

Docket No. 05-4474

IN THE UNITED STATES COURT OF APPEALS  
FOR THE FOURTH CIRCUIT

UNITED STATES OF AMERICA :  
 :  
 Appellee, :  
 :  
 V. : An appeal from the Eastern  
 : District of Virginia at Alexandria  
 : District No. 0422-1 CR-03-467.  
 WILLIAM ELIOT HURWITZ, M.D. : (Leonard D. Wexler, Senior Judge)  
 :  
 Appellant. :

**BRIEF FOR AMICUS CURIAE THE ASSOCIATION OF AMERICAN  
PHYSICIANS & SURGEONS FILED IN SUPPORT OF APPELLANT  
SUPPORTING REVERSAL OF THE JUDGMENT BELOW**

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**CORPORATE DISCLOSURE STATEMENT**

*United States of America v. William Eliot Hurwitz*, No. 05-4474

Pursuant to Federal Rule of Appellate Procedure 26.1, *Amicus Curiae* The Association of American Physicians and Surgeons makes the following disclosure:

1) For non-governmental corporate parties please list all parent corporations:

None.

2) For non-governmental corporate parties please list all publicly held companies that hold 10% or more of the party's stock:

None.

3) If there is a publicly held corporation that is not a party to the proceeding before this Court but which has a financial interest in the outcome of the proceeding, please identify all such parties and specify the nature of the financial interest or interests:

None.

Dated: September 6, 2005

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## STATEMENT OF IDENTITY, INTEREST AND SOURCE OF AUTHORITY TO FILE

The Association of American Physicians & Surgeons, Inc. (“AAPS”) is a non-profit national organization consisting of thousands of physicians in all specialties. Founded in 1943, AAPS is dedicated to defending the patient-physician relationship and the ethical practice of medicine. AAPS is one of the largest physician organizations funded virtually entirely by its physician membership. This enables it to speak directly on behalf of the ethical service to patients who entrust their care to the medical profession. AAPS files *amicus* briefs in cases of high importance to the medical profession, like this one. *See, e.g., Stenberg v. Carhart*, 530 U.S. 914 (2000) (Justice Kennedy frequently citing AAPS submission); *United States v. Rutgard*, 116 F.3d 1270 (9<sup>th</sup> Cir. 1997) (reversal of a sentence as urged by an *amicus* brief submitted by AAPS).

AAPS has a strong interest in preventing the chilling effect on the medical profession resultant from an unjust conviction and harsh sentence of a physician for treating pain in his patients. When an uninformed and misled jury defines the contours of medical practice rather than state medical boards, then the practice of medicine is affected and AAPS has a strong interest in submitting this brief. Physicians are no longer confident in prescribing pain medication without fearing overzealous prosecution and life imprisonment. As a direct result of the verdict

below, many physicians are choosing not to provide patients in pain with medically appropriate treatment, lest a court later disagree. Physicians have been left with the Hobson's choice of violating their duty to their patients under state authority or risking federal prosecution under the precedent below. Patients with the greatest needs are being denied optimal care, and AAPS has an obligation and right to object.

The prosecution, conviction, and virtual life imprisonment of Dr. William Hurwitz, a physician who compassionately cared for his patients, is a manifest injustice affecting all physicians who treat pain. AAPS has a strong interest in defending the medical profession here, and in correcting the individual injustice against Dr. Hurwitz. Congress has not authorized the prosecution of Dr. Hurwitz and physicians like him who abide by state medical boards in prescribing pain relief for needy patients. The prosecution in this case exceeded its statutory authority and arrogated power, properly reserved to the states, to a federal jury. AAPS has a clear and substantial interest in protecting the medical profession and patients against miscarriages of justice.

## SUMMARY OF ARGUMENT

The court below committed at least three reversible errors. First, its jury instructions encouraged the jury to define the contours of medical practice without assessing “good faith,” in contravention of the Supreme Court in *United States v. Moore*, 423 U.S. 122 (1975), and this Court in *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994). Second, the lower court erred in excluding evidence of defendant Dr. Hurwitz’s compliance with state authorities, and in excluding evidence of the conflicting federal positions on the central issues. Third, the court below erred in allowing expert testimony by the government that was grossly prejudicial and highly erroneous, rising to the level of plain and reversible error. The result is that an admittedly confused jury, untrained in medicine, superseded the Virginia Medical Board, the prevailing consensus of the medical profession in treating pain, and the consensus view of the federal government itself prior to this prosecution. This was error and a miscarriage of justice. Physicians practice medicine under state authority. Juries do not.

The court below rendered a verdict and a sentence that is shocking to physicians, patients, and many in the legal community. The court below imposed the equivalent of a life sentence on a very dedicated physician for the “crime” of responding too much to the observed needs of his patients suffering from pain.

This imprisonment of a highly skilled professional for practicing his profession in good faith, without a finding to the contrary, is unprecedented in Anglo-American law. The conviction and sentence below must be reversed.

The jury instructions invited jurors to pass judgment on whether they personally approved of Dr. Hurwitz's practice without making essential findings of intent for wrongdoing. In so doing, the jury instructions went far beyond the statutory authority of 21 U.S.C. § 841(a), conferring power on arbitrary decisions by the jury that Congress never intended. A physician is not to be sent to prison for the rest of his life because a jury disagrees with how he practices medicine in a developing field. There was never a bona fide finding of criminal intent that Dr. Hurwitz was engaging in drug dealing, and the jury instructions on this issue require reversal of the verdict.

Federal juries do not practice medicine and have no training or legitimate authority to attempt to define the boundaries of medical practice. The State of Virginia, through its duly authorized medical board, determines how medicine shall be practiced in that State. A federal court lacks authority to disregard the findings of the Virginia Medical Board and even conceal those determinations from a federal jury. At a minimum, faithful application of federalism requires reining in a federal jury from superseding state-defined parameters of medical

practice, especially without authority from Congress. Yet the jury instructions and rulings in this action contravened precedent by concealing and contradicting the regulation of medicine by the State of Virginia.

Finally, reversal is necessary due to plain error in the testimony by the key government expert Michael Ashburn. His statements amounted to junk science, and the court below failed to perform its gate-keeping role. The American Pain Society reviewed his testimony and was so shocked by it that six past presidents of this prominent Society wrote a letter to the trial judge explaining that Dr. Ashburn's testimony was "without foundation in the medical literature and we believe that it is, on its face, absurd." JA 752; *see also* Point III, *infra*. The bias and quackery in Dr. Ashburn's testimony would not be readily apparent to the jury, which was obviously swayed by his sweeping but false claims. The verdict must be reversed for plain error in the central expert testimony.

## ARGUMENT

### I. THE JURY INSTRUCTIONS ERRONEOUSLY ASKED THE JURY TO DEFINE WHAT CONSTITUTED MEDICINE, RATHER THAN DECIDING WHETHER DEFENDANT ACTED IN “GOOD FAITH,” AND THIS CONTRAVENED *UNITED STATES v. MOORE* AND *UNITED STATES v. TRAN TRONG CUONG*.

Federal juries are not authorized or trained to define the boundaries and parameters of medicine, and then convict a defendant-physician for going beyond that arbitrary boundary. The jury instructions below embodied that approach and contravened the controlling precedents of the Supreme Court in *United States v. Moore*, 423 U.S. 122 (1975), and this Court in *United States v. Tran Trong Cuong*, 18 F.3d 1132 (4th Cir. 1994).

The State of Virginia, not a federal jury, properly defines the practice of medicine in its jurisdiction. Virginia law explicitly allows doctors to prescribe the necessary dose of painkillers when acting in good faith:

In the case of a patient with intractable pain, a physician may prescribe a dosage in excess of the recommended dosage of a pain relieving agent if he certifies the medical necessity for such excess dosage in the patient’s medical record. Any person who prescribes, dispenses or administers an excess dosage in accordance with this section shall not be in violation of the provisions of this title because of such excess dosage, if such excess dosage is prescribed, dispensed or administered **in good faith** for accepted medicinal or therapeutic purposes.

Va. Code Ann. § 54.1-3408.1. *See also* Va. Code Ann. § 54.1-2971.01 (repeating good faith exemption).

In denying a “good faith” instruction, the court below usurped state authority in an unprecedented manner. If the federal government disagrees with the State of Virginia concerning the treatment of pain, then it has a simple federal remedy available: revoke the physician’s federal DEA registration. The draconian approach of federal prosecution and conviction of a physician who complied fully with governing state authority is offensive to federalism and to Rule of Law.

In *United States v. Moore*, 423 U.S. 122 (1975), the Supreme Court upheld the conviction of a physician for prescribing drugs because, unlike here, the federal remedy of revocation of his DEA registration was *not* an option. There, unlike here, “[r]egistration was mandatory for practitioners with state licenses” except under inapplicable exceptions. *Id.* at 138 n.15. Here, defendant Dr. Hurwitz was even cooperating with the DEA in his practice. Dr. Hurwitz had voluntarily agreed to extensive DEA monitoring, strongly indicating that he was practicing in good faith. JA 4144. Yet this information was kept from the jury. *See* Appellant’s Brief, Point III.B.1.

The *Moore* Court approved of how the trial judge:

instructed the jury that it had to find ‘beyond a reasonable doubt that a physician, who knowingly or intentionally, did dispense or distribute

[methadone] by prescription, **did so other than in good faith** for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States.’

*Id.* at 138-39 (emphasis added). The *Moore* jury was thus expressly instructed to convict or acquit based on its finding about good faith. *See also United States v. Linder*, 268 U.S. 5, 18 (1925) (acquittal required if the jury found that defendant-physician acted “in good faith” in prescribing narcotics).

It is unprecedented to convict a physician based on disagreement by the jury with his good faith medical judgment. Nothing in the *Moore* decision countenances such usurpation of state authority by federal juries. Nothing in common sense permits this either. Every innovative physician advances medical practice contrary to “generally recognized and accepted” treatments, but surely that is not the proper test for criminal prosecution. Good faith is, but the essential instruction was denied below.

In *Moore*, the defendant readily conceded that “he did not observe generally accepted medical practices.” *Id.* at 126. The Court observed that:

“[i]n billing his patients he used a ‘sliding-fee scale’ pegged solely to the quantity prescribed, rather than to the medical services performed. The fees ranged from \$ 15 for a 50-pill prescription to \$ 50 for 150 pills. In five and one-half months Dr. Moore's receipts totaled at least \$ 260,000. When a patient entered the office he was given only the most perfunctory examination. Typically this included a request to see the patient’s needle marks (which in more than one instance were simulated) ....

*Id.* In sharp contrast with this case, the flagrant practices in *Moore* were plainly non-medical in nature. The issue of what constitutes valid medical practice was essentially conceded in *Moore*, rather than submitted to the jury for uninformed determination as below.

The exclusion of a good faith instruction below also contravened the precedents of this Court, which has emphasized that criminal prosecution of a physician requires more than “use of a negligence standard.” *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994). This Court embraced a jury instruction declaring that if a “doctor dispenses a drug **in good faith** in medically treating a patient, then the doctor has dispensed the drug for a legitimate medical purpose in the usual course of medical practice. That is, he has dispensed the drug lawfully.” 18 F.3d at 1138 (emphasis added). The approved jury instruction then explained what “good faith” means. “Good faith in this context means good intentions in the honest exercise of best professional judgment as to a patient’s need. It means the doctor acted in accordance with what he believed to be proper medical practice. If you find the defendant acted in good faith in dispensing the drug, then **you must find him not guilty.**” *Id.* (emphasis added).

This Court intended – and indeed *Moore* requires – application of the “good faith” test to prosecution of physicians for services rendered. This Court elaborated on what the “good faith” proof entails:

A criminal prosecution requires more -- that is, proof beyond a reasonable doubt that the doctor was acting outside the bounds of professional medical practice, as his authority to prescribe controlled substances was being used not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit or of dispensing controlled substances for other than a legitimate medical purpose, **i.e. the personal profit of the physician.**

*Tran Trong Cuong*, 18 F.3d at 1137 (4th Cir. 1994) (emphasis added). That element of personal profit, which existed in *Moore*, is utterly lacking here.

The court below committed the same error that occurred – and was corrected – in the conviction and sentence of Dr. Stan Naramore for administering large quantities of painkillers to two patients who subsequently died. “[T]he jury apparently found, beyond a reasonable doubt, that Dr. Naramore’s actions were totally outside appropriate medical practice.” *State v. Naramore*, 25 Kan. App. 2d 302, 322 (1998). From that finding the jury concluded that Dr. Naramore had homicidal intent. “Having found that, it then apparently found there was no reasonable doubt that the source of his actions was homicidal intent.” *Id.*

The Supreme Court of Kansas properly overturned the conviction. It found that where, as here, there is a bona fide dispute in the medical community, then

reasonable doubt about criminal intent exists as a matter of law. “[T]here is a reason why there has yet to be in Anglo-American law an affirmed conviction of a physician for homicide arising out of medical treatment based on such highly controverted expert evidence as here.” *Id.*

The Tenth Circuit adhered to the *Naramore* ruling in reversing a conviction for involuntary manslaughter of a physician in connection with the death of a patient. *United States v. Wood*, 207 F.3d 1222 (10<sup>th</sup> Cir. 2000). “Well-intentioned but inappropriate medical care, standing alone, does not raise an inference that a killing was deliberate, willful, and premeditated.” *Id.* at 1232. Similarly, lack of good faith is not to be inferred here from a dispute over appropriate medical treatment and a disagreement by an untrained jury. A jury of laypersons is not to be told to decide what is good medicine and then infer criminal intent from that finding.

The jury below almost immediately expressed its confusion about the jury instruction asking it to define the scope of medical practice. Within hours of its initial deliberation, the jury passed this question to the judge:

Is it illegal to prescribe opioids to somebody you (a) suspect (b) think (c) know is addicted to illicit drugs? **Is there a definition in federal law of (a) legitimate medical purpose (b) beyond the bounds of medical practice that can be provided?** If not, can you provide us with definitions or criteria for those terms?

JA 734 (emphasis added). The jury immediately recognized how senseless its assignment was. Juries are not trained or authorized to establish the outer limits of a highly skilled profession. The answer to this question should have been the “good faith” instruction given in *Moore* and *Tran Trong*, but the judge would not give it.

The proper task for the jury is to determine whether defendant was acting in good faith, not whether the jury disagreed with the defendant about the boundaries of his skilled profession. It is the ultimate injustice for a compassionate and dedicated physician to be imprisoned virtually for the rest of his life for practicing medicine in a manner that most of his colleagues and patients applauded, but that an admittedly confused jury failed to understand.

## **II. THE EXCLUSION OF EVIDENCE OF DEFENDANT’S COMPLIANCE WITH STATE AUTHORITY, AND OF THE CONFLICTING FEDERAL POSITIONS ON THE TREATMENT OF PAIN, REQUIRE REVERSAL OF THE CONVICTION.**

The Court below excluded evidence of defendant Dr. Hurwitz’s compliance with state law. The court also excluded evidence of the conflicting federal positions towards the treatment of pain, as illustrated by the DEA’s endorsing and publicizing, but then later withdrawing, the government policy towards treating pain. *See* Appellant’s Brief Point III.

“It is settled that when the law is vague or highly debatable, a defendant, actually or imputedly, lacks the requisite intent to violate it.” *United States v. Critzer*, 498 F.2d 1160, 1162 (4<sup>th</sup> Cir. 1974). It was an abuse of discretion to withhold the conflict between the prosecution theory with state authority and even published federal policy. There is reasonable doubt here as a matter of law. A conviction cannot stand based on a prosecutorial theory that conflicts with state authority in an area – the practice of medicine – that is traditionally regulated exclusively by the states. Moreover, a conviction cannot be based on a prosecutorial theory that is disputed within the federal government itself. When the federal government cannot internally agree on an issue, and Congress has not spoken directly to it, then reasonable doubt exists as a matter of law.

**A. THE EXCLUSION OF EVIDENCE OF DEFENDANT’S COMPLIANCE WITH THE STATE MEDICAL BOARD VIOLATED HIS RIGHT TO DISPROVE INTENT.**

Defendant Dr. Hurwitz’s practice was thoroughly reviewed by the Virginia Medical Board, which found that Dr. Hurwitz “was practicing pain medicine in good faith, and for recognized and accepted medicinal or therapeutic purposes.” JA 281. Given that state medical boards have always held the authority to regulate the practice of medicine, any view that contradicted the Virginia Medical Board was “highly debatable” within the meaning of *Critzer*. The entire Virginia Medical Board, and most of the medical profession, would very much debate the findings of the jury to the contrary.

It was reversible error for the court below to invite the federal jury of laypersons to contradict the Virginia Medical Board, which undeniably possesses far greater skill on the issue. It was reversible error for the court below to rule inadmissible the findings of the Virginia Medical Board in 2003, after ruling admissible findings by the same board in 1996-98. JA 499, JA 4460-75. There was no rhyme or reason to the contradictory evidentiary rulings by the trial judge, or by the jury finding contravening the state medical board. As a matter of law, the

finding of the Virginia Medical Board demonstrates there was reasonable doubt as to defendant Dr. Hurwitz's intent.

“Criminal prosecution for the violation of an unclear duty itself violates the clear constitutional duty of the government to warn citizens whether particular conduct is legal or illegal.” *United States v. Mallas*, 762 F.2d 361, 363 (4<sup>th</sup> Cir. 1985) (Wilkinson, J.). Defendant Dr. Hurwitz was vindicated by the Virginia Medical Board, and there was no warning anywhere of the subsequent conviction. All physicians nationwide properly look to their state medical boards for guidance and discipline, not to the federal government. Novel theories of prosecution are neither fair nor constitutional, particularly when the defendant complies with the governing state regulatory authorities. *See United States v. Garber*, 607 F.2d 92, 100 (5<sup>th</sup> Cir. 1979) (*en banc*) (criminal prosecutions are not the place for “pioneering interpretations”).

Put another way, it was reversible error for the trial court to exclude essential evidence concerning *mens rea*. As William Blackstone famously observed, “in order to have a crime, there must be a vicious will.” William Blackstone, Commentaries 21. The Supreme Court has held likewise: “The contention that an injury can amount to a crime only when inflicted by intention 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.” *Staples v. United States*, 511 U.S. 600, 605 (1994) (quoting *Morissette v. United States*, 342 U.S. 246, 250 (1952)). The Court emphasized that “[t]he existence of a mens rea is the rule of, rather than the exception to, the principles of Anglo-American criminal jurisprudence.” *Staples*, 511 U.S. at 605 (quoting *United States v. United States Gypsum Co.*, 438 U.S. 422, 436 (1978), internal quotation marks omitted).

“[R]equiring mens rea is in keeping with our longstanding recognition of the principle that ‘ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity.’” *Liparota v. United States*, 471 U.S. 419, 427 (1985) (quoting *Rewis v. United States*, 401 U.S. 808, 812 (1971)). The defense of good faith, denied in the jury instructions below, deprived Dr. Hurwitz of the protection of the traditional requirement that *mens rea* be proven. No professional acting in good faith on behalf of patients should be subjected to life imprisonment for doing so. Yet the conviction below stands for the proposition that no physician can rely on the approval of his state medical board lest a future federal prosecution and a random jury disagree. This was reversible error to withhold from the jury defendant Dr. Hurwitz’s compliance with state authority.

**B. THE EXCLUSION OF EVIDENCE OF DEFENDANT’S COMPLIANCE WITH THE STATE MEDICAL BOARD VIOLATED PRINCIPLES OF FEDERALISM.**

The exclusion from evidence of defendant Dr. Hurwitz’s compliance with the Virginia Medical Board also violated federalism. By intent and effect, the actions of the federal government here completely superseded and interfered with the State of Virginia’s authority over medicine. This exclusion of evidence rendered the Virginia Medical Board meaningless both in this action and similar future ones. Such ruling violated well-established principles of federalism because it “alter[s] the ‘usual constitutional balance between the States and the Federal Government.’” *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) (quoting *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242 (1985)). “[I]t is incumbent upon the federal courts to be certain of Congress’ intent” before infringing on the state regulation of medicine. *Id.* (quotation marks and citation omitted). Congressional authorization under the Controlled Substance Act, 21 U.S.C. 841, *et seq.*, is not “unmistakably clear” that a physician practicing pursuant to state laws and regulations should be prosecuted despite such compliance, and that the jury should be denied hearing evidence about such compliance. *Id.*

“Obviously, direct control of medical practice in the States is beyond the power of the Federal Government.” *Linder*, 268 U.S. at 18. Not even the Supreme

Court, let alone a random jury, is “suited to be ‘the Nation’s *ex officio* medical board with powers to approve or disapprove medical and operative practices and standards throughout the United States.’” *Stenberg v. Carhart*, 530 U.S. 914, 968 (2000) (Kennedy, J., dissenting) (quoting *City of Akron v. Akron Center for Reproductive Health* 462 U.S. 416, 456 (1983) (O’Connor, J.)). How could a federal jury possibly be better qualified on medical issues than the Supreme Court? It cannot. “‘Irrespective of the difficulty of the task, legislatures, with their superior factfinding capabilities, are certainly better able to make the necessary judgments than are courts.’” *Stenberg*, 530 U.S. at 968 (Kennedy, J., dissenting) (quoting *City of Akron*, 462 U.S. at 456, n. 4) (O’Connor, J., dissenting)). The Virginia Medical Board, acting under authority from its legislature, performed that factfinding and its careful review and conclusions should, at a minimum, have been made available to the jury below.

The suppression of the evidence of Dr. Hurwitz’s compliance with the governing state authorities contravenes the principle established in *United States v. Morrison*, which prohibited federal interference in “criminal law enforcement ... where States historically have been sovereign.” 529 U.S. 598, 613 (2000) (quoting *United States v. Lopez*, 514 U.S. 549, 564 (1995)). See also *Solid Waste Agency of N. Cook County v. U.S. Army Corps of Eng’rs*, 531 U.S. 159, 173 (2001) (“This

concern is heightened where the administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power.”); *United States v. Bass*, 404 U.S. 336, 349 (1971) (“Unless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance.”).

The court below reduced the Virginia Medical Board to a nullity by excluding it from evidence. Under this approach, inquiries about pain treatments should be made to the local federal prosecutor rather than the state medical board. This plainly violates “the federal-state balance” without congressional mandate, and constituted reversible error. *Bass*, 404 U.S. at 349. *See also Gonzales v. Raich*, 125 S. Ct. 2195, 2222 (2005) (O’Connor, J., dissenting) (“The Constitution, we said, does not tolerate reasoning that would ‘convert congressional authority under the Commerce Clause to a general police power of the sort retained by the States.’”) (quoting *United States v. Lopez*, 514 U.S. 549, 567 (1995)).

Had the federal government issued a regulation for quantities of pain prescriptions, it would likely be invalidated by court challenge for lack of statutory basis. *See, e.g., Ass’n of Am. Physicians & Surgeons, Inc. v. United States Food and Drug Admin.*, 226 F. Supp. 2d 204, 222 (D.D.C. 2002) (“The issue here is not the Rule’s wisdom. Indeed, if that were the issue, this court would be a poor arbiter

indeed. The issue is the Rule's statutory authority, and it is this that the court finds lacking."). Where the federal government lacks authority to regulate, it likewise lacks authority to prosecute at the expense of state authority.

The court below should have interpreted applicable federal law in a manner consistent with state autonomy by admitting the medical board evidence. *See Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988) (“[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, [courts shall] construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress.” ).

In sum, the trial below eviscerated the state's traditional control and regulation of physicians under its jurisdiction. Congress never authorized such a complete disregard of state oversight of medical practice, an area in which “[s]tates lay claim by right of history and expertise.” *Gonzales v. Raich*, 125 S. Ct. at 2224 (O'Connor, J., dissenting) (quoting *Lopez*, 514 U.S. at 583 (Kennedy, J., concurring)). Federalism and Rule of Law require reversal of the conviction based on the exclusion of evidence about Dr. Hurwitz's compliance with the governing state medical board.

**C. THE EXCLUSION OF EVIDENCE OF DEFENDANT’S  
COOPERATION WITH THE DEA AND CONFLICTING  
FEDERAL POLICIES VIOLATED HIS RIGHT TO ESTABLISH  
LACK OF INTENT.**

The disagreement by the federal government with itself further warrants reversal. This Court held:

As a matter of law, defendant cannot be guilty of willfully evading and defeating income taxes on income, **the taxability of which is so uncertain that even coordinate branches of the United States Government plausibly reach directly opposing conclusions.** As a matter of law, the requisite intent to evade and defeat income taxes is missing. The obligation to pay is so problematical that defendant's actual intent is irrelevant. Even if she had consulted the law and sought to guide herself accordingly, she could have had no certainty as to what the law required.

*Critzer*, 498 F.2d at 1162 (emphasis added).

The federal government thoughtfully developed and published a document concerning the appropriate treatment of pain that reflected “a consensus, supported by the available literature and by the laws and regulations that govern the use of controlled prescription drugs.” JA 320. This document incorporated the views of leading pain experts, DEA representatives, and a dozen other leading experts from the fields of nursing, neurology, psychiatry, pharmacology, pharmacy and addiction medicine. JA 319-20. A press conference was held on August 11, 2004, by the DEA announcing the approval and publication of this document, which had

been four years in the making, and it was posted on the DEA website. It thoroughly supported defendant Dr. Hurwitz's practice.

The prosecution below obviously disagreed with this position by another department in the federal government, and it was eventually withdrawn. But that difference in opinion is precisely what required reversal of the conviction in *Critzer*. Here, not only did the court below ignore this evidence, it even excluded it from the jury. Proof that required acquittal as a matter of law in an analogous case was deemed inadmissible for the jury below even to consider. Such reasoning by the court below defies logic, and was reversible error.

The government's main argument for exclusion of this evidence was that Dr. Hurwitz had not relied on the document. But the *Critzer* defendant had not relied on the conflicting government positions either. Reliance is not the point. What matters is that Dr. Hurwitz's investigation of the legal requirements could not have provided him with clear notice of the prosecutor's theory. As this Court emphasized that point in *Critzer*, "Even if [Critzer] had consulted the law and sought to guide herself accordingly, she could have had no certainty as to what the law required." *Critzer*, 498 F.2d at 1162.

*Critzer* is widely followed by other Circuits. The Second Circuit reasoned in *United States v. Pirro* that "[c]riminal prosecution for the violation of an unclear

duty itself violates the clear constitutional duty of the government to warn citizens whether particular conduct is legal or illegal,” and held that the indictment should be dismissed for lack of violation of *known* legal duty. 212 F.3d 86, 91 (2nd Cir. 2000). The Fifth Circuit adhered to *Critzer* in reversing a conviction there. “When the taxability of unreported income is problematical as a matter of law, the *unresolved nature of the law* is relevant to show that defendant may not have been aware of a tax liability or may have simply made an error in judgment.” *United States v. Garber*, 607 F.2d 92, 98 (5th Cir. 1979) (emphasis added). *See also United States v. Harris*, 942 F.2d 1125, 1131 (7th Cir. 1991) (“‘[W]illful’ wrongdoing means the ‘voluntary, intentional violation of a known’—and therefore knowable—‘legal duty.’”) (quoting *United States v. Bishop*, 412 U.S. 346, 360 (1973)); *see also United States v. Dahlstrom*, 713 F.2d 1423, 1428 (9th Cir. 1983), *cert. denied*, 466 U.S. 980 (1984) (“We are convinced that the legality of the tax shelter program ... was completely unsettled by any clearly relevant precedent on the dates alleged in the indictment.”); *United States v. Phillips*, 600 F.2d 535, 540 (5th Cir. 1979) (reversing a conviction in finding that fraudulent intent was not shown).

Where, as here, “Congress has not spoken with the requisite clarity,” defendant Dr. Hurwitz cannot be constitutionally sentenced for virtually the rest of

his life for serving his patients to the best of his ability and in accord with state authority. *See, e.g., Dowling v. United States*, 473 U.S. 207, 229 (1985). In *Dowling*, the High Court affirmed the “‘time-honored interpretive guideline’ that ‘ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity.’” *Id.* (quoting *Liparota v. United States*, 471 U.S. 419, 427 (1985)).

As the Supreme Court has emphasized:

The constitutional requirement of definiteness is violated by a criminal statute that fails to give a person of ordinary intelligence fair notice that his contemplated conduct is forbidden by the statute. The underlying principle is that no man shall be held criminally responsible for conduct which he could not reasonably understand to be proscribed.

*United States v. Harriss*, 347 U.S. 612, 617 (1954) (citations omitted).

Courts have recognized “the bedrock principle that in a free country citizens who are potentially subject to criminal sanctions should have clear notice of the behavior that may cause sanctions to be visited upon them.” *United States v. McGoff*, 831 F.2d 1071, 1077 (D.C. Cir. 1987); *see also United States v. Apex Oil Co., Inc.*, 132 F.3d 1287 (9<sup>th</sup> Cir. 1997) (affirming dismissal of indictment because the conduct was not clearly forbidden by the regulations); *United States v. Harris*, 942 F.2d 1125, 1132 (7<sup>th</sup> Cir. 1991) (“If the obligation ... is sufficiently in doubt, willfulness is impossible as a matter of law, and the ‘defendant’s actual intent is irrelevant.’”) (citations omitted). Here, as in the Second Circuit’s reversal of a conviction of a physician, “[i]t takes no great flash of genius to conclude that

something is wrong somewhere.” *Siddiqi v. United States*, 98 F.3d 1427, 1438 (2d Cir. 1996).

The argument for reversal of the conviction here is even more compelling than the above cases, because defendant Dr. Hurwitz did investigate the legal requirements and complied fully with monitoring by the DEA. *See* Appellant Brief Point III.B.1. The exclusion of all this evidence from the trial below was reversible error.

### **III. THE EXPERT WITNESS TESTIMONY USED TO CONVICT DEFENDANT WAS HIGHLY ERRONEOUS AND GROSSLY PREJUDICIAL, AND CONSTITUTED PLAIN AND REVERSIBLE ERROR.**

The testimony of the chief government witness was so erroneous and prejudicial that we, as an organization of physicians, urge this Court to reverse the conviction for plain error. Rule 52(b) of the Federal Rules of Criminal Procedure provides that “plain errors or defects affecting substantial rights may be noticed although they were not brought to the attention of the court.” *See also United States v. Gastiburo*, 16 F.3d 582, 587 (4<sup>th</sup> Cir.), *cert. denied*, 513 U.S. 829 (1994). A trial court has an independent role as gatekeeper with respect to expert testimony and there was reversible failure in this essential regard. *See Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 589 n.7 (1993). In addition, Dr. Ashburn’s testimony at times gave the impression that he is a physician actively practicing in the field of pain management, which was not the truth.

After reviewing Dr. Ashburn’s testimony, six past presidents of the prominent American Pain Society wrote the trial judge to express their dismay at the “serious misrepresentations” in his testimony. These past presidents, who wrote that they were “stunned by his testimony,” hold prestigious positions at Memorial Sloan-Kettering Cancer Center, Johns Hopkins University Medical

Center, Beth Israel Medical Center and Albert Einstein College of Medicine, just to name a few. They observed that Dr. Ashburn's testimony was "without foundation in the medical literature and we believe that it is, on its face, absurd." JA 752. Dr. Ashburn's statements from the witness stand were without support in the medical community, without justification in the literature, and even contrary to work published in a textbook he edited. There is a miscarriage of justice when such testimony is used to imprison someone for virtually the rest of his life.

Dr. Ashburn's testimony flatly contradicted work he edited on the treatment of pain. He edited a medical textbook observing that "doses of opioids should be escalated until pain relief occurs or side effects intervene. There is no predetermined maximum dose of an opioid." ASHBURN & RICE, THE MANAGEMENT OF PAIN 132 (1998). It is unacceptable to allow a conviction to rest on testimony by an expert that contradicts a textbook published in his name.

Dr. Ashburn has not even been actively practicing as a physician, yet the jury was misled on that essential point also. He has been profitably employed by a drug company that recently obtained FDA approval for use of a local patch in treating pain. In connection with that announcement, his company's own press release describes Dr. Ashburn as having founded the company in 1997. *See*

[http://www.zars.com/ZARS\\_PR\\_07-11-05.pdf](http://www.zars.com/ZARS_PR_07-11-05.pdf) . Yet at trial, his testimony implied otherwise:

Q: And how long have you been working at Zars?

Ashburn: I started working full time for Zars in January of 2003.

Q: Okay. And prior to that, you were at the University of Utah?

Ashburn: Yes, sir.

JA 2441. In addition, Dr. Ashburn testified in terms of currently seeing and treating patients for pain. *See, e.g., id.* at 2451 (“even by the time [patients] see me, they’ve generally seen five or six or seven doctors by the time they get to me, I still look for possibilities that their pain can be cured, that we can make a new diagnosis and there’s something that can be changed ...”); *id.* at 2447 (“I continue to see [pain patients] periodically, indefinitely, making adjustments to how they respond to the care ...”). In fact, Dr. Ashburn had not personally engaged in the meaningful practice of medicine for quite some time.

Consider this testimony by Dr. Ashburn on a key issue that the jury later asked the judge about:

Q: Do you still treat [addicted patients’] pain, though, Doctor?

Ashburn: No.

Q: Why not?

Ashburn: It essentially continues their addiction behavior.

*Id.* at 2485.

All of the foregoing testimony falsely led the jury to think that Dr. Ashburn personally conducts a pain practice, when he does not. Moreover, the testimony expressly contradicts Supreme Court teaching of *Linder* that “a physician, who acts *bona fide* and according to fair medical standards” may not be prohibited from giving “an addict moderate amounts of drugs for self-administration in order to relieve conditions incident to addiction,” because such an interpretation of the statute in *Linder* “would certainly encounter grave constitutional difficulties.” 268 U.S. at 22. Relief of addiction of a drug addict is not at issue here, but the constitutional difficulties raised by deterring and prohibition physicians from treating patients are. Moreover, Dr. Ashburn was not qualified to speak as though he is a clinical physician treating pain, and certainly not qualified to mislead the jury.

The foregoing falsehoods in Dr. Ashburn’s testimony, which did not come to light until after the trial, constitute reversible error. *See United States v. Wallace*, 528 F.2d 863, 866 (4<sup>th</sup> Cir. 1976). The falsehoods were attributable to an expert witness for the government, which reinforces the need for this Court, *sua sponte*, to correct the injustice. *See United States v. David*, 83 F.3d 638 (4<sup>th</sup> Cir. 1996)

(reversing a conviction based on a finding of “plain error”); *see also Minasian v. Standard Chtd. Bank, P.L.C.*, 109 F.3d 1212, 1216 (7<sup>th</sup> Cir. 1997) (emphasizing “how vital it is that judges not be deceived by the assertions of experts who offer credentials rather than analysis” and “an expert’s report that does nothing to substantiate [its] opinion is worthless, and **therefore inadmissible**”) (emphasis added).

Physicians cannot practice innovative medicine in fear that some future government expert might disapprove, without justification, of their good faith treatment for a particular patient. Like the legal profession, the medical profession has many internal disagreements, but conviction based on such disputes is improper. “[I]t is highly disturbing that testimony by such an impressive array of apparently objective medical experts, who found the defendant’s actions to be not only noncriminal, but medically appropriate, can be dismissed as ‘unbelievable’ and not even capable of generating reasonable doubt.” *Naramore*, 25 Kan. App. 2d at 323.

Disputes within the medical profession are not new, but it is unprecedented and unauthorized by Congress to imprison a physician based on it. George Washington himself died in 1799 when two of the three physicians attending him insisted on the customary treatment of bloodletting rather than agree to the third

and youngest physician's proposal to perform a novel procedure – tracheostomy – to relieve the swelling and inflammation of General Washington's airways, which remains the treatment today for the condition from which he suffered, namely acute epiglottitis, and which was the only hope of saving his life in 1799. *See generally* David Morens, M.D., "Death of a President," 341 *New England J. Med.* 1845 (Dec. 9, 1999). A tracheostomy was outside the "bounds of medical practice" in our Nation at that time. Under the standard adopted below, performance of a tracheostomy could have subjected the physician to imprisonment had he failed, because a jury could have found it to be outside the bounds of medical practice in the United States at that time.

Fifty million Americans who suffer in pain have been held hostage to the horrific chilling effect caused by the conviction and sentence of Dr. Hurwitz. Congress has not authorized federal preemption of state authority over medical practice, but this prosecution created its own precedent here that will deter good faith treatment of pain. This conviction based on "absurd" medical testimony by a drug company consultant has no basis in federal law and conflicts with state law. No civilized society treats its professionals in this manner for acting in good faith, and the conviction below should be reversed.

## CONCLUSION

The verdict below should be reversed.

Respectfully submitted,

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UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT  
*United States of America v. William Eliot Hurwitz*, No. 05-4474

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Dated: September 6, 2005

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## CERTIFICATE OF SERVICE

Andrew L. Schlafly hereby certifies that he caused two true copies of this *Amicus* Brief Filed In Support of Appellant William Eliot Hurwitz to be delivered by overnight commercial carrier on this 6th day of September, 2005, to:

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