No. 22-685

IN THE

Supreme Court of the United States

JERRY WAYNE WILKERSON, *et al.*,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

REPLY BRIEF FOR PETITIONERS

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ARGUMENT

The government goes to great lengths to avoid addressing the question presented and instead mischaracterizes it. The question in this case is: "Must the government establish subjective intent to engage in unlawful conduct in order to convict a defendant of healthcare fraud and violation of the anti-kickback statute?" But the government opens its argument with the statement that this case is about sufficiency of the evidence. Opp. 14. That characterization is wrong and disingenuous.

As explained in the Petition, Petitioners did not "knowingly" or "willfully" defraud anyone or pay or receive illegal kickbacks—rather, they engaged in standard marketing conduct and made a profit. The district court found Petitioners liable because they purportedly failed to disclose to "someone" the cost of prescriptions (even though every affected party in fact knew or learned those costs). The Sixth Circuit affirmed on a different theory, collecting an assortment of cherry-picked and mischaracterized facts relevant to only some defendants, which it recognized could all have innocent explanations, and then attributed them to all defendants collectively and inferred that those facts are objective markers of the entire group's intent. Neither court assessed the subjective mental state of each individual defendant. It is *this* error that warrants review.

The analysis of the courts below conflicts with *Ruan v. United States*, 142 S. Ct. 2370 (2022), and creates a circuit split. In *Ruan*, this Court was clear that the government must establish subjective intent of unlawful conduct to sustain criminal convictions. *Id.*

at 2376, 2382 (requiring that government prove "a defendant knew or intended that his or her conduct was unauthorized"). This Court came to this conclusion reasoning that there is a presumption, "traceable to the common law, that Congress intends to require a defendant to possess a culpable mental state." *Id.* at 2376–77 (quoting *Rehaif v. United States*, 139 S. Ct. 2191, 2195 (2019)). Neither the district court's invention of a failure-to-disclose theory nor the Sixth Circuit's application of an objective test satisfies that standard.

And this also creates a circuit split. The First, Second, Fifth, and Eleventh circuits have agreed that the government must establish that the defendant knew that his or her actions were fraudulent or unlawful to be convicted of healthcare fraud or related offenses. *See, e.g.*, *United States v. Nora*, 988 F.3d 823, 831 (5th Cir. 2021) (holding defendant must have understood his actions to be fraudulent or unlawful to be convicted and acted with "bad purpose"); *United States v. Nerey*, 877 F.3d 956, 969 (11th Cir. 2017) ("[w]illful[ly]" means "with the specific intent to do something the law forbids, that is with a bad purpose"). The Fifth Circuit is split within itself, having previously held that such specific intent is not necessary. *See United States v. St. Junius*, 739 F.3d 193, 210 (5th Cir. 2013) (not requiring subjective intent).

The government does not deal with the actual legal issue presented of whether the lower courts applied the proper standard to determine whether each individual Petitioner had the required intent and can be held liable for healthcare fraud and violation of the anti-kickback statute. Rather, the government points

to legal conduct and emphasizes purported facts not supported by the record in an attempt to avoid the core issue. For example, the government states that Wilkerson's role in the business was to negotiate commissions with pharmacies and set up a company to receive commissions and pay employees. But none of this is illegal conduct—it is all standard pharmaceutical advertising practices. It also lists facts that are not supported by the record such as Wilkerson allegedly paying to backdate prescriptions (but fails to point to any testimony on this issue or any backdated prescriptions in evidence), and that Wilkerson supposedly paid nurse Craven to write prescriptions without seeing patients, while ignoring the testimony that in the overwhelming majority of instances Craven was "actually calling people and doing everything [she] w[as] supposed to do." Pet.App.65a–66a, 76a. But the government's misguided factual detours do not address the fundamental legal errors committed by the courts below.

Moreover, by its silence, the government concedes that this case presents an important and recurring issue and is an ideal vehicle. This issue is important and recurring because a defendant should be held criminally liable only when the government has carried its burden to establish intent and the intent standard is uniformly applied. Additionally, this case is an ideal vehicle for the question presented because the question was fully preserved and there are no alternative grounds on which the courts below based their rulings.

Accordingly, this Court should grant the Petition or, alternatively, grant the Petition, vacate the lower court decisions, and remand the case in light of *Ruan*.

I. The Government Is Wrong That *Ruan* Is Not Applicable

A. In *Ruan*, this Court clarified and confirmed that the government must establish a defendant's subjective mental state to uphold a criminal conviction. The government argues that *Ruan* does not apply because it "construed a different requirement in a different statute." Opp. 14. *Ruan*, however, is not so limited.

This Court in *Ruan* held that the "knowingly and intentionally" language of the Controlled Substances Act applies to the "except as authorized" language and required the government to prove that "a defendant knew or intended that his or her conduct was unauthorized." 142 S. Ct. at 2376, 2382. The requirement that the government establish a defendant "knew or intended" his conduct is not limited to the Controlled Substances Act—it is a *mens rea* standard that plainly applies to closely analogous statutes.

Indeed, in articulating that standard, this Court reasoned that there is "a longstanding presumption, traceable to the common law, that Congress intends to require a defendant to possess a culpable mental state." *Id.* at 2376–77 (quoting *Rehaif*, 139 S. Ct. at 2195); *see also United States v. X-Citement Video, Inc.*, 513 U.S. 64, 72 (1994); *Morissette v. United States*, 342 U.S. 246, 256–58 (1952). This is because, "as a general matter, our criminal law seeks to punish the 'vicious will.'" *Ruan*, 142 S. Ct. at 2376 (quoting *Morissette*,

342 U.S. at 251). "With few exceptions, 'wrongdoing must be conscious to be criminal.'" *Id.* (quoting *Elonis v. United States*, 575 U.S. 723, 734 (2015)). And a strict *mens rea* requirement "helps to diminish the risk of 'overdeterrence,' *i.e.*, punishing acceptable and beneficial conduct that lies close to, but on the permissible side of, the criminal line." *Id.* at 2378. Moreover, the penalty for a violation of the statute can be severe, counseling in favor of a strong scienter requirement. *Id.*

Far from being a unique feature of the Controlled Substances Act, this subjective intent standard is an entrenched feature of the common law and applies to criminal statutes. Any doubt about this was dispelled in *Ruan*, which makes clear that where a criminal statute requires knowing and intentional conduct the government must prove that an individual defendant subjectively knew he was acting unlawfully.

B. There can be no argument that the lower courts applied that standard. The government claims that it is "baseless" to complain that the Sixth Circuit inferred the requisite intent from circumstantial evidence. But again, that misses the point. Ignoring that many of the facts the Sixth Circuit relied on are not supported by the record or are legal conduct, the Sixth Circuit cobbled together those "facts" and found that in the aggregate they provided a sufficient basis to infer intent for every defendant in the group—but looking at those "facts" in the aggregate does not satisfy the requirement to determine whether each individual defendant had the required subjective intent. This is especially so, given that it is undisputed that defendants repeatedly conferred with counsel to

ensure that they were acting legally. *See* Pet.App.56a–57a; Pet.App.102a–103a.

C. *Staples v. United States*, 511 U.S. 600 (1994), a case that predates *Ruan* and does not involve healthcare fraud, does not help the government. There, the Court held that the government had to prove that the defendant knew of certain features that brought his gun within the scope of a criminal statute. *Id.* at 619. With respect to inferring knowledge from circumstantial evidence, the Court merely commented that knowledge could be inferred from a fact that made it "immediately apparent" to the defendant that a gun fell within the statute. *Id.* at 616 n.11. Additionally, there the Court had to determine simply whether the defendant *knew* certain facts, not whether the defendant knowingly and willfully *acted*, which involves a higher standard of intent. Similarly, this Court's comment in *Ruan* that knowledge may be shown through circumstantial evidence was qualified by the requirement that "the Government must still carry [its] burden." 142 S. Ct. at 2382. Nothing in either case supports that a court may aggregate innocent actions or isolated actions of a few defendants to infer criminal intent for all. That is particularly significant here given that the facts involved all have innocent explanations as the court below recognized (a point the government entirely ignores). Pet.App.22a.

D. Contrary to the government's claims, cases where this Court has granted certiorari, vacated lower court decisions, and remanded in light of *Ruan* support that at the very least the Court should do the same here. For example, *Hofstetter v. United States*, 143 S. Ct. 351 (2022) (No. 22-5346), which the

government ignores, involved a defendant who was a business manager, not a medical professional, and also involved allegations that the defendant wrote unnecessary prescriptions for compound pain creams. *See United States v. Hofstetter*, 31 F.4th 396, 421 (6th Cir. 2022). There, the district court had instructed the jury that the requisite intent could be inferred if the defendant had deliberately blinded herself to the existence of criminal conduct. That issue is analogous to the issue here of whether and when criminal intent can be properly inferred.

In short, *Ruan* clarified a broader principal with respect to the government's burden in criminal healthcare cases—that it must establish subjective intent as to an individual defendant. That principal is not limited to the Controlled Substances Act.

II. The Government Is Wrong That This Case Is About Sufficiency of the Evidence.

As repeatedly stated, the issue in this case is whether the lower courts properly found that each individual defendant had the subjective intent to defraud sufficient to uphold their convictions for healthcare fraud and violation of the anti-kickback statute. The government claims that "[a]t bottom, petitioners' principal complaint . . . appears to be that the court of appeals erred in finding the evidence sufficient to show that they acted knowingly and willfully." Opp. 17. This twists the issue presented.

At bottom, the government in its brief does the same thing the Sixth Circuit did—it ignores the district court's basis for finding liability, cobbles together various facts that only apply to some defendants, and then claims all defendants have the

requisite subjective intent. Specifically, the Sixth Circuit collected an assortment of cherry-picked and mischaracterized facts, which it attributed to all defendants collectively, and assumed that anyone committing all those acts must have a subjective intent to commit fraud. It did not assess the subjective mental state of each individual defendant. The Sixth Circuit uncritically accepted the government's factual assertions that defendants (1) on a few occasions, paid Craven to sign prescriptions without seeing patients (Opp. 12); (2) used a pre-set order form (Opp. 11); (3) mentioned a clinical trial that was ultimately not conducted (Opp. 18); (4) in a few instances paid some co-pays (Opp. 11); (5) targeted patients who had certain insurance (*id.*); (6) persuaded a few customers to order allegedly "unneeded and unwanted" creams or refills (*id.*); (7) in one instance allegedly discussed directing pharmacists to backdate a prescription (Opp. 5); (8) marketed drugs that were "excessively expensive" relative to their benefit (Opp. 11); (9) on a few occasions stamped prescriptions without the provider's knowledge (Opp. 18). Pet.App.24a.

It should be noted that the record is to the contrary. There is no evidence that Wilkerson paid Craven to sign prescriptions without seeing patients. Indeed, Craven testified that the vast majority of the time she saw and appropriately communicated with patients prior to issuing prescriptions. Pet.App.62a–63a, 76a. The government and court below ignored uncontradicted fact and expert testimony that preprinted prescription pads are an industry standard and that pharmacists, not defendants, determined formulas for the medications. Pet.App.113a; Pet.App.60a. The scant evidence presented to support

the idea that prescriptions were unneeded was anecdotal and originated from a small number of patients, rather than from a medical provider qualified to opine on medical necessity. Pet.App.59a; Pet.App.61a–63a. Craven also testified that she had exercised her medical judgment to ensure that all prescriptions were medically necessary. Pet.App.68a. The government cites no evidence that Wilkerson was involved in any of the handful of instances where Craven's signature may have been stamped on a prescription without her knowledge (and no such prescriptions were introduced into evidence) or any evidence that Wilkerson was involved in telling patients about any clinical trial (which in any event, is not illegal). *See* R. 313, PageID ##2803–04. The government also introduced no evidence that prescriptions were in fact backdated or that Wilkerson paid anyone to backdate prescriptions or create the formulas for the prescription pads. *See* R. 375, PageID ##6445–46. Lastly, instead of being "excessively expensive," many of the prescriptions were reimbursed at under $1,000. R. 576-2, Gov't Ex. 235, PageID ##11979–90.[1]

But these factual misstatements aside, it was error for the Sixth Circuit to agglomerate conduct that various defendants engaged in and then find that those actions taken together are sufficient to infer intent on behalf of all defendants (particularly where the conduct at issue—marketing prescriptions—is

[1] The government even exaggerates the profits, stating Wilkerson made over $13 million, when the evidence shows that he was paid only $2.4 million. R. 584-9, Gov't Ex. 716, PageID #12400.

legal and/or not supported by the record). For example, the Sixth Circuit stated that "they" (*i.e.*, the defendants) told customers that they were being paid for evaluating creams as part of a clinical study but the record shows that Wilkerson was not doing this. R. 378, PageID#7180. And the court claimed that "they" ordered extra creams for customers without their knowledge but there is no allegation that Hindmon did that. Such aggregation does not comply with the required intent standard articulated in *Ruan* or by the majority of other circuits.

And the government is also wrong that the district court's explanation of its theory of liability is irrelevant. Indeed, at sentencing, the district court explained the basis of its finding stating that "I believe that the overall fraud that the Court found . . . was, in fact, some duty on the part of the defendants . . . to disclose to someone, either the insurance company or the patient or . . . someone the cost of these creams[.] . . ." Pet.App.132a–33a; Pet.App.126a–27a ("somehow the defendants were under an obligation, even though the Court will probably concede that obligation is not as explicit as the government might hope it was, to disclose what was being provided to the patients and to their insurance companies and what the relative value of medical necessity was being served by these compounds versus what could be bought over the counter"). The district court's theory is relevant because it does not satisfy *Ruan*'s requirement of subjective intent, as the Sixth Circuit implicitly recognized. There is no basis to entirely disregard the court's own explanation of its theory of liability.

In short, the district court found liability based on a failure-to-disclose theory that is plainly wrong as a matter of law and the Sixth Circuit's attempt to sustain the convictions by cobbling together isolated incidents is precisely the type of objective analysis that *Ruan* makes clear is insufficient to support a conviction for knowing or intentional fraud or related conduct.

III. The Government Is Wrong That The Sixth Circuit Applied The Proper Standard Of Intent

The First, Second, and Eleventh Circuits uniformly hold that, in healthcare fraud and anti-kickback cases, the government must establish that defendant subjectively knew his or her actions were fraudulent or unlawful. *See, e.g.*, *Nora*, 988 F.3d at 831 (holding defendant must have "acted with 'bad purpose'" in carrying out his responsibilities; he must have understood his actions to be fraudulent or unlawful to be convicted); *Nerey*, 877 F.3d at 969 ("[w]illful[ly]" means "with the specific intent to do something the law forbids, that is with a bad purpose"); *United States v. Troisi*, 849 F.3d 490, 494 n.8 (1st Cir. 2017) ("'willfulness' is normally understood to encompass 'specific intent,' and both terms require a finding that the defendant acted with a purpose to disobey or disregard the law"); *see also Pfizer, Inc v. U.S. Dep't of Health & Hum. Servs.*, 42 F.4th 67, 77 (2d Cir. 2022) ("willfully" means "a voluntary, intentional violation of a known legal duty"). The Fifth Circuit is split within itself, having previously held that such specific intent is not necessary. *See St. Junius*, 739 F.3d at 210 (only requiring a showing that defendant "willfully committed an act that violated the" law).

The government dismisses in a conclusory manner Petitioners' argument that the Sixth Circuit's ruling conflicts with the foregoing standard, claiming that "the court of appeals applied the standard that petitioners advocate." Opp. 20. The government engages not at all with the argument that the Sixth Circuit's decision was in error because it considered Petitioners' conduct in the aggregate and then found intent to defraud on all their parts. But that is what the foregoing standard requires—that the government establish that an individual defendant had the specific intent, and bad purpose, to commit fraud. Aggregating defendants' actions and inferring intent does not satisfy that standard.

CONCLUSION

The Court should grant the petition or, alternatively, grant the Petition, vacate the lower court decisions, and remand the case in light of *Ruan*.

MAY 15, 2023

Respectfully submitted,

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