No. 21-5261

# In The
# Supreme Court of the United States

SHAKEEL KAHN,

*Petitioner,*

v.

UNITED STATES OF AMERICA,

*Respondent.*

**On Writ Of Certiorari To The United States Court Of Appeals For The Tenth Circuit**

## REPLY BRIEF


BEAU B. BRINDLEY
*Counsel of Record*
BLAIR T. WESTOVER

LAW OFFICES OF BEAU B. BRINDLEY
53 W. Jackson Blvd.
Ste. 1410
Chicago, IL 60604
(312) 765-8878
bbbrindley@gmail.com

*Counsel for Petitioner*



COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

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## ARGUMENT

No person should be imprisoned for decades absent a jury finding that they possessed culpable *mens rea* as to the essential element separating innocent from guilty conduct. This requirement is "as universal and persistent in mature systems of 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." *Morissette v. United States*, 342 U.S. 246, 250 (1952). It does not matter how broadly one defines the act necessary for conviction.

Respondent does not argue that §841 can be interpreted as a public welfare statute; nor that practitioners are definitionally guilty for issuing prescriptions not in conformity with "generally recognized" practices. Instead, Respondent obfuscates the issue by proposing a standard that no circuit has advanced and attacking a position that neither petitioner holds.

Respondent interprets 21 C.F.R. §1306.04(a) to mean that a practitioner must put forth an "objectively reasonable" or "objectively honest" effort to "to familiarize himself with professional standards." Resp.Br. 17, 37, 42. Under Respondent's interpretation, a practitioner would not be guilty for being wrong about what the standard of care requires or for failing to issue his prescription in accordance with that standard so long as he was "objectively reasonable" in the degree or quality of effort he put into educating himself on his field of medicine. *Id.* at 39.

Respondent's standard is novel. No circuit employs their proposed language. Nor is Respondent's standard consistent with *Moore* or the Harrison Act Cases.

In Respondent's standard, the words "objectively reasonable" apply only to the degree or quality of a practitioner's educational effort, not to his understanding of his professional obligations. A defendant misunderstanding the degree or quality of education required to meet Respondent's "objectively reasonable" standard is automatically guilty regardless of the sincerity or reasonableness of his belief that his efforts were sufficient. Negligent mistakes are not allowed. Hence, Respondent's standard imposes strict liability rather than negligence.

Respondent's standard does not resolve vagueness concerns regarding how "usual course of professional practice" is measured. Instead, Respondent introduces new levels of indeterminacy by tasking juries with determining how "objectively reasonable" effort should be measured.

Moreover, Respondent's standard does not address the ultimate evil Congress sought to prevent when enacting the CSA: diversion of narcotics from legitimate to illegitimate distribution channels. Whether a prescription is issued in the "usual course of professional practice" cannot be divorced from the question of whether it is issued for a legitimate medical purpose. A standard that defines "usual course of professional practice" exclusively by whether a doctor abides by

practices "generally recognized in the United States" is regulating the *manner* in which medicine is practiced. The same is true of a standard defining "usual course" as dependent only upon a practitioner's efforts to ascertain professional norms. Either way, guilt turns on the application or appreciation of the standard of care, not the ultimate purpose intended for a prescription. By reading the two phrases in the disjunctive, courts tell juries that a doctor may be guilty for violating medical norms, even if his prescriptions were intended to (or actually did) serve a legitimate medical purpose.

Respondent contends that requiring proof that a practitioner knew a given prescription to be outside the usual course of practice would allow every doctor to define professional practice standards for himself. Resp.Br.33. Petitioner argues no such thing. Whether a prescription falls within the usual course of practice is an objective question. Petitioner simply argues that the government must establish a knowing *mens rea* as to that element.

Respondent's proposed standard is inconsistent with the Tenth Circuit's decision and the instructions issued in Petitioner's case. Under either the standard proposed by Petitioner or Respondent, the instructions misstated both the act and mental state required for conviction. Such a significant error cannot be harmless.

## I. By Focusing The Question Of Defendant's Guilt On The Degree Of Effort Put Into Educating Himself On Proper Practices, Respondent's Standard Exacerbates Vagueness Problems And Is Inconsistent With *Moore* And Harrison Act Cases.

Respondent articulates its proposed standard as requiring physicians to make an "objectively reasonable" or "objectively honest effort" "to familiarize themselves with professional standards," Resp.Br.17, or as requiring physicians to "objectively [try] to rely on [their] DEA registration." *Id.* at 36.

It is unclear what is meant by "objectively honest effort." Honest means "good and truthful: not lying, stealing, or cheating." "Honest" *Merriam-Webster.com*. https://www.merriam-webster.com (2/04/2022). "Objective" means "based on facts rather than feelings or opinions." "Objective" *MerriamWebster.com*.https://www.merriam-webster.com (2/04/2022). Presumably, Respondent does not intend to criminalize doctors' conduct because, in selecting treatment methods, they were unduly influenced by feelings.[1]

Petitioner assumes Respondent intends to propose a standard requiring that a practitioner make an effort to familiarize himself with prevailing practice standards that (1) is subjectively sincere and (2) involves an "objectively reasonable" degree or quality of effort.

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[1] Nor is it clear what "objectively tries" could possibly mean. Resp.Br.36. "Trying" is necessarily subjective.

Respondent cites no circuit case defining "usual course of professional practice" as requiring only that a practitioner put forth an objectively "reasonable effort to familiarize himself with professional standards." Resp.Br.17. Respondent's proposal is inconsistent with how the circuits currently interpret 18 U.S.C. §841(a)(1) and 21 C.F.R. §1306.04(a). Every circuit, save the Ninth, interprets "outside the usual course of professional practice" and "for no legitimate medical purpose" as separate elements that address distinct questions. Pet.Br.15-16 n.2 (collecting cases); JA542.

"Legitimate medical purpose" concerns whether a doctor subjectively believed his prescriptions were issued for a medical purpose. *Id*. Whether a prescription is issued in the "usual course of professional practice" is not concerned with the defendant's intent or even whether the prescriptions, in fact, served a medical purpose. *See* Pet.Br.46-47. Rather, a prescription is issued in the "usual course of professional practice" only when the prescription is in accordance with the "standard of medical practice generally recognized and accepted in the United States." *United States v. Merrill*, 513 F.3d 1293, 1306 (11th Cir.2008).[2]

Respondent tosses out both considerations. Under Respondent's standard, a defendant's intent is entirely irrelevant. Nor is it clear what role a doctor's

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[2] This language links "usual course of professional practice" to the "standard of care." JA545. *See also United States v. Boettjer*, 569 F.2d 1078, 1081-82 (9th Cir.1978).

compliance with, or deviation from, the standard of care would play in determining guilt. The instructions in Petitioner's case indicated that he did not act in good faith unless he issued a prescription "in accordance with generally recognized and accepted standards of practice." JA537-38. Respondent would replace that question with a very different one that turns on the quality or degree of effort defendants put into educating themselves on professional practice norms. Resp.Br.42. The former question focuses on the correctness (however measured) of the prescription, the latter on the sufficiency of a defendant's educational efforts (however measured). Respondent's standard, therefore, redefines the *act* which renders a defendant-practitioner guilty, without actually addressing *mens rea*.

### A. Respondent's standard fails to resolve the indeterminacy plaguing current caselaw.

"It is common ground that this Court, where possible, interprets congressional enactments so as to avoid raising serious constitutional questions." *Cheek v. United States*, 498 U.S. 192, 203 (1991); *Skilling v. United States*, 561 U.S. 358, 408-09 (2010).[3] "Usual

[3] Respondent contends that Petitioner's vagueness arguments should be construed as an "as applied" challenge. Resp.Br.39-40. Not so. Petitioner argued that in the absence of a scienter requirement, when unmoored from "legitimate medical purpose," the phrase "usual course of professional practice" fails to give practitioners "fair notice of the conduct it punishes" and is "so standardless that it invites arbitrary enforcement." *Johnson*

course of professional practice" does not define the standard by which a practitioner's decisions should be judged. Nor does it identify the degree of deviation from the standard that renders a prescription criminal. *See* Pet.Br.44-52.

Respondent attempts to rectify this problem by requiring only an "objectively reasonable 'honest effort' to ascertain and adhere to professional medical boundaries." Resp.Br.19. Respondent theorizes that jurors need not determine what the standards of professional practice *are*, so long as Defendant engaged in objective reasonable efforts to ascertain them. Rather than address vagueness, this standard imposes additional levels of indeterminacy.

Respondent is emphatic that the sufficiency of a defendant's educational efforts must be judged from an "objective" standpoint. Hence, the question remains: what are the criteria for determining "objective reasonableness?" Does an "objectively reasonable" effort turn merely on the quantity of articles read or symposiums attended, or does it turn on the *quality* of articles and symposiums? At what point is an effort "objectively reasonable?" Is a doctor's effort objectively reasonable if he arrives at the wrong conclusion about what practice standards allow?

Petitioner testified that he put considerable effort into educating himself on pain management. 5/17/19

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*v. United States*, 576 U.S. 591, 597 (2015). *See* Pet.Br. 42-52. This renders the standard "impermissibly vague in all of its applications." *Hoffman Estates v. The Flipside*, 455 U.S. 489, 497 (1982).

Tr.43 ("I read journal articles. I joined the American Academy of Pain Management. I joined the American Academy of Pain Medicine. I did as many CME that I could do . . . I attended pain week in Las Vegas at one point to educate myself on pain practices. I must have read numerous, numerous articles by various authors on the pain management."). Attending CME's, joining professional organizations, and reading medical journals are acts that suggest a practitioner is attempting to "learn and comply with medical norms." Resp.Br.16.

Many sources Petitioner consulted advocated aggressive opioid use in chronic pain treatment. *Id.* at 43-45. This theory was not universally accepted.[4] *Id.* at 45. Therefore, he educated himself on writings of physicians advocating more restrictive opioid use with whom he ultimately disagreed. *Id.* Is Petitioner's effort at familiarizing himself with what he believed to be the best standard of care "objectively reasonable" if he reached what a jury determines to be the wrong result in assessing competing philosophies? Respondent provides no answer.

### B. Respondent's insistence on an objective standard does not separate criminal from apparently innocent conduct.

Respondent argues that "[t]he objective honest-effort standard appropriately distinguishes between innocent and guilty minds by protecting even a

[4] Unlike Moore, Petitioner testified that he believed his treatment methods accepted within the medical field. Tr.45.

physician's errors in ascertaining and acting within the bounds of professional practice—so long as he undertook the threshold step of *reasonably* trying to situate himself within the medical community." Resp.Br.17. Respondent claims that its standard would protect a doctor's *unreasonable* misunderstanding of his professional obligations, so long as he put an objectively reasonable effort into arriving at the correct result.[5]

Respondent's standard does not protect the "unwary" from being ensnared, but only changes the point at which ensnarement occurs. A doctor who sincerely believed he put in sufficient effort to educate himself on the requisite standard of care would still be guilty if the jury found his effort insufficient in quantity or quality. The unwary practitioner would still be convicted for honest mistakes.

What Respondent proposes is a standard under which a defendant might not be guilty simply because he failed to do enough to monitor his patients, but is definitionally guilty if he failed to do enough to ascertain what more he should have done. It would effectively impose strict liability on defendants who failed to correctly ascertain what educational efforts were "objectively" required of them before issuing prescriptions.

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[5] It is not clear this is true. A practitioner who reaches an unreasonable understanding of the standard's requirements has seemingly not engaged in an "objectively reasonable" effort at familiarization.

To decide the reasonableness of a defendant's effort at ascertaining the correct standard, juries would have to first determine what the standard is, thereby engaging in two nebulous inquiries rather than one. Insisting that a defendant take objectively reasonable steps to ascertain an already vague standard does not solve the vagueness problem. It exacerbates it. *Colautti v. Franklin*, 439 U.S. 379, 395 (1979) ("This Court has long recognized that the constitutionality of a vague statutory standard is closely related to whether that standard incorporates a requirement of *mens rea*.").

Petitioner presents a more elegant solution: Require proof that a defendant knew a prescription was outside the usual course of professional practice *and* that he intentionally acted without a legitimate medical purpose. This solves the vagueness problem, protects all unwary practitioners, and prevents the chilling effect on medical practice. Pet.Br.44-48.

### C. Respondent's insistence upon an objective standard is inconsistent with *Moore* and Harrison Act cases.

Respondent argues that "usual course of practice" and "legitimate medical purpose" constitute a "unitary requirement" and should be read together, imposing one standard. Resp.Br.37. In early CSA cases, courts did interpret "usual course of professional practice" in §841 as carrying the same meaning as "legitimate

medical purpose" in 21 C.F.R. §1306.04(a). *See*, *e.g.*, *United States v. Rosenberg*, 515 F.2d 190, 197 (9th Cir.1975); *United States v. Kirk*, 584 F.2d 773, 784 (6th Cir.1978). However, those cases assumed the government must prove that a doctor did not believe the prescription served a legitimate medical purpose. *Rosenberg* at 197; *United States v. Armstrong*, 550 F.3d 382, 395-98 (5th Cir.2008). In contrast, Respondent repeatedly advocates a standard defined exclusively by the "objective reasonableness" of a doctor's effort to familiarize himself with the standard of care.

Respondent argues that the "knowingly" *mens rea* generally required as to other elements under §841 is not required here because the words "except as authorized by this subchapter" precede the words "knowingly or intentionally." Resp.Br.24, 34. Respondent relies on *United States v. Yermian*, 468 U.S. 63 (1984). *Yermian* involved the question of whether 18 U.S.C. §1001 required proof that a defendant knew her false statement was within a federal agency's jurisdiction. This is a "jurisdictional requirement," the "primary purpose [of which] is to identify the factor that makes the false statement an appropriate subject for federal concern." *Id.* at 63, 68. Jurisdictional elements do not render a defendant's conduct blameworthy. *Torres v. Lynch*, 578 U.S. 452, 467-68 (2016). Respondent's reliance on *Yermian* ignores this Court's long-held presumption in favor of scienter on any element that describes the substantive "evil Congress seeks to prevent." *Rehaif v.*

*United States*, 139 S.Ct. 2191, 2196 (2019). The Court imposes a presumption of scienter "even where 'the most grammatical reading of the statute' does not support one." *Id.* at 2197; *United States v. X-Citement Video, Inc.*, 513 U.S. 64, 68-69 (1994).

Respondent concedes that at least *some mens rea* is required. Resp.Br.19 ("A physician who believes in 'good faith' that his activities fall within that standard lacks the requisite *mens rea.*"). However, Respondent maintains that "a physician cannot have such a 'good faith' belief unless he makes some objectively reasonable 'honest effort' to ascertain and adhere to professional medical boundaries." *Id.*

There is no other area of law where "good faith" is defined "objectively." Indeed, the two concepts seem mutually exclusive. Acting in good faith is a negation of a knowing or intentional *mens rea*. *Cheek*, 498 U.S. at 201. Respondent presents no reason to believe "good faith" should be defined differently for medical practitioners. If a defendant-doctor claims good-faith prescribing, the jury may examine how his practices differ from board guidelines or practices of others in the field. That information allows jurors to assess the sincerity of the doctor's purported belief that he issued prescriptions within the "usual course of practice." *Id.* at 203-04. Just as in other contexts, the consideration of good faith boils down to an evaluation of the sincerity of the doctor's beliefs. By rendering the practitioner's subjective beliefs irrelevant, Respondent makes "good faith" an incoherent concept. If not referring to the sincerity

of a subjective belief underlying conduct, what could good faith really refer to?

Contrary to Respondent's assertion, neither *Moore* nor Harrison Act cases support its "objective" good faith standard. Resp.Br.29-33. *Moore* does not stand for the proposition that a defendant may be convicted for misapprehending practices "generally recognized in the United States" without reference to subjective intent. Moore testified that *he knew* his practices were outside the scope of what he recognized as the "particularly clear" "limits of approved treatment." *United States v. Moore*, 423 U.S. 122, 144 (1975).

Nor does *Moore* indicate that deviation from what *most* doctors do is sufficient for conviction. The Court did not hold that experimentation with new theories is criminal because it deviates from practices of most doctors. *Id.* at 143. ("Congress understandably was concerned that the drug laws not impede legitimate research and that physicians be allowed reasonable discretion in treating patients and testing new theories."). The Court simply noted that, with respect to Moore's claimed views, "[t]he jury did not believe him." *Id. Moore* did not turn on an objective analysis of his efforts at ascertaining prevailing practices.

Similarly, Harrison Act caselaw does not support a purely objective standard. In *United States v. Behrman*, 258 U.S. 280, 286 (1922), the Court upheld the sufficiency of an indictment where the defendant distributed narcotics to an addict "known by the defendant to be so addicted." *Id. Behrman* suggested that

treating an addict with narcotics was, definitionally, not legitimate medical practice. However, *Behrman* was modified in *Linder v. United States*, 268 U.S. 5, 22 (1925) and *Boyd v. United States*, 271 U.S. 104, 107 (1926).

In *Linder*, the Court clarified that *Behrman* "related to definitely alleged facts and must be so understood. The enormous quantity of drugs ordered . . . *without explanation*, seemed enough . . . to exclude the idea of bona fide professional action." 268 U.S. at 22. The allegations in *Linder* involved smaller prescriptions. The Court concluded that those allegations were insufficient to "question the doctor's good faith" because "[t]he facts disclosed indicate no *conscious design* to violate the law." *Id*. at 17.

*Boyd* provided further clarification. The instructions in *Boyd* indicated that "good faith" must be determined by evaluating "whether or not the defendant in prescribing morphine to his patients was honestly seeking to cure them of the morphine habit. . . . It is not necessary for the jury to believe that defendant's treatment would cure the morphine habit, but it is sufficient if defendant honestly believed his remedy was a cure." *Boyd*, 271 U.S. at 105. The Court noted this instruction was "in accord with what [it] said in *Linder.*" *Id.* at 107. The Court agreed it was problematic to instruct jurors that Defendant could not "issue prescriptions to a known addict 'for amounts of morphine for a great number of doses, more than was sufficient for the necessity of any one particular administration.'" *Id*. However, the Court found this instructional error

remedied by other language indicating that Defendant's *lack of intent* to cure a morphine habit was essential to guilt. *Id*.

After *Boyd* and *Linder*, courts generally found that guilt under the Harrison Act turned on whether a practitioner's subjective intent was to prescribe for the treatment of a medical condition. Pet.Br.38-39. None of the early CSA or Harrison Act cases include language suggesting that guilt turns on the sufficiency of a practitioner's efforts to educate himself on medical guidelines.

## II. Petitioner Is Not Arguing For A Radical Standard Allowing Defendants To Define Practice Standards For Themselves.

Petitioner never advocated any standard that allows every doctor to define, for himself, the usual course of professional practice. Resp.Br.33. Nor does Petitioner argue for a subjective *definition* of "usual course of practice." Rather, Petitioner takes the unremarkable position of arguing for a subjective definition of *good faith*. Criminal statutes are presumed to include a *mens rea* requirement for each element that renders a defendant's conduct blameworthy. If the act rendering the practitioner blameworthy is prescribing outside of what the "usual course" of medical practice allows, then there must be a subjective scienter requirement with respect to that act.

This no more imposes a subjective standard for determining what the "usual course of professional

practice" is than the requirement that the government prove a defendant knowingly distributed "a controlled substance" renders the question of whether a thing constitutes a "controlled substance" subjective. Under 18 U.S.C. §1001, perjury requires the government to prove that the defendant *knew* the charged statement was false. No one claims that, as a result, the question of whether a statement is true becomes subjective.

Petitioner is not arguing for a standard that makes conviction impossible or allows issuance of prescriptions a practitioner knows to be improper. If a doctor testifies that he believes appropriate treatment includes issuing prescriptions that are vastly out of step with objective medical norms, jurors may consider that in determining whether writing these prescriptions represented the defendant's honest mistake or an after-the-fact justification. *Cheek*, 498 U.S. at 203-04. The further the deviation from the standards and norms accepted in the medical community, the more likely the defendant is deviating intentionally.

Tellingly, Respondent's brief is rife with language that implicitly acknowledges the need for a finding of intent. Resp.Br.42. ("Honest-effort criminal standard . . . allows for criminal conviction only where a doctor's lack of reasonable steps to accord with accepted medical practice show that he has *decided* to no longer to act recognizably as a doctor."). *Id.* at 35 (" . . . doctor cannot claim an innocent mind when he *opts* to remain ignorant of medical conventions or *deems himself above them*."); *Id.* ("The objective aspect of the inquiry simply looks to the broader picture of a physician's

decisions, including the point . . . at which *he came to the view that* he could ignore or disregard the terms of his DEA registration."); *Id.* at 26 ("When his *choice to remain ignorant* or *altogether disregard* medical norms leads him to drug distribution . . . he is not plausibly practicing medicine—or *even looking to do so*."); *Id.* ("Physician who *does not even try* to issue his prescriptions 'for a legitimate medical purpose' . . . has either *decided not to educate* himself about current medicine . . . or actually *knows about it* yet has decided that his own idiosyncratic view of 'medicine' is all that matters.").

If Respondent's standard is meant to address the underlying question of whether a defendant *intends* to practice bona fide medicine or *intends* to act as a drug dealer, there is a simpler means of doing so: ask the jury *that* question. Practitioners without credible justifications for deviating far outside the standard of care will have a difficult time convincing jurors of their sincerity.

## III. Because It Entirely Disregards A Prescription's Purpose, Respondent's Standard Is Inconsistent With The Purpose Of The CSA

The CSA's purpose is to prevent diversion of controlled substances from legitimate to illegitimate channels. *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006). The CSA was explicitly not intended to regulate or control the manner of medical practice. 21 U.S.C. §823(g)(2)(H)(i). The CSA regulates medical practice

"only insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood." *Gonzales*, 546 U.S. at 269-70.

As currently interpreted by the circuits, "usual course of professional practice" is directed at evaluating the methods by which a prescription is issued. Respondent's standard asks if a practitioner put "objectively reasonable" efforts into ascertaining what the "usual course" requires. Neither Respondent's standard, nor the circuits' interpretation of "usual course," addresses the specific evil Congress sought to prevent.

Even where a doctor *completely* fails to engage in *any* monitoring of his patients, if a patient is using their prescriptions to treat a legitimate condition, then those medications remain within the legitimate distribution chain. Those drugs are not being abused or diverted—regardless of whether the prescriptions were issued "in accordance with generally accepted standards of practice." Nothing in the CSA suggests Congress sought to mandate physicians' educational requirements. The crime here is not being an underqualified physician; the crime is knowingly facilitating the diversion of medication. If there is no diversion or abuse, the evil Congress sought to prevent has not obtained. Conversely, if a patient is diverting or abusing, but a practitioner is unaware, he lacks the knowing *mens rea* that this Court presumes criminal statutes to require. *Rehaif*, 139 S.Ct. at 2195.

In the absence of some finding that a medical practitioner knowingly issued a prescription for other than a "legitimate medical purpose," neither a doctor who fails to educate himself on the proper practices, nor a doctor who deviates from the standard of care, is "drug dealing as conventionally understood." *Gonzales*, 546 at 269-70 ("Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally."). To ensure the conviction of only practitioners whose conduct was meant to be criminalized by the CSA, juries must be instructed that a conviction requires *both* a finding that a prescription was knowingly issued outside the usual course of practice *and* knowingly issued for no legitimate medical purpose.

Respondent argues that requiring proof that a defendant acted without a legitimate medical purpose is inconsistent with the language and intent of §1306.04. Resp.Br.37-38. However, the question is not the intent of the attorney general who crafted the CFR, but rather the intent of Congress. Congress did not delegate the power to define medical practice. *Gonzales*, 546 U.S. at 257 ("the question here is not the meaning of the regulation but the meaning of the statute"). It certainly did not provide an "intelligible principle" guiding the delegation of that power. *United States v. Touby*, 500 U.S. 160, 166 (1991). The question is not how best to define "medical practice" or how the attorney general would prefer it be defined. *United States v. Nichols*, 784 F.3d 666, 668 (10th Cir.2015) (Gorsuch, J., dissenting) ("If the separation of powers means anything, it must mean that the prosecutor isn't allowed

to define the crimes he gets to enforce."). The question is whether Congress, in enacting the CSA, clearly intended to subject medical practitioners to decades in prison based on strict liability.

## IV. Even Under Respondent's Standard, Reversal Is Necessary Because It Is Inconsistent With The Tenth Circuit's Holding And The Instructions In Petitioner's Case.

The Tenth Circuit explicitly held that no *mens rea* whatsoever attaches to the "usual course of professional practice." JA542. A doctor who fails to grasp the extent of his obligations under the duty of care is strictly liable. Respondent does not defend that position. Respondent acknowledges that a defendant should not be convicted for even *unreasonable* mistakes. Resp.Br.35, 36, 39.

Respondent also proposes a meaning of "usual course of professional practice" that differs dramatically from the Tenth Circuit's. The Tenth Circuit held that "usual course of professional practice" is distinct from "legitimate medical purpose." The latter looks to the subjective intent of the physician; the former involves a doctor's "objective" adherence to the "standard of care." JA545. Respondent, by contrast, proposes a single standard that defines "the usual course of professional practice," not by whether the defendant objectively adheres to the standard of care, but rather by whether he makes an "objectively reasonable effort" to

"place himself in accord with 'accepted medical practice.'" Resp.Br.42.

Respondent's standard cannot be derived from the jury instructions in Petitioner's case. Those instructions required that the defendant issue the prescriptions "in accordance with generally recognized and accepted standards of practice." JA538. According to the Tenth Circuit, this language is intended to link the "usual course of professional practice" to the "standard of care." JA545. Respondent's standard requires far more than a simple failure to issue prescriptions "in accordance with generally recognized and accepted standards of practice." JA537-38. It requires the defendant to elevate "his own notions of medical practice to the point where other doctors would not describe them as such." Resp.Br.36.

The instructions issued in Petitioner's case did not include any language suggesting that good faith turns on a doctor's "reasonable effort to familiarize himself with professional standards." Resp.Br.17.

The instructions stated:

> 'Good faith' connotes an attempt to act in accordance with what a reasonable physician should believe to be proper medical practice.
>
> The good faith defense requires the jury to determine whether Defendant . . . acted in an honest effort to prescribe for patients' medical conditions in accordance with generally recognized and accepted standards of practice."

JA537-38.

Unlike Respondent's standard, this instruction did not allow Petitioner to make mistakes in assessing what constitutes "proper medical practice." Regardless of how much honest effort a defendant-practitioner puts into educating himself about the appropriate standards, he is guilty under these instructions if he arrives at a conclusion that differs from "what a reasonable physician should believe to be proper medical practice." *Id*.[6]

Respondent and the Tenth Circuit make much of the word "attempt" in these instructions. JA545 ("The district court instructed that Dr. Kahn need only 'attempt' to act reasonably"); Resp.Br.15. This argument ignores what the jury instructions actually state a practitioner must attempt to do. The instructions do not require that a defendant merely "attempt to act reasonably." Nor do they require that a doctor attempt to act within what he *honestly believes* to be the scope practice. Rather, the instructions require that a defendant attempt to act in accordance with what a "reasonable physician should believe" to be "proper medical practice." JA537-38.

The problem is that the instructions defined good faith as a doctor attempting to act in conformity, not

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[6] At trial, Ruan proposed an instruction with almost identical language. Ruan JA102 ("[Good faith] means that the Defendant acted in accordance with what he reasonably believed to be proper medical practice."). Ruan's brief indicates that this is a minimally sufficient standard. Ruan.Br.47. Petitioner wholly disagrees. Good faith definitions employing standards of objective reasonableness *always* permit conviction for honest mistakes.

with what he honestly believed proper practice to be, but with what he objectively *should* have believed it to be. If his sincere belief about what the standards require differed from what it objectively should have been, then he could not possibly attempt to conform his conduct to the correct standard. It is impossible to attempt to conform one's conduct to a requirement that he does not believe exists. These instructions render anyone who is sincerely mistaken about what the medical practice standards allow strictly liable for drug trafficking.

If honest mistakes are permitted under these jury instructions, they could only be mistakes in *application* of the standard, not mistakes in *determining* what the standard allows. Respondent claims that a doctor cannot be convicted for making an error in "ascertaining . . . the bounds of professional practice" so long as he put an "objectively reasonable" effort into ascertaining those bounds. Resp.Br.17. That is not what the instructions said. These instructions did not provide a defense for every practitioner who honestly attempts to arrive at a correct understanding of his obligations. Rather, they provide a defense only if he attempts to conform his behavior to what the jury determines he "should have believed" to be the correct standard of care. An honest error in ascertaining what he "should believe" about this standard results in an automatic finding of guilt.

Respondent claims that any instructional error was harmless.[7] This Court generally does not address harmless error in the first instance. *Rehaif*, 139 S.Ct. at 2200. However, in this case, Respondent cannot possibly establish harmlessness.

If this Court agrees with Petitioner on the underlying issues, the jury instructions misstated not only the *mens rea*, but also the *actus reus.* The instructions in Petitioner's case required conviction if the charged prescriptions were not within the scope of what "a *reasonable* physician *should* believe" to be proper medical practice. JA537-38. At *best*, this applies a negligence *mens rea*. This is inconsistent with the required knowing or intentional *mens rea*.

The *actus reus* is wrong because the jury instructions limited good faith to a doctor acting in accordance with "generally recognized and accepted standards of practice." *Id*. Jurors were not required to determine whether the charged prescriptions were issued for a legitimate medical purpose. Even under Respondent's standard, the instructions got the act element wrong. Under Respondent's standard, the act criminalized is failure to conduct sufficient research to familiarize

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[7] Respondent argues that the district court did not abuse its discretion in denying Petitioner's jury instructions because they were incorrectly phrased in the conjunctive. Resp.Br.46-47. However, Petitioner proposed instructions in the conjunctive to preserve the issue, acknowledging that, under Tenth Circuit law, the instructions must be in the disjunctive. R.729 at 17. He also argued that "in compliance with generally recognized and accepted standards of medical practice" be excised from the instructions. R.729 at 19-20.

oneself with the standard of care before prescribing, not issuing a prescription that is simply not accord with recognized practices. Under every standard, the instructions incorrectly stated the *actus reus*.

Respondent argues that evidence of guilt is overwhelming. Petitioner disagrees. However, even if the government's case were particularly strong, the harmless error inquiry asks not whether an appellate court believes the defendant guilty, but whether Respondent can prove the error "did not contribute to the verdict obtained." *Chapman v. California*, 386 U.S. 18, 24 (1967).

In undertaking harmless-error analysis "it is not the [reviewing] court's function . . . to speculate upon probable reconviction and decide according to how the speculation comes out." *Kotteakos v. United States*, 328 U.S. 750, 763 (1946). The question is not whether this Court would convict under the correct standard, but whether the government can prove beyond a reasonable doubt that the jury's verdict was unimpacted by instructional error.

If the instructions incorrectly defined both the act and the mental state required for conviction, it is hard to see what can be salvaged from the verdict. This is not a case where the jury's findings so "conclusively establish intent, so that no rational jury could find that the defendant committed the relevant criminal act but did not *intend* to cause injury." *Rose v. Clark*, 478 U.S. 570, 580-81 (1986). Under the facts of this case, there is simply "no way of knowing here whether the jury's

verdict was based on facts within the condemned instructions." *Carpenters v. United States*, 330 U.S. 395, 408-09 (1947) ("For a judge may not direct a verdict of guilty no matter how conclusive the evidence. . . . A failure to charge correctly is not harmless, since the verdict might have resulted from the incorrect instruction.").

It is one thing to say that an isolated omitted element can be harmless in the face of "uncontroverted" and "incontrovertible" evidence. *Neder v. United States*, 527 U.S. 1, 18 (1999). That is quite different from a situation where both the act and intent necessary to convict were incorrectly defined. Harmless error does not permit an appellate court to "become in effect a second jury." *Id.* at 19.

Surely, there was evidence from which jurors could evaluate Petitioner's intent. That evidence, however, cut both ways. For example, Respondent reads Petitioner's pain contract as suggesting guilt. Resp.Br.12. However, proclaiming that one is not a drug dealer to one's patients can just as easily be characterized as a statement of innocence. Petitioner's patients believed Petitioner would discharge them if he learned they were diverting or abusing medication. They went to great lengths to hide their abuse of medication from him. Petitioner's testimony provided an explanation for each of Respondent's cited facts. The problem is that, under the instructions issued, the jury was not necessarily called upon to evaluate the truth of these explanations. *Connecticut v. Johnson*, 460 U.S. 73, 86 (1983) (And where a jury "may have failed to consider

evidence [on an element], a reviewing court cannot hold that the error did not contribute to the verdict."). If Petitioner's view of what medical practice standards allowed was objectively wrong, the jury instructions compelled a finding of guilt regardless of whether the jury believed his explanations. Under these facts, a finding of harmless error is not possible.

## CONCLUSION

The Judgment of the Tenth Circuit should be reversed with the direction to order a new trial using the correct definition of good faith.

Respectfully submitted,

BEAU B. BRINDLEY
*Counsel of Record*
BLAIR T. WESTOVER

LAW OFFICES OF BEAU B. BRINDLEY
53 W. Jackson Blvd.
Ste. 1410
Chicago, IL 60604
(312) 765-8878
bbbrindley@gmail.com

*Counsel for Petitioner*