IN THE

Supreme Court of the United States

STEPHEN DOMINICK McFADDEN,

Petitioner,

v.
UNITED STATES OF AMERICA,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

REPLY BRIEF FOR THE PETITIONER

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TABLE OF CONTENTS

TABLE OF AUTHORITIESiii
REPLY BRIEF FOR THE PETITIONER1
I. The Government's "Regulated Status" Argument Is Meritless
A. The Government Is Not Asking For A Rule Limited To Defendants Who Know They Are Violating The CSA Itself, Or One That Allows Juries To Draw A Permissive Inference Based On The Defendants' Generalized Knowledge Of Unlawfulness
B. General Knowledge Of Unlawfulness Is No Substitute For Knowledge Of The Facts That Make A Defendant's Conduct Illegal
C. Nothing In The Text Or Purposes Of The CSA Or The Analogue Act Supports The Government's Position
D. The Government's "Regulated Status" Theory Fails To Cure The Statute's Vagueness
1. Absent A Robust Mens Rea Requirement, The Analogue Act Is Unconstitutionally Vague13
2. Only Petitioner's Interpretation Of The Statute Can Mitigate The Constitutional Problem15

II.	Even If Accepted, The "Regulated Status"	
	Theory Does Not Render The Jury	
	Instructions Proper Or The Instructional	
	Error Harmless	16
III.	. The "Regulated Status" Theory Is Waived	20
CO	NCLUSION	22
ΔP	PENDIX A	1๑

TABLE OF AUTHORITIES

Cases

Bryan v. United States, 524 U.S. 184 (1998)
Flores-Figueroa v. United States, 556 U.S. 646 (2009)11
Liparota v. United States, 471 U.S. 419 (1985)
Morissette v. United States, 342 U.S. 246 (1952)
Neder v. United States, 527 U.S. 1 (1999)
Posters 'N' Things, Ltd. v. United States, 511 U.S. 513 (1994)
Ryder v. United States, 515 U.S. 177 (1995)
Staples v. United States, 511 U.S. 600 (1994)
United States v. Ali, 735 F.3d 176 (4th Cir. 2013)8
United States v. Batchelder, 442 U.S. 114 (1979)16
United States a Committee
United States v. Gonzalez, 700 F.2d 196 (5th Cir. 1983)8
700 F.2d 196 (5th Cir. 1983)

United States v. Morales, 577 F.2d 769 (2d Cir. 1978)	8			
United States v. Ramirez-Ramirez,				
875 F.2d 772 (9th Cir. 1989)	8			
United States v. Turcotte, 405 F.3d 515 (7th Cir. 2005)	5			
United States v. Williams,				
504 U.S. 36 (1992)	22			
Statutes Statutes				
Controlled Substances Act,				
21 U.S.C. §§ 801 et seq	passim			
21 U.S.C. § 342(a)(2)(C)	7			
21 U.S.C. § 802(32)(A)	11, 19			
21 U.S.C. § 811(a)	19			
21 U.S.C. § 812(b)	19			
21 U.S.C. § 813	11			
21 U.S.C. § 841(a)	7, 10, 11			
21 U.S.C. § 841(b)	10, 11			
7 U.S.C. § 2024(b)(1)	9			
18 U.S.C. § 231(a)	14			
18 U.S.C. § 232(5)	14			
18 U.S.C. § 1028(d)(7)	12			
18 U.S.C. § 1028A(a)(1)	11			
18 U.S.C. § 1507	14			
18 U.S.C. § 2241(b)(2)				
26 U.S.C. § 5845(a)(6)	11			
26 U.S.C. § 5845(b)				
26 U.S.C. § 5861(d)				

Other Authorities

Food and Drug Administration,	
DMAA in Dietary Supplements,	
http://www.fda.gov/Food/Dietary	
Supplements/QADietarySupplements/ucm346	
576.htm	7
S. Rep. No. 99-196	14
Sup. Ct. R. 15.2	22

REPLY BRIEF FOR THE PETITIONER

The Government ends its brief where it should have begun: confessing that it led the Fourth Circuit into error when it insisted below that "the only mental state the government needs to establish to obtain an Analogue Act conviction is a defendant's intent that the substance be used for human consumption." U.S. Br. 45. The Solicitor General further acknowledges that the district court's misapprehension of the law led it to give an erroneous jury instruction. Id. 39; Pet. App. 57a-58a. The Government nonetheless urges the Court to affirm on the basis of a novel "regulated status" theory it never raised below and which would lead to affirmance only if this Court engaged in an intensely fact-bound harmless error analysis. The Court should reject that invitation. The Government's argument is meritless, would not affect the outcome even if accepted, and is waived in any event. Accordingly, the Court should reverse and remand for a new trial.

I. The Government's "Regulated Status" Argument Is Meritless.

The Solicitor General now admits that in an Analogue Act prosecution, the Government must "prove, *inter alia*, that the defendant knowingly distributed a controlled substance analogue." U.S. Br. 13. He further acknowledges that the jury instruction petitioner proposed was correct, at least as far as it went, in providing that the Government proves that a defendant knowingly distributed an analogue when it establishes "the defendant's knowledge of the characteristics in the statutory definition of a controlled substance analogue." *Id.* 28;

see J.A. 29-30. But he does not claim that the Government offered sufficient evidence to make that showing in this case, no doubt because there was no evidence petitioner was aware of the chemical structure of his products.

Instead, the United States insists that this "knowledge of identity" approach is simply one of "two ways to prove that a defendant knowingly distributed a controlled substance" under the Controlled Substances Act (CSA). U.S. Br. 26. The other way, the Government says, is the "knowledge of regulated status" approach. Under that approach, the prosecution needed only to prove that petitioner knew that "the substances he was distributing were illegal or regulated drugs." Id. 39 (emphasis added).

The United States acknowledges that the jury instructions did not require the Government to prove knowledge under either approach. U.S. Br. 39. But it argues that the instructional error was harmless because, in its view, the evidence proved "beyond a reasonable doubt that any rational jury would have found that petitioner knew he was dealing with illegal or regulated drugs," even if it did not show that petitioner knew his products had the features required to render them analogues under the statute. *Id.* 43; *see id.* 39-43.

That argument is wrong in the first instance because the "regulated status" theory as conceived by the Government has no basis in the law. Accepting it would work a radical transformation of the Government's burden not only in analogue cases, but also in prosecutions involving ordinary scheduled controlled substances.

A. The Government Is Not Asking For A Rule Limited To Defendants Who Know They Are Violating The CSA Itself, Or One That Allows Juries To Draw A Permissive Inference Based On The Defendants' Generalized Knowledge Of Unlawfulness.

Before explaining the error in the argument Government does make, it may be helpful to clarify what the United States is *not* arguing.

1. The Government is not arguing for a rule under which mens rea may be established by showing that the defendant knew his products were illegal under the CSA *itself*. That is, the Government's "regulated status" theory is not limited to cases in which the defendant knew that an item was illegal under the statute *of conviction*. If that were all the Government was claiming, petitioner might agree. For example, if someone handed a defendant a sealed box and told him it contained "a substance banned by the Controlled Substance Analogue Act," that might suffice as a matter of law to establish the defendant's mens rea, even if he knew nothing else about what was in the box.

But that is not because such proof is an alternative to the "knowledge of identity" approach. It is simply a special application of the approach, wholly consistent with the ordinary mens rea requirement that the defendant know the facts that make his conduct unlawful: if the defendant believed what he was told, he would know that the substances in the box necessarily had the characteristics that qualified them as analogues under the Act, which is

the only fact he needs to know in order to be aware that possessing the box is illegal under the CSA.

This kind of "regulated status" theory, however, is of no use to the Government in this case. The Solicitor General admits that the evidence "tends to show that petitioner believed that his actions did not violate the CSA specifically." U.S. Br. 42 (emphasis added). Indeed, it was undisputed at trial that petitioner had specifically researched whether the substances were illegal under the CSA and did not know the Analogue Act even existed. See Petr. Br. 9-10; D. Ct. Docket No. 217, at 73 (Government's closing argument) (disavowing any claim that petitioner saw information about the Analogue Act when reviewing the DEA website).

2. So the Government is forced to pursue a broader theory under which a defendant knowingly distributes a controlled substance if he believes his products are illegal or regulated under *any* law. U.S. Br. 29-30. In making that argument, the Government is not asserting the modest claim that generalized knowledge of unlawfulness is *evidence* from which a jury may draw a *permissive* inference that the defendant either knew that he was violating the CSA specifically or knew the facts that made his conduct unlawful under the CSA (*i.e.*, that his products contained cocaine).

Again, if that was all the Government was arguing, petitioner might agree. See Petr. Br. 33; see also, e.g., United States v. Hassan, 578 F.3d 108, 124-26 (2d Cir. 2008); United States v. Hussein, 351 F.3d 9, 20-21 (1st Cir. 2003). Allowing such inferences is not unique to CSA or Analogue Act prosecutions. A jury could just as easily infer that a defendant selling

machine guns in a dark alley for large sums of cash knew that he was selling machine guns, not ordinary rifles. But importantly, any such inference is purely permissive. A defendant might explain, for example, that she genuinely believed the guns to be single-shot replicas of machine guns, but was selling them she thought furtively because $_{
m the}$ sale nonetheless unlawful (e.g., because the guns were stolen, because even single-shot replicas of machine guns were prohibited under state law, or because the guns were illegally imported in violation of a federal import ban against Russia). Or a defendant might explain that he thought he was selling a dietary supplement in violation of FDA rules, but was that unaware the product contained methamphetamines. If a jury believed these defendants' explanations, it would be obliged to other (absent evidence) because defendants' belief that they were violating some other law does nothing to show that they knew they were distributing a "controlled substance" as that term is defined in the CSA.

Which is why the Government is not asking the Court to establish a permissive inference. Having admitted that the jury instructions were incorrect, it can prevail only by showing "beyond a reasonable doubt that the omitted element was uncontested and supported by overwhelming evidence." Neder v. United States, 527 U.S. 1, 17 (1999). Simply showing that the evidence would have permitted the jury to infer that petitioner had the required mental state does not satisfy that standard. See, e.g., United States v. Turcotte, 405 F.3d 515, 528-29 (7th Cir. 2005).

Instead, the Government seeks a rule under which it would be entitled to an instruction *requiring* the jury to find mens rea established if the prosecution proved the defendant knew his products were illegal or regulated under *some* law, even if he honestly believed they were legal under the CSA. It effectively asks the Court to convert what ordinarily would be a permissive inference into a mandatory one. Or, more accurately, it is proposing an alternative *definition* of what it *means* to knowingly distribute a controlled substance.

B. General Knowledge Of Unlawfulness Is No Substitute For Knowledge Of The Facts That Make A Defendant's Conduct Illegal.

The Government's "regulated status" definition of knowing distribution runs headlong into this Court's repeated teaching that when a statute punishes only knowing possession or distribution of a particular kind of item, the defendant must know "of the features of" the item "that brought it within the scope of the Act." Staples v. United States, 511 U.S. 600, 619 (1994); see Petr. Br. 36-38 (same rule applied in cases involving unregistered firearms, paraphernalia, false identification, pornography involving minors). The Government would now seemingly insist that it can avoid having to make that showing by demonstrating, instead, that the defendant believed he was acting unlawfully under state law or some other federal regulation, even if he was completely ignorant about the facts that made his conduct illegal under the federal statute of conviction, and even if he honestly believed

that he was complying with the federal statute he was accused of violating.

Such a rule makes no sense. Even if petitioner believed his products were illegal or regulated under a state drug law, FDA regulation, or import statute, that would hardly suffice to show that he knew that the products were "controlled substances" as required by Section 841(a). For example, a defendant handed a box and told that it contained Cuban cigars imported in violation of a federal trade embargo would know he was dealing with a "regulated or illegal" substance. But that would not prove he knew he possessed a "controlled substance" as that phrase is used in the CSA, even if it turned out that, unbeknownst to him, the cigars contained marijuana. His belief that the substance was illegal would reflect only his factual belief that his cigars came from Cuba and his legal knowledge of the import ban. Neither has anything to do with the CSA.1

The same would be true of a defendant selling diet pills containing a substance she believed to be illegal under the Food and Drug Act as an unsafe food additive. See 21 U.S.C. § 342(a)(2)(C).² If she was unaware that the substance was substantially similar to a controlled substance, her knowledge that

¹ Of course, an item regulated by an import law could be considered a "controlled substance" in a very literal sense (since it is "controlled" by virtue of the law). But if that is what the Government means, it is just playing word games.

 $^{^2}$ See generally Food and Drug Administration, DMAA in Dietary Supplements, http://www.fda.gov/Food/Dietary Supplements/QADietarySupplements/ucm346576.htm.

the pills were regulated or illegal under a federal drug law other than the CSA would not show that she knowingly sold a "controlled substance" within the meaning of the CSA.

None of the circuit cases the Government cites hold to the contrary. Most refer to knowledge of illegal or regulated status only as a short-hand for the principle that a defendant "knowingly possessed a controlled substance" if he "knew he possessed a controlled substance (even though he was either mistaken about or did not know its exact identity)." Hussein, 351 F.3d at 19; see also United States v. Ali, 735 F.3d 176, 186-87 (4th Cir. 2013); Hassan, 578 F.3d at 125; United States v. Ramirez-Ramirez, 875 F.2d 772, 774 (9th Cir. 1989); United States v. Gonzalez, 700 F.2d 196, 200 (5th Cir. 1983); United States v. Lewis, 676 F.2d 508, 512 (11th Cir. 1982); United States v. Morales, 577 F.2d 769, 776 (2d Cir. 1978).3 While some use broad language referring to "an illegal drug" or a "regulated" substance, there is no suggestion the courts had in mind laws other than the statute of conviction. See, e.g., Hussein, 351 F.3d at 21; Lewis, 676 F.2d at 512. To the extent any court has considered the possibility that a defendant might believe his substances were illegal under some other law, they have acknowledged that such a belief would not prove the knowledge required by the CSA.

³ This principle has no application to this case because the Government does not claim that petitioner knew he was distributing substances that were substantially similar to a controlled substance, but was simply mistaken or ignorant about which analogue he was selling.

See, e.g., Hassan, 578 F.3d at 126 (defendant's alleged knowledge that importing khat "violated U.S. customs laws" insufficient to prove knowledge required by the CSA (internal quotation mark omitted) (citation omitted)); Hussein, 351 F.3d at 21 (same).

The Government's citations to this Court's decisions, see U.S. Br. 42, are likewise unavailing. The statute in *Liparota v. United States*, 471 U.S. 419 (1985), for example, criminally punished anyone who "knowingly uses, transfers, acquires, alters, or possesses coupons or authorization cards in any manner not authorized by [the statute] or the regulations." *Id.* at 420 (alteration in original) (quoting 7 U.S.C. § 2024(b)(1)) (internal quotation mark omitted). It was a given that this language required the Government to prove that the defendant was aware of the *facts* that made his conduct illegal under the statute - specifically, that he "knew that he was acquiring or possessing food stamps." Liparota, 471 U.S. at 422. The question was whether there were special reasons to require the Government additionally to prove that the defendant knew his conduct to be illegal in some general or specific sense. See id. at 423. No one suggested that the Government could escape proving the defendant's knowledge of the facts by proving only that he was aware that his conduct was unlawful under some unspecified statute or regulation. Bryan v. United States, 524 U.S. 184 (1998), likewise was a case in which a special feature of the statute – specifically, the requirement that the defendant act "willfully" instead of simply "knowingly" - required the Government to prove *both* the defendant's knowledge of the facts that made his conduct illegal under the statute *and* his knowledge that his conduct was illegal. *See id.* at 191-92.

The Government has cited no decision by this Court interpreting any criminal statute to give the Government the option of proving the defendant's general knowledge of unlawfulness as a substitute for showing that he was aware of the facts that made his conduct illegal under the statute of conviction. To the contrary, with the exception of unusual cases like Liparota, the Court has generally "knowingly" requirements in criminal statutes to make the defendant's knowledge of the law See, e.g., Posters 'N' Things, Ltd. v. irrelevant. United States, 511 U.S. 513, 524-25 (1994); Morissette v. United States, 342 U.S. 246, 271 (1952).

C. Nothing In The Text Or Purposes Of The CSA Or The Analogue Act Supports The Government's Position.

Nothing in the text or purposes of the Analogue Act warrants a novel exception to traditional mens rea principles.

1. The Government stresses that "the 'knowingly' requirement in 21 U.S.C. 841(a) applies *only* to the aspects of the CSA violation included in Section 841(a) and not to other aspects of the CSA violation contained in Section 841(b), such as the identity or quantity of the controlled substance." U.S. Br. 23. But petitioner has never argued that the knowledge requirement extends to the words in subsection (b). Instead, the Government must prove that the defendant knows his substance is substantially similar to a controlled substance because that is what it *means* to knowingly possess "a controlled substance" in an analogue case as those words are

used in Section 841(a). Petitioner would make the same argument if subsection (b) had never been enacted.

The Government says that if "petitioner agrees that the 'knowingly' requirement of Section 841(a) does not apply to Section 841(b), no reason would support extending it to Section 802(32)(A)." U.S. Br. 24. Nonsense. When Section 841(a) prohibits selling a "controlled substance," it incorporates the statutory definition of that term, which, under Section 813, includes analogues as defined in Section 802(32)(A). The fact that the definition is in a different subsection of the statute is irrelevant. For example, in Staples, after construing the law to require that the defendant know that his rifle was a "firearm" within the meaning of the statute, this Court naturally turned to the statutory definitions (in a separate section of the law) to identify the facts the defendant must know to have the required mens rea. 602, 619; 26 511U.S. U.S.C. § 5861(d) (criminalizing unregistered possession of a "firearm"); id. § 5845(a)(6) (defining "firearm" to include a "machinegun"); id § 5845(b) (defining "machinegun"). Likewise, in Flores-Figueroa v. United States, the Court read the Aggravated Identity Theft statute to require the Government to prove the defendant knows, "at the very least, that the 'something' [he possesses] is a 'means of identification." 556 U.S. 646, 650 (2009). In so doing, the Court plainly contemplated that the Government would have to prove that the defendant knew he possessed an object with characteristics that made it a "means of identification" as defined by the statute, even though the definition was in another provision. U.S.C. § 1028A(a)(1) (punishing one who, among other things, "knowingly . . . uses, without lawful authority, a means of identification of another person"); id. § 1028(d)(7) (defining "means of identification").

2. Nor is the Government's position compelled by the Analogue Act's purposes. As petitioner's opening brief predicted (Petr. Br. 29-31), the Government is unable to claim that a traditional reading of the statute impedes the prosecution of the underground chemists who were the principal targets of the statute. The Government points out that the statute was not limited to chemists, but engages a straw man when it claims that petitioner proposes a "chemists only' limitation." U.S. Br. 32. In fact, petitioner has acknowledged that the statute applies to distributors as well, so long as they possess the mens rea required by the plain text of the statute. Petr. Br. 32-35. The Government simply ignores petitioner's detailed discussion of the ways in which the Government can, and frequently does, convict "street-level dealers" even in circuits that enforce the statute as written. Id.

Ultimately, the Government's position is that petitioner's interpretation of the law cannot be correct because it prevents prosecution of people like petitioner, *i.e.*, people unaware of the Analogue Act and the facts that make their conduct illegal. But that reasoning assumes its own conclusion. The best way to know whether Congress intended the Act to extend to such individuals is to apply the plain text of the statute in light of the traditions against which it was enacted.

D. The Government's "Regulated Status" Theory Fails To Cure The Statute's Vagueness.

The Court should also reject the Government's "regulated status" theory because it fails to mitigate the statute's vagueness.

1. Absent A Robust Mens Rea Requirement, The Analogue Act Is Unconstitutionally Vague.

The Government denies almost none of the premises of petitioner's vagueness argument. It does not dispute that: (a) the statute turns on facts that are inaccessible to ordinary people; (b) the statutory phrase "substantially similar" is inherently vague as to both the *degree* of similarity required and, more importantly, the *features* of chemical structure to be compared; as a consequence, (c) scientists cannot agree on either a methodology for judging similarity or the results with respect to particular substances; (d) the only way the Government can decide whether a substance is an analogue is to ask DEA scientists. who sometimes disagree; (e) when DEA scientists do reach a decision, they keep their conclusions a secret; and (f) even if one researches the case law, no sure answer can be provided because the Government is not bound in any future case by a jury's determination that a particular substance is not an analogue. Petr. Br. 45-51; see also NACDL Br. 3-8; Expert Forensic Scientists Br. 11-29.

At bottom, the Government does not seriously dispute that ordinarily there is no reasonable way for a non-chemist like petitioner to know whether selling a potential analogue is illegal under the Act, short of getting arrested and tried before a jury.

The Government nonetheless argues none of this is constitutionally problematic or even remarkable. It says that Congress has used "similar" in other criminal statutes (three, to be precise). U.S. Br. 35-But asking a protester to decide whether a 36. Molotov cocktail is similar to a "fire bomb," 18 U.S.C. § 232(5), is nothing like asking a construction worker to judge the degree of structural similarity between methcathinone and 3, methylenedioxymethcathinone. See Petr. Br. 11-13.4 The Government notes that the American Chemical informed "the Society Congress that term 'substantially similar' chemical structure meaningful to scientists." U.S. Br. 36 (emphasis added) (quoting S. Rep. No. 99-196, at 5 (1985)) (internal quotation mark omitted). But the constitutional question here is whether it meaningful to an ordinary person. Moreover, as demonstrated by briefs in this case, the Society's prediction has been proven wrong by more than 25 years of experience. See Expert Forensic Scientists Br.

The Government notes that experts disagree all the time and that juries resolve complex scientific questions. U.S. Br. 36. But the complaint here is not simply that a jury must resolve a complex scientific question; it is that an ordinary citizen must make

⁴ In addition, each of the statutes cited contains a conventional mens rea element. *See* 18 U.S.C. §§ 231(a), 1507, 2241(b)(2).

those same judgements without any of the expert testimony or lab reports available to jurors, subject to imprisonment if he reaches a conclusion in conflict with the view of the particular jury that hears his criminal case.

> 2. Only Petitioner's Interpretation Of The Statute Can Mitigate The Constitutional Problem.

Petitioner's interpretation of the Analogue Act's mens rea requirement would avoid a serious question of the Act's constitutionality as applied to petitioner and others like him. The Government's proposed "regulated status" test would not.

Government objects that accepting petitioner's interpretation would "do nothing to mitigate the vagueness problem of which petitioner complains," U.S. Br. 35, because on petitioner's view, the statute is "vague to the core," id. 34. Adopting petitioner's position would prevent unconstitutional convictions of people for whom the statute is hopelessly vague because the Government will be unable to satisfy the mens rea element of the crime. That is hardly a "meaningless limit on the statute's reach." Id. 35. At the same time, petitioner has not taken the position that the statute is incapable of ever being constitutionally applied. It may well be, for example, that a clandestine chemist intentionally sets make who out to small modifications to an existing controlled substance will know that the alterations are insubstantial under any conceivable standard.

The United States' proposed "regulated status" test, on the other hand, does not solve the vagueness problem. It allows the Government to convict

individuals like petitioner, even if they have no reasonable basis for determining whether what they are selling is an illegal analogue, so long as the prosecution can convince a jury that the defendant knew the substance was "regulated or illegal" under some law. But the fact that a defendant may understand that his conduct violates one law does not obviate the constitutional need for fair notice that it also violated the *statute* of conviction. defendants are entitled to clear notice of the criminal consequences of his acts. See, e.g., United States v. Batchelder, 442 U.S. 114, 123 (1979). Knowing that he is violating a state drug law hardly puts a defendant on notice that he may instead be subject to the frequently harsher penalties of the CSA.

* * * * *

If the Court rejects the Government's "regulated status" theory, the only appropriate disposition is reversal and remand for a new trial. The Government's sole objection to the instruction petitioner proffered is the instruction's failure to include a version of the "regulated status" theory. See U.S. Br. 39. And although the Government claims any instructional error is harmless, that argument is likewise dependent on the meritless "regulated status" theory. See id. 39-43.

II. Even If Accepted, The "Regulated Status" Theory Does Not Render The Jury Instructions Proper Or The Instructional Error Harmless.

Even if the Court concludes that the "regulated status" argument has merit, that would be no basis for reversal.

The United States does not dispute that the jury instructions actually given were erroneous even under its interpretation of the statute. See U.S. Br. 39.5 The Government also does not contest that this acknowledged error in the instructions is an independent and sufficient ground for reversal, even if the district court rightly rejected petitioner's proposed instruction. See Petr. Br. 36 n.22; U.S. Br. 39. It claims instead that any instructional error was harmless beyond a reasonable doubt "because no rational jury could have concluded that petitioner did not know that the substances he was distributing were illegal or regulated drugs (even if he did not know which law made his distribution of them illegal)." U.S. Br. 39.

That argument fails on its own terms because a rational jury would *not* have been compelled to find that petitioner knew his products were illicit drugs. To the contrary, the evidence was overwhelming that petitioner was entirely ignorant of the Analogue Act and believed that selling substances producing druglike effects was legal so long as they were not on the CSA schedules.

The evidence shows that petitioner made substantial efforts to ensure that his sales complied with federal drug laws. With the assistance of his

⁵ That is because the instructions did not require the Government to prove *either* that petitioner knew his products were chemically similar to a controlled substance *or* that he was aware they were "regulated or illegal" under the Government's new theory. *See* J.A. 40.

law enforcement brother, petitioner compared the ingredients in his products with the DEA's list of controlled substances. Petr. Br. 9-10. When he became aware that a substance in some of his products had been placed on the schedules, he promptly flushed the products down the toilet. *Id.* 10. When an undercover DEA agent attempted to purchase the newly scheduled chemicals from him, petitioner refused. *Id.* None of this is consistent with someone who believed all along that he was selling illegal substances and just did not care.

The Government thus admits that the evidence "tends to show that petitioner believed that his actions did not violate the CSA specifically," but argues that this "does not rebut the vast evidence demonstrating that he knew his actions were illegal more generally." U.S. Br. 42. Why, however, would petitioner bother consulting the CSA schedules if he was determined to sell his products whether they were legal or not? Why stop selling products containing one banned substance if he knew that his other products also contained illegal drugs and had decided to sell them anyway?

The Government says that searching the schedules shows that petitioner was aware that "the products he sold had drug effects sufficiently similar to those of controlled substances to support their eventual inclusion on the schedules." U.S. Br. 42. And it points to evidence that petitioner represented that his substances had effects similar to actual controlled substances. *Id.* 40-41. But this evidence is entirely consistent with petitioner's claim that he was ignorant of the Analogue Act and believed that such substances were legal so long as not listed on

the CSA schedules. That is, it shows that petitioner understood that his products *might* be illegal, such that research into their legality was prudent. Having discovered that his products were not on the CSA schedules, and believing them therefore to be legal despite their effects, he felt free to sell them and describe those effects to potential customers.⁶

Moreover, the Government's assumption that anyone would know that a substance having "drug effects" is illegal is counterfactual. The CSA prohibits drugs with psychoactive effects only if they meet additional criteria. See 21 U.S.C. §§ 811(a), And the Analogue Act criminalizes 812(b). distribution of substances that have substantially similar effects to previously scheduled controlled substances only if they are substantially similar in chemical structure. Id. § 802(32)(A). Thus, it is not so surprising that at the time petitioner was selling his products, bath salts were being sold openly in his neighborhood delis and gas stations, even advertised in local newspapers and magazines. See C.A. J.A. 635-36.

So the Government is left with its evidence allegedly showing that petitioner "attempted to conceal his activities," facts it says "suggest that he was conscious of his own wrongdoing." U.S. Br. 41 (emphasis added). That suggestion is undermined by

⁶ So, too, the Government's litany of other circumstantial evidence – the form of the substances and their packaging, names, and pricing – is perfectly consistent with petitioner (wrongly) believing that he was exploiting a legal opening in the drug laws.

the Government's insistence, in the immediately prior paragraph, that petitioner was not in fact, particularly careful to hide the nature of what he was selling, openly comparing them to illicit drugs. See id. 40-41. In any event, a reasonable jury would not be compelled to find knowledge of unlawfulness from this evidence. Petitioner might have worried that if he was more open about his sales, the police might arrest him even if his business was lawful -e.g., because they wrongly assumed that his products contained controlled substances, because they misapprehended the law, or because they just wanted to harass him. Or he might worry that even though he honestly believed his products were legal, he could In any event, the alleged evidence of be wrong. concealment is hardly sufficient to compel a jury to disregard the far more direct evidence that petitioner believed his business was lawful.

III. The "Regulated Status" Theory Is Waived.

Finally, in addition to being meritless and making no difference to the outcome of this case, the "regulated status" theory is waived, having been invented by the Solicitor General for the first time in the Government's brief on the merits.

In the Fourth Circuit, the Government's only objections to petitioner's proposed instructions were: (a) under circuit precedent the only relevant intent the Government need prove is intent for human consumption, U.S. C.A. Br. 60-63, and (b) petitioner's instruction incorrectly stated that he had to know (as opposed to intend) that the substance would be

consumed by human, id. 64-65.7 The Government also raised a one-paragraph harmless error argument that likewise had nothing to do with any "regulated status" theory. The brief noted that petitioner's proposed jury instruction permitted conviction if the jury found that he "had a strong suspicion that the distributing possessed substances he was characteristics of controlled substance analogues, as defined above, and that he deliberately avoided the truth." Id. 63 (emphasis added) (quoting petitioner's proposed instruction, reproduced at J.A. 29-30) (internal quotation mark omitted). The Government then claimed that given the evidence in the case "a rational jury would have found McFadden guilty under his own proposed instruction." U.S. C.A. Br. 64 (emphasis added). That is, the Government argued that a jury would have been compelled to convict petitioner under what it now calls the "knowledge of identity" approach embodied in petitioner's proposed charge.

The brief in opposition likewise said not a word about the present "regulated status" theory, and certainly did not assert with any clarity that any instructional error was harmless because the evidence showed that petitioner knew his conduct was unlawful even if he did not know anything about the chemical structure of his products. See, e.g., BIO 26 (arguing that if petitioner "had been unaware or unsuspecting that the products he sold had the characteristics of controlled substance analogues, he

⁷ The relevant section of the Government's brief is reproduced at Appendix A.

would never have checked the DEA's website to see whether they were already controlled" (emphasis added)).

As the cert. reply brief explained, the harmless error arguments the Government actually made below are meritless. Pet. Reply 10-12. "In granting certiorari, [this Court] necessarily considered and rejected [them] as a basis for denying review." United States v. Williams, 504 U.S. 36, 40 (1992). And, in any event, the Government has waived those arguments by failing to reassert them in its brief on the merits. At the same time, the Government's failure to raise its present theory in the lower court or in its brief in opposition forfeits the new argument in this Court. See Ryder v. United States, 515 U.S. 177, 186 (1995); Sup. Ct. R. 15.2.

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be reversed.

Respectfully submitted,

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APPENDIX A

EXCERPT FROM UNITED STATES' CORRECTED BRIEF OF THE APPELLEE IN THE FOURTH CIRCUIT

Docket No. 34, No. 13-4349 (4th Cir.)

* * *

[*54]VII. THE COURT PROPERLY INSTRUCTED THE JURY.

McFadden argues that the district court improperly instructed the jury in instructions failed to require the jury to find that McFadden knew that the [*55] substance he was selling had the essential characteristics of a controlled substance analogue, as outlined in § 802(32)(A)(i)-(iii). Br. of Appellant at 56-59. When jury instructions are challenged on appeal, the central inquiry is "whether, taken as a whole, the instruction fairly states the controlling law." Cobb. 905 F.2d at 788-89. Further, this Court reviews jury instructions in their entirety and as part of the whole trial. Park, 421 U.S. at 674. On that basis, this Court determines "whether the [district court] adequately instructed the jury on the elements of the offense and the accused's defenses." Fowler, 932 F.2d at 317. To determine whether denial of a requested jury instruction constitutes reversible error, this Court has articulated a three-part test. "A district court's refusal to provide an instruction requested by a defendant constitutes reversible error only if the instruction: (1) was correct; (2) was not substantially covered by the court's charge to the jury; and (3) dealt with some point in the trial so important, that failure to give the requested instruction seriously impaired the defendant's ability to conduct his defense." United States v. Lewis, 53 F.3d 29, 34-35 (4th Cir. 1995)(internal quotations and citations omitted). Accord United States v. Patterson, 150 F.3d 382, 388 (4th Cir. 1988), cert. denied, 525 U.S. 1086 (1999). But cf. United States v. Hurwitz, 459 F.3d 463, 476-82 (4th Cir. 2006)(although defendant's requested instruction was incorrect statement of law, and was therefore properly denied, [*56] district court's erroneous instruction on the same point, which went to the heart of the defense, held reversible error).

The district court's instructions in this case were in accordance with 21 U.S.C. §§ 802(32), 813 and 841, and were consistent with Fourth Circuit precedent. For the reasons herein, the court did not abuse its discretion in denying McFadden's proposed instruction, and McFadden's appeal in this regard should be denied.

Under 21 U.S.C. § 841(a)(1), it is a criminal offense to knowingly or intentionally distribute or dispense a controlled substance or to possess with an intent to distribute ordispense a controlled substance. The essential elements of such distribution offense are (1) possession of the controlled substance; (2) knowledge of the possession; and (3) intent to distribute. See United States v. Hall, 551 F.3d 257, 267 (4th Cir. 2009); United States v. Crockett, 813 F.2d 1310, 1316 (4th Cir.1987). Under 21 U.S.C. § 813, as enacted in the CSAA, a "controlled substance analogue" is treated as a controlled substance to the extent it is intended for human consumption. The statutory definition of a controlled substance analogue is:

A substance—[*57]

- i. the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;
- ii. which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or
- iii. with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.

21 U.S.C. § 802(32)(A).

At his trial, McFadden requested an instruction requiring the jury to find that the defendant knew the specific characteristics of a controlled substance analogue. The proposed instruction was as follows:

. . .You may find that the defendant knowingly participated in a conspiracy to distribute controlled substance analogues, and that he knowingly distributed controlled substance analogues, if you find beyond a reasonable doubt that he knew that the substances that he was distributing possessed the characteristics of controlled substance analogues-that is, that he knew that:

- 1. The chemical structure of the substance is substantially similar to the chemical structure of a controlled substance in Schedule I or II of the Controlled Substances Act;
- 2. The substance has an actual, intended or claimed stimulant, depressant, or hallucinogenic effect on the central nervous system that is [*58] substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II of the Controlled Substance Act; and
- 3. The substance would be consumed by humans.

You may find that the defendant knowingly distributed controlled substance analogues if you find beyond a reasonable doubt that he had a strong suspicion that the substances that he was distributing possessed the characteristics of controlled substance analogues, as defined above, and that he deliberately avoided the truth.

You may not find that the defendant acted knowingly if he was merely mistaken or careless in not discovering the truth, or if he failed to make an effort to discover the truth.

JA 191.01-.04, 191.11. In response to McFadden's motion, the district court entered an Order denying McFadden's request and advising the parties in its Order that "the court intends to utilize the elements set forth by the United States Court of Appeals for the Fourth Circuit in *United States v. Klecker*, 348 F.3d 69 (4th Cir. 2003), in its instructions to the jury." JA 105. Later, in response to McFadden's Motion for Judgment of Acquittal, the court reached the same conclusion. JA 919-23.

For the conspiracy offense charged in Count One of the indictment, the court instructed the jury that, in order to find McFadden guilty of Count One, the jury had to be convinced that the government has proven each of the following elements beyond a reasonable doubt: [*59]

First, that beginning in or around June of [2011,] and continuing until February 15, 2012, [two] or more persons, directly or indirectly, reached an agreement or understanding to accomplish a common plan;

Second[,] that the defendant knew the purpose of the agreement, and joined in it willingly, that is, with the intent to further the purpose of the plan;

Third, that the purpose of the plan was to distribute or possess with intent to distribute, for human consumption, a mixture or

MDPV. substance containing MDMC/ Methylone, or 4-MEC, which has an actual, intended, or claimed stimulant, depress[ant], hallucinogenic effect on the central nervous system that is substantially similar to that or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II of the Controlled Substances Act; Four, that the chemical structure of MDPV, MDMC/Methylene, or 4-MEC is substantially similar to the chemical structure of a controlled substance Schedule I or II of the Controlled Substances Act.

JA 919-20.

For the offense of distributing a controlled substance analogue, as charged in Counts Two through Nine of the indictment, the court instructed the jury that the government had to prove, as to each count, the following essential elements beyond a reasonable doubt:

First, that the defendant knowingly and intentionally distributed a mixture or substance that has an actual, intended, or claimed stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II of the Controlled Substances Act; [*60]

Second[,] that the chemical structure of the mixture or substance is substantially similar to the chemical structure of a controlled substance in Schedule I or II of the Controlled Substances Act[;] [a]nd,

Third[,] that the defendant intended for the mixture or substance to be consumed by humans.

JA 920.

In Klecker, 348 F.3d at 71, this Court set forth the necessary elements to establish a violation of the Analogue Act in, stating that the government must prove: (1) the alleged analogue and a controlled substance have substantial chemical similarity, (2) actual, intended, or claimed physiological similarity between the alleged analogue and the controlled substance, and (3) intent that the alleged analogue be consumed by humans. McFadden's argument largely relies instead upon the Seventh Circuit decision in Turcotte, 405 F.3d at 522, in which that Court held that "[a] defendant must know that the substance at issue has a chemical structure substantially similar to that of a controlled substance, and he or she must either know that it has similar physiological effects or intend or represent that it has such effects." But the district court's instructions in this case were entirely consistent with the Fourth Circuit's Klecker decision, 348 F.3d at 71-72, and required the Government to prove that the defendant intended for the [*61] substances to be consumed by humans, as required by § 813, and that the defendant must have "knowingly and intentionally" distributed substances, tracking the statutory language from § 841. The district court thus properly concluded that the additional instruction McFadden requested was not required by statute, or by Fourth Circuit precedent. JA 912; see id.

The statute at issue in this case contains a scienter requirement, in that § 813 requires proof of "intent for human consumption," before an analogue may be treated as a controlled substance. 21 U.S.C. § 813; see Klecker, 348 F.3d at 71; but see Forbes, 806 F. Supp. at 238; Carlson, 87 F.3d at 443, n.3 (citing Forbes and noting "the absence of a scienter requirement in the Analogue Act"); United States v. 118. 123 n.1 Roberts. 363 F.3d (2d 2004)(concluding that the scienter requirement of the CSA, 21 U.S.C. § 841 requires the Government to prove that the defendants knew that they possessed a controlled substance). The requirement that the Government prove intent for human consumption analogue cases distinguishes from distribution offenses under the CSA, which has no such The Klecker Court identified the requirement. essential elements of a violation of the Analogue Act and concluded that "[t]he intent requirement alone tends to defeat any vagueness challenge based on the potential for arbitrary enforcement." Klecker, 348 F.3d at 71(citing Carlson, 87 F.3d at 444). The *Klecker* decision lends [*62] additional support for the Government's position. In *Klecker*, the Court addressed the defendant's challenge that Foxy and DET were substantially similar. 348 F.3d at 71-72. The Court relied on chemical diagrams to find that the two substances were substantially similar for purposes of the analogue statute. Id. at 72. It held that it did not have to address the question of whether the defendants had actual knowledge that the substance was an analogue because, for purposes of the vagueness challenge, "the Analogue Act would not be unconstitutionally vague as applied to Foxy even with respect to a defendant who lacked actual notice." Id. at 71-72; see also United States v. DeSurra, 865 F.2d 651, 653 (5th Cir. 1989)("If a defendant possesses an analogue, with intent to distribute or import, the defendant need not know that the drug he possess is an analogue. It suffices that he know what drug he possesses, and that he possess it with the statutorily defined bad purpose."). For the same reasons as those underlying the *Klecker* Court's decision regarding the question of notice, there should be no requirement that the Government prove that the defendant knew that the substance he possessed had the characteristics of a controlled substance analogue. The fact that the substance in fact has those characteristics, in conjunction with proof of intent for human consumption suffices to establish that the defendant possessed or distributed the substance with the statutorily defined bad purpose. See id. Where the district [*63] court additionally instructed the jury that the distribution must have been knowing and intentional, McFadden cannot establish that the court abused its discretion.

Additionally, even if this Court were to determine that the district court erred in declining to give McFadden's proposed instruction, any such error is harmless. See Neder v. United States, 527 U.S. 1 (1999). The test for determining harmlessness, whether the error was noninstruction or

misinstruction, is whether "[it is] clear beyond a reasonable doubt that a rational jury would have found the defendant guilty absent the error." Neder, 527 U.S. at 18 (internal citations omitted). In conducting harmless error analysis, "a reviewing should consider not what effect court constitutional error might generally be expected to have upon a reasonable jury, but rather what effect it had upon the guilty verdict in the case at hand. . .." United States v. Hastings, 134 F.3d 235, 241 (4th Cir. 1998)(internal citation omitted). McFadden's proposed instruction includes an instruction on the notion of "willful blindness," and would have allowed the jury to convict McFadden if they found that he "had a strong suspicion that the substances he was distributing possessed the characteristics controlled substance analogues, as defined above, and that he deliberately avoided the truth. You may not find that the defendant acted knowingly if he was merely mistaken or careless in not discovering the truth, or if he failed to make an effort to discover the truth." [*64] Br. of Appellant at 57; JA 191.03-04. In light of the evidence in this case, and in particular the recorded telephone calls, in which McFadden likens his substances to crystal meth and cocaine, in addition to his statements establishing that he was sometimes avoiding explicit references to controlled substances, ("we don't talk about that, you know that." JA 744), it is clear beyond a reasonable doubt that a rational jury would have found McFadden guilty under his own proposed instruction.

Finally, McFadden's proposed instruction was not a correct statement of the law in at least one respect. His proposal would have required the jury to find beyond a reasonable doubt that the defendant "knew that: . . . 3. The substance would be consumed by humans." JA 191.03-04; Br. of Appellant at 57. The statute clearly does not require knowledge that the substance be consumed by humans, and even Turcotte does not go that far. See Turcotte, 405 F.3d at 527 (concluding that the Government must prove that the defendant "know that the substance at issue has a chemical structure substantially similar to that of a controlled substance, and he or she must either know that it has similar physiological effects or intend or represent that it has such effects."). McFadden's proposed instruction was not correct, and would have resulted in the jury being misinstructed on the scienter element in § 813, which clearly requires that the [*65] defendant intend that the substance be consumed by humans, not that he knows that it would be consumed by humans. See 21 U.S.C. § 813. McFadden's proposed instruction was not "correct," and under the three-part test, McFadden has not shown that the district court erred in declining to give this instruction to the jury. See *Lewis*, 53 F.3d at 34-35. * * *