

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

JODI GILL, as Attorney-in-Fact of GLENN OSCAR GILL; KENNETH WRIGHT; SHELBY GALTON; JUDITH MARIE as Guardian *Ad Litem* of DOROTHY UMSTEAD; JAMAL WILLIAMS as Guardian *Ad Litem* of LUCILLE WILLIAMS; JAMIE WORTHY-SMITH, Individually and as Administratrix of the Estate of KIM L. McCOY-WARFORD; MARK J. LANTON, Individually and as Administrator of the Estate of GLORIA LANTON; JACQUELINE YOUNG, Individually and as Administrator of MARION YOUNG; BRANDY HEDGER, Individually and as Administratrix of the Estate of REBECCA JOY VANKIRK; KERI BOYER, Individually and as Administratrix of the Estate of EARL DENBOW, JR.; DENISE ELDRIDGE, Individually and as Administratrix of the Estate of VIRGINIA ELDRIDGE; TRACY MINEO and SUSAN FRAGOMENI, Individually and as Co-Administratrixes of the Estate of NANCY KEMERER; PATRICIA MAZZOCCA and BARBARA MACURAK, Individually and as Co-Executrixes of the Estate of ALA MAZZOCCA; CHRISTINA CLAVELLI, Individually and as Administratrix of the Estate of JOSEPH “RANDY” CLAVELLI; and, BOBBIE JOHNSON, Individually and as Administratrix of the Estate of SHIRLEY M. MIKE,

Case No: 2:20-CV-1754-CB

Electronically Filed

Plaintiffs,

v.

COMPREHENSIVE HEALTHCARE MANAGEMENT SERVICES, LLC d/b/a BRIGHTON REHABILITATION & WELLNESS CENTER and DAVID G. THIMONS, D.O.,

Defendants.

BRIEF IN SUPPORT OF DEFENDANTS’ MOTION TO DISMISS PLAINTIFFS’ COMPLAINT PURSUANT TO RULE 12(B)(6), RULE 12(B)(1), AND RULE 8(A)

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I. INTRODUCTION

Plaintiffs' claims arise from Defendants' response to the COVID-19 pandemic. Plaintiffs here are either current or past residents of Brighton Rehabilitation and Wellness Center, or their representatives, who bring claims against Defendants, Comprehensive Healthcare Management Services, LLC d/b/a Brighton Rehabilitation and Wellness Center (hereinafter "Defendant Brighton" or "Brighton") and David G. Thimons, D.O. (hereinafter "Defendant Thimons" or "Dr. Thimons") for various causes of action, including Corporate Negligence, Vicarious Negligence, Wrongful Death, and Survival. More specifically, Plaintiffs allege that, in Defendants' management and operation of a COVID-19 countermeasure program and facility, they failed to protect Plaintiffs and/or their Decedents from the virus during the ongoing pandemic by virtue of the manner in which they administered, allocated, and used personal protective equipment ("PPE"), testing equipment, safety equipment, infection control measures, and other countermeasures in an attempt to prevent or mitigate the spread of COVID-19 at Brighton.

However, this action must be dismissed for several reasons. First and foremost, Defendants are immune from these claims under the federal Public Readiness and Emergency Preparedness Act, 42 U.S.C.A. §§ 247d-6d, 247d-6e (West 2020) ("PREP Act"). Congress has declared that healthcare providers, such as Defendants, who are working tirelessly to combat the COVID-19 global pandemic, are entitled to protection from lawsuits that second guess the manner in which they have administered countermeasures during this national public health emergency. The COVID-19 pandemic is an unprecedented and ongoing crisis that has warranted constant adjustment by our healthcare providers. The World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), and other public health authorities have issued continuously evolving recommendations, guidance, and advice based on the science of the moment. Despite aggressive efforts by our government and health care community, the pandemic

has continued to spread. Globally, there are approximately over 85 million confirmed cases. To date, more than 20 million people have contracted the virus across the United States, and over 352,000 Americans have passed away as a result of the virus. These statistics are increasing daily at a rapid pace.

The challenges and tragedies presented by COVID-19 have reinforced the critical need for legal immunities so that individuals and entities like Defendants are not subject to lawsuits that will hinder and discourage their critical and ongoing work to treat and prevent the spread of COVID-19 in the face of constantly evolving standards of care and treatment. Therefore, this Court can and should decide now, as a matter of law, that Defendants are immune from liability based on these federal laws. Delaying this determination until a later stage of the proceedings will only force health care providers to engage in expensive, disruptive, and protracted discovery in the middle of an unprecedented pandemic, thus diverting resources and depriving them of the very protections the federal and state immunities are intended to confer. Plaintiffs' claims arise directly from Defendants' efforts to combat the virus at Brighton with countermeasures. Accordingly, Defendants respectfully request that the Court determine that Defendants are immune from liability under the federal PREP Act and dismiss Plaintiffs' Complaint for failure to state a claim pursuant to Federal Rule 12(b)(6).

Plaintiffs' complaint also must be dismissed for lack of subject matter jurisdiction pursuant to either Federal Rule 12(b)(1) or Federal Rule 12(b)(6) because plaintiffs are alleging claims of loss relating to the administration or use of covered countermeasures in response to the COVID-19 emergency. As such, their exclusive remedy is through the PREP Act, thereby depriving this Court of subject matter jurisdiction over Plaintiffs' state law claims.

In the alternative, Defendants respectfully requests that the Court dismiss this action as the

Complaint improperly joins seventeen (17) Plaintiffs in one lawsuit, which is legally impermissible. Moreover, Plaintiffs' Wrongful Death and Survival claims are legally deficient and fail as a matter of law in that Plaintiffs do not and cannot plead the prima facie elements of negligence that underlies these claims. Further, Plaintiffs' Complaint inappropriately seeks damages for fear of future injuries that have not yet occurred. In the event this Court declines to dismiss this case in its entirety, Plaintiffs' claim for Punitive Damages must be dismissed, as Plaintiffs' unsupported and conclusory claims of reckless, willful, wanton, or malicious acts on the part of Defendants fail to rise to the requisite level to support a claim of entitlement to punitive damages, especially during a novel, global pandemic. As such, the request for punitive damages should be dismissed. Finally, Defendants also move to strike scandalous and impertinent matter from the Complaint, as large portions of the Complaint are included solely for improper, inflammatory purposes.

II. FACTUAL AND PROCEDURAL BACKGROUND

Defendant Brighton operates Brighton Rehabilitation and Wellness Center, which is a licensed nursing facility in Beaver, Pennsylvania. Defendant Thimons serves as Brighton's Medical Director. In response to the COVID-19 pandemic and in an effort to fight the spread and impact of COVID-19 and to save lives, Brighton developed, managed, supervised and administered infection control and COVID-specific programs at the facility under which countermeasures, including, but not limited to, face masks, gloves and other PPE, testing and safety equipment, visitation restrictions, and screening requirements, were used. As is widely known, and especially at the beginning of the pandemic, there has been a scarcity of available PPE on a global level, which required health care providers to adjust and adapt on a daily basis in an effort to fight the COVID-19 virus.

On October 21, 2020, Plaintiffs initiated this action by filing a Complaint in the Beaver

County Court of Common Pleas in a matter styled Jodi Gill, as Attorney-in-Fact of Glenn Oscar Gill, et al. v. Comprehensive Healthcare Management Services, LLC d/b/a Brighton Rehabilitation and Wellness Center and David G. Thimons, D.O., Case No. 2020-11109. A true and correct copy of Plaintiffs' Complaint and Jury Demand is attached hereto as Exhibit A. Defendants filed a Notice of Removal of this case to this Court on November 12, 2020.

III. LEGAL STANDARDS

Federal Rule of Civil Procedure 12(b)(6) provides that a court may dismiss a complaint “for failure to state a claim upon which relief can be granted.” In order to survive a motion to dismiss, a complaint must allege facts that raise a right to relief above the speculative level. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see also* Fed. R. Civ. P. 8(a)(2). While a court must accept as true all allegations in the Plaintiffs' complaint, and view them in the light most favorable to the plaintiff, *Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008), a court is not required to accept sweeping legal conclusions cast in the form of factual allegations, unwarranted inferences, or unsupported conclusions. *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997). The complaint must state sufficient facts to show that the legal allegations are not simply possible, but plausible. *Phillips*, 515 F.3d at 234. “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

A court must dismiss a claim under Rule 12(b)(6) “if the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.” *Johnsrud v. Carter*, 620 F.2d 29, 33 (3d Cir 1980). The Court may not assume that the plaintiffs can prove facts that they have not alleged. *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 263 n.13 (3d Cir. 1998) (quoting *Associated Gen. Contractors v. California State Council of Carpenters*, 459 U.S. 519, 526 (1983)). When evaluating a Rule 12(b)(6) motion to dismiss, the Court may consider “the allegations in the

complaint, exhibits attached to the complaint, matters of public record, and documents that form the basis of a claim.” *Lum v. Bank of Am.*, 361 F.3d 217, 221 n.3 (3d Cir. 2004).

Federal Rule of Civil Procedure 8 sets forth the general pleading requirements for claims brought in federal courts. The first step in testing the sufficiency of the complaint is to identify any conclusory allegations. *Iqbal*, 556 U.S. at 678. “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.* (citing *Twombly*, 550 U.S. at 555). That is, “a Plaintiffs’ obligation to provide the grounds of [his] entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555. Although the court must accept well pleaded factual allegations of the complaint as true for purposes of a motion to dismiss, the court is “not bound to accept as true a legal conclusion couched as a factual allegation.” *Id.*

The second step requires the court to review the remaining factual averments to ensure the plaintiff has set forth a factual basis that provides more than the mere possibility that the alleged misconduct occurred:

[O]nly a complaint that states a plausible claim for relief survives a motion to dismiss. Determining whether a complaint states a plausible claim for relief will, as the Court of Appeals observed, be a context-specific task that requires the court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not ‘shown’ – ‘that the pleader is entitled to relief.’

Iqbal, 556 U.S. at 679 (quoting Fed. R. Civ. P. 8(a)(2)) (citations omitted).

Federal Rule 12(b)(1) requires the dismissal of a case for lack of subject matter jurisdiction when the district court lacks the statutory or constitutional power to adjudicate it. The standard applied by the Court in reviewing a Rule 12(b)(1) motion for lack of subject matter jurisdiction depends on whether the motion presents a “facial” or a “factual” attack on the issue presented. *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir. 2012) (citing

Mortensen v. First Fed. Sav. & Loan Ass'n, 549 F.2d 884, 891 (3d Cir. 1977)). In reviewing a facial attack, the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff. In reviewing a factual attack the court may consider evidence outside the pleadings. *Gould Electronics Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000)(internal citations omitted). Also, a plaintiff's failure to exhaust administrative remedies may be decided on a Rule 12(b)(1) or Rule 12(b)(6) motion. *See Brady v. May*, 2005 U.S. Dist. LEXIS 39692 (W.D. Pa. 2005) (granting defendant's Rule 12(b)(1) and Rule 12(b)(6) motions to dismiss Plaintiffs' claims for failure to exhaust administrative remedies).

IV. ARGUMENT

A. PLAINTIFFS' COMPLAINT MUST BE DISMISSED PURSUANT TO RULE 12(B)(6) BECAUSE DEFENDANTS ARE IMMUNE FROM SUIT UNDER THE PREP ACT

1. Plain Language of the PREP Act

The plain language of the PREP Act mandates immunity from claims for losses that are precisely of the type brought in Plaintiffs' Complaint. 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.¹

42 U.S.C. § 247d-6d(b)(1) (emphasis added).²

By using the mandatory language, "*shall be immune* from suit and liability under Federal

¹ The PREP Act was enacted on December 30, 2005. It is a unique statutory scheme that lies dormant until it is invoked by the Secretary of Health and Human Services (the "Secretary") at the time of a public health emergency. At that time, the PREP Act authorizes the Secretary to issue a declaration to provide liability immunity to certain entities against any claim of loss caused by or relating to the use of countermeasures in response to the given emergency. Thus, as dictated by Congress, the Secretary, through the declaration, establishes the parameters to of the PREP Act's application with respect to the particular public health emergency.

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. *Id.* § 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." *Id.* § 247d-6d(a)(2)(B) .

and State law” the objective of immunity could not be clearer. The legislative history of the PREP Act reinforces that intent. Because individuals and entities are exposed to greater risk of liability when responding to a public health concern, a priority of the PREP Act was to remove such liability concerns – specifically for countermeasures and health care providers – so that resources would remain available during an emergency.³ In drafting the statute, the obvious concern was that if there is potential liability for health care providers and employers for the resources and countermeasures they used, such critical resources would simply shut down rather than expose themselves to endless lawsuits stemming from the response to an ever-changing infectious disease pandemic.⁴

The Act also has a broad reach in its intended scope of protection.⁵ 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. This Declaration was subsequently amended on April 15, 2020,⁶ to reflect newly enacted legislation and the addition of “respiratory protective device[s] approved by NIOSH” to the list of “covered countermeasures.” *See* 85 Fed. Reg. 21012. HHS also issued an Advisory Opinion regarding the Declaration on April 17, 2020, recognizing the broad,

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.

⁴ *See id.* at 294.

⁵ The sole exception to PREP Act immunity “shall be for . . . death or serious physical injury proximately caused by willful misconduct.” 42 U.S.C.A. § 247d-6d(c)(3). Further, any suits alleging an exception to the Act’s broad grant of immunity can only be brought before a three-judge panel in the United States District Court for the District of Columbia. *See* 42 U.S.C.A. § 247d-6d(c)(4); § 247d-6d(e)(1), (5) .

⁶ Unlike prior declarations issued by HHS in response to other public health emergencies, the COVID-19 Declaration has been amended four times, each time broadening the scope of the PREP Act as applied to the emergency response to this unique global pandemic.

preemptive nature of the Declaration. *See* Exhibit B. The Opinion states that “immunity covers claims for loss sounding in tort or contract” and “PREP Act immunity must be read in light of the PREP Act’s broad, express-preemption provision.” *Id.* at p. 2.

On August 14 and 31, 2020, two additional opinion letters were issued by HHS that: (a) unequivocally confirm that senior living communities, such as Defendant Brighton, are “covered persons,” that may be immunized under the PREP Act by virtue of their status as both “program planners” and “qualified persons”; and (b) verify that COVID testing in nursing homes are a covered countermeasure triggering the Act. *See* Exhibits C and D, respectively.

Additionally, on October 23, 2020, HHS issued “Advisory Opinion 20-04 on the Public Readiness and Emergency Preparedness Act and Secretary’s Declaration Under the Act,” clarifying that “administration” under the PREP Act is much broader than the mere physical provision of a countermeasure to a recipient and encompasses activities related to the “management and operation” of COVID-19 countermeasure programs and those facilities that provide countermeasures to recipients. *See* Exhibit E. This Advisory Opinion flatly rejects as “wrong” a prior New York trial court ruling in *Casabianca v. Mt. Sinai Medical Center*, 2014 WL 10413521 (New York Co. 12/12/14), that the PREP Act requires the “direct physical” administration of a COVID-19 countermeasure and that the Act is not applicable to claims involving an omission or failure to act.

Recently, on December 3, 2020, HHS issued a Fourth Amended Declaration to the PREP Act. *See* Exhibit F. This amendment expressly incorporates all of the aforementioned Advisory Opinions on the PREP Act issued by Office of General Counsel, giving those Advisory Opinions the force of the Declaration. *See id.* at p. 3. Further, this amendment specifically states that PREP Act immunity can apply in circumstances of non-use of a covered countermeasure, when there is

purposeful allocation or non-use is due to rationing of a scarce resource. *See id.* at pp. 24-25. Finally, this amendment discusses the importance of having a consistent PREP Act interpretation throughout the country, the unprecedented and overwhelming nature of the current health crisis, and the need to coordinate between federal, state, local, and private actors. It speaks directly to case law enumerated factors that point towards federal question jurisdiction under the PREP Act and Federal Officer jurisdiction. *See id.* at pp. 25-26.

Under the Act and its implementing authorities, therefore, an individual or entity is provided immunity under the PREP Act if (1) they are a “covered person”; (2) they are administering or using a “covered countermeasure” or not using a covered countermeasure in cases where they are limited, deliberately prioritized or purposefully allocated;⁷ (3) the claim against which immunity is asserted “arises out of, relates to, or results from” the administration or use of the subject countermeasure; (4) the administration or use occurs during the “effective period;” and (5) the “covered countermeasure” was obtained through a specified “means of distribution.” PREP Act, 42 U.S.C.A. §§ 247d-6d, 247d-6e; the Declaration, *supra*. As explained more fully herein, Defendants and their alleged activities meet all of these elements.

2. Defendants are “Covered Persons” Granted Immunity under the PREP Act.

The definition of a “covered person” includes:

[A] person⁸ 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

⁷ An entity or individual who complies with all other requirements will not lose PREP Act immunity—even if the medical product at issue is *not* a covered countermeasure—if that entity or individual reasonably could have believed it was a covered countermeasure. Likewise, a person who complies with all other requirements will not lose PREP Act immunity—even if the person at issue is *not* a covered person—if the entity or individual reasonably could have believed that the person was a covered person. *See* Exhibit B, Advisory Opinion, p. 2.

⁸ The Act broadly defines a “person” as “an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, state or local government agency or department.” 42 U.S.C.A. § 247d-6d(i)(5).

described in clause (i), (ii), (iii), or (iv).

U.S.C.A. § 247d-6d(i)(2)(B). Here, Defendants fit within the “program planners” and “qualified person” categories.

a. Defendants are “*Program Planners*” under the PREP Act.

The Act defines a “program planner” as a person or entity 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.A. § 247d-6d(i)(6). Importantly, the Declaration expressly states that 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 15202.

This provision, on its face, protects entities, including private employers, who engage in activities and decision-making related to pandemic planning. The discretionary nature of these decisions and choices by program planners is inherent in the very duties authorized to them by statute: “a person who has *established requirements, provided policy guidance, or supplied technical or scientific advice. . .*” 42 U.S.C. § 247d-6d(i)(6). By the plain language of the PREP Act, such activities certainly include, for example, developing the requirements of the plan, implementation of the plan, and the decisions made by committees and organizational leadership concerning which countermeasure to deploy, whether and when to deploy covered countermeasures, what sanitation practices to employ, when to request diagnostic tests for residents, how to monitor residents who may be infected with COVID-19, and how to handle staff shortages and quarantine after potential exposure to COVID-19. In other words, a person or entity (like Brighton), who develops a program to reduce the spread of COVID-19, and which includes

the provision and use of covered countermeasures, can and should claim PREP Act immunity.

In the context of residential health care facilities like Brighton, the distribution of covered countermeasures includes an infection control program against COVID-19 infection. Defendants were acting as "program planners" that supervised and/or administered the infection control and COVID-19 specific programs in the treatment of COVID-19 patients, under which countermeasures, including, but not limited to, the use of face masks and other PPE, visitation restrictions, and screening requirements at the Facility in an effort to prevent or mitigate the spread of COVID-19.

To be clear, this provision also provides immunity for decisions on whether and when to act (or not act) and protects omissions, such as delay in testing or treatment, or delay in countermeasure deployment. *See* Exhibit B, p. 7 (noting that certain "acts or *omissions*" remain immune from suit – even within the exception for willful misconduct: "Under the PREP Act, immunity is broad. As a general matter, a covered person is immune from liability for all claims for loss...that proximately caused death or serious injury." (emphasis added)). In other words, Plaintiffs cannot "plead around" immunity simply by inserting the word "failure." If the decision *not* to provide certain care (even if true) is the decision, it is still protected under the PREP Act as a matter of law. *See id.*; 42 U.S.C. § 247d-6d(i)(6) (defining a program planner as "a person who has *established requirements, provided policy guidance, or supplied technical or scientific advice. . .*") The reasonableness of this discretionary authority is underscored by the fact that experts from the WHO, CDC, and other public and private organizations issue constantly evolving recommendations, guidance, and advice based on the science of the moment. In fact, expert advice concerning when to provide countermeasures and whether to "use" covered countermeasures is often conflicted, and program planners must make the best decisions they can using the best

available information.

The challenges inherent in program planner decision-making was exacerbated here by such conflicting advice. For example, some infectious disease experts initially recommended *not* wearing masks during the initial COVID-19 response because they wanted to ensure that the limited supply went to hospital ICU units and first responders.⁹ Testing shortages also resulted in limiting testing to certain patients who met strict criteria. In efforts to flatten the curve and prevent the spread, multiple public health authorities at federal, state, local – and even international – levels offered separate guidance that changed over time, and imposed different restrictions.¹⁰ Health care providers and scientists are learning more about the disease every day, which has and continues to alter treatment decisions and modalities. For example, patients who were once ventilated may now be treated by the simple measure of placing them in a prone position.¹¹

In short, there is no requirement under the program planner provision for the countermeasures to be *actively* administered for PREP Act immunity to apply. A program planner is protected with respect to all planning of *how and when* countermeasures are to be used, as well as when treatment (the use of countermeasures) is to be deployed. The policy reasons for this protection are clear – the Act is intended to protect those who must make the hard choices during an extreme shortage of supplies. Otherwise, providers could choose to close their doors to avoid the risk of going out of business due to liability.

HHS's Second Amendment to its Declaration confirmed this very point, explaining in the

⁹ Exhibit C - NPR, Fauci: Mixed Messaging On Masks Set U.S. Public Health Response Back (July 12, 2020), *available at* <https://www.npr.org/sections/health-shots/2020/07/01/886299190/it-does-not-have-to-be-100-000-cases-a-day-fauci-urges-u-s-to-follow-guidelines>.

¹⁰ *E.g.*, CDC, Coronavirus, *available at* <https://www.cdc.gov/coronavirus/2019-ncov/index.html>; U.S. Dept. of Health & Human Servs., Coronavirus, *available at* <https://www.hhs.gov/coronavirus/index.html>; Kansas Dept. of Health & Environ., KDHHE Coronavirus (COVID-19 Response), *available at* <https://www.coronavirus.kdheks.gov/>; WHO, Rolling updates on coronavirus disease, *available at* <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen>.

¹¹ *Low-Tech Way to Help Some Covid Patients: Flip Them Over*, N.Y. Times (May 13, 2020).

preamble that the COVID-19 pandemic resulted in shortages of certain drugs and devices that the FDA has authorized.¹² Those shortages, therefore, are “harm[s] [COVID-19] might otherwise cause,” and as a result, mitigating efforts may receive protection under the Act: Filling those shortages caused by COVID-19 reduces the strain on the American healthcare system by mitigating the escalation of adverse health conditions from COVID-19 and non-COVID-19 causes. And mitigating that escalation conserves limited healthcare resources – from personal protective equipment to healthcare providers – which are essential in the whole-of-Nation response to the COVID-19 pandemic. Preamble to Second Amendment to DHHS Declaration, 85 Federal Register 35100, 35101-02 (June 8, 2020).

To summarize, Defendants are “program planners” within the meaning of the PREP Act. Defendants are required by Pennsylvania law to implement policies and procedures to combat the spread of infection.

b. Defendants are “Qualified Persons” under the PREP Act.

Defendants are also “covered persons” under the Act by virtue of being a “qualified person[s]¹³ who prescribed, administered, or dispensed” the countermeasures at issue. The PREP Act and Declaration define the term “qualified person” as:

(A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) a person within a category of persons so identified in a declaration by the Secretary.

See 42 U.S.C.A. § 247d-6d(i)(8). Importantly, “an official, agent or employee of a person or entity” that meets the above requirement is included in the definition of a “covered person.” See *id.* at §

¹² Preamble to Second Amendment to DHHS Declaration, Federal Register / Vol. 85, No. 110 / Monday, June 8, 2020.

¹³ The PREP Act defines a “person” as including “an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.” 42 U.S.C.A. § 247d-6d(i)(5).

247d-6d(i)(2)(B)(v). Defendants were acting as “qualified persons” because they are healthcare providers authorized to administer and/or use FDA approved medical devices, such as face masks, to prevent or mitigate the spread of COVID-19.

3. Plaintiffs’ Allegations Involve “Covered Countermeasures.”

The PREP Act defines a “covered countermeasure” to include, *inter alia*, “qualified pandemic or epidemic products,” as well as “drugs, biological products or devices authorized for investigational or emergency use,” or “a respiratory protective device” approved by NIOSH and determined to be a priority for use during a public health emergency. *See* 42 U.S.C.A. § 247d-6d(i)(1), (8).¹⁴ Additionally, the Declaration defines “covered countermeasure” as “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 any device used in the administration of any such product, and all components and constituent materials of any such product,” provided such countermeasure fits into at least one of the categories set forth under the PREP Act: “qualified pandemic or epidemic products;” “drugs,” “biological products,” and “devices” authorized for emergency use under the FD&C Act; and “respiratory protective devices.” 42 U.S.C.A. § 247d-6d(i)(1); 85 Fed. Reg. at 15202.¹⁵

The April 17, 2020 Advisory Opinion succinctly summarizes the definition of a “qualified pandemic or epidemic product,” explaining that, for immunity to attach, the “drug,” “biological

¹⁴ On March 18, 2020, the Families First Coronavirus Response Act (the “FFCRA”) was signed into law. The FFCRA added “respiratory protective device[s]” to the list of “covered countermeasures” under 42 U.S.C. § 247d-6b(i)(1). Subsequently, the Secretary of HHS amended the Declaration to include “any respiratory protective device.” 85 Fed. Reg. 21014 Sec. VI (Apr. 15, 2020). The Secretary further determined as part of the Declaration “that use of any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, is a priority for use during the public health emergency” *Id.* at 21013.

¹⁵ The PREP Act establishes “a rebuttable presumption that any administration or use, during the effective period of the emergency declaration by the Secretary . . . , of a covered countermeasure shall have been for the category or categories of diseases, health conditions, or threats to health with respect to which such declaration was issued.” 42 U.S.C.A. § 247d-6d(a)(1)(6). Here, there is no dispute that the time period in question was during the effective period of the Declaration. *See* Declaration (March 17, 2020).

product,” or “device”:

- (1) must be used for COVID-19; and
- (2) must be
 - a. approved, licensed, or cleared by FDA;
 - b. authorized under an EUA [Emergency Use Authorization];
 - c. described in an EUI [Emergency Use Instruction]; or
 - d. used under either an Investigational New Drug (IND) application or an Investigational Device Exemption (IDE).

Exhibit B, at p. 4. It further recognizes that “[t]he number of products used for COVID-19 that are approved, licensed, or cleared *are too numerous to list.*”¹⁶

Here, Plaintiffs’ claims arise out of *at least three* of those covered countermeasures: 1) PPE, 2) diagnostic testing, and 3) infection control procedures.

a. Personal Protective Equipment

Plaintiffs’ Complaint makes allegations relating to the use, or misuse, of PPE to prevent spread of COVID-19 at Brighton. *See, e.g.*, Compl. at ¶¶ 107, 303, 346, 355-356, 420(II)-(gg), 440(k), 456(g), 477(cc)-(ee), 497(i), 513(g). Further, the Complaint makes reference to Department of Health and CMS deficiency citations relating to alleged misuse of PPE, including gloves and face masks. *See id.* at ¶¶ 314-317, 339, 346.

PPE was initially identified as a covered countermeasure through March 2020 federal legislation. *See* Pub. Law. No. 116-127, Sec. 6005. Since then, the FDA has included numerous categories of PPE in their Emergency Use Authorizations related to COVID-19. *See* U.S. Food & Drug Administration, FDA Combating COVID-19 with Medical Devices (May 4, 2020), <https://www.fda.gov/media/136702/download>. PREP Act immunity therefore extends to the use

¹⁶ The Advisory Opinion (Exhibit B) does, however, cite to lists of medical devices and therapeutics that are covered by Emergency Use Authorizations. *See* U.S. Food & Drug Administration, FDA Combating COVID-19 With Medical Devices (May 4, 2020), <https://www.fda.gov/media/136702/download>; U.S. Food & Drug Administration, FDA Combating COVID-19 With Therapeutics (May 4, 2020) <https://www.fda.gov/media/136832/download>; *see also* U.S. Food & Drug Administration, Emergency Use Authorization (last visited May 7, 2020), <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas>.

of PPE by covered persons for the prevention and treatment of COVID-19.

Further, the PREP Act permits the Secretary to grant immunity for “covered countermeasures” that are obtained through a particular means of distribution, including those related to “public health and medical response of the Authority Having Jurisdiction to . . . distribute, or dispense the Covered Countermeasures 42 U.S.C.A. § 247d-6d(b)(2)(E). Plaintiffs’ allegations in this case relate to the use, or misuse, of PPE to prevent spread of COVID-19 at Brighton. *See, e.g.*, Compl. at ¶¶ 107, 303, 346, 355-356, 420(l)-(gg), 440(k), 456(g), 477(cc)-(ee), 497(i), 513(g). Further, the Complaint makes reference to Department of Health and CMS deficiency citations relating to alleged misuse of PPE, including gloves and face masks. *See id.* at ¶¶ 314-317, 339, 346. For all of these reasons, the use (or allegedly negligent use) of PPE in this context constitutes a covered countermeasure under the PREP Act.

b. Diagnostic Testing

Plaintiffs expressly plead allegations relating to the use of diagnostic testing for COVID-19 at Brighton. *See* Compl. at ¶¶ 242, 261, 352, 353, 420(t), 420(x), 477(u), 477(v). Again, the Declaration identifies “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” provided such countermeasure fits into at least one of the categories set forth under the PREP Act. 42 U.S.C.A. § 247d-6d(i)(1); 85 Fed. Reg. at 15202 (emphasis added). Importantly, the Secretary of Health and Human Services issued a letter dated August 31, 2020, confirming that testing for COVID-19 in senior living communities qualifies as a “covered countermeasure” triggering PREP Act immunity. *See* Exhibit D. To date, a very large number of diagnostic tests for use in detecting or preventing the spread of COVID-19 has been approved, licensed, or cleared by the FDA or subject to an EUA.¹⁷

¹⁷ See updated lists, *available at* <https://www.fda.gov/media/136702/download> and <https://www.fda.gov/media/136832/download>.

Accordingly, the use (or even allegedly negligent use) of diagnostic testing constitutes a covered countermeasure under the PREP Act triggering immunity.

c. Infection Control Program

Plaintiffs' Complaint also sets forth multiple allegations relating to Brighton's infection control policies and practices and other sanitary procedures. *See, e.g.*, Compl., at ¶¶ 420(a)-(m), (u), (v), (z), 440(a)-(f), (l), 425(c), (g), (bb), (cc), (ee), (kk), 445(g), (s-v), 456(a) (f), (g), 456, 477(a)-(n), (q), (x), (gg), 482(c), (h), (bb)-(ee), (kk), 497, 502(f), (s)-(v), (y), 513(a)-(b). These allegations directly implicate 28 Pa. Code § 211.10 and, in turn, trigger immunity under the PREP Act. Specifically, 28 Pa. Code § 211.10 requires long term care facilities to develop and implement policies and procedures to ensure that residents are protected from infection. 28 Pa. Code § 211.10(d). In compliance with 28 Pa. Code § 211.10, infection control procedures were developed and implemented at Brighton. Such compliance required use of qualified countermeasures which in turn affords PREP Act immunity.

4. Defendants Engaged in "Recommended Activities."

Defendants were also involved in "recommended activities" that warrant PREP Act immunity. The Declaration defines "recommended activities" as the manufacture, testing, development, distribution, *administration and use of* one or more covered countermeasures. *See* 85 Fed. Reg. at 15201 (emphasis added). This definition has been clarified to include, among other things, any activity that is part of an authorized emergency response at any level of government. *See* Advisory Opinion, Exhibit B. These activities can be authorized through guidance, requests for assistance, agreements, or other arrangements. *See id.* They are also still covered under the PREP Act – even if a state or local authority has not declared a state of emergency. *See id.*

Further, the covered countermeasures in Plaintiffs' Complaint were administered or used

within the effective period of the Declaration and were administered or used for the categories of diseases, health conditions, or threats to health contemplated by the Declaration. *See* 42 U.S.C.A. § 247d-6d(a)(3).

The Declaration defines “Administration of a Covered Countermeasure” as: (1) the physical provision of countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients; (2) management and operation of countermeasure programs; or (3) management of operation of locations for purpose of distributing and dispensing countermeasures. *See* 85 Fed. Reg. at 15200. The definition of administration extends not only to the physical provision of a countermeasure to a recipient *but* also includes activities related to management and operation of programs and locations for providing countermeasures to recipients, such as handing drugs to a patient, as well as activities related to management of operations of programs and locations, such as decisions and actions involving security and queuing. *See id.*

There is no dispute that the Plaintiffs’ alleged injuries are claimed to have directly resulted from the administration and use, or alleged negligent use, of covered countermeasures in preventing the spread of COVID-19 to residents. In the Complaint, Plaintiffs alleges that Defendants negligently and carelessly allowed Plaintiffs or Plaintiffs’ Decedents to develop COVID by, *inter alia*, failing to have adequate infection control, testing, and cohorting procedures, and negligent use and allocation of PPE. In sum, since Plaintiffs have alleged a “claim of loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure,” Defendants are afforded immunity as covered persons under the PREP Act. 42 U.S.C.A. § 247d-6d(a)(1). Accordingly, the PREP Act preempts and bars Plaintiffs’ state law claims, warranting dismissal of the Complaint pursuant to Rule 12(b)(6).

B. PLAINTIFFS' COMPLAINT MUST BE DISMISSED BECAUSE THEY FAILED TO EXHAUST ADMINISTRATIVE REMEDIES.

Congress clearly manifested an intent to preempt state law with respect to claims that invoke PREP Act immunity and created an exclusive federal remedy for such preempted claims. Upon the issuance of the COVID-19 Declaration by the Secretary, an “emergency fund” was established under the PREP Act “for purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries.” 42 U.S.C. § 247d-6e(a). Notably, this remedy is “exclusive of any other civil action or proceeding for any claim or suit” to which it applies. 42 U.S.C. § 247d-6e(d)(4). And in the event Plaintiffs exhaust those remedies available under the Fund, their sole recourse in certain very limited circumstances is a federal cause of action for death or serious physical injury proximately caused by willful misconduct,¹⁸ which action may only be filed in the United States District Court for the District of Columbia. 42 U.S.C.A. § 247d-6d(d)(e). However, even a claimant alleging “willful misconduct” must first apply for benefits under §247d-6e before filing such an action under §247d-6d (d) thus further illustrating Congress’ intent to ensure the exclusivity of those remedies provided under the Act. Plaintiffs’ Complaint should, therefore, be dismissed pursuant to Federal Rule 12(b)(6) and/or Rule 12(b)(1) because Plaintiffs have failed to exhaust their administrative remedies under the PREP Act.

Here, Plaintiffs are alleging claims of loss relating to the administration or use of a covered countermeasure in response to the COVID-19 pandemic which fall within the ambit of the PREP Act. (*See generally* Exhibit A). However, Plaintiffs failed to exhaust their administrative remedies because they did not apply for benefits under 42 U.S.C. § 247d-6e(a). Because administrative

¹⁸ “Willful misconduct” under the PREP Act, is defined as “**an act or omission that is taken—(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.**” (emphasis added). 42 U.S.C. §247d-6d(c)(1)(A). Plaintiff has the burden of proving by clear and convincing evidence, “willful misconduct” by each covered person sued and that such “willful misconduct” caused death or serious injury. 42 U.S.C. §247d-6d(c)(3).

exhaustion is a prerequisite to filing suit, Plaintiffs' failure to exhaust their administrative remedies under 42 U.S.C. § 247d-6e warrants dismissal of the Complaint. *See Brady v. May*, 2005 U.S. Dist. LEXIS 39692 (W.D. Pa. 2005) (granting defendant's Rule 12(b)(1) and Rule 12(b)(6) motions to dismiss Plaintiffs' claims for failure to exhaust administrative remedies). This Court does not have jurisdiction to adjudicate their claims. As this Court does not have subject matter jurisdiction over Plaintiffs' claims, Defendants respectfully ask this Court to dismiss the Complaint as against them pursuant to Federal Rule 12(b)(1) and/or 12(b)(6).

C. PLAINTIFFS' COMPLAINT MUST BE SEVERED AND DISMISSED BASED ON IMPROPER JOINDER

Federal Rule of Civil Procedure 20 allows persons to be joined in one action as Plaintiffs where the claims arise out of the same transaction, occurrence, or series of transactions or occurrences, and if common questions of law or fact affecting the liabilities of all such persons will arise in the action. F.R.C.P. 20. Importantly, Rule 20(a)'s purpose is to "promote trial convenience and expedite the final determination of disputes, thereby preventing multiple law suits." *Cooper v. Fitzgerald*, 266 F.R.D. 86, 88 (E.D. Pa. 2010) (citing *Al Daraji v. Monica*, No. 07-1749, 2007 WL 2994608, at *10 (E.D.Pa. Oct. 21, 2007)).

In the instant matter, the case was filed on behalf of seventeen (17) Plaintiffs. However, each Plaintiff has a different question of fact affecting liability and their respective damages. While Plaintiffs may have the same general theory of liability against Defendants relating to their handling of the COVID-19 pandemic, each individual received different care from different people in different units at different times. Further, there are absolutely no common questions of law or fact with respect to damages. Specifically, several of the Plaintiffs are living, and each of their alleged injuries vary. Moreover, several of the Plaintiffs are representatives of the estates of deceased individuals, who claim to have died from COVID-19. Such a determination of each

Plaintiff or Decedent's damages involves undertaking an individualized assessment into many factors, including, but not limited to, the individualized care they received, the nature of the resident's underlying medical problems, the COVID-19 protocols in place for each resident, how and when each resident was infected by COVID-19, the alleged pain and suffering experienced by each resident (for example, one resident could have been asymptomatic, while another could have required hospitalization), recovery time for each resident, and whether the resident has alleged to have died from COVID-19. These questions can only be determined on an individual basis for each aggrieved party. *See Cooper v. Fitzgerald*, 266 F.R.D. 86 (E.D. Pa. 2010) (holding that the mere fact that all plaintiffs' claims arise under the same general law does not necessarily establish a common question of law, under permissive joinder rule, and finding that plaintiffs were improperly joined, as each claim involved potentially different issues); *see also Coughlin v. Rogers*, 130 F.3d 1348 (9th Cir. 1997) (severing a case filed on behalf of 49 plaintiffs, holding that the mere common allegation of general delay in adjudicating their immigration applications was not enough to create a common transaction or occurrence, as each plaintiff waited a different length of time, suffering a different duration of alleged delay).

Finally, joinder in this case would not promote judicial economy or convenience. As the Ninth Circuit held in *Coughlin, supra*, trial efficiency will not be promoted by allowing all Plaintiffs to bring a single case when each claim raises potentially different issues, and must be viewed in a separate and individual light by the Court. *Coughlin*, 130 F.3d at 1351. In the instant case, each Plaintiff's case will certainly raise different issues, as set forth above, and the circumstances of their care and treatment must be analyzed separately.

Moreover, like in *Cooper*, where the Court explained that if it permitted joinder of the seven plaintiffs, each case would still need to be examined in light of their individualized

circumstances and the unique reasons surrounding any final adjudication delay, the same is true here. Even if the Court allows joinder of the seventeen Plaintiffs, each of their cases will need to be examined in light of its individual circumstances and alleged injuries.

Therefore, it was improper to join all sixteen (17) Plaintiffs to one action, and the Complaint must be dismissed and severed.

D. PLAINTIFFS' CAUSES OF ACTION FOR NEGLIGENCE AND WRONGFUL DEATH FAIL TO STATE A CLAIM UPON WHICH RELIEF MAY BE GRANTED

In the event that this Honorable Court does not rule that Defendants are immune from suit, and does not sever and dismiss Plaintiffs' Complaint pursuant to F.R.C.P. 20, Plaintiffs' negligence claims set forth in Counts II, III, IV, VI, and VII must still be dismissed because Plaintiffs cannot plead the requisite elements of that cause of action. More specifically, Plaintiffs have not, and cannot set forth, any facts that support the breach of any standard of care here, nor can they plead causation.

To allege a general negligence cause of action, Plaintiff must plead facts establishing: (1) a duty or obligation recognized by law; (2) a breach of that duty; (3) a causal connection between the conduct and the resulting injury; and (4) actual damages. *Estate of Swift by Swift v. Northeastern Hosp.*, 690 A.2d 719, 722 (Pa. Super. 1997)(internal citations omitted). Moreover, in any negligence action, "establishing a breach of a legal duty is a condition precedent to a finding of negligence." *Id.*

Here, Plaintiffs allege that Brighton and Dr. Thimons were negligent with regard to, *inter alia*, infection control procedures, testing residents, cohorting residents and staff, and use and allocation of PPE. However, these general allegations of negligence are not applicable to the standard of care at the facility during the COVID-19 pandemic - namely, what a reasonable healthcare provider would do in the face of an unprecedented, novel, global pandemic, that even the world's leading experts struggled, and continue to struggle, to respond to. Further, the

pandemic resulted in waivers of existing regulations and a slew of new government guidance and directives, which evolved along with the pandemic. It is **these directives and guidance** that are applicable in this case and set the standard of care. Plaintiffs fail to plead facts alleging that Defendants failed to follow these applicable government directives. Moreover, as detailed above, Defendants have immunity under the PREP Act with respect to the allegations relating to COVID-19 testing, PPE, and other “covered countermeasures.” Plaintiffs’ negligence causes of action therefore fails.

Likewise, Plaintiffs also cannot plead the element of causation. An understanding of the virus and pandemic and the seemingly chaotic manner in which the virus spreads is still developing as more information becomes known. There is no conduct pled nor is there any mechanism pled that could, or reasonably would have, prevented Plaintiffs or their Decedents from contracting COVID, and if or how any such perceivable conduct would have reasonably avoided their injuries or death, as such was and remains beyond the ability of medicine, especially in a skilled nursing facility environment.

Moreover, the issue of Wrongful Death secondary to negligent medical treatment is not a viable claim in the COVID-19 context. This is a new and novel virus with no known treatment other than supportive care, which to the extent possible in a skilled nursing facility, is alleged to have been provided. There is, and can be, no standard of care as there is no previous experience with this disease. Likewise, there can be no causation between a breach of some undefined standard of care and a resident’s demise for which there was no treatment beyond supportive care.¹⁹

Finally, beyond the aforementioned reasons, Plaintiffs’ Complaint must be dismissed

¹⁹ Further, to the extent the allegations in Plaintiffs’ Complaint allege that Dr. Thimons breached any duties owed under statutes that apply solely to skilled nursing facilities, such allegations must be dismissed, as Dr. Thimons, a doctor, has no duty to comply with federal laws directed solely to skilled nursing facilities. *See* Compl. at ¶¶ 461(d)-(e), 466.

because the allegations fail to meet the minimum pleading standards necessary to state a claim for which relief may be granted. Throughout the entire Complaint, Plaintiffs lump Defendants together rather than pointing to any specific act or omission taken by any particular defendant. *See, e.g. Compl.* Plaintiffs’ allegations also merely contain labels, conclusions, “formulaic recitation of the elements,” and “naked assertions” that do not meet minimum pleading requirements. *See, e.g., Iqbal*, 556 U.S. at 678; *Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 555-57 (2007).²⁰

E. PLAINTIFFS’ CLAIMS FOR FEAR OF POSSIBLE FUTURE INJURY MUST BE DISMISSED.

In their Complaint, Plaintiffs allege that Plaintiffs “may continue to suffer” future pain, suffering, infirmity, deterioration, debilitation, loss of enjoyment of life, anxiety, and isolation/confinement from contracting and being treated for COVID-19” and “may continue to incur hospital, medical, and nursing expenses” *See Compl.* at ¶¶ 485(a)-(b), 505(a)-(b), and 519(a)-(b). These claims for fear of a possible future injury are not compensable under Pennsylvania law. *See Simmons v. Pacor, Inc.*, 543 Pa. 664, 674 A.2d 232 (1996)(no recovery for asymptomatic pleural thickening after exposure to asbestos); *Lubowitz v. Albert Einstein Medical Center, Northern Division*, 424 Pa. Super. 468, 623 A.2d 3 (1993) (no recovery for fear of developing AIDS where plaintiff was asymptomatic); *Vazquez v. Friedberg*, 431 Pa. Super. 523, 637 A.2d 300 (1994) (finding that where there was no functional impairment at time of negligence, plaintiff had no injury); *Giffear v. Johns-Mansville Corp.*, 429 Pa. Super. 327, 632 A.2d 880 (1993) (holding that an injury cannot exist without functional impairment); *Cunningham v. Forbes Reg’l Hosp.*, No. 1961 WDA 2013, 2014 WL 6682459, at *1 (Pa. Super. 2014)(finding that Plaintiff failed to failed

²⁰ Plaintiffs’ cause of action for Survival Damages fails for similar reasons. Further, to the extent the allegations in Plaintiffs’ Complaint allege that Dr. Thimons breached any duties owed under statutes that apply to skilled nursing facilities, such allegations must be dismissed, as Dr. Thimons, a doctor, has no duty to comply with federal laws directed solely to skilled nursing facilities. *See Compl.* at ¶¶ 518(d)-(e).

to establish the requisite causal nexus between the hospital's negligence and his claimed injuries where Plaintiff claimed that the hospital's conduct potentially exposed him to illness).

Accordingly, allegations relating to the mere possibility that harm or death could occur in the future is not sufficient to meet the Plaintiffs' burden of establishing the element of harm. In, *Giffear, supra*, in addition to finding that the plaintiff could not recover from asymptomatic pleural thickening, the court also held that damages could not be based upon the mere possibility of subsequently developing cancer. In that case, the plaintiff argued that he had an injury insofar as there was the possibility that the pleural thickening could develop into cancer in the future. 429 Pa. Super. 327, 632 A.2d 880 (1993). The court explained that it would be manifestly unjust to allow the plaintiff to recover in the absence of any physical harm because the damages would be far too speculative. 429 Pa. Super. 327, 345, 632 A.2d 880, 889 (1993). Further, to award damages in the absence of an injury would allow a windfall to the plaintiff, who may never contract any disease or injury. *Id.* Fear that harm could occur in the future is also not a compensable injury. *See e.g., Lubowitz v. Albert Einstein Medical Center*, 424 Pa. Super. 468, 623 A.2d 3 (1993)(holding that plaintiff could not recover for fear of AIDS because she had no physical injuries, and fear was not a compensable injury).

Finally, Pennsylvania does not recognize a cause of action for increased risk of harm in the absence of proof that the anticipated harm actually occurred. *Weaver St. Christopher's Hospital for Children*, 44 Pa. D. & C.4th (C.P. Phila. Co. 1993), *rev 'd other grounds*, 769 A.2d 1219 (1993); *see also Hamil v. Bashline*, 392 A.2d 1280 (Pa.1978) (holding that it will only become a jury question when the plaintiff "has introduced evidence that a defendant's negligent act or omission increased the risk of harm to a person [plaintiffs] position, *and that the harm was in fact sustained. . . .*") (emphasis added).

Accordingly, in the instant case, Plaintiffs' allegations that Plaintiffs "may continue to suffer" future pain, suffering, infirmity, deterioration, debilitation, loss of enjoyment of life, anxiety, and isolation/confinement from contracting and being treated for COVID-19" and "may continue to incur hospital, medical, and nursing expenses" must be dismissed. The case law is clear that said damages are precluded, as a matter of law. *See* Compl. at ¶¶ 485(a)-(b), 505(a)-(b), and 519(a)-(b).

F. PLAINTIFFS' CLAIM FOR PUNITIVE DAMAGES FAILS TO STATE A CLAIM UPON WHICH RELIEF MAY BE GRANTED

Plaintiffs seek punitive damages against Defendants, claiming that Defendants' negligence "went beyond ordinary negligence, into gross negligence, recklessness, and willful and wanton conduct." *See* Compl. at ¶¶ 429, 449, 463, 486, 506, 520. Plaintiffs do not set forth any additional facts to support their claims of reckless, willful, or wanton conduct. Rather, they baldly state that Defendants' conduct was punitive in nature.

Punitive damages are recoverable only for conduct that is outrageous due to the defendant's evil motive or reckless indifference to the rights of others. *Rizzo v. Michener*, 401 Pa. Super. 47, 584 A.2d 973, 979 (1990); *McDaniel v. Merck, Sharp & Dohme*, 367 Pa. Super. 600, 533 A.2d 436, 447 (1987). Punitive damages are not a proper element of damage where the conduct complained of constitutes ordinary negligence, such as inadvertence, mistake, and errors of judgment. *McDaniel*, 533 A.2d at 477.

In *Martin v. Johns-Manville Corp.*, the Pennsylvania Supreme Court provided an overview of Pennsylvania law on the imposition of punitive damages. 494 A.2d 1088 (Pa. 1985). There, the court recognized that the Commonwealth of Pennsylvania espouses the principles set forth in *Restatement (Second) of Torts*, § 908(2), which provides:

Punitive damages may be awarded for conduct that is outrageous, because of the defendant's evil motive, or his reckless indifference to the rights of others. In assessing punitive damages, the trier of fact can properly consider the character of the defendant's act, the nature and extent of harm to the plaintiff that the defendant

caused or intended to cause and the wealth of the defendant.

Martin, 494 A.2d at 1096, citing *Restatement (Second) of Torts*, § 908(2).

The function of punitive damages is to deter and punish. *Martin*, 494 A.2d at 1096. The imposition of punitive damages to punish a civil defendant is appropriate only where the conduct complained of is **especially egregious**. *Martin*, 494 A.2d at 1096-97 (emphasis added). Punitive damages are **not** justified where the defendant's mental state rises to no more than negligence, or even gross negligence. *Martin*, 494 A.2d at 1098 (emphasis added). When assessing the propriety of the imposition of punitive damages, the state of mind of the actor is vital. *Hutchison v. Luddy*, 870 A.2d 766, 770-771 (Pa. 2005) (internal citations omitted). The act, or the failure to act, must be intentional, reckless or malicious. *Id.*

Additionally, and significantly, a defendant's acts that are independent from the conduct on which liability is premised may not serve as the basis for punitive damages. *See Gallagher v. Temple Univ Hosp.*, 2005 WL 2649868 (Pa. Super. 2005) (holding that the defendant's conduct in altering medical records to conceal the plaintiffs oxygen deprivation could not support a punitive damages award because the defendant's conduct was independent from the malpractice upon which liability was based).

Furthermore, Pennsylvania case law discussing the parameters of punitive damages claims against health care providers reflects that the health care provider's deviation from the applicable standard of care must be so egregious as to evince a conscious or reckless disregard of a patent risk of harm to the patient. *See e.g., Medvecz v. Choi*, 569 F.2d 1221, 1227-30 (3d Cir. 1987) (anesthesiologist who abandoned a patient on the operating room table and reportedly left the operating room for a lunch break without securing a suitable replacement could be liable for exemplary damages to a patient who suffered irreversible paralysis from an anesthesiology complication that developed during his absence); *Hoffman v. Memorial Osteopathic Hospital*, 492

A.2d 1382, 1386-87 (Pa. Super. 1985) (evidence that emergency room physician allowed a Guillain-Barre syndrome patient with neurological paralysis to remain crying and immobile on the floor for two hours as the physician repeatedly stepped over him was sufficient to establish the requisite motive and reckless indifference for punitive damages); *Scott v. Plucknett*, 102 Lacka. Jur. 445, 450 (2001) (allegations that the defendant obstetrician left the hospital grounds to return to her private office even though she knew that the patient's labor was not being properly monitored, blatantly ignored the advice of a consulting perinatologist regarding the need for an immediate Cesarean delivery, and inexplicably delayed the commencement of that recommended delivery for more than three hours despite obvious signs of fetal distress on the monitoring strips, adequately averred a claim for punitive damages); *Syslo v. Davis*, 102 Lacka. Jur. 210, 216-18 (2000) (punitive damages could potentially be awarded to a patient who was verbally berated by medical staff while she was recuperating from negligently performed surgery and addressed as an “alcoholic” and “whore”); *Wimer v. Macielak*, 47 Pa. D. & C.4th 364, 368-69 (Crawford Cnty. 2000) (surgeon's conduct in ignoring patient's communications about postoperative complications which caused paraplegia could constitute reckless indifference since it manifested a complete “disregard of the attempts to contact him, with knowledge of the postoperative dangers inherent in the Plaintiffs’ recent back surgery”). Clearly, the allegations set forth in the Complaint here are not comparable to the conduct cited in the aforementioned cases.

A careful review of the allegations asserted in the Complaint reveal that the facts pled clearly do not rise to the level necessary to support a claim for punitive damages – especially considering that Defendants were responding a novel, global health crisis that even the world’s leading experts struggled, and continue to struggle, to respond to. To say that front line healthcare providers acted recklessly, willfully, wantonly, or with an evil motive in putting forth their most

sincere and best effort to manage a global pandemic is simply outrageous.

There are neither allegations nor facts pled to support that any actions on the part of Defendants were intentional or undertaken with an evil motive or with reckless indifference to Plaintiffs. The Complaint contains mere bald allegations of intent with no supporting factual basis as well as allegations of mere negligence. Notably, the allegations regarding conduct not involving these Plaintiffs cannot be considered to determine the appropriateness of punitive damages. *See Gallagher, supra.*

Plaintiffs' unsupported and conclusory claims of reckless, willful, wanton, or malicious acts on the part of Defendants fails to rise to the requisite level to support a claim of entitlement to punitive damages. As such, the request for punitive damages should be dismissed.

G. SCANDALOUS AND IMPERTINENT MATTER SHOULD BE STRICKEN FROM THE COMPLAINT

In the event this Court declines to dismiss the Complaint in its entirety, Defendants move to strike scandalous and impertinent matter from the Complaint. Pursuant to Federal Rule of Civil Procedure 12(f), a court may "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." The purpose of a 12(f) motion to strike is to "avoid the expenditure of time and money that must arise from litigating spurious issues by dispensing with those issues prior to trial." *United States v. Consolidation Coal Co.*, 1991 U.S. Dist. LEXIS 15229, 1991 WL 333694, at *2 (W.D.Pa. July 5, 1991)(citations omitted); 5C C. Wright and A. Miller, Federal Practice and Procedure (Civil) 2d section 1382, at 465 (2004) ("Scandalous matter is that which improperly casts a derogatory light on someone, most typically a party to the action.") (footnote omitted); 2 Moore's Federal Practice section 12.37[3] at 12-97 ("Scandalous generally refers to any allegation that unnecessarily reflects on the moral character of an individual or states anything in repulsive language that detracts from the dignity of the court.") (footnote omitted).

“Immaterial” matter is that which has no essential or important relationship to the claim for relief. *Conklin v. Anthon*, 2011 U.S. Dist. LEXIS 37055, 2011 WL 1303299 (W.D. Pa. 2011). “Impertinent” matter consists of statements that do not pertain, and are not necessary, to the issues in question.” *Cech v. Crescent Hills Coal Co.*, No. 96-2185, 2002 U.S. Dist. LEXIS 15731, 2002 WL 31002883, at *28 (W.D. Pa. 2002).

Here, the Complaint contains a plethora of immaterial, impertinent, and scandalous matter including, but not limited to, allegations pertaining to other COVID-19 cases at the facility; unrelated DOH citations and alleged staffing information from multiple years before the time period in question; references to the National Guard being deployed to Brighton in May; and reference to a federal investigation into Brighton’s handling of the COVID-19 pandemic. Such allegations are scandalous, immaterial, and impertinent to the claims in this case and should be stricken. Defendants specifically move to strike the following language:

1. Paragraph 302, 309 – unfounded and inflammatory allegations that Brighton was reporting inaccurate COVID numbers
2. Paragraphs 303, 304 – irrelevant hearsay allegations relating to employee complaints
3. Paragraphs 305, 306, 308, 349 – irrelevant allegations that other residents (not Plaintiffs to this matter) contracted COVID-19 at Brighton or that other residents died due to a COVID-19 illness
4. Paragraph 314 to 340 – reference to unrelated and irrelevant DOH surveys and citations, which constitute inadmissible hearsay
5. Paragraphs 341 to 349 - references to the National Guard being deployed to Brighton and references to a federal investigation into Brighton
6. Paragraphs 350 to 357 – allegations relating to inadmissible hearsay statements of former employee
7. Paragraphs 358 to 410 - unfounded allegations relating to alleged understaffing from 2 to 4 years prior to the relevant time period (2016 to 2018), including citation to inadmissible hearsay.

Additionally, Defendants move to strike Exhibits 1 through 11, attached to Plaintiffs’ Complaint. Plaintiffs inappropriately attach 114 pages of Exhibits to their Complaint that amount to nothing more than inadmissible and inflammatory hearsay. Exhibit 1 to Plaintiffs’ Complaint is

a hearsay statement from an alleged former employee of Defendant Brighton. This statement serves no purpose other than to improperly cast a derogatory light on Brighton, and thus, should be stricken. Exhibits 2, 3, 4, and 5 are DOH citations for unrelated deficiencies from unrelated time frame. Not only do these surveys and citations amount to nothing more than inadmissible hearsay, they are not related to the Plaintiffs in the instant action. Many of the cited deficiencies are for entirely unrelated issues, and are from years prior to the time period in question. These exhibits serve no purpose other than to cast the facility in a derogatory light.

Exhibit 6 purports to be a document containing a chart of the COVID-19 cases at skilled nursing facilities in Pennsylvania, including Brighton. This information is entirely irrelevant to whether Defendants breached any purported standard of care with regard to the Plaintiffs and their relatives in this case, and therefore, must be stricken.

Exhibits 7, 8, 9, 10, and 11 are “Cost Reports” and alleged staffing and financial documents from the years 2016 to 2018. Not only do these documents constitute inadmissible hearsay, these references to alleged information and staffing data from multiple years before the time period in question are completely irrelevant to the instant matter. Importantly, the paragraphs citing these Exhibits consist of improper legal conclusions. These conclusory allegations relating to alleged financial information that is entirely irrelevant to Plaintiffs’ claims in this case. These Exhibits must be stricken.

The Court’s striking of offensive material is particularly appropriate when the offensive material is not responsive to an argument but, rather, constitutes an inappropriate attempt to abuse the Court’s process to attack an individual personally. Here, Plaintiffs have included allegations which clearly have no relevance whatsoever to the Plaintiffs or the allegations at hand. Rather, they are improperly included in the Complaint to cast a shadow on Defendants that is unnecessary,

unwarranted, and should not be allowed by this court. Furthermore, and to the extent that Plaintiffs seek to use these allegations of negligence as a basis for punitive damages, such a claim must fail. Under Pennsylvania law, “a defendant’s acts that are independent from the conduct on which liability is premised may not serve the basis for punitive damages,” nor do said acts assert a separate cause of action sounding in tort. *See Gallagher v. Temple University Hospital*, 2005 WL 2649868, *3 (Pa. Super. 2005) *rev’d on other grounds*, 901 A.2d 981 (Pa. 2006) (allegations that hospital altered and withheld medical records post-incident do not “relate to the malpractice being litigated” and cannot form the basis of a punitive damages claim); *Stroud v. Abington Memorial Hospital*, 546 F. Supp. 2d 238, 258-59 (E.D. Pa. 2008) (applying *Gallagher*).

V. CONCLUSION

Accordingly, for the reasons set forth above, Defendants’ Motion to Dismiss should be granted pursuant to Federal Rules 12(b)(6) (and/or 12(b)(1)) and 8(a), and Plaintiffs’ Complaint should be dismissed with prejudice.

Dated: January 4, 2021

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CERTIFICATE OF SERVICE

I, Andrew G. Kimball, hereby certify that I electronically submitted the foregoing Brief in Support of Defendants’ Motion to Dismiss Plaintiffs’ Complaint with the Clerk of the Court for the United States District Court for the Western District of Pennsylvania, using the electronic case filing system of the Court. The electronic case filing system sent a “Notice of Electronic Filing” to the following individuals who, by rule, have consented to accept the Notice as service of this document by electronic means:

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