

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS**

UNITED STATES OF AMERICA,

Plaintiff,

vs.

STEPHEN J. SCHNEIDER

and

LINDA K. SCHNEIDER, a/k/a

LINDA ATTERBURY,

d/b/a/ SCHNEIDER MEDICAL CLINIC,

Defendants.

) Case No.: 07-10234-WEB

)
) **DEFENDANTS' JOINT REPLY TO THE**
) **GOVERNMENT'S CONSOLIDATED**
) **RESPONSE IN OPPOSITION TO THE**
) **DEFENDANTS' JOINT MOTIONS TO**
) **DISMISS**

**DEFENDANTS' JOINT REPLY TO THE GOVERNMENT'S CONSOLIDATED
RESPONSE IN OPPOSITION TO THE DEFENDANTS' JOINT MOTIONS TO
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INTRODUCTION

The Government's Consolidated Response in Opposition to the Defendants' Joint Motions to Dismiss the Indictment dodges the bulk of the defendants' arguments, and is lacking in both logic and useful content. To be sure, the government's response cites a number of cases and quotes them extensively, but it fails to show how these general statements have any application to facts and issues of the case at bar. The government's express refusal to address the defendants' arguments is not helpful to the Court, and the Court should grant the defendants' Motions to Dismiss. Furthermore, given the parties' sharp disagreement regarding the meaning and scope of the CSA as applied to physicians,¹ the defendants request a pre-trial determination of the standard to be applied at trial with respect to the CSA counts that are not dismissed, if any.

¹ It appears to the defendants that the government intends to present what is, in essence, a medical malpractice case.

I. The Indictment Should be Dismissed as Unconstitutional

A. The Application of the Charging Statutes Violates and Threatens to Chill Constitutionally Protected Conduct

In its Opposition, the government quibbles with the burden of asserting a facial challenge to a statute, and doggedly insists that no constitutionally protected conduct is threatened by the application of the charging statutes because they involve only the rights of patients, rather than those of Dr. Schneider. (Doc. 116, p. 3). Regardless of whether the Court views this instant challenge as an as-applied challenge or a facial challenge, the important point is that the charging statute violates and threatens to chill constitutionally-protected rights.

The government's statement that Dr. Schneider has no constitutionally protected rights ignores the argument clearly made in the Defendants' Joint Motion to Dismiss the Indictment as Unconstitutional ("Constitutionality Motion"). (Doc. 98). There, the defendants' explained that the CSA violates Dr. Schneider's right not to be deprived of his license and profession without the due process of law, and his First Amendment right to advise and treat his patients as he deems necessary in his medical judgment. (Doc. 98, p. 11 (citing *Rust v. Sullivan*, 500 U.S. 173, 200 (1991); *Planned Parenthood v. Wichita*, 729 F. Supp. 1282, 1288 (D. Kan. 1990))). Furthermore, Dr. Schneider may assert the rights of *patients* under the principle of *jus tertii*. The physician against whom action has been taken (for treating patients) can assert a sufficiently direct threat of personal detriment as to constitute a justiciable controversy. *See Doe v. Bolton*, 410 U.S. 179, 188-89 (1973); *see also Eppersom v. Arkansas*, 393 U.S. 97 (1968); *Griswold v. Connecticut*, 381 U.S. 479, 481 (1965). Doctors may assert the rights of their patients as

against governmental interference with a medical decision, in either criminal or noncriminal contexts. *Singleton v. Wulff*, 428 U.S. 106, 115-116 (1976). As explained in the Constitutionality Motion, these patients have a right to relief from unnecessary suffering. *See Washington v. Glucksberg*, 521 U.S. 702 (1997).²

B. The Charging Statutes are Unconstitutionally Applied

1. 21 U.S.C. § 841(a)(1)

Essentially, the government argues that the CSA does in fact provide a “standard,” and quotes the familiar “legitimate medical purpose” and “in the usual court of practice” language as well as some select language from *Gonzales v. Oregon*. (Doc. 116, p.7-8 (quoting *Gonzales*, 546 U.S. 243, 269-270, 274 (2006))). The government argues that because this language exists, and because it will be provided to a jury at some future point in considering the evidence adduced at trial, it is thereby a “standard” that meets the requirements of due process. To bolster this argument, the government makes several other points: that the CSA contains a scienter requirement³ that mitigates vagueness, that no other cases have held the CSA impermissibly vague, and that there is no constitutionally protected conduct at issue. (Doc. 116, pp. 3-5). We address each of

² That the government would even suggest that the interests of the patients were of no legal import is astonishing. A physician’s medical duty is not applied in a vacuum; it is applied to real human beings. State medical practice standards are in fact designed to help those real human beings. The government only asserts a lack of “standing” because the government itself refuses to acknowledge that what it is essentially doing is substituting the judgment of a federal authority – here, a federal jury – for the role specifically constitutionally reserved to the state through its public health authority, i.e., defining the practice of medicine with respect to real human beings living in the State of Kansas.

³ The statute provides that the act must be done “knowingly or intentionally.” 21 U.S.C. § 841(a)(1).

these arguments in turn.

The government's view of what constitutes a "standard" is perverse, both in its failed logic and in light of the void-for-vagueness jurisprudence. The government claims that the CSA sets out a standard, but then argues that the government can allege any conduct that it deems to violate that standard in an indictment. In other words, the government's position is that the "standard" addresses any conduct the prosecutor deems not to be "legitimate medical practice," and that it is ultimately up to a jury to decide whether to accept the government's view.⁴ This is shown by the government's refusal to address the specific points made by the defendants as to why all of the actions alleged in the Indictment are consistent with medical practice, countering only with a broad statement that "under a reasonable construction of the controlled substances act and the healthcare fraud statute, the conduct alleged in the Indictment is prohibited." (Doc. 118, p.5). This cavalier assertion, coupled with the government's refusal to meaningfully engage the specific points regarding each of its allegations, shows that the government considers itself free to ignore the medical reality, and to impose its own medical practice standards through its own "construction." The government's argument is thus illogical in that it asserts that a meaningful standard is provided, but then suggests that the government can unilaterally construe that standard to include whatever conduct it chooses without having to account for medical science or the state's external control of the practice of medicine.⁵ While the government does not express the point in clear terms, the inescapable effect of its position is that what constitutes "legitimate medical practice"

⁴ Under the government's interpretation of the "standard", the CSA operates as an ex post facto law.

⁵ As explained in the defendants' papers, the government's claims fly in the face of medical science.

is a question of “fact” to be determined by a jury, rather than a matter of state law, thereby seeking to substitute the federal jury for the state medical board. *Gonzales v. Oregon* makes clear that the government lacks the authority to do this. Therefore, in order not to violate the CSA, the government must plead objective criminal conduct, rather than a mere disagreement with a physician’s medical judgment. On the other hand, if the government’s view is accepted, a federal jury is empowered to “second-guess”, overrule, or serve as a substitute for a state medical board, which not only renders the CSA unconstitutionally vague, but would also require the Court to abstain because it is violative of federalism, as described in *Gonzales v. Oregon*.

The government’s view of the term “standard” is also contradicted by the applicable authorities addressing the void for vagueness doctrine. Those authorities show that what is meant by the term “standard” is not merely a set of words that the prosecutor may define in any way she wishes and present to a jury. Rather, the impetus of the void for vagueness doctrine is to provide adequate enforcement standards for prosecutors and juries, and reasonable notice so that individuals may conform their conduct to the law. The government’s response confirms and supports the arguments presented in the Constitutionality Motion, which is that in the case as indicted, there are no meaningful standards for enforcement and no adequate notice that would have allowed the indicted individuals to conform their conduct to the law, since the heart of the case revolves around whether what the doctor did was – or was not – the legitimate practice of medicine (which is a conclusion of state law).

As to scienter, it is not clear that the government has even read the defendants’ motions and supporting memoranda. The government attempts to sidestep the

defendants' specific arguments as to why the scienter requirement, if not read as subjective, does not mitigate vagueness in this case. This is because when the government fails to allege any objective criminal acts, as here, a subjective mens rea requirement provides the only meaningful distinction between criminal conduct and poor medical judgment or malpractice. The government argues simply that because there is a scienter requirement, the statute is not vague. (Doc. 116, p. 5). Subsequently, the government argues that the scienter requirement is one of objective, rather than subjective intent. (*Id.*). Therefore, the government has completely failed to address the issue raised in the Constitutionality Motion.⁶

The government has not only failed to answer the defendants' point with respect to scienter, but has further supported the defendants' argument that the Indictment's application of the CSA is void for vagueness and violates the principles of federalism. If all that the government must prove to a jury in a case that does not involve "drug dealing as conventionally understood" is objective intent, then federal prosecutors and juries, and not the states, are the decision-makers as to what constitutes legitimate medical practice. The government's view of the mens rea requirement dismisses any doubt that it considers itself empowered to disagree with the substantive medical decisions of physicians, the practice standards of which are squarely within the province of state law to define.

⁶ The government has also attempted to distinguish *Colautti v. Franklin*, 439 U.S. 379 (1979), by arguing that the abortion statute at issue in that case had no mens rea requirement at all, while the CSA does. The government's analysis is directly contradicted by the clear discussion in *Colautti* itself. *Id.* at 394-395, (*see also* Constitutionality Motion, Doc. 98, p. 33). The statute in *Colautti* contained a mens rea requirement that applied to the issue of death, but not to the determination of viability. Therefore, the case is directly analogous to the Tenth Circuit's interpretation of the CSA's mens rea requirement, which applies it to the act of "distributing or dispensing" but not to the "legitimacy" element.

The government's argument that the CSA is not void for vagueness because previous courts have rejected the argument is also unpersuasive. The cases cited by the government, as well as other cases rejecting vagueness challenges to the CSA's application to physicians are inapplicable to the instant case. *See United States v. Prejean*, 429 F. Supp. 2d 782, 801-06 (E. D. La. 2006); *United States v. Collier*, 478 F.2d 268, 272 (5th Cir. 1973); *United States v. Pastor*, 419 F. Supp. 1318 (S.D.N.Y. 1975); *United States v. Deboer*, 966 F.2d 1066 (6th Cir. 1992). The cases either deal with general vagueness arguments, or with facts that are not similar to those in this case. The Constitutionality Motion, on the other hand, clearly and specifically addresses the vagueness of the CSA's application in this context. Therefore, the holdings of the prior cases are distinguishable and inapplicable, the Court must address the argument in light of the facts of this case, which presents a particularly egregious instance of federal overreaching.

The full extent of the government's view that it is empowered to regulate the practice of medicine, and the implications of this view, can be seen when considering an example from the Indictment. In Count 6, the government has argued that the off-label prescribing of Actiq (fentanyl citrate) for non-cancer pain was not a legitimate medical purpose. As pointed out in both the Constitutionality Motion and the Defendants' Joint Motion to Dismiss the Indictment as Defective Under Rule 7(c) ("7(c) Motion"), off-label prescribing is both common and legal. (Doc. 98; Doc. 94). Furthermore, there is extensive academic discussion regarding the off-label use of Actiq for non-cancer pain, and much literature advocating such off-label use. (Doc. 105, p. 24-26). Yet, despite the fact that there is extensive support in the academic literature for the off-label use of

Actiq, and despite the fact that the government does not deny that the patients who received Actiq all had pain that needed to be treated, the government nevertheless asserts that for some reason the use of Actiq with respect to the set of patients found in count 6 was not legitimate and was therefore criminal. This view exposes the extent to which the government considers itself empowered to invent and re-invent the meaning of the statute. It is clear that there can be no such thing as fair notice under such a reading of the statute, in which the views of federal prosecutors prevail over those expressed by eminently qualified physicians in peer-reviewed medical journals. In order to be safe from prosecution, physicians would thus have to stop prescribing drugs off-label entirely. Accepting this view also would require that there are no guidelines or limitations on enforcement. Both of these features render the statute unconstitutionally vague.⁷

2. 18 U.S.C. § 1347

The defendants' argument regarding the constitutionality of the Indictment's application of 18 U.S.C. § 1347 is tied closely to their argument regarding the government's defective pleading of the charges under that statute. These defects are discussed more fully below. However, we note here that the government has failed to address the two primary arguments. First, a fraud statute based on the complex and convoluted world of CPT coding and the bureaucratic HCBP policies and practices is one that is unconstitutionally vague. Second, the use of CPT codes and HCBP policies and internal audits as substantive criminal statutes is an unconstitutional delegation of the legislative authority to private parties.

⁷ The government allegations in count 6, and counts 10-12 must also be dismissed because they constitute substantive medical judgments that the government is not empowered or qualified to make, rather than allegations of drug dealing as conventionally understood.

II. The Counts of the Indictment Should be Dismissed as Defective Under Rule 7(c)

As with its arguments on constitutionality, the government fails to answer much of what the defendants have argued in their 7(c) Motion. (Doc. 105). The discussion in the instant Reply is therefore confined to the limited points that the government has attempted to make.

As the government acknowledges, an indictment must contain all of the elements of the offense and sufficiently apprise the defendant of what he must prepare to meet. (Doc. 116, p. 15 (citing *United States v. Radetsky*, 535 F.2d 556, 562 (10th Cir. 1976))). Although the government tries to draw the Court's attention away from its insufficient pleading, the fact remains that much of the Indictment fails to plead any crime, and that other parts of the Indictment fail to adequately inform the defendants of what they must prepare to meet.

The government seeks to characterize its failure to plead the elements of the charged offenses as "factual disputes," hoping that the Court will ignore the absence of the essential elements and send the insufficient case to a jury. (Doc. 116, p. 10). The government fails to address the fact that its own Indictment reveals, on its face, that it cannot prove the elements of the charging statutes. With respect to *actus reus*, the defect raised by the defendants is not that the government will be unable to prove the facts forming the basis for its disagreement with Dr. Schneider's medical judgment. Rather, the point is that even if the government were able to prove all of its allegations, the conduct would not constitute a violation of the CSA. As extensively discussed in both motions to dismiss, the CSA does not permit the government to assert its disagreement with the substantive medical decisions of physicians through the criminal process.

Gonzales v. Oregon, 546 U.S. 243. With respect to these counts, the government has laid out its “case” in considerable detail, exposing the fact that there actually is no criminal case. As noted above, what the government plans to present is not a case of drug dealing as conventionally understood, but rather its own view of the medical standard to be determined by a jury as “fact.” The government is not authorized to do this by the CSA or any other law.

Assuming, *arguendo*, that the government could sufficiently plead violations of the CSA by simply tracking the language of the statute, the Indictment’s discussion of facts in these counts clearly exposes that it could not meet the statutory standard, which requires proof of “drug dealing as conventionally understood.” *Gonzales*, 546 U.S. at 270. Similarly, with respect to the *mens rea* elements, the Indictment reveals that the government could not meet its burden even if all of its allegations were proven to be true. The government fails to address the underlying arguments on either point.

Counts 7-17 suffer from the same defects in that they fail to allege both materiality and *mens rea*, and the government similarly fails to deal with the arguments in the defendants’ 7(c) Motion. The government has chosen to set forth its theories of fraud in some detail, and should not now be allowed to hide from these details. For the reasons stated in the 7(c) Motion, the Indictment fails to allege materiality and *mens rea*. The government has failed to meaningfully address these deficiencies.

In sum, with respect to counts 2-4, 6, and 7-17, the government has chosen to lay out its bases for the belief that the charging statutes have been violated. In the process, the government has revealed the emptiness of its case, showing that even if all of its factual allegations were true the conduct would not constitute any violation of the

statutes. While the government now seeks to hide its lack of a case behind general and minimal pleading standards, the Court, having been made aware of the insufficiency of the case, should refuse to send it to a jury.

With respect to Count 5, the government argues that the count sufficiently tracks the language of the statute and is therefore sufficient. This argument should be rejected because, as reflected in the Indictment and in the government's consolidated response, the government apparently believes that the statutory language can take on any meaning the government chooses to give it, despite the fact that it lacks the authority to do so under *Gonzales v. Oregon*. 546 U.S. 243. The addendum to the Indictment reveals that the government also faults Dr. Schneider for the deaths of patients that he neither "contributed to" nor "caused."

Finally, with respect to counts 7-9 and 13-17, the government fails to address the specific points made in the 7(c) Motion. The government engages in no discussion of the legislative history of 18 U.S.C. § 1347 and of the impermissibility of using CPT codes, industry practices and HCPB policies and investigations as substantive law, which the Indictment unquestionably does. Indeed, the government seems to admit that although CPT codes and policies have not been "incorporated," the codes and policies nevertheless have been transplanted into the statute: "the codes, regulations, and policies are merely the benchmark against which the jury will determine if the defendants' claims were false and fraudulent." (Doc. 116, p.11). The government cites cases generally, but fails to identify any cases that specifically addressed the wholesale delegation of federal criminal law to CPT codes, industry practices and HCBP policies, which, by the government's own admission, are involved in this case.

CONCLUSION

For all of the foregoing reasons, the Indictment should be dismissed.

Respectfully Submitted,

Kevin P. Byers Co., L.P.A.

By: s/Kevin P. Byers

Kevin P. Byers

OSB # 0040253

107 South High Street, Suite 400

Columbus, Ohio 43215-3456

Telephone 614.228.6283

Facsimile 614.228.6425

Email Kevin@KPByersLaw.com

Eugene V. Gorokhov, PLLC

By: s/Eugene V. Gorokhov

Eugene V. Gorokhov

VSB # 73582

1800 Wilson Blvd., Suite 12

Arlington, Virginia 22201-6609

Telephone 703.310.7587

Facsimile 267.390.7587

Email eugene@evgpllc.com

The Law Offices of Uzo L. Ohaebosim

By: s/Uzo L. Ohaebosim

510 N. Topeka

Wichita, KS. 67203

Phone: 316.261.5400

Fax: 316.261.5404

Email u.ohaebosim@swolawfirm.com

Trial Co-counsel for Defendant

Linda K. Atterbury

For defendant Stephen J. Schneider
Williamson Law Firm, LLC

By: s/ Lawrence W. Williamson, Jr.
Lawrence W. Williamson
816 Ann Avenue
Kansas City, Kansas 66101
Telephone 913.871.7060
Facsimile 913.535.0736
Email L.Williamson@Williamsonfirm.com

CERTIFICATE OF SERVICE

I certify that on June 20, 2008, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system which will send notice of electronic filing to:

Tanya J. Treadway
Assistant United States Attorney
290 U.S. Courthouse
444 S.E. Quincy
Topeka, KS 66683-3592

s/Uzo L. Ohaebosim

Co-counsel for defendant Linda K. Atterbury