Docket No. 2020-01

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 Petitioner

## QUESTIONS PRESENTED

I. Whether a third-party payor has standing in a civil RICO claim against a pharmaceutical manufacturer who fraudulently misrepresented information about their drug directly to the TPP who would not have added the drug to their formulary but their reliance on the misrepresentations.

II. Whether a government official who orders the warrantless search of medical records from a health insurance company violates the Fourth Amendment, and if so, whether the official is protected from liability by the doctrine of Qualified Immunity.

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## CONSTITUTIONAL PROVISIONS INVOLVED

This case involves U.S. Const. amends. IV and XIV.

## STATEMENT OF THE CASE

### I. Factual History

In May 2019, a novel, highly infectious virus was discovered in Alexandria; the virus, Miasmic Syndrome, quickly spread, becoming a pandemic in months, infecting millions and killing thousands. (R. at 1.) In response to the pandemic, many pharmaceutical companies began testing existing drugs in "off-label" uses to treat Miasmic Syndrome. (*Id.*) One such company resides in Romulus; Respondent, Galen Research, had released Glukoriza, an FDA approved cancer medication, but announced testing results that indicated the drug may alleviate Miasmic Syndrome fatality rate and reduce recovery time. (*Id.*) Galen initially struggled to sell Glukoriza as a cancer treatment, achieving only limited market success; however, in 2019 once marketed as a treatment to Miasmic Syndrome, Galen increased production and found more market penetration. (R. at 2.) Galen marketed Glukoriza to physicians and insurance companies to persuade them to include Glukoriza as a possible treatment for Miasmic Syndrome. (*Id.*) Galen's recommended treatment of Miasmic Syndrome with Glukoriza required a much

higher dosage, four doses in two weeks, than when used as a treatment for cancer, one dose in six months. (R. at 1.) After mixed success, Galen scored a notable client in Romulus, Julius-Caesar Health System. (R. at 2.)

Julius-Caesar Health System is a formal partnership between a hospital system, Julius Medical Center, and the Caesar Health Plan, a health insurance company. (*Id.*) Under the agreement, almost all of Julius's patients are members of Caesar and Caesar encourages all members to receive their care at Julius by requiring prior authorization before going elsewhere. (*Id.*) Julius and Caesar are legally separate entities that operate in close coordination. (*Id.*) In agreeing to use Glukoriza as a Miasmic Syndrome treatment, Julius agreed to educate its physicians about the drug and Caesar agreed to fully cover the costs of prescribing Glukoriza as a Miasmic Syndrome treatment. (R. at 3-4.)

In response to various counterfeit, adulterated, and otherwise dangerous drugs promising a miracle cure for Miasmic Syndrome, the State of Romulus passed the Emergency Miasmic Syndrome Act (EMSA). (R. at 3.) The EMSA authorizes the Board of Health ("the Board") to inspect and collect records from any medical facility via an administrative subpoena for evidence of knowing or negligent, substandard care for Miasmic Syndrome. (R. at 3; *see* Appendix I.) The EMSA requires any subpoena to be narrowly drawn and can only be enforced against a licensed hospital (*Id.*) After over 10,000 prescriptions filled and paid for by Caesar, researchers at Julius were able to ascertain: (1) Glukoriza had no discernable effect in curing or ameliorating Miasmic Syndrome maladies; and, (2) Glukoriza caused

10% of patients, who received the recommended, condensed regiment, serious loss of kidney function. (*Id.*)

In March 2020, the Board received reports of patients seen at Julius Medical Center and the adverse effects Glukoriza was causing. (R. at 4.) The Board, led by Commissioner Livia Cleopatra, issued a subpoena ordering both Julius and Caesar to turn over all relevant medical records related to patients diagnosed with, tested for, or suspected of carrying Miasmic Syndrome. (*Id.*) Two groups of armed agents served the same subpoena, *see* appendix II, on each organization simultaneously. (*Id.*) Julius's attorneys challenged the subpoenas and refused to comply with the agent's demands even after agents threatened to arrest the Julius employees for obstruction of the investigation. (R. at 3, 4.) Caesar employees, absent their attorneys, initially refused to comply with the subpoena, but after being threatened with arrest they immediately turned over all documents and records regarding claims at Julius. (*Id.*)

The EMSA gives no arresting authority to the Board and requires a full board petition if a subpoena is questioned; the subpoena here made no mention of that right. (*See* appendix I, II.) The subpoena authorized the seizure of materials related only to Miasmic Syndrome claims; however, all of the claims from Julius Health Center were confiscated from Caesar. (R. at 5; Appendix I) The Board's agents intentionally executed the subpoena to create a sense of urgency intended to reduce the chances it would be questioned. (*see* Appendix III.) On March 30th,

based on the information received from the subpoena, and by unanimous vote, the Board suspended Julius's operating license. (R. at 5.)

On March 30th, the same day the subpoenas were executed, a whistleblower from Galen Research came forward with evidence suggesting Galen had falsified data and failed to properly follow up with patients serving as test subjects for Glukoriza treatment for Miasmic Syndrome. (*Id.*) Galen, whose sole proprietor is Livia Cleopatra, had intentionally not followed up with patients because of suspected harmful side effects; Galen researchers and staff systematically hid any report of the side effects. (*Id.*) After the whistleblower report was released, Cleopatra felt compelled to resign as Board of Health Commissioner; within two weeks, a new commissioner was named, and Julius's operating license was reinstated. (R. at 6.) Julius was able to show that all of their patients' excess kidney morbidity was directly caused by Glukoriza in treating Miasmic Syndrome. (*Id.*) While Julius's license was revoked, Julius-Caesar reported a loss of 15,000 members. (*Id.*)

## II. Procedural History

On May 1, 2020, Petitioner instigated two suits against Respondent, Livia Cleopatra. (R. at 6.) The first, as the sole proprietor of Galen Research, a civil RICO claim under 18 U.S.C. § 1964(c) alleging Galen induced Petitioner to underwrite prescriptions of and add Glukoriza to their formulary by means of fraud and absent that fraud, Petitioner would not have made any payments for Glukoriza. (*Id.*) The Second, against Cleopatra in her capacity as Commissioner of the Board, a 42

U.S.C. § 1983 civil rights claim alleging that she authorized an unconstitutional search, prohibited by the Fourth and Fourteenth Amendment. (*Id.*) Cleopatra filed a 12(b)(6) motion to dismiss the suits based on: first, Caesar lacks standing to allege a RICO violation; and, second, the EMSA subpoena was not in violation of any cognizable constitutional right, and even if it was, that the suit is barred by the doctrine of Qualified Immunity because such right was not recognized at the time of the alleged violation. (R. at 7.) The District Court rejected the 12(b)(6) motion. (R. at 7.; Opinion of the District Court of Romulus, R. at 27.) Cleopatra appealed the District Court's denial to the Fourteenth Circuit, who reversed the District Court's decision and ordered the motion granted in its entirety. (R. at 7; Opinion of the Fourteenth Circuit, R. at 39.) Petitioner was granted a writ of certiorari by this Court on both the RICO standing and constitutional questions. (R. at 7; R. at 40.)

## SUMMARY OF THE ARGUMENT

### I.

Petitioner, a third-party payor, has standing in a civil RICO suit against Respondent, a pharmaceutical company, that misrepresented the safety of their drug, Glukoriza, to increase sales. Petitioner directly relied on Respondent's misrepresentation and included it in their formulary, making Glukoriza their preferred treatment for Miasmic Syndrome. When Petitioner was made aware of Glukoriza's side effect risks, Petitioner removed it from the formulary. Respondent's violation is both the but for and proximate cause of Petitioner's injury, Petitioner's injury satisfies the three *Holmes* factors, and finding TPP standing among the

circuits can be observed. Accordingly, this Court should find Petitioner has standing in a RICO claim against the Respondent, reverse the Fourteenth Circuit Court of Appeals, and remand the case back to the District Court.

II.

Respondent, a government official, ordered a warrantless search of Petitioner, a health insurance company. Respondent was directly responsible for the manner in which the subpoena was executed and as such is liable under 42 U.S.C. § 1983 for the violative nature of the subpoena. The subpoena's lack of any precompliance review, neutral or otherwise, is in violation of the third *Patel* factor making the subpoena a violation of Petitioners Fourth Amendments rights. Additionally, Respondent is not entitled to protection under the doctrine of Qualified Immunity because the law surrounding this type of search is clearly established, and Respondent's actions were in violation of that law. Accordingly, this Court should find that the Respondent is not protected from liability under 42 U.S.C. § 1983, reverse the Fourteenth Circuit Court of Appeals, and remand the case back to the District Court.

## ARGUMENT

### I. Petitioner has standing in a civil RICO suit against Respondent because Respondent's fraud misrepresenting Glukoriza's safety directly caused Petitioner to pay for Glukoriza and was the proximate cause of Petitioner's injury.

Racketeer Influenced & Corrupt Organizations Act ("RICO") statutes were originally adopted to prosecute criminal activity but have created an avenue for "recovery in fraud cases brought against both and legitimate and illegitimate

enterprises." 18 U.S.C. § 1964(c)-(d); *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 499 (1985). In order to bring a civil RICO claim, the plaintiff bears the burden to prove two elements, a criminal RICO violation under 18 U.S.C. § 1962 and civil "RICO standing," under 18 U.S.C. § 1964. *Painters & Allied Trades District Council 82 Health Care Fund v. Takeda Pharm. Co.*, 943 F.3d 1243, 1248 (9th Cir. 2019). A plaintiff must prove "that the defendant engaged in (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity," in order to satisfy a violation of § 1962. *Chaset v. Fleer/Skybox Int'l. LP*, 300 F.3d 1083, 1086 (9th Cir. 2002) (citing 18 U.S.C. § 1962). Mail or wire fraud satisfies as a violation of 18 U.S.C. § 1962. *Hemi Grp. LLC v. City of New* York, 559 U.S. 1, 9 (2010). In order to allege standing, a plaintiff must show "injur[y] in his business or property *by reason of* a violation of section 1962 of this chapter." 18 U.S.C. § 1964(c) (emphasis added); *See, Hemi*, at 9 (plaintiff must show that violation "not only was a 'but for' cause … but was the proximate cause as well."). Congress modeled 18 U.S.C. § 1964(c) on civil-action provisions of federal antitrust laws that have been read to incorporate common-law principles of proximate causation. *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 267, 268 (1992) (finding that congressional use of § 7 of the Sherman Act and § 4 of the Clayton Act to form § 1964(c) signaled the intent to adopt, "the judicial gloss that avoided a simple literal interpretation"). Justice Souter enumerates a three-factor consideration the Court must address for proximate cause in a civil RICO case: (1) the less direct the injury is, the more difficult to ascertain the amount of plaintiff's damages caused by the violation; (2) recognizing

indirectly injured plaintiffs risks multiple recoveries; and, (3) more directly injured plaintiffs will attempt to vindicate their rights. *Id.* at 269-70 (internal citations omitted).

Here, Respondent does not dispute the alleged RICO violation, that there was an injury to Plaintiff's business or property, or that there was a pattern of racketeering activity. The only issue for this Court to decide is whether Respondent's alleged RICO violations were the proximate cause of the Petitioner's injury. Petitioner's injury is directly related to the violation, Petitioner's damages are not unreasonably difficult to ascertain, there is little chance for multiple recoveries, and the Petitioner is among the most direct plaintiffs for the harm it incurred. This Court should find that Respondent's RICO violation is both the but for and the proximate cause of the Petitioner's injury; therefore, the Petitioner has standing for a civil RICO claim.

Proximate causation serves as a limiting principle to reduce a flood of litigation and restricts a person's liability for the consequences of their acts. *Holmes*, 503 U.S. at 268. Historically, directness is a central element needed in order to allege plaintiff standing in RICO claims. *Ibid.* (holding civil RICO claims legislation, § 1964, was based on prior anti-trust legislation that required a direct relationship between the violation and injury). Generally, a court will not go beyond the first step when determining whether damages are directly caused by an action. *Id.* at 271. The Supreme Court has opined that proximate cause is a "flexible concept that does not lend itself to a black-letter rule that will dictate the result in

every case." *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639, 654 (2008) (finding that proximate cause is intended to limit the downstream effects of the defendant's actions, not keep a directly injured plaintiff from recovering).

A violation does not directly cause the injury when there are intervening causes and the link between the violation and injury is "too remote," "purely contingent," or "indirect[t]." *Holmes*, 503 U.S. at 271, 274 (finding that where the plaintiff's injury was "purely contingent" upon harm to a third party, the link between defendant's alleged violation and plaintiff's harm was too remote). The Supreme Court has not made a distinction about temporal proximity when evaluating the standing of a plaintiff in RICO suits. *Painters*, 943 F.3d at 1258. Plaintiff's reliance on the defendant's fraud is not necessary for the plaintiff to recover, nor is it necessary that the fraud be directed at the plaintiff. *See Bridge*, 553 U.S. at 646, 659 (finding while first-party reliance tends to show indirect injury, first-party reliance is not a requirement for proximate cause).

While claims by individual patient plaintiffs will almost certainly have RICO standing against a drug company that fraudulently misrepresents the safety of a drug, circuits are split as to whether patients' insurance companies or third-party payors (TPPs) also have standing. *See Painters*, 943 F.3d at 1257 n.13 (finding the First, Third, and Ninth Circuits concluded TPPs have standing in civil RICO claims against drug manufacturers, while the Second and Seventh Circuits have found TPPs too far removed to have standing). The Second and Seventh Circuit cases are, however, factually distinguishable; the underlying RICO violation was a drug

company illegally advertising their drug to physicians for off-label use, not misrepresenting the safety of the drug. *See UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010); *Sidney Hillman Health Center v. Abbott Labs*, 873 F.3d 574 (7th Cir. 2017). The First, Third, and Ninth circuit cases are factually on point. In all three Circuits, a pharmaceutical manufacturer misrepresented or omitted information about the drug they promoted physicians. *See Painters*, 943 F.3d 1243; *St. Luke's Health Network, Inc. v. Lancaster Gen. Hosp.*, 967 F.3d 295 (3d Cir. 2020); *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013).

### A. The Second and Seventh Circuit cases are factually distinguishable from Petitioner's case against Respondent.

The most recent Second and Seventh Circuit cases concerning TPP standing in civil RICO claims are factually distinguishable from the Petitioner's case against Respondent. *See UFCW Local*, 620 F.3d 121; *Sidney Hillman*, 873 F.3d 574. The Seventh Circuit had previously adjudicated a factually similar case, *Desiano v. Warner-Lambert Co.*, and found TPP standing in a civil RICO claim. 326 F.3d 339, 349 (2d Cir. 2003). This Court should find the facts of this case warrant holdings contrary to the Second and Seventh Circuit holdings.

The Second Circuit most recently declined to extend standing to a class of TPPs in situations where a safe drug was advertised for off-label purposes. *UFCW Local*, 620 F.3d 121, 123 (2d Cir. 2010). The class of TPPs was alleging two damage theories: (1) the "excess price theory" – that they overpaid for defendant's drug because of defendant's misrepresentations; and (2) the "quantity effect theory" that

they paid for prescriptions they otherwise would not have but for defendant's misrepresentations. *Id.* at 134. The Second Circuit held both damage theories were "too attenuated" because they rested with decisions by a third party, the physicians in deciding to prescribe, and the harm to a fourth party, the patients thus failing the first *Holmes* factor. *Holmes*, 503 U.S. at 269; *UFCW Local*, at 134, 135 (finding the plaintiff's argument that the ultimate source of information which physicians based their prescribing opinions was from the manufacturer unpersuasive). The Second Circuit could not certify the entire class of TPPs seeking standing for either damage theory; however, individually, a TPP could prove standing for RICO purposes via the quantity effect theory. *Id.* at 137 (the case was remanded for findings consistent with this holding, but the case settled before any determination by the District Court); *see e.g. Desiano*, 326 F.3d at 349 (finding the defendant's alleged misrepresentation directly caused economic loss to plaintiff TPP as they would not have purchased defendant's product). The Seventh Circuit found civil RICO standing for TPPs where the alleged misrepresentation was about the safety of the drug. *Desiano*, 326 F.3d at 349. The facts of this case are more similar to *Desiano* and warrant a similar finding.

In *Sidney Hillman*, the Seventh Circuit declined to extend civil RICO standing to TPPs, finding the direct causation between the alleged violation and injury to the TPPs too remote. 873 F.3d at 574, 575-76. The pharmaceutical company illegally marketed a drug for off-label use to physicians. *Id.* at 575, 576. Doctors prescribed it, but it was unclear whether the drug was effective so TPPs

sued. *Id.* at 576. The Seventh Circuit concluded the connection was too remote by considering three possibilities: first, the drug may have been useful to some patients; second, the difficulty in ascertaining when off-label prescriptions began as a result of the campaign and not beforehand; and three, physicians may consider factors independently of the marketing campaign. *Id.* at 577; *contra In re Neurontin*, 712 F.3d at 37 (finding the causal chain between drug company misrepresentation and injury to a TPP was "anything but attenuated," because the marketing program only worked if doctors prescribed the drug).

The Seventh Circuit opined that while TPPs parted with money, "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. The court found that patients were the most directly injured parties, not TPPs or the physicians, alluding to the first and second *Holmes* factors. *Holmes*, 503 U.S. at 269; *Sidney Hillman*, 873 F.3d at 576 (noting that the patients' health and financial loss come first in line temporally). This distinction, temporally different injured plaintiffs, has never been made by the Supreme Court. *Painters*, 943 F.3d at 1258 (holding multiple parties can be directly injured by the same RICO violation and that neither plaintiff should be favored over the other). The Seventh Circuit ended the *Sidney Hillman* opinion by holding, "that improper representations made to physicians does not support a [civil] RICO claim by [third-party] Payors." 873 F.3d at 578. Whether the misrepresentations were directed at physicians or the TPPs is a material differentiation. *In re Nat'l Prescription Opiate Litig.*, No. MDL 2804, 2020 Dist. LEXIS 30360, *79 (N.D. Ohio

Feb. 21, 2020) (finding the pharmaceutical company's misrepresentations were directed at the TPP, thus, *Sidney Hillman* would be improper to apply); *see also Painters*, 943 F.3d at 1259, 1260 (finding direct reliance is not necessary for standing in a civil RICO claim, but may aid in determining direct causation). *Sidney Hillman* is factually and materially distinguishable from the case before this Court; this case demands a different holding applied.

Petitioner's case is factually similar to *Desiano*: a pharmaceutical company misrepresents the safety of their drug, inducing a TPP to approve and underwrite the prescription of the drug for an off-label purpose to its insureds. (R. at 2.) Petitioner directly relied on Respondent's fraud when Respondent marketed the 'miracle' drug for Miasmic Syndrome directly to the Petitioner. (R. at 2-3, 6.) Petitioner would not have added Glukoriza to their formularies *but for* Respondent's false representations that: (1) the drug was safe; and, (2) the drug was effective as a treatment for Miasimc Syndrome. (R. at 2, 3.) Upon receiving and reviewing information that showed the ineffectiveness and safety issues of Glukoriza, Petitioner immediately revoked its status as a prescribable drug. (R. at 3.) Respondent knew of the dangerous side effects of the drug and intentionally omitted that information when marketing the drug to Petitioner. (R. at 5, 6.) Petitioner was to use the drug for off-label purposes, but Petitioner's claim is based on Glukoriza's ineffectiveness on the off-label use *and* its safety risks. (R. at 6.)

Petitioner's claim based on the quantity-effect theory; Petitioner as a TPP would not have paid for any prescriptions had they known Respondent's fraudulent

misrepresentations. (*Id.*) Petitioner directly relied on Respondent's fraud when Respondent marketed Glukoriza to both TPPs and physicians. (R. at 2.) Petitioner is a single TPP, therefore not a class of TPPs, seeking a RICO claim against a single pharmaceutical company that misrepresented information about their drug directly to the Petitioner, not through a potential third party. (*Id.*) Petitioner's damages are relatively easy to determine, there were no other TPPs or parties economically injured like Petitioner, and Petitioner is the best-situated plaintiff for the damages it suffered.

### B. There is a clear movement toward including TPP civil RICO claims against pharmaceutical companies.

A clear movement towards TPP standing in civil RICO claims against drug manufacturers' fraud and misrepresentation is observable and is supported by strong policy arguments. *E.g. In re Neurontin*, 712 F.3d at 39-40; *Painters*, 943 F.3d 1243; *In re Avandia Marketing, Sales & Product Liability Litig.*, 804 F.3d 633 (3d Cir. 2015); *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, No. MDL No: 2785, 2020 U.S. Dist. LEXIS 40789, at *163 (D. Kan. Feb. 27, 2020) (finding that the Tenth Circuit would likely follow [the First, Third, and Ninth Circuit's] lead and apply their principles to this case); *In re Nat'l Prescription Opiate Litig.*, LEXIS 30360, at 72-73 (finding "more persuasive [holding] … the Circuits that have allowed TPP claims against pharmaceutical companies to proceed"). This Court should cement the trend as a rule.

The Ninth Circuit, in *Painters*, weighs the holdings from the Third, Seventh, Second, and First Circuits in determining whether TPPs have standing against a pharmaceutical company in a RICO claim. 943 F.3d 1253-57. In *Painters*, a pharmaceutical company misrepresented and omitted the risk of bladder cancer associated with their drug, Actos, to physicians, consumers, and TPPs. *Id.* at 1247. The Ninth Circuit allowed a TPP to proceed in recovery on the basis of the quantity effect theory, on the basis that the TPP only sought to recover economic damages associated with the prescriptions, not patients' personal injury claims from taking Actos. *Id.* at 1247-48. There is a difference between fraudulent promotion for an off-label use and fraudulent failure to warn of a drug's risks of causing serious health risks. *Id.* at 1258. A drug manufacturer's failure to warn TPP, physicians, or patients of dangerous side effects makes damages more clearly attributable to the pharmaceutical company's alleged RICO violation. *Painters*, 943 F.3d at 1258 (finding the damages claimed from *Sidney Hillman* and *UFCW Local* are less directly attributable to the false promotion). A serious health risk would materially influence prescribing physicians' decisions on whether to prescribe the drug. *Painters*, 943 F.3d at 1258 (citing a study that 75% of physicians would have prescribed differently if they had known the risks of Actos). While the Seventh and Second Circuits determined physician's prescription were intervening causes, the Ninth Circuit correctly recategorizes the physicians as *intermediaries* and do not break the chain of proximate cause. *Painters*, 943 F.3d at 1257 (finding since the drug is "required to be prescribed," the act of prescription should not break the

causal chain because it is a foreseeable action). This Court should hold similarly allow the Petitioner the opportunity to prove a similar fact pattern.

That opportunity was afforded to a TPP plaintiff, in *In re Neurontin*, a First Circuit case which, on appeal, affirmed a jury's decision to award RICO damages to a TPP, Kaiser, after a pharmaceutical company, Pfizer, misrepresented information about their drug, Neurontin. 712 F.3d 21, 31. Pfizer marketed Neurontin for an off-label use and was found to be ineffective for that use; Kaiser directly relied on Pfizer's representations when they added Neurontin to their formulary. *Id.* at 38. The First Circuit rejected Pfizer's core defense of a break in the causal chain occurring when physicians prescribed Neurontin. *Id.* at 38, 39 (finding the causal chain was "anything by attenuated," because Pfizer's marketing scheme intended more prescriptions written in order to increase profit; only TPPs would pay for that profit). Kaizer sought only economic recovery for only the prescriptions it was fraudulently induced to pay for. *Id.* at 39 n.14 (finding first-party reliance not necessary to prove Kaiser's damages, but Pfizer targeting Kaiser shows that Kaiser was viewed as a third or fourth party). Kaiser added Neurontin to their formulary, or approved list of medicines, based directly on the misrepresentations of Pfizer and was allowed to recover for the RICO damages for prescriptions they would not have made but for the misrepresentation. *Id.* at 47. This Court should allow Petitioner the same opportunity Kaiser had; Petitioner should be able to present evidence to prove they underwrote prescriptions they would not have otherwise underwritten but for Respondent's fraud.

TPP reliance on pharmaceutical manufacturers' representations satisfies the *Holmes* considerations on directness; TPP damages are sufficiently direct. *In re Avandia*, 804 F.3d at 646. First, when a TPP bases its damages on the quantity effect theory and can prove prescriptions arising directly from the pharmaceutical company's misrepresentation, the damages are not unreasonably difficult to ascertain. *Painters*, at 1258, 1260; *In re Neurontin*, 712 F.3d at 46 (finding no reason why the theory would not be viable "with respect to individual claims by some TPPs"); *In re Avandia*, 804 F.3d at 644-45 (finding neither the quantity effect theory nor the excess price theory prohibited a TPP from RICO standing). Moreover, fact determination is necessary to determine whether the damages are too distinct from the alleged violation. *In re Avandia*, 803 F.3d at 645. Second, a TPP plaintiff seeking purely economic damages, as is the case here, does not require the court to adopt "complicated rules apportioning damages among plaintiffs" which would risk double recovery. *Holmes*, 503 U.S. at 269; *In re Avandia*, 803 F.3d at 645 (finding the damages alleged could only be recovered by the TPP plaintiff). The injury TPPs suffer is distinct from the potential harm suffered by patients and physicians. *See In re Neurontin*, 712 F.3d at 39; *In re Avandia*, 803 F.3d at 646; *Painters*, 943 F.3d at 1258-59. Finally, TPP plaintiffs are the best-suited plaintiffs to recover for the damages they incur from a pharmaceutical company's misrepresentations about their drug. *In re Neurontin*, 712 F.3d at 39; *In re Avandia*, 803 F.3d at 646; *Painters*, 943 F.3d at 1258-59. As the Third Circuit held in *In re Avandia*, this Court should find that Petitioner, "'need only put forth allegations that raise a

reasonable expectation that discovery will reveal evidence' of proximate causation," and has done so. 803 F.3d at 646 (internal citations omitted).

Glukoriza is being used for an off-label purpose and had serious, harmful side effects that Respondent knew of, and intentionally misrepresented or omitted in order to market Glukoriza to physicians and TPPs alike. (R. at 2, 5.) Petitioner would not have included Glukoriza in its formulary but for the fraudulent misrepresentations Galen directed at them. (R. at 6.) Petitioner has alleged a direct relationship between the alleged RICO violation and the damages they incurred. (R. at 6.) Petitioner has shown a finite amount of damages, the amount paid for Glukoriza as a treatment for Miasmic Syndrome; those damages are not difficult to ascertain because Caesar did not underwrite Glukoriza until it was marketed as a treatment for Miasmic Syndrome. (R. at 2.) Moreover, Petitioner is the only potential plaintiff that can claim damages by underwriting prescriptions; Julius Medical Center and the patients that take Glukoriza would have different damage theories (R. at 6.) Finally, Petitioner is the best-situated plaintiff because plaintiff was directly harmed by Respondent's alleged RICO violations. (R. at 2, 6.) At this stage of the litigation, Petitioner has satisfied all *Holmes* direct relationship considerations, shown enough evidence of direct causation, and plead damages on the quantity-effect theory.

This Court should find summary judgment inappropriate at this stage of the litigation and, in light of the facts presented, reverse the Fourteenth Circuit of Appeals and remand the case to be heard in accord with the Court's determinations.

## II. Respondent is liable for violating the Fourth Amendment rights of Petitioners because the Respondents warrantless search of Petitioner did not offer precompliance review and the law is clearly established as to the necessity of such review disqualifying Qualified Immunity.

The Fourth Amendment to the United States Constitution protects individuals and entities from improper searches and seizures. U.S. CONST. amend. IV. Further, 42 U.S.C. § 1983 allows for those persons, natural or otherwise, that have been subjected to improper searches and/or seizures to bring suit against the party or parties responsible. 42 U.S.C. § 1983 (2020). This rather straightforward process of prohibiting improper search and seizure while also providing a mechanism with which to hold parties responsible for those improper searches and seizures is unfortunately muddied with the idea of Qualified Immunity.

Qualified Immunity is designed to protect government officials from liability of rights violations due to official actions taken unless it can be shown that the government official knew or should have known that the action was a violation of statutory or constitutional rights. *Malley v. Briggs,* 475 U.S. 335, 341 (1986), *District of Columbia v. Wesby,* 138 S.Ct. 577, 589 (2018). The idea being that a government cannot function if the officials running said government are constantly concerned with the unforeseen liability of official acts. Qualified Immunity removes that burden allowing the government to be conducted more efficiently. What remains is a liability for rights violations of clearly established law.

### A. Fourth Amendment violation of the subpoena.

The Fourth Amendment, along with the rest of the Bill of Rights, was ratified by the required three-fourths of States on December 15, 1791. This was not the

genesis of search and seizure law, however, instead English common law dating back to the early 17th century created many of the fundamental ideas of search and seizure law. *Semayne's Case* (1604) 77 Eng. Rep. 194, 195; 5 Co. Rep. 91 a, 93 b.[1] The law of search and seizure, however, has not remained stagnated in the 17th and 18th centuries instead the Court has continually expanded the rights protected while balancing law enforcement considerations. *See generally, Weeks v. United States,* 232 U.S. 383 (1914) (case on the exclusionary rule holding evidence found during an improper search was inadmissible); *Mapp v. Ohio,* 367 U.S. 643 (1961) (holding States to the same standard of search and seizure as the Federal government through the Fourteenth Amendment); *Katz v. United States,* 389 U.S. 347 (1967) (expanding a person's expectation of privacy into public places); *But see, Schmerber v. California,* 384 U.S. 757 (1966) (allowing police to take a blood sample after a drunk driving accident).

Administrative searches conducted without Judicial oversight fall under even greater scrutiny with the Court calling them "per se unreasonable" unless within narrow exceptions. *City of Los Angeles v. Patel,* 135 S.Ct. 2443, 2452 (2015). The *Patel* decision lays out one such exception with three conditions to determine if an administrative search is reasonable; first, special circumstances making probable cause impractical, second, a purpose differing from crime control, and third, "an opportunity to obtain precompliance review before a neutral decisionmaker." *Id.*

[1] An English case questioning a Sheriff's ability to forcibly enter a residence to conduct a seizure of items that dealt with both the Castle Doctrine of home defense and knock-and-announce rules for law enforcement.

The alternative to this three-condition model is the idea of the "pervasively regulated industry" expressed in *New York v. Burger,* 482 U.S. 691 (1987).

Similarly to the *Patel* three conditions, *Burger* likewise has three similar conditions to make a warrantless search reasonable. *Burger,* 482 U.S. at 702-03. First, a substantial government interest, second, the inspections must facilitate a regulatory scheme, and third, a constitutionally adequate substitute for a warrant. *Id.* These *Burger* conditions, however, are only applicable to industries that are "closely regulated." *Id.* The Court has clarified that only four industries have been identified as "closely regulated" liquor, firearms, mining, and auto scraping, while at the same time cautioning against expanding that list. *Patel,* 123 S.Ct. at 2454. The reason for a lower standard of reasonableness for "closely regulated" businesses is the inherently lower privacy expectations that come with participation in one of these four industries. *Id.*

This case involves the healthcare industry, specifically the healthcare insurance industry. R. at 2. Neither healthcare nor health insurance is among the four pervasively regulated industries laid out by the Court. *Patel,* 123 S.Ct. at 2454. Further, while the healthcare industry as a whole is subject to regulations many of those regulations are specifically designed to increase the level of privacy. *See,* Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996). This is in direct contrast to the four industries listed by the court that the nature of their industry gives up a degree of privacy. *Patel,* 123 S.Ct.

at 2454. An increased level of privacy puts this case outside the narrow scope of *Burger* and instead within the general scope of *Patel.*

When examining the three *Patel* factors the first two factors are probably met due to the ongoing Miasmic Syndrome pandemic creating a valid public purpose for the subpoena outside a general interest in crime control, and the nature of investigating the adequacy of hospitals treatment regiments making a probable-cause requirement untenable. Opinion of the District Court of Romulus, R. at 19-20. This leaves the third *Patel* factor of precompliance review by a neutral decision-maker.

Even as written the enabling statute does not allow for precompliance review by a neutral party instead only allowing for precompliance review by the very Board that the Commissioner is the head of. RCL § 18.8.891 (e). This lack of neutrality renders this provision "constitutionally meaningless." Opinion of the District Court of Romulus, R. at 21. Without neutral precompliance review, the search fails the *Patel* test and would be unreasonable and a violation of the Fourth Amendment. Further, even if the option for review was deemed reasonable in spite of the *Patel* precedent the availability of this avenue of review was specifically omitted from the subpoena by Cleopatra. R. at 11. Further still, Cleopatra instructed the subpoena to be executed at the compliance deadline specifically to render precompliance review impossible. R. at 12.

The policy considerations behind neutral precompliance reviews are best seen when compared to warrant-based procedures. Warrants require probable cause

which in turn requires a Judge to examine the evidence and determine the validity and scope of the search. In the administrative subpoena-based system the required judicial review of the warrant system is substituted with a required possibility of neutral precompliance review. To allow an administrative subpoena to stand without even the possibility of neutral precompliance review would be tantamount to allowing warrants without Judicial input.

In addition to the lack of precompliance review, the subpoena as executed was not in compliance with the statute granting Cleopatra with subpoena powers. The statute specifies in § 18.8.891(c) that subpoenas be narrowly drawn yet agents seized every record of every Julius patient in the time period of the pandemic regardless of the patients' diagnoses. R. at 5. Further, this level of compliance was only obtained under the threat of arrest for obstruction of justice, a power of arrest it is unclear that the agents were granted. R. at 4. The heavy hand of the subpoena's enforcement was dictated by Cleopatra asking the agents to make sure the public knew the subpoenas were "serious business" and that the board did not "expect any backtalk." R. at 12.

In conclusion, the subpoena in question was issued against a business that was in an industry not pervasively regulated making *Patel* the controlling standard. The subpoena did not meet the *Patel* standard as it contained no provision for neutral precompliance review. The subpoena did not meet the requirements of the enabling statute. The subpoena's execution resulted in seizures beyond the scope of

the subpoena itself. The subpoena violated the Fourth Amendment rights of Caesar Health Plan.

**B. Disqualifying Qualified Immunity through clearly established law.**

The concept of Qualified Immunity protects government officers from 42 USC § 1983 claims unless the officers' actions violate "clearly established" law. *District of Columbia v. Wesby,* 138 S.Ct. 577 (2018). *Wesby* creates a two-step process in determining if the government official is protected by qualified immunity first if there was a violation of a statutory or constitutional right and second if the violation was "clearly established." *Id.* at 589. As seen above the fourth amendment rights of Caesar Health Plan were violated the crux of the issue then becomes if the law surrounding search and seizures is "clearly established."

The Court has defined clearly established as being "sufficiently clear that every reasonable official would understand that what he is doing is unlawful." *Id.* This definition has been clarified that the rule should not be interpreted generally as such an interpretation would render the rule moot. *Anderson v. Creighton,* 483 U.S. 635, 639-40 (1987). The essence of the rule has remained the same qualified immunity is designed to protect government officials acting in the unknown but not to protect those officials acting in a way they knew or should have known was violative of rights.

It would be improper to interpret the need for clarity as a need for absolute clarity. A particular statute requiring a defendant to testify against themselves in court may not have been adjudicated that would not make the law on this type of

self-incrimination any less clear. The hypothetical statue may be brand new and that would not make the law any less clear. Such a system would truly create the cynical system described by the dissent in *Zadeh* that any bad behavior would be excused "as long as they were the *first* to behave badly." *Zadeh v. Robinson,* 928 F.3d 457, 479 (5th Cir. 2019) (Willett, J., *dissenting*).

In the present case, we admittedly consider a new unchallenged statute granting subpoena authority to an administrative board regulating healthcare in a pandemic. R. at 8-10. While the Fourteenth Circuit focused on the circumstances of this statue, and found a lack of clarity because of them, the proper focus would be on the violation of Caesar Health Plan's rights. Opinion of the Fourteenth Circuit, R. at 37. While healthcare and hospitality may be separate industries the clarity that *Patel* brings to the considerations extends beyond the hospitality industry. *Patel* offers clarity of what industries are pervasively regulated for the purposes of search and seizure law and that clarity indicates that healthcare is not one of those industries. *Patel,* 123 S.Ct. at 2454. Further, *Patel* offers clarity in the form of simple requirements to validate warrantless searches. *Id.*

The crucial questions of this case are, does *Patel* apply and if so, did the subpoena meet the *Patel* standard. *Patel* does apply because the Court made clear that it was establishing a set of rules for those industries not among the list of pervasively regulated. *Id.* The Court could have indicated that the *Patel* factors were only for the hospitality industry, they did not. Instead, the Court took the time to discuss which industries were pervasively regulated and did not include

healthcare on that list. *Id.* Applying *Patel* brings the deciding question to the need for neutral precompliance review.

The subpoena in question was executed against Caesar Health Plan in such a way that it drew an objection from the employees of Caesar. R. at 4. While the statute may have given an avenue for non-neutral review not even this level of inadequate review was given Caesar Health Plan. R. at 4. Instead, the agents execute the subpoena threatened the employees with arrest to ensure their compliance. R. at 4. Further, the agents in executing the subpoena seized additional records that were not authorized. R. at 5. All of these actions were done at the behest and under the signature and authority of Livia Cleopatra. R. at 11-12.

In conclusion search and seizure law has been established since the founding of this country. This area of law was explicated in *Patel* in 2015 creating a black letter requirement for neutral precompliance review. This requirement is clearly established and clearly not met. Accordingly, in light of the facts presented, this Court should reverse the Fourteenth Circuit of Appeals and remand the case to be heard in accordance with the Court's determinations.

## CONCLUSION

For the foregoing reasons, this Court should REVERSE on both issues the judgment from the United States Court of Appeals for the Fourteenth Circuit.

Respectfully Submitted,

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ATTORNEYS FOR PETITIONER

# APPENDICIES

## APPENDIX I – ROMULUS CONSOLIDATED LAW

### CHAPTER 18 – HEALTH CARE AND PUBLIC HEALTH

### SUBCHAPTER 18.8 – BOARD OF HEALTH

§ 18.8.001 – DEFINITIONS

[SECTIONS A-FF OMITTED]

GG) HOSPITAL: A FACILITY OR INSTITUTION ENGAGED PRINCIPALLY IN PROVIDING SERVICES BY OR UNDER THE SUPERVISION OF A PHYSICIAN.

§ 18.8.100 – RESPONSIBILITIES OF THE BOARD

A) THE PRIMARY RESPONSIBILITY OF THE BOARD SHALL BE THE SAFEGUARDING OF THE PUBLIC HEALTH, WHICH SHALL BE BROADLY CONSTRUED TO INCLUDE THE PHYSICAL AND MENTAL WELLBEING OF THE PEOPLE OF THE STATE.

B) THE BOARD SHALL ESPECIALLY FOCUS ON THE CONTROL AND ELIMINATION OF CONTAGIOUS DISEASE WITHIN THE STATE.

C) THE BOARD SHALL, IN ITS DISCRETION, TAKE ALL ACTIONS AS SHALL BE NECESSARY IN SUPPORT OF THESE GOALS, WITHIN THE POWERS DELEGATED TO IT UNDER THE LAWS OF THE STATE OF ROMULUS.

§ 18.8.500 – LICENSING OF HOSPITALS

A) IT SHALL BE UNLAWFUL FOR ANY HOSPITAL TO CONDUCT BUSINESS WITHIN THE STATE, WITHOUT POSSESSING AN OPERATING LICENSE ISSUED BY THE BOARD.

B) THE BOARD SHALL ISSUE AN OPERATING LICENSE UPON A MAJORITY VOTE OF THE BOARD, IF THE BOARD IN ITS SOLE DISCRETION DETERMINES THAT THE OPERATION OF THE HOSPITAL SHALL BE IN THE INTEREST OF THE PUBLIC HEALTH, ACCORDING TO SUCH PROCEDURES AND REGULATIONS AS THE BOARD MAY SET.

C) UPON A FINDING A LICENSED HOSPITAL'S CONTINUED OPERATION IS NO LONGER IN THE INTEREST OF THE PUBLIC HEALTH, THE BOARD BY A MAJORITY VOTE MAY TAKE ANY OR ALL OF THE FOLLOWING ACTIONS:

1) INSTRUCT THE HOSPITAL TO MAKE CERTAIN CHANGES, SUCH THAT THE HOSPITAL'S CONTINUED OPERATION WILL BE IN THE INTEREST OF THE PUBLIC HEALTH;

2) REQUIRE THE HOSPITAL TO PAY AN APPROPRIATE AND PROPORTIONAL MONETARY FINE;

3) SUSPEND THE HOSPITAL'S OPERATING LICENSE, UNTIL A DATE CERTAIN OR UNTIL SUCH DATE AS CERTAIN REQUIREMENTS ARE MET; AND

4) Permanently revoke the Hospital's Operating License.

§ 18.8.890 – Miasmic Syndrome Response

A) The Board shall be responsible to take all reasonable actions within its authority to determine whether the level of service provided to Miasmic Syndrome patients at each licensed Hospital is in compliance with all relevant standards in the medical field.

B) If any Hospital is found to provide Miasmic Syndrome care which is not in compliance with all relevant standards in the medical field, the Board will consider this as evidence that the Hospital's operations are not in the interest of the Public Health.

§ 18.8.891 – Emergency Subpoenas in relation to Miasmic Syndrome

A) The Commissioner of the Board may authorize an administrative subpoena to any licensed Hospital, which may require the Hospital to:

1) Admit personnel of the Board onto their premises to inspect for evidence that the facility is providing substandard care for Miasmic Syndrome; and

2) Provide such records or documents to the Board as the Board may in its discretion require in order to determine if the Hospital is providing substandard care for Miasmic Syndrome.

B) The Commissioner of the Board may authorize an administrative subpoena to any other person or entity within the State, which may require that person to provide any records or documents to the Board as the Board may in its discretion require in order to determine if a licensed Hospital is providing substandard care for Miasmic Syndrome.

C) A subpoena issued under this section shall be no broader than is reasonably required to determine whether a Hospital is providing substandard care for Miasmic Syndrome.

D) If an entity fails to comply with a subpoena issued under this section:

1) If the entity is a licensed Hospital, the Board may treat this as evidence that the Hospital is providing substandard care for Miasmic Syndrome, and further may treat the act of refusal itself as evidence that the Hospital is providing care contrary to the Public Health; and

2) If the entity is not a licensed Hospital, the Board may seek a court order to enforce compliance with the subpoena.

E) Upon petition by an entity which is the target of a subpoena under this section, the full Board shall review the subpoena and may amend or quash it, if the Board agrees to do so by majority vote. No entity that so petitions will

BE PENALIZED FOR ITS REFUSAL, DURING THE PENDENCY OF ITS PETITION, TO COMPLY WITH A SUBPOENA UNDER THIS SECTION. DURING THE PENDENCY OF ANY SUCH PETITION, THE ENTITY WILL PRESERVE ALL EVIDENCE AS IS SOUGHT BY THE SUBPOENA. FAILURE TO PRESERVE SUCH EVIDENCE MAY CONSTITUTE OBSTRUCTION OF JUSTICE.

F) THE BOARD SHALL ONLY ISSUE A SUBPOENA UNDER THIS SECTION:

1) UPON REASONABLE SUSPICION THAT THE HOSPITAL ABOUT WHICH INFORMATION IS SOUGHT MAY BE PROVIDING SUBSTANDARD CARE FOR MIASMIC SYNDROME; OR

2) TO A LICENSED HOSPITAL AT RANDOM, AS PART OF A DOCUMENTED AND FAIR METHODOLOGY FOR CONDUCTING RANDOM INSPECTIONS.

CHAPTER 30: CRIMINAL LAW

SUBCHAPTER 30.50: INTERFERENCE WITH PUBLIC ADMINISTRATION

§ 30.50.120 – OBSTRUCTION OF INVESTIGATION

IT SHALL BE A MISDEMEANOR TO OBSTRUCT OR IMPEDE ANY DULY AUTHORIZED AGENT OF THE STATE OF ROMULUS IN THAT AGENT'S CONDUCT OF A SEARCH OR INVESTIGATION AUTHORIZED BY LAW.

## APPENDIX II – SUBPOENA FOR CAESAR AND JULIUS

State of Romulus
Department of Health
Livia Cleopatra, Commissioner

### SUBPOENA FOR INSPECTION AND PRODCUTION OF DOCUMENTS SPECIAL PUBLIC HEALTH NEED – EMSA

To CAESAR HEALTH PLAN (THE "ORGANIAZATION") AND ITS PERSONNEL,

Under the authority granted by the Emergency Miasmic Syndrome Act (PCL § 18.8.891), you are hereby COMMANDED to admit to the Organization's premises the personnel of the Romulus Board of Health, for the purposes of conducting an inspection and search for information relevant to potential negligent or substandard care for Miasmic Syndrome.

You are further COMMANDED to product to such personnel all records related to medical care at Julius Medical Center, which are:

1) Related to the diagnosis and/or treatment of Miasmic Syndrome, or

2) Related to patients who are suspected of carrying Miasmic Syndrome

Records sought under this subpoena include all insurance claims and medical records in the possession of the Organization which are related to such services and/or patient population, and which are dated on or after May 1, 2019.

Compliance with this subpoena will take place at 8 AM on March 19, 2020. Failure to comply by the Organization, through its personnel, may result in such legal actions by the Board of Health as are necessary to protect the public health. The Board is empowered to impose monetary penalties, and in appropriate situations to revoke a facility's operating license in the event of noncompliance with an EMSA subpoena. Illegally interfering with the execution of this legally-authorized collection of information is a criminal offence.

. Livia Cleopatra .
Livia Cleopatra, Commissioner
March 13, 2020

## APPENDIX III – E-MAIL FROM CLEOPATRA TO AGENTS EXECUTING SUBPOENA

Header:

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From: lcleopatra@health.romulus.gov (Livia Cleopatra, Commissioner [HEALTH])
To: mbrutus@health.romulus.gov (Marcus Brutus, Deputy Inspector [HEALTH])
Date: March 13, 2020, 7:38 PM
Subject: Caesar Subpoena

Body:

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DI Brutus,

See attached EMSA subpoena issued today against Caesar Health Plan, in regard to the Julius situation. Please review. A similar subpoena has been prepared against Julius.

I want you to take a team and execute this at Caesar's premises. Show up at the compliance deadline and get what we're entitled to on the spot. I don't want them to have time to hide anything.

DI Antony is executing the subpoena at Julius simultaneously. We're not leaving anything to chance here. This is the first time we've used this authority and the public might be resistant, so set a precedent that these subpoenas are serious business, and we don't expect any backtalk. The state gave us power and we're using it.

- LC

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Header:

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From: mbrutus@health.romulus.gov (Marcus Brutus, Deputy Inspector [HEALTH])
To: lcleopatra@health.romulus.gov (Livia Cleopatra, Commissioner [HEALTH])
Date: March 13, 2020, 9:41 PM
Subject: Re: Caesar Subpoena

Body:

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Received.

- Brutus