QUESTIONS PRESENTED

I. Did Caesar Health Plan, as a third-party payor, have standing to assert a RICO claim pursuant to 18 U.S.C. § 1964(c), where the proximate cause element is alleged to be satisfied because Caesar would not have underwritten a prescription for Glukoriza as a treatment for Miasmic Syndrome if Galen had not misrepresented side effects to prescribing physicians?

II. Does a state official, who orders an administrative subpoena to a health insurance provider requesting medical records and insurance claims related to patients diagnosed, treated, or suspected of carrying Miasmic Syndrome, violate the Fourth Amendment, where such search is conducted pursuant to a state's emergency statute that provides for precompliance review even if no precompliance review was afforded? If so, is the official protected from liability and immune from suit under 42 U.S.C. § 1983 by the doctrine of Qualified Immunity?

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STANDARD OF REVIEW

Courts review judgments on a motion dismiss under a Fed. R. Civ. P. 12(b)(6) *de novo*. *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, 943 F.3d 1243, 1248 (9th Cir. 2019). Whether a government official is entitled to qualified immunity is reviewed *de novo*. *Cockrell v. City of Cincinnati*, 468 Fed. Appx. 491, 494 (6th Cir. 2012).

STATEMENT OF THE CASE

Pursuant to SUP. CT. R. 24.2, Respondent is satisfied with the presentation of the statement of the case.

SUMMARY OF THE ARGUMENT

I.

This Court should affirm the lower court's Order to reverse and remand, because, firstly, petitioners fail to meet the causation standard required by 18 U.S.C. § 1964(c). Secondly, upholding the decision would be consistent with surrounding Circuits, and finally, affirming the decision promotes public policy. The Romulus District Court applied the incorrect standard for a finding of proximate cause when it analyzed this case in terms of "foreseeability" rather than on the existence of a sufficiently "direct relationship" between the fraud and the harm as set forth in *Hemi Grp., LLC v. City of N.Y.*, 559 U.S. 1, 6, (2010). Had the District Court applied the correct standard it would have found that the distinct conduct in the promotion of Glukoriza and the distinct parties between Julius Medical, Caesar Health Plan, and prescribing pharmacists, severed causation between the alleged RICO misconduct and petitioner's injury. Surrounding Circuits have faced similar situations and

declined to allot standing to third-party payors. Where courts did allow standing (namely, in *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, 943 F.3d 1243 (9th Cir. 2019)) there were at least three distinguishing factors which this Court pointed to in its precedent, namely: independent factors that account for respondents' injury, risk of duplicative recoveries by plaintiffs, and the presence of a more immediate victim better situated to sue. Because all three are present in the instant case, this Court should uphold the lower court's finding. Finally, reversing the lower court's Order would be detrimental to public policy, exacerbating a global pandemic.

II.

This Court should affirm the Appellate Court's judgment remanding the Civil Rights claim under 42 U.S.C. § 1983 because Respondent Cleopatra did not violate a constitutional or statutory right of Petitioner Caesar, nor was an alleged violation of such a right clearly established as required under the doctrine of qualified immunity.

Caesar Health Plan constitutes a pervasively regulated business and therefore the applicable Fourth Amendment analysis is that of *Burger v. New York*. Furthermore, Ms. Cleopatra satisfied the requirements under the *Burger* exception that required there be a "substantial government interest," the regulatory scheme "requires warrantless searches to further the government interest", and there is a "constitutionally adequate substitute for a warrant." *Burger v. New York*, 482 U.S. 691, 702-03 (1987).

Respondent Cleopatra likewise did not violate Petitioner Caesar's constitutional or statutory rights because the issuance and execution of the

administrative subpoena, pursuant to the Emergency Miasmic Syndrome Act, satisfied the requirements of *Patel*. The first *Patel* requirement that there be special needs that "make the warrant and probable cause requirement impracticable," *City of Los Angeles v. Patel*, 576 U.S. 409, 420 (2015), was satisfied because there was an unprecedent health crisis in the form of a pandemic sweeping the world, which required Respondent Cleopatra to act with urgency in such exigent circumstances therefore rendering the warrant requirement impracticable. The next *Patel* requirement that the search must not be be for the primary purpose of general crime control, *id.*, was also met because as both the lower courts noted, the primary purpose of the administrative subpoena was to protect public health and ensure Miasmic Syndrome patients were receiving adequate care. Finally, the third *Patel* requirement of the opportunity for a precompliance review was also satisfied because although not explicitly stated in the subpoena, the statute that granted the subpoena authority provided for such precompliance review, it is not that *Patel* requires that the precompliance review be satisfied, it is only required that the opportunity for such a review be afforded to the party that is subject to the subpoena.

In the alternative, whether a right was violated in this case is irrelevant because such violation was not clearly established as required under the doctrine of qualified immunity, therefore Respondent Cleopatra is immune from suit. The clearly established requirement necessitates that the violation be "sufficiently clear that every reasonable official would understand that what [s]he is doing is unlawful." *District of Columbia v. Wesby*, 138 S. Ct. 577, 589 (2018). As this is a case of first

impression, as described by the appellate court, and the statute that authorized Ms. Cleopatra to issue an administrative subpoena was enacted approximately five months prior to the alleged misconduct at issue, it was not possible for the alleged violation to be clearly established because there was not enough time for such a statute to be held unconstitutional or litigated in any manner to determine the confines under the statute.

Because there was no constitutional or statutory right violated, and in the unlikely event this Court holds that there was, Respondent Cleopatra is immune from suit due to the doctrine of qualified immunity since the alleged violation was not clearly established. Therefore, this Court should affirm the appellate court's judgment remanding the case to the district court for dismissal.

ARGUMENT

I. PETITIONERS FAIL TO MEET THE CAUSATION STANDARD REQUIRED BY THE RICO STATUTE, THE DECISION WOULD BE CONSISTENT WITH SURROUNDING CIRCUITS, AND AFFIRMING THE DECISION PROMOTES PUBLIC POLICY.

The Racketeer Influenced and Corrupt Organization Act (RICO) provides a private cause of action for "[a]ny person injured in his business or property by reason of a violation of section 1962 of this chapter." 18 U.S.C. § 1964(c). Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate . . . commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." "[R]acketeering activity" is defined to include a

number of so-called predicate acts, including the two at issue in this case - mail and wire fraud. See § 1961(1). *Hemi Grp., LLC v. City of N.Y.*, 559 U.S. 1, 6, (2010)

To allege civil RICO standing under 18 U.S.C. § 1964(c), a "plaintiff must show: (1) that his alleged harm qualifies as injury to his business or property; and (2) that his harm was 'by reason of the RICO violation." *Canyon County v. Syngenta Seeds, Inc.*, 519 F.3d 969, 972 (9th Cir. 2008). The Supreme Court set the standard for causation in a RICO claim in *Holmes* v. *Securities Investor Protection Corporation*. 503 U.S. 258 (1992). To prevail in a RICO action, plaintiff is required to show that a RICO predicate offense was not only a 'but for' cause of his injury, but was the proximate cause as well. *Id.*, at 268, 112 S. Ct. 1311, 117 L. Ed. 2d 532. Proximate cause for RICO purposes, we made clear, should be evaluated in light of its common-law foundations; proximate cause thus requires "some direct relation between the injury asserted and the injurious conduct alleged." *Ibid.* A link that is "too remote," "purely contingent," or "indirec[t]" is insufficient. *Id.*, at 271, 274, 112 S. Ct. 1311, 117 L. Ed. 2d 532.

A. CAESAR FAILS TO MEET THE CAUSATION STANDARD (PROXIMATE CAUSE) REQUIRED BY THE GOVERNING STATUTE.

1. The Romulus District Court applied the incorrect causation standard when it considered foreseeability rather than direct relationship.

The Romulus District Court applied the incorrect standard for a finding of proximate cause when it analyzed this case in terms of "foreseeability" rather than on the existence of a sufficiently "direct relationship" between the fraud and the harm. When the District Court made its causation analysis and came to its finding that no intervening cause barred respondents from liability, it opined that, "it is

foreseeable in the American health care system that while doctors prescribe the drugs, physicians would not be the ones paying for the drugs they prescribe." (R. at 16.) The District Court used as its authority *Painters & Allied Trades District Council 82 Health Care Fund v. Takeda Pharm. Co.*, where the Ninth Circuit, in siding for petitioners, held that "although prescribing physicians serve as *intermediaries* (. . .) prescribing physicians do not constitute an *intervening cause* to cut off the chain of proximate cause" because, "[a]n intervening cause is 'a later cause of independent origin that was not foreseeable.'" 943 F.3d 1243, 1257 (quoting *Mendez v. County of Los Angeles*, 897 F.3d 1067, 1081 (9th Cir. 2018).

This Court in *Hemi Grp., LLC v. City of N.Y.* not only laid out the proper standard of causation as a "direct relationship," it also denounced the use of a foreseeability test. 559 U.S. at 12. In *Hemi Group*, this Court considered whether the petitioner's asserted injury (lost tax revenue) came about "by reason of" respondents' allegedly fraudulent conduct, (violation of an Act requiring the reporting of cigarette purchasers to the State) as required by § 1964(c). *Id.* at 7-8. In deciding for respondents, the Court specifically rejected the argument that RICO's proximate cause requirement could turn on foreseeability, rather than on "existence of a sufficiently 'direct relationship' between the fraud and the harm. *Id.* at 12. With a tone of firm finality, the Court declared: "The concepts of direct relationship and foreseeability are of course two of the 'many shapes [proximate cause] took at common law,' (Citation omitted). Our precedents make clear that in the RICO context, the focus is on the directness of the relationship between the conduct and the harm."

Hemi Grp., LLC v. City of N.Y., 559 U.S. at 12. The Court recalled that it had maintained this same stance in *Anza v. Ideal Steal Supply Corp.*, , which, along with *Holmes,* "never even mention the concept of foreseeability." *Hemi Grp., LLC v. City of N.Y.*, 559 U.S. at 12 quoting *Anza v. Ideal Steal Supply Corp.*, 547 U.S. 451 (2006).

As stated above, the Romulus District Court relied on *Painters*, where the Ninth Circuit, in turn, had relied on *Bridge v. Phx. Bond & Indem. Co..* 553 U.S. 639, 128 S. Ct. 2131 (2008). The Ninth Circuit referenced *Bridge* directly when it said, "the unanimous Supreme Court . . . holding was that the plaintiffs' 'alleged injury . . . was a foreseeable and natural consequence of [the defendants' scheme.'" *Painters & Allied Trades Dist. Council 82 Health Care Fund* 943 F.3d at 1250 (citing *Bridge v. Phx. Bond & Indem. Co..* at 658.) The Ninth Circuit relied so heavily on *Bridge* that it stated: "Under the Supreme Court's *Bridge* precedent *alone*, we think Plaintiffs' allegations satisfy the Supreme Court's direct relation requirement." *Painters*, 943 F.3d at 1251. (Emphasis added.) However, like a house of cards, that reliance falls flat in light if *Hemi Group,* which was decided two years after *Bridge*, and clearly set aside emphasis on the foreseeability standard in favor of the direct relationship standard. Moreover, *Bridge* and *Painters* alike are distinguishable from *Holmes* and *Anza*, in that there were (1) no independent factors that accounted for respondents' injury, (2) no risk of duplicative recoveries by plaintiffs removed at different levels of injury from the violation, and (3) no more immediate victim is better situated to sue. Not only has *Hemi Group* clarified and brought to the forefront the importance of a direct relationship, as stated above, but section II of this issue's argument ("The

Three Variables") will also take each of the three additional distinguishing factors provided by *Bridge* and apply them to the case at bar.

This Court, ten years ago, called proximate cause "a flexible concept that does not lend itself to a black-letter rule that will dictate the result in every case." *Bridge v. Phx. Bond & Indem. Co.*, 553 U.S. at 654. This Court has, since then, removed some of those elements of uncertainty by clarifying that, while direct relationship and foreseeability are two of the many shapes proximate cause took at common law, "in the RICO context, the focus is on the directness of the relationship between the conduct and the harm." *Hemi Grp., LLC v. City of N.Y.*, 559 U.S. at 12. For these reasons, the Ninth Circuit's departure from this standard in *Painters* was in error, and the Romulus District Court's decision, which relied on same, was similarly erroneous.

Once a court applies the correct direct relationship standard, proximate cause is not met. In *Anza*, this Court saw that the cause of petitioner's harm was "a set of actions (offering lower prices) entirely distinct from the alleged RICO violation (defrauding the State)[.]" 547 U.S. at 453. Therefore the alleged violation had not "led directly to the plaintiff's injuries," and petitioner failed to meet RICO's "requirement of a direct causal connection" between the predicate offense and the alleged harm. *Id.* Later, this Court denied standing to third-party payors in *Hemi Group* because it found a "disconnect between the *asserted injury* and the *alleged fraud*" 559 U.S. at 10-11 (emphasis added.) Moreover, this Court, in siding against petitioners found

that petitioner's "theory of liability rest[ed] not just on separate *actions*, but separate actions carried out by separate *parties*. 559 U.S. at 11.

Applying the same test to the case at bar finds the same distinction not only between the alleged fraudulent conduct and plaintiff's harm, but also a distinction of parties. The conduct of Galen's misrepresentation of the extent of Glukoriza's side effects as presented to Julius Medical Center via a marketing campaign, is altogether distinct from the dispatch of sales representatives to physicians throughout the country, who would have to prescribe the treatment for it to be covered. (R. at 2.) Moreover, once Julius Medical agreed to make Glukoriza its preferred Miasmic Syndrome treatment, it also agreed to educate its providers about the benefits of Glukoriza as a Miasmic Syndrome treatment. *Id.* That conduct is, again, altogether distinct from Galen's misrepresentation of the extent of Glukoriza's side effects as presented to Julius Medical. Therefore, this case involves the distinct conduct and the distinct parties that sever causation as set forth in *Hemi Grp., LLC v. City of N.Y.*. 559 U.S. at 11.

2. This Court should promote consistency among the Circuit Courts considering the Second, Seventh, and Fourteenth Circuits' trend of denying Third-Party Payor standing.

The Second, Seventh, and Fourteenth Circuits all agree as to how to handle cases like the one at bar, having decided against third-party payors too far removed from the direct injury of RICO misconduct. Meanwhile, overturning the lower court's decision would allow an inconsistent approach to permeate into the courts. Rather, this Court has the opportunity to provide a reliable standard consistent with the

findings of the Second, Seventh, and Fourteenth Circuits. The following analysis describes cases in each of those circuits similar to the case argued today, and why this Court should treat them in a similar manner.

The Fourteenth Circuit in our case could not justify requiring pharmaceutical companies, to pay insurance companies and third-party payors for the improper representations made by drug manufacturers to physicians about the efficacy of their drug prescriptions. (R. at 33.) The Fourteenth Circuit described that form of liability as "several levels removed in the causal sequence of the injury calculus," because, entities like Caesar "play no role in making any formulary determinations as to treatment, and rely exclusively on each member to submit claims for medications that are reasonable and necessary for treatment[.]" (R. at 33.) Thus, the court found the injury to the third-party payors to be too attenuated from the conduct of the respondents.

The Second Circuit faced a comparable case in *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, where it affirmed the lower court's finding that improper marketing was directed at *physicians* and that tracing loss through the steps between promotion and payment would be too complex. 873 F.3d 574, 575-76 (7th Cir. 2017.) *Sidney Hillman* relied on this Court's decision in both *Holmes* and *Hemi Group* when it recalled that "[t]he general tendency of the law, in regard to damages at least, is not to go beyond the first step," *Holmes*, 503 U.S. at 271-72, quoted with approval in *Hemi Group*, 559 U.S. at 10. *Sidney Hillman*, 873 F.3d at 576. The Second Circuit agreed that the third-party payor plaintiffs in that case were not the "first step" in

terms of injury. *Id.* Rather, because patients suffered upon taking the drug in question, as they suffered adverse side effects not justified by medical benefits, or were dissuaded from taking drugs that would alleviate their conditions, third-party payors were "not the only, or even the most directly, injured parties." *Id.*

In the instant case, we need not go beyond the first step to locate the direct injury and allocate damages. As of February 2020, Glukoriza neither cured nor significantly ameliorated the symptoms of the patients diagnosed with Miasmic Syndrome. R. at 3. Instead, upwards of ten percent of the patients who received the Glukoriza dosage recommended by Galen for Miasmic Syndrome suffered serious loss of kidney function. *Id.* Patients at Julius Medical Center taking Glukoriza for Miasmic Syndrome bore the brunt Galen's misleading marketing when they relied on the drug for treatment, and instead faced possibly irreparable damage. R. at 3. Therefore, this Court need look no further than the first step. It need look no further than the patients who now battle not only Miasmic Syndrome, but impaired kidney function as well.

Meanwhile the Seventh Circuit also disagreed with the approach of the Romulus District Court and that of the Ninth Circuit when it described physicians not as "intermediaries" (*Painters,* 943 F.3d 1243, 1257) but as "independent actors" who "interrupted" and "thwart[ed] any attempt by petitioners' theory of proximate causation, based on the very nature of prescriptions and prescribing physicians. *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 124 (2d Cir. 2010). Aside from this quality of physicians as prescribers (thus serving as an intervening cause) other facts

in the *UFCW Local 1776* case bolster the argument that respondents in the instant case should be relieved of liability. Namely, whereas the drug manufacturer in that case relied on studies demonstrating the extent of the side effects to consumers where almost thirty percent of the patients on the drug in question reported significant side effects, (*Id.* at 124) in the case at bar, not only did Glukoriza result in a smaller percentage of patients with adverse side effects (upwards of ten percent) but the manufacturer, Galen, relied on a greater fraudulent marketing campaign based on results of inadequate clinical testing. R. at 3, 5, 29. Moreover, in *UFCW Local 1776,* the U.S. Food and Drug Administration (FDA) had overseen and made varying recommendations for the drug in question over the span of almost fifteen years. *Id.* at 124-25. On the other hand, in the instant case, Glukoriza's off-label use was an overly-optimistic emergency response to Miasmic Syndrome made only in a matter of months, and its use not yet approved by the FDA. R. at 1-2.

The significance of this second variable is made more clear with an understanding of the role that third-party payors play in the decision of what drugs they authorize for treatment. The *UFCW Local 1776* case provides such an explanation when it states:

> "TPPs [third-party-payors] typically pay for a prescribed medication only if the drug is authorized under their formulary, a list of medications approved for payment. The formulary is usually managed by a Pharmacy Benefit Manager ("PBM"). PBMs manage approximately seventy-five percent of all outpatient drug claims. Drugs placed on a formulary are approved by the PBM's Pharmacy and Therapeutics Committee, made up of physicians and clinical pharmacists. PBMs maintain their formulary based upon publicly available clinical information, which is in large part produced and disseminated by the drug manufacturers themselves. TPPs have the right to customize their

> formulary beyond what the PBMs advise, but in practice TPPs rarely modify the recommendations of their PBMs. On the rare occasions when a TPP customizes its formulary, it generally does so in consultation with the PBM's Pharmacy and Therapeutics Committee."
>
> *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 126 (2d Cir. 2010)

The foregoing information discloses the extent to which third-party payors, such as Caesar Health Plan, play in the decision-making process of which drugs to underwrite and the extent to which that decision is made jointly with physicians and clinical pharmacists. Thus, as the Fourteenth Circuit aptly noted, it is the responsibility of the physicians to determine the efficacy and health-benefits for off-label prescriptions, based on their independent assessment of the patient, the medication, and review of any clinical research or test trials conducted by the pharmaceutical companies. R. at 32. "[I]t is their job, as healthcare providers, to provide adequate healthcare to their patients based on their years of medical training and experience." R. at 32-33.

Thus, third-party payors, like Caesar Health Plan, are free to underwrite prescriptions in order to maintain the relationships they have with the prescribing physicians and medical service providers. (R. at 32). Given the foregoing information, if the court in *UFCW Local 1776* found for the drug manufacturer, and felt that, despite the manufacturer having studies in-hand which were *not* falsified, relaying their drug's extensive side-effects, and despite the third-party payors using an FDA approved drug for FDA approved purposes, then this Court has ample reason to come to the same conclusion regarding the case at bar, when respondents relied on faulty studies and petitioners chose to use an off-label drug for non-FDA approved use.

B. THREE VARIABLES THIS COURT LISTED AS FACTORS IN DECIDING PREVIOUS CASES ARE PRESENT IN THIS CASE AND POINT TO A LACK OF PROXIMATE CAUSE.

1. There are Independent Factors that Account for Plaintiff's injury.

When the Romulus District Court relied on *Painters*, (which in turn relied on *Bridges*) it invoted a critical look at three variables that this Court listed in *Bridges* which prompted this Court to give standing to third-party payors. Specifically, this Court noted in *Bridges* that: "here, unlike in *Holmes* and *Anza*, 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. *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 658 (U.S. June 9, 2008) (emphasis added.) Each of those three variables will be addressed in turn beginning with the independent factors.

The first remote action is Caesar's administration of an *array* of off label drugs to patients, which had not been adequately shown to be safe when used together. R. at 5. The Romulus Board of Health reported that Glokoriza was generally safe, but it had never before been used with the other elements of Julius' protocol such as certain antibiotics Ippomarathron and Gentiane. Without knowing the extent to which that array of drugs interacted with Glukoriza, a court cannot properly apportion fault nor allocate damages. A second remote action was recognized, and stressed, by the Seventh Circuit in *UFCW Local 1776*, and is present in the instant case. Namely, the court corrected plaintiff's argument that "the ultimate source for the information on which doctors based their prescribing decisions was [the drug manufacturer] and its

consistent, pervasive marketing plan." *UFCW Local 1776,* 620 F.3d at 124. Rather, the court considered that doctors *also* base prescribing decisions on an individual patient's diagnosis, past and current medications being taken by the patient, the physician's own experience with prescribing the drug, and the physician's knowledge regarding the side effects of the drug in question. *Id.*

2. There is risk of duplicative injury, and there is a better situated plaintiff with incentive to sue.

As for the risk of duplicative recoveries by plaintiffs removed at different levels of injury, these are present because patients may sue, as may the surviving families of patients who died as a result of treatment, as may the prescribing physicians, as has the third party payor here. This litany of injuries resembles the very situation the Seventh Circuit referenced when it stated: "Payors part with money, to be sure, but it is not at all clear that they are the initially injured parties, let alone the sole injured parties." *Sidney Hillman*, 873 F.3d at 576. Finally, a better situated plaintiff with incentive to sue is the patient who took Glukoriza and still suffers from Miasmic Syndrome, and even endures kidney failure as a result.

C. REVERSING THE LOWER COURT'S DECISION WOULD BE DETRIMENTAL TO PUBLIC POLICY BY EXACERBATING A GLOBAL PANDEMIC.

The final appeal in this argument is in regards to public policy and competing public interests. The District Court concluded its application of the RICO issue by "recognizing the public interest in holding Galen accountable for its actions. . . ." (R. at 17). However, this Court must also weight the public interest in protecting people most directly impacted by the pandemic. This Court, as the highest arbiter in the

land, should not be motivated by vindication, but by pursuing the common good. The preamble to our Constitution demands no less. U.S. Const. Preamble. In a time where we lack a cure for the Miasmic Syndrome virus, and where we owe a remedy to those killed by the virus, the District Court's emphasis on vindication and "holding Galen accountable" is misplaced zeal. Therefore, rather than draining Galen's resources in this litigation, all of our efforts would be better spent freeing Galen to sponsor more clinical trials as it did in Alexandria, to test new or existing FDA-approved medications for Miasmic Syndrome, or sponsoring trials for studying the link between the increased dosage and the side effects that brought us to court today. (R. at 1).

When Petitioners chose to sue under a RICO theory, they undertook the burden of proving a direct relationship between the alleged fraud and the resulting injury. Petitioners did not succeed in proving that relationship. Rather, based on lack of proximate cause, independent factors that account for respondents' injury, risk of duplicative recoveries by plaintiffs removed at different levels of injury from the violation, and the presence of a more immediate victim better situated to sue, this Court should uphold the lower court's finding. This Court should recognize that requiring Respondents to pay third-party payors would be an inequitable and arbitrary allocation of blame in an unfortunate scenario that involved no fewer than six different key players and many missteps along the way. Between the faulty clinical trials, Galen's marketing of the drug, Julius Medical's promotion of the drug, physician's prescribing of the drug, Caesar Health's coverage of the drug, and patient's negative results with the drug, numerous variables exist which sever

proximate cause. Rather than allowing Petitioners to find a scapegoat for the tragic results of faulty clinical trials, this Court should uphold the lower court's Order, and reverse and remand the District Court's decision, so that Galen may continue the important work of responding to the current pandemic.

II. THIS COURT SHOULD UPHOLD THE LOWER COURT'S RULING BECAUSE CAESAR'S RIGHTS WERE NOT VIOLATED, AND, IN THE ALTERNATIVE, MS. CLEOPATRA IS IMMUNE FROM SUIT DUE TO QUALIFIED IMMUNITY.

Qualified immunity is a judicially created doctrine that "shields government officials from civil damages and liability," and therefore precludes them from suit. *Reichle v. Howards*, 566 U.S. 658, 664 (2012). However, for a government official to be immune from suit under qualified immunity, a court must utilize a two-prong analysis to determine (1) whether a constitutional or statutory right has been violated and (2) whether that right was clearly established. *District of Columbia v. Wesby*, 138 S. Ct. 577, 589 (2018); *see Reichle* 566 U.S. at 663.

A. Ms. Cleopatra is immune from suit under the doctrine of Qualified Immunity because the alleged violation was not clearly established at the time of the alleged misconduct.

To determine whether Ms. Cleopatra is immune from suit due to the doctrine of qualified immunity, the inquiry rests upon whether a constitutional or statutory right of Caesar Health Plan was violated, and whether that right was clearly established at the time the alleged violation occurred. *Wesby*, 138 S. Ct. at 589 (2018); *see Reichle* 566 U.S. at 663. Furthermore, for a government official to be immune from suit due to qualified immunity, both elements regarding a violation of a right and that the right was clearly established must be satisfied. *Reichle*, 566 U.S. at 664.

However, this Court in *Reichle* advised that "[c]ourts may grant qualified immunity on the ground that a purported right was not 'clearly established' … without resolving the often more difficult question whether the purported right exists at all." *Id.* at 664. Because Petitioner's rights were not violated, it follows that the analysis should begin with the first prong.

A right is clearly established for qualified immunity purposes when the allegedly violated right has "a sufficiently clear foundation in then-existing precedent …. that, at the time of the" alleged violation, "the law was 'sufficiently clear' that every 'reasonable official would understand that what [s]he is doing' is unlawful." *Wesby*, 138 S. Ct. at 589 (quoting *Ashcroft v. al-Kidd*, 563 U.S. 731, 741 (2011)). Additionally, a right or legal principle is clearly established when the right is "settled law, which means it is dictated by controlling authority or a robust consensus of cases of persuasive authority." *Id.* at 589-90 (internal quotation marks omitted). There must be binding authority that is "clear enough that every reasonable official would interpret it to establish the particular rule the plaintiff seeks to apply. Otherwise, the rule is not one that 'every reasonable official' would know." *Id.* at 590 (citations omitted); *see, e.g.*, *Reichle*, 566 U.S. at 664, 666.

In *Wesby*, this Court explained that for warrantless arrests, the rule is clearly established if "the circumstances with which the particular officer was confronted constituted probable cause." *Wesby*, 138 S. Ct. at 590 (quoting *Anderson v. Creighton*, 483 U.S. 635, 640-641 (1987)) (alteration in original). Here, Romulus, as well as the entire world, was attempting to manage an unprecedented pandemic that was highly

contagious, infecting millions, and killing thousands. (R. at 1). In response to the pandemic, the Romulus state legislature passed the Emergency Miasmic Syndrome Act (EMSA). R.C.L. § 18.8.891. Acting within the purview of the EMSA, Cleopatra, in her official capacity as the Romulus Board of Health Commissioner, issued an administrative subpoena to Caesar requesting any records related to the diagnosis and treatment of Miasmic Syndrome, or related to patients suspected of carrying Miasmic Syndrome, which included insurance claims and medical records, dated on or after May 1, 2019. (R. at 3-4, 9, 11). The EMSA was enacted approximately five months before the subpoena was issued and executed. (R. at 3-4, 11). Before petitioner filed its suit against respondent, there had not been any litigation or clarification regarding the EMSA, the responsibilities and duties that fall under the EMSA, nor the constitutional requirements to issue and execute an administrative subpoena. (R. at 12, 37-38). By issuing an administrative subpoena, Ms. Cleopatra was following the letter of the statutory authority that granted her the authority to do so. *See* R.C.L. 18.8.891(a). Finally, because there was no settled law on the authority granted to Ms. Cleopatra, nor was there even a chance for such the law to become settled, the allegedly violated constitutional right of Caesar Health Plan was not a right that any reasonable official in Ms. Cleopatra would understand was being violated. Therefore, the second requirement under the doctrine of qualified immunity that requires a right or legal principle be clearly established is not satisfied in this case.

Furthermore, the requirement that a legal principle or right be clearly established "protects the balance between vindication of constitutional rights and

government officials' effective performance of their duties by ensuring that officials can 'reasonably … anticipate when their conduct may give rise to liability for damages.'" *Reichle*, 566 U.S. at 664 (quoting *Anderson*, 483 U.S. at 639. Therefore, to further this purpose, the right allegedly violated must be established "'not as a broad general proposition,' … but in a 'particularized' sense so that the 'contours' of the right are clear to a reasonable official." *Id.* at 665. If a right is to be protected and not infringed upon by a government official, the official must understand what conduct is prohibited and the confines of their duties and of the right their duties may infringe upon so that the official can act accordingly.

In *Harlow*, this Court held that if the government official asserting the affirmative defense of qualified immunity "claims extraordinary circumstances and can prove that [s]he neither knew not should have known of the relevant legal standard, the defense should be sustained." *Harlow v. Fitzgerald*, 457 U.S. 800, 817 (1982). As previously stated, this health crisis is an unprecedented global pandemic that is infecting millions, (R. at 1), and the statute at issue was only enacted approximately five months prior to the conduct at issue here. In accordance with the *Harlow* Court, Ms. Cleopatra should be immune from suit, and therefore the Fourteenth Circuit was correct to reverse and remand, because this health crisis created such extraordinary circumstances that it did not afford the ability for Ms. Cleopatra to know, nor could she have known, that by utilizing her statutorily granted authority she would violate any statutory or constitutional right.

B. The Public Policy Rationale That Created the Doctrine of Qualified Immunity Dictates That Ms. Cleopatra's Motion to Dismiss Should be Granted.

The doctrine of qualified immunity rests on a public policy argument. Claims may be brought against innocent and guilty government officials, which generally results in society bearing the brunt of the costs of litigation. In *Harlow v. Fitzgerald*, this Court explained that "[t]hese social costs include the expenses of litigation, the diversion of official energy from pressing public issues, and the deterrence of able citizens from acceptance of public office," all of which can create a "danger that fear of being sued will 'dampen the ardor of all but the most resolute, or the most irresponsible public official, in the unflinching discharge of their duties.'" *Harlow*, 457 U.S. at 814. To minimize the social costs associated with litigation against government officials, the doctrine of qualified immunity attempts to balance the "importance of a damages remedy to protect the rights of citizens…" against "'the need to protect officials who are required to exercise their discretion and the related public interest in encouraging the vigorous exercise of official authority.'" *Id.* at 818 (quoting *Butz v, Economou*, 438 U.S. 478, 504-06 (1978)). Furthermore, to limit the costs further, "[r]eliance on the objective reasonableness of an official's conduct, as measured by reference to clearly established law, should avoid excessive disruption of government and permit the resolution of many insubstantial claims on summary judgment." *Id.*

Here, Ms. Cleopatra was acting in her official capacity as the Commissioner for the Romulus Board of Health. Acting as such, Ms. Cleopatra issued and executed an administrative subpoena pursuant to R.C.L. § 18.8.891, which allows the

Commissioner of the Board to issue a subpoena to a licensed hospital, R.C.L. § 18.8.891(a), or to any other entity, R.C.L. § 18.8.891(b), to request any documents related to the treatment and diagnosis of Miasmic Syndrome "to determine if a licensed hospital is providing substandard care for Miasmic Syndrome." R.C.L. § 18.8.891(b). The state of Romulus and the entire world continue to face an unprecedented pandemic that has been "infecting millions and killing thousands." (R. at 1). To help handle the health crisis, the Romulus Legislature granted the Commissioner this statutory authority to ensure compliance with medical practices, to prevent further harm to patients receiving Miasmic Syndrome care with the Julius-Caesar Health System, and to protect the public health. (R. at 3-4, 9). The underlying public policy arguments that motivated this Court to create and uphold the doctrine of qualified immunity support the dismissal of Caesar's claim under § 1983 because the costs and distraction associated with the litigation related to the search and seizure of medical records is taking away vital resources that the Board could be using to help mitigate the current crisis.

C. There Was No Violation of Petitioner's Constitutional or Statutory Rights Because Caesar Health Plan is a Part of a Pervasively Regulated Industry, the Fourth Amendment Balancing Shows Petitioner's Interests Were Outweighed by the Government's Interests, and the Subpoena Complied with the "Patel Rule."

The Fourth Amendment of the United States Constitution provides the right of people "to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures," and that right "shall not be violated, and no warrants shall issue, but upon probable cause, supported by oath or affirmation, and particularly describing the place to be searched, and the persons or things to be

seized." U.S. Const. amend. IV. This Court has held that the Fourth Amendment right applies equally to individual citizens as well as businesses and commercial properties. *See v. City of Seattle*, 387 U.S. 541, 543 (1967). Although this Court has elaborated on what the Fourth Amendment right from unreasonable search and seizure means, it has also carved out specific exceptions to the Fourth Amendment warrant requirement. One relevant exception applied to businesses that are so closely regulated that there is no expectation of privacy which allows warrantless searches and seizures for such businesses. *New York v. Burger*, 482 U.S. 691 (1987). Another noteworthy exception is for "warrantless search[es] pursuant to statutory authority." Opinion of the District Court of Romulus, R. at 19; *e.g., City of Los Angeles v. Patel,* 576 U.S. 409, 419 (2015). Moreover, this Court has begun to apply a balancing test to determine whether a search and seizure under the Fourth Amendment was reasonable. *Camara v. Municipal Court of San Francisco*, 387 U.S. 523 (1967).

1. **Caesar Health Plan qualifies as a pervasively regulated industry, and therefore falls under the Burger Exception, because there is a substantial government interest, the subpoena was necessary to further the regulatory scheme, and the subpoena was a sufficient constitutional substitute for a search warrant.**

In *New York v. Burger*, the United States Supreme Court carved out another exception to the Fourth Amendment warrant requirement. *Burger*, 482 U.S. 691. The *Burger* exception allows administrative, warrantless searches and seizures "of industries that 'have such a history of government oversight that no reasonable expectation of privacy' exists for individuals engaging in that industry." *Zadeh v. Robinson*, 928 F.3d 457, 464 (5th Cir. 2019). Furthermore, courts deem a business to be pervasively regulated after considering "the history of warrantless searches in the

industry, how extensive the regulatory scheme is, whether other states have similar schemes, and whether the industry would pose a threat to the public welfare if left unregulated." *Id.* at 465; *see Burger*, 482 U.S. at 704.

There is no need for the opportunity for a precompliance review because the healthcare industry is closely regulated. The *Burger* exception is essentially defined by the pervasiveness and regularity of the federal and state regulations and the effect of such regulations upon the owner's expectation of privacy, and the duration of the particular regulatory scheme. *Burger*, 482 U.S. at 701. In *Zadeh*, the board cited several laws and regulations governing the behavior of doctors, however, the court determined only a specific group of doctors, and not the industry as a whole, that was not closely regulated. *Zadeh*, 928 F.3d at 466. Here, the Board does not only have laws and regulations governing hospitals, but also those of any entity that is dealing with the Miasmic Syndrome. Thus, the state and federal laws and regulations do not merely regulate a specific singular group, but the industry as a whole. This Court in *Barlow's* stated, "[a] central difference between those cases [Colonnade and Biswell] and this one is that businessmen engaged in such federally licensed and regulated enterprises accept the burdens as well as the benefits of their trade …. The businessman in a regulated industry in effect consents to the restrictions placed upon him." *Marshall v. Barlow's, Inc.*, 436 U.S. 307, 313 (1978) (quotation omitted).

Furthermore, if hospitals and health insurance providers were not heavily regulated, that would pose a grave risk to public safety. The medical profession in its entirety is tasked with diagnosing and treating medical conditions, both physically

and mentally. The health insurance providers fall into the healthcare industry because they facilitate the ability for patients to get diagnosed and treated, and they help patients and families pay for such services. Without the laws and regulations that are currently in place, the medical profession would be a hazard to public health. Regulations, such as those under Chapter 18 of the Romulus Consolidated Law, ensure that hospitals are providing adequate care for patients and safeguard the public health and mandate compliance in the event they are not. Additionally, the United States as a whole regulates the medical profession through various acts such as the Health Insurance Portability and Accountability Act (HIPAA), and individual states have additional regulations such as those found in the State of Romulus.

Caesar Health Plan, as a closely regulated industry, falls within the exception for administrative searches thereby eliminating the requirement of a precompliance review. This is compounded by the fact that Caesar Health Plan is regulated by federal and state laws, with an even more specified industry that has even more regulations in dealing with Miasmic Syndrome, and most, if not all, states have a similar regulatory scheme for the medical profession. Finally, if the medical profession went unregulated, it would cause grave danger to the public health and safety.

So long as a business or industry is pervasively regulated, there is no requirement that the business upon whom the subpoena is served have an opportunity for pre-compliance review. *Id.* at 464. However, "warrantless inspections in closely regulated industries must still satisfy three criteria: (1) a substantial

government interest, (2) a regulatory scheme that requires warrantless searches to further the government interest, and (3) 'a constitutionally adequate substitute for a warrant.'" *Id.* at 464-65 (quoting *Burger*, 482 U.S. at 702-703).

In *Zadeh*, there was no dispute as to the first two elements because the state has a substantial interest in regulating the prescription of controlled substances and inspecting a doctor's records would help the government in regulating the industry. *Zadeh*, 928 F.3d at 467. Similarly, there is a substantial government interest in the treatment of Miasmic Syndrome to ensure public health and safety are protected during a global pandemic where substandard care for Miasmic Syndrome compounds the crisis by causing serious kidney damage or even death. Furthermore, the records of different patients would aid the government to determine whether the public health is being safeguarded, and to see whether substandard care is being given by different hospital systems.

When analyzing the third criteria of the *Burger* exception, the subpoena must be a constitutionally adequate substitute for a search warrant, which requires that the subpoena perform the two basic functions if a warrant: "it must advise the owner of the commercial premises that the search is being made pursuant to the law and has a properly defined scope, and it must limit the discretion of the inspecting officers." *Id.* (quoting *Burger* at 730). In *Zadeh*, the board issued a subpoena for the production of books, records, and documents. *Id.*

However, the court determined the subpoena was too discretionary because the board was allowed to choose what doctors to subpoena and when to do so, and there

was "no identifiable limit on whose records can properly be subpoenaed." *Id.* In contrast, here the Board not only can subpoena licensed hospitals, but it can also subpoena any entity that would be able to provide records or documents to show substandard care for Miasmic Syndrome. R.C.L. § 18.8.891. Moreover, the scope of the administrative subpoena is limited to only records that are related to the diagnosis and treatment of patients with confirmed or suspected cases of Miasmic Syndrome. (R. at 9). Finally, the Commissioner can only issue a subpoena if there is reasonable suspicion substandard care is being provided for Miasmic Syndrome, or to random licensed hospitals "as part of a documented and fair methodology for conducting random inspections." R.C.L. § 18.8.891.

In *Dewey*, the Act prohibited forcible entries and required that those upon whom the subpoena is served file a civil action in a federal court to obtain an injunction against future refusals. *Donovan v. Dewey*, 452 U.S. 594, 606 (1981). However, here, if an entity refuses to comply with the subpoena the Board may seek a court order and if there is a petition by the entity that is the target of the subpoena the Board shall review it and may amend or quash it by a majority vote and no entity will be penalized so long as they preserve all evidence sought by the subpoena and failure to do so may constitute obstruction of justice. R.C.L. § 18.8.891. Moreover, the statute notifies the hospital or entities that inspections will be performed either because of reasonable suspicion or the fair methodology of random selection. It also informs them of what the statute is designed for and thus is looking for substandard care of Miasmic Syndrome. R.C.L. § 18.8.891.

Therefore, this Court should hold that the warrantless administrative subpoena was reasonable under the 4th Amendment because the state had a substantial interest in regulating the standard of care for miasmic syndrome and it is necessary to protect its citizens in regulating the care they receive from different hospital systems. Moreover, the subpoena was constitutionally adequate to replace the warrant because it limited the discretion and scope of inspecting officers and lastly, the search was being made pursuant to the law.

2. The Fourth Amendment balancing approach shows that there was no violation because the government's interests outweigh those of the Petitioner.

Generally, a search requires probable cause to create the basis for a warrant, and that warrant must be issued by a neutral and detached magistrate. U.S. Const. amend. IV. The probable cause standard first considers the "governmental interest which allegedly justifies official intrusion upon the constitutionally protected interests of the private citizen" to determine whether the search or seizure was reasonable. *Camara*, 387 U.S. at 534-535. In other words, the Camara Court relied more heavily on whether the search and seizure was reasonable, rather than whether there was probable cause for a search and seizure. *Id.*

In *Camara v. Municipal Court of San Francisco*, this Court began to utilize a reasonableness balancing approach to determine whether the warrant requirement was necessary. *Id.* at 523. This Court explained that in considering whether to create an exception to the warrant requirement, "the question is … whether the authority to search should be evidenced by a warrant, which in turn depends in part upon whether the burden of obtaining a warrant is likely to frustrate the governmental

purpose behind the search." *Id.* at 533. Furthermore, when public interest demands that there be an exception to the warrant requirement, the reasonableness requirement of the Fourth Amendment is still necessary. *Id.* at 535. Under the reasonableness requirement, a search or seizure is "'reasonable' only when there is 'probable cause' to believe that [the items sought] will be uncovered in a particular [location]." *Id.*

The municipal code that was at issue in *Camara* was one that regulated housing inspections to determine their compliance with the municipal building and housing codes. *Id.* The Court explained that "[t]he primary governmental interest at stake [was] to prevent even the unintentional development of conditions that were hazardous to public health and safety." *Id.* This governmental interest must then be weighed against the need for the search or seizure and against the rights of those it might infringe upon. *Id.* This Court found the code enforcement inspection at issue in *Camara* was reasonable based on several factors, the long history of judicial and public acceptance, the public interests demands that all dangerous conditions be prevented or abated" when there is no alternative to achieve the goals sought from the code, and "[f]inally, because the inspections are neither personal in nature nor aimed at the discovery of evidence of crime, they involve a relatively limited invasion of the urban citizen's privacy". *Id.* at 537. This Court elaborated with the same reasoning from the case it explicitly overruled, quoting *Frank v. Maryland*, that "to treat a specific problem," such as a global health crisis, "[t]ime and experience have forcefully taught that the power to inspect … is of indispensable importance to the

maintenance of community health …. The need for preventative action is great, and city after city has seen this need and granted the power of inspection to its health officials…." *Id.* (quoting *Frank v. Maryland*, 359 U.S. 360, 372 (1959)). Although this Court determined that both the inspection and its accompanying municipal code were reasonable, it also found that the legislative and administrative standards, such as the length of time between inspections and the nature and condition of the building and the surrounding area, did not foreclose the appellant's "constitutional right to insist that the inspectors obtain a warrant to search…" *Id.* at 538-539.

Although the *Camara* Court found that the appellant's constitutional rights had been violated, this Court cautioned that its holding is not "intended to foreclose prompt inspections, even without a warrant, that the law has traditionally upheld in emergency situations." *Id.* at 539. Furthermore, this Court provided several cases to illustrate where exigent circumstances, such as mandatory vaccinations, quarantines, destroying infected cattle, and seizing "unwholesome food," were of such urgency that the warrantless searches and seizures did not violate the Fourth Amendment. *Id.* This Court also endorsed the "prevailing local policy … of authorizing entry, but not entry by force, to inspect," and therefore "as a practical matter … it seems likely that warrants should normally be sought only after entry is refused unless there has been a citizen complaint or there is [an]other satisfactory reason for securing immediate entry." *Id.* at 539-40. Here, the exigent circumstances of the pandemic coupled with the urgency that was created through improper usage

of the prescription medication Glukoriza made the warrantless search and seizure requested through an administrative subpoena reasonable under the circumstances.

Based on the reasonableness and interest balancing approach the Court employed in *Camara*, experience and logic dictate that the issuance and execution of an administrative subpoena – pursuant to a statutorily granted authority during a global pandemic and health crisis – was reasonable under the circumstances and did not violate the Fourth Amendment.

a. The Patel exception to the warrant requirement was applicable because there was a special need making the warrant requirement impracticable, the primary purpose of the subpoena was not for crime control, and Petitioner had a chance for pre-compliance review.

In *Los Angeles v. Patel*, the Supreme Court created still another exception to the Fourth Amendment warrant requirement. *Patel*, 576 U.S. 409. As the Romulus District Court explained the "Patel Rule,"

> A warrantless search performed pursuant to statutory authority may be reasonable where three conditions are met. First, "special needs" must "make the warrant and probable cause requirement impracticable." Second, the "primary purpose of the searches" must be "distinguishable from the general interest in crime control." Third, while "administrative searches" conducted under such conditions may … be reasonable, "the subject of the search must be afforded an opportunity to obtain precompliance review before a neutral decisionmaker" unless another exception applies.

Opinion of the District Court of Romulus, R. at 19 (emphasis removed) (citations omitted).

The first *Patel* element is satisfied because the exigent circumstances made the warrant requirement impracticable. Patel, 576 U.S. at 420. The Miasmic Syndrome global pandemic and kidney failure that resulted from substandard treatment of Miasmic Syndrome, created an exigency that the world has not yet faced.

Had Ms. Cleopatra or the Board not responded with such urgency, more deaths could have resulted, or more patients could have faced untold dangers resulting from the cocktail of drugs Julius Medical administered in its "array of off-label drugs[.]" (R. at 5, 37). As the Appellate Court reasoned, "[a] reasonable officer in [Cleopatra's] position could have believed that EMSA subpoenas were inherently exigent, because they are necessary to combat an ongoing pandemic." (R. at 37).

The second *Patel* element is met because the administrative subpoena was not issued for the general purpose of detecting crime, but to regulate hospitals and determine whether the hospital was providing substandard care. The Romulus District Court also found that the first two requirements were satisfied, (R. at 20), and it is likely that the United States Court of Appeals for the Fourteenth Circuit would have held likewise if it had not followed this Court's advice on determining whether qualified immunity is applicable by dealing with the clearly established element first rather than the Fourth Amendment issue, (R. at 39).

The third requirement for the administrative search applies unless there is a previously established exception to the warrant requirement. *Patel,* 576 U.S. at 419. The Emergency Miasmic Syndrome Act (EMSA), codified in R.C.L. § 18.8.891, provides the petitioner an opportunity for the full Board to review the subpoena and amend or quash it. R.C.L. § 18.8.891. The administrative subpoena referenced the EMSA shows that there is an opportunity for precompliance review. Therefore, because the exigency made the warrant requirement impracticable, the subpoena was

not issued for general crime control, and Caesar was provided with the opportunity for precompliance review, no Fourth Amendment right was violated.

Respondent Cleopatra requests this Court affirm the appellate court's judgment remanding Petitioner Caesar's Civil Rights claim under § 1983 to the district court for dismissal. There was no violation of a constitutional or statutory right of Caesar, and even if there was, Ms. Cleopatra is immune from suit under the doctrine of qualified immunity because the alleged violation was not clearly established at the time of the misconduct.

CONCLUSION

For the foregoing reasons, Ms. Cleopatra respectfully requests that this Court affirm the judgment of the United States Court of Appeals for the Fourteenth Circuit finding that Caesar lacked standing to assert a civil RICO claim under 18 U.S.C. § 1964, and that Ms. Cleopatra was immune from suit due to the doctrine of qualified immunity.

DATED this 16th day of October, 2020.

Respectfully submitted,

Livia Cleopatra, Respondent

By: /s/ Team 212_____

Attorneys for Respondent