No. 22-___

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In *Ruan v. United States*, 142 S. Ct. 2370 (2022), this Court made clear that there must be subjective intent to commit an unlawful act to convict a defendant under the Controlled Substances Act. This case involves the very similar context of healthcare fraud and the anti-kickback statute, but the courts below found intent based on an objective intent standard.

Petitioners were marketers who advertised compound drugs. Medical professionals would, in their discretion, write a prescription and send it to a pharmacy. The pharmacy filled it and submitted a claim for reimbursement to a pharmacy benefit manager who processed the claim for the patient's insurance. The pharmacy then paid one Petitioner, Wilkerson, a commission and he passed a portion on to the others.

Neither lower court made specific findings of intent. The district court convicted Petitioners based on the failure to disclose the cost of advertised drugs. The Sixth Circuit affirmed on different reasoning, inferring intent based on a string of incidents involving one or more Petitioner, including that: they used a pre-set order form (created by pharmacies); some mentioned a clinical trial that was ultimately not conducted; in a few instances some paid co-pays; some targeted patients with certain insurance; and some were involved with a few prescriptions the court criticized but with no finding of lack of medical necessity. The court conceded these incidents could have innocent explanations but decided that by aggregating them it could infer intent for all Petitioners.

The question presented 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?

PARTIES TO THE PROCEEDING

The parties to the proceedings below were Petitioners Jerry Wayne Wilkerson, Billy Hindmon, Kasey Nicholson, and Michael Chatfield as defendants-appellants, Respondent the United States as the plaintiff-appellee, and Respondent Jayson Montgomery as defendant-appellant. There are no corporate parties requiring a disclosure statement under Supreme Court Rule 29.6.

STATEMENT OF RELATED PROCEEDINGS

Sixth Circuit: *United States v. Jayson Montgomery*, No. 20-5891 (Judgment Entered June 23, 2022); *United States v. Billy Hindmon*, No. 20-5897 (Judgment Entered June 23, 2022); *United States v. Kasey Nicholson*, No. 20-5920 (Judgment Entered June 23, 2022); *United States v. Michael Chatfield*, No. 20-5946 (Judgment Entered June 23, 2022); *United States v. Jerry Wilkerson*, No. 20-6010 (Judgment Entered June 23, 2022).

United States District Court for the Eastern District of Tennessee: *United States v. Jerry Wayne Wilkerson, Michael Chatfield, Kasey Nicholson, Billy Hindmon, & Jayson Montgomery*, No. 1:18-cr-00011-1 (Judgment Entered July 31, 2020 (Wilkerson), July 30, 2020 (Chatfield, Nicholson), July 22, 2020 (Hindmon), July 17, 2020 (Montgomery)).

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INTRODUCTION

Petitioners were convicted of, among other things, fraud and violating the anti-kickback statute; however, neither lower court was able to specifically identify the alleged illegal conduct committed. This is because Petitioners were engaged in industry-standard, legal, advertising practices and did not have the subjective intent to engage in unlawful conduct. Their convictions therefore conflict with this Court's recent precedent and create a split among lower courts on an issue of exceptional importance.

In the pharmaceutical world, it is common for pharmacies to retain marketers to advertise drugs. Patients who are interested in an advertised drug must seek a prescription from a medical professional and take that prescription to a pharmacy that fills it. The pharmacy then seeks reimbursement from the patient's insurance through a Pharmacy Benefit Manager ("PBM") and pays a portion of that reimbursement to the marketers as a commission. Obviously, insurance companies only reimburse claims for drugs that the insurance company had agreed to cover.

Petitioners advertised compound drugs with more than one active ingredient and, unsurprisingly, focused their efforts on patients who had insurance that covered compound drugs. One such insurance company was a government insurance program, Tricare. Tricare and other insurance companies' agreements to cover compound drugs did not depend on the reimbursement policies of the pharmacies and their representatives—it was simply a blanket agreement to cover those prescriptions. Prior to 2011, a pharmacy could only seek reimbursement for one ingredient per

prescription through a PBM. But in 2011, PBMs implemented a change and allowed pharmacies to request reimbursement for multiple ingredients for each prescription. This meant that compound drugs, which contain multiple ingredients, became much more profitable for pharmacies. This change drastically increased insurance companies' costs. But Tricare, which controls what drugs it covers, did not implement policy changes to control its costs until 2015. After realizing how much money Tricare had spent on these reimbursements, the government decided to attempt to recoup its costs from pharmaceutical sales representatives such as Petitioners, claiming that by marketing compound prescriptions these sales representatives somehow committed healthcare fraud and related offenses.

But Petitioners did not "knowingly" or "willfully" defraud anyone or pay or receive illegal kickbacks—they merely engaged in standard marketing conduct and made a profit. The district court concluded that Petitioners committed fraud because they failed to disclose to "someone" the cost of the prescriptions. The court did not find that each Petitioner had a subjective intent to engage in unlawful activity. On appeal, the Sixth Circuit affirmed but developed a new theory of liability by cobbling together various "facts" (that were only relevant to some, but not all of the Petitioners, and/or that the court conceded could have an innocent explanation) to infer that Petitioners had the requisite intent.

The rulings below conflict with this Court's precedent and create a circuit split. This Court made clear in *Ruan v. United States*, 142 S. Ct. 2370 (2022), is-

sued after the Sixth Circuit's decision, that the government had to establish that Petitioners subjectively intended to engage in unlawful conduct. The district court invented a failure-to-disclose theory of liability, and the Sixth Circuit essentially applied an objective intent test and inferred intent—neither court found that Petitioners had the subjective intent to commit unlawful acts as required under *Ruan*.

Moreover, the Sixth Circuit's decision 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 that 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); *United States v. Nerey*, 877 F.3d 956, 969 (11th Cir. 2017) (explaining that "[w]illful[ly]" under the anti-kickback statute 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, rather than by ignorance, accident, or mistake"); *see also Pfizer, Inc v. U.S. Dep't of Health & Hum. Servs.*, 42 F.4th 67, 77 (2d Cir. 2022) (explaining that "willfully" as used in the anti-kickback statute means "a voluntary, intentional violation of a known legal duty"; the willfulness element is meant "to avoid punishing 'an individual whose conduct, while improper, was inadvertent'"—

"the [anti-kickback statute] does not apply to those who are unaware that such payments are prohibited by law and accidentally violate the statute."). 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 to commit an *unlawful* act and instead requiring only a showing that defendant "willfully committed an act that violated the" law).

The question presented is important and recurring. It is important to ensure that the accused are held criminally liable only when they have the requisite intent and that the intent standard is uniformly applied. And this case is an ideal vehicle to address the question presented, as it is cleanly and squarely presented and there are no alternative grounds on which the courts below based their rulings.

Because the ruling below conflicts with this Court's decisions as well as decisions from other courts over an important and recurring issue, this Court should grant certiorari and answer the question presented.

OPINIONS BELOW

The opinion of the Sixth Circuit is unpublished and is reproduced at Pet.App.1a–35a.

JURISDICTION

The Sixth Circuit issued its opinion and judgment on June 23, 2022 (Pet.App.1a–35a) and denied rehearing on August 25, 2022 (Pet.App.36a–37a). On November 10, 2022, Justice Kavanaugh extended the time to file this petition until January 20, 2023. No. 22A433 (U.S.). This Court has jurisdiction under 28 U.S.C. § 1254.

STATUTORY PROVISIONS INVOLVED

The healthcare fraud statute provides:

> (a) Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice—
>
> (1) to defraud any health care benefit program; or
>
> (2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program,
>
> in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 10 years, or both. If the violation results in serious bodily injury (as defined in section 1365 of this title), such person shall be fined under this title or imprisoned not more than 20 years, or both; and if the violation results in death, such person shall be fined under this title, or imprisoned for any term of years or for life, or both.

18 U.S.C. § 1347(a).

The conspiracy to commit healthcare fraud statute provides:

> Any person who attempts or conspires to commit any offense under this chapter shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

18 U.S.C. § 1349.

The anti-kickback statute provides:

> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> > (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(1).

The wire fraud statute provides:

> Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses . . . transmits or causes to be transmitted by means of wire. . . in interstate or foreign commerce . . . shall be fined under this title or imprisoned not more than 20 years, or both.

18 U.S.C. § 1343.

The mail fraud statute provides:

> Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining

> money or property by means of false or fraudulent pretenses . . . places in any post office or authorized depository for mail matter, any matter or thing whatever to be sent or delivered by the Postal Service, or deposits or causes to be deposited any matter or thing whatever to be sent or delivered by any private or commercial interstate carrier . . . or knowingly causes to be delivered by mail or such carrier . . . shall be fined under this title or imprisoned not more than 20 years, or both.

18 U.S.C. § 1341.

The money laundering statute provides:

> Whoever, in any of the circumstances set forth in subsection (d), knowingly engages or attempts to engage in a monetary transaction in criminally derived property of a value greater than $10,000 and is derived from specified unlawful activity, shall be punished as provided in subsection (b).

18 U.S.C. § 1957(a).

STATEMENT OF THE CASE

A. Factual Background

1. Basic Structure

The healthcare industry is complex and involves numerous players. This case primarily involves Express Scripts (a PBM), Tricare (an insurance company), pharmacies, and sales representatives. In short, the process works as follows:

i. Manufacturers set price of drug ingredients. Newkirk Pet.App.108a.

ii. Insurance companies set up plans regarding what drugs they will cover. Pet.App.94a–96a.

iii. Insurance companies contract with PBM to administer plans. Pet.App.110a, 114a.

iv. Pharmacies hire marketers to advertise drugs covered by the plans. Pet.App.116a.

v. After receiving a prescription from a medical professional, a patient goes to a pharmacy. Pet.App.112a.

vi. The pharmacy fills the prescription and submits a reimbursement claim to the PBM. Pet.App.114a

vii. The PBM reimburses the pharmacy for covered drugs. Pet.App.80a–82a.

viii. The PBM then submits a claim to the insurance company. Pet.App.80a–82a.

ix. The pharmacy uses part of its reimbursement to pay a sales commission to any marketers it hired. *See* Pet.App.116a

PBMs are paid by insurance companies to process prescription drug claims, develop and manage pharmacy networks, determine drug formularies, set copays, and set criteria for prior authorizations. Pharmacists Society of the State of New York, Inc. (PSSNY), *PBM Basics*, https://www.pssny.org/page/PBMBasics (last visited Jan. 19, 2023). At trial, the government called two witnesses who testified about the relationships among PBMs, insurance companies, pharmacies, and patients. Steve McCall from CVS Caremark, a PBM, and James Gogue from Tricare, were the gov-

ernment's main witnesses on the structure of this relationship. Consistent with the description above, they explained as follows:

The patient's doctor submits a prescription to the pharmacy. The pharmacy fills the prescription, provides the prescribed medication to the patient, and collects the patient's co-pay. Pet.App.116a–117a. The pharmacy then submits a claim for reimbursement to the PBM, and the PBM pays the pharmacy for the claim. Pet.App.78a–79a. Once the PBM pays the pharmacy, the PBM bills the insurance company for the cost of the prescription. Pet.App.79a–82a. Notably, the insurance company is in control of what drugs it covers and whether there are any limitations on the drugs it decides to cover. For example, in 2015, Tricare implemented new requirements "to bring about the control of the costs that were transpiring with compound drugs submissions" by requiring prior authorizations for such prescriptions. Pet.App.141a.

Further, the price that the insurer pays the PBM for the prescription is set by contract between the insurer and the PBM. The PBM thus earns a profit, in part, by charging the insurance company more than it reimburses the pharmacy for the prescription. This explains why Express Scripts would "routine[ly]" "override" a $1,000 cap on reimbursement for compound prescriptions if a pharmacy asked it to do so. Pet.App.96a–97a; Pet.App.115a. (without override, "all compounds would have been reimbursed underneath the Tricare program at $999 or less").

Insurance companies contract with PBMs because PBMs are equipped to handle an incredibly high volume of prescriptions for insurers. CVS Caremark has

enough servers to fill a "football field," which enables it to process prescription drug claims in about one second. Pet.App.79a. As McCall noted, there is a clear financial incentive for insurers to contract with PBMs:

> [W]here an individual insurance company may, you know, like a Toyota plant out here may negotiate with maybe 10, 15 pharmacies that are right around the factory and get a certain price. When I'm negotiating, I'm negotiating for 66,000 pharmacies and 4,000 insurance plans, so the price we get is usually quite a bit better than an insurance plan can do on their own.

McCall Trial Tr., R. 334, PageID #3744.

The pharmacy, in turn, pays a commission for pharmaceutical sales generated by marketers, with commission amounts set by contract with the marketers. Pet.App.103a–104a.

2. Lack of Controls

Under their contracts, PBMs are paid by volume and price of claims they process, giving them a financial incentive to minimize controls on prescription drug costs. Thus, some PBMs, like Express Scripts, employ a "pay-and-chase" system to process claims. Pet.App.139a–140a. In short, a pay-and-chase system is designed to allow PBMs to do one thing—maximize profits. It uses computers to process millions of prescription drug claims in milliseconds, and the PBM does not engage in any efforts to investigate whether the payment of the claim was adequate or proper prior to paying the claim. *Id.* Tighter front-end controls on prescription drug claims would reduce the number of claims that can be processed, and less volume means less profit for the PBM.

The elite club of PBMs, Express Scripts and CVS Caremark included, earn hundreds of billions of dollars per year. According to McCall, CVS Caremark is third on the Fortune 500 list. McCall Trial Tr., R. 334, PageID #3845.

3. Setting The Price of Compounded Drugs

Mark Newkirk, who has a doctorate degree in pharmacy and specializes in compounding pharmacy compliance and auditing, testified for Wilkerson as an expert and explained that the price of compound medications is determined by the average wholesale price of the bulk chemicals used in compounded drugs. Pet.App.108a. Prior to 2011, pharmacies were permitted to bill PBMs for only one National Drug Code (NDC) ingredient per compound. *Id.*, 109a–110a. But in 2011, changes in practice ushered in a new era in the compounding industry. Pharmacies were suddenly permitted to bill PBMs for up to 25 ingredients in one compounded medication. *Id.*. As a result, compound drug prices skyrocketed. *Id.*, 111a. Gogue, the government witness from Tricare, testified that Tricare continued to pay for the compound prescriptions despite the astronomical price increases. Pet.App.140a–142a.

As explained above, pharmacies submit their bills to, and are reimbursed by, PBMs. The contract between the pharmacy and the PBM is governed in part by "pharmacy benefit manuals." Provider Manual, R. 576-7, PageID ##12027–62. Through these agreements, the pharmacies maintained confidentiality regarding pricing and other trade secrets. *Id.* McCall testified that contracts between PBMs and pharmacies prohibited pharmacies from disclosing the medication cost to patients. Pet.App.82a–83a.

Additionally, the contracts between the pharmacies and the marketers also prohibited the marketers from disclosing the cost of the compound drugs to the patients. During direct examination, Brian Tabor, an experienced pharmaceutical sales representative, reviewed sections of the contract between co-defendant Wilkerson's marketing company, Top Tier, and a pharmacy, Florida Pharmacy Solutions. Pet.App.98a–99a; Independent Consultant Agreement, R. 576-8, PageID ##12263–68. The contract between Top Tier and Florida Pharmacy Solutions specifically barred marketers from disclosing the price of compound drugs because the price was confidential. Pet.App.98a–99a; Independent Consultant Agreement, R. 576-8, PageID ##12263–68.

Patients most often learn about their prescription drug costs through what is known as an Explanation of Benefits, which insurance companies send to beneficiaries "after they've had some sort of treatment." Pet.App.105a. The Explanation of Benefits lists the name of the prescription drug provided to the patient, the price paid by the insurer to the pharmacy for the medication, and the out-of-pocket cost to the patient. Pet.App.142a–143a.

4. Industry Standards

Newkirk has conducted thousands of pharmacy audits during his career. Pet.App.108a. When asked about compounding pharmacies hiring people to market directly to patients, Newkirk testified that the practice would not be flagged in an audit as something irregular, improper, or illegal. *Id.*, 116a. Going one step further, he said he has never seen a claims denial based on direct-to-patient marketing by a pharmacy.

Id. Indeed, "all of the compounding pharmacies in the country were using . . . marketers," demonstrating that the commission-based system was standard in the industry. *See id.* Moreover, when a pharmacy contracts with a marketer, it does not have to disclose that to the PBM as part of the pharmacy's contract with the PBM. Pet.App.97a–98a.

In this case, the marketers directed their efforts toward prospective patients whose insurance plans covered compound pain-relieving creams. Initially, marketers working for Wilkerson focused on patients with private insurance. Pet.App.39a. Once they became aware that Tricare also covered compound medications, they directed their marketing efforts toward individuals with Tricare insurance. *Id.* Zachary Rice, a former staff sergeant in the Army, testified for the government and explained that most military personnel suffer from back pain and "take Ibuprofen like its candy." Pet.App.47a–48a. Rice testified that the topical pain cream he took alleviated his back pain when over-the-counter medications did not. Rice Trial Tr., R. 299, #1964. This was important, as Rice would not have been able to maintain his flight status while taking more powerful pain relievers, such as OxyContin. *Id.*, PageID #1956–57.

Although the government attempted to cast a negative light on this aspect of their business by labelling it as "targeting," such focused marketing is an industry standard. Brian Tabor, a sales representative for Arbor Pharmaceuticals, testified about an employer-provided software program that allows him to simply enter a specific drug and a zip code that then tells him which insurers in that area cover that drug. Pet.App.92a–93a. This type of focused marketing

strategy is employed regularly across the industry. *Id.*, 93a–94a.

5. The Marketing Business

In early 2014, Wilkerson formed Top Tier, a company that contracted with compounding pharmacies to market compound creams. Pet.App.101a–102a. In early 2014, Wilkerson became the co-owner of Karma Wellness Spa in Chattanooga. Brian Kurtz was Wilkerson's business partner in both Top Tier and Karma Wellness, and they split the proceeds fifty-fifty. *Id.*, 100a.

Karma Wellness provided beauty enhancement services such as Botox and Juvéderm. Pet.App.67a. At Karma Wellness, Candace Craven, a nurse practitioner, performed beauty enhancement services and met with patients to determine whether they needed compound creams and Toni Dobson assisted with patient consults. Craven spent about 40 to 50 percent of her time on cosmetic procedures and the rest on seeing or consulting with patients for compound creams. *Id.*, 68a.[1]

Wilkerson enlisted salespeople to market compound creams to potential patients. Most marketers approached friends and family members first. *See generally* McGowan Trial Tr., R. 311; Pet.App.51a–54a. The process for recruiting patients and submitting the paperwork was straightforward.

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[1] At trial, the government emphasized that Craven signed prescriptions "[p]robably ten times" for patients she never saw. Pet.App.65a–66a. However, Craven testified that when she worked at Karma Wellness she was "actually calling people and doing everything [she] was supposed to do." *Id.*, 76a.

Patients completed order forms indicating which creams they were interested in, sometimes with some assistance from the marketers. Pet.App.40a-41a. None of the marketing materials instructed marketers to market more expensive creams. Sales Process Information, R. 576-6, PageID ##12024–26; Ingredients, R. 576-11, PageID ##12276–79 (including only the ingredient information, not the cost of the creams).

Patients also completed two additional forms: a product use form, and an evaluation form to give the marketers "the ability to use the patient's evaluation of [the] product" in the event of a future study. Pet.App.42a–43a; Evaluation Form, R. 576-4, PageID ##12021. If a patient's insurance company did not cover the cream's cost, the patient had the option to pay a reduced price for the medication. Pet,App.43a–44a.

Occasionally, a marketer would approach a customer about becoming a sales representative for the compound medications. When that happened, the marketer would tell the customer that he or she could make a commission from any creams that he or she sold. Pet.App.48a–49a. As Kurtz testified, he and Wilkerson "were always working together with lawyers to try to make sure that everything," specifically this business model, "was above board." Pet.App.102a–103a.

Once prospective patients completed paperwork requesting certain creams, the forms were sent to a healthcare provider at Karma Wellness. Pet.App.69a–71a. Craven, or another licensed prescriber, would contact the person interested in the creams. *Id*., 67a. –68a. In general, patients spoke with one of several

healthcare providers: Craven, Dobson, or Dr. Vergot. Pet.App.89a–90a. Following that contact, Craven or another prescriber would sign a prescription for the creams, if warranted. Pet.App.68a–71a. Craven testified that she would "talk to the average patient about their needs and the[] creams," and that it was her responsibility "to talk to the patients and verify that there was a need for these creams." *Id.*, 71a–75a, 62a. Indeed, Craven testified that she declined to issue a prescription for compound medications if a patient was pregnant and "[she] was concerned about . . . what was in the compound creams." Pet.App.68a; *see also id.* at 74a, 76a (Craven testifying that she had the authority to adjust the formulas and that it was her responsibility to, and that she did, talk to patients to verify there was a need for the prescription and the proper use of the creams). The prescription was then sent to a pharmacy. *Id.*, 59a. Four pharmacies had contracts with Top Tier. Pharmacies, R. 576-2, PageID ##11976–12009. The marketers understood that if a patient did not speak with Craven or another healthcare provider, the patient would not be prescribed medication. Pet.App.44a.

Patients' insurance companies reimbursed the pharmacy for prescribed compound creams marketed by Top Tier, and the pharmacy then paid a commission to Top Tier. Pet.App.110a. Top Tier's commissions averaged 30 to 35 percent of the amount the insurer paid to the pharmacy. Pet.App.85a–86a. Wilkerson, through Top Tier, paid commissions in turn to Chatfield, Nicholson, and Hindmon, second-tier independent contractors who worked as marketers. Sales Proceeds, R. 576-3, PageID ##12010–15. Chatfield, Ni-

cholson, and Hindmon split a percentage of Wilkerson's commission payments. Pet.App.86a–89a. Hindmon recruited Jayson Montgomery as a third-tier independent contractor. Montgomery typically made 50 percent of Hindmon's commissions on the prescriptions Montgomery generated. Revised Presentence Report (Sealed), R. 444, PageID #9063. All five defendants received a large amount of money in commissions. However, their earnings were not out of the ballpark for the medical sales industry. For example, Brian Kurtz testified that he had been the youngest person in the company working at Brainlab selling image-guided surgery equipment and took home $250,000 a year in that job. Pet.App.100a.

B. Procedural History

After an eleven-week bench trial, the court convicted Wilkerson of (a) conspiracy to commit healthcare fraud; (b) healthcare fraud; (c) wire fraud; (d) mail fraud; (e) payment of illegal remuneration (payment of illegal kickbacks); (f) receipt of illegal remuneration (receipt of illegal kickbacks); and (g) money laundering. The court made exceedingly clear that it was delivering its findings orally. Judgment, R. 545, PageID #11040–41. During Chatfield's sentencing, the court explained that it thought the defendants committed healthcare fraud because they did not disclose the cost of prescriptions to "someone." Specifically, the court explained:

> I believe that the overall fraud that the Court found, okay, and I should be and I'm in a pretty good position to know, was that given the way that this, I'm going to refer to it as the scheme, played out, there was, in fact, some duty on the

> part of the defendants in the case or at least, at least Mr. Chatfield and others who may have been convicted in similar, to disclose to someone, either the insurance company or the patient or someone the cost of these creams, okay, that would be charged to the insurance company. And I feel further that there was probably some duty to disclose the relationship of that cost to be charged to the insurance company to the medical efficacy of the creams themselves.

Pet.App.132a–133a. During Wilkerson's sentencing, the court noted that "it would have been much better if the law had been clear about exactly where the duty was," but it in any event found "that there is somehow this overarching duty to disclose." Pet.App.135a. In sentencing Hindmon, the court repeated that the fraud was based on a failure to disclose—not on a lack of medical necessity, explaining that:

> I think we have a misunderstanding of what was found to be fraudulent in this case . . . . I'm not sure in my mind it deals so much with medical necessity. I mean, the ingredients for these creams that I heard, I mean, there is no question they were legitimate ingredients. They're used in other FDA approved medications. The problem — and, I mean, I don't think that I heard any proof that the particular ingredients weren't included in the creams that were distributed through this scheme. The problem and what I believe . . . it's that the prices that were being charged for these creams were in my mind extraordinarily exorbitant for any legitimate medical use that they may have conferred and could have been obtained on an open market at a very tiny fraction of the cost

> which was charged to the insurance companies. And that — and I think implicit in the Court's verdict had to be that, and this is where this whole case becomes difficult, that 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 in any corner, any corner pharmacy. I think that that's the fraud in this case.

Pet.App.126a–127a. The court also commented that it had made rulings "with which jurists of reason could differ." *See* Order Granting Joint Motion for Bond Pending Appeal, R. 573, PageID #11961 (court observing that "some of the issues presented in this case—and on which the Court made rulings—required it to make judgments with which jurists of reason could differ").

The court sentenced Wilkerson to prison for 165 months and ordered him to pay restitution to the PBMs Express Scripts and CVS/Caremark in the amount of $2 million, as well as a $2,800 special assessment. Judgment, R. 518, PageID ##11042–46. But the court urged that this is "a case that needs to be appealed." *See* Pet.App.123a–124a.

Nicholson was acquitted of being involved in the charged healthcare fraud conspiracy but was convicted on substantive counts. On July 27, 2020, the court sentenced Nicholson to 30 months incarceration,

finding "I view Ms. Nicholson's involvement in this case as being, and, I mean, good gosh, I know we live in a politically correct time, but I believe she was a tagalong for Mr. Wilkerson." Nicholson Sentencing R.548 PageID #11542. The court ordered no restitution.

Hindmon was sentenced to serve 51 months in prison, to be followed by three years of supervised release. Chatfield was sentenced to serve 108 months in prison, followed up a three years of supervised release.

On appeal, the Sixth Circuit affirmed the convictions, but entirely ignored the district court's reasoning. Instead, the court inferred a scheme to defraud because one or more of the Petitioners allegedly: (1) paid Craven to sign a few prescriptions without seeing patients (but there was no evidence that those prescriptions were not medically necessary); (2) created a pre-set order form (notwithstanding that pharmacies created these orders as is standard in the industry); (3) mentioned a clinical trial that was ultimately not conducted; (4) in a few instances paid some co-pays; (5) targeted patients who had certain insurance; (6) persuaded a few customers to order "unneeded and unwanted" creams or refills; (7) in one instance allegedly discussed directing pharmacists to backdate a prescription; and (8) marketed drugs that were "excessively expensive" relative to their benefit. Pet.App.21a. But the Sixth Circuit acknowledged that each of these incidents could have an innocent explanation. Pet.App.22a–23a.

On August 8, 2022, Petitioners filed a petition for panel rehearing and *en banc* rehearing. On August 25, 2022, the Sixth Circuit denied that petition

Pet.App.36a–37a. On November 10, 2022, Justice Kavanaugh extended the time to file this petition until January 20, 2023. No. 22A433 (U.S.).

REASONS FOR GRANTING THE PETITION

I. The Lower Court Decisions Conflict With This Court's Precedent Requiring A Showing Of Subjective Intent.

The district court's and the Sixth Circuit's decisions conflict with this Court's requirement that the government establish that a defendant had the subjective intent to engage in unlawful conduct. At the time of the Sixth Circuit's decision, it was already settled law that to sustain Petitioners' convictions, the government had to prove that Petitioners acted "knowingly and willfully." *See Bryan v. United States*, 524 U.S. 184, 191–92 (1998) ("[T]o establish a 'willful' violation of a statute, 'the Government must prove that the defendant acted with knowledge that his conduct was unlawful.'") (quoting *Ratzlaf v. United States*, 510 U.S. 135, 137 (1994)).

Since the Sixth Circuit's decision, this Court provided additional guidance in *Ruan*, clarifying that "knowingly and intentionally" is a subjective standard. That case involved licensed doctors convicted of violating the Controlled Substances Act, which makes it unlawful "[e]xcept as authorized . . . knowingly [and] intentionally" to distribute a controlled substance. 21 U.S.C. § 841. Ruan had requested a jury instruction requiring the government to prove that he subjectively knew that his prescriptions fell outside the scope of his prescribing authority, but the court rejected the request and the Eleventh Circuit affirmed. 142 S. Ct. at 2375–76.

This Court reversed, holding that the "knowingly and intentionally" language of the statute applied 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." *Id.* at 2376, 2382. 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 2377. 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. Ruan* thus clarifies that where a criminal statute requires knowing and intentional conduct, the government must prove that a defendant subjectively knew he was acting unlawfully. *Id.* at 2382.

This Court has granted certiorari, vacated lower court decisions, and remanded a number of cases in light of *Ruan*. *See, e.g.*, *Henson v. United States*, 142 S. Ct. 2902 (2021) (involving the government's required showing to convict a defendant under the Controlled Substances Act); *Mencia v. United States*, 142 S. Ct. 2897 (2022) (involving the proper mens rea required to overcome a good faith defense under the Controlled Substances Act); *United States v. Couch*, 142 S. Ct. 2895 (2022) (involving whether jury instructions properly explained the mens rea required to convict a defendant under the Controlled Substances Act); *Naum v. United States*, 142 S. Ct. 2893 (2022) (involving whether the government only needs to show that a prescription was prescribed outside the usual course of professional practice to convict a defendant under the Controlled Substances Act); *Bynes v. United States*, 143 S. Ct. 71 (2022) (similar); *Queg Santos v. United*

States, 143 S. Ct. 350 (2022) (involving whether good faith is a complete defense under the Controlled Substances Act); *Sakkal v. United States*, 143 S. Ct. 298 (2022) (involving whether court should grant, vacate, and remand judgment sustaining conviction where jury instruction on intent is inconsistent with *Ruan*); *Hofstetter v. United States*, 143 S. Ct. 351 (2022) (involving whether the holding in *Ruan* applies to offenses charged under 21 U.S.C. § 856); *Newman v. United States*, 143 S. Ct. 350 (2022) (same); *Womack v. United States*, 143 S. Ct. 350 (2022) (same); *Clemmons v. United States*, 143 S. Ct. 350 (2022) (same).

Notably, in *Hofstetter v. United States*, 143 S. Ct. 351 (2022) (No. 22-5346), also a case where the Court granted certiorari, vacated the Sixth Circuit decision, and remanded the case, the defendant was a business manager and not a medical professional. The issue was whether the lower courts had properly focused on her subjective belief to find criminal liability as required by *Ruan*. And the case also involved allegations by the government that a 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 a fact. The petition explained that the government spent a great deal of time discussing allegations of theft, gambling, and other nefarious alleged conduct to create an objective image of intent. But under *Ruan*, the petition argued, this was error. Conceding this argument, the United States filed a response agreeing that the Court should grant the petition for

writ of certiorari, vacate the decision below, and remand the case for further consideration in light of *Ruan*.

Here, the healthcare fraud statute requires the government to prove "knowing[] and willful[]" conduct, 18 U.S.C. § 1347, and to prove conspiracy to commit healthcare fraud the government must prove "knowledge and intent" to join an agreement to violate the law. *United States v. Bailey*, 973 F.3d 548, 565 (6th Cir. 2020). Under *Ruan*, these statutes required a showing of Petitioners' subjective intent.

This district court found Petitioners liable based on a failure to disclose theory. *See, e.g.,* Pet.App.126a–129a (court indicating that it is "hanging its hat" on the failure to disclose the prices of the medication). But there was no showing that Petitioners intended to engage in any unlawful conduct. Indeed, failing to disclose the costs of compound drugs cannot be illegal conduct—the insurers knew the costs and agreed to cover those drugs despite the costs, and the pharmacies knew the costs. Patients were not impacted by the costs at all, and in any event, were informed of the costs by the explanation of benefits sent by their insurance companies. Moreover, there was no affirmative duty to disclose and, therefore, any failure to disclose cannot amount to fraud. *Compare United States v. Maddux*, 917 F.3d 437, 443–44 (6th Cir. 2019) ("[W]here one . . . has a duty to speak" but "says nothing," that "concealment" amounts to fraud.) *with United States v. Steffen*, 687 F.3d 1104, 1116 (8th Cir. 2012) (indictment failed to allege fraud because "Government does not argue that [defendant] was bound by a fiduciary or statutory duty to disclose"). No court has held that a pharmaceutical marketer has a duty

to disclose the price of medication to either insurers or patients. And the district court commented that it had made rulings "with which jurists of reason could differ." *See* Order Granting Joint Motion for Bond Pending Appeal, R. 573, PageID #11961 (court observing that "some of the issues presented in this case—and on which the Court made rulings—required it to make judgments with which jurists of reason could differ").

The Sixth Circuit went out of its way to accept the government's version of events and did not focus on what the Petitioners subjectively knew or intended. Rather, just as in *Hofstetter*, it considered certain "facts" (that are not illegal and/or that the court conceded could have innocent explanations) and found that together, the court could infer fraudulent intent based on those incidents. The Sixth Circuit inferred fraud based on its view that one or more Petitioners: (1) on a few instances allegedly paid Craven to sign prescriptions without seeing patients (but there was no evidence that those prescriptions were not medically necessary); (2) used a pre-set order form (that was created by pharmacies and is standard in the industry); (3) mentioned a clinical trial that was ultimately not conducted; (4) in a few instances paid some co-pays; (5) targeted patients who had certain insurance; (6) persuaded a few customers to order "unneeded and unwanted" creams or refills; (7) in one instance allegedly discussed directing pharmacists to backdate a prescription; and (8) marketed drugs that were "excessively expensive" relative to their benefit. Pet.App.21a.

Putting aside that the Sixth Circuit acknowledged that these actions could have innocent explanations, these actions are not illegal. Pet.App.22a–23a. All

marketers in any industry target specific customers. And it is standard practice to collect patient information for possible use in a clinical trial. (Martin Jungkunz, *et al., Secondary Use of Clinical Data in Data-Gathering, Non-Interventional Research or Learning Activities: Definition, Types, and a Framework for Risk Assessment, Journal of Medical Internet Research*, J. Med. Internet Rsch. (2021) https://www.jmir.org/2021/6/e26631/), it is also standard practice for third parties to pay co-pays for some patients (Pet.App.117a), for medical professionals to use formula pads (Pet.App.113a, 119a–120a), and to pay commissions. The other "facts" that the Sixth Circuit relied on are not supported by the record. There is no evidence that defendants regularly paid medical providers to sign prescriptions without seeing patients (there were a few instances where Nurse Craven said she had not seen patients but she testified that the overwhelming majority of the time she did everything she was supposed to do (Pet.App.62a–63a, 76a)). And in any event, Petitioners only advertised the drugs—thereafter the process of obtaining a prescription was between the patient, the medical provider, the pharmacy, and the patient's insurance. The government also did not present any expert evidence that the creams were not medically necessary (anecdotal evidence from a small number of patients about their individual experiences does not disprove overall efficacy and cannot rebut the uncontradicted testimony of prescribing medical professionals that the drugs were medically necessary (Pet.App.59a; Pet.App.61a–63a)). Additionally, the government introduced no evidence of any prescriptions that were in fact backdated.

But listing certain of Petitioners' alleged actions and concluding that anyone engaged in those actions must have intended to engage in fraud is applying an objective test. Indeed, the Sixth Circuit conceded that each of those incidents of conduct could themselves have an innocent explanation. Pet.App.22a–23a. The government's overreach in attempting to cast lawful conduct as fraudulent, and the court below's acceptance of that, is exactly what this Court was seeking to curtail in *Ruan*.

Moreover, the conduct identified by the Sixth Circuit as providing grounds to infer fraud was not common to all defendants—the court agglomerated actions taken by various defendants and found that sufficient to infer the intent of all defendants. For example, there was no evidence that Wilkerson told any patient about any study. There was also no evidence that all defendants paid co-pays for patients (indeed, Hindmon was acquitted of any conspiracy to do so), and most of the defendants were not involved in the one conversation about possibly backdating a prescription. And there was no evidence that Hindmon arranged for a patient to order medically unnecessary creams.

Finally, the potential for overdeterrence in healthcare fraud and Anti-Kickback prosecutions is high and, without a strict intent requirement, lawful conduct—such as entering into marketing contracts with pharmacies and collecting commissions—can become criminalized, as in this case. And just as in *Ruan*, violation of the criminal statutes here carries severe penalties. Indeed, petitioners were sentenced to between 30- and 165- months' imprisonment plus millions of dollars in fines and restitution. *See* Pet.App.18a. These severe penalties counsel in favor

of applying a strict *mens rea* requirement here. *See Ruan*, 142 S. Ct. at 2378.

Because the lower courts did not find that each Petitioner subjectively intended to engage in unlawful conduct, their decisions conflict with this Court's decision in *Ruan*.

II. The Sixth Circuit's Decision Creates A Circuit Split.

The Sixth Circuit's decision creates a split among the First, Second, and Eleventh circuits, and deepens a split within the Fifth Circuit, as to the proper standard for intent in healthcare fraud and anti-kickback cases.

1. Most circuits agree that the government must establish that the defendant knew that his or her actions were fraudulent or unlawful. *See, e.g.*, *Nora*, 988 F.3d at 831 (5th Cir.) (holding that 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 (11th Cir.) (explaining that "[w]illful[ly]" under the anti-kickback statute means "with the specific intent to do something the law forbids, that is with a bad purpose"); *United States v. Medina*, 485 F.3d 1291, 1297 (11th Cir. 2007) (explaining that "in a health care fraud case, the defendant must be shown to have known that the claims submitted were, in fact, false"); *Troisi*, 849 F.3d at 494 n.8 (1st Cir.) ("'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, rather than by ignorance, accident, or mis-

take"); *see also Pfizer*, 42 F.4th at 77 (2d Cir.) (explaining that "willfully" as used in the anti-kickback statute means "a voluntary, intentional violation of a known legal duty"; the willfulness element is meant "to avoid punishing 'an individual whose conduct, while improper, was inadvertent'"—"the [anti-kickback statute] does not apply to those who are unaware that such payments are prohibited by law and accidentally violate the statute.").

For example, the Fifth Circuit in *Nora* held that a defendant did not have the requisite intent because, while the defendant coordinated new patient intakes and admissions and processed payments he knew were for patient referrals, the government did not establish that the defendant knew that those practices were fraudulent. 988 F.3d at 831. The Eleventh Circuit likewise found in *Medina* that the defendants did not have the requisite intent because, although a pharmacy and medical supply company submitted prescriptions with forged signatures to Medicare, the government did not establish that the defendants knew of the forgeries or forged the prescriptions themselves. 485 F.3d at 1299.

In contrast, the Eleventh Circuit found that a defendant did have a "bad purpose" and "specific intent to do something the law forbids" in *Nerey*, where the government established that the defendant had attempted to mask kickback payments as "therapy services," and had agreed to a "fallback story" with another individual in the event of a Medicare audit. 877 F.3d at 969. In *Troisi*, the First Circuit determined that the defendant acted with the purpose to disobey the law in a home health services scheme because the defendant would alter Medicare forms knowing that

they "did not accurately reflect the opinions of the medical professionals who had evaluated the patients," and she instructed medical professionals to put certain information in the forms regardless of its truth. 849 F.3d at 495–96. When those medical professionals complained to her, the defendant forced them to include the information even though she had no basis for disagreement and had not evaluated patients herself. *Id.* She would also recertify patients for further home health services even when the patients, nurses and primary care physicians had said those services were not needed. *Id.* at 496. In these cases, evidence of the defendants' subjective intent to disobey the law was plain because the defendants' conduct was either admittedly or inherently dishonest and fraudulent. All these cases agree: Where a defendant engages in conduct that is not in itself illegal, and/or has no bad purpose, there is no subjective intent sufficient to support a fraud or anti-kickback conviction.

2. The Fifth Circuit has issued a decision splitting from the cases cited above. In *United States v. St. Junius*, the court held that the government only had to establish that the defendant "willfully committed an act that violated the Anti-Kickback Statute," not that the defendant knew that the payments she received were illegal. 739 F.3d 193, 210 (5th Cir. 2013). The defendant had argued that her conviction under the Anti-Kickback Statute required the government to prove that she knew beyond a reasonable doubt that being paid a commission was illegal. *Id.* The Fifth Circuit rejected this argument finding that the government "was only required to prove that she willfully solicited or received money," in other words, that she "willfully committed an act." *Id.*

3. The Sixth Circuit did not follow the majority rule and deepens the split within the Fifth Circuit. The court inferred fraudulent intent based on conduct that is standard pharmaceutical marketing practice and is not illegal. As discussed above, engaging in conduct such as targeted advertising, paying co-pays, and using pre-set formula pads is not illegal. Unlike the defendants in *Nerey* and *Troisi*, Petitioners did not engage in conduct that was itself plainly fraudulent. Petitioners did not make false statements on forms, did not instruct medical professionals to make false statements, and did not attempt to hide the source of payments or create a "fallback story." *See Nerey*, 877 F.3d at 969; *Troisi*, 849 F.3d 495–96. Instead, this case involves conduct done without bad purpose, as in *Nora* and *Medina*. The Sixth Circuit accepted the government's story that Petitioners engaged in certain conduct; however, the court did not identify any illegal conduct that each specific Petitioner engaged in or specifically find that each defendant had a bad purpose and intended to violate the law. Indeed, the record supports the opposite: that at all times Petitioners were trying to carry out their marketing business lawfully. *See* Pet.App.102a–103a (stating Kurtz and Wilkerson "were always working together with lawyers to try to make sure that everything was above board"); Pet.App.103a (Petitioners declining to take certain actions based on advice of counsel); Pet.App.56a–57a (testifying that Chatfield "was convinced that everything we were doing was legal"). In other words, the evidence of Petitioners' subjective intent establishes that they were attempting to comply with the law and were seeking guidance as to whether their activities were authorized by law.

Lacking evidence of Petitioners' intent to violate the law, the Sixth Circuit strung together innocent and often unrelated conduct and extrapolated a supposed scheme to defraud. The Sixth Circuit itself acknowledged that the incidents of conduct on which it relied might not individually support a claim of fraud, but still found an intentional scheme to defraud by cobbling that conduct together. Pet.App.26a ("Even if these actions taken in isolation could have a plausible innocent explanation, when taken together, a reasonable factfinder could easily conclude that they establish an intentional scheme to defraud."). This finding of fraudulent intent based on extrapolation from innocent conduct puts the Sixth Circuit's decision at odds with *Ruan* and other circuit authority requiring a more rigorous standard for showing a defendant had the necessary *mens rea*.

III. The Question Presented Is Exceptionally Important And Recurring.

These cases are exceptionally important with respect to the intent required to convict defendants for healthcare fraud and violation of the anti-kickback statute.

First, the question presented is important because "[a] core principle of the American system of justice is that individuals should not be subjected to criminal prosecution and conviction unless they intentionally engage in inherently wrongful conduct or conduct that they know to be unlawful[]" because "[o]nly in such circumstances is a person truly blameworthy and thus deserving of criminal punishment." Brian W. Walsh & Tiffany M. Joslyn, *Without Intent: How Congress Is Eroding the Criminal Intent Requirement in Federal*

Law (2010), https://www.nacdl.org/getattachment/8d5312e0-70f8-4007-8435-0ab703dabda9/without-intent-how-congress-is-eroding-the-criminal-intent-requirement-in-federal-law.pdf. Moreover, "[t]his is not just a legal concept; it is the fundamental anchor of the criminal justice system." *Id.*

Indeed, this Court emphasized in its opinion in *Ruan* that, with few exceptions, "wrongdoing must be conscious to be criminal." *Ruan*, 142 S. Ct. at 2376 (quoting *Elonis v. United States*, 575 U.S. 723, 734 (2015)). As this Court recognized, the requirement that a criminal defendant be conscious of their wrongdoing is a principle "as universal and persistent in mature systems of [criminal] law as belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil." *Id.* at 2376–77 (quoting *Morissette v. United States*, 342 U.S. 246, 250 (1952)). The Sixth Circuit's decision below turns this crucial principle on its head, but this Petition presents this Court with the opportunity to right that wrong.

Second, this issue is also recurring, as demonstrated by the frequency with which petitions have been granted, vacated, and remanded by this Court for reconsideration in light of *Ruan*. *See, e.g.*, *Henson*, 142 S. Ct. 2902 (involving the government's required showing to convict a defendant under the Controlled Substances Act); *Mencia*, 142 S. Ct. 2897 (involving the proper *mens rea* required to overcome a good faith defense under the Controlled Substances Act); *Couch*, 142 S. Ct. 2895 (involving whether jury instructions properly explained the *mens rea* required to convict a defendant under the Controlled Substances Act);

Naum, 142 S. Ct. 2893 (involving whether the government only needs to show that a prescription was prescribed outside the usual course of professional practice to convict a defendant under the Controlled Substances Act); *Bynes*, 143 S. Ct. 71(similar); *Queg Santos*, 143 S. Ct. 350 (involving whether good faith is a complete defense under the Controlled Substances Act); *Sakkal*, 143 S. Ct. 298 (involving whether court should grant, vacate, and remand judgment sustaining conviction where jury instruction on intent is inconsistent with *Ruan*); *Hofstetter*, 143 S. Ct. 351 (involving whether the holding in *Ruan* applies to offenses charged under 21 U.S.C.§ 856); *Newman*, 143 S. Ct. 350 (same); *Womack*, 143 S. Ct. 350 (same); *Clemmons*, 143 S. Ct. 350 (same).

IV. This Case Is An Ideal Vehicle To Resolve The Question Presented.

This case is an ideal vehicle to decide the question presented. Although the pharmaceutical industry is complex, the facts of this case are simple. Petitioners engaged in industry standard marketing conduct pursuant to contracts with pharmacies to advertise drugs that insurance companies had agreed to cover under their benefit plans. The lower courts did not conclude that by engaging in this conduct each defendant subjectively intended to engage in unlawful conduct. Thus, this case presents a clean question of whether that is what the prosecution had to do to for the courts to find Petitioners liable.

This case is also an ideal vehicle because there are no outstanding collateral issues or procedural defects preventing this petition from being decided on the

merits. The Sixth Circuit reached the merits of the defendants' appeals of their convictions when it erroneously inferred healthcare fraud based on a series of innocent acts. *See* Pet.App.21a. This petition squarely presents this Court with the opportunity to reverse that error and reaffirm the subjective *mens rea* standard announced in *Ruan*.

Finally, this case is an ideal vehicle because the issues raised in this petition have been extensively developed below. Petitioners have raised and fully briefed the lack of *mens rea* to support their convictions before the Sixth Circuit, and the government has also briefed the issue. Petitioners again briefed the issue in their motion for rehearing en banc and their motion to stay the mandate. In sum, the question whether the correct *mens rea* standard has been applied to these Petitioners' convictions has been fully developed and considered in the courts below, and there are no procedural or other issues preventing this Court from considering the question presented on the merits.

CONCLUSION

The Court should grant the petition.

JANUARY 20, 2023

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