RECORD NUMBER: 05-4884

United States Court of Appeals

for the

Fourth Circuit

UNITED STATES OF AMERICA,

Appellee,

– v. –

RONALD A. MCIVER,

Appellant.

**ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA AT ANDERSON**

REPLY BRIEF OF APPELLANT

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I. PRELIMINARY REMARKS

The Government's Response castigates the Defendant-Appellant, Dr. Ron McIver, because he was a physician treating chronic pain with Opioids.

This treatment is a medical practice that the Justice Department abhors as an "illegitimate" medical practice despite the objections of State Attorneys General, Physicians and Pharmacists that the Justice Department's unbridled war against physicians is scaring physicians and chilling their treatment of chronic pain patients.

There is a calculus by which we distinguish between a physician who is easing chronic pain and another who is dealing in drugs.

But this case, involving Dr. Ron McIver, is about easing pain – no matter how cocksure the Government may argue the contrary proposition.

In any case, why would we credit the medical judgment of federal prosecutors and DEA Agents? The Supreme Court said as much in *Gonzales v. Oregon*, __ U.S. ___, 126 S. Ct. 904, at 922 (Jan. 17, 2006), when it criticized the Attorney General himself for having no medical expertise. And the prosecutor who handled Appellant McIver's trial, and wrote the government's Response on appeal, stated at the trial, "I know nothing about pain management." J.A. 1105.

The Justice Department's drug enforcement campaign against physicians has blithely disregarded not only its noteworthy critics but also the critical challenge

facing this nation of 55 million chronic pain patients who are not terminal cancer patients and who will live long and suffer greatly when they cannot dull their daily unremitting pain. Ronald T. Libby, *"Treating Doctors as Drug Dealers – the DEA's War on Prescription Painkillers"*, **CATO** Institute Policy Analysis (June 16, 2005) (http://www.cato.org/pubs/pas/pa545.pdf).

There are increasing numbers of chronic pain patients who need medication because advances in health allow us to live longer and prolong the process of dying. *See generally,* National Institute of Nursing Research, NIH & Office of Medical Applications of Research, NIH, National Institutes of Health State-of-the-Science Conference Statement (December 6-8, 2004) (http://www.consensus.nih.gov/2004/2004EndOfLifeCareSOS024html.htm); Joan Teno, "The Prevalence and Treatment of Pain in U.S. Nursing Homes," Brown University Center for Gerontology and Health Care Research (http://www.chcr.brown.edu/commstate/PAINMONOGRAPHWEBVERSION.PDF) .

If a patient's chronic pain is unrelieved, unsurprisingly, it may lead to suicide, just like what happened to Lawrence Shealy in this case who had crippling arthritis with chronic knee and back pain; both the prosecution and the defense at trial failed to uncover the fact that Mr. Shealy had tried to commit suicide before, and neither party at trial asked the obvious questions of Mr. Shealy's other physician, Dr. B. T. Mitchell, III, or even subpoenaed the medical records, that would have

uncovered that Mr. Shealy took his own life, among other reasons, because he believed he'd become a "burden on his family."[1] *See generally* Addendum

[1] While claims of ineffective assistance of counsel are allowed on direct appeal if it "conclusively appears" from the record "that counsel did not provide effective representation", *U.S. v. Richardson*, 195 F.3d 192, 198 (4th Cir. 1999), citing *U.S. v. Gastiaburo*, 16 F.3d 582, 590 (4th Cir. 1994), this "ineffectiveness" claim was not developed in Appellant's opening brief, and so I am somewhat hamstrung in this Reply; indeed prior counsel who served as trial counsel filed with another co-counsel the opening brief that would have had to confess the trial counsel's "ineffectiveness".

Nevertheless, we remain of the view, in reliance on *Strickland v. Washington*, 466 U.S. 668, 104 S. Ct. 2052 (1984), that trial counsel's performance was "deficient in that it fell below an objective standard of reasonableness and outside the range of professionally competent assistance" and that the deficient performance prejudiced the defense in that, but for counsel's unprofessional errors, the result of the proceeding would have been different." *Hunt v. Lee*, 291 F.3d 284, 289 (4th Cir. 2002).

The record of the trial reveals that trial counsel repeatedly failed to object to wide-ranging hearsay testimony that went on for pages, and references to absent documents referenced without any evidentiary foundation. But defense trial counsel was particularly unprofessional and unprepared in his handling of the expert testimony of the government's witness and of the accused's expert. Indeed, he never questioned how the government's expert could render any valid opinion in the absence of medical records, that were concededly incomplete, and without examining any of the patients themselves. Almost from the outset of his cross of the Government's expert, defense trial counsel was out of his depth. He began with a challenge to the expert as to the theory of titration and "cutting edge" pain medication, prompting the expert to say it was not an acceptable practice if "pushing the edge" was putting "a patient in a life-threatening situation". J. A. 562. Defense trial counsel's examination was so dismal, the prosecutor required no re-direct. J. A. 680.

Defense trial counsel did not even confer with his expert until the trial was underway, this according to the record, J. A. 1088, indeed having him review records the day he was summoned to testify and there was abundant evidence that

The State Attorneys General including the Attorney General for South Carolina objected that the Justice Department's "enforcement" campaign has "many physicians fear[ing] investigations and enforcement actions if they prescribe adequate levels of opioids or have many patients with prescriptions for pain medications." *See* State Attorneys General to DEA, "Comment on Dispensing of Controlled Substances for the Treatment of Pain," Docket No. DEA-261, at 1, dated March 21, 2005 (henceforth, "State AG Letter, at __") (http://www.naag.org/issues/pdf/20050321-Final-DEA-Comment.pdf)

The State Attorneys General disapproved DEA's stated policy, in reliance on the questionable proposition found in *U.S. v. Morton Salt*, 338 US 632-643 (1950), "that the Government 'can investigate merely on suspicion that the law is being violated or even just because it wants assurance that it is not.'" *Id.*, at p. 4.

The Federation of State Medical Boards of the United States stated that, even though we have in place "state pain policies recognizing the legitimate uses of opioid analgesics", chronic pain patients "continue to be under-treated" and the principal reason is the "*unnecessary* scrutiny by regulatory authorities" (emphasis

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much of what the defense trial counsel adduced, he was hearing for the first time with the jury.

While trial counsel did preserve the objection to the jury instruction that the jury should consider deviations from "professional norms", he did entirely fail to comprehend the inadmissible hearsay testimony of the supposed conspirators, and did not adequately challenge the corresponding jury instruction charge regarding the conspiracy count (discussed further in this Reply).

supplied). *See* Federation of State Medical Boards of the United States, Inc., *"Model Policy for the Use of Controlled Substances for the Treatment of Pain"* (http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf).

The American Pharmacists Association told Congress that "Every effort to prevent diversion and abuse has the potential to diminish appropriate prescribing and dispensing *exponentially*" (emphasis supplied) and the risk of this unbridled law enforcement effort is that we "negatively impact care to thousands of patients living in pain who could be helped by appropriate use of controlled substances." *See* Statement of the American Pharmacist Association, *"OxyContin and Beyond: Examining the Role of FDA and DEA in Regulating Prescription Painkillers"*, submitted to the House Government Reform Committee, Subcommittee on Regulatory Affairs (Boston, Mass. - September 13, 2005) (http://www.aphanet.org/AM/Template.cfm?Section=Search&section=Access_to_Drugs&template=/CM/ContentDisplay.cfm&ContentFileID=788).

In other words, this prosecution against Appellant McIver is the most recent in the Department's "enforcement" campaign, by which it criminalizes chronic pain medication.

The Department relies on a regulatory provision written by the Attorney General that the Supreme Court in *Gonzales v. Oregon*, *supra*, has now disapproved.

The Department further leads the trial court to error when it replaces the standard that Congress established in the Controlled Substances Act as the permissible bound for a physician, that is, "the course of professional practice", and tries to narrow the statutory test to "the norms of professional practice" – a less rigorous standard by which to convict a physician.

Physicians are targeted by the DEA based on "red flags" that the DEA contrives as indicia of "diversion" such as the "number of patients that visit a physician in a day". But the State Attorneys General questioned the validity of such "red flags" that the DEA prefers such as the "number of patients a physician attends to on a day" since "[t]hose physicians who are willing to treat such vulnerable patients are likely to see many because their colleagues are often afraid to do so." *See* State AG Letter, at p. 5.

No matter what the Justice Department says officially, its actions tell us that the government has adopted a no-tolerance regime for the prescription of opiates in America, and each of us may yet suffer for the zeal borne of this collective governmental ignorance as to what is necessary to manage the nation's chronic pain patients.

This criminal case, involving Dr. Ron McIver, is but one example of the Justice Department's over-reaching policy against opioids -- no matter how appropriate their use.

II. STATEMENT OF THE FACTS

Ron McIver's interest in medicine began, as a child, because of a girl who lived nearby, who was six or seven years younger, and diagnosed with leukemia. J. A. 1247. He watched her suffer, and die, and decided he would go to medical school to prevent suffering like that. Id.

There is no question that Dr. McIver did ease the suffering of his patients. Sarah Johnson came to Dr. McIver after she had broken her neck in an accident, and after awhile was able to return to work. J. A. 744. Mark Cooper, a computer instructor for the 12th grade, had neck and back pain with migraine headaches, caused by fibromyalgia, forcing him to lie down on the floor during his classes, and Dr. McIver helped him relieve the pain and return to work. J. A. 762-763. Valerie Sherard had pain following back surgery, and, following a combination of therapies, she was much improved. J. A. 774-776. Dr. McIver also helped Jerry Beacham, who could hardly move when he first visited Dr. McIver. J. A. 794.

Nor should we lose track of the fact that Dr. McIver was acquitted of charges relating to his treatment of patients Hannah, Riegel, Davis and Hawfield.

The Government focused instead on those patients who Dr. McIver had good reason to believe were in pain, but who swore at trial instead, that they were "conning" him, lying and misleading him, with elaborate explanations of the scars they had, that they'd used to fool Dr. McIver, and the pain they explained

corresponded to the evident scar tissue, so that they could convince Dr. McIver that they needed pain medication. Smith claimed that the scar on one wrist from an accident, and the arthritis in her other wrist, accounted for her pain, necessitating pain medication, but she was lying. J.A. 179, 188, 195. Dr. McIver found she had a syringe, but she claimed she used it for "juicing up" the bait. J. A. 185, 980. Boyer who had suture marks in his foot claimed he had pain, but he was lying. J. A. 249, 254-256. Boyer had track marks but didn't think that Dr. McIver ever saw them. J.A. 254.

Dr. McIver did in fact call and write the authorities asking whether his suspicions about some patients were well-founded, and whether he should discharge them as patients. J. A. 83-84, 981. But the government remained silent. J.A. 85-86.

Apparently, instead of supplying Dr. McIver the information that he might have acted upon, the government preferred a "gotcha" policy, by which they prosecuted physicians, and insisted – somehow or other - that it was the physician who turned a blind eye to his patient's "diversion".

On the other hand, the government insists that Dr. McIver conspired with his patients.

In fact and truth, there is and can be no conspiracy, as a matter of law, when the offense requires concerted action to begin with, for instance, bribery (requiring two

persons), or, as in this case, the distribution of a prescription drug (by a doctor to a patient); yet the jury was instructed that two persons who made a criminal agreement were sufficient to make out conspiracy.

No appropriate jury instruction was given that might have cured this plain error; nor did the defense counsel even murmur an objection – as he no doubt didn't appreciate that it was objectionable.

Perhaps the most egregious and unjust of these criminal charges was to claim that Mr. Lawrence Shealy, who suffered pain from crippling arthritis, back and knee pain, and who had tried to commit suicide once before (unbeknownst to the parties or the jury), and had succeeded at last, that his tragic death should be attributed to Dr. McIver.

Mr. Shealy had first tried OxyContin for his arthritis, back and knee pain when his family physician was Dr. Mitchell. J.A. 422, 963. When he presented himself to Dr. McIver, Mr. Shealy said he hurt "over his entire body," and had had these pains for years. J. A. 963. With a comprehensive pain management program, and by titrating (increasing) the dosage of OxyContin, Dr. McIver helped Mr. Shealy to feel better and to get back to work. J. A. 965-966. But then that "good feeling" subsided.

What none of the trial counsel considered, apparently because neither the prosecution nor the defense subpoenaed pertinent medical records, was that Mr.

Shealy had attempted suicide once before (*see* Addendum, Detox Admission to Self Memorial Hospital, referencing Mr. Shealy's suicide attempt, 5/29/87-6/2/87), and that he had a history of addiction that he had difficulty controlling (*see* Addendum, letter from family physician, Dr. Mitchell, to Dr. Gus Bazan with the pain clinic at Self Memorial Hospital, dated February 11, 1996).

The first indication of how extensive was his suicidal ideation was when he told Dr. McIver on March 25, 2002, that "he had, on many occasions, felt that his family would 'be a lot better off without me'" and, while he "had not formulated any specific plans for suicide", he'd thought about it a lot, and "I'd just need to make it look like an accident." *See* Addendum, McIver's treatment record, dated 3/25/02. The reason, he explained, that it would have to look "like an accident" was that "It would hurt my family too much if it looked like I had killed myself." *Id.*

On May 15, 2003, in another medical record not subpoenaed by defense trial counsel, Dr. Mitchell wrote that Mr. Shealy "has been having a lot of trouble lately" and states "that at times he feels that everyone would be better off i[f] he was gone. He continues to have a lot of pain on a daily basis. He feels that he is a burden to his family." *See* Addendum, RFP 73.

On that same day, Dr. Mitchell wrote that he was "very down, tearful at times", that Mr. Shealy was suffering from "major depression", "had these symptoms for

2-3 months" and that "[h]e is not working, has chronic back pain is not likely to get any better." *See* Addendum Riley 10.

On the day before he committed suicide, Mr. Shealy visited Dr. McIver who tried to determine what medication Dr. Mitchell prescribed.

But on the next day following, Mr. Shealy was found dead, of suicide. Dr. McIver did not cause Mr. Shealy's death, there was an intervening cause, Mr. Shealy took his own life.

III. ARGUMENT

A. THE TRIAL COURT'S JURY INSTRUCTIONS WERE IMPERMISSIBLE AND PLAIN ERROR.

This Circuit's decision in *United States v. Alerre*, 430 F.3d 681 (4th Cir., December 1, 2005) has nothing to do with Appellant McIver's objection to the jury instruction in this case inviting the jurors to apply "professional norms" as they saw fit when assessing Dr. McIver's medical practice.

This Court must also consider the effect of the recent Supreme Court decision in *Gonzales v. Oregon*, __ U.S. ___, 126 S. Ct. 904 (Jan. 17, 2006), holding that the Attorney General may not, by regulation - 21 C.F.R. Section 1306.4 (the "legitimate medical purpose" element) – criminalize the actions of registered physicians that the Attorney General deems "illegitimate". Accordingly, consistent with *Gonzales*, the Attorney General must constrain his prosecutorial zeal to the crime "as defined" in the Controlled Substances Act, that, by its express terms, is

limited to "prescriptions" made "outside the course of professional practice" – and without amplification or modification by any regulatory imposition the Attorney General might prefer as to what may be "legitimate medical purpose" or not.

The combination of these plain errors, that is, wrongly instructing the jury on the elements of the crime, by making inapt references both to "professional norms" and to "legitimate medical purpose," requires a new trial for Dr. McIver.

1. The *Alerre* decision has nothing to do with Appellant McIver's objection to the jury instruction at his trial.

The Government's curt response, to the effect, that this Court upheld the jury instruction in *United States v. Alerre*, 430 F.3d 681 (4th Cir., December 1, 2005) does not dispose of Appellant McIver's legal challenge to the erroneous instruction that is at issue in this appeal.

In *Alerre*, quite unlike this case, the Court did in fact and truth try to save the defense – and the prosecution - from error when Dr. Arthur Jordan, the government's expert witness, testified that the dosages were not what a "prudent physician in the state of South Carolina would give." *Alerre*, *supra*, at 686.

The trial court, and not the defense, considered the evidence improper and told the defense that there was "no reason to put something in the record which the jury may [consider] … that is not the standard." *Id.*

More than that, the court instructed the jury, when the evidence was first introduced, that, "[w]hether the doctors are negligen[t] or not, whether they were guilty of malpractice, is not an issue in this case." *Id.*

It was of some significance to the three-judge panel in *Alerre* that, when the prosecution presented evidence variously of "illegitimate medicine" and the medical practices that failed to meet "the ordinary standard of care", that "the defense lawyers did not object to such evidence" even though the trial court expressed its concern to the parties that "standard of care evidence might be irrelevant and confusing, in that it appeared to relate to civil negligence issues and not necessarily to whether the defendants had contravened the applicable criminal statutes." *Id.*

Unlike the circumstances of Appellant McIver's case, it appears that "the prosecutors, as well as the defense lawyers, repeatedly assured the court that such evidence was relevant and appropriate." *Id.*

No such somnolent assurance was given by the defense to the trial court in this case.

As significant is the fact that no curative instruction was provided to the jury, although the trial court was invited to do so by the defense.

In *Alerre*, the trial court found it persuasive, if not conclusive, that the Court told the jury that "it could not convict on the distribution and drug conspiracy

charges if it found only that the defendants' practices fell 'below the line of what a reasonable physician would have done.'" *Id*, at 687.

No instruction was given in Appellant McIver's case that could cure the Court's repeated reference to "the norms of professional practice." J. A. 1293.

In Appellant McIver's case, the court specifically invited the jury, when ascertaining guilt or innocence, to "consider the testimony you have heard relating to what has been characterized during the trial as the norms of professional practice." *Id.*

The defense objected in writing to this inapt reference in the instructions. J. A. 1302.

Nevertheless, the Court repeatedly instructed the jury that, "you should also consider the extent to which, if at all, any violation of professional norms you find to have been committed by the Defendant interfered with his treatment or his patients …." J. A. 1293. In that same paragraph, the Court further instructed the jury that it could consider "the extent and severity of any violations of professional norms you find he committed."

The defense objected to this entire paragraph. J. A. 1302. But the Court gave this instruction unchanged nonetheless.

The defense had also objected to the Court's instruction that equated "other than a legitimate medical purpose" with "the personal profit of the physician." J.

A. 1292. After all, as trial counsel noted, with rare exception, don't all physicians issue "prescriptions for personal profit?" J. A. 1302. Notwithstanding the argument that follows, the jury was misled when it was instructed that the fact that Dr. McIver made a profit meant that his "medical purpose" was not "legitimate."

Unlike the *Alerre* defense counsel, trial counsel suggested curative and clarifying language that was rejected by the Court, and trial counsel explained to the trial court that the instruction he was to render "comes close to saying if Dr. McIver violated the medical norms, then he is guilty of the criminal violations." J. A. 1302.

By the instruction he rendered, the Court countermanded Dr. Thomas Alexander Duc's testimony, J. A. 1061- 1137, to the effect, that a physician "may not be the norm or majority, but still be doing procedures that are for a legitimate medical purpose." J.A. 1303.

Trial counsel told the court that "[s]imply because a majority or overwhelming majority of physicians believe a procedure or technique wrong, does not mean that it is outside the bound of medical practice." J. A. 1303.

After the conviction, the defense restated this objection again, but with little effect. J. A. 1320-1322.

Finally, it is instructive to note that this is hardly a harmless error, as the only counts that resulted in conviction were those that were the subject of the

government expert's testimony, Dr. Steven Barry Storick, that is, the selfsame expert who set forth what were "the norms of professional conduct".

The prosecutor himself underscored this fact to the trial court when court and counsel were trying to understand how the jury could possibly have convicted Dr. McIver as to some patients but not others. J. A. 1326-1327.

Thus do we have these wrong instructions, "norms of professional conduct," that reinforced Dr. Storick's expert testimony, presented without the benefit of seeing any one of the patients himself, or even all of their medical records. In *U. S. v. Tran Trong Cuong*, 18 F.3d 1132, 1141 (4th Cir. 1994), a panel of this court found absent records and the failure of the expert, Dr. MacIntosh, to speak with "any of these patients" persuasive when dismissing the counts for insufficient evidence.

Without the fundamental information that you would think was necessary, compare *U.S. v. Tran Trong Cuong*, *supra*, the government's expert concluded that certain prescribing practices for Brown were simply not "appropriate" (J. A. 517), and suggested that methadone would have been "better" for Brown than OxyContin (J. A. 522).

All the more remarkable were the expert opinions that Dr. Storick rendered, without any of Dr. McIver's medical history, physical exam, or progress notes for Mr. Shealy, and based on Mr. Shealy's prescriptions alone. He concluded that Dr.

McIver had admistered "a lot of medicine" (J. A. 526). You wonder what other inference you could conclude from prescriptions alone. As Dr. Storick had none of the medical records, it should come as no surprise that he "wasn't sure what Dr. McIver was treating" but he did demur that Dr. McIver's approach was "a very complicated way of treating somebody, extremely high dose" (J.A. 527). As Mr. Shealy was unavailable to testify, this thin and uneven documentary veneer was hardly sufficient evidence. *U.S. v. Tran Trong Cuong*, *supra*, at 1142. While it may not be as bad as the indictment in *Tran Trong Cuong*, supra, the indictment here sure did "invite a jury to find guilt by association or a result of a pattern …". *Id.*

Constrained by the limits of his own chronic pain practice, Dr. Storick acknowledged that Kyle Barnes "maybe" had fibromyalgia, a pain syndrome, and thought that "the use of opioids" for treatment was "extremely controversial, and if they are used, ***the cases I see*** are usually in low dosages, not to the extent of eleven hundred milligram twice a day" (emphasis supplied). J. A. 533.

In his review of Angela Knight, Dr. Storick conceded the injury that required pain medication but he questioned why Dr. McIver did levels above the affected nerve, and why there was treatment to several joints, and why she'd travel the distance to Dr. McIver's office, and he would not have continued to prescribe these

medications. J. A. 534-543. These observations seemed more peevish than pertinent.

Lastly, as to John Davis, Dr. Storick said, "for no apparent reason," Mr. Davis was having "excruciating pain all over his entire body" and he questioned why Dr. McIver would have had to give Mr. Davis in his neck "epidurals along the nerves that come down as well as the brachial plexus …" and Dr. Storick thought that was "sort of a little extreme…". J.A. 546. Again, he thought this was "a lot of medicine." J.A. 547.

Upon such thin reeds as Dr. Storick's conclusory testimony, coupled with the erroneous jury instructions, do we obtain false convictions.

2. The Supreme Court's recent holding in *Gonzales v. Oregon* underscores the plain error in the jury instruction, when the Court repeatedly and wrongly referenced the Justice Department's administrative guideline, "legitimate medical purpose", found at 21 C.F.R. Section 1306.04(a), rather than the crime, as defined in the CSA without that provision.

Gonzales v. Oregon, __ U.S. ___, 126 S. Ct. 904 (Jan. 17, 2006), flatly stated that the Controlled Substances Act granted the Attorney General a limited role, and that grant of authority did not include defining the substantive standards of medical practice in administrative guidelines.

The specific regulatory section disfavored in *Gonzales* was the same 1971 regulation, promulgated by the Attorney General, and relied upon by the federal prosecutor in Appellant McIver's jury trial, requiring that every prescription for a

controlled substance "be issued for a [1] *legitimate medical purpose* by an individual practitioner [2] *acting in the usual course of his professional practice*" (emphasis supplied). *Gonzales v. Oregon*, *supra*, at 912; *see* 21 C.F.R. Section 1306.04(a)(2005).

Of course the statute defining the crime at issue here makes no reference to [1] "legitimate medical purpose"; rather it states that a practitioner may "distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance [2] *in the course of professional practice or research*" (emphasis supplied). 21 U.S.C. Section 802(21).

In *Gonzales*, the Court had reason to scrutinize this regulation because the Justice Department had pronounced an "interpretive rule" as to that same Section 1306.04(a), to the effect, that pain management and treatment involving assisted suicide was not "legitimate medicine".

Justice Kennedy made it crystal clear that the Attorney General "is not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law." *Gonzales v. Oregon*, *supra*, at 916.

More generally, the court concluded: "The CSA does not grant the Attorney General this broad authority to promulgate rules." *Id.* While the Attorney General may establish controls against diversion, the Court held, the Attorney General has

no authority "to define diversion based on his view of legitimate medical practice." Id.

If the Attorney General were right, that he derived power from his authority to de-register physicians, the Court said disapprovingly that then the Attorney General's "power to deregister necessarily would include the greater power to criminalize even the actions of registered physicians, whenever they engage in conduct he [the Attorney General] deems illegitimate." *Gonzales v. Oregon*, *supra*, at 918.

The Court further concluded that: "[i]t would be anomalous for Congress to have so painstakingly described the Attorney General's limited authority to deregister a single physician or schedule a single drug, but to have given him, just by implication, authority to declare an entire class of activity outside 'the course of professional practice,' and therefore a criminal violation of the CSA." *Id.*

More than that, the CSA "allocates decision-making powers among statutory actors [including the Attorney General] so that medical judgments, if they are to be decided at the federal level and for the limited objects of the statute, are placed in the hands of the Secretary [of Health and Human Services]." *Gonzales v. Oregon*, *supra*, at 920.

It is the Secretary of Health and Human Services who "determine[s] the appropriate methods of professional practice in the medical treatment of …narcotic

addiction." 42 U.S.C. Section 290bb-2a; 21 U.S.C. Section 823(g); *See* H.R. Rep. No. 91-1444, pt. 1 (1970).

When Congress ratified the Convention on Psychotropic Substances, February 21, 1971, 32 U.S.T. 543, T.I.A.S. No. 9725, it sought to assure itself that "nothing in the Convention will interfere with ethical medical practice in this country as determined by [the Secretary of Health and Human Services] on the basis of a consensus of the views of the American medical and scientific community." *Gonzales v. Oregon*, *supra*, at 921.

Worse, Kennedy concluded, if the Attorney General were free to make medical judgments, then those he "could make [would not be] limited to physician-assisted suicide." *Id.*

Kennedy disapproved any such broad grant of power that might enable the Attorney General to decide "whether any particular drug may be used for any particular purpose," or "whether a physician who administers any controversial treatment could be deregistered" and prohibited from lawfully prescribing any controlled substances. *Id.*

According to the Supreme Court, "Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood" but,

beyond this, "the statute manifests no intent to regulate the practice of medicine generally." *Gonzales v. Oregon*, *supra*, at 923.

Thus, the "legitimacy" element that the government insisted upon, in the jury instructions it requested, and throughout the trial, does not constitute, nor define an element of the "crime" found exclusively in the CSA itself.

After *Gonzales*, and for the reasons enumerated by the Court, and reviewed above, there is no "legitimacy" element of the crime.

It is instead as stated in the CSA when a physician is acting, prescribing or distributing, "outside the course of professional practice", meaning as a "drug pusher" instead of as a physician, as specifically illustrated in *United States v. Moore,* 423 U.S. 122, 143 (1975), and then and only then is the physician liable for his bad conduct.

The Court continues, stating, that "[t]he silence is understandable, given the structure and limitations of federalism, which allow the States 'great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort and quiet of all persons." *Id.* And thus, "[t]he structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the States' police powers." *Id.*

The rationale for the Supreme Court's decision is simple: the federal government must defer to the States' "great latitude under the police powers to

legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Id.*

No Attorney General may therefore bar a medical use that is at variance or "inconsistent" with another's "reasonable understanding of medical practice." *Gonzales v. Oregon*, *supra*, at 924.

Thus did the Supreme Court refuse "to effect a radical shift of authority from the States to the Federal Government to define general standards of medical practice in every locality." *Gonzales v. Oregon*, *supra*, at 925.

B. THE TRIAL COURT'S RULINGS WITH RESPECT TO EXPERT TESTIMONY WERE BOTH PLAINLY ERRONEOUS AND AN ABUSE OF DISCRETION.

Of all the cases that the Government could cite in support of its experts, it is remarkable that it invokes *Tran Trong Cuong*, *supra,* as "favorably" referencing the evidence offered by experts. *See* Government's Response, at 24.

As indicated elsewhere in this Reply, and reviewed again now, this Court had a series of reservations about the expert testimony of the government's expert, Dr. McIntosh, in *Tran Trong Cuong*, *supra*, at 1143, because the expert had bolstered his opinion with a second expert opinion at trial, plainly hearsay, since that second expert "did not testify" and his "report was not introduced into evidence" and, as bad or worse, that unavailable expert could not be cross-examined by the defense about his purported opinion.

This same government expert, Dr. McIntosh, was further criticized because he was unfocused except on a few of the patients, the only evidence he reviewed were prescriptions, a summary of evidence, and the expert had not interviewed any of the patients. *Tran Trong Cuong*, *supra*, at 1141.

Without restating what has already been said, the objective of Federal Rule of Evidence 702 is to provide expert opinions that may be helpful to the jury. *Kopf v. Skyrm*, 992 F.2d 374, 377-78 (4th Cir. 1993).

If the expert is offering nothing more than a legal conclusion, and that is tantamount to telling the jury what result it should reach, that is properly excludable. *Woods v. Lecureux*, 110 F.2d 1215, 1220 (6th Cir. 1997).

What purpose could the expert testimony in this case have except to direct the jury to embrace a legal conclusion, as the very language of the offending expert opinion mimicked precisely the jury instruction that we've challenged herein?

Instead of aiding the jury's deliberation, the purpose of the expert opinion was to supplant it, and by the prosecution's own analysis, it was effective as only those counts that were the subject of expert testimony resulted in a conviction.

C. THE GOVERNMENT'S EVIDENCE WAS INSUFFICIENT TO SUPPORT THE JURY'S VERDICT -

1. AS TO THE DECEDENT SHEALY

The evidence of Mr. Shealy's medical treatment is sparse and incomplete in the trial record, and there are otherwise large gaps that fall short of the mark, in terms of proving that Mr. Shealy's treatment was outside "the course of professional practice".

The differences in opinion about Mr. Shealy's treatment are about medical practices, of which reasonable physicians may well differ.

This might make out a "standard of care" argument in a negligence case, but it does not make out a crime.

Moreover, there was good and sufficient evidence in the record that supported an intervening cause for Mr. Shealy's death, namely, his suicide. Mr Shealy tried to commit suicide before, had a history of addiction, and said that he was seriously considering suicide shortly before he did commit suicide. *See generally* Addendum.

The prosecution exploited Mr. Shealy's death throughout the trial and at summation.

For the prosecution, Mr. Shealy's death confirmed the government's factually unsupported charge that Dr. McIver's treatment caused Mr. Shealy's death.

In order to inflame the jury, the prosecutor ran through the other witnesses, paused, and then said: "Didn't hear from Larry Shealy." J. A. 1156.

Moments afterwards, again, the prosecutor said, "We did not have Larry Shealy here …" J. A. 1162.

The government's expert was less than compelling on this issue, so the prosecutor invoked Mr. Shealy's son who was "here" – at trial – and who, the prosecutor said, "knew that his father was on too much of something." J.A. 1164.

The prosecution even charged, this physician got his patients "addicted", presumably including Mr. Shealy. J. A. 1171.

No matter that Mr. Shealy's death would never have occurred if Mr. Shealy had followed Dr. McIver's directions as to those prescriptions.

No matter that there was good cause to believe that Mr. Shealy might take his own life, for the reasons that he said he would, in the manner he said he would, and make it "look like an accident".

Finally, Dr. McIver is not only challenging the sufficiency of the evidence for the substantive offense; he is also challenging the substantial sentencing enhancement ascribed to Mr. Shealy's suicide.

Under 21 U.S.C. § 841(b)(1)(A), if "death or serious bodily injury results" from the use of a controlled substance unlawfully dispensed by the defendant, the defendant faces a minimum mandatory sentence of twenty years.

Appellant McIver contends, however, that this sentencing enhancement must be proven to the jury beyond a reasonable doubt.

In *United States v. Booker*, 543 U.S. ___, 125 S.Ct. 738 (2005), the Supreme Court confirmed that, in our federal system, the Sixth Amendment right to trial by jury is violated unless an enhancement is found beyond a reasonable doubt by the jury.

Justice Stevens wrote that "it has been settled throughout our history that the Constitution protects every criminal defendant 'against conviction except upon proof beyond a reasonable doubt of every fact necessary to constitute the crime with which he is charged.'" *Booker*, 125 S.Ct., at 748.

The Government had to prove beyond a reasonable doubt to the jury therefore that Dr. McIver's actions, and his actions alone, resulted in the death of Mr. Shealy.

There is case authority that Mr. Shealy's was an "intervening" cause that vitiates any possible sentencing enhancement.

The case for an "intervening cause" was not made out, as a matter of fact, in *U.S. v. Patterson*, 38 F.3d 139, 146 (4th Cir. 1994); the Court, in *dicta*, however left open its application under the right factual circumstances.

Similarly, in *United States v. Rodriguez*, 279 F.3d 947, 952 n. 5 (11th Cir. 2002), an "intervening cause" was impliedly favored, although under the facts of

that case as well, the Court concluded, it "need not decide." *Vinson v. Clarke Cty., Ala.*, 10 F. Supp. 2d 1282 (S.D. Ala. 1998) (applying Alabama law in a § 1983 action) (In a civil rights case, suicide was found to be an intervening cause of death that was not attributable to a Defendant's jailer).

2. AS TO PATIENTS BROWN, KNIGHT, BARNES, BOYER AND SMITH.

Brown. There was insufficient proof as to Dr. McIver's other patients as well. The Government's own expert conceded that there was debate among physicians about whether to treat former drug addicts, such as Brown, with opioids. J. A. 629-6340. Of course, the Supreme Court addressed this matter directly in *Linder v. U.S.*, 268 U.S. 5, 45 S.Ct. 446 (1925) when it set aside as unconstitutional the conviction of a physician, who in good faith dispensed small quantities of morphine and cocaine to an addict for the relief of conditions incident to addiction. An early harbinger of *Gonzales v. Oregon*, *supra*, the constitutional cornerstone for the earlier *Linder* decision was that "Congress may not in the exercise of federal power exert authority wholly reserved to the states." Thus, the Court could not say that a physician "by so dispensing [prescriptions], the doctor [had] necessarily transcended the limits of that professional conduct with which Congress never intended to interfere." *Linder*, *supra*, at 22.

Knight. There was no more weighty evidence in the case of Knight. The prosecution relied upon its "red flags" to conclude that Angela Knight, who had real pain, J. A. 647, traveled to see Dr. McIver, rather than to change physicians, J. A. 646, and Dr. McIver had titrated doses of pain medications, J. A. 542, and there were repeated drug screens administered even after Knight had negative screens. But this was a less than compelling argument that Dr. McIver was outside "the course of professional practice."

Barnes. The prosecution relied upon an expert's judgment whether fibromyalgia should be treated with opioids in the case of Kyle Barnes but the government's expert conceded that some physicians do use opioids. J.A. 662-663. While Barnes did not always take her pills, there was no evidence that Dr. McIver knew anything about that, and thus this claim falls short as well.

Boyer and Smith. While Boyer and Smith said they used their medications for recreation, there was no evidence that that's why Dr. McIver prescribed them, or that he knew that's what they were doing.

3. AS TO THE CONSPIRACY COUNT – INSUFFICIENT EVIDENCE BUT A PARTICULARLY ILL-FOUNDED CHARGE SINCE THE UNDERLYING OFFENSE ITSELF REQUIRED CONCERTED ACTION, AND THE CONSPIRACY INSTRUCTION WAS IN ERROR.

The conspiracy charge is not supported factually, and it is fatally flawed as a legal matter.

It's a well-established principle of conspiracy law that, "if a crime necessarily involves the mutual cooperation of two persons, and if they have in fact committed the crime, they may not be convicted of a conspiracy to commit it." *U.S. v. Zeuli*, 137 F.2d 845 (2d Cir. 1943).

The Supreme Court had earlier approved this doctrine, *U.S. v. Katz*, 271 U.S. 354, 355, 46 S.Ct. 513 (1926); *Gebardi v. U.S.*, 287 U.S. 112, 122, 53 S.Ct. 35 (1932), and the Second Circuit declared it settled law in *Zeuli*.

The classic example of an offense requiring concerted action is the crime of bribery. *See U.S. v. Sager*, 49 F.2d 725 (2d Cir. 1931).

In *Sager*, a defense attorney was charged with bribing a juror in the case he was trying. The charges alleged "concert between several intended givers of a bribe and the intended taker of the same bribe." *Sager*, *supra*, at 727.

By the court's analysis of these charges, "this concert of givers and plurality of agents are necessary elements in the substantive offense of agreeing to receive a bribe and of agreeing to give one." *Id.*

Thus, "[w]here concert is necessary to an offense, conspiracy does not lie. There may not be a conspiracy founded on a crime to commit bribery between persons, one charged with the intended taking and several charged with giving the same bribe." *Id.*

Still another way to look at it, "A person cannot agree with himself, receive from himself, or give to himself." *Id.*

Similarly, in this case, the alleged distribution of a controlled substance necessarily involves the concerted action of at least "two" persons and, in the context of this case, that is, the physician and the patient.

A conspiracy may not be founded upon that "transaction" – if the physician and patient are the only ones involved.

And given the plain errors in the conspiracy jury instruction, there is no way the jury could have avoided this error.

In the jury instructions at the trial, the Court wrongly told the jury that the "conspiracy, agreement or understanding to distribute or dispense the controlled substance … was formed, reached or entered into by *two* or more persons" (emphasis supplied) J.A. 1286.

But "two" is too "few" when the underlying offense, that is, "distribution", already requires concerted action between at least "two" persons.

The Court repeated this error in its instructions, to wit, that the agreement may be inferred if "*two* or more persons acted in concert to achieve an illegal goal" (emphasis supplied). J.A. 1287.

The prosecutor then told the jury during his summation that Appellant McIver was "like the spoke on the wheel." J.A. 1170.

It is doubtful that the jury understood the reference but, in the 1947 Supreme Court case, *Kotteakos v. United States*, 328 U.S. 750, 755 (1947), the Supreme Court held that a jury "could not possibly have found, upon the evidence, that there was only one conspiracy" among multiple individuals engaged in housing loan fraud, where the charged conspiracy took the form of a wheel with spokes [as argued here] but no rim."

The *Kotteakos* court found that variance between the charged and proved conspiracies prejudiced the defendant. *See Id.* at 768- 772. It would appear that the prosecution conceded this variance in its closing argument to the jury.

Accordingly, there was insufficient evidence of any agreement by and between Dr. McIver and anyone else and the charges were insufficient as a matter of law given the misapprehension by court and counsel alike of what constituted conspiracy.

CONCLUSION AND REQUEST FOR ORAL ARGUMENT

Oral argument is respectfully requested because, the Supreme Court's recent decision in *Gonzales v. Oregon*, ___U.S. ___, 126 S.Ct. 904, 74 USLW 4068 (Jan. 17, 2006), sanctioning the Justice Department's regulatory departure from the strictures of the Controlled Substances Act ("CSA"), applies to this criminal prosecution, as the Justice Department relied on its own regulation, without authority to do so, rather than the criminal code (the CSA), and thus was the jury

wrongly instructed by the trial court; in addition, there are complex matters concerned with defects in the expert testimony that was permitted at trial, challenges to the sufficiency of the evidence, in particular, as to the conspiracy charge and the "death result" sentencing enhancement; thus we respectfully request that a three-judge panel of this Honorable Court agree to hear oral argument.

Respectfully Submitted,

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John P. Flannery II
Counsel for Appellant

CERTIFICATE OF COMPLIANCE WITH TYPEFACE AND LENGTH LIMITATIONS

1. This reply brief has been prepared using fourteen point, proportionally spaced serif typeface, more particularly MS Word Times New Roman, 14 point.

2. This Reply Brief contains 6,928 words exclusive of any corporate disclosure statement; table of contents, table of citations, statement with respect to oral argument; any addendum containing statutes, rules or regulations, certificate of compliance and the certificate of service.

_____

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CERTIFICATE OF FILING AND SERVICE OF BRIEF

I certify that Counsel Press filed the foregoing APPELLANT'S REPLY BRIEF on February 24th, 2006, pursuant to Local Rule 31(c) and (d) by delivering eight copies thereof to:

Clerk, United States Court of Appeals
For the Fourth Circuit
1100 East Main Street, Suite 501
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I further certify that Counsel Press served the foregoing APPELLANT'S REPLY BRIEF on February 24th, 2006, pursuant to Local Rule 31(c) and (d) by mailing or delivering two copies of the original brief to:

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