NLWJC - Kagan

DPC - Box 002 - Folder 011

Assisted Suicide [2]

Assisted suicide

Ass. Suicide 4/21/98

Mtg w/ DOT and HHS

No support for any fed. leg [redacted]

Sure no existing law out there?
Not - CSA
Not - Anti-kickback Act
Not - anything that FDA has (FDCA)

But in fact FDA occas has gone after trs.

Bottom line - This does seem to be an off-label use

What does Harriet say about this?

[Don't say anything in letter.]

Assisted suicide

Elena / Hose

Important, interesting info.
I suggest we work with
these guys whatever we do.
Their counsel, Peter Leibold, is
a good friend of mine. Chris

THE
CATHOLIC HEALTH
ASSOCIATION
OF THE UNITED STATES

February 6, 1998

President William J. Clinton
The White House
Washington, DC 20500

Dear Mr. President:

On behalf of more than 1,200 Catholic-sponsored facilities and organizations nationwide that make up the membership of the Catholic Health Association of the United States (CHA), I write with regard to the critical issues surrounding the protection of life and the provision of pain relief for those nearing the end of life.

I am writing specifically to urge you to: 1) support the Drug Enforcement Agency's (DEA) recent legal interpretation of the Controlled Substances Act regarding physician-assisted suicide; 2) encourage you to issue enforcement guidelines to the DEA urging it to be sensitive to the legitimate concern that overly aggressive or misguided enforcement could have a chilling effect on pain relief for persons at the end of life; and 3) appoint a task force to make concrete recommendations on how to reduce legal and regulatory barriers to *appropriate* pain relief for dying persons.

First, CHA strongly supports DEA's declaration that "delivering, dispensing or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a legitimate medical purpose." The religious beliefs and values upon which both CHA and its member hospitals and long-term care facilities are founded compel us to reject assisted suicide. More generally, this practice is radically inconsistent with proper regard for the dignity of human life and irreconcilably incompatible with the appropriate ends of medicine.

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The DEA's legal interpretation is completely consistent with your support for the Assisted Suicide Funding Restriction Act passed last year. In that legislation, you supported the proposition that no federal funds, programs, or health facilities should be used to further assisted suicide. Thus, from the federal government's perspective, assisting in a suicide is not a legitimate medical practice. Consistency demands that you support the legal interpretation provided by the administrator of the DEA.

Second, your support for a consistent legal interpretation does not mean that you cannot take ameliorative steps with regard to enforcement. CHA is acutely aware that the DEA's correct, legal interpretation, if not carefully implemented, may *unintentionally* have a chilling effect on physicians who prescribe, dispense, and administer appropriate and effective amounts of

morphine and other opioids in treating pain as death approaches. Certainly, a physician would have reason for serious concern if the DEA routinely second-guesses his or her dosages to a dying person to determine if they violate the Controlled Substances Act. In a recent study, the Institute of Medicine (IOM) found that physicians have significant apprehension about legal sanctions related to addiction and anti-addiction regulations.

Therefore, when announcing your support for DEA's interpretation, CHA urges you to issue an enforcement directive to the agency concerning your expectations with regard to its agents' enforcement of the law. Specifically, the DEA must be aware of, and sensitive to, the impact that its investigation may have on the dispensing of needed pain relief medication to dying persons. The DEA should be aware that it is *not* a violation of the Controlled Substances Act to dispense controlled substances for the legitimate medical purpose of relieving pain, even if they may indirectly shorten the person's life. This essential distinction is codified in the Assisted Suicide Funding Restriction Act itself and was affirmed by the U.S. Supreme Court when it upheld laws prohibiting assisted suicide last June.

The DEA should initiate investigations or enforcement actions only when their agents have credible and substantive allegations that health care providers have established a pattern or practice of prescribing or dispensing controlled substances to persons for the purpose of helping them to take their lives. It is not, nor should it be, a DEA priority to expend significant resources second-guessing the opinions of health care providers about the controlled substances needed to adequately and appropriately relieve the pain of dying persons.

Third, CHA asks that you form a federal/state advisory task force to make concrete recommendations to you and to the 50 governors on how to reduce legislative and regulatory barriers to pain relief. A 1997 Institute of Medicine Study, *Approaching Death: Improving Care at the End of Life*, states the concern succinctly:

> Outdated and scientifically flawed drug-prescribing laws, regulations, and interpretations by state medical boards continue to frustrate and intimidate physicians who wish to relieve their patient's pain. Addiction to opioids appropriately prescribed to relieve pain and other symptoms is virtually non-existent, whereas underuse of these medications is a well-documented problem (pp 5&6).

Specifically, the IOM identifies, among others, triplicate prescription laws, limits on the number of medication dosages that may be prescribed at one time, medical board policies, and state anti-addiction laws as barriers to effective pain relief.

CHA recognizes the critical need to address illegal drug use and diversion. Yet, as the IOM points out, there is little evidence that the prescription of opioids in the care of dying persons contributes in any meaningful way to illegal drug use and drug diversion problems. It is both counterintuitive and counterproductive if drug control laws tragically result in the increasing reluctance of physicians and other health professionals to treat dying persons by seeking to alleviate their pain. Dying persons should not be held hostage by regulations that, while rightly motivated, can cause great suffering and distress for them and their families.

CHA and its member facilities and organizations are committed to provide dying persons and their families both competent and compassionate care. Toward that end several Catholic health systems and CHA have joined together in a collaborative effort, ***Supportive Care of the Dying: A Coalition for Compassionate Care***. One specific goal of this project is to ensure that adequate and effective pain management is available to every person living with life-threatening illness so that they may live well even while dying.

Mr. President, concrete recommendations for reform by a federal/state task force on these issues will allow you to suggest legitimate steps to improve pain relief for dying persons. In this way, you can continue your consistent support for the principle that assisting in a suicide is not a legitimate medical purpose and, at the same time, suggest appropriate and necessary public policy mechanisms to improve pain relief for dying persons.

In conclusion, CHA urges you to remain consistent on the federal government's treatment of assisted suicide while exploring all available and legitimate methods for improving pain relief for those in the last stages of life.

With personal best wishes, I am

Sincerely,

Rev. Michael D. Place, STD
President

cc: Attorney General Janet Reno

Assisted suicide

ISSUES TO BE ADDRESSED BY A PRESIDENTIAL ADVISORY TASK FORCE ON END-OF-LIFE CARE

1) What concrete actions can the federal government take to eliminate barriers to appropriate pain relief, provided that those actions are consistent with the President' opposition to assisted suicide?

2) What concrete actions can state governments take to eliminate barriers to appropriate pain relief, provided that those actions are consistent with the President's opposition ot assisted suicide?

3) What constructive steps can be taken by federal and state governments to encourage the medical education community to correct perceived deficiencies in education on end-of-life care?

4) What constructive steps can be taken by federal and state governments to make hospice and other forms of quality end-of-life care more readily available to those at the end of life?

LEGISLATIVE HISTORY OF FEDERAL DRUG LAW SUPPORTS AUTHORITY TO ACT AGAINST PHYSICIAN-ASSISTED SUICIDE

The Controlled Substances Act of 1970 was amended in 1984 to strengthen the Drug Enforcement Administration's ability to prevent diversion of federally regulated prescription drugs for illicit purposes. The amendments were approved by the U.S. Senate 91-to-1 on February 2, 1984 as part of a Comprehensive Crime Control Act (S. 1762). Almost identical language was approved by the House 392-to-1 as a free-standing "Dangerous Drug Diversion Control Act of 1984" (H.R. 5656) on September 18, 1984. The House and Senate versions were reconciled and ultimately approved as part of H.J. Res. 648, a continuing resolution which became law on October 12, 1984 (P.L. 98-473).

This legislative background helps answer some questions raised about the federal government's authority to apply this federal law against physicians who prescribe controlled substances to assist suicides:

Was the federal law directed primarily against street drugs like heroin and cocaine?

No, the 1984 amendments were directed specifically against the misuse or "diversion" of federally regulated prescription drugs which have a legitimate medical use. The prime House sponsor said these had become a more serious problem in some ways than street drugs but had "failed to get the societal or the enforcement attention that it deserves" (Rep. Hughes, Cong. Record, 9/18/84, H9679).

Was the law directed against physicians?

Yes, though not exclusively. "The bill gives to DEA greater latitude to suspend or revoke the registration of a practitioner who dispenses drugs in a manner that threatens the public health and safety" (Id.). As the chairman of the House Commerce Subcommittee on Health and the Environment said at the subcommittee hearing on this bill: "Today's pusher is not always a back alley salesman. He or she may well be a highly educated health professional" (Rep. Waxman, Hearing of July 31, 1984, Hearing Record No. 98-168, p. 365). There were also provisions directed at manufacturers and pharmacists.

Was the law directed against addiction, or against the use of drugs to cause death?

The chief concern cited was their potential to cause physical harm and death. Sponsors cited a government study indicating that "prescription drugs are responsible for close to 70 percent of the *deaths* and injuries due to drug abuse" (Rep. Hughes, Cong. Record, 9/18/84, H9679). The chairman of the Health subcommittee in the House agreed: "Drugs legally manufactured for use in medicine are responsible for a substantial majority of *drug-related deaths* and injuries" (Rep. Waxman, Hearing Record No. 98-168, op. cit., p. 365) One sponsor used the example of an

opiate widely used as a pain-killer, saying: "Because these pills have an even greater potential for *physical injury and danger*, they involve more than half of the hospital entries for illegal use and *overdose* of drugs" (Rep. Sawyer, Cong. Record, 9/18/84, H9680).

Was the law designed to defer to states' judgments on the proper medical use of drugs?

On the contrary: It was designed to give the DEA more independent authority to revoke a physician's registration in cases where a state *refused* to intervene. The 1984 amendments authorized the DEA to revoke a physician's registration if it deems that registration to be "inconsistent with the public interest" (in cases where, for example, revoking registration will serve "public health and safety"). As Rep. Charles Rangel said in support of the amendments: "Under current law, the DEA must register physicians, pharmacies, or other practitioners if they are authorized to dispense drugs by the law of the State in which they practice.... The public interest standard added by H.R. 5656 will provide greater flexibility to deny or revoke registrations in the most egregious cases" (Cong. Record, 9/18/84, H9682). (When a law is enacted to prevent prescription drugs from being used for lethal overdoses, there is nothing more egregious than a physician who *intentionally* dispenses drugs for such overdoses.) Prime Senate sponsor Strom Thurmond spoke similarly, saying that this provision "expands the standards for practitioner registration beyond the current exclusive reliance upon authorization by the practitioner's own jurisdiction" (Cong. Record, 2/2/84, S758). Sponsors said giving such flexibility to the federal government was necessary because states often did not respond adequately to these abuses: "State policing of these activities, as well as peer review within the profession, have not been adequate control measures. State laws regarding the dispensing of controlled substances are also inadequate" (Rep. Fish, Cong. Record, 9/18/84, H9680). At a hearing before the House Commerce Subcommittee on Health and the Environment, the DEA called the expanded federal authority to revoke practitioner registration "one of the most important sections of the bill," not only because states were often ill-equipped to enforce their own drug laws but also because "many controlled drug violations involving prescription drugs *are not felonies under state law* and therefore cannot be used in a DEA revocation action" under then-existing law (Testimony of Gene R. Haislip, Deputy Assistant Administrator, Drug Enforcement Administration, Hearing Record No. 98-168, p. 404). Congress's view was that while the states are the first line of defense against misuse of prescription drugs, the federal government must enforce its own objective standard as to what constitutes such misuse -- and it must have the authority to enforce that standard when a state cannot or will not do so.

In light of this history, it cannot be maintained that the Controlled Substances Act as it exists today was directed only against professional drug traffickers rather than physicians, or only against addiction rather than lethal drug overdoses, or only against physicians who violate state laws. Independent federal authority to enforce federal drug standards was intended to apply to "Schedule II" prescription drugs like barbiturates or morphine as much as to "Schedule I" drugs like marijuana or cocaine -- most especially when such drugs are being used to cause death.

3/10/98

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7

Legal Issues

The principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions.

Cruzan v. Director, Missouri Department of Health, 497 US 261, 278 (1990)

A *seriously ill or dying patient whose wishes are not honored may feel a captive of the machinery required for life-sustaining measures or other medical interventions.*

Justice Sandra Day O'Connor, concurring opinion in *Cruzan,* 497 US at 28

The roles of judges, legislators, and administrative officials in influencing care at the end of life vary from the dramatic to the commonplace. On the dramatic end of the continuum are the court cases about the legality of physician-assisted suicide, which were argued before the U.S. Supreme Court as this report was being drafted. In contrast, the right of people to refuse unwanted life-sustaining and other treatments—once the subject of highly charged court cases—is now commonly accepted and enforced (if not always perfectly).

Documenting the impact of statutes, regulations, case law, and administrative actions on clinicians, patients, families, and others can be difficult. In addition, the applicability of various statutes and judicial precedents to specific patient circumstances is quite often a matter of dispute and speculation rather than straightforward matching of law to facts. Nonetheless, in the committee's view, the legal issues discussed here raise concerns either about their possible effects on compassionate and effective care for those approaching death or about the unrealistic expectations they may create or both.

This chapter considers laws relating to prescription of opioids, informed consent and advance directives, and assisted suicide. Among those with clinical, administrative, or similar involvement in end-of-life care, much of the debate about issues such as prescription regulation or informed consent is practical. For example, how can prescription laws be modified so that they do not discourage effective pain management but still respond to legitimate concerns about misuse of controlled substances? For some issues, most notably assisted suicide and euthanasia, ethical concerns may dominate legal discussions, but practical issues also arise as described later in this chapter. The focus here is primarily on how laws may affect the quality of care for dying patients.

Although the impact of malpractice litigation on medical practice is a complex and disputed question, it is discussed only briefly because the committee did not view the prospect of malpractice litigation as likely to have a significant impact on end-of-life care specifically. The committee, however, recognized concerns that physicians may engage in defensive medicine (e.g., ordering extra tests, prescribing unnecessary medications, performing hopeless CPR) because they fear being sued for a bad outcome that plaintiffs might attempt to attribute to lack of a test or procedure. Similarly, decisions might sometimes be influenced by the fear of being sued for not following a family's wishes, even if those wishes were contrary to the doctor's clinical judgment and the patient's own wishes. The committee did not find evidence that physicians were concerned about liability for failure to intervene to relieve pain or other symptoms.

In any case, many of the steps proposed in this report would tackle problems of undertreatment, overtreatment, or mistreatment of dying patients in ways that should reduce the potential for litigation and physician uncertainties and fears about being sued. At the practitioner level, these steps include changing clinicians' attitudes, knowledge, and practices so that they communicate more effectively with patients and families, engage patients and families in a process of goal setting and decisionmaking that increases trust and minimizes misunderstanding, and properly assess and treat pain and other symptoms. At the system level, they include strategies for measuring, monitoring, and improving care that seek to identify and respond to the preferences, experiences, and feelings of patients and families. If, however, these strategies fail to correct the deficits identified in Chapter 3 and if patients come to understand that the standards of care (e.g., practice guidelines) call for efforts to relieve symptoms, then litigation stemming from inattention to symptom management might become more likely—but not necessarily productive. The primary injured plaintiff would, in the case of a dying patient, likely have died, and although a family could claim injury and testify about the decedent's suffering, damages would be hard to establish. In addition, the status of practice guidelines in the courts

is still evolving. Overall, the committee was doubtful that malpractice litigation could be relied upon as an instrument to improve care at the end of life.

PRESCRIPTION LAWS AND BARRIERS TO PAIN RELIEF

All patients who suffer pain—not just the dying—deserve relief through treatments that are known to be effective for most pain. Indeed, early treatment of pain as a part of a continuum of good care for those who are seriously ill may be the best approach to minimizing pain at the end of life. Other parts of this report document deficiencies in pain management and gaps in scientific knowledge. This section examines how effective pain management may be compromised by prescription drug laws that are intended to minimize drug addiction and diversion of drugs from legal to illegal sources. (Relief of dyspnea may also be affected by these laws, although this has not been the subject of much attention.) Because these laws both arise from and interact with the misperceptions and attitudes of physicians, medical boards, lawmakers, patients, and the public, reform needs to go beyond revisions in written policies to affect knowledge and values.

Anti-Diversion Policies

The Problem of Diversion and Regulatory Responses

Diversion occurs when persons with legal access to controlled substances distribute them or use them for illegal purposes or when people fradulently obtain drugs from legal sources (Cooper et al., 1992; Cooper et al., 1993).[1] Pain relief medication, for example, might be prescribed to phony patients and then sold on the streets. Alternatively, people might forge prescriptions or misrepresent their symptoms to secure prescriptions. Newspaper articles and television news reports periodically expose the problems of diverted opioids and clinician addiction. No reliable studies document the extent of opioid diversion specifically or compare it to other illegal sources (e.g., illegal imports and domestic production). A 1990 household survey estimated that 4 percent of the population over the age of 12 had used prescription analgesics, stimulants, tranquilizers, or sedatives at least once for nonmedical reasons in the preceding year, and almost 1.5 percent were currently using them (NIDA, 1991). A California estimate puts the

[1]Theft and other forms of illegal access are also problems but are less susceptible to control through anti-diversion regulations.

dollar value of diverted controlled substances during the mid-1980s at somewhere between $500 million and $1 billion (Marcus, 1996).

Legal and regulatory policies intended to prevent diversion include triplicate prescriptions and limits on the number of medication dosages that may be prescribed at any one time. These policies are burdensome and appear to deter legitimate prescribing of opioids (see, e.g., Cooper et al., 1992; IOM, 1995a, 1996d; Joranson, 1995a). Triplicate prescription programs require the prescribing physician to complete detailed, multiple-copy prescription forms. The forms themselves are often difficult to obtain and, if incorrectly filled out, must be completed again by the physician. The triplicate forms also become available to the state medical board, which may choose to pursue disciplinary measures on the basis of such information. Electronic forms and monitoring systems would ease the burden on physicians as well as allow easier monitoring but such systems have not been widely adopted or rigorously evaluated nor have appropriate norms to guide such oversight been developed and tested.

Some states have laws limiting the dosages a physician may prescribe to one patient at any given time. These laws force patients who suffer pain that requires frequent medication to request and renew prescriptions repeatedly. This not only inconveniences both patients and physicians but may subject patients to possible interruptions in pain management if something disrupts the timely requests and responses. Such problems are a special concern for patients who are not in a medical facility but are at home or in a care facility without an on-site physician.

The committee recognizes the problems created by illegal drug use and drug diversion and the need for law enforcement responses. It, however, knows of no evidence, anecdote, or other reason to believe that the prescription of opioids in the care of dying patients contributes in any meaningful way to drug diversion problems.

Effects on Care at the End of Life

The effect of anti-diversion policies on their intended targets is unclear. They do, however, appear to affect the rate of prescriptions and perhaps increase the use of less effective or even harmful medications (Cooper et al., 1993; Joranson and Gilson, 1994a, b; IOM, 1995a, 1996d). One study reported that when Texas introduced a multiple-copy prescription program, prescriptions for opioids to control pain were halved (Sigler et al., 1984). It is not known whether this dramatic drop resulted from declines in inappropriate prescribing and diversion or whether physicians and pharmacists became reluctant to prescribe appropriate medications. Nonetheless, the magnitude of the change makes it reasonable to expect that the regulation had some impact on patient care (Von Roenn et al., 1993; Wastila and

Bishop, 1996). Surveys of physicians—discussed further below—suggest that anti-diversion and anti-addiction policies combined with social antipathy toward real or imagined addiction discourages effective, appropriate, and legal pain prevention and management.

Options for Improvement

How can laws be constructed and interpreted in ways that minimize drug diversion without obstructing effective medical management of pain? Options include (1) replacing triplicate forms with electronic reporting of prescriptions and (2) allowing standing prescriptions for outpatients (to be monitored by home health care professionals or pharmacists). In addition to reducing regulatory barriers to effective pain prescribing practices, states could require that pain experts or palliative care specialists be represented on state medical boards to help inform board policies and interpretations. Information collected from triplicate or electronic prescriptions might also be analyzed to identify questionable prescribing practices, which could be used to guide education of physicians and pharmacists about effective and appropriate use of opioids. Another IOM committee has already recommended additional research on the effects of controlled substance regulations on patient care and scientific research (IOM, 1996d).

Anti-Addiction Policies

The creation of new addictions is a separate issue from the diversion of drugs to the black market. A collection of social forces joins with legal restrictions to create a general antipathy toward drug use that flows into the area of medical practice and undermines effective pain management. Even the terminology muddies the waters when chronic use of opioids, which produces physical dependence, is sometimes equated with addiction. For example, California law defines addicts as "habitual users," which might include patients with chronic pain who regularly and appropriately take opioids necessary to manage their pain (Marcus, 1996).

States have addressed the perceived problem of medically induced drug addiction through varied combinations of laws, regulations, and medical board disciplinary policies. Because the committee concluded that policies often reflect inadequate understanding of the mechanisms of pain and addiction, these mechanisms will be described before the policies are considered.

Mechanisms of Pain and Addiction

Efforts to devise reasonable anti-addiction policies are complicated by

ignorance and confusion about the biological and psychological mechanisms of pain management and addiction (Bruera et al., 1987; WHO, 1990; Nestler et al., 1993; Von Roenn et al., 1993; Portenoy et al., 1994; Buchan and Tolle, 1995; Joranson, 1995a; Portenoy, 1996). Research indicates that addiction in patients appropriately receiving opioids for pain is very small, ranging from roughly 1 in 1,000 to less than 1 in 10,000 (Porter and Jick, 1980; Angell, 1982; Jaffe, 1985; Rinaldi et al., 1988; Portenoy and Payne, 1992; Portenoy, 1996).

The committee concluded that drug tolerance and physical dependence should be more uniformly and clearly distinguished from addiction. *Tolerance* occurs when a constant dose of a drug produces declining effects or when a higher dose is needed to maintain an effect. *Physical dependence* on opioids is characterized by a withdrawal effect following discontinuation of a drug. Such dependence is a common effect in chronic pain management, but it is not restricted to opioids. Other agents such as beta-blockers, caffeine, and corticosteroids also produce physical dependence. Further, clinical evidence suggests that patients receiving opioids can be easily withdrawn from them in favor of an alternative, effective pain control mechanism if that is clinically indicated. Typical practice is to reduce the dose by fractions, stopping administration of opioids altogether after a week or so (Doyle et al., 1993). This practice may not be relevant, however, for dying patients.

Neither physical dependence nor tolerance should be equated with addiction or substance abuse. Portenoy and Kanner (1996) proposed that "addiction is a psychological and behavioral syndrome characterized by (1) the loss of control over drug use, (2) compulsive drug use, and (3) continued use despite harm" (p. 257). This is consistent with a definition proposed by the American Medical Association: "the compulsive use of a substance resulting in physical, psychological, or social harm to the user and continued use despite that harm" (Rinaldi et al., 1988, p. 556). The federal Controlled Substances Act defines an addict as someone who habitually uses an opioid in ways that endanger public health or safety (AHCPR, 1994a).

Unfortunately, the general term *substance dependence* is often used as a synonym for addiction, perhaps because the latter is more stigmatizing. For example, the American Psychiatric Association sets out criteria for dependence rather than addiction in its *Diagnostic and Statistical Manual of Mental Disorders* (4th ed., 1995). Despite a disclaimer that the scheme focuses on "maladaptive" substance use, the discussion of substance dependence may nonetheless mislead (p. 181). A later disclaimer about distinguishing legitimate medical purposes from opioid dependence is not specific, given that, as described below, many seem to be confused about what is legitimate. The committee is particularly concerned about misinterpreta-

tion of criteria related to tolerance, withdrawal, and overuse. Tolerance and withdrawal are, in general, clinically acceptable (although not necessarily invariable or desirable) consequences of effective use of opioids to manage pain, and "overuse" as defined above may be difficult to distinguish from increasing use due to uncontrolled pain, which may result from increasing pathology, tolerance, or other sources (Weissman and Haddox, 1989). Similarly, some behaviors suggestive of addiction may be confused with those resulting from inadequately managed pain or anxiety about the reliability of pain management.

Regulatory Responses

Responses to the problem of addiction take several forms including some of those already identified in the discussion of drug diversion. Federal and state laws and regulations attempt to control the prescribing behavior of physicians, nurses, and pharmacists by criminalizing certain activities. In addition to legislatures and courts, state medical boards set policies that, although not having the official force of law, may be just as powerful in their effect. These policies dictate the standards by which physicians may be professionally disciplined. Laws and medical board policies are also intertwined, in that legislatures may place legal limitations on the extent of a medical board's powers.

Medical Board Policies. State medical boards may establish guidelines on pain-prescribing practices that constitute official statements of board policy. Such guidelines describe acceptable medical practice and notify health care practitioners of professional boundaries. Violating them may lead to disciplinary action. The sometimes restrictive perspective of state boards could interfere with the treatment of pain. In 1987, for instance, the Washington State Medical Disciplinary Board stated that it did "not recognize repeated prescribing of controlled drugs as appropriate therapy for chronic pain" (cited in Joranson, 1995a, pp. 2–3).

Several state medical boards have issued guidelines that deal with the use of opioids to treat intractable pain.[2] In California, the nursing and pharmacy boards have also created guidelines addressing the same issue (Joranson, 1995b). These guidelines are intended not only to instruct phy-

[2]State medical boards that have issued guidelines regarding the use of controlled substances to treat pain (along with the year in which the guidelines were first issued) include: Utah (1987), Minnesota (1988), Massachusetts (1989), Arizona (1990), Georgia (1991), Oregon (1991), Alaska (1993), Texas (1993), Wyoming (1993), Alabama (1994), California (1994), Idaho (1995), Colorado (1996), Florida (1996), Maryland (1996), Montana (1996), North Carolina (1996), and Washington (1996) (Joranson, 1997).

sicians and other caregivers on the proper use of opioids in pain management but also to reduce physicians' fear of attracting board discipline for such use. Another way for state medical boards to improve pain control might be for the boards to educate the physicians within their states about how to comply with laws, regulations, and board-set standards. Information collected from triplicate prescription forms could be used in this educational effort.

Some state boards, however, continue to require that physicians avoid the potential for addiction and that they justify the continued prescribing of opioids (Joranson, 1995b). A survey of state medical board members conducted in 1991 showed that most would discourage the use of opioids to relieve chronic, noncancer pain; a third of them said they would investigate such a prescription as a potential violation of the law (Joranson et al., 1992). There is still, it seems, an inappropriate sense of distrust on the part of the medical boards, which this committee believes has developed, in part, on the basis of misperceptions discussed above about the nature and consequences of dependence and addiction.

Laws and Regulations. In 1974, the federal government, through the Federal Intractable Pain Regulation, clarified the federal law that prohibits physicians from prescribing opioids to detoxify or maintain an opioid addiction (Code of Federal Regulations, Title 21 Part 1300). The regulation states that the prohibitive regulations are "not intended to impose any limitation on a physician . . . to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable effort" (21 Code of Federal Regulations, Title 21 Sec. 1306.7[c]). The policies of the Drug Enforcement Administration are similarly explicit.

Even when antiaddiction laws exempt those with intractable pain, the protections generally do not extend to those already addicted (Joranson, 1995a). When these people become patients suffering intractable pain, physicians are not free to prescribe opioids to relieve their suffering. This problem becomes especially acute in the AIDS wards of many urban hospitals.

At the state level, a number of prescribing laws include provisions that could interfere with effective medical use of opioids. For example, in New Jersey, regulations call on physicians "periodically to either cease the medication or taper down the dosage . . . to reduce the addiction propensity for the patient" (Joranson, 1995a).

In 1988, the Commonwealth of Virginia passed the first state law addressing the need to treat pain in terminally ill cancer patients (Joranson, 1995a). The legislation—despite its positive provisions—also illustrated the misperceptions surrounding the treatment of pain. It allowed physicians to

prescribe heroin to their terminally ill patients even though heroin is not legally available under federal law and has no significant advantages over other available opioids (Joranson, 1995a).

Texas was the first state to pass an Intractable Pain Treatment Act, in 1989. California followed suit in 1990 and Florida in 1994 (Joranson, 1995a).[3]

Some state pain treatment laws, (e.g., Colorado and Washington) recognize the benefits of pain control and allow physicians to prescribe controlled substances but do not address concerns about inappropriate discipline by medical boards. The Texas and California acts do address this problem by prohibiting medical board discipline of physicians who follow the provisions within the laws. Both acts also define intractable pain (following the model of the Federal Intractable Pain Regulation[4]), authorize physicians to prescribe controlled substances to treat intractable pain, and prohibit health care facilities within the states from limiting such prescriptions. California's act requires an evaluation of the patient by a specialist.

Effects on Care at the End of Life

Surveys suggest that physician apprehension about addiction and anti-addiction regulations is widespread (Cleeland et al., 1986; Portenoy, 1990; Weissman, Joranson et al., 1991; Hill, 1993; Von Roenn et al., 1993). Such apprehension is not limited to physicians within the United States. In a survey of all the governments in the world conducted by the International Narcotics Control Board (within the United Nations International Drug Control Program), 47 percent of responding governments cited health care provider reluctance due to concerns about legal sanctions as an impediment to medical use of opioids (Joranson and Colleau, 1996).

The frequency of punitive action against physicians for apparently legitimate prescribing practices is unknown, but the committee heard many

[3]States with intractable pain treatment policies (along with the year in which the policy was instituted) include Virginia (1988), Texas (1989), California (1990), Colorado (1992), Washington (1993), Florida (1994), Missouri (1995), Nevada (1995), Oregon (1995), and Wisconsin (1996) (Joranson, 1997).

[4]Both statutes define intractable pain as "a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain" (Code of Federal Regulations [1988] Title 21 Sec. 1306.07[c]).

anecdotes about threatening statements by medical disciplinary boards and about physicians who find the scrutiny and requirements sufficiently burdensome that they choose not to prescribe medications needed to manage pain effectively. In addition, the earlier discussion of regulations to limit drug diversion indicate that these policies may discourage the appropriate medical use of opioids and may discourage research to develop better medications.

Options for Improvement

More states could pass carefully drawn pain treatment laws. The American Medical Association (AMA) recently adopted a resolution to create a model state law, based on the Texas and California acts (AMA, 1996a). By protecting physicians from disciplinary actions, the AMA hopes to "provide patients with the security and knowledge that intractable pain resulting from terminal illness need not persist in a chronic, unrelieved manner" (AMA, 1996a, p. 4).

Although such laws constitute an important step to promote effective pain management for patients, they may not go far enough or may imply clinical clarity that does not exist. By making positive statements about the benefit of opioid use in the control of pain, legislators hope to reduce the fear of arbitrary medical board discipline. Yet they do not, in all cases, mark a clear area of medical practice in which physicians feel free to manage their patients' pain. The more specific laws, for example those that set out detailed prescription practices, may actually afford physicians less leeway in the practice of medicine. Additionally, by carving out an area of pain treatment that is immune from medical board discipline, there may be an implication that other forms of pain treatment should be subject to disciplinary review.

Even the strongest intractable pain law is still limited by the term *intractable.* Many cases are ambiguous, and physicians may believe that they must delay opioid treatment until pain is far enough along to be called intractable. An additional problem arises when state laws define addiction without regard to pain management. As noted earlier, California defines addicts as "habitual users," which might include patients taking opioids for chronic pain. Such confusing definitions once again expose physicians to the threat of medical board discipline.

Finally, the legal affirmations in these laws of the importance of pain control do not, in themselves, correct practice patterns or improve physician training. Laws could, however, encourage patients to expect diligence in pain relief, including use of generally effective medications. Medical boards could consider disciplining physicians who fail to apply proven methods of pain control.

Overall, the committee is encouraged by recent actions to revise drug prescribing. It urges continued review of restrictive state laws, revision of provisions that deter effective pain relief, and evaluation of the effect of regulatory changes on state medical board policies, physician attitudes and practices, patients, and illegal or harmful drug use.

INFORMED CONSENT AND ADVANCE CARE PLANNING

A series of legal decisions over the past three decades has affirmed the right of people to refuse unwanted medical treatments (President's Commission, 1982; Faden et al., 1986; Appelbaum et al., 1987). As stated in an important 1960 California Supreme Court case, "Anglo-American law starts with the premise of thoroughgoing self-determination," which includes the right of individuals to refuse medical treatments (*Natanson v. Kline,* 1960). This legal reasoning reinforced a shift in emphasis in medical ethics from a dominant paternalism (i.e., action in the best interest of patients as judged by physicians) toward autonomy (i.e., patients' right to choose the course they prefer) (Childress, 1982).

One means for recognizing patient autonomy in decisionmaking is informed consent, which means that patients voluntarily accept (or refuse) a medical intervention after disclosure of its expected benefits and risks and discussion of the alternatives. For dying patients who are unconscious or in such distress that they cannot reasonably communicate their wishes when a treatment decision needs to be made, the legal concept of informed consent may have limited application.

In response, the concept of *advance care planning* was devised to allow people (whether or not they are "active patients") to specify how they want to be treated should serious illness or injury leave them without the capacity to make decisions or communicate (see, e.g., President's Commission, 1982; AARP, 1986; Emanuel and Emanuel, 1989; Annas, 1991; Burt, 1994). Documents used in advance care planning, called advance directives, take several forms, including surrogate decisionmaking arrangements and what are popularly called "living wills." For purposes of this report, advance directives refer particularly to statements intended to be legally binding.[5]

As discussed in Chapter 3, advance care planning is a broader, less legally focused concept than that of advance directives. It encompasses not

[5]Guardianship involves the court appointment of a decisionmaker in cases where the patient is, for some reason, incompetent to make decisions for him or herself. A guardian is usually appointed for reasons other than health care, such as financial management. State guardianship laws vary on the power of a guardian to consent to or refuse medical treatments. The committee here limits its discussion to decisionmakers appointed by patients themselves.

only preparation of legal documents but also discussions with family members and physicians about what the future may hold for people with serious illnesses, how patients and families want their beliefs and preferences to guide decisions (including decisions should sudden and unexpected critical medical problems arise), and what steps could alleviate concerns related to finances, family matters, spiritual questions, and other issues that trouble seriously ill or dying patients and their families. Impediments to advance planning and the implementation of written directives may be less a matter of law than of ordinary inertia or unwillingness to consider unpleasant matters. The rest of this section discusses resuscitation orders, living wills, designation of surrogates, and the Patient Self-Determination Act of 1991.

Do Not Resuscitate Orders

Do not resuscitate orders or DNRs are orders placed by a physician with a patient's or surrogate's consent into the patient's treatment chart. As discussed in Chapter 2, it is not unusual for severely ill patients, who may be dying from any of a variety of diseases, to suffer cardiac or respiratory arrests. The normal action when this occurs is called a "code."[6] DNRs, or "no-codes," inform hospital staff or other caregivers that, in the event of such an episode, no attempts at revival should be made. Even when attempted, success rates of cardiopulmonary resuscitation are often low, especially for elderly patients (Murphy et al., 1989). For that reason, DNRs are sometimes called DNARs or "Do Not Attempt to Resuscitate" orders.

Because DNRs are physicians' orders, they come out of the clinical rather than the legal tradition. They thus have more in common with orders for medication or lab tests than they do with such legal documents as living wills or durable powers of attorney. Additionally, many hospitals had DNR options in place before they were required to do so by law. DNRs might, however, have some legal significance, if courts take them into account when determining whether a patient's preferences have been followed. Also, because the decision by the physician to place the DNR in the chart should be made in consultation with the patient and should reflect a patient's decision to forego certain forms of life-prolonging treatment, DNRs share with living wills and durable powers of attorney a role in the process of advance care planning.

[6]Caregivers attempt, through the insertion of breathing tubes and a pump, or by electric shock to the heart, to revive the patient. These attempts may stabilize the patient or may result in actual damage, leaving the patient alive but in a worse condition than before the code.

Living Wills

As of 1990, 40 states and the District of Columbia allowed adults to create what is popularly called a "living will" (Strauss et al., 1990). These statutes vary in their particulars, but they generally envision that individuals may make legally binding arrangements to the effect that they shall not be sustained by medical treatment that artificially prolongs the dying process if they are in a terminal condition and can no longer make decisions.

The statutes include several safeguards against abuse. Most include a requirement that the two witnesses to the signing of the document be neither related to the patient nor involved in his or her treatment or financial support. Also, the determinations that the patient fits the statutory definition of terminal and is unable to make decisions sometimes must be made by at least two physicians. A mentally competent individual is always entitled to revoke his or her advance directive. The statutes vary on whether nutrition and hydration are considered "artificially life-sustaining" treatments. Some statutes explicitly exempt nutrition and hydration from the care a patient may choose to refuse, others give the signer the option to explicitly include them, while a third group is silent on the matter (Strauss et al., 1990).

Skeptics of living wills argue that these documents, which may be standard forms approved by the legislature of some states, provide little practical guidance in real life clinical situations, which often involve many more factors or contingencies than anticipated by standards forms (see, e.g., Brett, 1991; Lynn, 1991). Indeed, by leading patients to believe that the signing of a living will means that their preferences for an end-of-life treatment plan have been made clear, these documents could even discourage active and ongoing discussions among patients, their families, and health care professionals. In contrast, a document designating a surrogate decisionmaker could encourage such communication.

Designation of Surrogate Decisionmakers

Adults

Another legal option for advance care planning involves the designation of a surrogate to act on one's behalf in the event one becomes incompetent to make decisions about medical care. State statutes (or, in some cases, sections within the living will statutes) vary in the amount of authority a person can assign to a surrogate. For example, in California, the patient's agent, who is assigned durable power of attorney[7] for health care

[7]"Durable" power of attorney differs from general power of attorney in that it does not expire when the designator loses the competence to make decisions. This is integral to healt

may make all health care decisions that the patient could make for himself or herself, had he or she the capacity (California Civil Code Sec. 2500). The attorney-in-fact's duty is to follow the wishes of the power's grantor, but specific instructions need not be included in the document. In contrast, Nevada and Rhode Island that require statutory forms be used (Nevada Chapter 449 Secs. 2–8; Rhode Island Sec. 23-4.10-1). Grantors of the power of attorney choose options on the form, instructing their agents when to consent to or refuse life-sustaining treatments.

In one sense, although the statutes that provide for standard forms and checked options seem more specific, they may still lead to ambiguities of definition and decision. For example, when an agent is instructed to refuse treatment when that treatment's burdens outweigh the expected benefits, it remains up to the agent (with the help of the health caregivers and others involved) to make the determination. In fact, under the broader powers available under California's statute, the grantor and the agent may be more likely to sit down together and discuss the grantor's wishes, rather than have the grantor check a box and leave it at that.

Other states place even more limits on the powers of the agent. In New York, power of attorney may not be used to delegate medical decision-making authority, only to communicate the wishes of the grantor (Strauss et al., 1990). This inflexible provision restricts people's ability to plan ahead and may prevent humane care at the end of life.[8]

Children

Decisions regarding dying children involve special considerations (Lantos and Miles, 1989; Strain, 1994; AAP, 1995; Fleischman, 1996). Although specific state laws vary, those below a certain age are legally unable to agree to or refuse medical treatment, and so others must make decisions for them. Even so, the best interests of these patients often oblige caregivers to discuss the situation with the children in ways appropriate for their developmental level and physical condition. This discussion may go beyond the sharing of information to ask children what they want for themselves (see discussion in Chapter 3). Problems arise when those with the power to consent to treatment for children disagree with each other or with clinicians. For health care providers, parental decisionmaking may also be complicated by spousal disagreement or evidence of child abuse.

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care decisionmaking, as it is exactly at the time of a patient's incompetence that the designated attorney-in-fact's role begins.

[8]The Conference of Commissioners on Uniform State Laws has recently proposed a Uniform Act on surrogate decisionmaking.

Parents' decisionmaking discretion is not absolute, and pediatricians view themselves as having a professional obligation to look after the best interest of their patients (AAP, 1995). In some cases, their conclusions may conflict with those of the patients' families. Some of the most difficult cases arise from parents' demands for what clinicians regard as "futile" or "inhumane" care. The possibilities for resolving conflict include sensitive conversations between the child's physician and the parents; involvement by social workers, ethicists, pastoral counsellors, or others trained in working with grief-stricken families; mediation by a hospital ethics committee; or recourse to the legal system. The latter is widely viewed as a last resort because of the burden it places on families, the stress it creates for clinicians, and the potential for negative publicity for families and institutions.

The Patient Self-Determination Act

The Patient Self-Determination Act (PSDA) was enacted by Congress in 1990 and went into effect in December 1991 (White and Fletcher, 1991; GAO, 1995b). The PSDA requires health care institutions that receive Medicare or Medicaid funds to provide written information to adult patients about state laws regarding advance directives. It also requires those institutions, among other things, to note any advance directive in a patient's file, not to discriminate between patients on the basis of whether they have an advance directive, and to educate staff and community about the availability of advance directives.

The purpose of the PSDA was to encourage greater awareness and use of advance directives so that situations of ambiguity, as illustrated by the Nancy Cruzan case, might be avoided. In that 1990 case, the United States Supreme Court recognized a competent patient's right to refuse life-sustaining treatment, but left it to the lower courts to determine whether testimony of Nancy Cruzan's previously expressed oral wishes was persuasive. In *Cruzan v. Director, Missouri Health Department*, Justice Sandra Day O'Connor suggested in a concurring opinion that written advance directives could dispel such ambiguity. That year, Congress passed the PSDA.

The law, however, appears to have had modest effects (Teno, Lynn et al., 1994; Morrison et al., 1994; Emanuel, 1995a; see also Chapter 3). There are no national studies on the rates of persons completing advance directives, but studies of discrete populations (e.g., nursing home residents or hospital patients) conducted both before and after passage of the PSDA show rates between 5 percent and 29 percent (GAO, 1995b; Yates and Glick, 1995). The SUPPORT investigators found a small increase of seriously ill patients having an advance directive since the PSDA went into effect (from one in five to one in four), but this increase did not translate

into higher rates of documented resuscitation discussions or DNR orders for patients who seemed to want them (Teno, Lynn, Wenger et al., 1997).

Although it requires health care organizations to provide information, the PSDA does not specify the content of that information. Often, patients are informed of their rights regarding advance directives during admission to a hospital or long-term care facility. The information is provided on a piece of paper, one of many that crosses the table during this usually stressful time. Other problems with implementation of the PSDA exist. One study found problems in the accessibility of previously completed advance directives during subsequent hospitalizations (Morrison et al., 1995). Another study found that, of the patient charts that indicated the existence of an advance directive, only 57.5 percent actually contained a copy of the directive (Yates and Glick, 1995). The study also revealed that a mere 32 percent of medical institutions covered by the law had done any community education on advance directives. The lack of involvement of physicians, especially primary doctors, also contributes to the tendency of patients to overlook the information offered.

The committee, while recognizing the value of advance directives, questions the urgency of intensive efforts to universalize their use. In this area of decisionmaking at the end of life, the law's favorite product—the legally binding document—may sometimes stand in the way of, rather than ease, the process, especially if these documents are naively viewed as ultimate solutions to the difficulties of decisionmaking. Rather, the documents known as advance directives should be seen as a set of tools useful in the ongoing process of advance care planning. Methods must be developed for encouraging continuing conversation among patients, their families, and the health professionals involved in their care. Less legalistic ways to approach planning and decisionmaking at the end of life were discussed in Chapter 3.

PHYSICIAN-ASSISTED SUICIDE

"Physician-assisted suicide" refers to a practice by which physicians provide, but do not directly administer, the means for a patient voluntarily to hasten his or her own death. This typically is done by prescribing lethal doses of medication that the patient then ingests. "Euthanasia," in contrast, is a practice by which the means of hastening death are administered directly by the physician, for example, when a doctor injects a patient with a lethal medication.

Controversies about assisted suicide have received recent widespread attention as a result of two lawsuits challenging the constitutionality of New York and Washington laws that prohibit physician-assisted suicide. The U.S. Supreme Court heard arguments on the cases (*Vacco v. Quill*, No.

95-1858 and *State of Washington v. Glucksberg*, No. 96-110) in early 1997.[9] The litigation followed popular referenda in California and Washington in 1990 and 1991 in which proposals to legalize physician-assisted suicide were defeated. In 1992, however, Oregon voters approved a similar proposal. Oregon thus became the first jurisdiction in the United States to provide formal legal recognition of the practice of physician-assisted suicide, although court challenges delayed implementation of the law and legislative reconsideration was being discussed as this report was completed.

The committee agreed that it would not take a position on the legality or morality of assisted suicide, but it did examine some of the issues that might arise if the Supreme Court ultimately ruled either that a terminally ill person who is mentally competent and voluntarily chooses suicide has a constitutional right to self-administer lethal drugs received with the assistance of a physician or that it was constitutionally permissible for individual states, such as Oregon to permit the practice. Many of these issues were explored in friend-of-the-court briefs filed with the Court.[10]

Although proposals to legalize physician-assisted suicide typically include various safeguards or restrictions to protect patients and physicians, these provisions involve a number of ambiguities that might make them impossible or impractical to implement. For example, as noted earlier in this report, the status of being "terminally ill" has not been satisfactorily defined conceptually or in application because no boundary prognosis correlates precisely with an important clinical change and none can reliably be supported by data (Lynn et al., 1996). Subjective definitions of illness can be criticized as being so variable as to seem capricious. Already, several hospices have been challenged over terminal illness identifications, prognoses of survival, and small percentages of patients who survive for more than six months (see Chapter 6). In the case of care that is widely viewed as beneficial, the acceptance of some prognostic errors for a large population of patients is reasonable. It is harder to be so sanguine about such errors when the issue is assistance in suicide.

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[9]On June 30, 1997 (after the initial release of this report), the Supreme Court ruled that there is no general constitutional right to physician assistance in suicide. Some of the justices, however, wrote statements that suggested that a narrowly defined right might be upheld in specific circumstances.

[10]See, for example, the briefs filed by the American Geriatrics Society, the American Medical Association, the American Nurses Association, the American Psychiatric Association et al., the Project on Death in America, and Ronald Dworkin, Thomas Nagel, Robert Nozick, John Rawls, Thomas Scanlon and Judith Jarvis Thomson. The latter was reprinted in *The New York Review of Books*, March 27, 1997, pp. 41–47. Several briefs are available at www.soros.org/death/brieftxt.html.

The criterion of voluntariness also presents problems in determining patient status and articulating boundaries (e.g., what constitutes undue influence by another party). Further, the question can be raised whether serious socioeconomic disadvantage nullifies voluntariness. If a desirable treatment would bankrupt a patient's family and, therefore, a patient chooses suicide, should a physician be authorized to assist? The dilemma between complicity with societal inequalities (by allowing assisted suicides) and magnification of them (by refusing assistance in suicides) is not readily resolvable.

Similarly, requiring that patients be mentally competent raises questions about what standards will be used, what threshold will be set, how fluctuating capacities will be handled, and what will be done about directions in advance. If competence requires very good mental functioning, then few persons known to be near death may qualify. If, however, one cannot direct suicide in advance of becoming incompetent, then people may consider preemptive suicide far in advance of death.

Proposals typically require that self-administrated prescription drugs be authorized by a physician. If many physicians consider themselves ethically or otherwise precluded from doing so, pressure for more involvement of nonphysicians is likely to arise and, perhaps, to require new safeguards.

In sum, the proposed restrictions and intended safeguards in initiatives to legalize physician-assisted suicide are problematic: difficult to define, uncertain in implementation, or vulnerable to unanticipated and unwanted consequences for those they propose to protect. Resolving uncertainties would likely be a difficult process for clinicians, and the courts almost certainly would be involved in further challenges to the implementation of assisted-suicide laws.

Other questions can be posed concerning autonomy—an individual's right to exercise free choice regarding his or her life. This is the core principle that is advanced in favor of physician-assisted suicide. The committee agrees that this principle is a centrally important value. It also believes that the current serious deficiencies in the provision of care to dying people—deficiencies highlighted throughout this report—themselves compromise the autonomy principle by depriving individuals of many choices that should, and realistically can, be made available to them. As discussed in Chapter 5, substantial numbers of dying people today suffer from avoidable pain and other symptoms, and many of the arguments for physician-assisted suicide reflect fear of pain. Offering these patients just two options—either physician assistance for hastened death or continued life with untreated pain—is a highly constricted choice that undermines the principle of autonomy. Truly autonomous choice would allow for adequate relief of pain and other distressing symptoms, adequate psychological support from properly trained health care professionals, and adequate financial and per-

sonal service support for home care in preference to impersonal hospital or nursing home settings.

If, one way or another, Oregon proceeds, the committee believes that its implementation of legal physician-assisted suicide should be carefully and intensively monitored. One key objective would be to learn whether legal safeguards are truly effective. A second objective would be to determine whether general deficiencies in the care of dying people influence individual choices for physician-assisted suicide and whether legalization stimulates correction of deficiencies. If the Oregon law is implemented, advantage should be taken of the opportunity to develop a more adequate factual basis for evaluating the competing claims for and against legal recognition of physician-assisted suicide.

Individual committee members had varied views about the morality, legality, and administrability of assisted suicide. The group fully agreed, however, that the current deficiencies in the provision of care for dying people are so extensive that they may provide inappropriate incentives for people to choose hastened death if that option is made available to them without accompanying remedial measures to improve their care. The nation should not need the prod of assisted suicide to drive it to act in behalf of the dying, although this committee, realistically, believes that media coverage of the assisted suicide cases has put the issues before the public and the professions in a very attention-getting fashion.

CONCLUSION

Reliable, excellent care at the end of life is an objective that should be supported, not impeded, by public policy. Unfortunately, some laws, regulations, and policies of public/private regulatory bodies may obstruct good care, either by their specific provisions or by the fear and misunderstanding they create. Drug-prescribing laws stand out in this regard and, in the view of the committee, warrant revisions to minimize discouragement of effective pain management. Other laws and regulations reflect an overly optimistic view of the effectiveness of laws and legal documents in clarifying how people wish to be treated when dying. Legal documents have a role to play but should not deflect attention from the more significant and complex process of advance care planning as considered in Chapter 3.

Deficiencies in care of the dying were recognized well before recent assisted suicide referenda, legislative activities, and court challenges. Nonetheless, much of the recent attention to deficiencies in end-of-life care arose only when the issue of assisted suicide came before the Supreme Court. Even if assisted suicide becomes legal, both society and the professions should feel confident that no one who chooses suicide does so because care systems are deficient in meeting their needs.

Assisted Suicide

Bruce / Tom –

Karen Popp called this week to say that DOJ is ready to opine that Oregon doctors who assist suicides are not violating the Controlled Substances Act. (This is contrary to an initial DEA ruling.) We need to decide whether to accompany this ruling with a request for new legislation making assisted suicide a federal crime. I think this is a fairly terrible idea, but I know Bogala likes it. Do we need to run some kind of policy process?

Elena

U. S. Department of Justice
Office of Legal Counsel
Office of the
Assistant Attorney General
Washington, D.C. 20530

January 16, 1998

MEMORANDUM TO THE ATTORNEY GENERAL

THROUGH: THE DEPUTY ATTORNEY GENERAL

THROUGH: THE ASSOCIATE ATTORNEY GENERAL

FROM: Dawn E. Johnsen
Acting Assistant Attorney General, Office of Legal Counsel

John C. Keeney
Acting Assistant Attorney General, Criminal Division

Frank W. Hunger
Assistant Attorney General, Civil Division

SUBJECT: Physician-Assisted Suicide

In October 1997, Oregon's "Death with Dignity Act" (Oregon Act), codified as Oregon Revised Statutes ("O.R.S.") §§ 127.800-127.995, which had been approved by referendum in 1994, went into effect. The Oregon Act removes all state law disabilities and penalties that otherwise might be imposed on physicians for prescribing medication to enable their competent, terminally ill patients to end their lives, as long as physicians comply with the detailed terms of the act. In response to a joint letter from Senator Orrin G. Hatch and Representative Henry J. Hyde to the Drug Enforcement Administration ("DEA"), Administrator Thomas A. Constantine wrote on November 5, 1997, that "delivering, dispensing or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a 'legitimate medical purpose,'" and that such actions would therefore constitute "a violation of the [Controlled Substances Act, 21 U.S.C. §§ 801-971 (1994) ("CSA" or "Act")]" and could lead to the "initiat[ion] of revocation proceedings [to withdraw the physician's DEA controlled substances registration]." Id. at 2. A joint letter of December 15, 1997, addressed to you and signed by 64 members of Congress, urges the Department to support the DEA's position, while others have urged the Department to reject that view. According to Senator Hatch and Representative Hyde, the American Medical Association ("AMA") and 45 other professional associations have stated that assisted suicide is outside legitimate health care. In a meeting with Department employees, the AMA and the Oregon Medical Association affirmed that view, but

took the position that the federal government should not take adverse action against a physician who engages in such practice.

In connection with these events, you have asked us to review DEA Administrator Constantine's position and also address the relation between responses to the Oregon Act under the CSA and the federal government's response to the Arizona and California initiatives regarding the purported medical use of marijuana. This memorandum provides a brief overview of the possibility of a response under the CSA and our ultimate recommendation. We have also attached a more extensive background memorandum prepared by several attorneys in our components. Neither this memorandum nor the background memorandum considers potential actions under statutes other than the CSA. The letters from Senator Hatch and Representative Hyde requested only DEA's views on the CSA and other federal laws subject to DEA enforcement, and DEA Administrator Constantine's response discussed only actions under the CSA. We understand that members of Congress have written to the Department of Health and Human Services ("HHS") about possible adverse action against physicians under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-395 (1994), which includes criminal penalties, and that HHS has replied that it does not intend to proceed under the FDCA against physicians for assisting their patients in committing suicide in compliance with Oregon law.

The Oregon Act provides for a detailed procedure by which a mentally competent, terminally ill patient may request to end his or her life "in a humane and dignified manner." O.R.S. § 127.805. The procedure requires, for example, that the patient's competence and the voluntariness of the request be documented in writing and confirmed by two witnesses, see id. § 127.810(1), that the patient's illness and competence and the voluntariness of the request be confirmed by a second physician, see id. § 127.820, and that the physician and patient observe certain waiting periods, see id. §§ 127.840, 127.850. Once a request has been properly documented and the requisite waiting periods have expired, the patient's attending physician may prescribe, but not administer, medication to enable the patient to take his or her own life. As a matter of state law, physicians acting in accordance with the Oregon Act are immune from liability as well as any adverse disciplinary action for having rendered such assistance.

The Office of Legal Counsel, the Criminal Division, and the Civil Division, all agree that the federal government does not have authority under the CSA to take adverse action against a physician for assisting a suicide in compliance with the Oregon Act, and would be happy to assist in preparing responses to congressional or other inquiries regarding this matter. Because they reach this conclusion for somewhat different reasons, the two views are briefly summarized below.

I. Views of the Office of Legal Counsel and the Criminal Division

In refraining from striking down state laws banning the practice permitted by Oregon, the Supreme Court recently noted: "Throughout the Nation, Americans are engaged in an earnest

and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society." Washington v. Glucksberg, 117 S. Ct. 2258, 2275 (1997). Although the Court rejected a challenge that such a ban is unconstitutional whenever applied to mentally competent, terminally ill patients, it left open the possibility of a successful, particularized challenge brought by an individual patient. Id. at 2275 n.24. A decision by the Department to pursue adverse action against physicians for assisting in suicide would not necessarily end the national debate (because it could ultimately be overturned by federal legislation), but, as we discuss below, such a decision would have an impact on this debate beyond anything Congress would have intended in crafting the CSA.

The relevant provisions of the Controlled Substances Act allow for criminal prosecutions against physicians who are acting beyond "the course of professional practice," 21 U.S.C. § 802(21), and it provides for the revocation of physicians' licenses for such criminal conduct or for "conduct which may threaten the public health and safety," id. § 823(f)(5). The statute itself provides virtually no guidance on the scope of these terms. Apart from expressly authorizing the Secretary of HHS, in consultation with the Attorney General, to determine "the appropriate methods of professional practice in the medical treatment of . . . narcotic addicts," 42 U.S.C. § 257a (1994), the CSA is silent with respect to determining the proper scope of the professional practice of medicine.

In the context of a criminal enforcement action, especially given the rule of lenity, the statute must be read as authorizing the prosecution of physicians only when they are not reasonably and in good faith acting as physicians. To the extent that federal law does not specifically address this question, the inquiry must be factual. The Department has not been authorized to decide what, as a normative matter, it believes ought to be part of the course of professional practice. In light of the considered judgment of the state as primary regulator of the profession to authorize this conduct as part of the practice of medicine, and recent reports revealing that a significant minority of physicians throughout the United States have, in fact, engaged in this conduct, we are unable to conclude that assisting the suicide of a competent, terminally ill patient is beyond the course of professional practice within the meaning of the CSA. We therefore believe that the CSA does not authorize the prosecution of physicians for assisting in suicide in compliance with Oregon law.

A license revocation proceeding for "conduct which may threaten the public health or safety," although somewhat less implausible, should ultimately be rejected as well. As we have just stated, a physician who assists a mentally competent, terminally ill patient in committing suicide in compliance with state law, cannot be said to be acting beyond the current practice of medicine within the meaning of the CSA. In light of the purposes of the CSA, Oregon's clear judgment that the benefits of physician-assisted suicide outweigh the risks, and the existing practice of a significant minority of physicians, we do not see the basis on which the Department could conclude that such assistance threatens the public health and safety within the meaning of the CSA. The CSA, which is concerned primarily with the abuse of drugs deriving from their "stimulant, depressant, or hallucinogenic effect on the central nervous system," 21 U.S.C. § 811(f), and which was drafted to give some deference in license revocation proceedings to state

licensing authorities, was not generally intended as a means to weigh in on debates about good or bad practices of medicine.

A determination that the Department lacks the authority to proceed against physicians who assist in suicide would not necessarily undermine efforts to prevent the use of marijuana for purported medical purposes in states, such as California, that have eliminated state law prohibitions on such use of the drug. Congress initially placed marijuana in Schedule I, and the Attorney General (as delegated to the DEA Administrator) is justified in refraining from rescheduling it to Schedules II-V as long as the drug has a "high potential for abuse," and there is "no currently accepted medical use in treatment in the United States" and "a lack of accepted safety for use of the drug . . . under medical supervision." 21 U.S.C. § 812(b)(1). Once having scheduled marijuana as a substance that may not be prescribed, the Attorney General (through the DEA Administrator) may reasonably find that prescribing the drug even for purported medical use threatens the public health and safety. The CSA does not give the Attorney General or the DEA Administrator any comparable authority to determine for the nation whether a particular use of a Schedule II-V drug is part of "the course of professional practice."

Finally, a decision by the Department to apply the "public health and safety" factor in a manner that would intrude into state affairs as deeply as it would here, risks offering courts an opportunity to limit the Department's administrative discretion. The Fourth Circuit has twice held that administrative interpretations that fundamentally shift the federal/state balance must be "clearly" authorized by statute. See United States v. Wilson, ___ F.3d ___, 1997 WL 785530 (4th Cir. Dec. 23, 1997); Virginia Dep't of Educ. v. Riley, 106 F.3d 559 (4th Cir. 1997) (en banc). The Administration has taken issue with the holding of these cases. A Department interpretation that the CSA authorizes revoking the licenses of Oregon physicians or assisting in their patients' suicides in accordance with state law may prompt a court to entrench, or even further expand, this principle limiting executive branch authority.

II. Views of the Civil Division

Civil Division agrees with the conclusion that the federal government does not have authority to take adverse action against a physician for assisting a suicide in compliance with the Oregon Act, but for reasons different than those expressed by the Office of Legal Counsel and the Criminal Division or the background memorandum. Civil Division believes that the meaning of the CSA's term "in the course of professional practice" is ambiguous. Because of this ambiguity, it is necessary to look to the legislative history to discern Congressional intent. That legislative history shows that Congress was concerned with drug abuse, and concerned with doctors as a source of drug diversion to illegal markets. Therefore, Civil Division believes that the CSA should not be read to allow for criminal or civil action where a doctor prescribes medicine within a *bona fide* physician-patient relationship, pursuant to a physical examination or similar inquiry, where there is no implication for drug diversion. (Civil Division does not agree with the argument that any improper use of a drug constitutes diversion and/or conduct

outside the course of professional conduct.) Civil Division does believe that if a doctor violates state law within a *bona fide* physician-patient relationship, the CSA authorizes federal action regardless of the implications for diversion.

Because the Civil Division believes that the CSA does not authorize the federal government to take adverse action against a physician for prescribing medicine within a *bona fide* relationship, and because prescribing under the Oregon Act would, by definition, occur within that relationship, the Civil Division believes that the federal government has no authority under the CSA to take adverse action against a physician for assisting in suicide in compliance with Oregon law.

Finally, Civil Division agrees that the conclusion that the federal government does not have authority to take adverse action against a physician for assisting a suicide in compliance with the Oregon Act is not inconsistent with the government's position in the "medical marijuana" cases. The CSA does allow the federal government to intrude into a *bona fide* relationship when a Schedule I substance is at issue. In contrast to the practice of medicine generally, Congress specifically gave the federal government the authority to determine whether drugs have a "currently acceptable medical use in treatment in the United States."

Assisted Suicide

U.S. Department of Justice

Criminal Division

Washington, DC 20530-0001

January 16, 1998

MEMORANDUM

To: Jonathan Schwartz
Associate Deputy Attorney General

Through: John C. Keeney
Acting Assistant Attorney General

Mary Lee Warren
Deputy Assistant Attorney General

From: Theresa M.B. Van Vliet
Chief, Narcotic and Dangerous Drug Section

Re: Physician-Assisted Suicide

This memorandum reviews DEA Administrator Constantine's conclusion in a letter to Senator Hatch and Representative Hyde of November 5, 1997, that "delivering, dispensing or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a 'legitimate medical purpose,'" and that such actions would therefore constitute "a violation of the [Controlled Substances Act, 21 U.S.C. §§ 801 et seq. (CSA or Act)]" and could lead to the "initiat[ion] of revocation proceedings [to withdraw the physician's DEA controlled substances registration]." It also provides a brief discussion of the relation between responses to the Oregon Act under the CSA and the federal government's response to the Arizona and California initiatives regarding the purported medical use of marijuana.

Part I of this memorandum reviews the mechanisms and key provisions of the Oregon law. Part II considers whether the CSA could provide the basis for adverse criminal, civil, or administrative enforcement action against Oregon physicians who, in compliance with Oregon law, assist a patient in committing suicide. Part III briefly surveys the Supreme Court's recent decisions on assisted suicide and includes a short discussion of "medical marijuana." Part IV offers some policy considerations and suggestions for action.

I. THE OREGON DEATH WITH DIGNITY ACT

On November 8, 1994, Oregonians voted in favor of the "Oregon Death with Dignity Act" ("the Act"), codified as Oregon Revised Statutes (O.R.S.) §§ 127.800-127.995, which allows Oregon physicians to prescribe medication to enable competent terminally ill patients to end their lives. See Attachment A. The operation of the Act was stayed by an injunction that was lifted by court order on October 27, 1997. Oregon voters rejected a ballot measure that would have repealed the Act on November 4, 1997.

An adult resident of Oregon, who has been determined to be suffering from a terminal disease and has voluntarily expressed a wish to die, may initiate a request for medication for the purpose of ending his or her life "in a humane and dignified manner." O.R.S § 127.805.

The procedure requires two oral requests and one written request. The written request must be signed by at least two witnesses who attest that the patient is "capable" of making an informed decision to end his or her life and is acting voluntarily. O.R.S. § 127.810(1). At least one witness must be someone other than a relative, beneficiary of the estate or operator or employee of the health care facility. O.R.S. § 127.810(2). In addition, the attending physician cannot be a witness. O.R.S. § 127.810(3). The two oral requests must be at least 15 days apart. At the time of the second oral request, the attending physician shall offer the patient the opportunity to rescind it. O.R.S. § 127.840. The actual prescription cannot be written until 48 hours after the patient has made a written request, and at least 15 days after the initial oral request. O.R.S. § 127.850. A patient may rescind his or her request at any time and in any manner, without regard to his or her mental state. O.R.S.§ 127.845.

The attending physician must ensure that the patient is making an informed decision, ensure compliance with the terms of the Act, and refer the patient to a second physician, who shall confirm that the patient is terminally ill, capable, acting voluntarily and has made an informed decision. O.R.S. § 127.815(1-3). The attending physician shall also request that the patient notify his or her next of kin, inform the patient that his or her request may be withdrawn at any time and in any manner, and ensure that all appropriate steps are carried out prior to writing a prescription that will enable the patient to end his or her life. O.R.S § 127.815(5), (6) and (9). The confirming physician shall examine the patient and his or her medical records, and verify in writing that the patient is suffering from a terminal disease, is capable of making an informed decision to end his or her life, and is acting voluntarily. O.R.S. § 127.820.

The Oregon Death with Dignity Act does not permit a physician

or any other person to end a patient's life by lethal injection, mercy killing or active euthanasia. Essentially, the Act requires that the patient must take his or her own life through self-administration of medication provided by the attending physician. However, actions taken in accordance with the Act "shall not, for any purpose, constitute suicide, assisted suicide, mercy killing or homicide, under the law." O.R.S. § 127.880. Moreover, no person (including those present at the suicide) shall be subject to civil or criminal liability or professional disciplinary action for good faith compliance with the Act. O.R.S. § 127.885. Finally, any individual who coerces or exerts undue influence on, or without authorization alters or forges a request for medication that ultimately causes the patient's death, is subject to a class A felony. O.R.S. § 127.890.

As long as a physician complies with the procedures of the Act, he or she will face no adverse consequences under state law for assisting a suicide. The next section considers whether a physician who complies with the Act could nonetheless be subject to adverse consequences under the CSA.

II. FEDERAL LAW AND ASSISTED SUICIDE

Two federal statutes are potentially implicated when a physician prescribes controlled substances to a terminally ill patient for use in suicide: the Controlled Substances Act (CSA or Act), 21 U.S.C. § 801 et seq., and the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq. As a general matter, the CSA provides much more straightforward theories for criminal prosecution, civil penalties, injunctions and administrative action triggered by the (illegal) prescribing practices of a physician. It is, however, important to note at the outset that the CSA was not intended to regulate the quality of the practice of medicine. Except for specific implementing regulations dealing with the treatment of addicts, see 42 U.S.C. 257a; CFR § 291.505, the CSA is essentially silent with regard to regulating the practice of individual physicians. The FDCA is even less concerned with physician prescribing practices, and is instead primarily designed to ensure that drugs marketed in the U.S. are safe and effective, making theories for prosecution of physicians substantially more attenuated and complex under the FDCA than the CSA.

The applicable statute depends on the drug involved. We understand that a lethal dose would probably involve a combination of drugs. First, the patient would be sedated using either a barbiturate (e.g., sodium pentothal) or an opiate (e.g., morphine). Then, one or more drugs would be used to paralyze the muscles and/or

stop the heart.[1] The sedatives are controlled substances subject to strict federal controls under the CSA. Most lawfully available opiates and barbiturates are in Schedule II of the CSA, the most strictly regulated category of substances available for non-research purposes.[2] Other depressants which might be used to sedate the patient may include benzodiazepines in Schedule IV.[3] Other drugs that could be used are not controlled substances under the CSA, but are regulated under the FDCA. It is noteworthy that in cases where both controlled and non-controlled substances are used in an assisted suicide, the actual agent of death is intended to be the non-controlled substance; the controlled substance is simply used to sedate the patient so that the onset of death is painless. Because HHS has indicated that it would not pursue adverse action under the FDCA against physicians who prescribe drugs to assist a terminally ill patient in suicide, we limit our examination of potential adverse action against the physician to the CSA.

I. Criminal Felony Prosecution — 21 U.S.C. § 841

1. Statutory and Regulatory Analysis

The basic domestic drug trafficking provision of the Controlled Substances Act (CSA), 21 U.S.C. § 841, applies to actions of physicians who prescribe drugs illegally, as well as street dealers. Section 841 makes dispensing a controlled substance unlawful unless otherwise permitted by the law: "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to distribute . . . or dispense . . . a controlled substance." 21 U.S.C. § 841 (emphasis added). Although the word "prescribe" does not appear in this provision, the

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[1] The procedures for lethal injection for capital defendants in the State of Oregon, for example, call for, in order, 2.0 grams of thiopental sodium (a barbiturate) in 50 cc of diluent, 50 cc of saline solution, 100 mg of pancuronium bromide (a neuromuscular blocking agent that paralyzes the muscles and makes them go limp) in two 50 cc applications, 50 cc saline solution, and three applications, 50 cc each, of potassium chloride (a cardioplegic agent that stops the heart). Thiopental sodium is scheduled under the CSA; pancuronium bromide and potassium chloride are not.

[2] See 21 C.F.R. § 1308.12(b), (c) and (e). The CSA grants scheduling authority to the Attorney General, see 21 U.S.C. §§ 811(a) and 812(a), which is in turn delegated to the DEA, under 21 C.F.R. § 0.100(b).

[3] See 21 C.F.R. § 1308.14(c). The founder of the Hemlock Society, Derek Humphrey, lists both barbiturates and depressants in his practical guide to assisted suicide, Final Exit, 117-120 (1991).

definition of "dispense" includes prescribing: i.e., "to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance." 21 U.S.C. § 802(10) (emphasis added).

The "subchapter" referred to in the first clause of § 841 is Subchapter I, Chapter 13, Title 21 of the U.S. Code. Part C of the subchapter governs the registration of those persons, including physicians, who may lawfully handle controlled substances. Physicians and other health practitioners who wish to "dispense" (to include prescribe) controlled substances must register with the Attorney General (a function delegated to the DEA) and renew that registration periodically.[4] 21 U.S.C. § 822(a)(2). These registrants are "authorized to . . . dispense [including prescribe] such substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter." 21 U.S.C. § 822(b).

Under this subchapter, "practitioner" has special meaning. It includes "a physician, dentist, . . . pharmacy . . . or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices, to dispense . . . [or] administer . . . a controlled substance in the course of professional practice." 21 U.S.C. § 802(21). Thus, in order for a prescription to be authorized by this subchapter, it must be written in "the course of professional practice."[5]

Although the statute does not define the scope of "the course of professional practice," the Act contains the implicit assumption elsewhere that prescriptions written in the course of professional practice are for a medical purpose. See 21 U.S.C. § 829. Under § 829(a), which, on its face, addresses mainly the form a

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[4] The current registration and renewal period is three years. 21 C.F.R. § 1301.13.

[5] The limitation of the CSA's approval of a physician's actions to those taken "in the course of professional practice" is implicit elsewhere in the Act as well. See, e.g., 21 U.S.C. § 827(c)(1)(A) (rendering certain reporting requirements inapplicable when drugs are prescribed or administered "by a practitioner in the lawful course of his professional practice"); 21 U.S.C. § 828(e) (unlawful for any person to obtain drugs with order forms "for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business in such substances or in the course of his professional practice or research"); 21 U.S.C. § 844(a) (prohibiting possession of controlled substances unless obtained "from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized").

prescription must take, a written prescription is required for the distribution or dispensing of a Schedule II controlled substance. Under § 829(b), either a written or oral prescription will suffice for substances in Schedules III and IV. Under § 829(c), no prescription is required for Schedule V substances, but they may be distributed or dispensed only "for a medical purpose." Although the text of § 829(a) and (b) do not contain an express "medical purpose" limitation, the Supreme Court has noted that "[t]he medical purpose requirement explicit in subsection (c) could be implicit in subsections (a) and (b)." United States v. Moore, 423 U.S. 122, 138 n.13 (1975).

The DEA has issued a regulation that, according to the Supreme Court's decision in Moore, "makes [this medical purpose limitation] explicit." Moore, 423 U.S. at 138 n.13. Section 821 of Title 21 authorizes the "[t]he Attorney General . . . to promulgate rules and regulations . . . relating to the regulation and control of the . . . dispensing of controlled substances." More general regulatory authority is vested at 21 U.S.C. § 871(b), which provides:

> The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.

Pursuant to that authority, the DEA has promulgated a regulation at 21 C.F.R. §1306.04(a):

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. . . . . An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of [§ 829] and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties for violations of the provisions of law relating to controlled substances. (emphasis added).

Section 829, as noted above, sets forth technical requirements of prescriptions in the various controlled substance schedules, e.g., that a prescription for a Schedule II drug must be written, except in emergency circumstances, and that it may not be refilled. § 829(a). The "hook" for the practitioner in § 829 is the very requirement of a "prescription." When a prescription is written other than in "the usual course of professional treatment" or for other than a "legitimate medical purpose," it is not a prescription at all, and thus the prescriber enjoys no protection from penalties applicable to lay persons under the CSA.

2. Application of the Law

In reported cases in which physicians and other health professionals have been prosecuted under 21 U.S.C. § 841, courts have not always been clear which theory of criminal liability they are applying: a statutory analysis (in which only "in the course of professional practice" would be explicitly relevant), a regulatory analysis (in which case "usual course of professional practice" and "legitimate medical purpose" would be explicitly relevant) or a combination.[6] The Supreme Court in United States v. Moore, 423 U.S. 122 (1975), implicitly endorsed an instruction that included both concepts.

In Moore, the trial court instructed the jury:

> [1] that it had to find, "beyond a reasonable doubt, that a physician, who knowingly or intentionally, did dispense or distribute (methadone) by prescription, did so other than in good faith for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States,"[7]

and

> [2] that [the defendant] could not be convicted if he merely made "an honest effort" to prescribe . . . in compliance with an accepted standard of medical practice.[8]

The question decided by the Court in Moore, however, did not concern the particular standard by which to judge whether a physician's prescribing practices may violate the CSA, but instead addressed whether a registered physician was, by virtue of such registration, entirely immune from criminal prosecution under 21 U.S.C. § 841. In resolving the question of absolute immunity, the Court summarized its holding "that registered physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice," id. at 124, and explained that "the statute, viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the

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[6] An excellent discussion of the legal bases for prosecution of physicians appears in a case decided after the D.C. Circuit Court's decision in Moore but before the Supreme Court decision in Moore. See United States v. Green, 511 F.2d 1062, 1069-70 (7th Cir. 1975).

[7] United States v. Moore, 423 U.S. 122, 139 (1975)

[8] Id. at 142 n.20.

course of his 'professional practice.'" Id. at 140. The government had argued that the defendant's practices were "inconsistent with all accepted methods of treat[ment]," and the defendant had conceded that "he did not observe generally accepted medical practices." 423 U.S. at 126 (emphasis added). In upholding the defendant's conviction under § 841, the Court noted that the physician was not acting within the realm of "reasonable discretion in treating patients and testing new theories," and that the defendant's conduct "exceeded the bounds of 'professional practice'":

> [H]e gave inadequate physical examinations or none at all. He ignored the results of the tests he did make. He did not give methadone at the clinic and took no precautions against its misuse and diversion. He did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded. He did not charge for medical services rendered, but graduated his fee according to the number of tablets desired. In practical effect, he acted as a large-scale 'pusher' not as a physician.

Id. at 142-43. In other words, the defendant in Moore could be prosecuted because he was no longer "act[ing] . . . as a physician." See also id. at 140 ("Implicit in the registration of a physician is the understanding that he is authorized only to act 'as a physician.'").

Courts following Moore have used a "good faith" standard in evaluating whether the actions of a physician who prescribed a controlled substance have violated the CSA. Whether the standard is objective or subjective has not been clearly addressed, with courts looking at the surrounding circumstances as well as expert testimony in reaching a conclusion. See United States v. Kaplan, 895 F.2d 618, 624 (9th Cir. 1990); United States v. Vamos, 707 F.2d 1146, 1151 (2d Cir. 1986); and United States v. Norris, 780 F.2d 1207, 1209 (5th Cir. 1986).

The legal test may well be formulated in several ways: (1) Is a physician's prescription for a controlled substance for use in suicide issued "in the course of professional practice" (under pure statutory analysis); (2) is it for a "legitimate medical purpose" and "in the usual course of his professional practice" (under a regulatory analysis); (3) does it comport with "a standard of medical practice generally recognized and accepted in the United States" (under the jury charge implicitly approved in Moore); or (4) is the physician no longer "acting as a physician" (as Moore alternatively noted).[9]

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[9] The legislative antecedent to the Controlled Substances Act, commonly known as the Harrison Anti-Narcotic Act, included both the terms "in the course of his professional practice" and "the

However the legal test is phrased, the analytical path will be similar.[10] To the extent that a subjective good faith inquiry is relevant, we can assume that a physician will act in good faith by assisting a dying patient to commit suicide in a humane manner, pursuant to state law. However, subjective good faith alone is not sufficient. There remains the normative inquiry, present in some form in all of the reported cases, whether physician-assisted suicide is considered (to choose the statutory formulation) part of "the course of professional practice."

The CSA itself and the legislative history provide little guidance on how this normative inquiry should be conducted, let alone how it should be resolved. The only discussion in the statute about the proper method of determining the scope of medical practice is with regard to standards for the treatment of narcotic addicts. As part of the CSA, Congress specifically authorized the Secretary of Health, Education, and Welfare (now Health and Human Services (HHS)), in consultation with the Attorney General and national addict treatment organizations, to "determine the appropriate methods of professional practice in the medical treatment of . . . narcotic addiction." 42 U.S.C. § 257a. In the context of passing this provision, Congress expressed concern in its 1970 House Report about "federalizing" standards of medical practice, yet recognized that such federal determinations are inevitable where a federal criminal statute punishes unlawful physician prescribing. Experience had shown that few physicians would treat addicts because of uncertainty as to the extent to which they could prescribe narcotics. In the House Report to the bill that allowed for federal determination of the appropriate scope of medical treatment of narcotic addicts, the Committee on Interstate and Foreign Commerce noted:

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legitimate practice of his profession." See Anti-Narcotic Act of December 17, 1914, 38 Stat. 785, Sec. 2. Other parts of this law were amended, but not Section 2, by the Revenue Act of 1918, February 24, 1919, 40 Stat.1057, 1130. There is no indication that Congress intended elimination of the latter phrase to alter the scope of a physician's authority to prescribe drugs.

[10] Courts have found no distinction between the statutory phrase "in the course of professional practice" and a "legitimate medical purpose." United States v. Rosenberg, 515 F.2d 190, 192 (9th Cir. 1975). Cf. United States v. Kirk, 584 F.2d 773, 784 (6th Cir. 1978); United States v. Plesons, 560 F.2d 890, 897 n.6 (8th Cir. 1977), both of which find no difference between what they dub the "statutory" (actually regulatory) phrase "in the usual course of professional practice" (the statute omits the word "usual") and the regulatory phrase "legitimate medical purpose." Taken together, the courts appear to find all three phrases synonymous.

> Although the committee is concerned about the appropriateness of having Federal officials determine the appropriate method of the practice of medicine, it is necessary to recognize that for the last 50 years this is precisely what has happened, through criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinion of the Federal prosecutors of what constitutes appropriate methods of professional practice. In view of this situation, this section will provide guidelines, determined by the principal health agency of the Federal Government, after consultation with the appropriate national professional organizations.[11]

This passage indicates that Congress was cognizant of the problem of federal officials determining the appropriate methods of medical treatment, though prepared to permit such federal intrusion in the area of narcotics treatment, and that it made the deliberate decision to assign the responsibility of determining standards for such treatment to the highest federal health officials who were to consider the views of national professional organizations before issuing guidelines. The CSA provides no comparable mechanism, however, for federal officials to determine the scope of medical practice beyond the sphere of narcotics treatment. Neither this passage in the House report, nor the language of 42 U.S.C. § 257a itself, then, resolves the issue of legislative intent as to the reach of the criminal provisions of the CSA with respect to areas beyond the treatment of narcotic addicts, such as where a state has promulgated standards of medical practice but the federal government has not.[12]

The caselaw is only marginally more helpful than the statute and the legislative history in approaching the normative issue of the scope of professional practice. A close reading of Moore would appear to indicate that conduct may be part of medical practice despite considerable disagreement within the profession about the particular course of action. The trial judge charged

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[11] H.R. Rep. No. 91-1444, 91st Cong., 2d Sess. (1970, reprinted in 1970 U.S.C.C.A.N. 4566, 4581.

[12] In a letter to Jonathan Schwartz dated December 3, 1997 from Oregon Deputy Attorney General David Schuman, at page 5, the first clause of this passage -- that Congress was "concerned about the appropriateness of having federal officials determine the appropriate method of the practice of medicine" -- is cited for the proposition that the legislative history supports Oregon's position, but the countervailing reality of federal prosecution of physicians, cited in the second clause, was omitted from the letter.

the jury to balance Dr. Moore's conduct in light of an acceptable course of professional conduct, not a nationally accepted standard, by instructing the jury that in order to convict, it must find that "a physician, who knowingly . . . did dispense or distribute . . . did so other than in good faith for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally accepted in the United States," and that the defendant could not be convicted "if he merely made 'an honest effort' to prescribe for detoxification in compliance with an accepted standard of medical practice." (emphasis added). Later courts, in contrast, while correctly quoting Moore with regard to this jury charge, have apparently read it to require that a physician's actions conform to a standard accepted by physicians throughout the nation, See, e.g., Vamos, 707 F.2d 1146, 1151.

Ultimately, however, none of these cases settles the issue of the parameters of the normative inquiry, because none involved a reasonably widespread, though controversial, standard of practice. Moreover, certainly no court has considered the significance of a clearly distinct local or specialized practice, or the issue of whether the scope of "the course of professional practice" under federal law would be influenced by an explicit, state statutory grant of permission to physicians to do something contrary to the predominant medical norm.[13] In virtually all of

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[13] Cases challenging the Administrator's refusal to reschedule drugs from Schedule I to Schedule II, which involve the related question whether a drug has a "currently accepted medical use in treatment in the United States," 21 U.S.C. § 812(b)(1), have involved the question of the significance of the view of "a respectable minority of physicians." These cases, however, are also ultimately inconclusive, because they do not translate into guidance for how the scope of "the course of professional practice" should be determined for purposes of § 841. In Grinspoon v. DEA, 828 F.2d 881 (1st Cir. 1987), for example, the court on the one hand held that "Congress did not intend 'accepted medical use in treatment in the United States' to require a finding of recognized medical use in every state," Id. at 886, while on the other dismissing the argument that Congress intended "to have certain members of the medical community [as opposed to the Administrator of the DEA] determine whether a substance has an 'accepted medical use in treatment in the United States.'" Id. at 892. Alliance for Cannabis Therapeutics v. DEA, 930 F.2d 936, 939 (D.C. Cir. 1991), also involved a challenge to the Administrator's refusal to move a substance (marijuana) from Schedule I to Schedule II despite the fact that a "respectable minority of physicians" found the substance useful for medical treatment. In light of the fact that Congress required the Administrator to consider "'the scientific evidence of [the drug's] pharmacological effect' and the 'state of current scientific

the reported cases we discovered, the doctor's trafficking activities have been so blatant as to render it unnecessary to make fine distinctions on legal standards. Nearly every diversion case has involved, in one guise or another, a "pill mill" or "script selling" operation, and typically includes one or more of the following fact patterns:

- No physical examination, or only a very perfunctory initial examination, of patients (in many cases the patients being undercover investigators), and no follow-up examinations prior to subsequent prescriptions;

- Missing or inadequate entries concerning the medications on the patient charts;

- Patients request the number and type of pills they want, often using street names (e.g., "reds" or "whites");

- The fee -- often paid in cash -- is set by the number of pills prescribed rather than the patient visit; or

- One or more specified pharmacies, known to the physicians and patients, participate in the scheme.[14]

We have found only two reported cases in which the government sought to penalize less blatant prescribing practices of a physician. Both resulted in reversals of the adverse action initially taken against the physician.[15]

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knowledge regarding the drug,' 21 U.S.C. § 811(c)(2), (3)," however, the court held it was not an "unreasonable application of the statutory phrase ['accepted medical use']" for the Administrator "to emphasize the lack of exact scientific knowledge as to the chemical effects of the drug's elements" and discount the available "anecdotal evidence." Id. at 939.

[14] See, e.g., Moore, 423 U.S. at 126; United States v. Vamos, 707 F.2d 1146, 1148 (2nd Cir.. 1986) (nurse convicted of aiding and abetting physician); United States v. Rosenberg, 515 F.2d 190, 192 (9th Cir. 1975); Jin Fuey Moy v. United States, 254 U.S. 189 (1920).

[15] Linder v. United States, 268 U.S. 5, 22 (1925) (reversing a conviction under the Harrison Narcotics Act of a physician who gave an addict "moderate amounts of drugs for self-administration in order to relieve conditions incident to addiction"); Humphreys v. Drug Enforcement Administration, 96 F.3d 658 (3d Cir. 1996)

Although the statute, legislative history, and caselaw do not provide definite guidance on how to determine whether a given course of conduct is within the scope of professional practice, the statute and legislative history do indicate that, as a general matter, Congress appears to have been conscious of the state's general prerogative to regulate the practice of the profession. Congress required the DEA to consider the actions of state licensing and disciplinary authorities as a criterion for initial registration, under 21 U.S.C. § 823(f), and for DEA administrative sanctions, by reference in 21 U.S.C. § 824(a)(4). A plausible reading of the Supreme Court's leading case, Moore, fairly suggests that a standard of practice need not be the leading national course of treatment to qualify as part of the practice of medicine. Where Congress has not charged any particular federal official with the task of determining the scope of medical practice generally, one might accordingly consider three factors in determining the scope of "the course of professional practice": (1) relevant federal and state[16] law; (2) the opinions of respected professional organizations; and (3) the actual conduct of physicians.

There is little relevant federal law bearing directly on the question whether physician-assisted suicide forms part of the practice of medicine. According to a July 29, 1997, letter from Senator Orrin Hatch and Representative Henry Hyde, "[t]he Health Care Financing Administration has stated that physician-assisted suicide is not 'reasonable and necessary' to the diagnosis and treatment of disease or injury and is therefore barred from reimbursement under Medicare." Coverage of expenses by the Medicare program, however, does not necessarily indicate whether a procedure is considered part of the practice of medicine. Cosmetic surgery, for example, is not covered under Medicare "except as required for the prompt repair of accidental injury or

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(reversing license revocation for prescribing drugs in the names of close associates of a famous patient) (discussed *infra.* at II.C., p. 21).

[16] To be sure, as a general matter, the CSA prevails over conflicting state and local laws, even when they regulate the practice of the medical profession. As the Ninth Circuit put it: "The question of whether federal criminal laws have been violated is a federal issue to be determined in federal courts." Rosenberg, 515 F.2d 190, 198 n.14 (9th Cir. 1975). The question faced here, however, goes to determining the scope of the federal prohibition itself not whether the federal prohibition, once determined, trumps state law. In light of Congress's concern for states' ability to regulate the medical profession, it would appear reasonable to look in part to state law in determining the scope of "the course of professional practice."

for improvement of the functioning of a malformed body member," 42 U.S.C. § 1395y(a)(10), although such surgery is undoubtedly part of the practice of medicine. The letter from Senator Hatch and Representative Hyde also cites the "Assisted Suicide Funding Restriction Act of 1997," P.L. 105-12, signed into law on April 30 of this year to bar the use of federal funding for assisted suicide. Although this law clearly indicates that the federal government will not provide financial support for assisted suicide, the law at the same time recognizes that "it may become lawful in areas of the United States to furnish services in support of such activities." 42 U.S.C. § 14401(a)(3).

State law in Oregon, of course, is clear on the matter and would indicate that such action is part of medical practice. The Oregon Death With Dignity Act ("Oregon Act") was approved by the voters of that state through a referendum known as Measure 16, and reaffirmed earlier this year through a rejection of a repeal by referendum. This Act establishes that Oregonians believe the benefits of narrowly circumscribed assisted suicide law outweigh the risks. The Act provides immunity from civil, criminal or professional disciplinary actions for practitioners who participate in a patient's suicide in good faith compliance with the law. O.R.S. §127.885. And, presumably to increase the protection afforded physicians, the Act provides that actions taken in accordance with its provisions "shall not, for any purpose, constitute . . . assisted suicide." O.R.S. §127.880.

Professional disciplinary bodies and professional associations have generally stated that physicians should not assist in suicide. The American Medical Association, for example, has concluded that "[p]hysician assisted suicide is fundamentally incompatible with the physician's role as healer." AMA Code of Ethics § 2,211 (1994). According to a July 29, 1997, letter from Senator Orrin Hatch and Representative Henry Hyde, the AMA is joined in this view by the American Nurses Association, the American Psychiatric Association, and at least 43 other national specialty and state medical societies that have condemned assisted suicide. In recent meetings with Department employees, however, representatives of the AMA, the Oregon Medical Association, and the American Society of Anesthesiology, while affirming that a physician should not assist in suicide, took the position that the federal government should not take adverse action against a physician who engages in such a practice. Without reading too much into this latter position, it may indicate a difference between the "endorsement" of a given practice by professional organizations, which physician-assisted suicide clearly lacks, and the recognition by professional organizations that a given course of conduct is currently part of the good faith practice of respectable practitioners, which may be increasingly true of physician-assisted suicide.

Indeed, the reality is that assisted suicides are not uncommon practices in the United States. In one study conducted before the Oregon Act became effective, seven percent of Oregon physicians surveyed admitted to writing a prescription for a lethal dosage for at least one patient.[17] In a study in Washington State, 26% of physician respondents (i.e, 216 of 826) had received a request from a patient for assistance in hastening death within the past year. Of the 156 patients who specifically requested physician-assisted suicide during the one-year survey period, the physician provided the requested prescription in 38 cases (24%); they also granted 14 of 58 (24%) requests for euthanasia.[18] In sum, viewing the official positions of leading professional organizations against the real-world practice of medicine, the observation of a Boston Globe writer appears apt that "[a] profound gap is widening between longstanding legal and medical prohibitions and an emerging practice of assisting death."[19]

3. Penalties for Conviction Under § 841

If a physician were convicted in an assisted suicide case under § 841, the penalty under the statute and guidelines might be severe. Assuming a Schedule II barbiturate or opiate were prescribed and it was found that "death or serious bodily injury resulted from the use of such substance," the doctor would be subject to imprisonment for 20 years to life, plus a fine of the

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[17] Melinda A. Lee, et al., *Legalizing Assisted Suicide - Views of Physicians in Oregon*, 334 N.Eng.J.Med. 310, 313 (1996). This study is cited in Peter G. Daniels, Comment, *An Illinois Physician-Assisted Suicide Act*, 28 Loy.U.Chi.L.J. 763, 772 & n.86. (1997). Daniels notes that other studies have reported higher figures, but they have posed the question more broadly. He cited as an example Ezekiel J. Emanual, et al., *Euthanasia and Physician-Assisted Suicide: Attitudes and Experiences of Oncology Patients, Oncologists, and the Public*, 347 The Lancet 1805 (June 29, 1996).

[18] Anthony L. Back, et al., *Physician-Assisted Suicide and Euthanasia in Washington State-Patient Requests and Physician Responses*, 275 JAMA 919, 919-20, 922 (1996). In the 114 of 155 cases (73%) in which no lethal prescription was provided, the reason cited most often had to do with the specific patient: e.g., that the symptoms were potentially treatable or the patient was depressed. It should be noted that in 34 of the rejected requests, the reporting physicians expressed the view that physicians should never participate in an assisted suicide. Id at 922.

[19] Dick Lehr, *Increasingly, Secretly, Physicians are Helping the Incurably Ill to Die*, Boston Globe, April 25, 1993 (City Edition), Metro Region at 1.

greater of $1,000,000 or that authorized under Title 18. 21 U.S.C. § 841(b)(1)(C). The U.S. Sentencing Guidelines provide for a penalty range of 19.5 to 24.4 years.[20] Needless to say, death is a likely result contemplated by the doctor who issues a lethal dose prescription (although many such prescriptions are never taken), and death is the precise result envisioned by the patient who self-administers the lethal dose. In what we expect to be the typical case where the controlled substance is used only to sedate the patient and a non-controlled drug is the actual agent of death, an argument can be made the controlled substance prescription did not "result" in death. In a case where the controlled substance prescription is the agent of death, the argument is not as strong. However, a physician could still argue (as in the first scenario) that it was the patient's separate and independent act that caused the death. If death is not found to "result" from the physician's actions, the mandatory minimum provisions by virtue of the patient's death would not apply. In that case, only the quantity-driven penalties apply; because of the very low quantities involved in the single distribution, penalties would fall in the range of 0-16 months.[21]

4. The Rule of Lenity Weighs Against the Government in a Criminal Prosecution

The rule of lenity "demand[s] resolution of ambiguities in criminal statutes in favor of the defendant." Hughey v. United States, 495 U.S. 411, 422 (1990). See also United States v. Granderson, 511 U.S. 39, 54 (1994) ("where text, structure, and history fails to establish that the Government's position [regarding a criminal statute] is unambiguously correct -- we apply the rule of lenity and resolve the ambiguity in [defendant's] favor").

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[20] U.S.S.G. § 2D1.1(a)(2) provides for a base offense level of 38 -- 235-293 months, i.e., 19.5 to 24.4 years, for a person with no criminal history -- "if the offense of conviction establishes that death or serious bodily injury resulted from the use of the substance." The deceased's consent and grave condition may be a basis for a downward departure, but there would be no escape from the mandatory minimum penalty. No resort to the "safety valve" provision of 18 U.S.C. § 3553(f) is possible; the court could not find that the offense did not involve death or serious bodily injury, which is a required element under § 3553(f)(3).

[21] U.S.S.G. § 2D1.1(c)(14) and (17) provide for a base offense level 6 (0-6 months for a first offense for prescribing less than 250 units of a barbiturate, a Schedule II depressant), and base offense level 12 (10-16 months for a first offense for prescribing less than five grams of a Schedule II opiate).

In Moore, the physician suggested that it was unclear whether the CSA felony provision covered physicians at all, and argued that due to the ambiguity, the rule of lenity should lead the Court to hold physicians immune from prosecution under that provision. 423 U.S. at 145. The Court rejected that argument, holding that lenity principles do not allow a court to override "common sense" and "evident statutory purpose" as long as "the words are given their fair meaning in accord with the manifest intent of the lawmakers."

The statutory purpose of the CSA with regard to physician-assisted suicide is far from evident. If § 841 is construed to allow for the imposition of criminal penalties whenever a physician prescribes scheduled drugs in a manner that is beyond "the course of professional practice," prosecution should not be permitted in instances in which it is unsettled--and ultimately indeterminate--whether the prescription was beyond the legitimate scope of medical practice. Given the profound uncertainties about the role of physician-assisted suicide in the practice of medicine, the rule of lenity would appear to require that the CSA not be construed to extend to such assistance in a state that has taken the step of removing all state law prohibitions regarding such conduct.

A. Criminal Misdemeanor Prosecution or Civil Penalty — 21 U.S.C. § 842(a)(1)

Another provision of the CSA of possible relevance is 21 U.S.C. § 842(a)(1), which provides that "it is unlawful for any person, . . . who [must register with the DEA] to distribute or dispense a controlled substance in violation of section 829 of this title." As noted earlier, see Part II.A.1., section 829 simply sets forth technical requirements for prescriptions in the various controlled substance schedules, e.g., that a prescription for a Schedule II controlled substance must be written, except in emergency circumstances, and that it may not be refilled (§ 829(a)), that a prescription for a Schedule III or IV controlled substance may be refilled up to five times and is valid for up to six months (§ 829(b)), and that a Schedule V substance may be distributed or dispensed only for a "medical purpose" (§ 829(c)). It might be argued, however, that prescribing a controlled substance for use in suicide would not be for a "medical purpose," as is required by § 829(c), and implicitly required for all scheduled drugs. Similarly, it could be argued that such a prescription would not be for a "legitimate medical purpose," as required by the governing regulation that makes this an explicit condition for prescription and distribution of all scheduled drugs, 21 C.F.R. § 1306.04(a). See generally Part II.A.1, supra.

Under either formulation, a similar analysis of "the course

of professional practice" or the "usual course of professional conduct" and "legitimate medical purpose" is implicated under § 842(a)(1) as it was under § 841 discussed above. See United States v. Clinical Leasing Service, Inc., 759 F.Supp. 310, 316-17 (E.D. La. 1990) (holding clinic physician liable for civil penalties for writing a prescription for Diazepam (Valium) to the clinic's office manager, for dispensing to other patients, knowing that she was not the ultimate user of the drug). Thus, the same difficulties identified with regard to pursuing criminal prosecution under § 841 apply here.

The potential penalty exposure, however, is very different under 21 U.S.C. § 842 because the violation is at most a misdemeanor. If the violation is alleged by information or indictment to be committed knowingly and the trier of fact so finds, the offender is subject to imprisonment for up to one year and a fine up to $25,000, or both, for a first offense. 21 U.S.C. § 842(c)(2)(A). These penalties are doubled for subsequent offenses, under § 842(c)(2)(B). (Compare this with the 20-year to life penalty by application of 21 U.S.C. 841(b)(1)(C), discussed above.) If the violation is not charged by information or indictment, it is subject to a civil penalty of up to $25,000 per violation. 21 U.S.C. § 842(c)(1).

B. DEA Administrative Action against Registrants under the CSA

The Attorney General (delegated to the DEA Administrator and in turn to the Deputy Administrator) may take administrative action to revoke or suspend the DEA certificate of registration of a physician, which entitles him or her to prescribe or dispense controlled substances, upon a finding that the registrant "has committed such acts as would render his continued registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. § 824(a)(4). (emphasis added).[22] The factors to be considered under § 823(f) are as follows:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

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[22] The other grounds listed in 21 U.S.C. § 824(a), including falsification of the application for registration, conviction of a felony under state or federal law, state disciplinary action against the registrant's license or registration to handle controlled substances and exclusion from Medicare or Medicaid, are not likely to be applicable.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health or safety.

At least one appellate court has approved DEA's longstanding view[231] that "[t]he five factors are independent, and the Deputy Administrator may revoke a registration based on one factor or a combination of several factors."[24] Humphreys v. Drug Enforcement Administration, 96 F.3d 658, 661 (3d Cir. 1996), citing Henry J. Schwartz, M.D. 54 Fed. Reg. 16,422, 16, 424 (1989). If the DEA sought to take administrative action against a physician for writing a prescription for assisted suicide, Factor 1, referring to the actions of state licensing boards and disciplinary authorities, is likely to be favorable to the practitioner. The Oregon initiative precludes negative action by these state bodies. Moreover, they may make affirmative statements of support for any licensee threatened with adverse federal action. Assuming that the health practitioner will normally have experience with the medication prescribed in the assisted suicide, Factor 2 will likewise be favorable for the practitioner. Factor 3 is unlikely to illuminate this question.

The effect of Factor 4 will depend on the interpretation of the criminal provisions of the CSA. Assuming the physician has adhered to the strictures of the Oregon Death With Dignity Act, he will be in compliance with applicable state (and presumably local) law. As for compliance with federal law, this factor will be favorable to a physician if federal law is not construed to

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[23] See Michael G. Sargent, M.D., 60 Fed. Reg. 22076, 22077 (May 4, 1995); Jay Wheeler Cranston, M.D., 59 Fed. Reg. 36786, 36788 (July 19, 1994); Richard A. Cole, M.D., 57 Fed. Reg. 8677 (March 11, 1992); Veera Sripinyo, M.D., 56 Fed. Reg. 64809 (Dec. 12, 1991); and Denis C. Chan, M.D., 55 Fed. Reg. 8205 (March 7, 1990).

[24] While the statute grants the registration and disciplinary authority to the Attorney General, 21 U.S.C. §§ 823 and 824, it has been delegated to the DEA Administrator, 28 C.F.R. § 0.100(b), who has in turn delegated disciplinary matters to the Deputy Administrator.

criminalize prescribing a controlled substance for use in suicide, as suggested by Part II.A., supra.

Factor 5, which addresses whether the physician's actions "threaten the public health and safety," is likely to be a central element of any DEA administrative action, and requires further elaboration here. DEA would face several problems if it were to rely heavily on the "public health and safety" factor.

First, in interpreting this factor, it must be borne in mind that the CSA was concerned with trafficking in legally manufactured controlled drugs, many of which have "street" value, and with the facilitation, knowingly or unwittingly, by physicians of improper drug use by patients. The House Report noted that about 60-70% of all drug-related deaths and injuries involve drugs that were originally part of the legitimate drug production and distribution chain.[252] The drug use that Congress intended to prevent was that deriving from the drug's "stimulant, depressant, or hallucinogenic effect on the central nervous system," 21 U.S.C. § 811(f). Congress was not generally concerned about weighing in on debates about good or bad practices of medicine. Although there is a statement in the legislative history that "[m]isuse of a drug in suicides and attempted suicides, as well as injuries resulting from unsupervised use are regarded as indicative of a drug's potential for abuse," 1970 U.S.C.C.A.N. at 4602, this passage does not necessarily indicate that "misuse" in suicide is itself the kind of "abuse" that the Act sought to prevent but may reflect the view that such "misuse" in suicides is to be taken as indicating "abuse" of the drug as a "stimulant, depressant, or hallucinogenic."

Second, the legislative history behind the "public interest" ground for non-registration, which was enacted in 1984 as Sections 509 and 510 of P.L. 98-473, indicates that Congress continued to view as significant the states' role in regulating health professionals.[26] The 1984 amendments were motivated by a recognition that the bases for denial or revocation of a physician's registration under the 1970 law were too narrow. Under prior law, registration with the DEA had been "a matter of right where the individual or firm is engaged in activities involving these drugs which are authorized or permitted under

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[25] H.R. Rep No. 98-1030, 98th Cong., 2nd Sess. (1094), 1984 U.S.C.C.A.N. 3182, 3442.

[26] See, e.g., remarks of Rep. Rangel, 130 Cong. Rec. H9682 (daily ed. Sept. 18, 1984).

State law."[27] The 1984 amendment continued to require the Attorney General to register applicants unless they fell short on the enumerated criteria, but Congress added as a basis for denial or revocation that the registration is "inconsistent with the public interest."

Congress intimated that state prerogatives to regulate health practitioners should continue to be important in making public interest determinations, if only through expressions of congressional aspirations:

> [T]he amendment would continue to give deference to the opinions of State licensing authorities, since their recommendations are the first of the factors to be considered with respect to practitioner applications.[28]

Third, the same facts that would support a construction that a prescription to assist in suicide is part of "the course of professional practice" or a "legitimate medical purpose" can be marshaled to argue that the prescription is consistent with "public health and safety." Indeed, a strong argument could be made that a statewide referendum is a close proxy for a statement of what at least the citizens of Oregon view as their "public health and safety." In maintaining a comprehensive system of controls on substances in the five schedules, DEA can generally make a strong argument that its system of federal controls serves a national interest in preventing diversion of controlled substances. In furtherance of such an argument, the DEA might cite the positions taken by the AMA and Congress on assisted suicide. DEA's claim to serve this putative interest in public health and safety weakens, however, as the matter moves away from efforts to curtail conventional controlled substance diversion (i.e., diversion for use as a stimulant, depressant, or hallucinogenic) and reaches more into the practice of medicine. Physician-assisted suicide presents no special danger of conventional diversion.

Fourth, in cases presenting a colorable defense of a legitimate medical practice, sole reliance on the "public health and safety" factor may prove untenable for DEA. In the recent Humphreys decision, 96 F.3d at 658, 665-66, the physician wrote

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[27] 1970 U.S.C.C.A.N. at 4590. This statement did not apply to registration to conduct research with Schedule I controlled substances.

[28] 1970 U.S.C.C.A.N. at 3449. In view of the fact that the five factors are viewed independently and in no priority order by both courts - see Humphreys 96 F.3d at 66 - and the DEA, the importance of this "deference" is diminished in practice.

admittedly fictitious prescriptions for antidepressants to a law clerk and secretaries of former Pennsylvania Supreme Court Justice Rolf Larsen, in order to protect his privacy. In addition to finding that the DEA had not adequately considered the defense that such prescribing practices were commonplace in the treatment of famous patients and therefore part of the "usual course" of medical practice, 96 F.3d at 662, the court found "overly broad" and "implausible" the DEA Deputy Administrator's inference of a threat of public harm by this practice. "The conclusion that substantial risk of diversion existed because Larson or the secretaries and the law clerk might resell the drugs, under these circumstances, is so unlikely as to be unsustainable." 96 F.3d at 666.

Fifth, based on our review of the cases and discussions with attorneys in the DEA Office of Chief Counsel, the general "public health and safety" clause has not, in the past, been relied on by itself, but has been used in conjunction with other grounds for administrative sanctions, e.g., prescribing for other than legitimate medical purposes.

In sum, administrative action against a physician or pharmacist's DEA certificate of registration, while less implausible than criminal prosecution, would have to surmount some substantial contrary considerations. These would include: (a) state support for such practices under Oregon law, which would mitigate under Factor 1; (b) the practitioner's likely compliance with those state laws under Factor 4; (c) also under Factor 4, our conclusion that, on the better view of the CSA, the Act does not prohibit physician-assisted suicide as outside the usual course of professional practice and not for a legitimate medical purpose; and (d) DEA incursion into areas not central to its statutory mission to determine what "threatens the public health and safety" under Factor 5.

C. Injunctive Relief — 21 U.S.C. §§ 824(f) and 882

The CSA has two provisions to enjoin conduct that do not require a criminal conviction. The more generally applicable provision, 21 U.S.C. § 882, gives the federal district courts jurisdiction to enjoin any violations of "this subchapter," which is Subchapter I of Chapter 13 of Title 21, encompassing 21 U.S.C. §§ 801-904. If we were to argue that the prescribing of a controlled substance for use in the suicide of a terminally ill patient was a violation of the CSA, and if the government could obtain standing, it could use this authority to attempt to enjoin Oregon physicians from participating in an assisted suicide as a potential violation of 21 U.S.C. §§ 841 or 842.

Another recently enacted section specifically authorizes the Attorney General "to commence a civil action for appropriate

declaratory or injunctive relief" for violations of 21 U.S.C. §§ 842 or 843. 21 U.S.C. § 843(f).[29] These actions are governed by the Federal Rules of Civil Procedure, except that if an indictment has been returned against the respondent, discovery is governed by the Federal Rules of Criminal Procedure. § 842(f)(4). The United States could use this section to obtain injunctive relief for potential violations of § 842(a)(1).

III. SUPREME COURT ASSISTED SUICIDE JURISPRUDENCE AND RELATED ISSUES

Recent decisions by the Supreme Court rejected a challenge that state bans on physician assistance in suicide are generally unconstitutional as applied to the class of terminally ill, mentally competent patients, although the cases leave open the possibility that individual plaintiffs may succeed in asserting more particularized claims in the future. The Court's decisions emphasize the importance of state experimentation in this area, without, however, indicating how it might resolve a conflict between federal and state law on this issue.

A. Recent Cases: Glucksberg and Vacco

Earlier this year, the Supreme Court on the same day upheld two state statutes that prohibit assisted suicide, applying a due process analysis in Washington v. Glucksberg, - U.S. -, 117 S.Ct. 2258 (1997), and an equal protection analysis in the New York case of Vacco v. Quill, - U.S. -, 117 S.Ct. 2293 (1997). The plaintiffs in Glucksberg — doctors, terminally ill patients, and a non-profit organization that counsels people considering physician-assisted suicide -- sought a declaration that Washington's ban on "assis[ting] or aid[ing]" a suicide, is facially unconstitutional. 117 S.Ct at 2261. Specifically, plaintiffs asserted "the existence of a liberty interest protected by the Fourteenth Amendment which extends to a personal choice by a mentally competent, terminally ill adult to commit physician-assisted suicide." Id. at 2261-62 (citation omitted).

Writing for the Court, Chief Justice Rehnquist conducted a traditional substantive due process analysis. First, the Court required a "careful description" of the allegedly fundamental interest at issue. Id. at 2268. In arriving at that description, the Court rejected plaintiffs' various articulations of the alleged right, which included the "liberty to choose how to die" and "control of one's final days." Id. at 2269. Instead, the Court described the alleged right at issue as the

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[29] 21 U.S.C § 843(f) was added through Section 206 of the "Comprehensive Methamphetamine Control Act of 1996," P.L 104-237, 110 Stat. 3099, enacted Oct. 3, 1996.

"right to commit suicide which itself includes a right to assistance in doing so." Id. at 2269.

The Court then analyzed whether that right was a fundamental right deserving of the highest protection. Id. at 2268. In conducting that analysis, the Court looked to the "Nation's history and tradition." Id. at 2268 and 2271. The Court found that "[i]n almost every state -- indeed, in almost every western democracy – it is a crime to assist a suicide" and that "for over 700 years, the Anglo-American common law tradition has punished or otherwise disapproved of both suicide and assisting suicide." Id. at 2263. The Court concluded that "opposition to and condemnation of suicide – and therefore of assisted suicide – are consistent and enduring themes of our philosophical, legal, and cultural heritages." Id. at 2263.[30]

Holding that the alleged right was not a fundamental right, the Court subjected the prohibition to a rational basis review. Id. at 2271. The Court held that the prohibition was rationally related to several legitimate state interests, including the interests in preserving human life, protecting vulnerable groups, protecting the integrity of the medical profession[31] and avoiding embarking down a slippery slope leading to voluntary and involuntary euthanasia. Id. at 2272-74.

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[30] The majority opinion of the Court notes in passing that the American colonies abolished the harsh common-law penalties for suicide, which included confiscation of the decedent's assets. As explored in more depth in Justice Souter's concurring opinion in Glucksberg, 117 S.Ct. at 2286-87, the reasons why states repealed statutes were: (1) the impossibility of punishing the perpetrator; (2) that the attendant forfeiture of goods and ignominious burial visited unwarranted punishment on the suicide's blameless family; and (3) the act "came to be regarded as the act of a mentally ill, sick, and depressed individual, who required medical treatment not punishment, compassion not culpability." Maria T. CeloCruz, Note and Comment, *Aid-in-Dying: Should We Decriminalize Physician-Assisted Suicide and Physician-Committed Euthanasia?*, 18 Am. J. L. and Med. 368, 375 (1992). It is true that the vast majority of states have statutorily enacted punishments for assisting suicide; a footnote in the Glucksberg opinion put the number at 44 states, the District of Columbia and two territories. Id. At 2263 n. 8, citing Compassion in Dying v. Washington, 79 F.3d 790, 847, and nn. 10-13 (9th Cir. 1996) (Beeter, J., dissenting).

[31] The Court noted, as we did in Part II above, that the American Medical Association has concluded that "[p]hysician assisted suicide is fundamentally incompatible with the physician's role as a healer." Id. at 2273 (citation omitted).

Foreshadowing its decision in Vacco, the Court distinguished its earlier decision in Cruzan v. Director, Missouri Dept. of Health, which held that a competent patient had a constitutional right to refuse hydration and nutrition. Cruzan, 497 U.S. 261 (1990). The Glucksberg Court explained that Cruzan was premised on the idea that forced medication was a battery and that the case "gave no intimation that the right to refuse unwanted medical treatment could be somehow transmuted into a right to assistance in committing suicide." Glucksberg, 117 S.Ct. at 2270. While the Court rejected the Ninth Circuit's specific holding that the Washington statute was unconstitutional as applied to the class of terminally ill, mentally competent patients, they did not, however, "foreclose the possibility that an individual plaintiff seeking to hasten her death, or a doctor whose assistance was sought, could prevail in a more particularized challenge." Id. at 2275.

Vacco was a challenge to a New York law prohibiting aiding another to commit or attempt suicide. 117 S.Ct. at 2296. In Vacco, physicians and "gravely ill" patients claimed that because New York allows competent patients to refuse life-sustaining treatment, the challenged prohibition, which proscribes what they argued was "'essentially the same thing,'" violates the Equal Protection Clause. Id. at 2296-97. Conducting traditional equal protection analysis, the Chief Justice, writing for the Court, first analyzed whether the prohibition was subject to heightened scrutiny because it burdened a fundamental right or targeted a suspect classification. Id. at 2297. The Court concluded that the prohibition did not involve a suspect classification and, relying on Glucksberg, concluded that the prohibition did not infringe a fundamental right. Id. Thus, the Court subjected the prohibition to rational basis review.

The Court found that the distinction the New York state legislature drew between assisting suicide and withdrawing life support was rational. Id. at 2298. The Court found that "the law distinguishes actions taken 'because of' a given end [to end a patient's life] from actions taken 'in spite of' their unintended but foreseen consequences [that the patient will die]." Id. at 2299 (citations omitted). The Court held that the interests the statute advanced, which were similar to those asserted by Washington in Glucksberg, were legitimate. Id. at 2302.

In Glucksberg, the Court noted that the nation is engaged "in an earnest and profound debate about the morality, legality and practicality of issue of physician-assisted suicide," and that its holding "permits this debate to continue, as it should in a democratic society." Id. at 2275. Justice O'Connor, who provided the fifth vote for the majority's opinion, emphasized the importance of current state consideration of this issue:

"States are presently undertaking extensive and serious evaluation of physician-assisted suicide and other related issues. In such circumstances, the . . . challenging task of crafting appropriate procedures for safeguarding . . . liberty interests is entrusted to the 'laboratory' of the States . . . in the first instance." Id. at 2303 (internal quotation marks and citations omitted). Justice Souter, writing in concurrence, similarly emphasized that, in light of current state experimentation, "[t]he Court should . . . stay its hand to allow reasonable legislative consideration [of this difficult issue]." Glucksberg, 117 S.Ct. at 2293.

B. The Department's Positions in Glucksberg and Vacco

The Department filed *amicus curiae* briefs in both Glucksberg and Vacco, basing its interest on the fact that "[t]he United States owns and operates numerous health care facilities which permit patients to refuse life-sustaining treatment, but do not permit physicians to assist patients in committing suicide by providing lethal doses of medication." Brief for the United States as *Amicus Curiae*, Washington v. Glucksberg (S. Ct. No. 96-110) at 1. In both cases, the government argued that the Court should uphold the challenged ban on assisted suicide.

In Glucksberg, the government argued that there is no right to obtain lethal medication or recognized liberty interest in deciding the timing and manner of one's death. Id. at 12, 25. However, the Department maintained :

> [A] competent, terminally ill adult has a constitutionally cognizable liberty interest in avoiding the kind of suffering experienced by the plaintiffs in this case. That liberty interest encompasses an interest in avoiding not only severe pain, but also the despair and distress that comes from physical deterioration and the inability to control basic bodily or mental functions in the terminal stages of illness.

Id. at 8. The government asserted that state action infringing that right should be held to an intermediate level of scrutiny. Id. at 17.

The Department concluded, however, that Washington had an overriding interest in "prohibiting physicians from purposeful taking of another person's life." Id. at 9. While conceding that creating an exception for the terminally ill had some appeal, the Department concluded that a state could find that such an exception would endanger incompetent patients, lead to possible patient coercion and pose a risk to those who are not in

fact terminally ill. Id. at 9.

In a statement with potential ramifications for the instant inquiry, the Department stated that state legislatures "undoubtedly have the authority to create the kind of exception to assisted suicide fashioned by the Court of Appeals." Id. at 10. According to the Department's characterization of the Court of Appeals decision, such an exception would allow for assisted suicides in those cases where a competent, terminally ill adult has voluntarily requested lethal medication and there are procedural safeguards in place to ensure those requirements are met. Id at 7. That discussion could reasonably be read to describe the Oregon Death with Dignity Act.

At oral argument, in response to a question from Justice Souter, Acting Solicitor General Dellinger stated that there was insufficient experience with assisted suicide to conclude that "there could be adequate safeguards to protect those who are suffering from depression." Glucksberg Oral Arg. Transcript at 22. He was then asked whether it would be best for the Court to wait "for more experience abroad or in Oregon." Id. at 23. In response, reading from a New York State Task Force report, ASG Dellinger stated that "the reality of existing medical practice in doctor's offices and hospitals. . . . generally cannot match these expectations, however any guidelines or safeguards might be framed." Id. at 25-26.

In Vacco, the Department argued that important state interests justified distinguishing between assisting suicide and withdrawing life support.[32] The Department asserted that the two situations were distinguishable in several respects, including their respective potential for erosion of the distinction between killing and letting die, the consequences of an erroneous diagnosis of terminal illness and the invasive nature of life support. Id. at 10.

C. Physician-assisted suicide and "medical marijuana."

With the enactment of the Controlled Substances Act, Congress established a comprehensive regulatory scheme in which controlled substances are placed on one of five "Schedules" depending on their potential for abuse, the extent to which they lead to psychological or physical dependence, and whether they have a currently accepted medical use in treatment in the United States. Drugs listed on Schedule I are subject to the most stringent regulation because they have been determined to have a "high potential for abuse," "no currently accepted medical use in

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[32] Brief for the United States as *Amicus Curiae*, Vacco v. Quill (S. Ct. No. 95-1858) at 7-8.

treatment in the United States," and a "lack of accepted safety for use under medical supervision." 21 U.S.C. § 812(b)(1). Drugs on Schedules II through V are subject to decreasing levels of control because they have been determined to have some currently accepted medical uses in treatment in the United States and less potential for abuse. 21 U.S.C.§§ 812(b)(2)-(5).

Marijuana is a controlled substance in Schedule I.[33] Moreover, under the Federal Food, Drug and Cosmetic Act, the FDA has not approved marijuana in its smokeable form as safe and effective for any use. Taken together, this means that except in the context of research projects approved and tightly controlled by the FDA and DEA, marijuana may not be lawfully prescribed by physicians or possessed or used by patients in the United States. A prescription for marijuana would exceed the authority of a physician, 21 U.S.C.§ 822(b); a doctor would be subject to prosecution for distribution under § 841(a), the patient for possession under § 844(a). In contrast, as noted in II above, the drugs that are expected to be used in a physician-assisted suicide are both controlled Schedule II-IV substances and non-controlled substances. Bringing a revocation action against an Oregon physician who participates in an assisted suicide through the prescription of a Schedule II-IV controlled substance, based upon a finding that the registrant has committed an act inconsistent with the public interest as determined under § 824(a)(4), is vastly different from bringing the same action against a California physician who prescribes a Schedule I controlled substance that has been properly classified as illegal contraband, except for research purposes.

When deciding to place a substance in, or to refrain from removing a drug from, Schedule I, the Administrator has express statutory authority to rely on several enumerated factors. These include whether the substance has "a high potential for abuse," and there is "no currently accepted medical use in treatment in the United States" and "a lack of accepted safety for use of the drug . . . under medical supervision." 21 U.S.C. § 812(b)(1). In making that scheduling decision, the Administrator has been advised to consider the potential for, history of, and significance of abuse (described elsewhere in the Act by reference to its "stimulant, depressant, or hallucinogenic effect on the central nervous system," 21 U.S.C. § 811(f)), the scientific evidence and knowledge of its pharmacological effects, and its dependence liability, along with the currently accepted medical use for treatment in the United States. See 21 U.S.C.

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[33] "Marihuana" is denominated a "hallucinogenic substance" and is placed in Schedule I by regulation at 21 C.F.R. § 1308.11(d)(19). Congress initially placed it in that schedule when the CSA was enacted. See 21 U.S.C. § 812(c)(10).

§ 811(c), 812(b)(1). In deciding to keep marijuana in Schedule I, then, the Administrator may, within reason, place unequal weight on scientific uncertainties and anecdotal evidence, and discount the opinion of even a "respectable minority of physicians" while relying more heavily on the lack of scientific evidence and data regarding the specific effects of the drug. See Alliance for Cannabis Therapeutics v. DEA, 930 F.2d 936, 939 (D.C. Cir. 1991).

This authority to determine a substance's "currently accepted medical use in treatment in the United States," however, does not imply the existence of similar authority to construe the scope of a practicioner's "course of medical practice" under the other provisions of the CSA. To the contrary, there is no comparable authority to determine the scope of professional practice. Although the DEA Administrator is given general authority to issue implementing regulations under the CSA, in the one area where the federal government is given license to set standards of medical practice with respect to dispensing controlled substances, Congress required consultation with another agency. Specifically, Congress authorized the Secretary of Health, Education, and Welfare (now Health and Human Services (HHS)), in consultation with the Attorney General (as delegated to the Administrator of the DEA) and national addict treatment organizations, to "determine the appropriate methods of professional practice in the medical treatment of . . . narcotic addiction." 42 U.S.C. § 257a.[34] In light of this express authorization for the Secretary of HHS to determine the scope of professional practice in a specific field of treatment, Congress should not be read as having given wide latitude to the Administrator to determine "the scope of professional practice" of medicine generally.

IV. POLICY CONSIDERATIONS AND SUGGESTED COURSES OF ACTION

Even if were legally plausible to proceed against Oregon physicians who participate in a lawful assisted suicide under the Oregon Act, we would deem it inadvisable. The definition and punishment of the crimes of murder and suicide, as well as regulation of the practices of health professionals, fall squarely within the traditional province of state law. As a matter of comity, the Federal Government ought to have a compelling reason to intrude on matters traditionally within the states' purview.

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[34] Indeed, the force of even these regulations is limited. Violations of these regulations would not appear, as a matter of law, to lead to the conclusion that the physician has acted beyond the scope of "the course of professional practice" for purposes of criminal prosecution under § 841.

There may be some federal interests in controlling the use of the controlled substances or prescription drugs prescribed by Oregon health practitioners for assisted suicides, but these interests are, at best, tangential to those served by the federal statutes involved. The Controlled Substance Act (CSA) is primarily intended to stop trafficking in illicit drugs and trafficking and abuse of licit drugs. A prescription for controlled substances to assist a terminally ill adult patient to commit suicide presents no particular risk of diversion; the CSA is simply too thin a foundation to support what may be today's federal notions of what is appropriate care for the dying. The Federal Food, Drug, and Cosmetic Act is intended to regulate manufacturing and distribution of drug products and to ensure that drugs are safe and effective. The FDA has indicated that it does not intend to pursue adverse action against physicians who follow the Oregon Act in assisting their patients in committing suicide. Accordingly, the United States should, as a matter of policy, exercise its discretion not to prosecute or proceed civilly or administratively against Oregon physicians for assisting in suicide in compliance with Oregon law.

In the alternative, should the government intend to initiate actions against Oregon physicians for participating in assisted suicides, we should seek to do so, at least initially, in a context other than criminal prosecution, especially under the CSA, which includes severe penalties. We should recognize that an administrative action to revoke or suspend a physician's DEA registration is a severe penalty that may (depending on the doctor's specialty) amount to a de facto revocation of a license to practice medicine. The best context in which to litigate this matter might be through a government-initiated injunctive action, or in defense of an injunctive action brought by affected physicians and patients, assuming the parties have proper standing. Practitioners who wish to make use of the law should know in advance the potential consequences of their actions.

An additional consideration that supports a decision not to proceed even in a civil context against Oregon health practitioners is the danger that an adverse judicial decision could pose to existing deference afforded administrative agencies, including the DEA. Federal agencies currently have broad authority to interpret federal statutes within their respective areas. See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). Where a statute is arguably unclear, an agency's interpretation of the statute will normally withstand a challenge if it is merely a permissible construction of the statute. See First City Bank v. National Credit Union Administration Board, 111 F.3d 433, 437 (6th Cir. 1997), *reh'g denied*, 1997 (discussing Chevron). This authority has been an important tool for the Administration, both in carrying out its work and in defending its actions in federal

court.

Each time a court holds that an agency's construction of a statute is impermissible, it potentially weakens the broad authority accorded agencies under the Chevron doctrine. Perhaps even more important, an aggressive interpretation of the CSA here, could present a court with the opportunity to entrench, or even expand on, two recent court of appeals decisions that we believe were wrongly decided and that have imposed something like a clear statement rule on legislation authorizing administrative interpretations shifting the federal-state balance.[35] Given the balance of federal and state interests involved and the purpose of the CSA, it would be unwise to proceed under a questionable administrative interpretation.

We recommend that the Department make its position not to proceed known through a public statement so that physicians, pharmacists, and Oregon citizens have fair notice. Our failure to do so would have a "chilling effect" on actions by physicians that are currently lawful under federal and Oregon law, and would thus undermine the state's prerogative to legislate, including legislation through popular referendum. Indeed, this precise concern was noted in the December 3, 1997, letter to you from Oregon Deputy Attorney General Schuman.[36]

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35 Virginia Dep't of Educ. v. Riley, 106 F.3d 559 (1997) (en banc); United States v. Wilson, __ F.3d __, 1997 WL 785530 (4th Cir. Dec. 23, 1997);

36 In the "Conclusion" section of the letter, at pp. 9-10, Mr. Schuman states:

> Until the Department of Justice clarifies its position regarding Administrator Constantine's letter, Oregon physicians are not only going to be reluctant to follow the law that has been twice endorsed by the state's voters; they are also going to be chilled in their decisions regarding palliative prescriptions for terminally ill patients.

Given that Mr. Constantine's letter is the only public statement on this matter so far by an official of this Department, this is undoubtedly an accurate representation of the dilemma faced by Oregon physicians.