

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

TERRI HANSEN, Personal)
Representative of the Estate of)
CHARLES SECREST,)
)
Plaintiff,)
)
And)
)
BEVERLY SHINNEN, Personal)
Representative of the Estate of)
SOPHIE STAR SAKEWICZ,)
)
Plaintiff,)
)
v.)
)
BRANDYWINE NURSING AND)
REHABILITATION CENTER, INC.,)
A Delaware Corporation,)
)
Defendant.)

C.A. No. N21C-03-233 CEB

Submitted: January 9, 2023
Decided: January 23, 2023

OPINION

Upon Consideration of Defendant Brandywine Nursing and Rehabilitation Center, Inc.'s Motion to Dismiss,
DENIED.

Neil R. Lapinski, Esquire, Phillip A. Giordano, Esquire, and Madeline R. Silverman, Esquire, GORDON, FOURNARIS & MAMMARELLA, P.A., Wilmington, Delaware; Michael P. Minuti, Esquire, MCCAN DILLON JAFFE & LAMB, LLC, Wilmington, Delaware. *Counsel to Terri Hansen, Personal Representative of the Estate of Charles Secrest, and Beverly Shinnin, Personal Representative of the Estate of Sophie Star Sakewicz.*

Stephen J. Milewski, Esquire, and Roopa Sabesan, Esquire, WHITE AND WILLIAMS LLP, Wilmington, Delaware. *Attorneys for Defendant Brandywine Nursing and Rehabilitation Center, Inc.*

BUTLER, R.J.

Plaintiffs Charles Secrest and Sophie Star Sakewicz (the “Plaintiffs”) were elderly residents of Brandywine Nursing and Rehabilitation Center, Inc. (“BNR”). While in the care of BNR, the Plaintiffs fell ill with COVID-19 and subsequently died. This action is brought by the Plaintiffs’ personal representatives and seeks damages for negligence surrounding their deaths. BNR now argues that the immunity provision of the PREP Act requires the Court to dismiss the action against it. The Court finds to the contrary. Accordingly, BNR’s motion to dismiss will be denied.

BACKGROUND

1. The Parties

BNR is a private, skilled nursing facility located in New Castle County.¹ It operates an authorized 169 beds and accepts Medicaid/Medicare as payment.² It is heavily regulated at both the state and federal levels.

The Plaintiffs were both residents of BNR. Charles Secrest was 82 years old and suffering from dementia.³ Sophie Star Sakewicz was 95 years old.⁴ The Plaintiffs died while in the care of BNR and this action is brought by their personal

¹ Compl. ¶ 3, D.I. 1 [hereinafter “Compl.”].

² *Id.* ¶ 6.

³ *Id.* ¶ 15.

⁴ *Id.* ¶ 18.

representatives. Most of the factual allegations in the Complaint are made “[u]pon information and belief” of the personal representatives.⁵

2. The Allegations

The Plaintiffs both allegedly died of complications from COVID-19 in April 2020, shortly after the beginning of what is now called “the Pandemic.”⁶ The Plaintiffs claim that BNR failed to properly hire, train, or direct staff as to the proper protocols to be followed in the face of the Pandemic.⁷ The Plaintiffs further allege that BNR failed to follow emergent CDC guidelines concerning hygiene, segregation and visitation, and were “negligent in other respects that may be uncovered during discovery.”⁸

The Complaint contains five counts: (1) Count I is for wrongful death under 10 *Del. C.* § 3724; (2) Count II is the corollary survival action under 10 *Del. C.* § 3704; (3) Count III alleges BNR was grossly negligent; (4) Count IV alleges BNR engaged in willful and wanton misconduct; and (5) Count V alleges BNR is liable under the doctrine of *respondeat superior*.

⁵ *Id.*

⁶ *Id.* ¶¶ 66, 80.

⁷ Compl. ¶¶ 87, 92, 94.

⁸ *Id.*

3. The PREP Act

A basic understanding of the Public Readiness and Emergency Preparedness (“PREP”) Act of 2005⁹ is important to grasp the arguments before the Court. The Court therefore considers a very brief history of the PREP Act.

A. Health Crises Predating the PREP Act

In 1918, an estimated 500 million people around the world were infected during an influenza epidemic, sometimes called “the Spanish Flu.”¹⁰ In the United States, the epidemic claimed some 675,000 lives.¹¹ The culprit in this tragedy was finally determined to be the H1N1 virus, to which there was no pharmaceutical intervention available at the time.¹²

So, in 1976, when two soldiers at Fort Dix, New Jersey tested positive for the H1N1 virus, public health officials had ample reason for alarm.¹³ In response, President Gerald Ford announced the National Influenza Immunization Program

⁹ Pub. L. No. 109-148, div. C, § 2, 119 Stat. 2680 (codified as amended at 42 U.S.C. §§ 247d-6d, 247d-6e).

¹⁰ See *History of 1918 Flu Pandemic*, Ctr. for Disease & Control Prevention (March 21, 2018), <https://www.cdc.gov/flu/pandemic-resources/1918-commemoration/1918-pandemic-history.htm>.

¹¹ *Id.*

¹² *Id.*

¹³ See generally Efthimios Parasidis, *Recalibrating Vaccination Laws*, 97 B. U. L. Rev. 2153, 2192–93 (2017).

(“NIIP”), and Congress budgeted \$135 million to produce enough vaccine to inoculate the entire U.S. population against H1N1.¹⁴

Pursuant to the NIIP, drug manufacturers were enlisted to produce the vaccine. But the insurers for the manufacturers balked; they were unwilling to take on the potentially ruinous liability if the vaccines produced unanticipated, harmful results or side effects.¹⁵ Given the breadth of the potential liability, the manufacturers demanded that the government agree to protect them from such lawsuits.¹⁶ The government obliged, immunizing the manufacturers from tort liability for the vaccine. Further, to ensure some level of protection for U.S. citizens injured by the vaccine, the government agreed to waive sovereign immunity and assume any liabilities.¹⁷ The manufacturers thereupon undertook mass production, and the government undertook mass vaccination.¹⁸

Some 4,000 lawsuits were subsequently filed concerning side effects from the NIIP vaccine.¹⁹ Most suits claimed that patients developed Guillain-Barré Syndrome from taking the vaccine.²⁰ The resulting government litigation costs

¹⁴ See generally *id.* at 2192–200; Arnold W. Reitz, *Federal Compensation for Vaccine Related Injuries*, 13 B.C. Env’t Aff. L. Rev. 169, 170–75 (1986).

¹⁵ See Parasidis, *supra* note 13, at 2195.

¹⁶ *Id.* at 2196–97.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.* at 2199.

²⁰ *Id.* Guillain-Barré Syndrome is a rare disorder in which the body’s immune system attacks the nerves. With treatment, most people recover fully, but some cases result

amounted to approximately \$90 million, nearly doubling what was spent on the vaccination program itself.²¹

i. The Project Bioshield Act

While other public health emergencies have come along since 1976, none have had such a profound effect on law and public health policy as the 9/11 terrorist attacks and coincident anthrax scares. In addition to the Homeland Security Act of 2002,²² Congress passed the Project Bioshield Act of 2004.²³ The Project Bioshield Act was an “ambitious [project aimed at] creat[ing] a new biodefense industry for the expeditious development and production of medical countermeasures and related products and services to secure the U.S. homeland against bioterrorism.”²⁴ The Act authorized the Secretary of Health and Human Services (“HHS”) to permit distribution of products approved on an “emergency use authorization” in response to a biological, chemical, radiological or nuclear attack, or other “material threat” to the health and safety of American citizens.²⁵

in permanent nerve damage. In some cases, Guillain-Barré Syndrome has led to death. *See Guillain-Barré Syndrome*, Ctr. for Disease & Control Prevention (June 27, 2022), <https://www.cdc.gov/campylobacter/guillain-barre.html>.

²¹ *See* Parasidis, *supra* note 13, at 2199.

²² Pub. L. No. 107-296, 116 Stat. 2135.

²³ Pub. L. No. 108-276, 118 Stat. 835.

²⁴ Frank Rapoport et al., *Project Bioshield Act of 2004: Dawn of a New Industry?*, 40 SPG Procurement L. 3, 3 (2005).

²⁵ *Id.* at 4–5.

Problems arose with developing and stockpiling vaccines and antidotes. First, there was but one customer—the U.S. government—which would have to remain committed to buying and storing the supply.²⁶ Next, very expensive, first-line research was needed because not all known pathogens had known antidotes.²⁷ Then there was the problem lingering from the NIIP debacle: how to protect manufacturers from liability claims over a drug created only at the behest of the government.²⁸ Finally, there was the question how to administer and pay for the claims of citizens who were harmed by the vaccines or antidotes themselves.²⁹

B. PREP Act Immunity

This very simplified history of how the PREP Act came to be demonstrates that the immunity provided for in the Act exists to guarantee a supply of vaccines and related countermeasures in the event of a public health emergency.³⁰ The

²⁶ *See generally id.* at 5 (explaining that government contracts for countermeasures could last up to five years but could be extended for up to eight years with options for renewal).

²⁷ *See id.* at 3 (“The statute creates mechanisms to accelerate new research and development and production of drugs, medical devices, and biological products (hereinafter “countermeasures”) to combat bioterrorism.”).

²⁸ *See id.* at 6 (“The pharmaceutical industry has made it clear that BioShield’s commitments and regulatory streamlining were not sufficient to overcome its concerns about the litigation risks inherent to a new family of medicines that could be used on a prophylactic basis during a period of heightened alert prior to a threatened attack.”).

²⁹ *See id.*

³⁰ Readers with a general interest in the history of Project Bioshield and the PREP Act might consider the following articles: James G. Hodge et al., *From [A]nthrax to [Z]ika: Key Lessons in Public Health Legal Preparedness*, 15 *Ind. Health L. Rev.*

immunity ensures that drug manufacturers will not be sued should the vaccine or other government-ordered countermeasure turn out to be defective or harmful.

The PREP Act provides immunity for “covered countermeasures” undertaken by “covered persons” in response to a declared state of emergency.³¹ On March 10, 2020, the Secretary of HHS declared COVID-19 a public health emergency with an effective date of February 4, 2020.³² The Plaintiffs concede that BNR is a “covered person” under the statute, leaving the Court to consider whether BNR was engaged in “covered countermeasures” with respect to the activities alleged in the complaint.³³

PROCEDURAL HISTORY

The Plaintiffs filed their Complaint with this Court in March 2021. BNR filed a notice of removal to the U.S. District Court for the District of Delaware in May 2021. In the district court, BNR took the position that the dispute may only be heard in federal court because (1) the PREP Act is a “complete preemption” statute which supplants all state causes of action; and (2) the Secretary of HHS has declared that

23 (2018); Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government’s Lackadaisical Liability and Compensation Policies in the Context of Pre-Event Vaccine Immunization Programs*, 8 J. Health Care L. & Pol’y 7 (2005); Brian Kurt Copper, “*High and Dry?*” *The Public Readiness and Emergency Preparedness Act and Liability Protection for Pharmaceutical Manufacturers*, 40 J. Health L. 65 (2006).

³¹ 42 U.S.C.A. § 247d-6d(a)(1).

³² 85 Fed. Reg. 13907-01 (Mar. 10, 2020).

³³ Pls.’ Br. in Opp’n to Def.’s Mot. to Dismiss, D.I. 10 at 15 [hereinafter “Pls.’ Br.”].

all claims involving the PREP Act were removable to federal court.³⁴ Those issues were fully briefed in the district court.

While the matter was pending in the district court, the Third Circuit Court of Appeals decided the case of *Maglioli v. Alliance HC Holdings LLC*.³⁵ *Maglioli* was brought by the estates of residents of a nursing home in New Jersey.³⁶ Those residents contracted COVID-19 and died while in the care of said nursing home.³⁷ As here, the nursing home removed the case to federal court, essentially making the same “complete preemption” arguments that BNR raised in the District Court of Delaware.³⁸

In affirming the district court’s remand to state court in *Maglioli*, the Third Circuit held that the doctrine of complete preemption does not apply to the PREP Act.³⁹ The Court further ruled that HHS could not expand or contract federal court jurisdiction by issuance of an Advisory Opinion and that any attempt to do so was not entitled to “*Chevron* deference.”⁴⁰ Thus, the Third Circuit’s ruling was that the

³⁴ Notice of Remand, D.I. 6 at 3; *see also* 86 Fed Reg. 7872-02, 2874 (Feb. 2, 2021) (“The plain language of the PREP Act makes clear that there is a complete preemption of state law. . .”).

³⁵ *Maglioli v. Alliance HC Holdings LLC*, 16 F.4th 393 (3d Cir. 2021).

³⁶ *Id.* at 400.

³⁷ *Id.* at 403–04.

³⁸ *Id.*

³⁹ *Id.* at 406.

⁴⁰ *Id.* at 403. When analyzing administrative actions, in accordance with “*Chevron* deference,” the Court should defer to the agency’s interpretation so long as it is

defendant in a state court tort claim concerning COVID-19 contracted in a nursing home could not remove the action to federal court.⁴¹ In light of *Maglioli*, it is no surprise that the district court in this action remanded this matter to state court.

Following the remand to this Court, BNR filed the instant motion to dismiss. BNR seeks dismissal on the grounds that the immunity provision of the PREP Act requires this Court to dismiss the action against them.⁴² This is so, they argue, because they are “covered persons” who were conducting “covered countermeasures” under the PREP Act.⁴³

STANDARD OF REVIEW

1. Motion to Dismiss for Lack of Subject Matter Jurisdiction

A party may move to dismiss under Rule 12(b)(1) for “[l]ack of jurisdiction over the subject matter.”⁴⁴ When considering a Rule 12(b)(1) motion, “the Court need not accept Plaintiffs’ factual allegations as true and is free to consider facts not alleged in the complaint.”⁴⁵ Dismissal is appropriate if “it appears by suggestion of

reasonable. *See generally Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

⁴¹ *Maglioli*, 16 F.4th at 412–13.

⁴² Def.’s Mot. to Dismiss, D.I. 8 [hereinafter “Mot. to Dismiss”].

⁴³ *Id.* at 17.

⁴⁴ Super. Ct. Civ. R. 12(b)(1).

⁴⁵ *Appriva S’holder Litig. Co. v. EV3, Inc.*, 937 A.2d 1275, 1284 n.14 (Del. 2007) (internal quotation marks omitted).

the parties or otherwise that the Court lacks subject matter jurisdiction.”⁴⁶ “Notably, [t]he burden of establishing the Court’s subject matter jurisdiction rests with the party seeking the Court’s intervention.”⁴⁷

2. Motion to Dismiss for Failure to State a Claim

A party may move to dismiss under Rule 12(b)(6) for failure to state a claim on which relief can be granted.⁴⁸ In considering a Rule 12(b)(6) motion, the Court (1) accepts as true all well-pleaded factual allegations in the complaint; (2) credits vague allegations if they give the opposing party notice of the claim; (3) draws all reasonable factual inferences in favor of the non-movant; and (4) denies dismissal if recovery on the claim is reasonably conceivable.⁴⁹ Dismissal is inappropriate unless “under no reasonable interpretation of the facts alleged could the complaint state a claim for which relief might be granted.”⁵⁰

⁴⁶ *Blue Cube Spinco LLC v. Dow Chem. Co.*, 2021 WL 4453460, at *5 (Del. Super. Sept. 29, 2021).

⁴⁷ *Laws v. Handy*, 2017 WL 3127783, at *2 (Del. Super. July 21, 2017) (quoting *Airbase Carpet Mart, Inc. v. Aya Assocs., Inc.*, 2015 WL 9302894, at *2 (Del. Super. Dec. 15, 2015)) (internal quotation marks omitted).

⁴⁸ Super. Ct. Civ. R. 12(b)(6).

⁴⁹ *Cent. Mortg. Co. v. Morgan Stanley Mortg. Cap. Holdings LLC*, 27 A.3d 531, 535 (Del. 2011).

⁵⁰ *Unbound Partners Ltd. P’ship v. Invoys Holdings Inc.*, 251 A.3d 1016, 1023 (Del. Super. 2021) (internal quotation marks omitted).

Delaware’s motion to dismiss standard is “minimal.”⁵¹ It asks “whether there is a possibility of recovery.”⁵² The Court, however, need not “accept conclusory allegations unsupported by specific facts or . . . draw unreasonable inferences in favor of the non-moving party.”⁵³ The Court may reject “every strained interpretation of the allegations proposed by the plaintiff.”⁵⁴

“The complaint generally defines the universe of facts that the trial court may consider in ruling on a Rule 12(b)(6) motion”⁵⁵ The Court may consider matters outside the complaint only if “the document is integral to a plaintiff’s claim and incorporated into the complaint[.]”⁵⁶ “[A] claim may be dismissed if allegations in the complaint or in the exhibits incorporated into the complaint effectively negate the claim as a matter of law.”⁵⁷

⁵¹ *Cent. Mortg.*, 27 A.3d at 536.

⁵² *Garfield v. BlackRock Mortg. Ventures, LLC*, 2019 WL 7168004, at *7 (Del. Ch. Dec. 20, 2019) (citing *Cent. Mortg.*, 27 A.3d at 537 n.13 (“Our governing ‘conceivability’ standard is more akin to ‘possibility,’ while the federal ‘plausibility’ standard falls somewhere beyond mere ‘possibility’ but short of ‘probability.’”)).

⁵³ *Price v. E.I. DuPont de Nemours & Co.*, 26 A.3d 162, 166 (Del. 2011), *overruled on other grounds by Ramsey v. Ga. S. Univ. Advanced Dev. Ctr.*, 189 A.3d 1255, 1277 (Del. 2018).

⁵⁴ *Malpiede v. Townson*, 780 A.2d 1075, 1083 (Del. 2001).

⁵⁵ *In re Gen. Motors (Hughes) S’holder Litig.*, 897 A.2d 162, 168 (Del. 2006).

⁵⁶ *Windsor I, LLC v. CWCap. Asset Mgmt. LLC*, 238 A.3d 863, 873 (Del. 2020) (internal quotation marks omitted).

⁵⁷ *Malpiede*, 780 A.2d at 1083.

ANALYSIS

1. The Defendant is not entitled to dismissal.

BNR argues that this Court lacks subject matter jurisdiction over the claims and the Plaintiffs otherwise fail to state a claim on which relief can be granted. If BNR is correct that the immunity provision of the PREP Act immunizes its conduct giving rise to the complaint, then dismissal would be appropriate. But the Court finds that the complaint does not concern “covered countermeasures” immunized by the PREP Act. So dismissal is not appropriate.

A. Infectious disease protocols are not covered countermeasures.

Our analysis begins with the plain language of the immunity provision of the PREP Act. The statute says:

[A] covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual *of a covered countermeasure* if a declaration under subsection (b) has been issued with respect to such countermeasure.⁵⁸

As noted earlier, the Secretary of HHS issued a declaration of a public health emergency in early 2020, thus triggering the immunity provision of the Act.⁵⁹

A “covered countermeasure” is defined as:

⁵⁸ 42 U.S.C.A. § 247d-6d (emphasis added).

⁵⁹ See *supra* Procedural History.

- (A) “a qualified pandemic or epidemic product;”⁶⁰
- (B) “a security counter measure;”⁶¹
- (C) a “drug”, “biological product”, or “device that is authorized for emergency use;” or
- (D) “a respiratory protective device that is approved by the National Institute for Occupational Safety and Health and that the Secretary determines to be a priority for use during a public health emergency.”⁶²

The Plaintiffs do not contest that BNR could be viewed as “covered person” within the meaning of the statute.⁶³ For example, one might imagine a suit that sought to force the defendant into court because it administered a vaccine that caused deleterious side effects. Such a defendant would probably be a covered person. But that is not this case.

As to the meaning of “covered countermeasure,” BNR agrees that the complaint is not about drugs, biological products, respiratory devices or other pandemic related “products.”⁶⁴ BNR characterizes the complaint as one about staff

⁶⁰ The code goes on to define a “qualified pandemic or epidemic product” as a “drug,” “biological product” or “device.” These have nothing to do with social distancing or hand washing. 42 U.S.C.A. § 247d-6d(i)(7).

⁶¹ Security countermeasures are drugs, biological products, or devices that respond to chemical, biological, or nuclear attacks. *Id.* § 247d-6b(c)(1)(B).

⁶² *Id.* § 247d-6d(i)(1).

⁶³ Pls.’ Br. at 15.

⁶⁴ Mot. to Dismiss at 6.

and resident screening practices as well as supplies and deployment of personal protective equipment (“PPE”).⁶⁵

BNR asks the Court to read the PREP Act to immunize any “manner in which Defendants used, administered, and allocated countermeasure products against COVID-19.”⁶⁶ Because some countermeasure or another was used at the facility—thermometers, examination gowns, surgical apparel, etc.—BNR says this is a suit about the administration of countermeasures which are immunized by the PREP Act.⁶⁷

BNR’s argument confuses suits over the administration of a countermeasure itself—which is clearly immunized—with suits concerning prevention of infection. BNR would have the Court read “covered countermeasure” to include everything undertaken by a nursing home during the pandemic. While the Court can accept that “covered persons” under the statute should be read broadly, BNR’s suggestion that “covered countermeasure” be read to include basic infectious disease prevention is beyond broad—it is unreasonable.

To make this truth more evident, consider suits over *not* using an actual countermeasure, such as a vaccine. The immunity exists to benefit the producers and distributors of the countermeasures. If such countermeasures are not used, they

⁶⁵ *Id.* at 6–7.

⁶⁶ *Id.* at 23.

⁶⁷ *Id.* at 21–22.

cannot have caused a harm and therefore do not need immunity. So immunity is not available. Numerous courts have ruled that there is no immunity for *not* employing a countermeasure.⁶⁸

Not all “measures” are “covered countermeasures” under the Act. In *Maglioli*, the district court noted that “many of the measures with which Defendants allegedly failed to comply were acts such as social distancing, quarantining, lockdowns, and others . . . These are not covered ‘countermeasures’ under the PREP Act at all.”⁶⁹

This is hardly the first nursing home to be sued concerning COVID-19 infection. *Whitehead v. Pine Haven Operating LLC* was a case against a nursing

⁶⁸ See, e.g., *Casabianca v. Mount Sinai Med. Ctr.*, 2014 WL 10413521, at *4-5 (N.Y. Sup. Ct. Dec. 2, 2014) (holding that immunity covers administration or use of a countermeasure, not a claimant who was not administered a vaccine); *Robertson v. Big Blue Healthcare, Inc.* 523 F. Supp. 3d 1271, 1282 (D. Kan. 2021) (identifying 13 similar cases in which not administering a covered countermeasure did not implicate PREP Act immunity); *Saunders v. Big Blue Healthcare, Inc.*, 522 F. Supp. 3d 946 (D. Kan. 2021); *Dupervil v. Alliance Health Operations, LLC*, 516 F. Supp. 3d 238 (E.D.N.Y. 2021); *Eaton v. Big Blue Healthcare, Inc.*, 480 F. Supp. 3d 1184, 1196 (D. Kan. 2020) (“the PREP Act addresses the administration or use of covered countermeasures. There is simply no room to read it as equally applicable to the non-administration or non-use of covered countermeasures of the PREP Act.”); accord *Rosen v. Montefiore*, 582 F. Supp. 3d 553, 561 (N.D. Ohio 2022) *appeal filed* No. 22-3172 (Mar. 2, 2022); *Gwilt v. Harvard Square Ret. & Assisted Living*, 537 F. Supp. 3d 1231, 1241 (D. Colo. 2021); see generally Ruan Meintjes, *The Art of Dodging Bullets: How Covid-19 Drug Manufacturers and Providers Plan to Escape Tort Liability*, 24 SMU Sci. & Tech. L. Rev. 113 (2021).

⁶⁹ *Est. of Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 518, 534 (D. N.J. 2020), *aff’d*, 16 F.4th 393 (3d Cir. 2021) (internal quotation marks omitted).

home alleging a failure to enforce social distancing, timely restrict visitors, ensure residents and staff wore face coverings, screen staff and visitors, and failure to discontinue group activities.⁷⁰ The defendant moved to dismiss on the grounds of PREP Act immunity.⁷¹ The New York Supreme Court ruled that the immunity provisions “were meant to protect pharmaceutical companies who rapidly developed the COVID-19 vaccine, and now cannot be read to afford a free pass to residential nursing homes who failed to adequately protect their residents from illness and death during the pandemic.”⁷²

The Court recognizes that the General Counsel for the Secretary of HHS issued an Advisory Opinion expressing the view that PREP Act immunity could extend to inaction by a “covered person.”⁷³ That inaction might occur, for example, when the “covered person” must choose who to administer a vaccine to—a highly vulnerable person or one with less vulnerability—when the vaccine is in short

⁷⁰ 170 N.Y.S.3d 855 (N.Y. Sup. Ct. 2022).

⁷¹ *Id.* at 857.

⁷² *Id.* at 861; *see also Arbor Management Services, LLC v. Hendrix*, 875 S.E.2d 392, 398 (Ga. 2022) (“[T]he allegedly wrongful conduct is based on decisions made by AMS regarding visitation, staffing, recreation and socialization – conduct that has nothing to do with administrations of a ‘covered countermeasure’ such as a drug, device, or other object as identified by HHS.”); *Dupervil v. Alliance Health Operations, LLC* 516 F. Supp. 3d 238 (E.D. N.Y. 2021), *vacated as moot*, 2022 WL 3750009 (2d Cir. Aug. 1, 2022).

⁷³ Dept. of Health & Human Serv., Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act Scope of Preemption Provision (Jan. 8, 2021) at 3.

supply.⁷⁴ Those facts may present a more difficult case. But again, that is not this case. Rather, BNR simply throws out the possibility that Plaintiffs’ deaths were a result of conscious decisions over allocation of limited “covered countermeasures.” The argument is a misreading of the Plaintiffs’ Complaint.

BNR’s construction of PREP Act immunity is not consistent with the purpose or meaning of the PREP Act and not consistent with the many similar cases that have denied immunity to nursing homes.

B. The HHS Advisory Opinions do not broaden the meaning of the PREP Act.

The PREP Act authorizes the Secretary of HHS to declare a public health emergency, to recommend the manufacture or distribution of “covered countermeasures,” and to declare which countermeasures are immune from suit.⁷⁵ With respect to a declaration of a public health emergency, the Secretary’s decision is not reviewable by the courts.⁷⁶

In addition to the COVID-19 declaration, and its multiple amendments made over time, the Secretary’s General Counsel has issued Advisory Opinions. These opinions are an effort to “clarify the Department’s legal position on a critical

⁷⁴ *Id.*

⁷⁵ 42 U.S.C.A. § 247d6d(b)(1).

⁷⁶ 42 U.S.C.A. § 247d-6d(b)(7).

issue.”⁷⁷ As explained by the General Counsel, “the Advisory Opinions do not create binding legal norms, are not meant to bind the public in any way, do not have the force and effect of law, and are not final agency action.”⁷⁸ Ignoring this caveat, the Secretary, in its Fourth Amended Declaration of Emergency under the PREP Act—a document with legal authority—declared that the Advisory Opinions issued by its General Counsel were incorporated into the Declaration.⁷⁹

Although an Advisory Opinion was issued opining that the PREP Act is a “complete preemption” statute, and the Opinion was incorporated by reference into the Fourth Amended Declaration,⁸⁰ that position has been soundly rejected by the federal courts.⁸¹ Those courts have found little reason to accord the Advisory Opinion the judicially created “*Chevron* deference” to agency decisions.⁸²

This would not be particularly germane to the Court’s discussion but for BNR’s frequent references to the Advisory Opinions in its briefs. The Secretary of HHS has never amended the Declaration of Emergency to include preventative

⁷⁷ See generally *HHS Advisory Opinions* (June 24, 2021), <https://www.hhs.gov/about/agencies/ogc/advisory-opinions/index.html>.

⁷⁸ *Id.*

⁷⁹ 85 Fed. Reg. 79190-01 (Dec. 9, 2020).

⁸⁰ Advisory Opinion 21-01 at 2.

⁸¹ See *Maglioli*, 16 F.4th at 404; *Est. of Jones through Brown v. St. Jude Operating Company, LLC*, 524 F. Supp. 3d 1101, 1109 (D. Or. 2021) (identifying multiple cases which hold that the PREP Act does not trigger preemption for state claims relating to COVID-19 deaths).

⁸² See, e.g., *Maglioli*, 16 F.4th at 403.

measures concerning infectious airborne diseases. Nor has any Advisory Opinion opined that nursing homes are immune from suit. This makes sense. Nursing homes are not in the business of manufacturing materials to respond to public health emergencies. That said, nursing homes may be immune from suit over the administration of a vaccine manufactured by others, but that is not the question before the Court.

Plaintiffs concede that BNR is immune from suit over the “covered countermeasures” themselves.⁸³ But again, that is not this lawsuit. Plaintiffs assert, and the Court agrees, that BNR is being sued over its allegedly negligent administration of basic infectious disease protocols.⁸⁴ These are not “covered countermeasures” under the PREP Act, the Declaration of the Secretary, or any Advisory Opinion to which the Court has been directed.

C. The PREP Act did not create a new defense to standard negligence claims.

Although BNR may be a “covered person” entitled to immunity to the extent the allegation concerns its negligence in administering a “covered countermeasure,” the complaint makes no such allegation. Rather, it is a claim of “ordinary” negligence, set against the backdrop of extraordinary times.

⁸³ Pls.’ Br. at 15.

⁸⁴ Compl. ¶¶ 87, 92, 94.

BNR has access to all the usual defenses available in a negligence case. COVID-19 and the PREP Act's "covered countermeasures" did not establish a new defense to such claims, nor did they foreclose BNR from showing that it acted within the standard of care at the time the Plaintiffs contracted COVID-19. Indeed, interesting questions will surely arise over the standard of care in a nursing home during the early days of the Pandemic. But those questions are for another day and another time. The Court will leave all that to a more complete record as developed by the parties through the course of discovery.

CONCLUSION

For the foregoing reasons the Defendant's motion to dismiss is **DENIED**.

IT IS SO ORDERED.



Charles E. Butler, Resident Judge