IN THE COURT OF APPEALS
STATE OF ARIZONA
DIVISION ONE

ROBIN ROEBUCK, Plaintiff/Appellant, v. MAYO CLINIC, et al. Defendants/Appellees.	No. 1 CA-CV 22-0508 Maricopa County Superior Court No. CV2021-090429

ANSWERING BRIEF OF APPELLEES

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INTRODUCTION

This case tests the application and constitutionality of Arizona's COVID-19 immunity statute, A.R.S. § 12-516, which shields Defendants from lawsuits such as this one, because Defendants are health care professionals/a health care institution, who were providing medical care to Plaintiff in response to his COVID-19 diagnosis during the law's effective period. Alternatively, the PREP Act's broad application of immunity applies to Defendants because they are "covered persons" engaged in the administration or use of "covered countermeasures" during the COVID-19 global pandemic and national health emergency.

Together, these state and federal liability protections are critically important because the COVID-19 pandemic was an unprecedented crisis. Experts from the World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), and other public health authorities issued continuously evolving recommendations, guidance, and advice based on the science of the moment. Despite aggressive efforts by our government and healthcare community to limit the spread, health care providers and health

care facilities, such as Mayo Clinic Arizona, experienced disproportionate hardship.

Recognizing the uncertainty of the virus and the challenges faced by health care providers, the federal government and several state governments issued declarations and laws protecting those who protect us by extending immunity from lawsuits to health care providers relating to their efforts to treat and prevent the spread of COVID-19. This immunity recognizes the uncertainties associated with treatment and prevention of COVID-19 and ensures health care providers are not subject to lawsuits that hinder and discourage their critical and ongoing work.

STATEMENT THE CASE

This is a medical malpractice case which Plaintiff Robin Roebuck ("Plaintiff" or "Mr. Roebuck") brought against Mayo Clinic Arizona, Mayo Clinic Hospital, Nicole Secrest, N.P. and Robert Scott, M.D. (Collectively "Mayo" or "Defendants.") Plaintiff alleges that Defendants negligently performed an arterial blood gas ("ABG") test on Mr. Roebuck while he was being treated for COVID-19 at Mayo in April of 2020, which allegedly led to complications, including compartment syndrome, which necessitated

emergency surgery. [ROA 14, ¶¶ 11 & 12.][1] Defendants moved for summary judgment based on the immunity provided under A.R.S. § 12-516 and the Public Readiness and Emergency Preparedness Act, 42 U.S.C.A. §§ 247d-6d, 247d-6e (West 2020) ("PREP Act"). [ROA 27 (Motion), ROA 31 (Response), ROA 35 (Reply).] The trial court found that Plaintiff's claims were not barred by the PREP Act, but granted Defendants motion based on the immunity provided via A.R.S. § 12-516. [ROA 43.] The trial court issued a signed final judgment on November 21, 2022, which perfected Plaintiff's appeal. [ROA 63 & 52.]

STATEMENT OF THE FACTS

Plaintiff Robin Roebuck presented to Mayo Clinic Arizona on April 20, 2020, complaining of cough, fever, and diarrhea. [ROA 28, Ex. A.] That same day, Plaintiff was diagnosed with COVID-19 and admitted to Mayo Clinic Arizona. [*Id*. at Exs. A & B.] Plaintiff developed worsening hypoxia on April 23, 2020. [*Id*. at Ex. C.] On April 24, 2020, Hasan Ashraf, M.D. ordered right-side arterial blood gas ("ABG") test[2] on Plaintiff. [*Id*. at Ex. D.]

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[1] This brief will use "ROA" for the clerk's index to the record on appeal. When citing to specific Exhibits, this brief will cite to the Exhibit letter or number of the Record document.

[2] ABG analysis is a diagnostic tool used to assess a patient's partial pressure

The ABG showed a PF ratio 2.01, thus "constituting Tocilizimab 800 mg." [*Id*. at Ex. E.] The ABG results came back at 1233, after which the first dose tocilizimab was ordered to treat Plaintiff's COVID-19 at 1251. [*Id*. at Exs. D & F.] Plaintiff was given two (2) doses of the medication tocilizumab for his COVID-19. [*Id*. at Ex. D.] Plaintiff was discharged from Mayo Clinic Arizona on May 7, 2020. [*Id*. at Ex. C.]

Plaintiff's Amended Complaint alleges that Mayo nurse practitioner, Nicole Secrest, negligently performed the ABG test and that Plaintiff developed complications, including compartment syndrome, which necessitated emergency surgery. [ROA 1, ¶¶ 11 & 12.][3] Plaintiff alleges that the "purpose of performing the ABG stick on Plaintiff was to evaluate the health of Plaintiff's heart owing to Plaintiff having undergone a heart transplant at Mayo Clinic in 2017 . . .." [*Id*. at ¶ 11.]

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of oxygen (PaO2) and carbon dioxide (PaCO2). PaO2 provides information on the oxygenation status, and PaCO2 offers information on the ventilation status (chronic or acute respiratory failure). *See* Castro D, Patil SM, Keenaghan M. Arterial Blood Gas. [Updated 2021, Jan. 27]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan-Available from: https://www.ncbi.nlm.nih.gov/books/NBK536919/

[3] The ABG was actually performed by Mayo-employed respiratory therapist Curtis Saczalski. Plaintiff was informed of this during the court-ordered discovery, but did not seek to amend his complaint. This does not change any of the arguments on appeal.

Mayo moved to dismiss Plaintiff's Amended Complaint, arguing Plaintiff's claims were barred as a matter of law by the immunity provided by Arizona Senate Bill 1377 ("SB 1377")[4], Arizona Executive Order 2020-27 the "Good Samaritan" Order ("E.O. 2020-27"), and the Public Readiness and Emergency Preparedness Act, 42 U.S.C.A. §§ 247d-6d, 247d-6e (West 2020) ("PREP Act"). [ROA 15.] The trial court denied Mayo's Motion, holding in relevant part:

> Defendants' arguments hinge on whether the blood draw was done in furtherance of their treatment of Plaintiff for COVID-19. Plaintiff alleges in his First Amended Complaint that he was injured when Defendants drew his blood for the purpose of evaluating the health of his heart. Whether the treatment was for Plaintiff's heart condition or COVD-19 is a factual dispute. For purposes of considering Defendants' Motion to Dismiss, the Court will assume the allegations in the First Amended Complaint are true and that the blood draw pertained to his heart condition rather that treatment for COVID-19. That necessitates the Court denying Defendants' Motion.
>
> As an alternative to immediate dismissal, Defendants have requested a hearing pursuant to Rule 12(i) of the Arizona Rules of Civil Procedure. The Court believes

[4] Defendants' Motion to Dismiss was filed prior to the law's codification as A.R.S. § 12-516.

> that it is appropriate to initially limit the scope of discovery in this case to the issues of the purpose of the blood draw. After discovery has been complete on that issue, the parties may either file motions for summary judgment or seek and evidentiary hearing on that issue.

[ROA 23.]

Subsequently, the parties engaged in limited discovery related to the purpose of the ABG, to include the depositions of: Plaintiff Robin Roebuck, Robert Scott, M.D., and Hasan Ashraf, M.D. [ROA 28, Ex. G (Deposition testimony of Robin Roebuck), Ex. H (Deposition testimony of Hasan Ashraf, M.D.), and Ex. I (Deposition testimony of Robert Scott, M.D.).]

A. <u>Plaintiff's Testimony</u>

Plaintiff testified that he had two (2) previous heart transplants, one in 1993 and one in 2017. [ROA 28, Ex. G, pg. 14:18-25.] Plaintiff testified that after his 2017 transplant, his heart was doing well and that, prior to his COVID-19 diagnosis in April of 2020, he was "very healthy." [*Id*. at pgs. 17:11 – 18:1.] Plaintiff confirmed that, after his presentation to Mayo in April of 2020, he was diagnosed with COVID-19; Plaintiff testified that COVID-19 is a "killer." [*Id*. at pgs. 22:17 – 23:15.] According to Plaintiff, based on his COVID-19 diagnosis, he was admitted to Mayo's COVID floor

for monitoring. [*Id*. at pg. 32:4-23.] Plaintiff recalls being treated with convalescent plasma for his COVID-19. [*Id*. at pgs. 37:22 – 38:17.] Plaintiff testified that he does not recall being told that an ABG was going to be done and/or what the purpose of the ABG was. [*Id*. at pgs. 42:18-25; 45:12-15.] Plaintiff acknowledged that the ABG was not necessarily performed to "evaluate the health" of his heart, but, as he understands it, the ABG was done to evaluate the "oxygen in [his] blood." [*Id*. at pgs. 46:16 – 48:12.]

B. Hasan Ashraf, M.D.'s Testimony

Hasan Ashraf, M.D. is a cardiologist and was the senior fellow on the congestive heart failure ("CHF") team at Mayo Clinic Arizona in April of 2020 when Plaintiff was admitted. [ROA 28, Ex. H, pgs. 8:1-4; 8:12 – 9:19; 10:5-25; 11:6-23.] Dr. Ashraf testified that when Plaintiff presented to Mayo, he was initially placed under the care of the CHF team; specifically, Dr. Ashraf testified: "Any patient who has a heart transplant in the past is admitted to the CHF service, whatever the nature of their problem." [*Id*. at pgs. 15:1 – 16:18.] Dr. Ashraf confirmed that Plaintiff was diagnosed with COVID-19. [*Id*. at 16:14-18.] On April 23, 2020, Dr. Ashraf ordered an echocardiogram for Plaintiff to see "baseline information with regards to the heart." [*Id*. at pg. 23-1-7.] Dr. Ashraf testified that Plaintiff's

echocardiogram "confirmed that his heart was doing pretty well" and "suggested that the patient was not having primary cardiac issues. . .." [*Id*. at pg. 24:17-23.]

Dr. Ashraf testified that because of Plaintiff's COVID diagnosis and testing to show no primary cardiac issues, Plaintiff was handed over to the physician assistants because his issues were not cardiac related, but related to COVID-19. Dr. Ashraf testified:

> Once his COVID test came back positive and it was, to some level, clear that we weren't dealing with a primary cardiac issue, I kind of handed him over to the physicians assistants and went to take care of other cardiac patients.

[*Id.* at 16:14-18.]

> And our management thereafter confirmed that, in which we didn't proceed with any cardiac kind of management, but we proceeded with regards to the management of COVID.

[*Id*. at pg. 25:7-10; *see also Id*. at pgs. 52:12 – 53:8.]

Dr. Ashraf affirmed that an ABG test does not measure heart disease and doesn't "provide any direct kind of information with regards to the heart." [*Id*. at pgs. 39:16 – 40:9.] Regarding the ABG test ordered on April

24, 2020, Dr. Ashraf confirmed that the ABG was related to Plaintiff's COVID diagnosis; specifically, Dr. Ashraf testified:

> Q. Do you know why you ordered the ABG test for Mr. Roebuck?
>
> A. Yes.
>
> So if the patient was becoming progressively hypoxic, then the ABG provides additional information that the pulse oximeter, which measures the oxygen saturation in a non-invasive way, would not be able to provide.
>
> So, for one, it provides the direct oxygen content, as you can see here on the screen, the PO2 being 64.3. That's the direct measurement of the oxygen in the arterial blood, which the pulse oximeter does not.
>
> It does based on a mathematical calculation based on certain physical assumptions, which may or may not be accurate.
>
> The second thing is that it provides additional information with regards to the CO2, watch the pulse oximeter it does not.
>
> So these are just examples of the kind of incremental data that the ABG is providing.
>
> **Specifically with regards to this patient, you know, he had COVID. And these COVID positive patients,**

> **many of them, at that time, we thought that they could have normal pulse oximeter but be severely hypoxic, which, in this case, was the reality.**
>
> **And saw this provided confirmation that the patient had very low oxygen content in his blood.**
>
> That's the main reason that I ordered this test.

[*Id*. at pgs. 40:24 – 42:3 (emphasis added); *see also Id*. at pgs. 56:23 – 57:15.]

Dr. Ashraf recalls that his colleagues in infectious disease were considering giving Plaintiff the medication tocilizumab for his COVID and that the information from the ABG would support giving this medication. [*Id*. at pgs. 59:7 – 60:5.]

C. Robert Scott, M.D.'s Testimony

Robert Scott, M.D. is a cardiologist and a member of Mayo Clinic Arizona's section of advanced heart failure and cardiac transplantation. [ROA 28, Ex. I, pg. 6:10-23.] He is also the director of the pulmonary hypertension clinic at Mayo Clinic Arizona. [*Id*.]. Dr. Scott was a member of Plaintiff's care team in April of 2020. [*Id*.] Dr. Scott consulted with Dr. Ashraf regarding Plaintiff's April 23, 2020 echocardiogram results and confirmed that Plaintiff's overall "cardiovascular function was good" and "did not support anything along the lines of possible rejection." [*Id*. at pgs.

13:1 – 14:10.] Dr. Scott explained that the primary purpose of an ABG test is to "definitively know exactly what a person's oxygenation is, or how much oxygen is actually being delivered in their blood." [*Id*. at pgs. 13:1 – 14:10.]

Dr. Scott unequivocally testified that the April 24, 2020 ABG performed on Plaintiff was related to his COVID-19 diagnosis and potential treatment; Dr. Scott testified:

> Q. Were one of the tests or follow-up treatment that you and Dr. Ashraf resolved on for Mr. Roebuck after the echocardiogram results were available to do an ABG?
>
> A. The ABG, yeah, as I stated, his oxygenation was getting worse, and there are some medications that have been found — again, we're going back, you know, April, of March 2020, when we were really sort of flying by the seat of our pants with Covid treatment. There were certain protocols that we had in place that we felt were effective based upon the research that was available.
>
> And one of these — but these protocols required you to meet certain measures, having to do with the oxygenation status, having to do with some of the biomarkers.
>
> **So the ABG, or arterial blood gas, was done to see whether or not he would meet criteria for treating with tocilizumab**.

[*Id*. at pg. 19:3-19 (emphasis added).]

Q. So let me ask it this way. In Dr. Ashraf ordering that an ABG be done, was part of the purpose to assess his condition related to the Covid diagnosis?

A. That was the whole point of all of this. I mean that's not to sound flip, but, yeah, it's all related to that. Every — Covid is a perfect weapon for killing patients because it attacks just about every organ system that's involved. It attacks the lung tissue, attacks the heart. It affects the kidneys. It attacks the blood vessels in the sense that it causes you to have more blood clots, increase the likelihood of blood clotting.

So it's like the perfect weapon for killing patients. And patients who are immunosuppressed are at the greatest risk of these things happening.

So we are very aggressive about trying to be proactive in a safe but effective manner and people who are risk for dying from Covid. And that's primarily people who are immunosuppressed who get sick, so —

* * *

The reason for doing a blood gas is because despite having a sat monitor on him, he was doing worse clinically.

So we want to get as up-to-date, accurate information as possible so as to probably take care of him in the best manner possible.

So that was the reason for the blood gas.

[*Id*. at pgs. 21:11 – 22:13.]

Q. And so the sole purpose of the arterial blood gas was to determine the amount of oxygen in the blood, because Mr. Roebuck's oxygenation requirements were getting worse and him requiring higher amounts of oxygen as a direct result of his COVID-19 disease; true?

MR. GREGORY: Form and foundation.

THE WITNESS: That is true.

BY MR. MONTELL:

Q. The arterial blood gas, the sole purpose of that was to — was a result of his COVID-19 illness; true?

MR. GREGORY: Form.

THE WITNESS: The reason we obtained the blood gas was because of his worsening oxygenation secondary to the Covid infection.

Our other reason behind it is in order to continue to be aggressive about treating him for Covid, one of the requirements of the drug that we gave him, the

> **tocilizumab, is that you have to meet certain requirements regarding the oxidization. And the way to get that information was to do a blood gas.**
>
> So it was all designed to try and more effectively treat Mr. Roebuck and try to save his life from this potentially life-threatening disease.

[*Id*. at pg. 33:2-25. (emphasis added).]

To the extent additional facts are relevant, they will be detailed in the argument section below.

ISSUES PRESENTED FOR REVIEW

1. **Arizona Immunity Statute.** A.R.S. § 12-516 provides immunity to health care providers for damages in any civil action for an injury allegedly negligently caused while providing treatment to a patient for COVID-19 unless a plaintiff can prove willful misconduct or gross negligence by clear and convincing evidence. A.R.S. § 12-516 applies to all claims "filed before or after September 29, 2021 for an act or omission by a person that occurred on or after March 11, 2020." In this case, Plaintiff's January 29, 2021 lawsuit claims that a Mayo employee negligently performed an ABG in April of 2020, the purpose of which was specifically related to his COVID-19 diagnosis and treatment. Plaintiff did not plead

gross negligence and/or willful misconduct. Did the trial court correctly grant Defendants Motion for Summary Judgment based on the immunity provided in A.R.S. § 12-516?

2. **Federal Immunity Statute.** The PREP Act provides immunity "from suit" to "covered persons" engaged in the administration or use of "covered countermeasures" during the COVID-19 global pandemic, unless there is willful misconduct that caused a serious physical injury. Even if willful misconduct is alleged, a plaintiff must exhaust all administrative remedies before filing suit. In this case, Defendants are "covered persons" because they are licensed health care providers. The ABG was a "covered countermeasure" used to assess Plaintiff's respiratory status during Plaintiff's COVID-19 treatment. Plaintiff did not pursue any administrative remedies. Did the trial court correctly rule that Plaintiff's state law claims are not barred by the PREP Act?

ARGUMENT

I. STANDARD OF REVIEW.

Under Rule 56, Ariz. R. Civ. P., the Court "shall grant summary judgment if the moving party shows that there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law." The

summary judgment rule is an "efficient instrumentality to expedite the business of the court by permitting the summary adjudication of meritless claims without the necessity of trial." *Orme School v. Reeves*, 166 Ariz. 301, 305 (1990). The Arizona Supreme Court in *Orme School* noted the policy behind the summary judgment rule:

> Summary judgment procedure is not a catchpenny contrivance to take unwary litigants into its toils and deprive them of a trial, it is a liberal measure, liberally designed for arriving at the truth. Its purpose is not to cut litigant off from their right of trial by jury *if they really have evidence which they will offer on a trial*, it is to carefully test out in advance of trial by inquiring and determining whether such evidence exists.

Id. (quoting *Whitaker v. Coleman*, 115 F.2d 305, 307 (5th Cir. 1940) (emphasis in original).

Pursuant to *Orme School*, summary judgment must be granted if "the facts produced in support of the claim . . . have so little probative value, given the quantum of evidence required, that reasonable people could not agree with the conclusion advanced by the proponent of the claim . . .." *Id*. at 309, 802 P.2d at 1008. Furthermore, as held in *Orme School*:

> [W]hen discovery has been completed and the proponent of a claim . . . is unable to produce evidence sufficient to send the claim . . . to the jury, it would

> effectively abrogate the summary judgment rule to hold that the motion should be denied simply on the speculation that some slight doubt (and few cases have complete certainty), some scintilla of evidence, or some dispute over irrelevant or immaterial facts might blossom into a real controversy in the midst of trial. The purpose of the summary judgment rule is to enable trial courts to rid the system of claims that are meritless and do not deserve to be tried.

Id. at 311.

This Court reviews summary judgments and partial summary judgments *de novo*, *Weitz Co. L.L.C. v. Heth*, 235 Ariz. 405, 408, ¶ 11 (App. 2014), and "may affirm the judgment based on any . . . grounds" that were "properly presented in the superior court." ARCAP 13(b)(2).

II. THE TRIAL COURT CORRECTLY HELD THAT DEFENDANTS ARE IMMUNE FROM CIVIL LIBAILTIY FOR PLAINTIFF'S CLAIMS PURSUANT TO A.R.S. § 12-516.

The trial court correctly held that Plaintiff's claims against Defendants are barred pursuant to the civil immunity protections afforded to Defendants under A.R.S. § 12-516. The statute provides specific protections for health professionals and health care institutions, stating:

> A health professional or health care institution that acts in good in faith, is not liable for damages in any civil action for an injury or death that is alleged to be caused by the health professional's or health care institution's action or omission

> while providing health care services in support of the State's response to the State of Emergency declared by the Governor unless it is proven by clear and convincing evidence the health professional or health care institution failed to act or acted with willful misconduct or gross negligence.

A.R.S. § 12-516(A).

Further, the statute provides:

> Subsection A applies to **any action or omission that occurs during a person's screening, assessment, diagnosis or treatment and that is related to the public health pandemic** that is the subject of the State of Emergency . . ..

A.R.S. § 12-516(B) (emphasis added).

The statute also provides a presumption that health professionals or health care institutions acted in good faith if they relied on and reasonably attempted to comply with applicable published guidance. A.R.S. § 12-516(D). The law applies retroactively, covering acts or omissions occurring after March 11, 2020 for suits file before or after September 29, 2021. A.R.S. § 12-516(E). A.R.S. § 12-516 does not provide civil immunity to a healthcare professional or healthcare institution if it can be proven by clear and convincing evidence that there was gross negligence or willful misconduct.

A.R.S. § 12-516 clearly applies to Plaintiff's claims and provides Defendants immunity for the acts giving rise to Plaintiff's lawsuit. After the

court-ordered limited discovery, it cannot be disputed that the ABG Plaintiff claims was negligently performed, was provided in response to Plaintiff's COVID-19 diagnosis and constitutes health care services provided as part of Plaintiff's screening, assessment, diagnosis or treatment for COVID-19. Specifically, both Dr. Ashraf and Dr. Scott unequivocally testified that the April 24, 2020 ABG performed on Plaintiff was related to his COVID-19 diagnosis and potential treatment.

Given these undisputed facts, Defendants are entitled to immunity under both A.R.S. § 12-516 because:

(1) Defendants are licensed healthcare professionals and a healthcare institution;
(2) Defendants' actions constitute health care services provided as part of Plaintiff's assessment, diagnosis, and treatment for COVID-19;
(3) The actions alleged occurred during the effective term of the state law; and
(4) Plaintiff does not allege – and cannot prove via clear and convincing evidence – that Defendants' actions constitute gross negligence or willful misconduct.

The trial court correctly held that Defendants are immune from

Plaintiff's suit pursuant to A.R.S. § 12-516.

In his Opening Brief, Plaintiff argues that the trial court erred by holding that Plaintiff's claim was barred by A.R.S. § 12-516 for five (5) reasons: (1) There are genuine issues of material fact concerning the purpose of the ABG; (2) The language of the statute is ambiguous; (3) A.R.S. § 12-516 is unconstitutional; (4) Plaintiff did not have the opportunity to conduct discovery on the issue of gross negligence and/or willful misconduct; and (5) A.R.S. § 12-516 was not effective when Plaintiff filed his Complaint. Taking each argument in turn, Plaintiff does not offer any valid legal and/or factual reason why Defendants are not immune from suit.

A. The ABG was undisputedly ordered for and related to Plaintiff's COVID-19.

Plaintiff apparently believes that because the ABG could have been ordered related to treatment for chronic conditions unrelated to COVID-19, this creates a genuine issue of fact. This is incorrect. Plaintiff relies on alleged testimony of Dr. Ashraf where he allegedly "ordered Appellant undergo the ABG procedure" because the results of Plaintiff's echocardiogram showed he had "reduced right ventricular function and a possible echogenicity in the right atrium." [OB, pg. 10.] First, the deposition

testimony cited by Plaintiff in support of this alleged contention does not support it. [ROA 33, Ex. 5, pg. 22:13 – 23:20.] Instead, the cited testimony relates to what an echocardiogram is, why it's used, and why Dr. Ashraf ordered it for Plaintiff. The cited testimony does not explain the result of the echocardiogram and/or that Dr. Ashraf ordered the ABG based on the result of the echocardiogram.

To the contrary, the undisputed testimony from both Dr. Ashraf and Dr. Scott proves that the April 24, 2020 ABG performed on Plaintiff was related to his COVID-19 diagnosis and potential treatment. [ROA 28, Ex. H, pgs. 40:24 – 42:3, 56:23– 57:15; ROA Ex. I, pgs. 19:3-19, 21:11 – 22:13, 33:2-25.] More specifically, the ABG "was done to see whether or not [Plaintiff] would meet criteria for treating with tocilizumab," for his COVID-19. [ROA 28, Ex. I, pg. 19:3-19.] Plaintiff himself admits that he was not told why the ABG was being performed and the ABG was not necessarily performed to "evaluate the health" of his heart, but, as he understands it, the ABG was done to evaluate the "oxygen in [his] blood." [ROA 28, Ex. G, pgs. 42:18-25; 45:12-15, 46:16 – 48:12.] The fact that Plaintiff had other medical conditions and previously had an ABG done related to those conditions, does not

negate the undisputed fact that the ABG done in April of 2020 was unequivocally related to his treatment of COVID-19.

B. A.R.S. § 12-516 is not ambiguous and the Legislature's intent is clear.

Plaintiff argues that the language of A.R.S. § 12-516 is ambiguous. "Ambiguity exists if there is uncertainty about the meaning or interpretation of a statute's terms." *Hayes v. Continental Ins. Co.*, 178 Ariz. 264, 268 (1994) (*citing State v. Sweet*, 143 Ariz. 266, 269, (1985)). Specifically, Plaintiff takes issue with the following language from the statute:

- "A health professional or health care institution that acts in good in faith, is not liable for damages in any civil action for an injury or death that is alleged to be caused by the health professional's or health care institution's action or omission ***while providing health care services in support of the State's response to the State of Emergency declared by the Governor*** . . ."

Regarding the above emphasized language, Plaintiff argues that it is ambiguous because it does not provide "any guidance" on its meaning and does not specify whether the treatment performed must be exclusively as a measure for treating COVID-19. [OB, pg. 12.] This is incorrect. The "State of Emergency" obviously refers to the COVID-19

pandemic. So, the language clearly means that immunity applies for acts or omissions during the time that a health care provider is delivering health care services in support of the COVID-19 response. It is not ambiguous.

- "Subsection A applies to any action or omission that occurs during a person's screening, assessment, diagnosis or treatment and ***that is related to the public health pandemic.***"

Regarding this emphasized language, Plaintiff argues that it is ambiguous because it is "unclear if this language suggests that any medical care rendered during a pandemic extends immunity to the healthcare provider, or does the medical care in question have to be exclusively done in treatment of a pandemic-related condition . . .." [OB, pg. 12.] Again, this argument is untenable. The use of the word "and" means that each of the enumerated conditions must be related to the COVID-19 pandemic. So, we can break out the language as follows: Subsection A applies to any action or omission that occurs:

- During a person's screening for COVID-19;
- During a person's assessment for COVID-19;
- During a person's diagnosis of COVID-19; and
- During a person's treatment for COVID-19.

The statute further provides that immunity may apply to medical treatment unrelated to COVID-19 if:

> [T]he health professional's or health care institution's action or omission was in good faith support of this state's response to the state of emergency, including any of the following:
>
> 1. Delaying or canceling a nonurgent or elective dental, medical or surgical procedure.
> 2. Providing nursing care or procedures.
> 3. Altering a person's diagnosis or treatment in response to an order, directive or guideline that is issued by the federal government, this state or a local government.
> 4. An act or omission undertaken by a health professional or health care institution because of a lack of staffing, facilities, equipment, supplies or other resources that are attributable to the state of emergency and that render the health professional or health care institution unable to provide the level or manner of care to a person that otherwise would have been required in the absence of the state of emergency.

A.R.S. § 12-516(B).

The language of the statute is not uncertain. The law clearly and unequivocally provides broad protections for healthcare institutions and providers from civil claims for COVID-19 related issues.

Even if the statute is ambiguous, that does not mean it would not apply. It simply means that the Court "may resolve doubt by resorting to

statutory interpretation" and should "determine and give effect to the legislature's intent." *Hayes*, 178 Ariz. at 672. In this case, the Arizona legislature clearly intended to provide immunity to front line health care providers from suits just like Plaintiff's suit. Experts from the World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), and other public health authorities issue continuously evolving recommendations, guidance, and advice based on the science of the moment. Despite aggressive efforts by our government and healthcare community to limit the spread, health care providers and health care facilities, such as Mayo Clinic Arizona, have experienced disproportionate hardship. On the front lines combating this deadly illness are health care providers and others who care for patients at Mayo Clinic Arizona. These individuals are dedicated to caring for their patients suffering from various illnesses, while simultaneously working to care for those who contract COVID-19.

Recognizing the uncertainty of the virus and the challenges faced by health care providers, the Arizona Legislature enacted A.R.S. § 12-516 to protect those who protect us by extending immunity from lawsuits to health care providers relating to their efforts to treat and prevent the spread of

COVID-19. This immunity recognizes the uncertainties associated with treatment and prevention of COVID-19 and ensures health care providers are not subject to lawsuits that hinder and discourage their critical and ongoing work. A.R.S. § 12-516, Arizona Executive Order 2020-27 the "Good Samaritan" Order ("E.O. 2020-27").[5] As such, even if A.R.S. § 12-516 is open to interpretation, the Legislature's intent is not. A.R.S. § 12-516 applies to Plaintiff's lawsuit and provides immunity to Defendants.

C. A.R.S. § 12-516 is constitutional.

Plaintiff alleges that A.R.S. § 12-516 violates the Arizona Constitution by unlawfully stripping plaintiffs of the right to recover damages for their injuries. Article 18, § 6 of the Arizona Constitution provides that "[t]he right of action to recover damages for injuries shall never be abrogated, and the amount recovered shall not be subject to any statutory limitation...." Ariz. Const. art. 18, § 6.

While anti-abrogation limits the legislature's ability to abrogate a common law claim, the legislature can lawfully regulate common law

[5] *See* Executive Order 2020-27, The "Good Samaritan Order" — Protecting Frontline Healthcare Workers Responding To The COVID-19 Outbreak. Available at https://azgovernor.gov/executive-orders

claims. *Cronin v. Sheldon,* 195 Ariz. 531, 540–41 ¶¶ 44–46 (1999). To that end, "[o]ur anti-abrogation jurisprudence normally asks whether a statute unconstitutionally deprives a litigant of access to the courts." *Nunez v. Prof'l Transit Mgmt. of Tucson, Inc.,* 229 Ariz. 117, 123 (2012). In *Nunez*, the Court held that the application of a different duty of care did not violate the anti-abrogation clause because the defendant still had a reasonable possibility to obtain legal redress. *Id.* at 122–23 ¶¶ 24–26. In *Watts v. Medicis Pharm. Corp*., the Arizona Supreme Court held that the "LID" (learned intermediary doctrine) did not abrogate any right to recover damages in contravention of the anti-abrogation clause, but instead provided a means for a manufacturer to fulfill its duty to warn the end user by properly warning the learned intermediary. 239 Ariz. 19, 27 (2016). The Court further noted that the LID does not prevent a plaintiff from asserting an action against the manufacturer in appropriate circumstances, such as when the full medical information and warnings are not given to the medical provider. *Id.* (*citing State Farm Ins. Co. v. Premier Manufactured Sys., Inc.*, 217 Ariz. 222, 228 (2007)).

Here, as in *Nunez*, the applicable immunity laws do not prevent litigants' access to the courts, but instead modify the duty of care and

standard necessary to obtain redress. That the law may make it more difficult to obtain relief does not render it unconstitutional. *See, e.g, Franklin v. Clemett*, 240 Ariz. 587, 595 (App. 2017) (holding that a statute does not effectively abrogate a claim by making it more difficult for the claimant to obtain a recovery or even when, in the claimant's view, it may weaken the claimant's case); *State Farm Ins. Co. v. Premier Manufactured Sys., Inc.*, 217 Ariz. 222, 229, ¶¶ 35–37 (2007) (rejecting argument that A.R.S. § 12–2506, which abolished joint and several liability in strict products liability cases, violates Article 18, § 6); *Governale v. Lieberman*, 226 Ariz. 443, 447–48 (App. 2011) (statute limiting potential expert witnesses a plaintiff may use did not effectively abrogate plaintiff's right of recovery). Moreover, as in *Watts*, the immunity laws do not prevent a plaintiff from asserting a civil action in appropriate circumstances, including instances of failure to act, willful misconduct, or gross negligence. Because the statute does not abrogate any viable right of action to recover damages, it does not violate article 18, § 6.

D. Plaintiff has not pled and cannot prove gross negligence and/or willful misconduct by clear and convincing evidence.

Within the anti-abrogation argument section of his Opening brief, Plaintiff argues that the trial court erred by not allowing him to conduct

discovery "that would inform him as to whether any of defendants engaged in willful misconduct or gross negligence." [OB, pg. 17.] This statement implies that Plaintiff believes he can somehow prove via clear and convincing evidence that Defendants were grossly negligent. First, Plaintiff has waived any such legal claim because: (1) He did not plead gross negligence and/or willful misconduct in his Complaint. *See generally Walls v. Arizona Dept. of Pub. Safety*, 170 Ariz. 591, 596 – 597 (App. 1991) (denying motion to amend complaint to add claim of gross negligence); and (2) The trial court explicitly allowed Plaintiff the opportunity to amend his complaint to add a claim of willful misconduct or gross negligence if "such claims can satisfy the requirements of Rule 11 of the Arizona Rules of Civil Procedure." [ROA 43, pg. 6.] Plaintiff failed to file an amended complaint, thus admitting that he could not ethically plead facts in support of such claims and confirming his waiver of those claims.

Second, there is absolutely no interpretation of the pled and/or known facts which provide the requisite evidence to support a claim of gross negligence and/or willful misconduct. In Arizona, in order to present the issue of gross negligence to the jury, the evidence "must be more than slight and may not boarder on conjecture." *DeElena v. S. Pac. Co.*, 121 Ariz.

563, 569 (1979). "A court may withdraw the issue of gross negligence from the jury when no evidence is introduced that would lead a reasonable person to find gross negligence." *Walls*, 170 Ariz. at 595. Trial courts commonly grant summary judgment disposing of gross negligence claims on this basis. *See, Armenta v. City of Casa Grande*, 205 Ariz. 367, 373 (App. 2003); *Badia v. City of Casa Grande*, 195 Ariz. 349, 358 (App. 1999); *Xu v. Gay*, 257 Mich. App. 263, 668 N.W.2d 166 (2003); *Walls*, 170 Ariz. at 595.

A party is grossly or wantonly negligent if he acts or fails to act "when he knows or has reason to know facts which would lead a reasonable person to realize that his conduct not only creates an unreasonable risk of bodily harm to others but also involves a high probability that substantial harm will result." *Walls*, 170 Ariz. at 595 (citations omitted). Gross negligence involves a risk of harm that is "substantially in excess of that necessary to make the conduct negligent." *Townsend v. Whatton*, 21 Ariz.App. 566, 560 (App. 1974). Thus, "[a] person can be very negligent and still not be guilty of gross negligence." *Kemp v. Pinal County*, 13 Ariz.App. 121 (App. 1970). *See also, Scott v. Scott*, 75 Ariz. 116, 122 (1953) ("Wanton negligence is highly potent, and when it is present it fairly proclaims itself in no uncertain terms. It is 'in the air', so to speak. It is flagrant and evinces a lawless and

destructive spirit."). Per Plaintiffs' own admission, this is not a gross negligence case. Plaintiff's sole claim is that the ABG "was done negligently resulting in significant and permanent injury." [ROA 31, pg. 12.] Further, while limited, the testimony of Plaintiff, Dr. Ashraf, and Dr. Scott, all lend support to the conclusion that the ABG was routinely performed and not something completely out of the ordinary and/or performed in a "lawless" or "destructive" manner. *Scott*, 75 Ariz. at 122. Plaintiff provides no argument and/or evidence to show how an ABG may be performed in a grossly negligent manner such that any amount of discovery would uncover such facts.

E. A.R.S. § 12-516 applies to Plaintiff's suit.

Plaintiff's argument that A.R.S. § 12-516 does not apply retroactively and was not effective until after he filed suit is clearly incorrect. Under A.R.S. § 1-244, a statute is not retroactive "unless expressly declared therein." In other words, if a statute provides that it is retroactive, it will be retroactive. A.R.S. § 12-516(E) provides:

> This section applies to all claims that are filed before or after September 29, 2021 for an act or omission by a person that occurred on or after March 11, 2020 and that relates to a public health pandemic that is the subject of the state of emergency declared by the governor.

This language could not be any clearer and proves that A.R.S. § 12-516 applies to Plaintiff's suit. Plaintiff filed suit on January 29, 2021 for alleged negligence that occurred in April of 2020.

Plaintiff's comparison of the language in A.R.S. § 12-516 to the language in A.R.S. § 12-515 makes no sense. First, A.R.S. § 12-515 is not the "enabling statute" of A.R.S. § 12-516. [OB, pg. 20.] While the statues are both related to the COVID-19 pandemic and were enacted at the same time, they are separate statutes providing different immunity protections. Second, the language cited by Plaintiff for A.R.S. § 12-515(B) is incorrect. [OB, pg. 19.] In fact, the language of A.R.S. § 12-515(B) is the same as A.R.S. § 12-516(E). Further, the fact that the Governor lifted the state of emergency does not change the analysis since there is no dispute that the events alleged occurred during its effective period. In sum, the immunity afforded at the state level, which is undeniably broad in scope, clearly applies to Plaintiff's claims and immunizes Defendants.

III. THE TRIAL COURT ERRED IN HOLDING THAT THE PREP ACT DOES NOT BAR PLAINTIFF'S SUIT.

If this Court agrees with the trial court's finding that Defendants are immune from Plaintiff's suit based on A.R.S. § 12-516, then the grant of

summary judgment must be upheld. If this Court does not so agree, Defendants request this Court still uphold the grant of summary judgment because Defendants are immune from Plaintiffs suit based on the immunity provided under the PREP Act. The PREP Act issue was fully briefed and considered by the trial court and is, as such, an alternative ground by which to uphold the grant of summary judgment. ARCAP 13(b)(2).

A. The absence of removal jurisdiction does not prevent a finding of immunity under the PREP Act.

While the trial court agreed that the ABG was a "covered countermeasure" and that Defendants were "covered persons" under the PREP Act,[6] it found that because the district court did not find "complete preemption" and remanded the case, Plaintiff's claims were not barred by the PREP Act. [ROA 43, pg. 5.] This was an incorrect ruling. The fact that the district court remanded the case, finding no removal jurisdiction under the PREP Act, does not affect or preclude the application of the PREP Act's substantive immunity. The district court did not decide the issue of whether the PREP Act applies in this case. It simply addressed whether federal question jurisdiction existed in favor or removal under "complete

[6] *See* Section II, B for a detailed review of the PREP Act and its definitions.

preemption" or "substantial federal question." However, a case can be dismissed in state court based on the immunity provided under the PREP Act even if it is remanded for absence of complete preemption. *See Retail Prop. Tr. V. United Bhd. Of Carpenters & Joiners of Am.*, 768 F.3d 938, 948 (9th Cir. 2014) ("'[m]any federal statutes – far more than support complete preemption – will support a defendant's argument that because federal law preempts state law, the defendant cannot be held liable under state law.'"); *Cotton v. Massachusetts Mut. Life Ins. Co.*, 402 F.3d 1267, 1292 (11th Cir. 2005) ("if a district court remand to state court claims that are not completely preempted, the defendant may still attempt to raise [defensive] preemption ads a defense in the state court.").

In short, the trial court erred in holding that the remand prevented it from ruling that the state claims presented here are preempted by the PREP Act, which dictates that if a claim arises out of the Defendants' administration of a countermeasure to combat COVID-19, Defendants "shall be immune from suit under Federal and State law." 42 U.S.C. § 247d-6d(a)(1).

B. Defendants are immune from suit under the PREP Act.

Defendants are immune from Plaintiff's claims under the PREP Act, as well as its implementing Declaration under the PREP Act for Medical

Countermeasures Against COVID-19. 85 Fed. Reg. 15198 (Mar. 17. 2020), amended by 85 Fed. Reg. 21012 (Apr. 15, 2020) ("the Declaration"). Understanding the legislative history of the PREP Act is critical when applying the statute. Because corporations 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.[7] 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.[8] In the PREP Act, Congress made the judgment that, in the context of a public health emergency, immunizing certain persons and entities from liability was necessary to ensure that potentially life-saving

[7] *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.

[8] *Id.* at 294.

countermeasures will be efficiently developed, deployed, and administered. Notably, Courts have characterized PREP Act immunity as "sweeping," as it applies to all types of legal claims under state and federal law. *Parker v. St. Lawrence Cty. Pub. Health Dep't,* 102 A.D.3d 140, 143, 954 N.Y.S.2d 259 (2012).

Here, the PREP Act applies to Plaintiff's negligence claim because it is based upon the administration of medications, treatment, diagnosis, and use of medical devices to treat, prevent, or mitigate COVID-19 by health care providers. *See* 42 U.S.C. §§ 247d-6d, 247d-6e (2006); *See also* 85 Fed. Reg. 15198 (Mar. 17, 2020). 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.

See 42 U.S.C. § 247d-6d(b)(1) (emphasis added).[9] By using the mandatory

[9] "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).

language, "***shall be immune from suit and liability under Federal and State law***" the objective of the immunity afforded could not be clearer. The legislative history of the PREP Act further reinforces that intent. The Act has a broad reach in its intended scope of protection, and the application of the PREP Act in the context of the COVID-19 pandemic is a novel issue. The sole exception to PREP Act immunity "shall be for... death or serious physical injury proximately caused by willful misconduct." *See* 42 U.S.C. A. § 247d-6d(c)(3). Willful misconduct by Defendants is not alleged in the instant case.[10] 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)(l),(5).

The PREP Act specifically empowers the Secretary of HHS to issue a written declaration identifying the "covered persons" who shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration or use by an individual of a "covered countermeasure"

[10] *See* Section II, D.

during a health emergency. *See* 42 U.S.C. § 247d-6d(a)(l)&(b). Under this enabling power, the Secretary of HHS issued such a Declaration, which became effective as of February 4, 2020, providing liability immunity for "recommended activities" including the distribution, administration and use of covered countermeasures against COVID-19. *See* 85 Fed. Reg. 15201. This Declaration was subsequently amended on April 15, 2020 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. The Office of the Secretary also later issued an Advisory Opinion regarding the Declaration on April 17, 2020 specifically addressing the PREP Act. *See* Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration Under the Act, HHS (Apr. 17, 2020) (the "Advisory Opinion").[11]

If described within the scope of the Declaration, the PREP Act immunizes a covered person from legal liability for all claims for loss relating to the administration or use of a covered countermeasure. Thus, the requirements for PREP Act immunity break down into four elements:

[11] Available at: https://www.hhs.gov/sites/default/files/Drep-act-advisorv-opinion-april-14-2020.Ddf.

(1) the individual or entity must be a "covered person"; (2) the legal claim must be for a "loss"; (3) the loss must have a "causal relationship" with the administration or use of a covered countermeasure; and (4) the medical product that caused the loss must be a "covered countermeasure." *See* 42 U.S.C.A. §§ 247d-6d, 247d-6e; and the Declaration, *supra.* Here, Defendants and their care and treatment of Plaintiff meet all of these elements.

1. ***Defendants are "Covered Persons" granted immunity under the PREP Act.***

Defendants are "Covered Person[s]" under the PREP Act. The definition of a "covered person" includes:

> [A] person[12] 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; (v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

See 42 U.S.C.A. § 247d-6d(i)(2)(B).

Specifically, Mayo Clinic Arizona and its providers fit within the

[12] The PREP 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."

"qualified person" category, which include the following:

> (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).

Additionally, "an official, agent or employee of a person or entity" that meets the above requirement is included in the definition of a "covered person." *Id.* at § 247d-6d(i)(2)(B)(v).

Here, Defendants are "qualified person[s]" afforded immunity from suit under the PREP Act. Defendants (and each of them) are licensed health care providers. Clearly, licensed health care providers are authorized to prescribe, administer, or dispense countermeasures (i.e. ABG test, detailed below) in the state of Arizona. Therefore, Mayo Clinic Arizona and its employees are "covered persons" for purposes of PREP Act immunity.[13]

2. ***Plaintiff alleges a loss causally related to the administration of a "Covered Countermeasure."***

   Plaintiff alleges that Defendants' negligent administration of an ABG

[13] The trial court agreed with this conclusion. [ROA 43, pg. 5.]

test caused him to develop compartment syndrome and resulting injury. Because the ABG stick that was performed on Plaintiff was a "covered countermeasure" used to assess his respiratory status during the course of Plaintiff's COVID-19 treatment, the loss causally related to the administration of a covered countermeasure.

The Declaration defines a "covered countermeasure" as "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product," 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 FDC Act; and "respiratory protective devices." 42 U.S.C.A. § 247d-6d(i)(l); 85 Fed. Reg. at 15202.[14] The Advisory Opinion summarizes the definition of a

[14] Moreover, 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

"qualified pandemic or epidemic product," explaining that, for immunity to attach, the "drug," "biological 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).

See Advisory Opinion, at 4. The Advisory Opinion goes on to recognize that "[t]he number of products used for COVID-19 that are approved, licensed, or cleared are too numerous to list." In addition, drugs, biological products, or devices used to treat the side effects of a pandemic or epidemic product, or to enhance their effects, may themselves be covered countermeasures.

Here, Plaintiff specifically alleges that Defendants were negligent in performing an ABG on Plaintiff while treating him for COVID-19, which resulted in Plaintiff developing compartment syndrome. Thus, Plaintiff's claims arise out of the performance of a covered countermeasures: the use

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health with respect to which such declaration was issued." 42 U.S.C.A. § 247d-6d(a)(l)(6). Here, there is no dispute that Plaintiff's care was rendered during the effective period of the Secretary's Declaration. *See* Declaration (March 17, 2020).

of an ABG stick, a diagnostic test that was performed on Plaintiff to assess the sufficiency of his respiratory status while he was in the hospital being treated for COVID-19.

Defendants are "covered persons" who administered or used a "covered countermeasure," in their care and treatment of Plaintiff's COVID-19, which allegedly caused Plaintiff's injury. As such, the allegations in Plaintiff's Amended Complaint meet the four elements required to invoke PREP Act immunity.

3. Plaintiff failed to exhaust administrative remedies.

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." *See* 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. *See* 42 U.S.C. § 247d-6e(d)(4). And in the event a plaintiff exhausts those remedies available under the Fund, his or her sole recourse in certain very limited circumstances is a federal cause of action "for death or serious physical injury proximately caused by willful

misconduct,[15]" which is not alleged here. *See* 42 U.S.C.A. § 247d-6d(c)(3). 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.

Here, Plaintiff seeks compensation for alleged negligence by a covered person in the administration or use of a covered countermeasure (even if Plaintiff does not use the terms "covered person" and "covered countermeasure"). However, Plaintiff failed to exhaust his administrative remedies because he did not apply for benefits under 42 U.S.C. § 247d-6e(a). Because administrative exhaustion is a prerequisite to filing suit, Plaintiff's failure to exhaust his administrative remedies under 42 U.S.C. § 247d-6e warranted summary judgment in favor of Defendants. *Accord Adams v. U.S.*

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[15] "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).

Capitol Police Bd., 564 F.Supp. 2d 37, 40 (D.D.C. 2008) ("When a plaintiff fails to exhaust administrative remedies, dismissal under 12(b)(1) is appropriate.")

CONCLUSION

For the foregoing reasons, Defendants respectfully request the Court to affirm the judgment in their favor.

REQUEST FOR COSTS ON APPEAL

Pursuant to ARCAP 21(a) and A.R.S. §§ 12-341 and -342(A), Defendants/Appellees respectfully requests this Court award their costs on appeal.

RESPECTFULLY SUBMITTED this 21st day of February, 2023.

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