

No. 05-4474

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IN THE UNITED STATES COURT OF APPEALS  
FOR THE FOURTH CIRCUIT

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UNITED STATES,

*Plaintiff-Appellee,*

v.

WILLIAM ELIOT HURWITZ,

*Defendant-Appellant.*

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ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA

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**BRIEF OF AMICI CURIAE RUSSELL K. PORTENOY, RICHARD  
PAYNE, PEGGY COMPTON, CELESTE JOHNSTON, ROBERT  
TWILLMAN AND WILLIAM L. MARCUS**

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David T. Goldberg  
99 Hudson Street, 8th Floor  
New York, N.Y. 10013  
(212) 334-8813

Sean H. Donahue  
2000 L St., N.W. Suite 808  
Washington, D.C. 20036  
(202) 466-2234

September 2005

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## Statement of Interest\*

*Amici* are professionals who research and teach about pain and its treatment and care for individual patients suffering from acute and chronic pain.

Dr. Russell K. Portenoy is Chairman of the Department of Pain Medicine and Palliative Care, Beth Israel Medical Center and Professor of Neurology and Anesthesiology at the Albert Einstein College of Medicine. Dr. Portenoy is a past President of the American Pain Society (APS); serves as Secretary of the International Association for the Study of Pain; chairs the American Board of Hospice and Palliative Medicine, and holds leadership posts in numerous national pain management and research organizations. He is Editor-in-Chief of the *JOURNAL OF PAIN AND SYMPTOM MANAGEMENT* and is an editor of *PAIN*, the *JOURNAL OF SUPPORTIVE ONCOLOGY*, and *THE ONCOLOGIST*. Dr. Portenoy has written, co-authored or edited 17 books and more than 400 papers.

Dr. Richard Payne is Director of Duke University's Institute on Care at the End of Life. He has been Chief of the Pain and Symptom Management Section and Professor of Neurology at the University of Texas' MD Anderson Cancer Center, served as President of the American Pain Society, and served on the Institute of Medicine committee that issued the influential report *APPROACHING*

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\*All parties have consented to the filing of this brief. See Fed. R. App. P. 29(a).

DEATH: IMPROVING CARE AT THE END OF LIFE (National Academy Press 1997).

Dr. Payne serves on the editorial boards of THE JOURNAL OF PAIN and THE JOURNAL OF PAIN AND SYMPTOM MANAGEMENT, and has authored or co-authored more than 200 peer-reviewed papers, invited reviews, book chapters and abstracts.

Dr. Peggy Compton is an Associate Professor at the UCLA School of Nursing. Her research program explores pain and opioid addiction, including the pain responses of opioid-addicted individuals and opioid-induced hyperalgesia; detection of opiate abuse and addiction in chronic pain patients; opioid analgesia and reward responses; the pain experience of addicts; and the phenomenology of addiction in patients with pain. Her areas of clinical expertise include neuroscience, addiction and pain.

Dr. Celeste Johnston is James McGill Professor and Associate Director for Research at the McGill School of Nursing. She is a Consultant to the Nursing and Pain and Palliative Care Service of the Montreal Children's Hospital, and to the Nursing Department of the Royal Victoria Hospital (Montreal). Dr. Johnston's research interests include pain assessment and measurement of pain in infants.

Robert Twillman, Ph.D., is the Pain Management Program Director at the University of Kansas Hospital and a Clinical Associate Professor of Psychiatry and Behavioral Sciences at the University of Kansas School of Medicine. Dr.

Twillman was formerly the Director of Psychosocial Services at the University of Kansas Cancer Center and founder of the Center's Cancer Pain Management Service. He serves as Chair of the APS's Analgesic Regulatory Affairs Committee and as Immediate Past Chair of the Advisory Council of the American Alliance of Cancer Pain Initiatives. Dr. Twillman's academic interests embrace all aspects of pain management, with an emphasis on how public policy affects the availability of adequate pain management for patients.

William L. Marcus is former Deputy Attorney General of California and a past President of the National Association of State Controlled Substances Authorities, past President of the Council on Licensure, Enforcement and Regulation, and served as an official advisor to the National Conference of Commissions on Uniform State Laws, revision of model Controlled Substances Act. He is co-author of PHARMACY LAW FOR CALIFORNIA PHARMACISTS (5th ed. 2005), and currently teaches law and ethics at the School of Pharmacy of the University of California at San Diego.

*Amici* do not minimize the seriousness of drug abuse and addiction and harbor no sympathy for doctors who betray their core professional duties by participating in the drug trade. But we are also deeply concerned about the obstacles, including public and professional fear and misunderstanding, that

continue to prevent millions of individuals suffering from acute and chronic pain from receiving effective, medically appropriate treatment. We submit this brief out of concern that the seriously erroneous rules of law and scientific theories relied on to convict in this case will needlessly set back efforts to overcome those obstacles.

### **Summary of Argument**

The trial court in this case committed a series of discrete legal errors with a common tendency: to lower, to the point of insignificance, the prosecution's burden with respect to the state of mind of a physician charged under the Controlled Substances Act's ("CSA") drug trafficking prohibition, and to reduce to legal irrelevance evidence that the physician acted for benign, medical reasons. This reading of the Act is at odds with decades of precedent, which establish that Congress did not intend the CSA to criminalize physicians' good faith efforts to prescribe drugs to help their patients, and with fundamental principles of statutory construction and of criminal law.

The consequences of approving the decision below will ramify far beyond Dr. Hurwitz's case. The adverse effects of an unduly expansive reading of the CSA will not be borne primarily by *physicians* – who always remain able to avoid liability by taking a medically inappropriate, overcautious approach in treating patients with

chronic and acute pain (or by refusing to treat such patients altogether) – so much as by *patients*, who will be denied care that their physicians would, as a matter of professional judgment, otherwise provide. Worse still, this risk of deterring proper care arises in the context of what researchers have described as an “epidemic” of *undertreated* pain – a public health problem serious enough to have attracted the attention not only of medical professionals but of courts, legislatures, regulators, and even law enforcement authorities.

In addition to minimizing the distorting effect of federal law on medical practice, a decision of this Court enforcing the legislatively intended limitations on the CSA’s reach would uphold the historic role of the States as regulators of medical practice within their borders. For reasons of legal principle as well as of public health, disapproval of *bona fide* medical practices should be expressed through State-level sanctions, rather than federal criminal trials. Not only are State licensing authorities plainly better positioned than lay jurors to articulate the “bounds” of pain medicine (and less likely to chill appropriate treatment practices), but an expansive reading of federal criminal law would effectively nullify important recent efforts at the State level (including in Virginia) to encourage physicians to overcome their traditional reluctance and provide patients with proper palliative therapy.

Finally, even aside from the trial court’s untenable interpretation of the statute,

it would be manifestly unjust to let stand the conviction in this case – a widely publicized result that already may be chilling physicians’ willingness to take on hard-to-treat cases. If a physician is ever to be prosecuted or convicted under the CSA for providing treatment in good faith, on the grounds that the treatment exceeded some ostensibly “objective” outer “bound[] of medicine,” it becomes that much *more* important that the standard communicated to the jury be grounded in science. Not only did the trial court indefensibly exclude critical evidence supportive of Dr. Hurwitz on this point, but the prosecution’s case relied on “expert” testimony that so seriously misstated the relevant medical and scientific principles as to prompt six former presidents of the APS, including *amici* Drs. Portenoy and Payne, to submit an extraordinary letter of objection to the district court. See JA752.

I. FEDERAL CRIMINAL LIABILITY FOR WRONGFUL PRESCRIPTION OF CONTROLLED SUBSTANCES MUST BE LIMITED TO CASES IN WHICH THE DOCTOR ACTED FOR ILLEGITIMATE PURPOSES OR WITH KNOWLEDGE THAT HIS ACTIONS WERE UNAUTHORIZED

A. Basic Legal Principles Support Construing the CSA To Require Proof of Conscious Wrongdoing

Jurors in this case were told repeatedly that they could convict Dr. Hurwitz for prescriptions written in good faith for a legitimate medical purpose – *i.e.*, for patients he was in fact treating for chronic pain – if they determined that a given prescription exceeded the “bounds of medic[ine].” See, *e.g.*, J.A. 4752. Indeed, the trial court not

only refused to give the instruction given in *United States v. Tran Trong Cuong*, 18 F.3d 1132 (4th Cir. 1994), *i.e.*, that the jury ““must find [Dr. Hurwitz] not guilty”” if he acted with ““good intentions in the honest exercise of best professional judgment as to a patient’s need” and “in accordance with what he believed to be proper medical practice,”” *id.* at 1138, but the court did not even permit the defense to introduce *evidence* of Dr. Hurwitz’s good faith – ruling that such evidence was legally *irrelevant*. (Even without the benefit of much of Dr. Hurwitz’s strongest evidence on this point, the jury returned not guilty verdicts on the two counts in which jurors were told they *could* consider Dr. Hurwitz’s good faith). The court similarly interpreted the scienter requirement of Section 841(a) as only requiring proof that a physician was “aware” (JA4752) that the medication prescribed was federally controlled.

This construction of the statute – as authorizing the same punishment for a doctor who prescribes opioid analgesics for beneficent reasons, in the good faith belief that doing so is necessary to alleviate his patient’s pain, as for a drug pusher who diverts drugs to the illicit market for entirely malign reasons – is contrary to precedent and to fundamental principles of criminal law and statutory interpretation. Although Congress intended that doctors who functioned as “drug pushers” be prosecuted under § 841(a), see *United States v. Moore*, 423 U.S. 122, 141 n.19 (1975), it assuredly did not intend that physicians’ good-faith errors in professional

judgment would be treated as the moral or legal equivalent of drug dealing.

On the contrary, because of the fundamental difference between physicians, who have an ethical *responsibility* to dispense controlled substances to patients with legitimate medical needs, and drug dealers, whose actions are self-evidently wrongful, courts have emphasized that prosecutions of physicians under § 841(a) (and predecessor provisions) should be reserved for instances where the defendant acted for an illicit purpose or *knowingly* violated his statutory “[]authoriz[ation],” 21 U.S.C. 841(a).

Thus, courts have long ruled that a doctor’s good faith therapeutic purposes preclude conviction. *Tran Trong Cuong* is but one recent example. Decades ago, the Supreme Court indicated that a physician could not be convicted under the predecessor of the CSA provision if he “believed in good faith” that the narcotic prescription at issue was “for the purpose of relieving [his patient’s] pain,” *Linder v. United States*, 268 U.S. 5, 16 (1925). One year later, the Court sustained a conviction of a doctor only because the jury had been told that “if [the prescriptions at issue] were issued in good faith, ‘for the purpose of curing disease or relieving suffering,’ he should be acquitted,” *Boyd v. United States*, 271 U.S. 104, 108 (1926). See

*Moore*, 423 U.S. at 134-35 (noting that CSA tracks its predecessors in this regard).<sup>1</sup> And this Court has explained, “the question \* \* \* in any case where a pharmacist is charged with illegal distribution of controlled substances, is *whether he knew* that the purported prescription was not issued for a legitimate medical purpose or in the usual course of medical practice.” *United States v. Lawson*, 682 F.2d 480, 482-83 (4th Cir. 1982) (emphasis added); accord *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995) (affirming conviction because evidence supported finding that defendant ““did not act in good faith in the honest exercise of his best professional judgment as to these patients’ needs””); *Dunford v. United States*, 216 F.2d 184 (4th Cir. 1954) (“The only real question in the case was whether the appellant, in giving prescriptions to the government agents, was acting in good faith in the proper practice of his profession or was intending to aid drug addicts to obtain narcotic drugs unlawfully”).<sup>2</sup>

In stark contrast, the district court here did not inform the jury that it had to make *any* finding concerning Dr. Hurwitz’s mental state with respect to the medical

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<sup>1</sup> The theory of the prosecution in *Moore* was that the doctor was acting for profit, *i.e.*, without a legitimate medical purpose.

<sup>2</sup> As noted, the instruction given in *Tran* clearly required the jury to find bad faith on the part of the defendant physician. Although the Court in *Tran* did not have occasion to decide whether such an instruction is required under the CSA, it did observe that the “Controlled Substances Act \* \* \* requires that [defendant] act with *specific intent*,” 18 F.3d at 1144 (emphasis added), a characterization quite incompatible with the jury instructions here.

appropriateness of the prescriptions he issued. The *only* mental element required was that Dr. Hurwitz was required to have known the nature of the drugs he prescribed. But what makes it criminal for a physician to prescribe drugs is not the physician's knowledge that the substance at issue is controlled. Indeed, prescribing controlled substances is a pivotal, socially useful function of doctors, and a doctor who did *not* know what he is prescribing should be deemed more culpable, rather than less. Rather, the essence of the offense under the CSA is that the drugs are being dispensed not to treat patients' health problems, but for improper ends.

The instructions given in this case, however, required no showing that Dr. Hurwitz possessed any culpable mental state – even negligence – regarding the central element that separates an ordinary, socially desirable medical practice from a federal felony.<sup>3</sup> But it is not enough to prove a defendant had “knowledge only of traditionally lawful conduct,” *Staples v. United States*, 511 U.S. 600, 618 (1994);

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<sup>3</sup> The trial court, apparently uncomfortable with eliminating *mens rea* altogether, instructed the jury that mere “negligence” was not enough, JA4908, but the implication – that some level of intent *between* negligence and “knowledge” (*e.g.*, “gross negligence”) would suffice – is contrary to the statute's text, and the judge's definition of the elements of the offense gave jurors no way to give effect to uncertainty regarding Dr. Hurwitz's mental state. Likewise, the district court's explanation that “knowledge” could be inferred from a “combination of suspicion and indifference to the truth,” JA4907, JA4929, could only have perplexed a jury instructed that the only requisite “knowledge” was Dr. Hurwitz's awareness that the opioids he prescribed were controlled substances.

rather, statutes must be construed to require the prosecution to prove a defendant “kn[ew] the facts that make his conduct illegal,” *id.* (emphasis added); *United States v. X-Citement Video, Inc.*, 513 U.S. 64, 72 (1994) (the “presumption in favor of a scienter requirement should apply to each of the statutory elements that criminalize otherwise innocent conduct”). This rule of construction serves to “limit[] criminality to \* \* \* those with the level of ‘culpability \* \* \* usually require[d] in order to impose criminal liability,’” *Arthur Andersen LLP v. United States*, 125 S. Ct. 2129, 2136 (2005) (citation omitted); see *id.* (reversing because jury instruction allowed conviction of defendant accounting firm “even if [it] honestly and sincerely believed that its conduct was lawful”), and requires reversal here. Far from being a “‘jurisdictional fact’ that enhances an offense otherwise committed with an evil intent,” *X-Citement Video*, 513 U.S. at 73 n.3 (citation omitted), improper purpose is the *sine qua non* of the Section 841 offense of distribution of unlawful drugs by registered physicians.<sup>4</sup>

The court below treated proof that a physician exceeded the “bounds of medicine” as a freestanding, alternative basis for criminal liability – accepting the

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<sup>4</sup> Because the crucial “illegitimate-purpose” finding separates socially harmful drug dealing from socially beneficial medical practice, the case for requiring proof of scienter with respect to the “unauthorized” nature of the defendant’s actions is even stronger here than in *Liparota v. United States*, 471 U.S. 419, 426 (1985).

prosecutors’ argument that a physician may be equated to a drug trafficker *either* if he dispenses drugs for personal financial gain (or some other illegitimate purpose) *or* if his care fall outside some ostensibly objective standard of medical practice. Although testimony concerning generally accepted practice involving controlled substances should be relevant and admissible (on an even-handed basis, see *infra*), as circumstantial *evidence* that the physician *knew* his actions were unauthorized – the text and structure of the statute do not suggest that such proof may *substitute* for proof of *mens rea*, and, as the proceedings below well illustrate, this construction is fraught with peril. Holding that honestly-intended but seriously wrong medical practice could suffice to place a physician on the same footing as a drug trafficker invites a “battle of the experts” akin to those common in civil malpractice cases – but with lay jurors deciding whether to deprive a physician of his *liberty* based on which expert it found most impressive.<sup>5</sup>

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<sup>5</sup>As explained below in Part II, reversal would be required *even if* the CSA could bear the construction imposed. But given the grave public interest at stake, the Court should make clear here and now that Congress *did not* intend to dispense with a meaningful *mens rea* requirement. The unpublished opinion in *Hitzig v. United States*, 63 Fed.Appx 83 (4th Cir. 2003), is not to the contrary, since the instructions in that case required that defendant act “willfully” and with a “bad purpose to disobey or disregard the law,” *id.* at 86 & n.4, and did not question this Court’s prior decision in *Lawson*, 682 F.2d at 482-83. Although the “bounds” language first appeared in *Moore*, it was not part of the *jury instruction* in that case – which included a direction that “honest effort” would have precluded conviction, 423 U.S. at 142 n.20. Instead the Court used the term to *describe* the actions of a physician, who had presented a

B. Endorsing The Standard Adopted Below Would Interfere With Pain Sufferers' Already Inadequate Access To Necessary and Lawful Medical Treatment.

The requirement that prosecutors prove a defendant's culpable state of mind is fundamental; as Justice Jackson observed, the principle "that an injury can amount to a crime only when inflicted by intention" is "universal and persistent in mature systems of law," *United States v. Morrissette*, 342 U.S. 246, 250 (1952). But the traditional "restraint" courts have exercised "in assessing the reach" of criminal prohibitions, *Andersen*, 125 S. Ct. at 2130, has special force in applying CSA provisions to physicians' prescribing practices. The conduct on the lawful side of the statutory line is not merely "innocent" – like the routine destruction of documents in *Andersen* – but beneficent: the prescription of medication for the purpose of alleviating patients' suffering, *cf. X-Citement Video*, 513 U.S. at 84-85 (Scalia, J., dissenting) (emphasizing low social value of conduct "chilled"). The adverse consequences of an unduly expansive reading will be borne most heavily by those undeniably innocent and deserving individuals. See *Washington v. Glucksberg*, 521 U.S. 702, 747 (1997) (Stevens, J., concurring) ("Encouraging the development and ensuring the availability of adequate pain treatment is of utmost importance").

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defense that he *was* prescribing for a legitimate purpose – which the jury was permitted to hear, but "did not believe," *id.* at 122.

1. Under-Treatment of Pain is A Grave Public Health Problem.

Enforcing the congressionally-enacted limitations on the CSA's reach is especially imperative in light of evidence establishing (1) the relative benefits and risks of the class of drugs – opioid pain relievers – that Dr. Hurwitz was convicted for prescribing and (2) the extent to which under-treatment of patients with chronic malignant pain is *already* a public health problem of great magnitude.

Under-treatment of pain is such a serious and wide-spread health problem that it has been aptly called an “epidemic.”<sup>6</sup> Over the past two decades, research has established that a disturbingly large percentage of the millions of Americans suffering from acute and/or chronic pain receive inadequate treatment for their pain or no treatment at all. One recent study, for example, demonstrated that 41.2 percent of the 2.2 million residents of U.S. nursing homes have “persistent pain,” see Teno, *et al.*, *Persistent Pain in Nursing Home Residents*, 285 JAMA 2081 (2001), while a 1993 survey of physicians found that 86 percent believed that the majority of patients with cancer pain were undermedicated (with only 51 percent answering that pain control *in their own practice setting* was “good” or “very good”), Von Roenn, *et al.*, *Physician*

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<sup>6</sup>See Examining the Effects of the Painkiller OxyContin, Hearing Before the Senate Comm. on Health, Education, Labor and Pensions, 107th Cong., 2d Sess. 33 (2002) [hereinafter “Senate Hearing”] (testimony of H. Westley Clark, MD).

*Attitudes and Practices in Cancer Pain Management*, 119 ANNALS INTERNAL MED. 121 (1993). See Martino, *In Search of a New Ethic for Treating Patients with Chronic Pain: What Can Medical Boards Do?*, 26 J.L. MED. & ETHICS 332, 333 (1998).

This state of affairs is *not* the result of any lack of effective drug therapies: modern medicine now has the ability to relieve or reduce suffering caused by nearly all types of pain.<sup>7</sup> Indeed, concerted efforts to improve palliative care for those at the end of life have helped to highlight the effectiveness of opioid drugs in relieving pain in a broader class of patients.<sup>8</sup>

Nor is pervasive undertreatment reflective of any clinical consensus that these pain relief benefits are outweighed by some countervailing danger. On the contrary, evidence establishes that the risk of drug addiction (historically, the principal *medical* justification for withholding or limiting opioids) is far *less* substantial than long and

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<sup>7</sup> See NATIONAL ACADEMY OF SCIENCES, INSTITUTE OF MEDICINE, COMMITTEE ON CARE AT THE END OF LIFE, *APPROACHING DEATH: IMPROVING CARE AT THE END OF LIFE* 132 (1997) [“APPROACHING DEATH”].

<sup>8</sup> It remained common practice at least into the mid-1980s to deny opioids even to patients facing imminent death and excruciating cancer pain. See James, *Painless Human Right: Treatment of Cancer Pain in Developing Countries*, 342 LANCET 567 (1993); Portenoy & Payne, *Acute and Chronic Pain*, in SUBSTANCE ABUSE, A COMPREHENSIVE TEXTBOOK 563, 567 (J. Lowinson, *et al.*, eds., 1997).

widely assumed.<sup>9</sup> The Institute of Medicine found that “addiction in patients appropriately receiving opioids for pain is very small, ranging from 1 in 1,000 to less than 1 in 10,000,” APPROACHING DEATH at 193, *i.e.*, rates comparable to those in American society as a whole. See Portenoy & Payne, *supra*, at 581; cf. Brown, *et al.*, *Substance Abuse Among Patients with Chronic Back Pain*, 43 J. FAM. PRAC. 152 (1996); Porter & Hick, *Correspondence: Addiction Rare in Patients Treated with Narcotics*, 302 NEW ENG. J. MED. 123 (1980).

People in pain respond differently to opioids than do persons who use the same drugs nontherapeutically. In contrast to recreational drug users, pain patients who use opioids rarely experience euphoria, see, *e.g.*, Portenoy & Payne at 581; and once the source of pain is removed, many are able to voluntarily decrease or discontinue their use of opioids. *Id.* at 564; APPROACHING DEATH at 193.

Much of the concern about patients’ becoming “addicted” reflects widespread failure to appreciate the distinction between, on the one hand, (1) *tolerance* – the body’s tendency to become accustomed to a substance so that, over time, a larger

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<sup>9</sup> Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Clinicians’ Perspective*, 24 J.L., Med., & Ethics 296, 296 (1996); see also Portenoy & Payne, *supra*, at 581; Morgan, *American Opiophobia: Customary Underutilization of Opioid Analgesics*, in CONTROVERSIES IN ALCOHOLISM AND SUBSTANCE ABUSE 171 (Stimmel, ed. 1986); Davidson, *Pain and Opiophobia*, 40 HEALTHCARE FORUM J. 64 (May/June 1997).

amount is needed to produce the same physical effect (pain relief) and *physical dependence* – the state defined by the experience of adverse symptoms if a drug is abruptly withdrawn, *id.* at 564 – each of which is common with pain patients – and, on the other, (2) the psychological and behavioral patterns – an unhealthy craving for, compulsive use of, and unhealthy fixation – that characterize *addiction*. See Portenoy & Savage, *Clinical Realities and Economic Considerations: Special Therapeutic Issues in Intrathecal Therapy – Tolerance and Addiction*, 14 J. PAIN & SYMPTOM MGM'T S27, S34 (1997) (confusing tolerance, dependence, and addiction leads “many clinicians \* \* \* to reject opioid therapy in patients for whom it is clearly appropriate”); see also Foley, *The Treatment of Cancer Pain*, 313 NEW ENG. J. MED. 84, 88 (1985).<sup>10</sup>

Chronic and acute pain is a serious, potentially debilitating health problem that requires treatment -- whether it is caused by cancer, other diseases, traumatic injury,

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<sup>10</sup> Just as it is possible to have addictive behavior (*e.g.*, gambling) that does not involve any physical dependence, neither tolerance nor physical dependence necessarily leads to addiction. Indeed, the fact that pain patients sometimes exhibit behavior that is *misinterpreted* as addictive underscores the need for attention to the distinction between dependency and addiction. Drug Enforcement Administration guidance for pharmacists acknowledges that “drug tolerance and physical dependence may develop as a consequence of the patient’s sustained use of opioid analgesics for the legitimate treatment of chronic pain,” and adds that “[i]t is also important to understand that the quantity of drugs prescribed and the frequency of prescriptions filled alone are no indicators of fraud or improper prescribing.” *Pharmacists’ Manual: An Information Outline of the Controlled Substances Act of 1970* 55 (April 2004), available at ([http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/2pharm\\_manual.pdf](http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/2pharm_manual.pdf)).

burns, or other causes. See Johnson, *Disciplinary Actions and Pain Relief: Analysis of the Pain Relief Act*, 24 J. L. MED. & ETHICS 319, 324 (1996) (“Pain does not discriminate”); Portenoy, *Chronic Nonmalignant Pain*, 24 J. L. MED. & ETHICS at 296; Gilson & Joranson, *Controlled Substances and Pain Management: Changes in Knowledge and Attitudes of State Medical Regulators*, 21 J. PAIN & SYMPTOM MGMT 227 (2001). Moreover, “for many patients opioid analgesics \* \* \* are the most effective way to treat pain of moderate to severe intensity and often the only treatment that provides significant relief.” Senate Hearing at 41 (Statement of *amicus* Richard Payne).

## 2. Many Physicians Remain Reluctant To Provide Appropriate Pain Care

The primary explanation for this widespread undertreatment of pain is reluctance on the part of many physicians to prescribe the analgesic medicines available to them. This reticence is in considerable part a product of a professional culture and system of training that long placed disease-fighting – but not the alleviation of pain – at the center of the physician’s mandate and that failed to educate doctors about the actual benefits (and risks) of available pain therapies. See, *e.g.*, APPROACHING DEATH at 207 (noting link between curricular “[d]eficiencies \* \* \* [and] a medical culture that defines death as failure and ignores care for dying people as a source of professional accomplishment and personal meaning”); Ziegler & Lovrich,

*Pain Relief, Prescription Drugs, and Prosecution: A Four-State Survey of Chief Prosecutors*, 31 J. L. MED. & ETHICS 75 (2003).

But these lingering misconceptions are not the only reason for the continuing failure to treat chronic pain adequately. A substantial and consistent body of research establishes that many physicians' practices are significantly influenced by fear that prescribing opioids will invite regulatory and law enforcement scrutiny.<sup>11</sup> “[P]hysicians are particularly easily deterred by the threat of governmental investigation and/or sanction from engaging in conduct that is entirely lawful and medically appropriate \* \* \* \* A physician’s career can be effectively destroyed merely by the fact that a governmental body has investigated his or her practice.” *Conant v. Walters*, 309 F.3d 629, 640 n.2 (9th Cir. 2002) (Kozinski, J., concurring) (quoting with approval expert report of Alice Pacetta Mead); see also *Hoover v. Health Care Admin. Ag’y*, 676 So. 2d 1380, 1381 n.4 (Fla. App. 1996) (“Many physicians avoid caring for patients who require Schedule II substances to relieve their suffering”).

If approved, the standards of criminal law reflected in the district court’s

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<sup>11</sup>See Portenoy, *Chronic Nonmalignant Pain* at 204; Johnson, *supra*, at 319-27; Gilson & Joranson, *supra*, at 228; Reynolds, *Morphine or Malpractice*, 15 ST. JOHN’S J. LEGAL COMMENT. 79, 83 (2000); Haddox & Aronoff, *The Potential for Unintended Consequences from Public Policy Shifts in the Treatment of Pain*, 26 J. L. MED. & ETHICS 350, 351 (1998); Shapiro, *Health Care Providers’ Liability Exposure for Inappropriate Pain Management*, 24 J. L. MED. & ETHICS 360, 363 (1996).

decision would severely exacerbate these problems. Given the large numbers of physicians who *already* refrain from prescribing opioids for needy patients out of fear of a reputation-shattering federal investigation, it is hard to imagine a standard that would discourage appropriate treatment more than the one embraced by the district court – whereby a doctor may be convicted of serious federal crimes carrying long sentences based on prescriptions issued in good faith for therapeutic purposes – as long as the government and its expert are able to persuade a lay jury that the doctor overstepped some “bound[] of medicine.”

C. Reading the CSA to Lack any Scientist Requirement as to the Medical Legitimacy of the Physician’s Actions Would Unnecessarily Upset The State-Federal Balance.

In addition to its potential to impair patients’ access to appropriate care, the district court’s construction of the CSA would unsettle the traditional – and beneficial – balance of authority between the federal government and the States.

The Supreme Court has repeatedly emphasized that regulation of the practice of medicine – including the formulation of appropriate standards of conduct and the policing of violations of those standards – is primarily a matter for the States. See *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 386 (2002); *Pegram v. Herdrich*, 530 U.S. 211, 237 (2000); *Linder*, 268 U.S. at 18. Both the text of the statute and general rules of construction confirm that Congress did not intend for the CSA to

repudiate this traditional allocation of responsibility. See, e.g., 21 U.S.C. 903 (disclaiming broad preemptive effect); *id.* § 802(21) (defining ““practitioner”” with reference to licensing rules of “the jurisdiction in which [physician] practices”). Rather, the statute reflects a division of authority by which the federal government is empowered to punish “drug dealing” (whether by street criminals or physicians), while the States retain control over defining and enforcing the standards governing, among other things, when it is appropriate for physicians to prescribe specific drugs to specific patients. Thus, while the CSA requires that Schedule II drugs ordinarily be issued by written prescription, *id.* § 829, neither that provision nor any other purports to define the medical standards that determine when prescription of those drugs is permissible.<sup>12</sup>

The benefits of this traditional allocation of power are not abstract or theoretical, and the costs of subverting it are especially serious in this setting. Reading federal statutes with respect for States’ traditional roles preserves their capacity to serve as “laboratories” on matters involving sensitive and difficult policy judgments,

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<sup>12</sup>In 1998 the DEA reaffirmed that it would not address either the selection or quantities of drugs prescribed by a doctor, as those were “medical decisions [that] arise from the prescribing physician’s medical judgment.” *The Drug Enforcement Administration and Proposed Model Guidelines for the Use of Controlled Substances in Pain Management* at 2 (1998) (<http://medsch.wisc.edu/painpolicy/domestic/dea98.htm>).

see *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting); *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991); *Washington v. Glucksberg*, 521 U.S. 702 at 737 (O'Connor, J., concurring), and State authorities have, in fact, taken a leading role in addressing pain undertreatment.

In response to the evidence described above concerning the benefits of – and barriers to – opioid therapy, many States, including Virginia, have adopted laws and policies intended to encourage physicians to provide effective treatment to patients suffering from acute and chronic pain by taking steps to lessen the fear of regulatory sanctions while, at the same time, endeavoring to minimize abuse by developing practice standards, enforceable through disciplinary proceedings.<sup>13</sup>

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<sup>13</sup>Virginia took a national leadership role in favor of high-dose opioid therapy for chronic pain treatment. In 1997, the Medical Society of Virginia issued its Guidelines for the Use of Opioids in the Management of Chronic, Non-Cancer Pain – a document “reported to be the first of its kind in the United States,” that “clarifies a mechanism by which physicians can more comfortably, safely, and intelligently prescribe proper analgesics to the unfortunate and underserved population of chronic pain patients with less fear of regulatory repercussion.” Long, *Pain – the Public, the Politics, the Perception: The Virginia Experience, Part 2*, 8 American Pain Soc. Bulletin No. 4 (1998) (available at <http://www.ampainsoc.org/pub/bulletin/jul98/policy.htm>). In 1998, those guidelines were approved by a joint resolution of the General Assembly, Sen. 1. Res. No. 165, and endorsed by the Board of Medicine pursuant to a new statute, Va. Code § 54.1-2912.2. Virginia’s Guidelines were followed closely by the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*, adopted by the National Federation of State Medical Boards in 1998. See Gilson, Joranson & Maurer, *Improving State Medical Policies: Influence of a Model*, 31 J. L. MED. & ETHICS 119 (2003) (discussing state reforms). Dr. Hurwitz was instrumental in Virginia’s policy shift.

The approach taken by the court below would effectively drain these important State initiatives of their practical significance. If a doctor's *bona fide* belief that his or her actions conform to professional standards is rendered irrelevant to federal criminal prosecution, physicians will surely be deterred from taking actions that *State* regulators have determined to represent proper patient care.<sup>14</sup> Responsibilities traditionally vested in State legislators and medical regulators will be reassigned instead to lay jurors forced to confront a "battle of the experts." Such a shift is especially undesirable in the field of pain management, where misunderstanding (both lay and professional) and undertreatment have long prevailed. Professional controversies and disagreements remain that should be resolved in state legislatures and state medical regulatory boards, not federal criminal proceedings.<sup>15</sup>

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<sup>14</sup> Relying on its theory that Dr. Hurwitz's good faith was irrelevant to his liability, the court refused to admit evidence that tended to show that he in fact had acted in good faith, including the Virginia Medical Board's finding that, while Dr. Hurwitz had engaged in substandard prescribing practices, he nonetheless "believed he was practicing medicine in good faith, and for recognized and accepted medical purposes," JA281 – even as the court *admitted* evidence from earlier Board proceedings when the prosecution sought to establish the very fact the court deemed irrelevant when raised in Dr. Hurwitz's defense.

<sup>15</sup> State medical regulators are generally better equipped than jurors to determine whether a physicians' conduct reflects more than a reasonable (albeit controversial) application of accepted principles and are less likely to be swayed by the distortions that can occur in professional disputes about proper practice, see *infra*.

II. THE EVIDENCE HEARD BY (AND KEPT FROM) THE JURY DOES NOT REPRESENT THE ACTUAL “BOUNDS OF MEDICINE” IN THIS FIELD AND AGGRAVATES THE SERIOUS PRACTICAL CONSEQUENCES OF PERMITTING THE CONVICTION TO STAND

As explained above, the district court’s minimalist conception of the CSA scienter requirement – and outright exclusion of key evidence of Dr. Hurwitz’s good faith – are errors sufficient to require reversal of his conviction. But the district court’s *application* of the standard it embraced was also deeply troubling and could further deepen physicians’ reluctance to rely on their best medical judgment in treating patients in pain.

In addition to its incorrect (and one-sided) rulings concerning the evidence of good faith, the district court inexplicably excluded evidence directly relevant to what the “bounds of medicine” encompass as to opioid therapy. Most important, the court excluded, *on relevance grounds*, a 48-page publication jointly issued (though later withdrawn) by the federal DEA and leading pain researchers, entitled “Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals, and Law Enforcement Personnel” (JA318-65). This “FAQ” directly supported Dr. Hurwitz’s defense on numerous points, including establishing that there

is no categorical prohibition against prescribing opioids to persons with substance abuse problems who also suffer from acute or chronic pain, JA358.

The prosecution's argument for excluding this evidence – that it was “irrelevant” because the document's release post-dated the prescriptions at issue – while accepted by the district court, strikes *Amici* as seriously misguided. As a factual matter, the FAQ did not purport to represent a statement of the very latest data, but rather a distillation of sound practices developed over time – precisely the sort of evidence a “bounds of medicine” standard would seem to contemplate. But even if the document were more time-specific, the suggestion that a doctor could be sentenced to decades in prison for issuing prescriptions that conform to a medical standard prevailing *at the time of trial*, on the (hypothetical) ground that the practice had not quite attained full acceptance at the time of the charged acts, is yet another feature of this case that chills conscientious practitioners.

Compounding matters further, Dr. Hurwitz's conviction was obtained through “expert” testimony that fell short of the standards of scientific reliability that are a precondition for admitting such evidence in federal court. *See* Fed. R. Evid. 702; *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593-97 (1993). The primary evidence supporting the prosecution's claim that Dr. Hurwitz had gone beyond the “bounds of medicine” was from Dr. Michael Ashburn. Although Dr.

Ashburn's qualifications were unassailable, his testimony on key points so seriously departed from accepted standards in the field that they should not have received into evidence.

First, Dr. Ashburn testified, in direct conflict with the United States government's own official position, JA358, that prescribing drugs to a pain patient with an ongoing drug addiction problem is categorically impermissible. He also told the jury that, in a prosecution where many of the charges involved claims that the quantities of opioids prescribed by Dr. Hurwitz were criminally high, "[t]he literature would define high-dose therapy as doses that are in the neighborhood of 195 mg a day or equivalent of morphine," and that there was "virtually no data in the medical literature to support the use of high-dose opioids" for patients with serious non-cancer pain. JA2456. These latter assertions were seized upon by the prosecution, which, in closing argument (JA4766), took the position that a dosage over 195 milligrams of morphine per day was per se beyond the "bounds of medicine:"

You also heard Dr. Ashburn's testimony about high dosages. Dr. Ashburn said that prescriptions over 195 milligrams, 195 milligrams, haven't been shown to be safe and effective.

I am going to repeat that. There is no safe and effective study that shows that high dosage opioids over 195 milligrams is safe, proper.

As six former Presidents of the APS – including *amici* Portenoy and Payne –

explained in a letter to the district court, these assertions do not present even an arguable view of the relevant medical science. On the contrary, it is universally recognized that there is no one maximum dosage for opioids; that there is enormous patient-to-patient variation; and that 195 mg per day is nowhere near the high end of the ordinary range – let alone approaching the outer bounds of accepted practice. A text co-edited by Dr. Ashburn confirms that “there is no predetermined maximum dose of an opioid.” ASHBURN & RICE, *THE MANAGEMENT OF PAIN* 132 (1998), and the Oxford Textbook of Palliative Medicine (Doyle, *et al.* eds. 1993) explains that legitimate dosages “may range from 2.5 mg. 4-hourly to 2500 mg. 4-hourly,” noting “anecdotal reports of much higher [therapeutic] doses.” *id.* at 169. This is more than *sixty times* greater than the amount deemed by the prosecution to be sufficient to render a prescription criminal, and the prescribing doctor, a “drug dealer.” See also DEA PHARMACISTS’ MANUAL at 55 (“the quantity of drugs prescribed and the frequency of prescriptions filled alone are no indicators of fraud or improper prescribing”).

Indeed, the prosecution expert’s statements – while surely intuitively appealing to lay jurors grasping for an objective standard – are contrary to the basic medical understanding of how opioids work, namely, that, because of differences in individual physiology and the “tolerance” effect, the dose required to treat one person’s pain can

be dramatically greater than that needed to treat another's. See OXFORD TEXTBOOK at 169 (noting that opioids are unique in that a "dose range of a thousand-fold or more [can] achieve the same end-point"); ASHBURN & RICE at 132 ("doses of opioids should be escalated until pain relief occurs or side effects intervene").<sup>16</sup>

Although we recognize that the defense did not move to preclude the jury's consideration of these "stunning" and unscientific assertions, JA752, it is manifestly unjust to allow a conviction obtained through such testimony.<sup>17</sup> In view of the district court's emphatic rulings that proof of conscious wrongdoing was not required (and its refusal even to entertain evidence of good faith), it was imperative that the district court ensure that the prosecution's expert testimony on the "objective" medical standard was accurate. Scientifically unsupported opinion – harmful enough if

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<sup>16</sup>Unlike most other prescription drugs, the commonly used opioid medications have no known toxic effect on major organs systems at any dosage.

<sup>17</sup>Although erroneous admission of expert testimony that was not objected to at trial is subject to the same standard of review in criminal as in civil cases, *i.e.*, for "plain error," see Fed. R. Evid. 103(d); *United States v. Diaz*, 300 F.3d 66, 73, 76 (1st Cir. 2002); *Macsenti v. Becker*, 237 F.3d 1223, 1232 (10th Cir. 2001), courts applying that standard should take into account the different standards of proof; the uniquely onerous consequences of a conviction obtained through unreliable testimony, see *Daubert*, 509 U.S. at 596 (referencing standard for directed verdict in civil cases); cf. *Napue v. Illinois*, 360 U.S. 264, 269 (1959), and procedural differences between civil litigation (in which expert witnesses must submit reports and subject themselves to deposition) and criminal cases, where objectionable "expert" opinions may be heard for the first time at trial.

presented only as one expert's view – is especially likely to mislead the jury where, as here, it is presented as if it represented a consensus of experts in the field.

### **CONCLUSION**

The judgment of the district court should be reversed.

Respectfully submitted,

David T. Goldberg  
99 Hudson Street, 8th Floor  
New York, N.Y. 10013  
(212) 334-8813

Sean H. Donahue  
2000 L St., N.W. Suite 808  
Washington, D.C. 20036  
(202) 277-7085

September 2005

## CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a) I hereby certify that the foregoing brief is printed in a proportionately spaced, 14-point type, and that according to the word-count function in Wordperfect, it contains 6,971 words.

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Sean H. Donahue

## CERTIFICATE OF SERVICE

I hereby certify that on this 9<sup>th</sup> day of September, 2005, I served copies of the foregoing brief upon the following attorneys, by first-class United States Mail, postage prepaid:

Eugene Rossi  
Assistant United States Attorney  
2100 Jamieson Avenue  
Alexandria, VA 22314

Donald J. Russell  
Robbins, Russell, Englert, Orseck &  
Untereiner LLP  
1801 K Street, N.W., Suite 411  
Washington, D.C. 20006

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Sean H. Donahue  
2000 L St., NW Suite 808  
Washington, D.C. 20036