UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MICHAEL EMERSON, ESTATE OF ALBERTS C. ROBERTS BY BRIAN ROBERTS, ADMINISTRATOR AD PROSEQUENDUM, AND ESTATE OF MICHELE DESBIENS BY PAUL DESBIANS, ADMINISTRATOR AD PROSEQUENDUM, individually and on behalf of themselves and all other similarly situated, *Plaintiffs*, v. ANDOVER SUBACUTE REHABILITATION CENTER I, ANDOVER SUBACUTE REHABILITATION CENTER II, ALTITUDE INVESTMENTS, LTD; ALLIANCE HEALTHCARE, HEALTHCARE SERVICES GROUP, JOHN DOES 1 through 100 said names being fictitious and unknown persons, and ABC CORPORATIONS 1 through 100, said names being fictitious and unknown entities, *Defendants*.	Civil Action No.: 2:20-cv-20066-SDW-LDW

MEMORANDUM IN SUPPORT OF MOTION TO DISMISS

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PRELIMINARY STATEMENT

Plaintiffs' complaint arises from defendants' response to the COVID-19 pandemic and falls within the ambit of the Public Readiness and Emergency Preparedness Act ("PREP Act"), 42 U.S.C. 247d-6d, 247d-6e, and the New Jersey COVID immunity statute, (S-2333/A-3910). Based on the actual facts pled in the complaint, it is readily apparent that this action seeks compensation for defendants' alleged negligent use and administration of covered countermeasures in failing to prevent the transmission and spread of the novel COVID-19 coronavirus which resulted in various alleged injuries. However, such claims are specifically barred by the PREP Act and New Jersey legislation that provide healthcare providers, such as defendants, with immunities and other protections against these claims. Therefore, these claims must be dismissed. This is true regardless of how these claims are characterized because they arise from, and are causally related to, defendants' use and administration of countermeasures in their effort to prevent and mitigate the transmission and spread of the novel COVID-19 coronavirus at their facilities.

The PREP Act also specifies that the remedy provided by the Countermeasure Injury Compensation Program (the "Fund") under the statute "shall be **exclusive** of any other civil action or proceeding for any claim or suit this section encompasses, except for a proceeding [for willful misconduct] under section 247d–6d of this title" which must be filed in the District Court for the District of Columbia after first filing a claim with the Fund. See §247d-6e(d)(4). Consequently, as plaintiffs have failed to exhaust their exclusive administrative remedies under the PREP Act, this Court does not have jurisdiction over these claims, and the complaint must also be dismissed for that reason as well.

Moreover, in an attempt to draft around the federal and state statutory immunities, plaintiffs concoct various statutory violations arising out of defendants' alleged negligent transmission and

spread of COVID-19 in their licensed long term care facilities, but those statutory claims fail in their own right even absent any immunity. First, while N.J.S.A. 30:13-1 establishes certain responsibilities for the operators of long term care facilities, the statute does not include a private cause of action for violations of state or federal regulations. Second, the New Jersey Consumer Fraud Act ("CFA"), N.J.S.A. 56:8-2 is a remedial consumer protection statute that specifically exempts Learned Professionals, including licensed long term care facilities and medical providers. Finally, the factual allegations in the complaint go well beyond the 2-year statute of limitations. Consequently, all claims arising from these allegations are barred.

Accordingly, plaintiffs' claims are both without legal merit and barred by statutory immunity. Therefore, plaintiffs' complaint should properly be dismissed.

FACTUAL AND PROCEDURAL HISTORY

The COVID-19 pandemic is an unprecedented and ongoing crisis that has required a comprehensive response from national healthcare providers who face constantly evolving standards of care, scarce resources and limited support. Major public health organizations including the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare and Medicaid Services (CMS) have issued dozens of recommendations, guidance, and directives to healthcare providers based on scientific data that continues to progress and evolve on an almost daily basis. In response, individual healthcare providers and facilities have been forced to constantly modify and adapt their response to the COVID-19 pandemic in order to align with the most recent priorities set forth by the major public health institutions. Despite these aggressive efforts by our government and the healthcare community at-large, the pandemic continues to spread. As of this date, more than 28 million people

have contracted the virus across the United States, and over 511,000 Americans have lost their lives to COVID-19.[1]

In response to this unprecedented outbreak, healthcare facilities such as defendants have dedicated themselves to caring for residents suffering from illness and advanced age by providing direct patient care while also simultaneously adapting and modifying treatment plans and administrative strategy to comply with continuously shifting guidance and standards to combat COVID-19 while trying to best allocate scarce resources such as critical PPE. Since the very beginning of the pandemic, there has been both evolving guidance regarding PPE, testing, testing supplies, visitation, cohorting, infection control, and therapeutics, as well directives regarding prioritizing, purposefully allocating, and distributing countermeasures within healthcare facilities.

In recognition of the whole-of-nation effort required to fight the COVID-19 outbreak, on March 10, 2020, the Secretary of HHS issued a Declaration triggering the PREP Act so as to protect healthcare facilities, such as defendants which are now being sued for decisions made in the face of ever-changing guidance and the national scarcity of COVID countermeasures, and to maximize the Nation's response to the COVID-19 pandemic. Recognizing the uncertainties of the virus, scarcity issues, developing science, and therapeutics, the federal government – through the PREP Act, Amendments to the Declaration triggering the PREP Act, and numerous HHS Advisory Opinions and guidance letters – has sought to protect healthcare providers by extending immunity from lawsuits related to their efforts to respond to the COVID-19 crisis, while also providing injured individuals a federal remedy by which to seek compensation. This framework was put in place to incentivize the medical community to respond to the present crisis and to ensure that

[1] *https://covid.cdc.gov/covid-data-tracker/#datatracker-home* (data retrieved on March 1, 2021).

critical healthcare providers and countermeasures remain available during this public health emergency.

Despite these protections and the evolving pandemic, on December 21, 2020, plaintiffs filed a complaint alleging that Michael Emerson, Albert Roberts and Michele Desbiens suffered harms arising from the alleged acts and omissions of the Andover defendants in their COVID-19 response efforts. Complaint at (ECF 1, ¶1-8). The complaint specifically faults Andover II for failing to ensure that "staff properly used personal protective equipment (PPE) when caring for COVID-19 positive or COVID-19 suspected residents" as well as an improper use of infrared thermometers and the negligent administration of their infection control programs, which include numerous countermeasures such as PPE and testing and safety equipment designed to combat the transmission of COVID-19. Id. ¶32. Similar failures as to improper use of COVID-19 countermeasures are alleged as against Andover I. Id. The complaint further alleges that this "substandard level of care" to plaintiffs or their decedents "caused them to suffer serious bodily harm." Id. ¶18. Plaintiffs specifically complain that, as a result of these failures: plaintiff Emerson contracted COVID-19 in March 2020 (id. ¶19d); plaintiff Desbiens contracted COVID-19 in March 2020 and died as a result on May 11, 2020 (id. ¶20l-m); and plaintiff Roberts contracted COVID-19 in March 2020 and died as a result on April 1, 2020. Id. ¶21d-e.

Based on these allegations contending that defendants improperly used PPE and other COVID-19 countermeasures and provided a "substandard level of care" causing plaintiffs or their decedents to suffer serious bodily harm, plaintiffs attempt to plead violations of the 1987 Omnibus Reconciliation Act ("OBRA"), the Federal Nursing Home Reform Act ("FNHRA"), N.J.S.A. 30:13-1, and the New Jersey Consumer Fraud Act("CFA").

LEGAL ARGUMENT

STANDARD OF REVIEW

1. Rule 12(b)(1) - Lack of Subject-Matter Jurisdiction

Federal courts are courts of limited jurisdiction. The burden of establishing federal jurisdiction rests with the party asserting its existence. See Kokkonen v. Guardian Life Ins. Co., 511 U.S. 375, 377 (1991). Challenges to subject matter jurisdiction under Rule 12(b)(1) may be facial or factual. A facial attack "concerns 'an alleged pleading deficiency' whereas a factual attack concerns 'the actual failure of [a plaintiff's] claims to comport [factually] with the jurisdictional prerequisites.'" Lincoln Benefit Life Co. v. AEI Life, LLC, 800 F.3d 99, 105 (3d Cir. 2015) (citing Common Cause of Penn. v. Pennsylvania, 558 F.3d 249, 257 (3d Cir. 2009)). "In reviewing a facial attack, the court must only consider the allegations of the complaint and documents referenced herein and attached thereto, in the light most favorable to the plaintiff. Id. (citing Gould Elecs. Inc. v. United States, 220 F.3rd 169, 176 (3d Cir. 2000)). The court reviews "only whether the allegations on the face of the complaint, taken as true, allege facts sufficient to invoke the jurisdiction of the district court." Common Cause of Penn at 257. (quoting Taliaferro v. Darby Twp. Zoning Bd., 458 F.3d 181, 188 (3d Cir. 2006)). A factual attack, on the other hand, permits the Court to consider and weigh evidence extrinsic to the pleadings. Gould Elecs. Inc, at 178. Such a factual attack "does not provide plaintiffs the procedural safeguards of Rule 12(b)(6), such as assuming the truth of plaintiff's allegations. CNA v. United States, 535 F.3d 132, 144 (3d Cir. 2008).

Defendants' challenge is facial because it "concerns an alleged pleading deficiency" with respect to plaintiffs' failure to exhaust administrative remedies. See Davis v. Wells Fargo, 824 F.3d 333, 346 (3d Cir. 2016). A motion filed before the filing of an Answer is considered to be

"facial." See Askew v. Church of the Lord Jesus Christ, 684 F.3rd. 413, 417 (3d Cir. 2012). Here, plaintiffs' causes of action fail because plaintiffs' claims arise under the PREP Act, and plaintiffs have failed to exhaust its administrative remedies pursuant to the Act. See, e.g., Adams v. U.S. Capitol Police Bd., 564 F.Supp. 2d 37, 40 (D.D.C. 2008) (failure to exhaust administrative remedies goes to subject matter jurisdiction, and plaintiff has the burden of persuasion); Wright & Miller, 5B Fed. Prac. & Proc. §1350, Note 5 (3d ed.) (collecting cases).

2. Rule 12(b)(6) – Failure to State a Claim

Rule 12(b)(6) is intended to screen out claims for which there is no cognizable claim or remedy. See Port Auth. v. Arcadian Corp., 189 F.3d 305, 312 (3d Cir. 1999). Although a court considering such a motion must generally take well-pleaded factual allegations in the complaint as true, that rule does not apply to legal conclusions. Mere "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Ashcroft v. Iqbal, 556 U.S. 662, 663 (2009); see also Klein v. General Nutrition Cos., 186 F.3d 338, 342 (3d Cir. 1999); Ridgewood Board of Educ. v. Stokely, 172 F.3d 238, 252 (3d Cir. 1999).

In order to survive a motion to dismiss pursuant to Rule 12(b)(6), a complaint must "raise a right to relief above the speculative level" by stating plausible grounds to support the claims asserted. See Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007); see also Iqbal, 556 U.S. at 678. In other words, a court addressing such a motion must determine whether the complaint "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." See Iqbal, 556 U.S. at 663.

While the court is to assume the truth of all factual allegations in the complaint, the court "need not accept as true 'unsupported conclusions and unwarranted inferences.'" City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 263 n. 13 (3d Cir. 1998) (quoting Schuylkill

Energy Res., Inc. v. Pennsylvania Power & Light Co., 113 F.3d 405, 417 (3d Cir. 1997)). '"[C]ourts have an obligation in matters before them to view the complaint as a whole and to base rulings not upon the presence of mere words but, rather, upon the presence of a factual situation which is or is not justiciable.'" Grant, Inc. v. Great Bay Casino Corp., 232 F.3d 173, 184 (3d Cir. 2000) (quoting West Penn Power, 147 F.3d at 263).

Additionally, in evaluating a Rule 12(b)(6) motion to dismiss, a court may consider the complaint, as well as exhibits attached to and referenced in the complaint, matters of public record, and undisputedly authentic documents if the plaintiff's claims are based upon those documents. Pension Benefit Guar. Corp. v. White Consol. Indus., 998 F.2d 1192, 1196 (3d Cir. 1993). This means documents "integral to or explicitly relied upon in the complaint may be considered without converting the motion to dismiss into one for summary judgment.'" U.S. Express Lines Ltd. v. Higgins, 281 F.3d 383, 388 (3d Cir. 2002) (quoting In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1426 (3d Cir. 1997)) (internal quotations omitted). Under this standard, plaintiffs' complaint fails to state a claim upon which relief can be granted and must be dismissed.

POINT I

PLAINTIFFS' COMPLAINT FAILS TO STATE A CLAIM BECAUSE IT IS BARRED BY THE PREP ACT.

An examination of the facts and allegations pled in the complaint reveals that the crux of this action is that defendants negligently used covered countermeasures, such as PPE and thermometers, in combatting COVID-19 at the facilities and thus purportedly provided their residents a "substandard level of care" to plaintiffs "caus[ing] them to suffer serious bodily harm." (ECF 1, ¶18). The complaint specifically faults both facility defendants for their staff's improper use of PPE and thermometers when caring for COVID-19 positive or COVID-19 suspected

residents. Id. at ¶32. These allegations trigger the application of the PREP Act. As such, plaintiffs' complaint is barred by the PREP Act's immunity provision.

A. CONGRESS EXPRESSLY PROVIDED IMMUNITY FOR DEFENDANTS.

The Public Readiness and Emergency Preparedness Act, 42 U.S.C. §§ 247d 6d, 247d-6e(2006) and the Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020) (together, the PREP Act") are federal statutes that apply specifically to medical providers such as defendants in the administration of countermeasures to prevent or mitigate the spread of COVID-19. This legislation empowers the Secretary of Health and Human Services (HHS) to issue a declaration providing immunity for "covered persons" to suits and liability under federal and state law relating to the administration of a "Covered Countermeasure" during a health emergency. As the Act expressly states:

> [A] covered person ***shall be immune from suit and liability under Federal and State law 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 if a declaration under subsection (b) has been issued with respect to such countermeasure.[2]

42 U.S.C. § 247d-6d(b)(1) (emphasis added).

The PREP Act was designed to protect individuals and entities exposed to a greater risk of liability in responding to a public health emergency. The primary function of the PREP Act is to remove liability concerns, specifically when employing countermeasures, so that resources would remain available during an emergency.[3] The Act also has a broad reach in its intended scope of

[2] Loss is broadly defined as "any type of loss," including death, physical injury, mental injury, emotional injury, fear, property loss and damage, and business interruption loss.§ 247d-6d(a)(2)(A) . Moreover, the immunity applies to any claim "that has a causal relationship with the administration to or use by an individual of a covered countermeasure." § 247d-6d(a)(2)(B).

[3] See P. Binzer, The PREP Act: Liability Protection for Medical Countermeasure Development, Distribution, and Administration, Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science, Vol. 6, No 4, 2008.

protection. The Act empowers the Secretary of HHS to issue a written declaration identifying the "covered persons" who shall be immune from suit. 42 U.S.C. § 247d-6d(a)(1)&(b). Here, the Secretary of HHS issued just such a "Declaration," effective February 4, 2020, providing liability immunity for "recommended activities," including the distribution, administration, or use of covered countermeasures against COVID-19. See 85 Fed. Reg. at 15201. Unlike prior declarations issued by HHS in response to other public health emergencies, the COVID-19 Declaration has been amended six times, each time broadening the scope of the PREP Act as applied to the emergency response to this unique global pandemic.

B. DEFENDANTS QUALIFY AS COVERED PERSONS UNDER THE PREP ACT.

Defendants are "covered persons" pursuant to the PREP Act because they can be considered both "qualified persons" and "program planners." Under the PREP Act, a "covered person" includes (i) the United States; (ii) manufacturers and distributors of covered countermeasures; (iii) **program planners**; and (iv) **qualified persons who prescribe, administer or dispense covered countermeasures**. 42 U.S.C.§ 247d-6d(i)(2). (emphasis added). "Qualified persons" include licensed health professionals and other individuals authorized to prescribe, administer, or dispense covered countermeasures under state law, as well as other persons identified in a declaration by the Secretary. 42 U.S.C. § 247d-6d(i)(8). "Program planners" include state and local governments or other persons who supervise or administer programs that dispense, distribute, or administer covered countermeasures, *or* provide policy guidance, facilities, and scientific advice on the administration or use of such countermeasures. 42 U.S.C. § 247d-6d(i)(6). The meaning of "program planner" and "qualified person" has been clarified as follows:

> …State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a

> security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with [the Secretary's declaration].

42 U.S.C. § 247d-6d[i][6].

Under the Secretary's declaration, "[**A] private sector employer or community group or other 'person' can be a program planner when it carries out the described activities**." 85 Fed. Reg. at 15,202. Furthermore, on August 14, 2020, the Office of General Counsel confirmed that senior living communities are "covered persons" subject to immunity under the PREP Act as "program planners" and "qualified persons." [OGC Letter to Thomas Barker.] The Office of General Counsel also published a Guidance confirming that COVID testing in nursing homes is a covered countermeasure triggering the Act.[4]

On October 23, 2020, the Office of the General Counsel's Advisory Opinion No. 20-04 verified that the term "program planner" is broadly defined.[5] The opinion also explained that PREP Act coverage will apply to a covered person using a covered countermeasure in accordance with any public health guidance from an "Authority Having Jurisdiction." The January 8, 2021 Advisory Opinion 21-01 more broadly outlined that a "program planner" under the Act is "someone who is involved in providing or allocating covered countermeasures," and that "program planning inherently involves the allocation of resources." The Advisory Opinion thereby concluded that "**decision-making that leads to the non-use of covered countermeasures by**

[4] HHS, *Office of the General Counsel, Letter to Thomas Barker, Foley Hoag LLP* (Aug. 14, 2020) *available at* https://www.govinfo.gov/content/pkg/FR-2020-08-24/pdf/2020-18542.pdf [Aug. 31, 2020].

[5] HHS, Office of the General Counsel, "Advisory Opinion No. 20-04 *on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration Under the Act"* (Oct. 22, 2020, as modified Oct. 23, 2020), *available at* (*https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO%204.2_Updated_FINAL_SIGNED_10.23.20.pdf* [Advisory Opinion 20-04.]

certain individuals is the grist of program planning, and is expressly covered by [the] PREP Act."

Defendants qualify as "covered persons" under the PREP Act. During the time set forth in the underlying Complaint, defendants acted as both "qualified persons" and "program planners." Defendants operated as skilled nursing facilities licensed by the New Jersey Department of Health. Defendants employed various medical professionals including administrators, directors, nursing personnel, physicians, therapists, and nursing aides who were authorized to allocate, administer, prescribe, and dispense the covered countermeasures set forth in plaintiffs' Complaint, including PPE (such as facemasks, gloves, gowns, face shields, N95 masks), COVID testing materials, thermometers, and other items which qualify as pandemic or epidemic products. Additionally, these individuals developed, administered, and oversaw policies, procedures, and programs related to infection control.

C. THE PREP ACT IS TRIGGERED BECAUSE PLAINTIFFS' CLAIMS ARISE FROM DEFENDANTS' USE AND ADMINISTRATION OF "COVERED COUNTERMEASURES."

The PREP Act is applicable with respect to a "covered countermeasure," which by definition includes: "(1) a qualified pandemic or epidemic product (as defined in § 247d-6d (i)(7)) . . . or (4) a respiratory protective device that is approved by the National Institute for Occupational Safety and Health ("NIOSH") and that the Health and Human Service Secretary determines to be a priority for use during a public health emergency declared under section 247d." 42 U.S.C. § 247d-6d(i)(1). A "qualified pandemic or epidemic product" is defined as: a drug, biologic product or device that is:

> "(A)(i) a product manufactured, used, designed, developed, modified, licensed, or procured—

> (I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or
> (II) to limit the harm such pandemic or epidemic might otherwise cause;
> (ii) a product, manufacture, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious of life-threatening disease or condition caused by a product described in clause (i); or
> (iii) a product or technology intended to enhance the use or effect of a drug, biologic product, or device described in clause (i) or (ii); and
> (B)(i) approved or cleared under chapter v. of the Federal Food, Drug, and Cosmetic Act or licensed under section 262 of this title;
> (ii) the object of research for possible use as described in subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act; or
> (iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug and Cosmetic Act."

See 42 U.S.C. § 247d-6d(i)(7).

The March 17, 2020 Declaration expanded the categories of "covered countermeasures" eligible for immunity to include *any* device used to treat, diagnose, cure, prevent or mitigate COVID-19 or its spread. The Declaration was subsequently amended to add respiratory protective devices like N95 masks to the list of covered countermeasures. See 42 U.S.C. § 247d-6d(i)(1)(D); see also 85 Fed. Reg. at 21,014. Also, in response to the Coronavirus Aid, Relief, and Economic Security (CARES) Act § 3103, Pub. L. No. 116-136 (March 27, 2020), the PREP Act COVID-19 declaration was amended to **add respiratory protective devices** to the list of covered countermeasures so long as they are NIOSH approved and determined by the Secretary to be a priority for use during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act.5 See 42 U.S.C. § § 247d, 247d-6(i)(1)(D). On June 8, 2020, the Declaration was amended again to reflect the HHS's original intent to "identify the full range of qualified countermeasures" as permitted under the PREP Act. 85 Fed. Reg. 35100. Thus, a covered countermeasure includes a broad range of products and devices specified as: (i) a qualified pandemic or epidemic product; (ii) a security countermeasure; (iii) a drug, biological product, or device that the U.S. Food and Drug Administration (FDA) has authorized for emergency use; and,

(iv)a NIOSH-approved respiratory protective device. Improper use of these countermeasures, including masks, is specially alleged in the complaint satisfying this element necessary to confer immunity to defendants under the PREP Act.

D. THE PREP ACT APPLIES AS THERE IS A CAUSAL NEXUS BETWEEN DEFENDANTS' ADMINISTRATION AND USE OF A COVERED COUNTERMEASURE AND PLAINTIFFS' ALLEGED LOSS.

Immunity under the PREP Act "applies to any claim for loss that has a **causal relationship** with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the . . . distribution . . . **purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure**." 42 U.S.C. § 247d-6d (a)(2)(B). While the term "administration" is undefined in the PREP Act, the March 17, 2020 Declaration explained that "Administration of a Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and **decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures."** 85 Fed. Reg. at 15,200. Thus, the definition of "administration" extends not only to the physical provision of countermeasures to recipients, , but also "**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."** Id.

Advisory Opinion 21-01 affirms that the PREP Act is triggered even in instances involving non-use or the non-administration of a covered countermeasure. The Advisory Opinion specifically notes "[p]rioritization of purposeful allocations of a Covered Countermeasure,

particularly if done in accordance with a public health authority's directive, can fall within the PREP Act." Furthermore, "a conscious decision not to use a covered countermeasure could relate to the administration of the countermeasure." AO 21-01 further clarifies that the PREP Act would still be triggered when a facility "fails to administer [a] therapeutic…assuming the non-use of the therapeutic was the result of conscious decision-making." The Advisory Opinion explains that the PREP Act should be applied to the broadest extent possible, and even in rare instances where a plaintiff argues that "defendant failed to make any decisions whatsoever," federal courts are "**free to entertain discovery to ascertain, for jurisdictional purposes, the facts underlying the complaint**." (citing United Surgical Assistants, LLC v. Aetna Life Ins. Co., 2014 WL 4059889 at *1 (M.D. Fla. Aug. 14, 2014). Indeed, since AO 21-01 was issued in January 2021, at least one federal district court has adopted and incorporated this opinion into its rulings, dismissing plaintiffs' claims which arise under the PREP Act. See Garcia v. Welltower OpCo Grp, No. 20-cv-2250-JVS-KES (C.D. Cal.)

In the present matter, plaintiffs' complaint on its face alleges that the Andover facilities negligently administered their COVID-19 infection control program, including specifically improper use of PPE and thermometers, to individuals within the facility. Plaintiffs' claims thereby arise from the nexus between the administration and use of a covered countermeasure and the injuries being alleged in this manner. During the initial outbreak of COVID-19 in March 2020, the Andover facilities took proactive steps to procure PPE, including facemasks, gowns, gloves, and other countermeasures to limit the transmission and spread of COVID-19. The facilities' response specific to the procurement, administration, allocation, and use of these countermeasures, as well infection control protocols that utilize such countermeasures, directly invoke immunity under the PREP Act.

The allegations in complaint are precisely the types of allegations which the PREP Act is designed to protect. Therefore, defendants are entitled to the immunity protection provided within the statute, and plaintiffs' complaint should be dismissed in its entirety.

E. PLAINTIFFS' COMPLAINT MUST ALSO BE DISMISSED FOR FAILURE TO EXHAUST ADMINISTRATIVE REMEDIES OF THE COUNTERMEASURES INJURY COMPENSATION PROGRAM.

The complaint specifically faults the facilities for failing to ensure… "staff **properly** used personal protective equipment (PPE)" and thermometers "when caring for COVID-19 positive or COVID-19 suspected residents" as well as for inadequate COVID-19 infection control programs that by design include numerous covered countermeasures. Id. at ¶32. These allegations trigger the application of the PREP Act and the administrative remedies specified by the Act. Plaintiff has failed to exhaust these remedies thus depriving this Court of jurisdiction and requiring dismissal of the complaint.

The failure to exhaust administrative remedies when required by statute has been held to deprive the court of subject matter jurisdiction for purposes of a motion to dismiss brought under F.R.C.P. Rule 12(b)(1). See, e.g., Adams v. U.S. Capitol Police Bd., 564 F.Supp. 2d 37, 40 (D.D.C. 2008) (failure to exhaust administrative remedies goes to subject matter jurisdiction, and plaintiff has the burden of persuasion); Wright & Miller, 5B Fed. Prac. & Proc. §1350, Note 5 (3d ed.) (collecting cases). Moreover, where an administrative remedy is required by statute, there is no room for judicial discretion if a claimant fails to satisfy the statutorily proscribed exhaustion protocols. Ross v. Blake, 136 S.Ct. 1850, 1857 (2016). Alternatively, dismissal for failure to exhaust administrative remedies can be considered an exercise of judicial discretion for the dual purposes of "protecting administrative agency authority and promoting judicial efficiency." See, e.g., McCarthy v. Madigan, 503 U.S. 140, 145 (1992) (abrogated by statute on other grounds); Anversa v. Partners Healthcare Sys., Inc., 835 F.3d 167, 176 (1st Cir. 2016) (exhaustion

administrative remedies will create "a useful record for subsequent judicial consideration, especially in a complex or technical factual context").

In codifying HHS's authority to coordinate the national response to a public health emergency, Congress took great pains to set out an extensive, streamlined no-fault federal administrative claims process to ensure remedy and fairness for claimants and respondents by

a) Setting up a no-fault monetary fund (CCPF) to compensate eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure. See 42 U.S.C. §247d-6e(a);

b) Directing that access to the monetary fund must be **exhausted** before being allowed to proceed to the alternative federal civil claims process of §247d-6d. See §247d-6e(d)(1);

c) Requiring an exclusive federal remedy: "The remedy provided by [the monetary fund] shall be **exclusive** of any other civil action or proceeding for any claim or suit this section encompasses, except for a proceeding [for willful misconduct] under section 247d–6d of this title." See §247d-6e(d)(4) (emphasis added);

d) Mandating that the only recovery for claims under the PREP Act shall be through the monetary fund or through the PREP Act claims process: "the individual has an **election** to accept the compensation [under the monetary fund] or to bring an action under section 247d–6d(d) of this title." See §247d-6e(d)(5) (emphasis added).

Crucial to Congress' intent to preclude COVID-19 claims is this establishment of a streamed lined no-fault monetary fund process—known as the CCPF—which provides causation presumptions for claimants and compensates eligible individuals for covered injuries. §247d-6e(a). Before a claimant may file a lawsuit (and, then, only one claiming willful misconduct), they must first exhaust administrative remedies through the federal emergency no-fault fund designated by the PREP Act. See §247d-6e. Only after a claimant exhausts those administrative remedies will they be allowed to bring a litigation claim, and then, only for willful misconduct brought in the United States District Court for the District of Columbia (D.D.C.) See §§247d-6d(c)(4), (e)(1), (5) (the D.D.C is designated as the exclusive jurisdiction for PREP litigation

claims). The CCPF process is the exclusive prerequisite vehicle for recovery where a COVID-19 countermeasure negligence or willful misconduct claim is pled.

Here, plaintiffs were required to pursue administrative remedies before filing suit against defendants. Plaintiffs' complaint makes no reference to any attempt to pursue or exhaust the remedies potentially available with the CCPF. This was specifically the Court's concern in Garcia. In that matter, the Court noted that all of plaintiff's claims essentially alleged "unsuccessful attempts at compliance with federal and state guidelines - something which the PREP Act, the Declaration, and the January 8, 2021 Advisory Opinion cover. See Garcia, at *14.

Accordingly, plaintiffs failed to plead exhaustion of administrative remedies as required under the PREP Act, which necessarily requires dismissal of this action.

POINT II

PLAINTIFFS' COMPLAINT FAILS TO STATE A CAUSE OF ACTION BECAUSE IT IS BARRED BY THE NEW JERSEY COVID-19 IMMUNITY STATUTE.

Plaintiffs' complaint seeks to recover damages for injuries arising from defendants allegedly providing a "substandard level of care" during the COVID-19 pandemic, causing their residents to "suffer serious bodily harm." (ECF 1, ¶18). It is alleged that the substandard level of care resulted in plaintiffs or their decedents contracting COVID-19 while at the defendants' facilities. Id. at ¶19(d), ¶20(l) and ¶21(d). All of these allegations arise exclusively from care or treatment received during the COVID-19 pandemic. In particular, plaintiffs allege that defendants' failed to prevent the transmission and spread of COVID-19 within the facilities by virtue of the manner in which they administered and used PPE, thermometers and other infection control countermeasures. Specifically, plaintiffs allege the facility failed to ensure:

1. Appropriate transmission based precautions were ordered and implemented for suspected COVID-19 residents.
2. A system of surveillance to prevent the spread of infection.

3. Staff properly used PPE when caring for COVID-19 positive or COVID-19 suspected residents.
4. Staff were properly trained to use the infrared forehead thermometer on staff, visitors and residents

Id. at ¶32.

Defendants are immune from liability for these actions, and indeed any omissions, made in connection with their efforts to prevent the spread of COVID-19 by application of the New Jersey COVID-19 Immunity Statute. (S-2333/A-3910).

The statute is retroactive to March 9, 2020, and offers expansive immunity to healthcare providers responding to the COVID-19 pandemic. Medical professionals along with the facilities and health systems that they work for "shall not be liable for civil damages for ***injury*** or death alleged to have been sustained as a result of an act or omission . . . in the course of providing medical services in support of the State's response to the outbreak of coronavirus disease[.]" The sweeping immunity also extends to "any act or omission undertaken in good faith by a healthcare professional or healthcare facility or a health care system to support efforts to treat COVID-19 patients and to prevent the spread of COVID-19." The immunities granted pursuant to the statute extend until the state of emergency and public health emergency declarations by the governor are rescinded.

The complaint seeks civil damages for injury and death sustained as the result of the alleged acts or omissions on the part of defendants, licensed healthcare facilities, in treating the health of their resident in responding to the COVID-19 pandemic as they worked to prevent the transmission and spread of the virus within the facilities. The statute is explicit that that immunity extends to any "injury" arising from the defendants' acts or omissions in responding to the ongoing pandemic. The language of the statute does not limit or specifically define "injury." However, injury, by definition generally, is not limited to mere bodily injury but extends to any "hurt, damage, or loss

sustained" including a "violation of [a] right for which the law allows an action to recover damages."[6] Consequently, all injuries alleged in the complaint, inclusive of not only all bodily injuries but also all alleged violations of statutory rights, are precisely the type of claims against which the New Jersey COVID Immunity Statute immunizes healthcare facilities. As such, plaintiffs' complaint must be dismissed in its entirety.

POINT III

PLAINTIFFS' COMPLAINT FAILS TO STATE A CLAIM AS THERE IS NO PRIVATE CAUSE OF ACTION UNDER N.J.S.A. 30:13-1 FOR VIOLATIONS OF NURSING HOME ACT RESPONSIBILITIES.

Plaintiffs' complaint at Count II seeks damages for violations of N.J.S.A. 30:13-1(NHA), et seq., alleging "defendants failed to comply with the minimum standards of care set forth" by the statute. (ECF 1, ¶57-61). These "minimums" are more commonly referred to as the "responsibilities" sections of the NHA. They are enumerated under N.J.S.A. 30:13-3(a)-(j) and include a long term care facility's responsibility to: (i) maintain complete records of a resident's funds and personal property; (ii) provide for the spiritual needs and wants of residents; (iii) admit only the number of residents for which it could safely provide care; (iv) ensure applicants and residents are not subject to discrimination based on age, race, religion, sex, or national origin; (v) ensure that drugs are not employed as punishment or for the convenience of the staff; (vi) permit access by legal services staff; (vii) ensure compliance with all applicable state and federal statutes, rules and regulations; (viii) provide residents with a written statement of services and charges; and (ix) provide the resident or family with a copy of the admissions contract. Id.

[6] See Merriam-Webster. (n.d.). Injury. In Merriam-Webster.com dictionary. Retrieved March 2, 2021, from https://www.merriam-webster.com/dictionary/injury

The NHA, under the provision of N.J.S.A. 30:13-8(a), does not authorize an individual to bring a private cause of action to enforce the "responsibilities" of the nursing facility as defined under the statute. As enacted, N.J.S.A. 30:13-8(a) provides that any plaintiff may bring a cause of action for a violation of the "rights" provisions; however, only the Department of Health and Human Services ("DOH") may bring an action for alleged violations of the "responsibilities" portion of the Act. Id

In Ptaszynski v. Atl. Health Sys., Inc, 440 N.J. Super. 24, 36 (App. Div. 2015)), cert. denied, 2016 N.J. LEXIS 988 (2016), the Appellate Division rejected plaintiff's attempt to expand the private cause of action permitted under N.J.S.A. 30:13-4.2 to the entirety of the NHA, including the "responsibilities" sections. The plaintiff alleged the defendant nursing facility was negligent insofar as it failed to comply with New Jersey statutes and regulations relating to the care of nursing home residents, and failed to comply with federal regulations applicable to the defendant nursing home. Id. at 30.

The Appellate Division rejected plaintiff's attempt to expand the class of permitted claimants, holding that this interpretation would violate the most basic rules of statutory construction. Id. at 34-35. The Appellate Division held:

> There is no indication that, in enacting the amendments to the NHA, the Legislature intended to confer upon nursing home residents the ability to bring actions to enforce any violation of the NHA. The 1991 legislation imposed upon nursing homes new, specific requirements pertaining to security deposits, and allowed residents to bring actions to enforce those requirements, *not other responsibilities that nursing homes have under the law.*

Id. at 35 (emphasis added).

The Appellate Division then concluded that private plaintiffs are not permitted "to assert a cause of action for the alleged failure by defendant to fulfill its responsibility under N.J.S.A.

30:13–3(h) to comply with all applicable state and federal statutes, rules and regulations." Id. at 36. Indeed, the Court specifically noted:

> The plain language of N.J.S.A. 30:13-4.2 and the context in which the phrase 'this act' is used in N.J.S.A. 30:13-4.1 and the N.J.S.A. 30:13-4.2 indicate that the Legislature intended the phrase to mean the amendatory legislation enacted in 1991, *not the whole of the NHA*.

Id. at 35 (emphasis added).

In Count II of their complaint, plaintiffs assert a private cause of action for the very claims rejected in Ptaszynski. Count II of the Complaint alleges violations of N.J.S.A. 30:13-1 et seq., and refers to defendants' alleged failure to fulfill their responsibilities under N.J.S.A. 30:13–3(h) to comply with all applicable state and federal statutes, rules and regulations. However the Appellate Division held in Ptaszynski that such claims fall under sub-section (h) of N.J.S.A. 30:13-3 and are only actionable by the New Jersey Department of Health. As such, even putting aside the immunity that bars these claims, Count II of the complaint also fails to state a claim upon which relief can be granted under the statute itself, and it must be dismissed.

POINT IV

COUNT III OF THE COMPLAINT FAILS TO STATE A CLAIM BECAUSE THE NEW JERSEY CONSUMER FRAUD ACT DOES NOT APPLY TO CLAIMS AGAINST LEARNED PROFESSIONALS.

Count III of the complaint alleges that defendants violated the CFA. The CFA provides that it is unlawful for persons to use or employ, "any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise." N.J.S.A. 56:8-2. The CFA allows for "a private cause of action, but only for victims of consumer

fraud who have suffered an ascertainable loss." Weinberg v. Sprint Corp., 173 N.J. 233, 249, 801 A.2d 281 (2002).

In New Jersey, courts have consistently shielded healthcare providers from any CFA claims under the Learned Professional exception. It is well settled under New Jersey law that learned professionals are beyond the reach of the CFA so long as they are operating in their professional capacities. See Shaw v. Shand, 460 N.J. Super. 592 (App. Div. 2019). New Jersey courts have held that physicians, lawyers, dentists, accountants, and engineers are learned professionals. Id. Semi-professionals are also be excluded from CFA liability.[7]

The learned professional exception shields healthcare facilities and entities from CFA claims as well. In Hampton Hosp. v. Bresan, 288 N.J. Super. 372 (App. Div. 1996), the Appellate Division found that there was no purpose to require hospitals to be within the purview of the CFA when the same services fall within the purview of the Department of Health. The goal of the CFA, namely, to protect consumers, is already being accomplished by the Department. Similarly, in Atlantic Ambulance Corp. v. Cullum, 451 N.J. Super. 247 (App. Div. 2017), the Appellate Division held that ambulance service providers are not subject to consumer fraud claims because under the "learned professional" exception ambulance services are comprehensively regulated by a state agency. In reaching its conclusion, the Cullum court reviewed the relevant statutory and regulatory provisions concerning ambulance services. It found that, by statute, the Department of Health is charged with overseeing the provision of health care services to the public, which specifically include ambulance services, the Department's regulations establish stringent licensure

[7] See e.g. Plemmons v. Blue Chip Ins. Servs., Inc., 387 N.J. Super. 551 (App. Div. 2006) (an insurance broker was a semi-professional because brokers are subject to testing, licensing and other regulation)

requirements for ambulance services, and the Department has the right to take enforcement action against them.

The Learned Professional exception has likewise been applied to nursing homes, shielding such facilities from CFA claims. See Manahawkin Convalescent v. O'Neill, 426 N.J. Super. 143 (App. Div. 2012) aff'd, 217 N.J. 99(2014). Like hospitals, nursing home facilities are strictly regulated, particularly those accepting patients who receive federally funded medical assistance through Medicaid and Medicare. Id. at 155. Pursuant to these regulations, the New Jersey Department of Health is authorized to maintain an action in the name of the State to enforce the provisions of the New Jersey Nursing Home Act and any regulations promulgated pursuant to N.J.S.A. 30:13-8(a). The Appellate Division in O'Neill found that applying the CFA to a nursing facility that is subject to state regulation would "create an impermissible circumstance where divergent determinations and penalties for the same subject matter may occur. Id. (citing Daaleman v. Elizabethtown Gas Co., 77 N.J. 267, 272(1978)). As such, the Appellate Division determined that nursing homes would be shielded from CFA claims under the learned professional exception.

Similar to O'Neill, defendants here operate a private nursing home that is strictly regulated by the New Jersey Department of Health under the Nursing Home Act. Indeed, plaintiffs have alleged violations of the detailed Federal and New Jersey statutory schemes regulating and imposing responsibilities on defendants. As defendants' nursing home facilities are regulated by the Department of Health, the goal of the CFA, which is to protect consumers, is already being accomplished by these and other regulations. Accordingly, defendants are shielded from plaintiffs' CFA claims under the learned professional exception, and plaintiffs' CFA claims must be barred.

POINT V

ANY ALLEGATIONS BEFORE DECEMBER 21, 2018 ARE BARRED BY THE STATUTE OF LIMITATIONS AND FAIL TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED.

Plaintiffs' complaint was filed December 21, 2020. It seeks damages for personal injury and also alleges §1983 claims. In the context of personal injury claims, federal courts apply the applicable state's statute of limitations. See Sameric Corp. of Del., Inc. v. City of Philadelphia, 142 F.3d 582, 599 (3d Cir. 1998); Mikhail v. Kahn, 991 F. Supp. 2d 596, 641 (E.D. Pa. 2014). Section 1983 does not create substantive rights; it provides a federal cause of action for the violation of a federal right. See Oklahoma City v. Tuttle, 471 U.S. 808, 816(1985); Dique v. N.J. State Police, 603 F.3d 181, 185 (3d Cir. 2010). State law, however, determines when the claim accrues and provides the statute of limitations applicable to a §1983 claim. See Wallace v. Kato, 549 U.S. 384, 387 (2007); Dique, 603 F.3d at 185. A §1983 claim is characterized as a personal injury claim and is therefore governed by the applicable state's statute of limitations for personal injury claims. Cito v. Bridgewater Twp. Police Dep't, 892 F.2d 23, 25 (3d Cir. 1989).

In this matter, New Jersey is the applicable state. New Jersey's statute of limitations governing personal injury claims, including claims sounding in negligence, is found at N.J.S.A. 2A:14-2, which states:

> Every action at law for an injury to the person caused by the wrongful action, neglect or default of any person within this state shall be commenced within two years next after the cause of action shall have accrued.

N.J.S.A. 2A:14-2 (emphasis added)

The purposes of New Jersey's statute of limitations are two-fold: "(1) to stimulate litigants to pursue a right of action within a reasonable time so that the opposing party may have a fair opportunity to defend, thus preventing the litigation of stale claims, and (2) to penalize dilatoriness

and serve as a measure of repose." Gantes v. Kason Corporation, 145 N.J. 478, 486 (1996);. As the New Jersey Supreme Court explained in Vispisiano v. Ashland Chemical Co., 107 N.J. 416 (1987), "when an injured party sleeps on his rights so long as to let the customary period of limitations expire, 'the pertinent considerations of individual justice as well as the broader considerations of repose coincide to bar his action.'" Id. at 482 (quoting Farrell v. Votator Div. of Chemetron Corp., 62 N.J. 111(1973)).

Despite this well settled law, plaintiffs' complaint contains allegations well predating December 21, 2018, which are consequently barred by the statute of limitations. For example, the complaints sets forth allegations of negligent care involving plaintiff Desbiens beginning in 2016 unrelated to her death of COVID-19 related complications on May 11, 2020. (ECF 1, ¶20). All allegations of improper care before December 21, 2018 are barred by the statute of limitations. Further, plaintiff relies on inspections performed by the Centers for Medicare &Medicaid Services ("CMS") dating back to 2015 in the statement of common facts for all counts of the complaint. Id. at ¶23-30. Any claims for personal injury and any §1983 claim based on these facts predating December 21, 2018 are barred by application of the statute of limitations.

CONCLUSION

In light of the foregoing, it is respectfully requested that Defendants' Motion to Dismiss the Complaint be granted in its entirety.

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Counsel to Defendants, Alliance HC Holdings, LLC d/b/a Andover Subacute & Rehabilitation I; Alliance HC II LLC d/b/a Andover Subacute & Rehabilitation II (Alliance Healthcare being improperly pleaded by name and as a separate entity)

By: ***/s/ Malinda Miller***
Malinda A. Miller, Esq.