

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF OREGON

STATE OF OREGON,

Plaintiff,

and

RICHARD HOLMES, KARL STANSELL,
JANE DOE #1, and JAMES ROMNEY, on
behalf of themselves and others similarly
situated,

Plaintiff-Intervenors,

PETER A. RASMUSSEN, M.D. and DAVID
MALCOM HOCHHALTER, Ph.D.,

Plaintiff-Intervenors,

v.

JOHN ASHCROFT, in his official capacity as
United States Attorney General, *et al.*,

Defendants.

Case No. CV 01-1647-J0

EXCERPT FROM:

BRIEF OF AMICI CURIAE AMERICAN
ACADEMY OF PAIN MANAGEMENT,
CALIFORNIA MEDICAL ASSOCIATION,
AMERICAN GERIATRICS SOCIETY,
SAN FRANCISCO MEDICAL SOCIETY,
THE SOCIETY OF GENERAL
INTERNAL MEDICINE AND A
COALITION OF DISTINGUISHED PAIN
AND PALLIATIVE CARE
PROFESSIONALS IN SUPPORT OF
PLAINTIFF

V. **THE ASHCROFT DIRECTIVE WILL INTERFERE WITH PHYSICIANS' PAIN
MANAGEMENT DECISIONS**

As demonstrated above, the Directive will adversely impact the democratic development of public policy in this difficult arena. Equally important is its effect on the practice of medicine today. The Directive's edict will inevitably interfere with doctors' abilities to care effectively for their terminally ill patients. The intrusion of an ill-equipped DEA into the oversight of physicians' decision-making already has created—and will continue to create—fear among physicians who treat terminally ill patients. Moreover, the potential scope of the Directive, if upheld, will make it impossible for physicians to determine whether or not their conduct runs afoul of the law. Several features of the Directive are especially alarming in this regard.

First, as discussed above, by asserting that he has the power to define the term

"legitimate medical purpose" the Attorney General seeks to both vastly expand the CSA's
Page 20 - BRIEF OF AMICI CURIAE AMERICAN ACADEMY OF PAIN MANAGEMENT,
CALIFORNIA MEDICAL ASSOCIATION, AMERICAN GERIATRICS SOCIETY, SAN FRANCISCO
MEDICAL SOCIETY, SOCIETY OF GENERAL INTERNAL MEDICINE AND A COALITION OF
DISTINGUISHED PAIN AND PALLIATIVE CARE PROFESSIONALS IN SUPPORT OF PLAINTIFF

jurisdiction over the practice of medicine and convert the basis of physician liability. As argued above, it is one thing to make a determination that an individual is not practicing medicine in good faith. It is quite another to determine what constitutes the practice of medicine. And it is yet another leap to the Attorney General's assertion that he can determine the legitimacy—and consequently the liability—for physician conduct without considering whether that conduct is consistent with professional practice. The notion that the Attorney General and the DEA are now empowered to determine the “legitimacy” of a particular medical practice is itself sufficient to cause alarm among physicians.

This unprecedented effort to rewrite the CSA is improper and places physicians and medical professionals in a quandary. While the DEA has prosecuted those professionals who stepped over the line of legitimate treatment, until now it has not asserted that it, and it alone, can determine that otherwise appropriate and state sanctioned treatment of patients can result in criminal liability.³² Doctors will be faced with a short menu of unpalatable choices: undermedicate to avoid second-guessing by the DEA, thus harming their patients; medicating pursuant to full disclosure and risking second-guessing and possible criminal prosecution; or medicating and lying, thus once again risking prosecution. Nothing in the CSA itself demands

³² *United States v. Oakland Cannabis Buyers' Co-op.*, 532 U.S. 483, 121 S.Ct. 1711 (2001) is not to the contrary. There, the Supreme Court rejected a marijuana distributor's contention that the CSA should be read with an implicit medical necessity defense for the distribution of a Schedule I drug. The case is inapposite for a variety of reasons, including that a distributor rather than a physician or patient sought to use the defense and that the drug at issue is a Schedule I drug, which by definition has no currently accepted medical use. See *id.* at 1723. (Stevens, J. concurring). In his concurrence, Justice Stevens noted that federalism “imposes a duty on federal courts, whenever possible, to avoid or minimize conflict between federal and state law, particularly in situations in which the citizens of a State have chosen to ‘serve as a laboratory’ in the trial of ‘novel social and economic experiments without risk to the rest of the country.’” *Id.* at 1723-24 (citation omitted).

this unpalatable menu; only the Directive forces physicians to choose between their patients and their freedom.

Second, even if the Directive's conclusion were somehow found to comport with the statutory framework, the scope of the discretion the Attorney General has arrogated to himself would necessarily have a profoundly chilling effect. If the agency can unilaterally determine what constitutes legitimate medical practice without reference to state law on one issue, in the absence of some limiting principle there is no logical basis for assuming that this power could not be extended beyond the issue at hand. The Government has not advanced any such principle: under the Government's interpretation of the CSA, the AG is empowered to determine the legitimacy of any medical practice involving controlled drugs for enforcement purposes. Thus, for example, under the Attorney General's interpretation of his authority, he could also preempt the pain treatment acts that many states have enacted.³³ Consequently, there is nothing to stop the Attorney General from regulating any practice of medicine that involves *any* product regulated under the CSA.

While the Government has stated that it does not plan to enforce its "conclusion" beyond Oregon's borders, it has not said that it lacks the power to increase its enforcement reach. This potentially vast authority to reach deep into the medical community has understandably concerned medical professionals throughout the country. Their concerns are not circumscribed by the borders of Oregon or the community of physicians who approve of the ODWDA. The reach of the Directive is necessarily national, for there is no reason to think that the Government

³³ A 1998 article found that thirty-three states had enacted some form of statute, rule or guidance for the use of narcotics to treat pain. Ann Martino, *In Search of a New Ethic for Treating Patients with Chronic Pain: What Can Medical Boards Do?*, 26 J. L. Med. & Ethics 332, 332 (1998).

would confine itself to determining the legitimacy of a practice in a single state despite the Directive's statement to the contrary, and indeed, the Directive was circulated to DEA offices across the country. The Directive purports to reverse a prior Justice Department interpretation of the CSA that clearly held that the DEA was not equipped to oversee physician judgments. Given these facts there is no reasonable way to interpret the Directive as anything other than an intrusion by the DEA into medical judgments across the country. In effect, the AG is asserting the power to create an entirely new medical regulatory authority.

Because the bull-in-a-china shop approach of the Directive has the potential to eviscerate longstanding state based standards of practice with executive fiat it therefore should be no surprise that physicians everywhere are seeing themselves as subject to potential criminal prosecution for simple compliance with the obligations of their profession.³⁴ Physicians already practice "defensive medicine" in this area because of anxieties about the fear of legal repercussions.³⁵ Faced with the threat of criminal investigation, revocation of their prescription licenses, and even possible imprisonment, physicians will respond by undertreating those patients with the most severe pain.³⁶

³⁴ It is important to note that bringing the DEA into this context is a marked departure from past practice. A 1998 study of prosecutions of medical personnel for their pain management of dying patients found that *none* of the investigations and subsequent prosecutions were initiated by the state but were instead the result of "informants" bringing cases to the attention of the authorities. Ann Alpers, *Criminal Act or Palliative Care? Prosecutions Involving the Care of the Dying*, 26 J. L. Med. & Ethics 308, 315 (1998). Given that physicians are already concerned about the effects of scrutiny, the active intrusion of the DEA will give rise to additional concerns. There is a world of difference between the up till now hands off approach of law enforcement, which relies upon participants in the system to alert law enforcement, and the world of the Directive, where a physician's actions will be scrutinized by the state *regardless of any allegation of wrongdoing*.

³⁵ See Marshall B. Kapp, *Treating Medical Charts Near the End of Life: How Legal Anxieties Inhibit Good Patient Deaths*, 28 U. Tol. L. Rev. 521, 523 (1997).

³⁶ There is evidence that physicians alter their pain prescriptions out of concern over potential legal and regulatory actions. See Michael J. Reynolds, *Note, Morphine or Malpractice: Should Courts Recognize a Legal Duty to Prescribe Opiates for Treating Chronic Pain?*, 15 St. John's J. Legal Comment. 79, 83 (2000), *citing* C. Stratton

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The Directive's broad sweep—and the possibility of further, even more invasive Directives—must necessarily counsel physicians to be prudent, for under the Government's view, a single prescription, dispensed in accord with the relevant standard of care, could trigger an investigation and prosecution. This is not a trivial concern for physicians, for the mere fact of an investigation can have extremely serious consequences. Investigations, even where no disciplinary action results, may result in the loss of reputation and privileges that could have the same effect as the loss of a license.³⁷ In this new regime, where untrained DEA agents untrained in medicine determine the appropriateness of a prescription, the highest costs imposed by the Ashcroft Directive will ultimately be borne by patients with intractable pain.

Even if the Government does not avail itself of its newly-decided power to invade vast swaths of medical practice, the Directive will inevitably have a chilling effect upon all physicians who deal with the terminally ill. Physicians who are not familiar with the nuances of the law may simply avoid prescribing pain medication altogether so as to avoid what they may perceive, rightly or wrongly, as the shadow of the law.³⁸ More significantly, research suggests that physician attitudes remain strongly biased toward risk reduction and away from pain

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Hill, Jr. *Government Regulatory Influences on Opioid Prescribing and Their Impact on the Treatment of Pain of Nonmalignant Origin*, 11 J. Pain & Symptom Mgmt. 287, 289-92 (1996); S.H. Johnson, *Disciplinary Actions and Pain Relief: An Analysis of the Pain Relief Act*, 24 J. Law, Med. & Ethics 319-27 (1996); Alpers, *Criminal Act*, *supra* note 35, at 308.

³⁷ Martino, *What Can Medical Boards Do?*, at 340.

³⁸ See J. David Haddox and Gerald M. Aronoff, *Commentary: The Potential for Unintended Consequences from Public Policy Shifts in the Treatment of Pain*, 26 J. L. Med. & Ethics 350, 351 (1998).

alleviation.³⁹ As one commentator has observed, this bias has an effect on the treatment of patients even when the concern lacks a factual foundation:

[H]owever weak the factual foundations, the anxieties felt by physicians and other health care providers about potential criminal, civil, and/or regulatory liabilities are real and palpable influences on the quality and humanity of medical care actually provided to the most vulnerable patients. This is true even for those physicians who understand that their own legal exposure is minimal. The very fact that physician conduct in this most delicate of areas could conceivably be questioned in a legal context is enough to skew behavior.⁴⁰

The Directive will only reinforce these concerns.

Third, the Directive also glosses over the significant medical issues involved in palliative care. For example, the Directive purports to create a distinction between the "proper" distribution of pain medication and the "improper" use of medicine to hasten death.

Unfortunately, the Directive's distinction is truly a distinction without a difference, for it is a well-accepted fact that the practice of medicine sometimes entails the application of the doctrine of "double effect," which acknowledges the value of treating the severe pain of the terminally ill even when it is known that a consequence of that treatment may be the hastening of death.⁴¹

Ignoring this difficulty, the Directive purports to have DEA agents second-guess a physician in an area where pain relief and death are inextricably joined. This widely embraced doctrine is too

³⁹ See Martino, *What Can Medical Boards Do?*, at 332 ("[T]he early data—both hard and anecdotal—strongly suggest that fear of regulatory reprisal continues to be the reason physicians most frequently cite for not providing adequate treatment for chronic pain."), and sources cited in note 31, *supra*.

⁴⁰ Kapp, *supra* note 36, at 545.

⁴¹ See Howard Brody M.D., *Physician-Assisted Suicide in the Courts: Moral Equivalence, Double Effect, and Clinical Practice*, 82 Minn. L. Rev. 939, 943-950 (1998) (discussing doctrine and observing that it is difficult to distinguish the differences in intent between palliative care and assisted dying since practitioners "must believe . . . in a form of the principle of double effect in order to provide optimal symptom relief at the end of life."

complex to be adequately figured into the enforcement of the CSA.⁴² One expert has noted that the effect of the Directive will be that DEA agents “with absolutely no experience in end-of-life care will be determining if large doses of medication physicians sometimes prescribe[] to treat terminally ill patients are used with the intent of hastening death or relieving pain.”⁴³ Another observed:

[C]ompassionate doctors caring for the terminally ill . . . simply want to relieve their patients’ suffering, and that is what their patients want and expect of them, sometimes in whatever way possible. Not only is it difficult in such cases to parse the intent behind each element in the treatment, it is also doubtful that anyone should want to try. Mercy, especially in doctors, is not something to be rooted out.⁴⁴

In *Glucksberg*, Justice Stevens noted that “the American Medical Association unequivocally endorses the practice of terminal sedation—the administration of sufficient dosages of pain-killing medication to terminally ill patients to protect them from excruciating pain even when it is clear that the time of death will be advanced.”⁴⁵ The Ashcroft Directive does nothing more than pay lip service to these very real concerns and makes no effort to parse among the myriad ways pain medications may be used.

⁴² Timothy Quill, Rebecca Dresser and Dan Brock, *The Rule of Double Effect—A Critique of Its Role in End-of Life Decision Making*, N. Engl. J. Med. 1997, Vol. 337, No. 24; 1768-71 (Dec. 11, 1997). In *Glucksberg*, Justice Stevens recognized the difficulty of distinguishing intent as a practical matter when, speaking of the distinction between the withdrawal of life support and assisted suicide, he noted that there might not be “a significant difference between the intent of the physicians” in these two situations. *Glucksberg*, 521 U.S. at 750. See also Cantor and Thomas, *supra* note 7, at 114, noting that “[t]he elusiveness of specific intent in this context is thus patent.”

⁴³ Groopman, *supra* note 4.

⁴⁴ Marcia Angell, M.D., *Caring For the Dying—Congressional Mischief*, 341 New Engl. J. Med. No. 25, 1923-25 (Dec. 16, 1999).

⁴⁵ *Glucksberg*, 521 U.S. at 751 (Stevens, J., concurring); see also Margaret P. Miller, *Bootstrapping Down a Slippery Slope in the Second and Ninth Circuits: Compassion in Dying is Neither Compassion Nor Constitutional*, 30 Creighton L. Rev. 833, 855 (1997) (“Although some drug therapies have ‘double effect’ of providing pain relief, while simultaneously hastening death, the value of the pain relief is such that the American Medical Association permits such therapy, despite its detrimental effects.”).