by Bloomington Rehab in arguing that the PREP Act can give rise to complete preemption.

The PREP Act's operative provisions apply to "any claim for loss that has 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), where the "covered countermeasure" "was administered or used"

consistent with certain conditions, *id.* § 247d-6d(a)(3). Those provisions do not apply to the plaintiff's claims of negligence and willful misconduct because the complaint does not allege that Ms. Hill's death was caused by the administration to or use by an individual of any covered countermeasure. Rather, Ms. Martin's claims relating to policies and practices that do not involve "covered countermeasures" are outside the scope of the PREP Act. And even to the extent that the complaint references measures that could qualify as "covered countermeasures," it refers only to the *non*-use of such measures—claims to which the PREP Act does not apply.

I. The PREP Act is inapplicable to claims that do not involve "covered countermeasures."

The PREP Act applies only to certain claims based on injuries caused by the administration or use of a "covered countermeasure." 42 U.S.C. § 247d-6d(a)(1), (2)(B). Under the statute, only certain drugs, biological products, and devices are eligible to be designated as "covered countermeasures." *Id.* § 247d–6d(i)(1).

Here, the complaint alleges that Bloomington Rehab failed to implement COVID-19 isolation and infection control procedures, maintain adequate nursing staff, and provide Ms. Hill with nursing and

medical care—allegations that do not implicate any drug, device, or product that could qualify as a "covered countermeasure" under the Act. For example, the complaint alleges that Ms. Hill's death was caused by Bloomington Rehab's failure to provide "sufficient levels of staff"; failure "to timely isolate" symptomatic residents; failure to communicate with Ms. Hill's physician and family; and failure to monitor Ms. Hill's vitals. *See* Compl. ¶¶ 142.a–ll, at 29–31; *id.* ¶¶ 156.a–kk, at 44–46. As numerous courts have held, claims based on staffing, isolation, infection control, and monitoring policies and procedures do not relate to the administration or use of "covered countermeasures" under the Act. *See, e.g.*, *Gibbs v. Southeast SNF LLC*, 2021 WL 1186626, at *3 (W.D. Tex. Mar. 30, 2021) ("Plaintiff's allegations that failures to wash hands, follow internal policies and procedures, and adequately staff Southeast do not implicate any countermeasure identified in the PREP Act or added by amendments to the Declaration."); *Ossowski v. St. Joseph Transitional Rehab. Ctr., LLC*, 2021 WL 4699235, at *3 (D. Nev. Oct. 6, 2021) ("Isolation and social distancing measures are not Covered Countermeasures under a plain reading of the statute. Nor have any of the subsequent HHS Secretary Declarations or Amendments included

these protocols as a Covered Countermeasure."). Claims like these "facially rest on an alleged duty arising from or related to proper standards of general medical and nursing care, not the administration or use of certain drugs, biological products, or devices, *i.e.*, the countermeasures covered under the PREP Act." *Dupervil v. Alliance Health Ops., LCC*, 516 F. Supp. 3d 238, 257 (E.D.N.Y. 2021).

II. Claims relating to *non*-use of covered countermeasures are not within the scope of the PREP Act.

The alleged claims are outside the scope of the PREP Act for the additional reason that the complaint does not allege loss caused by the "administration to" or "use by an individual" of a covered countermeasure. 42 U.S.C. §§ 247d-6d(a)(1), (2)(B). Such claims of inaction are unambiguously outside the scope of the PREP Act, as demonstrated by the text, purpose, and history of the statute. The HHS interpretations cited by Bloomington Rehab are based on factual scenarios *not* implicated by the complaint here, and no deference is owed to the agency's statements in any event.

A. The text, purpose, and history of the statute show the PREP Act does not apply to claims of injury based on non-use.

1. The statute unambiguously limits the Act's immunity to claims alleging the affirmative provision of a covered countermeasure.

"Statutory interpretation … begins with the text." *Ross v. Blake*, 578 U.S. 632, 638 (2016). "Statutory terms or words will be construed according to their ordinary, common meaning unless they are specifically defined by the statute or the statutory context requires a different definition." *Precision Indus., Inc. v. Qualitech Steel SBQ, LLC*, 327 F.3d 537, 544 (7th Cir. 2003). "When the words of a statute are unambiguous," the court's "'judicial inquiry is complete.'" *Id.* at 544 (quoting *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253–54 (1992)). If, however, the statutory language "is ambiguous" or would "lead[] to absurd results," the court may consider "legislative history or other sources to glean the legislative intent of the statute." *Preston v. Midland Credit Mgmt., Inc.*, 948 F.3d 772, 783 (7th Cir. 2020) (internal quotation marks and citation omitted).

The PREP Act unambiguously provides immunity only against claims with a causal relationship to the affirmative use of a covered countermeasure: it explicitly requires a "causal relationship with the administration to or use by an individual of a covered countermeasure."

42 U.S.C. § 247-6d(a)(2)(B); *see also id.* § 247-6d(a)(1) (providing that covered persons are immune "with respect to 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"). The Act's willful misconduct carveout in subsection (d) of the Act, in providing a narrow "exception to the immunity … set forth in subsection (a)," *id.* § 247-6d(d)(1), likewise applies only to claims within the scope of subsection (a)—i.e., claims for loss with a "causal relationship with the administration to or use by an individual of a covered countermeasure," *id.* § 247-6d(a)(2)(B).

The phrase "the administration to or use by an individual" in the text of the PREP Act shows that the Act applies only to claims alleging the affirmative provision of a covered countermeasure to a person, or a person's actual use of a covered countermeasure. The Act does not define "administration" or "use." According to the dictionary, "administration" means "the act or process of administering something," *Administration*, Merriam-webster.com Dictionary, https://www.merriam-webster.com/dictionary/administration, and to "administer" means to "provide or apply; dispense," *Administer*, Merriam-webster.com Dictionary, https://

www.merriam-webster.com/dictionary/administer. Something (here, a covered countermeasure) can be administered or "dispense[d]" to a person only if it is provided to that person.

Other provisions in the Act confirm that it applies only to claims related to the affirmative administration or use of a covered countermeasure. For instance, the statute's list of protected activities includes only affirmative acts:

> the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of [a covered] countermeasure.

Id. § 247d-6d(a)(2)(B). The list does not include a failure to act. In addition, the statute provides that immunity "applies only if" the countermeasure was "administered or used" during the period of the declaration, for the health condition specified in the declaration, and "administered to or used by" an individual within the population or geographic area specified in the declaration. *Id.* § 247d-6d(a)(3). Further, licensed health professionals may invoke PREP Act 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) (emphasis added). These provisions would not make sense if the PREP Act applied where a countermeasure was *not* administered to or used by an individual.

Arguing that the PREP Act applies to claims of non-use, Bloomington Rehab omits key words from the statutory text. Bloomington Rehab states (at 38) that the statute provides for immunity for claims "'relating to' the 'administration' or 'use' of covered countermeasures." What the statute actually provides is immunity 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) (emphases added). The words that Bloomington Rehab omits—"to" and "by an individual"—are critical because they show the correct meaning of the term "administration" in the Act. By cherry-picking words from the statutory text, Bloomington Rehab appears to invoke an alternative definition of "administer" that means "to manage or supervise the execution, use, or conduct of." *Administer*, Merriam-webster.com Dictionary. When the statutory provision is quoted in full, however, only the definition of "administer" that means "to provide or apply; dispense" makes sense, given the use of the prepositions "to" and "by," and the

inclusion of the term "an individual." When a facility decides not to use a covered countermeasure, it may be administering its policies, but it is not *administering a covered countermeasure to an individual*, and the countermeasure is not being *used by an individual*. And any resulting claims do not relate to such administration or use.

Bloomington Rehab asserts that the statutory text of the PREP Act permits claims of inaction because the Act "covers 'acts and **omissions**.'" Appellant's Br. 38 (emphasis added by Appellant). The portion of the Act that Bloomington Rehab quotes, however, is from the definition of "willful misconduct" for purposes of the section (d) carveout from the PREP Act's section (a) immunity. *See* 42 U.S.C. § 247d-6d(c)(1)(A). The provision does *not* alter the threshold "administration to or use by an individual" requirement contained in section (a) that must be met for a claim to be subject to any aspect of the PREP Act at all. Rather, the definition of "willful misconduct" simply establishes that certain "act[s] or omission[s]" associated with the affirmative administration to or use by an individual of a covered countermeasure can be the basis of a section (d) willful misconduct claim. For example, an "omission" could result in "willful misconduct" if a nursing home intentionally failed to warn a

patient about materials in a covered countermeasure to which the patient was allergic, and the covered countermeasure was "administered to" that patient and caused the patient to develop a serious allergic reaction, resulting in a claim for loss.

Further, the inclusion of acts or omissions in the term "willful misconduct" does not transform all claims involving omissions into claims within the scope of the PREP Act. Instead, for a willful misconduct claim, the Act requires 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) (emphases added). The statute's requirement that the "administration or use" of a covered countermeasure be the proximate cause of injury or death means that the covered countermeasure must have been *actually* administered or used. That is, an injury or death cannot be proximately caused by an "administration or use" that never occurred. Thus, even if the phrase "relating to … the administration to or the use by an individual of a covered countermeasure" in subsection (a) of the PREP Act were construed broadly to encompass certain circumstances of inaction (and it cannot be, as explained above), the willful misconduct federal cause of

action does not include within its scope claims of *non*-administration or *non*-use, because the statutory language of the cause of action requires "the administration or use" of a covered countermeasure to be the proximate cause of injury or death. Moreover, as explained above, the phrase "the administration or use of a covered countermeasure" makes sense only if a covered countermeasure is affirmatively administered to or used by an individual.

The purpose and history of the PREP Act confirm the text's plain meaning. 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* 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); *see also* 151 Cong. Rec. S14242-01 (daily ed. Dec. 21, 2005)

(statement of Sen. Clinton noting that the "provision is being billed as a simple liability protection to help those who would manufacture avian flu vaccine").

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 & Reform, Serial No. 116-96 at 43 (2020) (testimony of HHS Asst. Secretary for Preparedness and Response, urging addition of respiratory protective devices in order to boost supply). 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 *non*-administration or *non*-use "would defeat the

basic purpose of the statute," as the district court correctly recognized. A-21.[3]

Moreover, when Congress intends to immunize *inaction*, it knows how to do so. For example, in 2020, Congress separately immunized volunteer healthcare professionals for harms "caused by an act *or omission* of the professional in the provision of health care services during the public health emergency with respect to COVID–19." Pub. L. No. 116-136, § 3215(a), 134 Stat. at 374 (emphasis added). If providing immunity for an act necessarily confers immunity for the failure to act, the term "or omission" would be superfluous. Notably, throughout 2020, Congress debated—but did not enact—liability protections for claims like those alleged in this case. *See*, *e.g.*, 106 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 that are "following public health guidelines to the best of their ability"). The debate over whether to

[3] 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).

immunize entities that failed to take adequate infection control measures confirms that Congress had not already created such immunity through the PREP Act in 2005.

In sum, as district courts in this Circuit and throughout the country have held, because the plaintiff "alleges 'that it was inaction, rather than action,' that caused [the plaintiff's loss], the PREP Act's immunity provision does not shield [the defendant] from suit or liability." *Ruiz v. ConAgra Foods Packaged Foods, LLC*, 2021 WL 3056275, at *5 (E.D. Wis. July 20, 2021); *see also Mackey v. Tower Hill Rehab., LLC*, 2021 WL 5050292, at *4 (N.D. Ill. Nov. 1, 2021) (stating that the "court therefore joins the overwhelming weight of authority in concluding that the PREP Act does not address state-law claims based on a failure to deploy countermeasures, and therefore the Act cannot completely preempt such suits" (collecting cases)); *Dupervil*, 516 F. Supp. 3d at 255 (discussing the "growing consensus among courts across the country that state-law claims of negligence and wrongful death brought against a nursing home for failure to protect against the spread of COVID-19 … are not properly characterized as federal-law claims under the PREP Act"). "There is simply no room to read [the PREP Act] as equally applicable to the *non-*

administration or *non*-use of covered countermeasures." *Eaton v. Big Blue Healthcare, Inc.*, 480 F. Supp. 3d 1184, 1195 (D. Kan. 2020).

2. Plaintiff's claims do not relate to an injury caused by the affirmative use of a covered countermeasure.

The PREP Act's immunity provision applies only where the injury giving rise to suit has 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). Thus, for a plaintiff's claim to fall within the scope of the immunity provided under subsection (a), and thus within the federal cause of action for willful misconduct under subsection (d), the claim for loss must have been (1) caused by the affirmative administration or use of (2) a covered countermeasure.

Here, the complaint does not allege a causal relationship between the administration or use of a covered countermeasure and Ms. Hill's death. Nowhere does the complaint allege that the plaintiff's loss was caused by the affirmative administration of a covered countermeasure to a person, or someone's affirmative use of a covered countermeasure. Rather, the allegations concern Bloomington Rehab's general *non*-use of measures to protect against the spread of COVID-19.

Nonetheless, Bloomington Rehab asserts (at 40) that the allegation that it failed to use "adequate" personal protective equipment (PPE) or other measures "necessarily implies that Bloomington Rehab did, in fact, administer and use PPE." Not all PPE, however, is a "covered countermeasure" under the PREP Act. Rather, PPE is a "covered countermeasure" under the Act only if it qualifies as a medical device under 21 U.S.C. § 321(h) and is authorized for emergency use by the FDA, or is a respiratory protective device approved by NIOSH, 42 U.S.C. § 247d-6d(i)(1), (7). The PPE that Bloomington Rehab identifies—"face masks, gloves, and gowns," Appellant's Br. 11—are not medical devices or respiratory protective devices that could qualify as a "covered countermeasure" under the Act.

Moreover, the inference that Bloomington Rehab used "covered countermeasures" does not "necessarily" follow from the allegations in the complaint, and Bloomington Rehab's attempts to recast those allegations do not provide a basis for federal jurisdiction. *See Mackey*, 2021 WL 5050292, at *4 (stating that "a defendant may not manufacture federal jurisdiction by reading its preferred set of facts into the Complaint"). "To the extent Defendant[] want[s] to argue that the PREP

Act applies, [it] must do so based on the complaint as it is—not as Defendant[] would prefer it to be." *Eaton*, 480 F. Supp. 3d at 1194. Indeed, courts have consistently rejected such "mental gymnastics" to convert a plaintiff's allegations of inaction into ones of action. *Anson v. HCP Prairie Vill. KS OPCO LLC*, 523 F. Supp. 3d 1288, 1300 (D. Kan. 2021); *see Jackson v. Big Blue Healthcare, Inc.*, 2020 WL 4815099, at *7 (D. Kan. Aug. 19, 2020) (rejecting the argument "that a facility using covered countermeasures somewhere in the facility is sufficient to invoke the PREP Act as to all claims that arise in that facility"); *Shapnik v. Hebrew Home for the Aged at Riverdale*, 535 F. Supp. 3d 301, 321 (S.D.N.Y. 2021) (rejecting the argument that immunity applies "as long as a plaintiff suffered an injury at the hands of a person charged with administering a covered countermeasure, without regard to whether there was a 'direct relationship' between the injury and the use of a covered countermeasure").

Had Ms. Hill been injured by a NIOSH-approved respiratory device, a claim based on that injury might be subject to PREP Act immunity. *See Parker v. St. Lawrence Cty. Pub. Health Dep't*, 102 A.D.3d 140 (N.Y. App. Div. 2012) (finding that the PREP Act applied to battery and negligence

claim based on the administration of a vaccine). Because the complaint does not allege injuries resulting from the administration or use of a covered countermeasure, the statute has no relevance to the claims in this case.

B. HHS's views do not support the applicability of the PREP Act here.

In support of its arguments that the PREP Act applies to the claims brought here, Bloomington Rehab points to statements made by HHS as to the scope of the statute in the Secretary's Declaration and Fourth Amended Declaration and the HHS General Counsel's Advisory Opinions 20-04 and 21-01. *See* Appellants' Br. 38–39. These statements are irrelevant to the claims alleged here. Moreover, HHS's statements on this issue are entitled to no deference.

1. The HHS statements are inapplicable to the claims in this case.

Bloomington Rehab seeks support from several statements by HHS. To start, it quotes (at 39) the Secretary's March 17, 2020, Declaration, which defines "Administration of a Covered Countermeasure." The Declaration states:

> The definition of 'administration' extends only to *physical provision* of a countermeasure *to a recipient*, such as

> vaccination or handing drugs to patients, and to 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.

85 Fed. Reg. at 15,200, A-44 (emphases added). That definition supports Ms. Martin's position that "administration" means the affirmative administration of a covered countermeasure. The phrases "physical provision of a countermeasure to a recipient" and "providing countermeasures to recipients," as well as the examples included in the Secretary's definition, involve the affirmative provision of designated countermeasures to individuals—not the failure to provide those measures generally.

Next, Bloomington Rehab cites (at 38) the Secretary's statement that "there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act." 85 Fed. Reg. at 79,194, A-72. Yet Bloomington Rehab omits the Secretary's description of these "situations": The Secretary stated 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 is a result of "prioritization or purposeful allocation." 85 Fed. Reg. at 79,197, A-75.

Similarly, the advisory opinions cited by Bloomington Rehab (at 38) discuss scenarios involving the prioritization or purposeful allocation of a covered countermeasure. In both, the HHS's General Counsel discussed hypothetical examples where a person failed to receive a COVID-19 vaccine because the provider prioritized a different population for receiving that vaccine. In Advisory Opinion 20-04, the General Counsel opined that PREP Act immunity would apply to a suit against a pharmacy that did not provide a COVID-19 vaccine to a person because it "prioritize[d] CDC-designated populations," of which the person was not a part, for receiving the vaccine. *See* Advisory Op. 20-04, at 6–7, A-65–66. Advisory Opinion 21-01 similarly discusses a failure to administer the COVID-19 vaccine to one population as a result of prioritization to another more vulnerable population. Advisory Op. 21-01, at 3, A-79. There, the General Counsel opined that the text of the PREP Act distinguishes "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." *Id.* at 4, A-80 (emphases added).

These statements, which all concern decisions stemming from the purposeful allocation and prioritization of limited resources, have nothing to do with this case. Nothing in the agency interpretations cited by Bloomington Rehab indicates that *all* claims alleging failures to act are within the scope of the PREP Act. Here, the complaint alleges loss resulting from Bloomington Rehab's failure to implement adequate protection measures generally—not loss resulting from a purposeful allocation of a covered countermeasure to one person instead of another. Nothing in the complaint alleges that Bloomington Rehab faced a shortage of any covered countermeasure, or that the facility failed to administer covered countermeasures to Ms. Hill because it was administering them to others. As the district court correctly noted, the "subset of nonuse" described in the agency statements "clearly does not apply here" because "[t]he Complaint nowhere alleges Plaintiff's mother contracted COVID-19 as a result of Defendant's purposeful allocation of countermeasures to other individuals." A-18.

Because the complaint's allegations do not concern the prioritization or purposeful allocation of covered countermeasures, the agency statements cited by Bloomington Rehab do not support the notion

that the claims alleged are within the scope of the PREP Act. As many courts have explained, where, as here, the "plaintiff alleges neither (1) limited covered countermeasures nor (2) a failure to administer those countermeasures to him 'in order to administer it to another individual,'" *Goldblatt v. HCP Prairie Vill. KS OPCO LLC*, 516 F. Supp. 3d 1251, 1264 (D. Kan. 2021) (quoting 85 Fed. Reg. at 79,197, at A-75), the plaintiff's claims are not within the "species of 'inaction' claims" discussed in the agency's interpretations of the Act, 516 F. Supp. 3d at 1264. *See McCalebb v. AG Lynwood, LLC*, 2021 WL 911951, at *5 (C.D. Cal. Mar. 1, 2021) (explaining that even under the agency's interpretation, "cases of general neglect [must] fall outside the protection of the PREP Act" because "[o]therwise, the [opinion's] limiting language and illustration would be superfluous, if not confounding"); *Padilla v. Brookfield Healthcare Ctr.*, 2021 WL 1549689, at *5 (C.D. Cal. Apr. 19, 2021) (explaining irrelevance of Advisory Opinion 21-01 to analogous claims).

2. The HHS statements on which Bloomington Rehab relied are entitled to no deference.

In any event, no deference is owed to HHS's statements opining on the meaning of "administration" or "use" or the hypothetical scenarios of purposeful allocation that, in HHS's view, could fall within the meaning

of those terms. A court owes no deference to an agency interpretation of an unambiguous statute. *See*, *e.g.*, *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) ("If uncertainty does not exist, there is no plausible reason for deference."); *Preston*, 948 F.3d at 784 n.22 ("Resort to agency interpretations … is unnecessary when the statutory language is clear[.]"). In addition, before the court may "wave the ambiguity flag," it "must carefully consider the text, structure, history, and purpose." *Kisor*, 139 S. Ct. at 2415. As explained above (at pp. 12–22), the text, history, and purpose of the PREP Act demonstrate that claims of *non*-use are not within the scope of the immunity provided under the Act. The inquiry stops there.

Furthermore, an "administrative implementation of a particular statutory provision qualifies for *Chevron* deference [only] when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001). Here, the Secretary's statements are not within the scope of the Secretary's delegated authority. Congress delegated to the Secretary the 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). This authority does not carry with it the authority to define the meaning of subsection (a). *Cf. id.* § 247d-6d(c)(2)(A) (providing rulemaking authority to "further restrict" the scope of the term "willful misconduct" for purposes of the subsection (d) cause of action).

Moreover, the advisory opinions on which Bloomington Rehab heavily relies expressly state that they lack the "force or effect of law." Advisory Op. 21-01, at 5, A-81; Advisory Op. 20-04, at 7, A-66. As the district court correctly held, "informal agency interpretations such as those contained in opinion letters … which lack the force of law—do not warrant *Chevron*-style deference." A-19 (quoting *Am. Fed'n of Gov't Emps., Local 2119 v. Rumsfeld*, 262 F.3d 649, 656 (7th Cir. 2001)); *see Dupervil*, 516 F. Supp. 3d at 252 (explaining that the HHS advisory opinion "explicitly was not 'promulgated in the exercise of th[e] authority'" delegated by Congress and thus "is not entitled to *Chevron*

deference"); *Mackey*, 2021 WL 5050292 at *5; (holding *Chevron* does not apply to Advisory Opinion 21-01's views about non-use). In addition, the statement in the Fourth Amended Declaration that Bloomington Rehab cites appears in the amended declaration's preamble, not in its legally operative designation of countermeasures. 85 Fed. Reg. at 79,194, A-72. For that reason as well, it is not eligible for deference. *See Middleton v. City of Chicago*, 578 F.3d 655, 661 (7th Cir. 2009) (declining to defer to an agency's interpretation in a preamble); *see also Martin v. Soc. Sec. Admin., Comm'r*, 903 F.3d 1154, 1162 (11th Cir. 2018) (stating that a "regulatory preamble" was "plainly not *Chevron*-eligible").

Citing section 247d-6d(b)(7) of the PREP Act, Bloomington Rehab asserts (at 42) that the HHS documents it cites carry the force of law. Section 247d-6d(b)(7) provides that "[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, *any action by the Secretary under this subsection*." 42 U.S.C. § 247d-6d(b)(7) (emphasis added). The referenced "subsection"—subsection (b) of the Act—concerns declarations by the Secretary that "recommend[] … the manufacture, testing, development, distribution, administration, or use of one or more covered

countermeasures." *Id.* § 247d-6d(b)(1). Section 247d-6d(b)(7) has nothing to do with conferring authority on the Secretary to issue interpretations of the statute that carry the force of law; rather, it simply bars judicial review of declarations by the Secretary issued pursuant to subsection (b). "In the context of § 247d-6d(b) ('Declaration by Secretary'), this provision clearly means that the Secretary's decision to declare a public health emergency is insulated from judicial review, not that the Secretary's interpretation of the PREP Act has the force of law." *Mackey*, WL 5050292, at *5 n.7 (rejecting the argument that § 247d-6d(b) provides the agency's statements with the force of law as "borderline frivolous"). As the Third Circuit recently held, section 247d-6d(b)(7) "merely strips courts of jurisdiction to review the Secretary's determinations under the PREP Act." *Maglioli*, 16 F.4th at 403. It does not provide a basis for the court to defer to the Secretary's views on federal jurisdiction under the PREP Act. *See id.*

Bloomington Rehab also asserts (at 42) that the agency's statements in the advisory opinions are "entitled" to *Auer* deference, which refers to the deference accorded to an agency's interpretation of its own regulation. *Auer v. Robbins*, 519 U.S. 452 (1997); *see Kisor*, 139 S.

Ct. at 2411 (explaining that the doctrine of *Auer* deference refers to the court's deference "to the agency's construction of its own regulation"). Because HHS is not interpreting a regulation that it issued in implementing the PREP Act, *Auer* deference does not apply.

Finally, the agency's statements are not entitled to respect under *Skidmore v. Swift Co.*, 323 U.S. 134 (1944). "Under *Skidmore*, a court will respect an agency's interpretation of the statute it administers, but only to the extent that the agency's interpretation possesses the "power to persuade." *Vulcan Const. Materials, L.P. v. Fed. Mine Safety & Health Rev. Comm'n*, 700 F.3d 297, 316 (7th Cir. 2012) (quoting *Skidmore*, 323 U.S. at 140). "In assessing the persuasive power of an agency's interpretation, [the court] examine[s] 'the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.'" *Vulcan Const. Materials*, 700 F.3d at 316 (quoting *Arobelidze v. Holder*, 653 F.3d 513, 520 (7th Cir. 2011)).

Here, the agency's interpretations of what constitutes "administration" or "use" lack any such power because, as the district court correctly held, the agency's statements have "neither a legal nor

logical basis for reading wholesale nonuse into the statute." A-20–21 (concluding that Advisory Opinion 21-01 "is unpersuasive and merits no deference under *Chevron* or *Skidmore*); *see also Mackey*, 2021 WL 5050292 at *5; *WorkCare, Inc. v. Plymouth Med., LLC*, 2021 WL 4816631, at *5 (C.D. Cal. Aug. 20, 2021). The agency opined on the "administration" or "use" of a covered countermeasure without examining the relevant statutory language, including the requirement of a "causal relationship" with the administration "to" or "use by an individual," or the statutory history or purpose. Accordingly, no weight is accorded to the agency's statements under *Skidmore*.

CONCLUSION

For the foregoing reasons, the decision below should be affirmed.

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Respectfully submitted,

/s/ Scott L. Nelson
Scott L. Nelson
Michael T. Kirkpatrick
Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
(202) 588-1000

Attorneys for Amicus Curiae Public Citizen

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and 7th Cir. R. 29 because it contains 6,763 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionately spaced typeface using Microsoft Word Century Schoolbook 14-point font.

/s/ Scott L. Nelson
Scott L. Nelson

CERTIFICATE OF SERVICE

I hereby certify that on March 7, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Scott L. Nelson
Scott L. Nelson