Team 204

Docket No. 2020–01 **Team 204**

IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM 2020

CAESAR HEALTH PLAN, INC.,

Petitioner,

v.

LIVIA CLEOPATRA,

Respondent.

ON WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE FOURTEENTH CIRCUIT

BRIEF FOR RESPONDENT

QUESTIONS PRESENTED

I. Is the proximate cause element of a civil RICO matter satisfied (and therefore, standing conferred) where a third-party payor alleges that they would not have underwritten an off-label prescription had the pharmaceutical manufacturer not misrepresented the safety risks to independent physicians?

II. Does an administrative subpoena violate the Fourth Amendment when it is issued against an insurance company for the inspection of medical records—to determine if patients of Miasmic Syndrome received substandard care—and when its authorizing statute provides an avenue for pre-compliance review? If so, does the doctrine of Qualified Immunity protect the government from liability under 42 U.S.C. § 1983?

TABLE OF CONTENTS

TABLE OF AUTHORITIES

United States Supreme Court Cases

Circuit Court Cases

Other Cases

United States Constitution

Federal Statutes

Romulus State Statutes

CITATIONS TO THE OPINIONS BELOW

The opinions from the United States District Court of Romulus and the United States Court of Appeals for the Fourteenth Circuit have not been officially reported and appear in the record at pages thirteen and twenty-eight, respectively.

CONSTITUTIONAL PROVISION INVOLVED

This case involves U.S. Const. amend. IV.

STATEMENT OF THE CASE

I. Factual History

An Invisible Enemy. In May 2019, the world was introduced to an unknown, indiscriminate, highly contagious viral disease identified as Miasmic Syndrome. (R. at 1.) Originating from the nation of Alexandria, this invisible enemy invaded the United States of America, the state of Romulus, and ultimately the world. (*Id.*) After transcending international borders, infecting millions, and killing thousands, Miasmic Syndrome was formally classified as a global pandemic. (*Id.*)

Race for a Cure. In response to this threat, Galen Research ("Galen"), an American pharmaceutical company, began to test whether their FDA-approved cancer treatment medication, Glukoriza, could also treat Miasmic Syndrome symptoms. (*Id.*) The Alexandrian government sponsored the clinical trial, and in September of 2019, the results proved promising. (*Id.*) The trial demonstrated that Glukoriza cut the fatality rate in half while hastening a patient's recovery time by several days. (*Id.*)

Following the breakthrough, Galen began campaigning Glukoriza. (R. at 2.) In anticipation of the drug's popularity, Galen rapidly expanded its manufacturing

capacity while simultaneously marketing the drug's off-label[1] use to physicians and health insurance providers across the country, relying on the trial data as evidence of the drug's effectiveness. (*Id.*) In November 2019, Julius-Caesar Health System ("Julius-Caesar") agreed to make Glukoriza their preferred Miasmic Syndrome treatment, and in return, Caesar agreed to cover the prescription when ordered as a treatment for Miasmic Syndrome. (*Id.*)

Julius-Caesar is a formal partnership between two legally independent companies, Julius Medical Center ("Julius") and Caesar Health Plan ("Caesar"). (*Id.*) Julius is the largest healthcare provider in Romulus and Caesar is a health insurance company, together becoming a payor-provider for Romulus citizens. (*Id.*) Although the two legal entities are independent, not sharing leadership members or board directors, they mutually benefit each other in practice. (*Id.*)

Caesar strongly encourages its members to receive all or most of their care at Julius. (R. at 2.) Caesar promotes this policy by discouraging outside care, requiring its members to seek prior authorization and clinical necessity before they may be reimbursed for any care received. (*Id.*) Additionally, Caesar generously covers prescriptions issued by Julius. (*Id.*) As a result, nearly all of Julius' patients choose to be insured by Caesar. (*Id.*) As expected, when Julius purchased Glukoriza in

1 An "off-label" prescription refers to prescription medication used in a manner neither specified nor approved by the U.S. Food and Drug Administration. While the practice is common and legal, healthcare providers "prescribe the drug for an unapproved use when they judge that it is medically appropriate for the patient." *Understanding Unapproved Use of Approved Drugs "Off Label",* FDA (Feb. 5, 2018) https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label.

November of 2019, Caesar agreed to fully cover the prescription when issued as a treatment for Miasmic Syndrome. (R. at 2–3.)

Glukoriza as a Therapeutic. By February 2020, over 10,000 prescriptions had been prescribed by Julius and paid for by Caesar. (R. at 3.) During this time, Julius researchers charted Glukoriza's effectiveness, and the data revealed two facts. (*Id.*) First, Glukoriza had no significant curing qualities in treating Miasmic Syndrome. Second, patients who received Glukoriza suffered substantial negative side effects. (*Id.*) Upwards of 10% of patients receiving the treatment suffered loss of kidney function. (*Id.*) Based on this information, Julius-Caesar jointly decided to take the drug out of circulation for Miasmic Syndrome treatment. (*Id.*)

The Fall Out. Soon after Miasmic Syndrome cases were reported in the state of Romulus, a wide array of counterfeit, adulterated, and dangerous drugs claiming to be "miracle cures" flooded the market. (R. at 3.) The Romulus government watched in horror as drug manufacturers profited off the false hope of its citizens. (*Id.*) In response, the Romulus legislature enacted the Emergency Miasmic Syndrome Act ("EMSA") in October of 2019. (*Id.*) In effect, EMSA authorized Romulus' Board of Health ("the Board") and its Commissioner to issue administrative subpoenas on healthcare providers who were knowingly or negligently providing substandard medical care to patients diagnosed with Miasmic Syndrome. (R. at 3–4.) This authority, however, was not granted to the Board without proper limitations. (*Id.*)

Reports of Substandard Care. Before either the Board or the Commissioner could think about issuing a subpoena, the EMSA required sufficient evidence to

support a finding of reasonable suspicion, that a specific licensed hospital was providing Miasmic Syndrome patients with substandard care. (R. at 4.) In March 2020, the Board received reports that Miasmic Syndrome patients treated at Julius had noticeably worse health outcomes than patients anywhere else in the state. (*Id.*) In reliance on these reports, Livia Cleopatra, the Commissioner of the Board, issued an administrative subpoena against Julius and Caesar, respectively, on March 13, 2020, pursuant to EMSA authority. (*Id.*)

The Inspection. Five days later, on the morning of March 19, 2020, two groups of agents from the Board of Health simultaneously arrived at Julius Medical Center and Caesar Health Plan with a subpoena. (*Id.*) The subpoena sought access to medical records relevant to a patient's treatment and diagnosis of Miasmic Syndrome. (*Id.*)

At Julius, Board agents presented the front desk employees with a copy of the subpoena, demanding compliance. (*Id.*) Julius' employees immediately called on their attorneys, who soon arrived and challenged the subpoena's validity as overbroad. (*Id.*) Julius' employees refused to comply pending a hearing on this issue. (R. at 4.) In response, the agents respected the challenge and walked away; empty-handed. (*Id.*)

Meanwhile, at Caesar Health, agents were able to procure the documents from Caesar's employees. (*Id.*) Unlike Julius, Caesar Health did not have their attorneys on hand to contest the subpoena. (R. at 5.) Receiving no formal contest, the agents encouraged production by informing employees that failure to comply violates RCL § 30.50.120 and may be considered obstruction of justice, punishable by arrest. (*Id.*) In an effort to comply, the employees began collecting the documents requested. (*Id.*)

Although Caesar was given a five-day notice, their employees were not prepared nor able to determine which of their documents were pertinent to Miasmic Syndrome patients. (R. at 5.) To avoid confusion or missing information, the agents instructed the employees to turn over all data from the start of the pandemic, including medical records underlying each claim. (*Id.*) By the time Caesar's attorneys arrived, the agents had already been given the documents. (*Id.*)

Substandard Care. After reviewing the data from Caesar Health, the Board's reasonable suspicion that Julius had been providing substandard care, was confirmed. (*Id.*) Based on Caesar's documents, Julius had a remarkably high rate of kidney failure among its patients receiving treatment for Miasmic Syndrome. (*Id.*) The Board concluded that Julius was providing substandard care and actively causing them harm. (*Id.*) The Board authored a report, noting that Julius' protocol involved administering a cocktail of off-label drugs to patients, whose combined side-effects were unknown. (*Id.*) On March 30, 2020, the Board unanimously decided to suspend Julius's operating license. (R. at 5.)

Whistleblower. That same day, a whistleblower from the nation of Alexandria exposed severe discrepancies in the Glukoriza 2019 clinical trial. (*Id.*) The report suggested that researchers falsified results and repeatedly failed to follow up on patients who had started showing signs of kidney damage. (*Id.*) Internal documents by Galen, who conducted the trial, revealed that its staff concealed this information from the public and its owner, Livia Cleopatra. (*Id.*) Within a week, Galen was engulfed in scandal. (R. at 6.) Although Ms. Cleopatra was completely unaware of her

staff's misrepresentations, she resigned from her position as Commissioner of the Board of Health. (*Id.*)

On April 14, 2020, following the Commissioner's immediate replacement, the Board voted to restore Julius Medical Center's license. (*Id.*) In a 6-5 vote, their license was reinstated. (*Id.*) Julius provided evidence showing that 100% of their patients who suffered from kidney failure resulted from the use of Glukoriza, a drug Julius no longer uses. (*Id.*) In the interim, 15,000 patients dropped their membership with Julius-Caesar, enrolling with different providers and insurance companies. (*Id.*)

II. Nature of the Proceeding

Caesar Health filed a civil action against Livia Cleopatra in her official capacity as the sole proprietor of Galen Research and in her official Capacity as the Commissioner of the Romulus Board of Health, in the federal district court for the District of Romulus alleging two causes of action. (R. at 6.)

First, a civil RICO action under 18 U.S.C. § 1964, claiming that Galen Research fraudulently induced Caesar to underwrite Glukoriza as a treatment for Miasmic Syndrome. (*Id.*) Second, a 42 U.S.C. § 1983 civil action, alleging Ms. Cleopatra authorized an unconstitutional search of their premises, prohibited under the Fourth Amendment. (*Id.*)

In response, Livia Cleopatra filed a motion to dismiss, alleging: 1) Caesar Health does not have standing to allege a RICO violation; 2) the EMSA subpoena and its method of execution were constitutionally valid under the Fourth Amendment;

and even if all facts alleged by Caesar were proven, the suit is barred under the doctrine of Qualified Immunity. (R. at 7.)

United States District Court of Romulus denied Livia Cleopatra's Motion to Dismiss in its entirety. (*Id.*) For the civil RICO claim, the court held that Caesar, as a third-party payor ("TPP"), adequately pled the causation requirement to prove standing. (R. at 13.) On the § 1983 claim, the court ultimately found that the issued subpoena was an illegal search of a business that did not know it was subject to regulation. (*Id.*)

The Fourteenth Circuit reversed the District Court, granting the Motion to Dismiss in its entirety. (*Id.*) For the civil RICO, the court found that TPPs do not generally rely on a pharmaceutical's actual misrepresentation, but rather a TPP is a mere negotiator and that more directly injured victims exist. (R. at 35.)

As to the second claim, the court focused primarily on the qualified immunity claim, holding that Livia Cleopatra had no reasonable belief that what she was doing was unlawful. (R. at 38.) The Circuit Court reasoned that since no court has adjudicated Fourth Amendment protections afforded to health insurance companies subpoenaed for medical records during a global pandemic, this is a matter of first impression. (*Id.*)

Petitioner filed a writ of certiorari. (R. at 7.) This Court granted certiorari on September 14, 2020. (R. at 40.)

SUMMARY OF THE ARGUMENT

I.

The Petitioner cannot demonstrate proximate cause, and therefore lacks standing to bring a civil RICO claim against Galen and Ms. Cleopatra. This Court has held expressly, that even if the harm is plainly foreseeable, the Petitioner must still show that the alleged violation led directly to their alleged injuries. Here, Petitioner cannot show that Galen was the direct cause of their injuries. Instead, a series of independent, intervening events stand between the alleged violation and Petitioner's eventual harm. After Galen marketed Glukoriza to physicians at Julius Health Center: doctors were free to rely on their own experience and training when prescribing Glukoriza for off-label use; Glukoriza was then administered to patients in tandem with Ippomarathron and Gentiane without consulting Galen; individual patients then had to fill their prescriptions for Glukoriza, take the medication as prescribed; and when patients filed claims, only then did Petitioner reimburse the cost of those Glukoriza prescriptions. Petitioner asks this Court to leap far beyond the "first step" and find proximate cause where no direct relation exists between Galen's act and Petitioner's injury. Therefore, Petitioner lacks standing.

II.

The Subpoena issued by the Romulus Board of Health does not violate the Fourth Amendment. Petitioner errs in proposing that a warrant is a feasible—much less required—alternative in this circumstance. EMSA empowers the Commissioner of the Board of Health to investigate violations of care. While compliance is

encouraged, EMSA does not explicitly authorize criminal penalties for non-compliance. It does, however, provide the target an opportunity for pre-compliance review. While Petitioner challenges the "neutrality" of such review, this Court has made clear that pre-compliance only requires *opportunity*, not form.

Even if this Court holds that the administrative subpoena is unconstitutional, Ms. Cleopatra is entitled to qualified immunity. The Fourteenth Circuit properly reversed the district court's ruling because this is a matter of first impression and not "clearly established" by existing case law. Should this Court conclude that the generalized application of the Fourth Amendment is sufficient to govern this case, Ms. Cleopatra's conduct was reasonable because ample case law supports enforcing the subpoena. Therefore, this Court should affirm the Fourteenth Circuit.

ARGUMENT

I. Petitioner does not have standing to bring a RICO claim

Petitioner argues that Galen conspired to commit mail and wire fraud under 18 U.S.C §§ 1341, 1343 when Galen intentionally mislead Julius-Caesar Health System into relying on false information, namely that Glukoriza could treat Miasmic Syndrome. However, the central "question before [this Court] is not, 'are the injuries sufficiently harrowing to justify RICO liability' – but rather were Galen's actions *the direct cause* of the injuries that occurred to Caesar, as a third-party payor." (R. at 32). Ms. Cleopatra submits, that they are not.

The Racketeering Influenced Criminal Organization ("RICO") statute was originally enacted to prosecute the leaders of criminal organizations, but it has since

morphed into "a tool for everyday fraud cases brought against respected and legitimate enterprises." *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 499 (1984).

Generally, there are two parts to a civil RICO claim. First, the defendant must violate 18 U.S.C. § 1962, requiring an unlawful pattern of racketeering activity. Second, the plaintiff must have standing under 18 U.S.C. § 1964(c), which provides "any person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefore in any appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee." Unlike Article III standing, the plaintiff bringing a civil RICO claim must additionally plead injury to a business or property and "that a RICO predicate offense 'not only was a 'but for' cause of injury but was the proximate cause as well.'" *Hemi Grp., LLC v. City of New York*, 559 U.S. 1, 9 (2010) (citing *Holmes v. Sec. Inv'r Protection Corp.*, 503 U.S. 258, 268 (1992)).

A. Conduct must be the direct cause of an injury to satisfy standing

Borne from similar language in antitrust statutes, this Court has used proximate cause, in civil RICO cases, as a limiting principle intended to stymie a flood of litigation, reserving recovery for those who have been *directly* affected by a defendant's wrongdoing. *See Holmes*, 503 U.S. at 268 ("[W]e use 'proximate cause' to label generically the judicial tools used to limit a person's responsibility for the consequences of that person's own acts."). As opposed to its more generic definition at common law, "[o]ur precedents make clear that in the RICO context, the focus [of proximate causation] is on the *directness* of the relationship between the conduct and

the harm" rather than "the concept of foreseeability." *Hemi Grp.*, 559 U.S. at 12 (2010) (emphasis added).

In *Holmes*, this Court articulated three practical considerations concerning the directness of injury. First, "indirect injuries make it difficult 'to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent factors.'" *In re Avandia Mktg.*, 804 F.3d 633, 642 (3d Cir. 2015) (quoting *Holmes*, 503 U.S. at 269). Second, indirect injuries risk duplicative recoveries, the "courts would have to adopt complicated rules apportioning damages to guard against this risk." *Id.* Third, directly injured victims can be counted on—and are best positioned to— "vindicate the law as private attorneys general," leaving no need to extend civil RICO's private right of action to those with more remote injuries. *Holmes*, 503 U.S. at 269–70.

To show a "direct relation between the injury asserted and the injurious conduct alleged," any alleged fraud must not be contingent on another event or action. *Id.* at 269, 271. Although a plaintiff is not required to claim first-party reliance on a defendant's purported misrepresentation, *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 657–58 (2008), the cause of an injury that is "entirely distinct from the alleged RICO violation" may be too attenuated to meet the proximate cause requirement. *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 458 (2006). Relatedly, a more direct victim of the purported violation or independent, intervening factors may also break the chain of causation. *See Hemi Grp.*, 559 U.S. at 15.

This Court has not yet addressed the exact problem at issue here, whether TPPs have standing to sue pharmaceutical companies for concealing a drug's possible safety risk. *Holmes* and its progeny have given us the framework, that the Court looks for a direct relation between conduct and resulting injury, not the foreseeability of injury.

This Court has also applied the *Holmes* factors in analyzing proximate cause multiple times. *Holmes*, 503 U.S. at 271 (finding no proximate cause where the link between the injurious conduct and the harm suffered was purely contingent on harm suffered by a third-party); *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451 (2006) (finding no proximate cause where the cause of harm was "a set of actions entirely distinct from the alleged RICO violation"); *Bridge,* 553 U.S. 639 at 658 (finding a direct injury and proximate cause where "there [we]re no independent factors" that caused the harm); *Hemi Grp.*, 559 U.S. at 11 (finding no proximate cause where "the conduct directly causing the harm was distinct from the conduct giving rise to the fraud").

While the Supreme Court has yet to rule on the exact issue at hand, several lower circuits have issued competing opinions interpreting the proximate cause element of civil RICO, in the context of TPPs suing pharmaceutical companies. As acknowledged by the Ninth Circuit in *Painters and Allied Trades District Council v. Takeda Pharmaceuticals Co.*, there is a split as to whether TPPs have standing to sue Pharmaceutical companies under civil RICO. *See* 943 F.3d 1243 (9th Cir. 2019). The Second, Seventh, and Fourteenth Circuits have followed the policy principles in

Holmes and found that TPPs do not have standing, as they fail to satisfy the direct relation aspect of proximate cause. The First and Ninth Circuits found proximate cause after adding a foreseeability element to their analysis. Most recently, the Third Circuit held that prior Supreme Court precedent made it clear: directness of relationship, not foreseeability, was the key to proximate cause under civil RICO. *St. Luke's Health Network, Inc. v. Lancaster General Hospital*, 967 F.3d 295, 300 (3rd Cir. 2020).

B. Petitioner cannot show that Galen's conduct was the direct cause of its injuries, and fails to demonstrate proximate cause

As the Circuit court found below, Petitioner cannot show the proximate cause needed to proceed with their claim because Galen's actions were not the direct cause of Petitioner's injuries, as a TPP. The analysis used by the Fourteenth Circuit mirrors that of the Second and Seventh, neither of which would have found proximate cause in the case at bar.

i. The Second, Seventh, and Fourteenth Circuits have correctly applied a direct cause analysis

The Seventh Circuit, in *Sidney Hillman Health Center of Rochester v. Abbot Laboratories*, addressed civil RICO claims brought by TPPs who provided coverage for patients' purchases of a prescription off-label drug. 873 F.3d 574, 575 (7th Cir. 2017). On the ground that the manufacturer made fraudulent statements to physicians in promoting the drug, the plaintiffs sought treble damages. *Id.*

The district court dismissed, concluding that "tracing loss through the steps between promotion and payment would be too complex." *Id.* at 576–77. And the

Seventh Circuit affirmed, articulating three reasons why the plaintiff's suit, for "wrongs committed while marketing pharmaceuticals," could not establish direct injury even if the alleged harms were foreseeable. First, the court reasoned, some of the prescriptions may have been "beneficial to patients," such that any damages calculation would require the court to determine whether the drugs' benefits offset the cost of any wrongfully written prescriptions. *Id.* at 577. Second, it held, some prescriptions would have been written regardless of the alleged wrongdoing, such that calculating damages would necessitate determining the volume of prescriptions that would have occurred without unlawful activity, which might "not be an easy task." *Id.* And third, tracing injury would necessarily require a showing that every doctor who wrote an allegedly wrongful prescription did so in reliance on the wrongful conduct alleged. *Id.* "Disentangling the effects of the" wrongful conduct "from the many other influences on physicians' prescribing practices would be difficult-much more difficult than following the one-step causal link in *Bridge*." *Id.*

The court next rejected the plaintiffs' effort to sidestep the aforementioned issues of proximate cause by means of regression analysis. *Id.* The court noted, a mathematical showing that the alleged wrongdoing was a but-for cause of an increase in the number of prescriptions still failed to address the issues with proximate cause. *Id.* The court held, that the "causal chain" in a TPP suit against a drug manufacturer "is longer than" causal chains the Supreme Court has already "deemed too long." *Id.* at 578. Continuing, "that there are so many layers, and so many independent

decisions, between promotion and payment that the causal chain is too long to satisfy the Supreme Court's requirements." *Id.*

The Second Circuit has also dismissed RICO claims for lack of standing in cases like the case at bar. *UFCW Local 1776 v. Eli Lilly and Co*. involved putative classes of patients and TPPs seeking treble damages for payments made for off-label prescriptions that allegedly would not have been issued, but for alleged misrepresentations by the manufacturer. 620 F.3d 121, 123–24 (2d Cir. 2010). In finding no proximate cause, the Second Circuit stated that any "theory of liability" that tied a particular drug purchase to conduct in marketing necessarily, "rests on the independent actions of third and even fourth parties." *Id.* at 134 (quoting *Hemi Grp.*, 559 U.S. at 15). The court explained that TPPs "typically pay for a prescribed medication only if the drug is authorized under their formulary[2], a list of medications approved for payment" and "usually managed by a Pharmacy Benefit Manager ["PBM"]." *UFCW,* 620 F.3d. at 126. The court further noted that TPPs rarely modify their formularies, and on "the rare occasions" they do, it is in consultation with the PBMs. *Id.* Moreover, in the pharmaceutical context any "negotiations over price . . . do not intersect with the therapeutic choice of what drug a patient should take." *Id.* This is a decision made by a doctor with minimal input from their patient or the TPP. *Id.* Generally, "physicians . . . do not take the price of a drug into account when

2 Drug formularies are insurers' lists of medications approved for coverage. *See UFCW Local 1776*, 620 F.3d at 126 (discussing generally the use and function of drug formularies in the prescription drug insurance industry). Formularies are managed by PBMs, who act as agents for the insurers. "The PBMs list a drug on the insurers' formularies—which frequently consist of at least three tiers of approved drugs—only after they have approvingly assessed the drug's clinical safety, efficacy, and cost effectiveness for its FDA-approved uses." *Ironworkers Local Union 68 v. AstraZeneca Pharmaceuticals, LP*, 634 F.3d 1352, 1366 (11th Cir. 2011).

deciding among treatment options, and often do not even know the price of the drugs they prescribe." *Id.* at 126–27.

Considering this complexity, the court held that a TPP hoping to show proximate cause would have to demonstrate the degree to which any individual physicians prescribing the drug relied on the alleged misstatement or omission and that a prescription written in such reliance "actually caused loss, given the likelihood of substitute prescriptions for other drugs." *Id.* at 136. The court held that no such proximate cause showing could be made. *Id.* at 134, 136. The Second Circuit reaffirmed its interpretation of proximate cause in the realm of civil RICO in *Sergeants Benevolent Association Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71 (2d Cir. 2015). The court held that a plaintiff's RICO claims involving allegedly fraudulent pharmaceutical marketing were foreclosed by the *UFCW* holding on proximate cause.

ii. The First and Ninth Circuits have incorrectly relied on foreseeability

As was repeatedly acknowledged in *Painters*, the decisions of the First and Ninth Circuits are inapposite with the decisions of the Second and Seventh Circuits on the issue of RICO proximate cause.

In the present case, the district court and Petitioner, primarily look to the Ninth Circuit and their analysis in *Painters*. In *Painters*, the defendants allegedly misled consumers, physicians, and insurance companies into believing that a prescription drug designed to lower blood sugar in type 2 diabetics, did not increase a person's risk of developing bladder cancer. The plaintiffs were TPPs who

reimbursed their members' claims for prescription medications. Defendants challenged plaintiff's standing based on the "direct relation" requirement for civil RICO claims.

The Ninth Circuit found that the "decisions of prescribing physicians and pharmacy benefit managers" "do not constitute an intervening cause to cut off the chain of proximate cause," between the drug manufacturer and the TPP. *Painters,* 943 F.3d at 1257. Because "[a]n intervening cause is 'a later cause of independent origin that was not *foreseeable*.'" *Id.* (quoting *Mendez v. County of Los Angeles*, 897 F.3d 1067, 1081 (9th Cir. 2018) (emphasis added)). It is "*foreseeable*," however, that in the American health care system while doctors prescribe the drugs, "physicians would not be the ones paying" for them. *Id.* at 1257 (quoting *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 38 (1st Cir. 2013)); *but see Hemi Grp.*, 559 U.S. at 12 (noting that RICO's proximate cause requirement turns on the existence of a sufficiently direct relationship, not foreseeability).

The First Circuit, in *Neurontin*, held that the causal chain between the manufacturer's wrongdoing and the purchaser's injury was not attenuated. 712 F.3d 21, 38 (1st Cir. 2013). The court dismissed the fundamental role physicians play in deciding which medications their patients are prescribed as irrelevant to a proximate cause analysis. *See id.* at 39. Reasoning that their role went only to the "total number of prescriptions that were attributable to" the alleged fraudulent scheme. *Id.* at 39. The Court found proximate cause where a TPP was the primary and intended victim and the injury was foreseeable. *Id.* The First Circuit relied heavily on *Bridge* in its

analysis. *See id.* at 36–39. In particular, the court looked to *Bridge's* language about "foreseeable and natural consequence[s]." *Id.* at 37 (quoting *Bridge*, 553 U.S. at 658). *Bridge* represents a diversion from the rest of this Court's RICO proximate cause jurisprudence.

In *Bridge*, a RICO defendant, who allegedly defrauded a county tax lien auctioneer to gain an advantage over competing bidders, argued that the competing bidders were barred from suing without allegations that they, as opposed to the auctioneer, had relied on the defendant's fraudulent statements. *Bridge,* 553 U.S. at 642–45. The Court granted certiorari solely "to resolve . . . whether first-party reliance is an element of a civil RICO claim predicated on mail fraud." *Id.* at 646, 661.

The Court held that first-party reliance was not necessary to show directness because "there are no independent factors that account for respondents' injury, there is no risk of duplicative recoveries by plaintiffs removed at different levels of injury from the violation, and no more immediate victim is better situated to sue." *Id.* at 658. In further discussion, far afield from the question presented, the Court makes a passing mention of the "foreseeable and natural consequence" of the fraudulent scheme. *Id.* While the First and Ninth Circuits have decided to run with this phrase, this Court reigned itself in, in *Hemi Grp*. The plurality opinion in *Hemi Grp.* roundly rebuked the role of foreseeability in RICO proximate cause analysis:

> The dissent would have RICO's proximate cause requirement turn on foreseeability, rather than on the existence of a sufficiently "direct relationship" between the fraud and the harm. It would find that the [plaintiff] has satisfied that requirement because "the harm is foreseeable; it is a consequence that [the defendant] intended, indeed desired; and it falls well within the set of risks that Congress sought to prevent." *Post*, at 997 – 998

> (opinion of BREYER, J.). If this line of reasoning sounds familiar, it should. It is precisely the argument lodged against the majority opinion in *Anza*. There, the dissent criticized the majority's view for "permit[ting] a defendant to evade liability for harms that are not only foreseeable, but the intended consequences of the defendant's unlawful behavior." 547 U.S., at 470 (THOMAS, J., concurring in part and dissenting in part). But the dissent there did not carry the day, and no one has asked us to revisit *Anza*.
>
> The concepts of direct relationship and foreseeability are of course two of the "many shapes [proximate cause] took at common law," *Holmes*, *supra*, at 268. Our precedents make clear that in the RICO context, the focus is on the directness of the relationship between the conduct and the harm. Indeed, *Anza* and *Holmes* never even mention the concept of foreseeability.

Hemi Grp., 559 U.S. at 12.

iii. The Third Circuit is poised to traverse the circuit split

In *Painters*, the Ninth Circuit was eager to count the Third Circuit among its ranks of circuits willing to defy the established approach to proximate cause and incorporate foreseeability into their analysis. *See Painters*, 943 F.3d at 1256 (citing *In re Avania Marketing, Sales Practices & Product Liability Litigation*, 804 F.3d 633 (3d Cir. 2015)). However, in their most recent case, the Third Circuit made it clear that foreseeability is not the means of finding proximate cause in RICO cases. *See St. Luke's*, 967 F.3d at 300.

The suit in *Avandia* was a RICO class action brought by TPPs claiming that a diabetes drug maker misrepresented heart-related safety risks. *See* 804 F.3d at 634–36. Any argument that "the presence of intermediaries, doctors and patients, destroys proximate cause because they were the ones who ultimately decided whether to rely on [the defendant's] misrepresentations," was rejected by the court. *Id.* at 645. That is because, the Third Circuit believed, that *Bridge* established that any plaintiff, no

matter how far removed from a wrong, can establish directness sufficient to satisfy RICO merely by claiming that their injury was the "foreseeable and natural consequence of the scheme." *Id.* at 645. The court concluded, "*Bridge* precludes" any proximate cause argument based on the need to prove reliance by third parties, no matter how many intervening third parties there are. *Id.*

The Third Circuit has since reconsidered their application of RICO proximate cause in *St. Luke's*. The facts of *St. Luke's* do not involve TPPs and pharmaceutical companies; however, the court's analysis sheds light on where its RICO proximate cause jurisprudence is headed. The case involved a state-run program to reimburse hospitals for treating indigent patients. *St. Luke's*, 967 F.3d at 297. One group of hospitals and health care networks sued another hospital and hospital system, for RICO violations. *Id.* Defendants allegedly submitted fraudulent claims for reimbursement and received an unduly inflated proportion of the available funding, while the plaintiffs were reimbursed an artificially smaller share. *Id.* The court quoted from *Hemi Grp* and explained that Supreme Court precedent has made it clear that the focus of RICO proximate cause "'is on the directness of the relationship between the conduct and the harm' rather than 'the concept of foreseeability.'" *Id.* at 300 (quoting *Hemi Grp.,* 559 U.S. at 12). The court found direct relationship between the defendant's wrongful conduct and the plaintiff's injury to show proximate cause. *St. Luke's*, 967 F.3d at 302. Additionally, the court held that the case satisfied the *Holmes* policy principles for directness of injury. *Id.*

C. Petitioner's allegations are not supported by the policy principles laid out in *Holmes*

The RICO proximate causation analysis is primarily controlled by *Holmes* and its progeny. This Court has held that even when the harm is plainly foreseeable, the inquiry does not end there, the "central question" the Court must ask is "whether the alleged violation led directly to the plaintiff's harm." *Anza*, 547 U.S. 461. The *Holmes* Court provided three policy factors with which to assess whether proximate cause exists under RICO. First, the directness of the injury: indirect injuries make it difficult "to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent factors." *Holmes*, 503 U.S. at 269. Second, the risk of duplicative recoveries: if claims for indirect injuries are recognized, the Court would need to create complicated rules to correctly apportion damages over various degrees of harm. *Id.* Third, the likelihood of vindication by others: the need to grapple with the problems presented by indirect claims may be unjustified "since directly injured victims can generally be counted on to vindicate the law as private attorneys general." *Id.* at 269–70.

Petitioner alleges that Galen not only promoted Glukoriza for unapproved "off-label" use, but also that Glukoriza was ineffective at treating Miasmic Syndrome, or even harmful for some of those that took it. (R. at 2–3). Galen conducted a trial in hopes that Glukoriza would benefit those suffering from Miasmic Syndrome, which Petitioner claims was fraudulently manipulated to hide patients who suffered kidney damage. (*Id.)* And that despite the possible harm to some patients Galen continued to market Glukoriza to doctors and health insurance companies. (*Id.)* Before reaching

a deal with Julius-Caesar Health Systems as a preferred treatment for Miasmic Syndrome.

i. Petitioner cannot show a direct relation between Galen's alleged fraud and their eventual injury

Petitioner's theory of liability does not show the direct relation that is requisite for finding proximate cause. Petitioner draws a causal chain in which Galen fraudulently markets Glukoriza to doctors and health insurance companies, doctors at Julius relied on that misinformation, and then Petitioner paid for the prescriptions. This narrative bypass several steps and obscures more attenuated links between Galen's alleged fraud and Petitioner's ultimate injury.

Let us consider the full causal chain that is at play here: Galen developed Glukoriza as a cancer drug in 2014; this drug was FDA approved as a safe medical treatment; Galen conducted a trial that showed Glukoriza was an effective Miasmic treatment but hid possible kidney issues; Julius-Caesar began using Glukoriza as one of their Miasmic treatments; Petitioner (the TPP) chose to cover Glukoriza or delegated that decision to PBMs; PBMs recommended Petitioner include off-label use of Glukoriza on the payor's formulary; doctors, exercising their professional judgment while considering each patient's unique medical history, chose to prescribe Glukoriza instead of another preferred Miasmic treatment; Julius doctors prescribed Glukoriza in tandem with Ippomarathron and Gentiane without consulting with Galen; the individual patients filled their Glukoriza prescriptions; the individual patients took Glukoriza as directed; the individual patients paid out of pocket for Glukoriza or

submitted their costs to Petitioner for reimbursement; finally, Petitioner reimbursed those prescriptions. (*See* R. at 1–3.)

Therefore, in this case "the conduct directly causing harm was distinct from the conduct giving rise to the harm." *Hemi Grp.* 559 U.S. at 11. Petitioner's "theory of liability rests on the independent actions of third or even fourth parties." *Id.* at 15. Patients, Julius and its doctors, and PBMs all play a role in the chain between Galen and the Petitioner. (*See* R. at 2–3.)

ii. The independent acts of Julius's doctors sever the causal chain

Petitioner has sued to recover damages for every dosage of Glukoriza that Petitioner has paid for, however, determining just how many of those doses were purchased in response to Galen's alleged fraud would be difficult to compute. Further, comparing the patients' health costs (and out-of-pocket expenses) with Petitioner's costs may be difficult. And is only compounded by other issues:

First, Galen and Julius-Caesar may have reached a deal to make Glukoriza "a preferred treatment method for Miasmic Syndrome", but it was not the only treatment method. (R. at 2). The phrase "a preferred treatment" invariably indicates that Glukoriza was not the exclusive treatment. Therefore, every dose of Glukoriza given at Julius was done at the discretion of a doctor, who considered their years of medical training and experience before choosing which drug to prescribe to their patient.

Second, Julius's protocol for administering Glukoriza may have been negligent. The Romulus' Board of Health found that Glukoriza was generally safe but had never

been administered with the cocktail of other antibiotics used by Julius (Ippomarathron and Gentiane). (R. at 5). Two independent board members "argued that Julius's use of the Glukoriza-Ippomarathron- Gentiane cocktail in the first place showed unacceptable irresponsibility." (R. at 6). How much of the harm caused by Glukoriza was actually attributable to Julius's misuse?

Third, some Julius doctors were doubtless proof against Galen's campaign of disinformation. They may have changed their prescribing practices in response to information that Galen did not influence. As Miasmic Syndrome tore through the state of Romulus, some doctors were likely desperate to help their patients and may have relied on anecdotal evidence from their own practice. "Disentangling the effects of the improper promotions from the many other influences on physicians' prescribing practices would be difficult—much more difficult than following the one-step causal link in *Bridge*." *Sidney Hillman*, 873 F.3d at 577.

iii. Those directly affected are better positioned to hold Galen accountable

There also remains the issue of who is the right party to hold Galen accountable or are there in fact multiple groups that are more immediate, and therefore better situated to take Galen to task than Petitioner. TPPs are not the only or even the most directly injured parties here. Miasmic Syndrome patients suffer if they take Glukoriza even though it is useless and possibly even harmful to them. Patients can suffer adverse health effects if (1) Glukoriza aggravates their existing medical conditions, (2) produces side effects not justified by their medical benefits, and/or (3) dissuades them from taking other medication that would alleviate their

symptoms. Many patients also incur economic loss as filling prescriptions usually entails some out-of-pocket costs to patients even when health insurance plans cover most of the expense. The patients' health and financial costs come first in line temporally; that pharmacies then send bills to TPPs, which cover the remainder of the expense, does not make those Payors the initial losers from the promotional scheme Galen allegedly engaged in.

Doctors may also lose. Miasmic Syndrome is a global pandemic and people around the country are scared, need help, and want answers. If a physician prescribes an ineffective medicine and so does not provide that help, patients may turn elsewhere. Or become disillusioned with the health care system in general. Physicians affected by off-label promotions thus may lose business, creditability, and revenue.

In sum, this Court should not find proximate cause because (1) Petitioner was not directly affected by Galen's alleged actions, (2) allowing Petitioner's claim to go forward would result in duplicative recoveries, (3) and there are multiple parties better positioned to hold Galen accountable than Petitioner.

II. The Subpoena issued by the Romulus Board of Health does not violate the Fourth Amendment

The Fourth Amendment protects "[t]he right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures," stating that, "no Warrants shall issue, but upon probable cause." U.S. CONST. amend. IV. However, reasonableness cannot be—and historically has not been—limited to *only* a finding of probable cause. *Arkansas v. Sanders*, 442 U.S. 753, 759 (1979);

Skinner v. Ry. Labor Executives' Ass'n, 489 U.S. 602, 619 (1989). When public interest demands a more flexible approach, the Court has identified exceptions to the general rule. *Arizona v. Gant*, 556 U.S. 332, 338 (2009) (citing *Katz v. United States*, 389 U.S. 347, 357 (1967)); *City of Los Angeles v. Patel,* 135 S. Ct. 2443, 2452 (2015). An administrative subpoena is one such exception. *See Camara v. Mun. Ct. of City and Cnty. of San Francisco*, 387 U.S.535, 534 (1967).

Time and experience have forcefully taught that the power to inspect is of indispensable importance to the maintenance of community health; a power that would be "hobbled" by a blanket requirement of probable cause. *Frank v. Maryland*, 358 U.S. 360, 372 (1959). Thus, a constitutionally adequate substitute to the warrant requirement must exist. *See New York v. Burger*, 482 U.S. 691, 703 (1987).

A. The EMSA's statutory scheme authorizing an administrative subpoena is a qualifying exception to the warrant requirement

Reasonableness is the touchstone of the Fourth Amendment. *United States v. Knight,* 534 U.S. 112, 188 (2001). The Constitution provides for protection against "*unreasonable* searches and seizures." U.S. CONST. amend. IV (emphasis added). Generally, a warrantless inspection is presumptively unreasonable, subject to few exceptions. *Kentucky v. King*, 563 U.S. 452, 459 (2011). Absent a finding of probable cause, reasonableness may be constitutionally adequate where three conditions are met. First, where special needs make the probable cause requirement impracticable. *Patel*, 135 S. Ct. at 2452 (quoting *Skinner*, 489 U.S. at 619). Second, "where the 'primary purpose' of the search is '[d]istinguishable from the government's general interest in crime control." *City of Indianapolis v. Edmond*, 531 U.S. 32, 44 (2000).

Third, when "the subject of the search [is] afforded an opportunity to obtain pre-compliance review before a neutral decision maker." *Id; See v. Seattle*, 387 U.S 541, 545 (1967); *Donovan v. Lone Steer*, Inc., 464 U.S. 408, 415 (1984). Without the opportunity for pre-compliance review, there exists an "intolerable risk" that searches will exceed statutory limits or be used as pretext to harass individuals. *Patel*, 135 S. Ct.at 2452–53.

While the Fourteenth Circuit ultimately reached the proper conclusion, the court did not engage in a Fourth Amendment analysis. Ms. Cleopatra submits that the administrative subpoena at issue, and the Board subsequent inspection, are lawful exceptions to the warrant requirement.

i. A warrant would only frustrate the Board's need to conduct frequent inspections to ensure compliance

Unlike a warrant, an administrative subpoena requires no "specific charge or complaint of violation of law." *Oklahoma Press Pub. Co. v. Walling*, 327 U.S. 186, 215–16 (1946). Rather, an agency can exercise its "power of inquisition" "merely on suspicion that the law is being violated, or even just because it wants assurance that it is not." *United States v. Morton Salt Co.*, 338 U.S. 632, 642–43 (1950). Imposing a warrant requirement on a state agency charged with preserving public health reduces the state's ability to keep its citizens safe. Where the burden of obtaining a warrant is likely to frustrate the government's purpose behind the search, the interest in dispensing with the warrant is strong. *Skinner*, 489 U.S. at 622; Ca*mara,* 387 U.S. at 529–31. In assessing whether the public interest demands exception to the warrant

requirement depends upon whether public interest justifies the type of search in question. *Id.* at 533.

In *Camara*, an inspector from the Department of Health was repeatedly denied access by the appellant, to inspect an apartment building, insisting the inspector provide a warrant. 387 U.S. 523, 526 (1967). The Court held that the Department of Health violated the Fourth Amendment because the state's interest in conducting warrantless inspections to prevent hazardous conditions and promote safety did not outweigh an individual's Fourth Amendment rights. *Id.* at 534. However, the Court was clear to distinguish routine inspections from inspections supported by emergency situations. *Id.* at 539. There was no threat of emergency present in *Camara* justifying the Department's entry.

The facts of *Camara* are distinguishable from the case at bar and rely on the Courts distinction between routine inspections and authorized inspections based on emergency situations. The inspection in *Camara* was routine and indiscriminate, supported only by the state's general interest in safety. Here, the subpoena was not routine or random, rather it was a calculated directive to address the emergency that is Miasmic Syndrome. In fact, the inspections authorizing statute is appropriately named the *Emergency* Miasmic Syndrome Act. The inspection of medical records to ensure a hospital is providing adequate standards of care for patients is critical. Authorization for the inspection, in this case, must be viewed against the backdrop of unknowns surrounding a global pandemic, a fact that was not present for the Court's consideration in *Camara*.

The inspection here was authorized by statute to address the health concerns surrounding a global pandemic. Given the pervasive nature of the virus and the failed attempts at adequate treatment, inspections like these are the only means by which the government may ensure that those who catch the virus are properly cared for.

ii. The subpoena does not serve the general interest in deterring crime when penalties do not attach to non-compliance

A warrantless inspection for the general welfare of the community, and not as a means of deterring crime, is a widely accepted concept, rooted in our nation's culture. *Frank*, 358 U.S. at 367.

In *Camara*, the appellant was advised that he was required by law to permit access for inspection as part of the Housing Code. *Camara,* 387 U.S. at 534. He continuously denied the inspector entry, leading to his arrest for failing to comply with the inspection. *Id.* at 526–27. The city focused its argument on the government's interest in ensuring safety, treating appellant's arrest as merely incidental to the government's higher purpose. *Id.* at 531. However, the Court considered the criminal penalties associated with the appellant's non-compliance, holding that broad statutory safeguards are no substitute for individualized review, particularly when those safeguards may only be invoked at the risk of a criminal penalty. *Id.* at 533. A warrantless inspection cannot be valid, even if authorized by statute when the only means to challenge the inspection invokes criminal penalties. *See id.* at 532–33.

As recent as 2016, this court revisited this key point in *Patel*. In *Patel*, a hotel operator's failure to turn over guest information, as mandated by statute, subjected the operators to on-the-spot arrests. *Patel*, 135 S. Ct. at 2452. The Court reasoned

that whenever criminal penalties are attached to an individual's failure to comply with an administrative inspection, traditional Fourth Amendment requirements, necessitating a warrant, are triggered. *Camara,* 387 U.S. at 534; *see Patel*, 135 S. Ct. at 2453.

Ms. Cleopatra submits that there are overriding material differences between the present case, *Patel*, and *Camara* such that neither holding should apply here. An arrest was actually made against the appellant for his failure to comply in *Camara*. 387 U.S. at 526–27. No such arrest happened here, only the threat of arrest. In *Patel*, the threat of arrest against hotel operators for their failure to comply was sufficient to hold that the inspection was unconstitutional. 135 S. Ct. at 2448. However, that threat was supported by statutory authorization, explicitly permitting criminal penalties in the face of non-compliance. *Id.* No such authority exists within the authorizing statute in this case. No such effort to deter criminal conduct persists. Thus, no traditional Fourth Amendment analysis is triggered here. Rather, the Board's remedy to seek a court order in the face of non-compliance is the strongest penalty authorized by the EMS.

iii. The administrative inspection scheme provides a meaningful opportunity for pre-compliance review

In the alternative, if the Court finds criminal penalties attach to non-compliance, then the subject of an administrative inspection must be afforded an opportunity to obtain pre-compliance review before a neutral decisionmaker. *Patel*, 135 S. Ct. at 2453. Indeed, even the appellant in *Camara* was summoned to the

district attorney's office where he could have raised pre-compliance questions. *Camara*, 387 U.S. at 526.

In *Patel*, the criminal penalty attached to a hotel operator's non-compliance with an administrative subpoena was on-the-spot arrests. *Patel*, 135 S. Ct. at 2452. The Court held that this scheme was unconstitutional because it did not afford any opportunity for pre-compliance review." *Id.* at 2447. The Court explained that the hotel operator was entitled to obtain pre-compliance review because criminal penalties attached to his failure to comply, and when criminal penalties attach, review must be made by a neutral decisionmaker. *Id.* at 2452.

The Petitioner asserts that the administrative inspection here fails, namely because the subpoena did not spell out how Petitioner should seek review before the inspection. The subpoena does, however, cite its authorizing statute. Further inquiry leads to section (e) of the statute, plainly discussing how one may seek review. (R. at 9).

Petitioner further implies that pre-compliance review is only appropriate before a neutral detached *judicial* magistrate. However, this Court has never held so. (emphasis added). On the contrary, *Patel* only requires review before a "neutral *decisionmaker*." 135 S. Ct. at 2452 (emphasis added). *Patel* does not stand for the proposition that a judicially reviewable administrative subpoena is the minimum requirement for pre-compliance review. *See id.* This Court "has never attempted to prescribe the exact form an opportunity for pre-compliance review must take." *Id.* at 2452, 2454. Pre-compliance only requires *opportunity* for review. *Id.* at 2446.

Petitioner was afforded ample opportunity. While Petitioner claims the threat of arrest on the date of execution is what ultimately triggered the necessity for pre-compliance review, the subpoena here was sent nearly five days before its execution, affording Caser the opportunity to review, research and reject the subpoena.

But even if some factor of *Petal* lacks here—which none do—the Board's subpoena is still reasonable under *New York v. Burger,* 482 U.S. 691 (1987). A warrantless inspection prohibited under *Patel* may be permissible under *Burger* if no allowance of pre-compliance review is made but some other "constitutionally adequate substitute for a warrant" is present. *Id.* at 703.

B. An administrative subpoena is a constitutionally adequate substitute for a warrant under *Burger* because the medical profession is closely regulated

Under *Burger*, a statute authoring an administrative inspection is a constitutionally adequate warrant substitute when it advises the property owner that the commercial premises subject to inspection is authorized by law and has been properly defined in scope and limited in discretion. *Id.* (citing *Marshall v. Barlow's Inc.*, 436 U.S. 307,323 (1987)). However, where a statute is too broad, allowing warrantless inspections against nearly anyone rather than against closely regulated industries, where such regulations are already pervasive, no exception will apply. *See Marshall*, 436 U.S. at 331.

Burger defines closely regulated industry using a multi-factor evaluation of "pervasiveness," "regularity," and "duration," 482 U.S. at 701. Indeed, the medical profession is "closely regulated," under *Burger*, and a properly tailored statute may provide for the warrantless administrative inspection of such a business. *Marcowitz*

v. Dep't of Pub. Health, State of Illinois, 435 N.E. 2d 1291, 1295 (Ill. App. Ct. 1982) ("That there has been pervasive, long-standing regulation of the health care industry. . ."). It is the profession's use of controlled substances and broad prescription power that requires it to be more closely regulated. *Beck v. Texas State Bd. Of Dental Examiners*, 204 F. 3d 629, 638 (5th Cir. 2000) (treating "the regulation and monitoring of the use of controlled substance" as a "substantial state interest" capable of regulation by "administrative or regulatory searches" without warrants under *Burger*).

The State has a substantial interest in inspecting the medical records of patients to ensure Hospitals provide the medically necessary standard of care. The magnitude of the problems the state of Romulus, and arguably the world face, are memorialized in statute through the enactment of the Emergency Miasmic Syndrome Act. Even if the inspection of medical records held by an insurance company is not a "closely regulated industry," it is heavily regulated for the critical purpose of ensuring the health, safety, and welfare of citizens– especially in the face of a global pandemic, an invisible enemy.

It would be inapposite to this Court's long-standing qualified immunity jurisprudence to hold an investigator liable for doing something previously sanctioned without an intervening decision that clearly established otherwise. For the Petitioner to overcome Ms. Cleopatra's right to qualified immunity, the Petitioner must show both a violation of a clearly established constitutional right and that the official's conduct was not objectively reasonable. Petitioner here can show neither.

Therefore, the Court should affirm the Fourteenth Circuit, finding that the issuance of an administrative subpoena against Caesar Health did not violate Petitioner's Fourth Amendment rights.

C. Even if this Court finds a violation of the Fourth Amendment occurred, Ms. Cleopatra is entitled to qualified immunity

Appealing dismissal of a complaint requires Petitioner to prove "a genuine fact issue [exists]" regarding the official's allegedly wrongful conduct, a question of law reviewable *de novo*. *Siegert v. Gilley*, 500 U.S. 226, 231–232 (1991).

The Fourth Amendment provides individuals crucial rights and protections, for which this Court has a duty to uphold. Often, when called to decide upon whether an individual has been deprived of said rights and protections, an opposing claim for qualified immunity follows. More often than not, the issue of qualified immunity requires courts to "balance between the evils inevitable in any available alternative." *Harlow v. Fitzgerald*, 457 U.S. 800, 813 (1982). The specific "evils" this Court refers to is when the government's interests in deterring unlawful conduct compete with the government's need to act for the benefit of the people without fear of repercussions. *Id.* at 819. In effect, courts are often required to sacrifice one interest for the benefit of the other.

This case, however, does not ask this Court to decide against deterring unlawful conduct. Instead, the EMSA and Ms. Cleopatra's subsequent administrative subpoena sought to protect its most vulnerable citizens by ridding Romulus of unlawful, fraudulent substandard medical practices. (R. at 3–4.) This case must ultimately be decided based upon an objective determination. *District of Columbia v.*

Wesby, 138 S. Ct. 577, 589 (2018). Qualified immunity is proper when the Petitioner can prove no reasonable official, on the particular day and under the same circumstances, would have believed the conduct was lawful. *Id.*

Considering this objective standard, the Fourteenth Circuit Court properly dismissed this complaint, reasoning that the subpoena issued to combat the substandard medical treatments plaguing Romulus during the pandemic is a matter of "first impression" lacking "clearly established" law. (Opinion of the Fourteenth Circuit, R. at 37–38.) Accordingly, this Court should affirm the Appellate Court's decision, as Petitioner cannot prove sufficient authority exists to render this issue "clearly established" by law. *Ashcroft v. al-Kidd*, 563 U.S. 731, 741 (2011); *United States v. Lanier*, 520 U.S. 259, 269 (1997); *Anderson v. Creighton*, 483 U.S. 635, 640 (1987).

i. A constitutional right recognized in a case of first impression cannot be "clearly established," because the issue is not "beyond debate"

This Court has consistently held that the standard for qualified immunity provides room for discretionary mistakes and should only be withheld when the public official knowingly violates the law or acts in a manner described as "plainly incompetent." *Hunter v. Bryant*, 502 U.S. 224, 229 (1991); *Malley v. Briggs*, 475 U.S. 335, 343 (1986); *Davis v. Scherer*, 468 U.S. 183, 196 (1984). In *Wesby*, this Court provided two elements the Petitioner must prove to overcome the *presumption of immunity*. *Wesby*, 138 S. Ct. at 589.

The first element requires this Court determine whether a constitutional right was violated. *Id.* The second requires *Petitioner to prove* Ms. Cleopatra's conduct violated a "clearly established" right, meaning *every reasonable official* in that moment would have believed the conduct was unlawful. *Wesby*, 138 S. Ct. at 589. We address the issue of "clearly established" first.

Further, the objective analysis is limited to the reasonableness of conduct compared to settled law addressing similar circumstances, not a debate of alternative courses of action later constructed in a courtroom. *Hunter*, 502 U.S. at 227–28. Every argument before this Court in favor of Petitioner is either opinion or a debate of "what-ifs" and "what should have been's", none of which may serve as the basis for sufficient controlling precedent or persuasive case law.

1. The district court could not point to a single case to put the issue beyond debate

Proving a right is clearly established is a "*demanding*" standard that requires Petitioner to proffer existing precedent that places the constitutional right as an issue "beyond debate." *Wesby*, 138 S. Ct. at 589; *White v. Pauly*, 137 S. Ct. 548, 551 (2017) (emphasis added). "To evaluate whether a particular question is beyond debate, a court looks for cases of controlling authority in [the governing] jurisdiction at the time[,] or a consensus of cases of persuasive authority such that a reasonable officer could not have believed that his [or her] actions were lawful." *Kramer v. Cullinan*, 878 F.3d 1156, 1163–64 (9th Cir. 2018).

Ultimately, Petitioner cannot prove that issuing an administrative subpoena on a health insurance company during a pandemic is a "clearly established" violation

of the Fourth Amendment, putting the practice "beyond debate." *White*, 137 S. Ct. at 551. The District Court relied heavily upon *Patel* to "clearly establish" the unconstitutionality of the administrative subpoena, however that court ignored this Court's exception stated therein. (R. at 21.) In *Patel*, this Court provided three elements administrative subpoenas must follow to be deemed constitutional. *City of Los Angeles v. Patel*, 135 S. Ct. 2443, 2452 (2015). Within the same sentence, this Court acknowledged exigent circumstances as an exception, of which the District Court materially failed to consider. *Id.*

The District Court held that immunity was not available because Ms. Cleopatra should have known *Patel* prohibited the Board's actions, despite never analyzing whether the pandemic is classified as an exigent circumstance. (R. at 21, 25–26.) The court reasoned that because "a week went by between Cleopatra becoming aware of allegations against Caesar and her decision to write the subpoena[,]" there was no exigency. (R. at 26.) Waiting a week hardly proves lack of exigency, especially when the record is silent as to why Ms. Cleopatra waited. (R. at 4, 26.) It is more likely that the week was used to gather more data on the "reports" to ensure reasonable suspicion existed when the subpoena was issued on Petitioner. *(Id.)*

The District Court failed to cite case law addressing either government authority during a pandemic, or Fourth Amendment implications on issuing subpoenas for medical records during a pandemic to support its holding. (*See* Opinion of the District Court of Romulus, R. at 13–27 (failing to cite any authority that closely

mirrors the facts of this case).) If the District Court could not point to one case where a pandemic was or was not declared an exigency, then the issue is not "beyond debate." *Wesby*, 138 S. Ct. at 589–90.

2. Because the issue is not beyond debate, the government's belief was reasonable

Accordingly, "beyond debate" cannot be proven with opinions or by speculating that this Court would reach the same decision as another circuit court, but rather by showing precedent is so clear, so established, that every reasonable official would agree the conduct was unlawful. *Wesby*, 138 S. Ct. at 590; *al-Kidd*, 563 U.S. at 741.

Specifically, the Circuit Court found Ms. Cleopatra's conduct reasonable, as any reasonable official could have believed the petitioning process provided in RCL § 18.8.891(e) satisfied the pre-compliance review articulated in *Patel*. *(Id.)* The subpoena's self-imposed limitation, requesting only records concerning Miasmic Syndrome, was an adequate substitute for a warrant under *Burger*. *(Id.)*

Accordingly, the lack of any cited controlling or persuasive authority addressing the exigency of substandard medical care during a pandemic proffered by either lower court and Petitioner, proves that no reasonable officer under the same circumstances as Ms. Cleopatra would have known the potential challenges of the events that transpired on March 19, 2020. *See Wesby*, 138 S. Ct. at 590; *Kramer*, 878 F.3d at 1163–64. The Fourteenth Circuit correctly identified this case is not "beyond debate," and therefore this Court should affirm the decision. *Wesby*, 138 S. Ct. at 589; *White*, 137 S. Ct. at 551.

Therefore, this Court should follow the Fourteenth Circuit's conclusion that this is a matter of "first impression" because Petitioner has not and will not be able to meet their burden of proof. *Wesby*, 138 S. Ct. at 589; *White*, 137 S. Ct. at 551. If "particularized" case law existed, certainly it would have been brought before either the District Court or the Fourteenth Circuit, however, both opinions are completely void of any case resembling the facts at hand. Reason being, no such facts exists, until now. Absent such, the extent of this Court's authority stops at the analysis of the Fourth Amendment and cannot continue so far as to deny qualified immunity when this decision will be the first of its kind. *Myers v. Morris*, 810 F.2d 1437, 1462 (8th Cir. 1987).

D. Where the issue is a matter of first impression there is no particularized case law

This Court has piggybacked on the requirement to prove this issue is "beyond debate" by emphasizing the Petitioner's burden also includes proffering particularized case law. *Lanier*, 520 U.S. at 269 (indicating that prior decisions must exist to put the public official on notice that the conduct violates a constitutional right); *Anderson*, 483 U.S. at 640 (holding that a public official's illegal conduct must be apparent according to pre-existing law). Further, this Court has "repeatedly stressed that courts *must not define clearly established law at a high level of generality*, since doing so avoids the crucial question whether the official acted reasonably in the particular circumstances he or she faced." *Wesby*, 138 S. Ct. at 590 (citing *Plumhoff v. Rickard*, 134 S. Ct. 2012, 2023 (2014)) (emphasis added).

Circuit courts have consistently applied this reasoning by awarding qualified immunity when Petitioner cannot produce sufficiently tailored case law. *See Kramer*, 878 F.3d at 1164 (Ninth Circuit awarded immunity when the generalized law was not sufficiently particular to put the official on notice that the particular conduct was unlawful); *Kerns v. Bader*, 663 F.3d 1173, 1187, 90 (10th Cir. 2011) (Tenth Circuit awarded immunity, reasoning that the smallest factual differences could result in a different constitutional outcome); *Doe v. Delie*, 257 F.3d 309, 320–22 (3d Cir. 2001) (Third Circuit awarded qualified immunity to public official because all case law cited were "factually and legally distinguishable" from the instant case); *Hodorowski v. Ray*, 844 F.2d 1210, 1216–17 (5th Cir. 1988) (Fifth Circuit held that the public official was entitled to qualified immunity because the constitutional right was "too general" to conclude that the official knew the specific conduct violated said right).

Accordingly, for a case to be sufficiently "particular," it must have a "high degree of specificity" to the facts of the instant case. *Wesby*, 138 S. Ct. at 590; *White*, 137 S. Ct. at 552. Therefore, Petitioner must bring to this Court case law "developed in such a *concrete and factually defined context* to make it *obvious to all* reasonable government actors, in the [Ms. Cleopatra's] place, that what he [or she] is doing clearly violates federal law." *Shafer v. Cnty. of Santa Barbara*, 868 F.3d 1110, 1117 (9th Cir. 2017) (emphasis added).

The Fourteenth Circuit applied this Court's principle of "particularity" properly when it identified this case as a matter of first impression, as these facts have never been adjudicated before. (Opinion of the Fourteenth Circuit, R. at 36.) The

lower court stated that it " is unfamiliar with any cases in this circuit or in the Supreme Court that involve a warrantless search of an insurance company for medical records pertaining to a hospital as authorized by a statute in response to a pandemic." (Opinion of the Fourteenth Circuit, R. at 37.)

The District Court, on the other hand, failed to adhere to this Court's clear prohibition on rendering decisions based upon application of non-particularized case law. *Wesby*, 138 S. Ct. at 590; *White*, 137 S. Ct. at 552; *Plumhoff*, 134 S. Ct. at 2023. Specifically, qualified immunity was withheld solely based upon the rule in *Patel*, since "[a]ll government officials had five years to educate themselves [. . .] between the decision of *Patel* in 2015 and the instant search in 2020." (Opinion of District Court, R. at 25–26.) This reasoning is fundamentally flawed, as public officials cannot be expected to believe a case with *little to no factual similarities* governs over their circumstances. *Wesby*, 138 S. Ct. at 590; *White*, 137 S. Ct. at 552.

i. The facts of *Patel* do not make the conduct obviously unlawful

In *Patel*, this Court analyzed the constitutionality of law enforcement officer's inspection of hotel records carried out without a warrant or subpoena, pursuant to a state statute. *Patel*, 135 S. Ct. at 2448. *This case lacks any resemblance to Patel* because it considers the lawfulness of a statute-supported administrative subpoena issued on an insurance company for medical records relating to an ongoing pandemic. (Opinion of the Fourteenth Circuit, R. at 37.) Additionally, this Court's prohibition of threatening business owners with jail to receive compliance in *Patel* cannot carry over

to this case where the issue addresses the exigency of a global pandemic involving a viral disease that has killed thousands. *Patel*, 135 S. Ct. at 2452.

The *factual similarities between these cases are scarce*, and therefore *Patel* cannot be considered sufficiently "particularized" case law to put Ms. Cleopatra on notice of her unlawful conduct. *Wesby*, 138 S. Ct. at 590; (*see also Hunt v. Bd. of Regents*, 792 F. Appx. 595, 606 (10th Cir. 2019) (awarded immunity to a public official where case law in the governing jurisdiction "ha[s] not bridged the unmistakable [factual] gaps" to warrant application to the case)). Accordingly, the Fourteenth Circuit decision must be affirmed, as no "particularized" case exists for this matter of first impression. *Wesby*, 138 S. Ct. at 590; *Harlow*, 457 U.S. at 818.

ii. The facts of *Zadeh* are sufficiently particular and support Ms. Cleopatra's reasonable belief that the conduct was lawful

Even if this Court relies upon the general rights afforded by the Fourth Amendment to decide the constitutionality of the events that transpired on March 19, 2020, existing case law with the closest factual similarities support Ms. Cleopatra's reasonable belief that the conduct was lawful. *United States v. Zadeh*, 820 F.3d 746, 756–58 (5th Cir. 2016). By no means do the aforementioned opinions disprove that this is an issue of first impression, as no decision ruling upon an administrative subpoena issued on an insurance company during a pandemic exists. These decisions do, however, support Ms. Cleopatra's reasonable belief that her conduct was lawful.

The Fourth Amendment requires the "reasonable relevance" standard to be applied when medical records are the subject-matter of a subpoena. *Id.* at 756. The

standard protects the privacy of the patients and is constitutional against the entity subpoenaed when: "(1) the subpoena is within the statutory authority of the agency; (2) the information sought is reasonably relevant to the inquiry; and (3) the demand is not unreasonably broad or burdensome." *Id.* at 755 (quoting *United States v. Transocean Deepwater Drilling, Inc.*, 767 F.3d 485, 488 (5th Cir. 2014)).

In *Zadeh*, the subpoena of Dr. Zadeh's patient records were upheld under this standard because it was issued under the Controlled Substance Act, the information sought was "relevant and material to a legitimate" investigation, and the subpoena was "specific and limited in scope." *Zadeh*, 820 F.3d at 758. The court was not persuaded by Dr. Zadeh's claim that the subpoena violates the privacy interests of his patients, reasoning that "these privacy concerns are best protected by a court order narrowly confining the scope of production to the ongoing government investigation[.]" *Id.*

Many other circuit courts have enforced subpoenas for medical records under the reasonable relevance standard as well. *See In re Subpoena Duces Tecum*, 228 F.3d 341, 346–51 (4th Cir. 2000) (denied motion to quash a subpoena of medical records in an investigation for healthcare fraud, as it met the reasonable relevance standard); *Gilbreath v. Guadalupe Hosp. Foundation, Inc.*, 5 F.3d 785, 790–91 (5th Cir. 1993) (enforced medical records to be turned over because the subpoena was issued under federal law pursuant to a proper purposed investigation and records listed were relevant to the investigation); *United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, 575–76 (3d Cir. 1980) (upheld the subpoena for employee medical

records under the reasonable relevance standard, but remanded the case to provide requirements to give notice and opportunity to intervene).

Although no existing case law has ruled on a Fourth Amendment issue involving an administrative subpoena for medical documents during a pandemic, Ms. Cleopatra reasonably believed the conduct was lawful based upon the "reasonable relevancy" standard as applied by the above courts. *Zadeh*, 820 F.3d at 758.

First, the administrative subpoena was issued by the Commissioner, who was granted authority to do so under RCL § 18.8.891(b). Second, the subpoena's scope was limited to medical documents regarding the diagnosis and treatment of Miasmic Syndrome patients, and third, the scope was further limited to patients diagnosed or suspected to be diagnosed, on or after May 1, 2019. (R. at 11.) It is uncontested that the Board's subpoena was pursuant to a valid law, as the EMSA was active and never-before contested for constitutionality. (R. at 37.)

Additionally, it can hardly be said that that the Board lacked a proper purpose behind their investigation into Julius or that the documents requested from Petitioner were not reasonably related to their investigation. *Transocean Deepwater Drilling, Inc.*, 767 F.3d at 488; *Gilbreath*, 5 F.3d 785 at 790–91. The Romulus government bestowed the Board with the authority in RCL § 18.8.891 to act within the scope of pandemic-related substandard medical care, the exact purpose and scope of the issued administrative subpoena. (R. at 11.) The subpoena specifically requested documents regarding the treatment of potential and diagnosed Miasmic Syndrome

patients, and only sought such information from entities that would naturally have such information.

Further, the discretion to issue subpoenas on non- "hospital" entities is limited in RCL § 18.8.891 to those who possess evidence of the hospital's substandard care to Miasmic Syndrome patients. It is universally known that only a few entities would hold medical records and even fewer that would additionally have documents specifying a patient's diagnosis. Aside from the hospital itself, health insurance companies are one of the selective few that would hold such documents, thus constitutionally limiting the scope of the Commissioner and the Board's authority.

Finally, the administrative subpoena issued on March 19, 2020, was not overbroad or too burdensome. The documents requested in the subpoena were limited to only Miasmic Syndrome patients treated on or after May 1, 2019, thus placing two layers of specificity, and decreasing the number of documents to be overturned by Petitioner. (*Id.*)

Therefore, this Court can logically conclude that Ms. Cleopatra reasonably believed that the subpoena issued comported with case law governing access to medical records. *Zadeh*, 820 F.3d at 755; *Transocean Deepwater Drilling, Inc.*, 767 F.3d at 488; *Gilbreath*, 5 F.3d 785 at 790–91. Accordingly, this Court cannot find, nor can Petitioner prove, that this challenge of Ms. Cleopatra's conduct is "clearly established" by the broad protections afforded by the Fourth Amendment when such case law exists supporting Ms. Cleopatra's conduct. *Wesby*, 138 S. Ct. at 589; *al-Kidd*, 563 U.S. at 741 (2011); *Anderson*, 483 U.S. at 640.

CONCLUSION

For the foregoing reasons, this Court should AFFIRM on both counts the judgment of the United States Court of Appeals for the Fourteenth Circuit.

Respectfully Submitted,

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ATTORNEYS FOR RESPONDENT