THE WHITE HOUSE
WASHINGTON

4/18

TO: ERIC
From: Roger Ballentine

For odd reasons, this was sent to me.

Re: PRPA

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October 1, 1999

HEALTH -

ABT
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95128-0003

Via Facsimile & Overnight Courier

The Hon. Ron Wyden
United States Senate
Hart Senate Office Building
Washington, DC 20510

Re: S. 1272, The Pain Relief Promotion Act of 1999

Dear Senator Wyden:

On behalf of clients who are deeply concerned with Senator Nickles's euphemistically-titled "Pain Relief Promotion Act of 1999" (the "PRPA"), S.1272, we write to present our analysis of the legal implications of the PRPA. In short, we have found significant health policy and constitutional law infirmities with the legislation as currently proposed. Most importantly, the proposed legislation will have an effect opposite of its purported intent: it will have a chilling effect on the effective use of medication for palliative care. In its zeal to overturn Oregon's twice-passed Death With Dignity Act, the PRPA will subject physicians *in all states* to possible criminal prosecution with respect to the medically and ethically difficult decision making process that they must engage in when providing care during the often painful end of life period.

The PRPA is bad legislation for both public policy and constitutional reasons: First, by subjecting physicians' prescription of medications used to treat the severe pain suffered by the terminally ill to criminal investigations focused on the subjective intent of the physician prescribing those medications, the PRPA would have a major chilling effect on physicians' palliative care that could undermine doctor-patient relationships across the country. Second, it constitutes an assault on the principles of federalism that are central to our form of government. It should be defeated.

I. Background.

Last year, Senator Nickles and Representative Hyde introduced identical companion bills, both entitled the Lethal Drug Abuse Prevention Act of 1998 ("LDAPA"). The LDAPA would have amended the Controlled Substances Act ("CSA") to prohibit physicians from dispensing or distributing controlled substances with the purpose of causing or assisting in the "suicide" of a terminally ill patient.[1] S. 2151, Section 2(b)(1)(B) (proposing to amend 21 U.S.C. § 823). Both bills failed to pass.

On June 17, 1999, Senator Nickles proposed a successor bill to the LDAPA, the PRPA, S.1272. Representative Hyde introduced an identical bill in the House of Representatives, H.R. 2260. The PRPA provides that "alleviating pain or discomfort . . . is a legitimate medical purpose for the dispensing, distributing, or administering a controlled substance that is consistent with public health and safety, even if the use of such a substance may increase the risk of death." S. 1272, Title I, Section 101. However, the Act states explicitly that "[n]othing in this section authorizes intentionally dispensing, distributing, or administering a controlled substance for the purpose of causing death or assisting another person in causing death." *Id.* In effect, the PRPA would expose physicians who prescribe pain management drugs to dying patients to possible criminal investigation and prosecution by federal, State and local law enforcement.

In essence, the PRPA is simply the LDAPA dressed up in different clothes. Clearly an attempt to respond to criticism levied at the earlier bill, the PRPA stakes out seemingly more benign territory by purporting to promote palliative care for terminally ill patients. Nonetheless, the goal of the PRPA clearly is the same as the LDAPA: to use the CSA as a vehicle to prohibit physician-assisted suicide through federal legislation. While the LDAPA would have provided that dispensing a controlled substance with the intent to assist suicide may result in suspension, revocation, or denial of a physician's registration under the CSA, the PRPA goes further by making such prescription a CSA violation subject to possibly harsher criminal penalties. The PRPA, in requiring the training of local, State, and federal law enforcement personnel in investigating authorized uses of palliative care, also promotes much broader enforcement than the earlier bill. As a result, the consequences of the PRPA may be worse for both physicians and their patients.

Furthermore, as described below, the PRPA, like the LDAPA, remains a bald assertion of federal legislative power to overturn a State statute twice enacted by a State's

[1] The term "physician-assisted suicide" refers to the prescribing of medications a competent terminally ill patient could consume to bring about a humane hastened death.

voters, *i.e.*, Oregon's Death With Dignity Act. Oregon physicians that prescribe controlled substances in accordance with Oregon's Death With Dignity Act will become subject to criminal penalties under the federal CSA to be enforced by State and local authorities. While Congress is of course not bound by the CSA currently in effect today, that law was never intended to regulate the medical profession, and passage of the PRPA would amend the CSA in a manner inconsistent with its history and original intent. The PRPA offends the concept of federalism that is integral to the United States constitutional system. In sum, the regulation of the practice of medicine, the patient-physician relationship, and a terminally ill patient's desire to die a dignified death are reserved to the States — and not to the federal government.

II. The PRPA Subjects Physicians In All States To Criminal Exposure For Providing Aggressive Pain Management, Thereby Further Chilling Good Palliative Care

A. The PRPA's Provisions of Promoting Palliative Care Are Redundant to Existing Law, So The Real Target of the PRPA Is Oregon's Physician Suicide Law

The proposed PRPA amendments to the CSA are ostensibly directed to the laudable goal of promoting aggressive pain management and palliative care. Besides providing modest research grants and a federal program to promote palliative care, the PRPA supposedly "for the first time affirms, by law, that federally controlled substances should be used for pain control, even if use of such substances increases the likelihood of death."[2] Notwithstanding this proclamation, however, the PRPA actually does little more than affirm the status quo of the law regarding pain medication.

No State laws or regulations consider the use of opioids for intractable pain to be an illegitimate practice. Furthermore, there exists no federal law impediments to pain management and palliative care. Current federal law governing controlled substances such as opioids does not deter aggressive pain management through the use of controlled substances. Only one federal regulation addresses a physician's opiate prescription practice.[3] It prohibits physicians from prescribing opioids to detoxify or maintain opioid addiction and clearly makes a distinction between the treatment of opioid addiction and pain treatment. However, it goes on to provide: "This section is not intended to impose *any* limitations on a physician or authorized hospital staff . . . to administer or dispense

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[2] Press Release, "Nickles Introduces Pain Relief Promotion Act," June 17, 1999.

[3] 21 CFR §1306.07.

narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts."[4]

Congress passed the Patient Self Determination Act (the "PSDA") in 1990 to promote patient autonomy in medical decision-making by requiring healthcare providers to inform patients of their rights under State law to make decisions concerning their medical care.[5] Congress recognized that the adequate treatment of pain is an integral aspect of medical care. Thus, to the extent that State law recognizes a right to make medical decisions about the treatment of pain, the PSDA created an enforceable obligation on the part of healthcare providers to inform patients of this right.[6]

When Congress amended the PSDA in 1997 to specifically exclude the provision of information relating to assisted suicide, it did not choose to exclude information relating to pain treatment.[7] To the contrary, Congress expressly recognized the

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[4] 21 CFR §1306.07(c) (emphasis added).

[5] P.L. 101-508, § 4206, *codified at* 42 U.S.C. §§ 1395cc(f)(1)(A)(i) & 1395a(w).

[6] The PSDA reads in relevant part:

> . . . the requirement of this subsection is that [a healthcare provider receiving Medicare or Medicaid funds] maintain written policies and procedures with respect to all adult individuals receiving medical care by or through the provider or organization —
>
> (A) to provide written information to each such individual concerning —
>
> (i) an individual's rights under State law (whether statutory or as recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives . . . .

Id. The term "medical care" as used in the PSDA is defined as "the diagnosis, cure, mitigation, treatment, or prevention of disease." 42 U.S.C. § 300gg-91(a)(2); *see also* 26 U.S.C § 213. Because the use of controlled substances to relieve pain is an integral part in the mitigation or treatment of disease, the term "medical care" indisputably includes pain management. Thus, the PSDA clearly requires healthcare providers to inform patients of any rights they may have under State law to make decisions about the treatment of pain.

[7] *See United States v. Smith*, 499 U.S. 160, 166-67 (1991) ("Where Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied, in the absence of evidence of a contrary legislative intent.") (quoting *Andrus v. Glover Constr. Co.*, 446 U.S. 608, 616-17 (1980)).

importance of effective pain management to the treatment of terminal or chronic illness.[8] Thus, as part of the same legislation that amended the PSDA to exclude the provision of information about assisted suicide, Congress directed that grant preferences be given to medical research on pain management, and to the training of health care practitioners and faculty in the effective management of pain.[9] In addition, the U.S. Supreme Court has recognized that patients have a right to receive pain medication, even if it hastens death.[10]

Accordingly, the pain management provisions of the PRPA are somewhat redundant to the federal authorities that recognize aggressive palliation of pain as a legitimate medical practice. **If further federal legislative encouragement of palliative care is deemed warranted, alternative bills pending set forth reasonable legislation to achieve that goal without the health policy problems and constitutional infirmities created by the PRPA's prohibition of physician-assisted suicide.**[11]

The real target of the PRPA is found in its other mandate: to prohibit physician-assisted suicide. Oregon is the only State that has a duly enacted law permitting physician-assisted suicide. Physician-assisted suicide hastens a patient's death, yet it is nonetheless a legitimate medical practice subject to State regulation. The Oregon Death

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[8] *See* P.L. 105-12 (Assisted Suicide Funding Restriction Act of 1997), §12(a)

[9] *Id.* §12(b).

[10] In *Glucksberg v. Washington*, 117 S. Ct. 2258, 2267 (1997), and the companion case *Quill v. Vacco*, 117 S.Ct. 2293 (1997), cases considering whether there is a federal constitutional right to choose a physician-assisted hastened death, Justices O'Connor and Breyer stated the view that provision of pain medication to a patient even if it hastened death would not violate state laws prohibiting assisted suicide and indeed is something a dying patient has a right to access: "a patient who is suffering from a terminal illness and who is experiencing great pain has no legal barriers to obtaining medication, from qualified physicians, to alleviate that suffering, even to the point of causing unconsciousness and hastening death." *Glucksberg*, 117 S. Ct. at 2303 (O'Connor, J., concurring). Justice O'Connor further stated: "There is no dispute that dying patients . . . can obtain palliative care, even when doing so would hasten their deaths." *Id.* *See also id.* at 2311-12 (Breyer, J., concurring). Justice Breyer expressed the view that "the laws before us do not force a dying person to undergo that kind (severe physical pain(connected with death)) of pain." Id. The concurring Justices in *Glucksberg* and *Quill* have recognized that there is a constitutional right to have access to adequate pain medication. Distinguished scholars have observed this recognition. *See e.g.* Robert A. Burt, The Supreme Court Speaks: Not Assisted Suicide, But a Constitutional Right to Palliative Care, 337 *New Eng. J. Med.*1234-36(1997); John Robertson, Bioethical Dilemmas-The Case of Physician Assisted Suicide, 45 *Cleveland St. L. Rev.* 329(1997).

[11] *See, e.g.*, S. 941, entitled the "Conquering Pain Act of 1999," introduced on May 3, 1999.

With Dignity Act sets forth when physician-assisted suicide will be allowed, enumerating specific criteria that must be fulfilled for the physician to avoid criminal and civil liability. These criteria must be satisfied by the patient before a clinician can write a prescription for medication to humanely hasten the patient's impending death. Yet, the PRPA would directly override the Oregon law by subjecting physicians that comply with the state law to criminal prosecution. By their own admission, the sponsors of the PRPA admit that the proposed legislation is designed to apply only in one state -- Oregon. Thus, Oregon's law is the true target of the PRPA.

B. The PRPA Constrains A Physician's Ability To Treat Pain By Subjecting Physicians' Prescription Of Medications For Pain In Terminally Ill Patients To Criminal Investigations and Prosecution

The legal effect of the PRPA is at odds with its appealing title. Although proponents of the legislation purport to have included new statutory support for aggressive pain management, the PRPA would potentially expose to criminal prosecution physicians ***in every State*** who prescribe pain management drugs in dosages that they knew would or could increase the likelihood of the patient's death.

Section 401 of the CSA contains a broad prohibition on the distribution and dispensing of federally controlled substances.[12] Violation of Section 401 carries criminal penalties.[13] Section 303, however, provides a so-called safe harbor from the broad prohibition for the medical profession: allowing physicians to use such federally controlled substances — which include the drugs necessary to ease the pain of patients — in the course of their practices.[14] As currently drafted, S.1272 adds to the end of that safe harbor section two new elements of law that, when read in the context of the CSA, radically affect the ability of physicians to practice medicine. First, the amendment includes the deceptively physician-friendly support for aggressive pain management that "may increase the risk of death." The amendment next adds, however, a provision removing from Section 823 the use of such federally controlled substances to *intentionally cause or assist in the causing of a patient's death.* As a consequence, without the safe harbor provision, physicians in Oregon who comply with the wishes of their patients pursuant to that State's Death with Dignity Law will be subject to the CSA criminal sanctions. Moreover, this notion of *intent*, and the unclear manner in which it is used in S.1272, creates troubles for physicians *in all states*, whether or not they plan to engage in physician-assisted suicide. Legally, *intent* is considered to be established

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[12] 21 U.S.C. § 841.

[13] 21 U.S.C. § 841(b).

[14] 21 U.S.C. § 823(g)

where there is knowledge that the death is substantially certain to occur as a result of the conduct; however, *intent* also can be found where death should have been reasonably expected to occur as a result of the conduct. The PRPA would mandate that the criminal process resolve those difficult, subjective questions after the fact. Thus, the PRPA not only removes physician-assisted suicide from the safe harbor section, it also would leave physicians exposed to the general criminal penalties associated with Section 841(a) if they potentially *should have known* that the dosage they prescribed would result in death — even if their subjective intent in fact was to provide palliative care. By comparison to this unclear new standard, physicians' actions previously have been kicked out of the safe harbor provision and into the general criminal prohibition only if their dispensing of federally controlled substances occurred outside of the usual course of their professional practice.

Professor Orentlicher, Director of the Center for Law and Health at the University of Indiana School of Law, has cautioned that since such intent to cause death can be inferred from the drug or dose ordered, the potential exists that physicians can be incarcerated for up to 20 years if the local authorities view, in retrospect, the dosage received by the patient as excessive.

C. The Chilling Effect: The Possibility Of Criminal Investigation And Prosecution Will Discourage Doctors In Every State From Providing Adequate Palliative Care

While the issue of physician-assisted suicide is being debated seriously in State houses throughout the nation, one consideration in this debate has enjoyed near unanimous agreement: no one beyond the Beltway wants local police and prosecutors second-guessing physician's decisions on the provision of medications to alleviate the pain of their terminally ill patients. Yet, in criminalizing the intimately private decision making process embarked upon by the physician and her patient — and by empowering state and local authorities to review those decisions after the fact — that is exactly what the PRPA proposes to do.

The PRPA's proposed amendment to the CSA does not imbue the U.S. Drug Enforcement Agency with any additional powers to enforce the PRPA's new requirements. Such enforcement will fall largely upon state and local authorities with no medical or palliative care expertise. This will result in the possibility of unsophisticated prosecutorial hindsight being applied to complex end of life and palliative care medical decisions. Knowing this cannot help but color the decision making of every physician who provides care in what are often both medically and ethically difficult circumstances. This aspect of the PRPA emerges when the subtle language of S.1272 is read in the context of the entire regulatory regime governing federally controlled substances.

The PRPA purports to teach law enforcement officials how to recognize legitimate pain treatment. S.1272 includes authorization for the Attorney General of the United States to create education and training programs for local, state and federal personnel "on the necessary and legitimate use of controlled substances in pain management and palliative care." Because the essential element in distinguishing a physician's legal use of federally controlled substances from a criminal use is the *intent* of the physician, local authorities — trained only the Attorney General's education program as background — will be called upon to second guess the thought processes of formally, medically trained physicians and revisit difficult, stressful and often time-sensitive decisions made at the end of a patient's life.

Fostering the belief in law enforcement officials that they can discern a physician's intent from their prescribing practice will have a profound impact on pain treatment. Physicians who prescribe high levels of sedation for patients do not necessarily know the results of the prescription at the time it is given: the sedation will help relieve pain and provide comfort, but it may also depress respiration and hasten death. The PRPA will encourage law enforcement officials to investigate this type of palliative pain relief to determine whether the physician actually intended to allow the patient to hasten death in violation of the PRPA. The criminalization of physician-assisted suicide will result in federal, state and local prosecutors intervening in the core practice of medicine.

As a consequence of the blunt language criminalizing physician-assisted suicide, the PRPA would inevitably have a chilling effect on aggressive pain management by physicians in all States. Doctors in *every* state providing adequate palliative care during the period at the end of a patient's life will be subject to increased likelihood of investigation when a patient who has received controlled substances dies. Threatened with investigation, physicians will undertreat a patient's pain, thereby subjecting the patient to unnecessary suffering. Accordingly, the increased risk of investigation will exacerbate an already existing problem. **Undertreatment of pain is epidemic in the United States,[15] due in part to physician fear that prescribing controlled substances will invite regulatory oversight.**[16]

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[15] *See e.g.* SUPPORT Study Principal Investigators, "A Controlled Trial To Improve Care For Seriously Ill Hospitalized Patients," *JAMA* 1995; 274:1591; *see also* "Management of Pain in Elderly Patients with Cancer," 279 *JAMA* 1998; 279:1877 (pain is prevalent and undertreated in elderly cancer patients); A. Jacox, D. Carr, and R. Payne, New Clinical-Practice Guidelines for the Management of Pain in Patients with Cancer, *N. Engl. J. Med.* 1994; 330: 651 (pain associated with cancer is frequently undertreated); David Joranson et al, "Opioids for Chronic Cancer and Non-Cancer Pain: A Survey of State Medical Board Members," *Federation Bulletin: the Journal of Medical Licensure and Discipline*, 1992; 79(4):15-49 (reporting on

It should also be noted that while the PRPA would increase physician concern that provision of adequate pain care could bring scrutiny, thus increasing pressure on physicians to underprescribe pain medications, at the same time we are seeing an emerging accountability for physician failure to treat pain adequately, in both the medical disciplinary and civil tort contexts.[17] Were the PRPA to pass, physicians would be placed between the proverbial "rock" and "hard place", a situation that benefits neither physicians nor their patients.

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studies that reflect "that adequate pain control is not being achieved in a significant portion of patients, and that patients often do not receive analgesics to match the severity of their pain", notwithstanding that pain can be well-controlled for more than 85% of all cancer patients.)

[16] *See* "Breaking Down The Barriers to Effective Pain Management", *Recommendations to Improve the Assessment and Treatment of Pain in NY State. Report to the Commissioner of Health*, January 1998 (70% of NY physicians acknowledge declining to prescribe controlled substances when indicated due to concern that prescribing would bring scrutiny); Institute of Medicine, *Approaching Death. Improving Care at the End of Life*, at p. 191, 197(National Academy Press)(1997)(system of oversight for prescribing controlled substances is burdensome and deters legitimate prescribing of opioids to patients at the end of life.); David Joranson, State Medical Board Guidelines for Treatment of Intractable Pain, *American Pain Soc. Bulletin*, Vol. 5, No. 3(May/June 1995, at 2 (citing California study reflecting that physicians avoid prescribing controlled substances including "triplicate" drugs for patients with intractable pain for fear of discipline by the medical board); Robyn S. Shapiro, "Health Care Providers' Liability Exposure for Inappropriate Pain Management," 24 *J. Law, Med. & Ethics* 360,363(Winter 1996)(identifying fear of legal penalties, especially disciplinary action, as one of the most important reasons health professionals undertreat pain. 69% of California physicians acknowledge that the potential for disciplinary action made them more conservative in theiruse of opioids in pain management.)

[17]Until recently, there has been no accountability for failure to treat pain adequately. However, this is beginning to change. The emergence of guidelines and standards governing appropriate pain care, and mandatory evaluation and routine charting of pain, permits establishing that in a specific case, the pain care provided was inadequate and should result in professional discipline or possibly civil liability on various theories, including professional negligence and elder abuse. State medical boards will increasingly become involved in this area, the first case of a state medical board disciplining a physician for undertreatment of pain has come to pass: the *Bilder* case in Oregon in 1999. Cases of inadequate pain treatment are also beginning to result in civil liability with significant financial implications. *E.g. Gaddis v U.S.*, 1997 WL 907939(SC 1997) (damages awarded to deceased patient's estate and to family for failure to treat pain of cancer patient adequately.); *Bergman v. Eden Medical Center*, No. H205732-1, Superior Court, Alameda County, CA (medical negligence and elder abuse for failure to adequately treat pain in elderly patient dying of lung cancer).

II. Federalism Requires That Congress Allow the States to Address the Issue of Physician-Assisted Suicide.

A. The U.S. Supreme Court Already has Declared that States Should Decide the Issue of Physician-Assisted Suicide.

In its 1997 decision in *Washington v. Glucksberg*, the U.S. Supreme Court expressly recognized that "the States are currently engaged in serious, thoughtful examinations of physician-assisted suicide and other similar issues."[18] In that case, the Court conducted an in-depth and extensive examination of the history of physician-assisted suicide, focusing on the States' approaches to suicide laws. The Court decided that the States ought to be allowed to continue to address the issue of physician-assisted suicide because the States are the appropriate forum for decisions about physician-assisted suicide:

> 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.[19]

Justice O'Connor expounded on this holding in her concurrence:

> There is no reason to think the democratic process will not strike the proper balance between the interests of terminally ill, mentally competent individuals who would seek to end their suffering and the State's interest in protecting those who might seek to end life mistakenly or under pressure. As the Court recognizes, States are presently undertaking an 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.'"[20]

Hence, the Court explicitly refrained from settling the ongoing debate in the States and provisionally denied recognizing a constitutional right out of a deference to the

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[18] *Washington v. Glucksberg*, 117 S. Ct. 2258, 2267 (1997).

[19] *Id.* at 2275.

[20] *Id.* at 2302 (O'Connor, J., concurring) (citations omitted).

principles of federalism.[21] Indeed, the Court's majority opinion rests part of its decision on the sanctity of State law.

B. The Principles of Federalism Should Compel Congress to Let the States Decide Whether to Allow Physician-Assisted Suicide.

The Supreme Court's decision in *Glucksberg* is grounded in federalism — a basic tenet of American democracy, a concept as central to our form of government as the separation of powers.[22] Federalism is commonly defined as the division of powers among the federal and State (and local) governments according to which performs them best. For example, the national government has general responsibility for defense and international affairs; the States, for most prisons and roads; and local governments, for schools and land-use. Certain powers, such as taxation and the regulation of commerce, are shared. While the Constitution does not specifically allocate each and every governing function between the States and federal government, tradition and functional optimization create a strong presumption that some things are better left to the States.[23] This division of powers makes possible innovative approaches to problems developing out of the experiments of 50 State governments. Our unique form of government fosters greater creativity, freedom, greater efficiency, and more direct representation than a model based upon a monolithic national bureaucracy.

The issue of physician-assisted suicide is profoundly moral and deeply personal, and is being faced every day by citizens across the country who are terminally ill and suffering agonizing pain. That it is a national issue there is no doubt. That does not, however, make it a *federal* issue. Within the scope of powers allocated to it under the federal-State system, the State of Oregon has decided to address the issue of physician-assisted suicide by allowing physicians in narrowly prescribed circumstances to prescribe medication which competent, terminally ill patients may take to bring about a humane, hastened death. Indeed, the voters of the State approved the measure on two separate ballots. Regardless of the amount of attention that Congress now may give to this issue, Congress should respect the State electorate's decision and must recognize that the relationship between a patient and doctor lies properly within the regulatory regimes of the individual States.

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[21] *Id.* at 2269 (majority opinion).

[22] *See New York v. United States*, 505 U.S. 144, 155 (1992); *United States v. Lopez*, 514 U.S. 549, 575 (Kennedy, J., concurring, with O'Connor, J., joining); *Printz v. United States*, 521 U.S. 898, 117, S.Ct. 2365, 2376 (1997); *see also* Michael C. Dorf, "Foreward: The Limits of Socratic Deliberation," 112 Harv. L. Rev. 4, 62-63 (1998).

[23] *See, e.g., U.S. v. Lopez*, 514 U.S. 549, 583 (Kennedy, J., concurring).

Under the principles of federalism, neither the State nor the nation can be supreme: both must be subordinated to the Constitution itself. This balancing between the federal and State levels of government fosters a true laboratory model of democracy as developed by the States. Justice O'Connor noted in *Federal Energy Regulatory Commission v. Mississippi*[24] that:

> . . . The 50 States serve as laboratories for the development of new social, economic and political ideas. This State innovation is no judicial myth. When Wyoming became a State in 1890, it was the only State permitting women to vote. That novel idea did not bear national fruit for another 30 years. Wisconsin pioneered unemployment insurance, while Massachusetts initiated minimum wage laws for women and minors. . . .
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> In addition to promoting experimentation, federalism enhances the opportunity of all citizens to participate in representative government. Alexis de Tocqueville understood well that participation in local government is a cornerstone of American democracy . . . . If we want to preserve the ability of citizens to learn democratic processes through participation in local government, citizens must retain the power to govern, not merely administer, their local problems.[25]

Building upon her opinion in this 1982 decision, in 1992 Justice O'Connor expounded upon the principles of federalism in *Gregory v. Ashcroft*:[26]

> This federalist structure of joint sovereigns preserves to the people numerous advantages. It assures a decentralized government that will be more sensitive to the diverse needs of a heterogeneous society; it increases opportunity for citizen involvement in democratic processes; it allows for more innovation and experimentation in government; and it makes government more responsive by putting the States in competition for a mobile citizenry.
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> Perhaps the principal benefit of the federalist system is a check on abuses of government power. "The 'constitutionally mandated balance of power' between the States and the Federal Government was adopted by the Framers to ensure the protection of 'our fundamental liberties.'" Just as the

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[24] 456 U.S. 742 (1982).

[25] *Id.* at 788 and 791 (O'Connor, J., concurring in the judgment in part and dissenting in part).

[26] 501 U.S. 452 (1992).

> separation and independence of the coordinate branches of the Federal Government serve to prevent the accumulation of excessive power in any one branch, a healthy balance of power between the States and the Federal Government will reduce the risk of tyranny and abuse from either front.[27]

Justice O'Connor was not breaking new ground with these decisions. These principles of federalism have long been fundamental to the American system of government. Indeed, fifty years earlier, Justice Louis Brandeis wrote, "Denial of the right to experiment may be fraught with serious consequences to the Nation. *It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel and social and economic experiments without risk to the rest of the country.*"[28]

Three very recent decisions are instructive that the doctrines of State sovereignty and federalism place sharp curbs on the ability of Congress to control matters solely within the province of the States.[29] While the cases centered on States' sovereign immunity, the direction and resolve of the Court in favor of recognizing States' rights *vis-à-vis* federal mandates and harnessing the States' judicial machinery cannot be understated. In *Alden v. Maine*, Justice Kennedy, writing for the Court, insisted that federalism limits what laws Congress may impose upon States: "Congress has vast powers but not all power. When Congress legislates in matters affecting the States, it may not treat these sovereign entities as mere prefectures or corporations. Congress must accord States the esteem due to them as joint participants in a federal system."[30] Further, where a concern is local, like education or land use, the federal government may not be the ideal mechanism for expressing the will of the people: "In choosing to ordain and establish the Constitution, the people insisted upon a federal structure for the very purpose of rejecting the idea that the will of the people in all instances is expressed by the central power, the one most remote from their control."[31]

The PRPA clearly aims to nullify Oregon's Death With Dignity Act and mandate national uniformity on a question the U.S. Supreme Court has expressly encouraged

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[27] *Id.* at 458-59 (citations omitted).

[28] *New Ice Cream Co. v. Liebman*, 285 U.S. 262, 311 (1932) (emphasis added).

[29] *Alden v. Maine*, ___ U.S. ___, 119 S.Ct. 2240 (1999); *Florida Prepaid Post Secondary Expense Bd. v. College Savings Bank*, ___ U.S. ___ 119 S.Ct. 2199 (1999); *College Savings Bank v. Florida Prepaid Post Secondary Expense Bd.*, ___ U.S. ___, 119 S.Ct. 2219 (1999).

[30] *Alden v. Maine*, 119 S.Ct. at 2268.

[31] *Id.*

State-by-State experimentation. The Oregon electorate's social policy "experiment" with physician-assisted suicide poses no risk to the rest of the country; indeed, the data emerging from Oregon reveals that none of the abuses speculated to occur have in fact occurred. [32] The PRPA would constitute a direct assault on our nation's core tenets of federalism. In addition, the PRPA would tread on the common law and possibly constitutional rights of individuals to make decisions about pain treatment, recognized by the Supreme Court. [33] As such — regardless of one's views on the morality of physician-assisted suicide — the PRPA is bad public policy and a danger to the foundational principles of our democratic form of government.

III. Conclusion: The PRPA Should Be Defeated.

For the reasons set forth above, we respectfully request that you and your colleagues vote against S. 2151. Other legislation (such as the Conquering Pain Act) — that would truly encourage aggressive palliative care — can address the nationwide problem of undertreatment of pain, without creating the serious health policy and constitutional problems engendered by the PRPA.

Yours very truly,

Nicholas W. van Aelstyn

Nicholas W. van Aelstyn

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[32] Chin, A., *et al.* "Legalized Physician-assisted Suicide in Oregon -- The First Year's Experience." *New Eng. J. Med.* 1999; 340: 577-583.

[33] *See* Dorf, "Foreward: The Limits of Socratic Deliberation," *supra* note 22, at 64-65 (When, as in the physician-assisted suicide cases, the possibility of experimentation by the states plays a substantial role in the provisional decision to deny recognition to a right, the Court ought to limit the federal government's ability to adopt a uniform national solution before there has been a substantial period for experimentation.).

ACTION MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed
Chris Jennings

SUBJECT: Assisted Suicide legislation

On Wednesday, the House is tentatively scheduled to vote on H.R. 2260, the Pain Relief Promotion Act of 1999. As you will recall, this legislation, sponsored by Congressman Hyde, modifies the Controlled Substances Act (CSA) to create criminal penalties for the use of a controlled substance in physician assisted suicides. It also takes new steps to protect the appropriate provision of palliative care, a significant modification to the previous version of this legislation.

While the Department of Justice strongly supports the palliative care provisions of the bill, it has strong concerns about the federalism issues it raises and the penalty structure it creates. They would like to forward the attached letter of opposition to the House Judiciary Committee outlining these concerns. This letter does not include a veto threat. We recommend that the letter be sent, but that the White House refrain from public comment on the legislation.

BACKGROUND

Representative Hyde introduced the H.R. 2260 this summer. It is the second generation of the legislation known as the Lethal Drug Abuse Prevention Act of 1998 (LDAP). As you will recall, you and virtually every respected consumer and health care provider group, including the AMA, opposed LDAP because of the fear that the legislation would inhibit pain relief for the terminally ill. The provisions of most concern to provider and consumer groups included the establishment of broad prosecutorial authority for law enforcement officials, allowing the investigation of health care providers that were suspected of planning to use or of having used a controlled substance to assist in a suicide, and the absence of a proactive statement protecting the provision of appropriate palliative care.

H.R. 2260 would make physician-assisted suicide using controlled substances subject to administrative, civil, and criminal sanctions, and effectively ban the practice in all 50 states. However, Representative Hyde has modified the old version of this legislation to incorporate an explicit statement that using a controlled substance to alleviate pain and discomfort is a legitimate medical purpose, even if the use of the controlled substance increases the likelihood of death. It also narrows prosecutorial authority to suspected cases of the use of a controlled substance in an assisted suicide, and requires local, state, and Federal law enforcement personnel to receive information on palliative care in continuing education programs. Because of these modifications, the bill is now supported by many of the groups who previously

opposed it, including the AMA, the National Hospice Association, and the National Academy of Pain Management.

Notwithstanding the modifications to the bill, a number of provider organizations, including the American Nurses Association and the American Academy of Family Physicians, still oppose this legislation because they feel that H.R. 2260 will place the Department of Justice in the position of regulating the practice of medicine, which is traditionally the purview of the states. In addition, since this legislation would effectively nullify the Oregon Death With Dignity Act, Governor Kitzhaber and Senator Wyden view this legislation as an unnecessary intrusion into state policy making and oppose its passage.

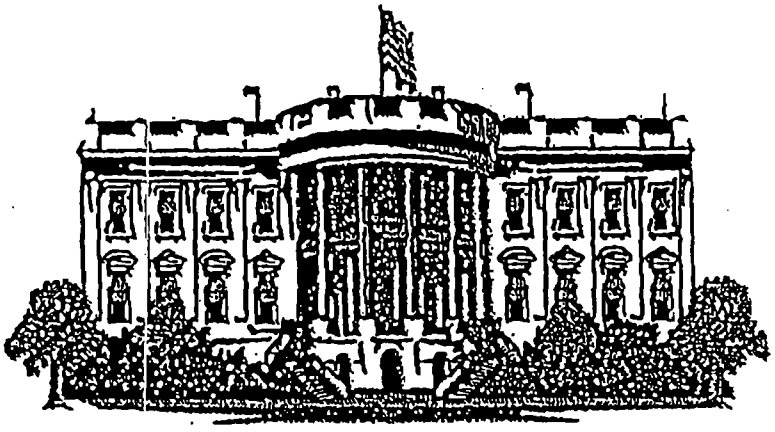
The Justice Department is very supportive of the new provisions protecting appropriate palliative care. However, because H.R. 2260 effectively blocks all state policy-making on the issue of physician assisted suicide, the Attorney General shares the federalism concerns of the Oregon delegation. In addition, she believes that the legislation establishes criminal and administrative sanctions that will be burdensome and difficult to implement and enforce.

RECOMMENDATION

The Department of Justice wants to ensure that their concerns are not construed as opposition to the legislation's intent. The Attorney General, like you, strongly opposes physician assisted suicide, but believes the legislation's approach can be improved. Although she has no interest in engaging in a protracted dispute with Senator Nickles (who has introduced a similar bill in the Senate) and Congressman Hyde, she feels strongly that her Department should formally voice their concerns to the Congress, with the hope of an opportunity to address some of them, particularly the criminal and administrative penalty provisions, in conference.

We would recommend that the Department of Justice be permitted to forward this letter. Having said this, and given the cross-currents of opinion on this issue and on this bill, we believe that there should not be a strong White House public statement on the legislation until and unless it has been submitted to you for signature.

THE WHITE HOUSE



Christopher C. Jennings
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U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

Honorable Henry Hyde
Chairman
Committee on the Judiciary
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This letter presents the views of the Department of Justice on H.R. 2260, the "Pain Relief Promotion Act of 1999."

H.R. 2260 makes two changes to federal drug law as it relates to the use of controlled substances by terminally ill patients. First, the bill clarifies that controlled substances may be used to alleviate pain in the course of providing palliative care to terminally ill patients. The bill also funds research and education on the appropriate use of controlled substances for this purpose. The Department strongly supports these provisions of H.R. 2260.

Second, H.R. 2260 states that the use of controlled substances to assist a terminally ill person in committing suicide is not authorized by federal law. The Department opposes physician-assisted suicide, but is concerned about the propriety of a federal law that would unquestionably make physician-assisted suicide a federal crime with harsh mandatory penalties. Imposing such penalties would also effectively block State policy making on this issue at a time when, as the Supreme Court recently noted in Washington v. Glucksberg, 117 S. Ct. 2258, 2275 (1997), the States are still "engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide."

Palliative Care

Section 101 of H.R. 2260 amends section 303 of the CSA, 21 U.S.C. § 823, to specify that the use of controlled substances to "alleviat[e] pain or discomfort in the usual course of professional practice" is a "legitimate medical purpose" under the Controlled Substances Act, 21 U.S.C. § 841, "even if the use of such a substance may increase the risk of death." Because a physician who acts with a "legitimate medical purpose" is acting

in compliance with the Act.[1] H.R. 2260 creates a "safe harbor" against administrative and criminal sanctions when controlled substances are used for palliative care. Sections 102, 201 and 202 amend the CSA and the Public Health Service Act (42 U.S.C. § 299) to authorize the Attorney General, the Administrator of the Agency for Health Care Policy and Research, and the Secretary of the Health and Human Services Department to conduct research on palliative care, to collect and distribute guidelines for the administration of palliative care, and to award grants, cooperative agreements, and contracts to health schools and other institutions to provide education and training on palliative care.

The Department fully supports these measures. H.R. 2260 would eliminate any ambiguity about the legality of using controlled substances to alleviate the pain and suffering of the terminally ill by reducing any perceived threat of administrative and criminal sanctions in this context. The Department accordingly supports those portions of H.R. 2260 addressing palliative care.

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[1] See, e.g., 21 C.F.R. § 1306.04(a) (authorizing prescriptions only for "legitimate medical purposes").

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The Administration strongly opposes the practice of physician-assisted suicide and would not support the practice as a matter of federal policy. H.R. 2260 side-steps the federal policy question, however, and operates instead by blocking state policy making on an issue that many, including the Supreme Court, think is appropriately left to the States to decide as each chooses.[4]

Moreover, H.R. 2260 would affirmatively interfere with state policy making in a particularly heavy handed way by using 20-year mandatory prison sentences (as well as civil and administrative sanctions) to effectively preclude states from adopting any policy that would authorize physician-assisted suicide, even if that authorization contains carefully drafted provisions designed to protect the terminally ill.

For these reasons, H.R. 2260 is particularly intrusive to state policy making and the Department accordingly opposes this portion of the bill.[5] The Department would, however, be willing to work with the Committee in formulating a legislative or regulatory solution that obviates the concerns identified in this letter.[6]

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Thank you for this opportunity to present our views. The Office of Management and Budget has advised us that from the standpoint of the Administration, there is no objection to the submission of this letter. Please do not hesitate to call upon us if we may be of further assistance.

Sincerely,

Robert Raben
Assistant Attorney General

cc: Honorable John Conyers, Jr.
Ranking Minority Member

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Reed
Jennings
Podesta

10-19-99

THE WHITE HOUSE
WASHINGTON

October 18, 1999

ACTION MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed
Chris Jennings

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ASSISTED SUICIDE

WASHINGTON

Russia, China, N. Korea top list of possible threats to U.S.

Russia, China and North Korea pose the greatest threat to the United States from long-range ballistic missiles, the CIA said in a report Thursday. The report comes as the Republican-led Congress pushes President Clinton to endorse a national missile defense system.

The new threats are from North Korea, which might test-fire a new long-range missile this year, and Iran, which over the next 15 years is likely to develop missiles that reach the United States. The threat from North Korea is heightened by its "willingness to sell its missiles," an unclassified summary of the report said. It said the emerging missile forces could kill millions of Americans and could be armed with nuclear, chemical or biological warheads.

The United States has no means of shooting down long-range ballistic missiles, although the Pentagon is spending billions of dollars to develop anti-missile missiles to shield the United States against a limited attack.

President Clinton has opposed deployment of a national ballistic missile defense system. Citing concerns about Russia's reaction and the effect on strategic arms treaties, Clinton favors research of such a system but wants to delay a decision whether to deploy one.

AP file photo

Coburn: Introduced reform bill

PATIENTS' RIGHTS: Rep. Tom Coburn, R-Okla., introduced a managed-care reform bill that would allow patients to sue their HMOs under certain limited circumstances. "We want to hold health plans accountable for health care that should be given," said Coburn, who is a physician. He said he has situations once or twice a week where an HMO denies treatment he believes is needed. "And I'm only practicing one or two days a week," Coburn said. "You should hear my partners. They are really screaming."

Mike Schwartz, Coburn's chief of staff, said the bill would allow for fewer lawsuits than a Clinton-backed version because it would encourage settlement of cases by patients' review boards. Coburn expects to win backing for his legislation from House Speaker Dennis Hastert, R-Ill., Schwartz said. — Kathy Kiely

LOGGING RULES: The Senate voted 52-45 to give federal agencies more leeway in assessing the potential effects of logging and other activities on rare plants and animals. The provision, part of a spending bill, would allow the Forest Service and Bureau of Land Management to use existing studies rather than conduct individual surveys for each sensitive species. It would effectively overturn two federal court rulings. Proponents said the survey requirement is unnecessary, costly and harmful to economies that rely on the timber industry. "This is about pitting a survey of fungus, snails and slugs against children and families who need streets and schools," Sen. Gordon Smith, R-Ore., said. But Sen. Max Cleland, D-Ga., called the vote "a defeat for anyone who cares about our national forests."

ASSISTED SUICIDE: The House Judiciary Committee began considering legislation that would overturn Oregon's physician-assisted suicide law and possibly change how doctors nationwide manage their patients' pain. The Republican-led panel rejected two Democratic measures that would allow states to set their own laws on assisted suicide.

Opponents of the measure noted that Oregon voters twice approved the controversial law. Rep. Jerrold Nadler, D-N.Y., said individuals or states, not the federal government, should be the arbiter.

Proponents said the legislation is needed to uphold the federal Controlled Substances Act, which allows narcotics and certain other drugs only for legitimate medical purposes. Others said they want to preserve life at both its beginning and end. — Wendy Koch

MONEY MATTERS: Automated teller machines would be banned from casino floors under legislation introduced by Rep. John LaFalce, D-N.Y. He said the proposed ban was recommended in a recent report by the National Gambling Impact Study Commission. Wayne Mehl, a lobbyist for the Nevada Resort Association, said ATMs don't induce people to gamble and are "primarily used by customers for nongaming activities such as entertainment, retail (shopping) and food."

ON THE CAMPAIGN TRAIL

By Charles Rex Arbogast, AP

Aboard the Bradley bus: Bill Bradley heads for Keokuk, Iowa, Thursday.

BRADLEY HEALTH CARE: Democratic presidential candidate Bill Bradley said he'll soon propose a health-care plan that offers "coverage for as many people as possible." The former senator from New Jersey didn't say how many of the 44 million uninsured his plan would cover or how much it would cost.

Standing under his childhood basketball hoop in Crystal City, Mo., Bradley said he'll make those decisions soon. He said the country is more receptive to health-care changes now than it was in 1993 when Congress rejected a complex, ambitious plan that was developed by a task forced headed by first lady Hillary Rodham Clinton. Bradley said doctors, hospitals and patients are increasingly unhappy about "large corporate entities with bureaucrats" making medical decisions.

Bradley also criticized the Clinton administration foreign policy as "misdirected and ineffective." He said the United States has become a missionary for "international capitalism" instead of being "the undisputed giant of the world, acting out of our own national interest." — Jill Lawrence

GORE GETS THE HOOK: Some New England fishermen are angry because they thought the $5 million in emergency aid that Vice President Gore announced last week in Boston was new assistance to the financially troubled industry. But it actually had been announced last fall by members of Congress who spent much of the year putting it together. "It really stinks of cheap, election-year politics," Paul Cohane of the Gulf of Maine Fisherman's Association told *The Boston Globe*. "Mr. Gore had very little to do with this, and yet he came and took all the glory." Gore spokesman Chris Lehane said, "The vice president was extremely pleased to be able to make the formal official announcement on behalf of the administration to make available emergency relief."

CAMPAIGN ADS: Broadcasters must sell larger blocks of air time for political candidates to run longer ads, the Federal Communications Commission said. The 4-1 vote means political ads won't have to fit within the usual 30- or 60-second time slots typically sold to commercial advertisers. Public advocacy groups sought the change, so candidates can delve into greater detail of their policies. Broadcasters said politicians and commercial advertisers should be treated the same.

BAUER CAMPAIGN: Republican presidential candidate Gary Bauer said he's hit the $5 million mark in fund-raising. Bauer, the former head of the Family Research Council, had raised $3.4 million as of June 30, the last time candidates filed their fund-raising reports.

Written by Paul Leavitt with staff and wire reports

USA TODAY · FRIDAY, SEPTEMBER 10, 1999

Danforth to probe Waco's 'dark' side

By Kevin Johnson
USA TODAY

WASHINGTON – In a blunt assessment of his mission, former senator John Danforth said Thursday that he intends to explore what he called "the dark questions" about the deadly Branch Davidian standoff in Waco, Texas, in 1993 to determine whether federal officers killed innocent people.

Danforth formally accepted the appointment as special counsel to investigate the Waco matter by saying he would use all of the power at his disposal and "let the chips fall where they may."

"My job is to answer the dark questions," Danforth said after being introduced to reporters by Attorney General Janet Reno. "Was there a cover-up? And did the government kill people?"

For the past two weeks, Reno had been searching for an outside investigator because the FBI admitted, six years after the fact, that it indeed launched flammable tear-gas canisters near the Branch Davidian complex several hours before it burned to the ground April 19, 1993. More than 80 people were killed.

Reno, who ordered the government's final assault on the compound, continues to believe that the FBI's previously undisclosed actions did not contribute to the fatal conflagration.

Nevertheless, she announced Thursday that she would have no oversight of Danforth's activities. Instead, Deputy Attorney General Eric Holder, the department's second-ranking official, who was not involved in the Waco operation six years ago, will oversee the investigation.

Danforth said that, as a condition of his employment, he was provided the broadest possible investigative authority, including the power to question Reno and FBI Director Louis Freeh and to empanel a grand jury if he sees fit.

The Justice Department released a statement outlining the points of inquiry:

▶ Did government officials make false or misleading statements?

▶ Was evidence or information about the siege destroyed, altered or suppressed by government agents?

▶ Were incendiary or pyrotechnic devices used by law officers on the day the Davidian compound burned?

▶ Did government agents start or contribute to the spread of the deadly fire?

▶ Did government agents turn gunfire on the compound on the day it burned?

"The recent revelations (by the FBI) have caused the American people to raise new questions," Reno said. "Sen. Danforth, I think, is a person who can find those answers."

By Paul J. Richards, Agence France-Presse

Mission begins: Janet Reno and John Danforth

Asked whether she considered resigning, as demanded Wednesday by Senate Majority Leader Trent Lott, Reno offered a smile and a brief, defiant response.

"I don't run from controversy," she said.

Though declining to speculate about the course of his inquiry, Danforth said he was all but certain that the FBI would have no role in it. "I don't believe the FBI should be investigating the FBI," he said.

Danforth suggested he would seek investigative help outside the Justice Department. Officials said later that he might hire postal inspectors or private investigators.

Unlike the open-ended style of investigations conducted under the now-expired independent-counsel law, Danforth asserted Thursday that his inquiry will be limited in scope and budget. It will focus simply on whether the government started the fire.

"Our country can survive bad judgment," the former senator said. "But the thing that really undermines the integrity of government is whether there were bad acts, whether the government killed people."

Congressional leaders already were staking out their own separate examinations of Waco and promising detailed analyses of the government activities there, no matter how incidental they might have been to the siege's tragic end.

"It was appropriate for the attorney general to appoint someone with credibility on Capitol Hill," Senate Judiciary Committee Chairman Orrin Hatch said. "Still, I believe it is in the best interests of the Department of Justice, the FBI and the public that Congress conduct its own independent examination of the circumstances and events which led to evidence being concealed."

▶ Lessons from Reno, 19A

Bush posts campaign donor list on Web site

Internet update shows candidate has raised $49 million

By Jim Drinkard and Judy Keen
USA TODAY

Republican presidential front-runner George W. Bush published a list of his campaign donors on his Internet site Thursday, becoming the first candidate to make such disclosures ahead of the quarterly schedule dictated by federal law.

The list showed that as of Aug. 26, Bush had raised $49.2 million, an unprecedented sum that put him on a pace to surpass $55 million by Sept. 30, the end of the third quarter.

How high can he go? "Our success speaks for itself," said Don Evans, Bush's chief campaign fund-raiser.

Spokeswoman Mindy Tucker said the Web site posting, less than a week before Congress opens debate on revamping the law governing campaign financing, underscored Bush's belief in disclosure as the best way to prevent fund-raising abuses. Tucker said that the Web list will be updated daily, with a two-week lag between when money is received and when it is listed.

The Internet listing appeared to be, in part, a rebuttal of criticism that Bush's campaign is tainted by its extraordinary cash resources. His closest Republican competitor in fund-raising, Arizona Sen. John McCain, reported raising $4.3 million as of June 30, when the previous reporting period ended.

Some of his GOP opponents have suggested that Bush is trying to buy the party's nomination. Democrats have been critical of his decision to forgo federal matching funds, which allows him to escape spending limits for the state primaries.

The Web list contained more than 30,000 names of people who have given to the campaign since June 30.

It included lobbyists such as Frank Zarb, head of the National Association of Securities Dealers, who with his wife, Patricia, each gave the $1,000 maximum; and executives such as John Dasburg, CEO of Northwest Airlines, Peter Coors of Coors Brewing, and NBC President Robert Wright. All are $1,000 donors.

Another $1,000 giver was former senator John Danforth, R-Mo., whom Attorney General Janet Reno has just named to investigate the FBI's involvement in the Branch Davidian standoff near Waco, Texas. Danforth's wife, Sally, also gave $1,000.

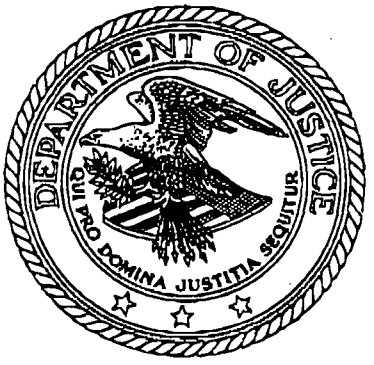
Other donors: Brayton Yerkes, a Hollywood stuntman who gave $1,000, and Brian Willhite, a night auditor at an Indianapolis hotel, who gave $15.

The list showed that during the summer, usually the slowest political fund-raising time, Bush brought in $6 million a month. That pace is likely to increase this fall as he makes his first foray to the nation's biggest political money center, New York City, for an early October fund-raiser.

UNITED STATES DEPARTMENT OF JUSTICE

Office of Nicholas M. Gess
Associate Deputy Attorney General

950 Pennsylvania Avenue, N.W.
Room 4220
Washington, DC 20530
Telephone: (202) 514-0835



HRLS

ERIC - FYI

NOT URGENT BR

TO: **Bruce Reed, 456-2878**
Thurgood Marshall, 456-2525

OFFICE NUMBER:

FAX NUMBER:

FROM: **Nicholas M. Gess**

DATE/TIME: **July 26, 1999**

NUMBER OF PAGES INCLUDING THIS SHEET:

TELEPHONE NUMBER OF PERSON TO CONTACT UPON RECEIPT:

* * * FAX NUMBER: (202) 514-9368 PHONE NUMBER 202-514-0835 * * *

REMARKS: Please see attached

BS 1/26/00
Success

U.S. Department of Justice

Office of the Deputy Attorney General

Office of the Associate Deputy Attorney General

Washington, D.C. 20530

July 26, 1999

MEMORANDUM

TO: Bruce Reed
Thurgood Marshall, Jr.

FROM: Nick Gess

SUBJECT: Physician Assisted Suicide

Earlier today, you may have received a draft views letter on HR 2260 (Physician Assisted Suicide). Attached is an updated letter which has now cleared OLC. This has not been seen by either the AG or Eric Holder. There is a markup on this bill tomorrow and although it is unlikely that anything will clear before that time, I wanted to make certain that we got this over to you because I know that this was of personal interest to the President and senior staff when the issue arose last year.

Please call (514-0835) or page (514-5000) me if you have any questions.

Enclosure

DRAFT
7/26/99-1825

Honorable Henry Hyde
Chairman
Committee on the Judiciary
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This letter presents the views of the Department of Justice on H.R. 2260, the "Pain Relief Promotion Act of 1999."

H.R. 2260 makes two changes to federal drug policy as it relates to the use of controlled substances by terminally ill patients. First, the bill makes it clear that controlled substances may be used to alleviate pain in the course of providing palliative care to terminally ill patients. The bill complements this authorization by funding research and education on the appropriate use of controlled substances for this purpose. The Department supports these provisions of H.R. 2260.

Second, H.R. 2260 strongly implies — but does not explicitly state — that the use of controlled substances to assist a terminally ill person in committing suicide is not authorized by federal law. The Department is concerned about this aspect of the bill in two respects -- its impact on the Attorney General's discretion in regulating controlled substances and its use of the Controlled Substances Act as the instrument of federal policy with respect to physician assisted suicide.

We will address these aspects of the bill separately.

Palliative Care

Section 101 of H.R. 2260 amends section 303 of the Controlled Substances Act, 21 U.S.C. § 823, to specify that the use of controlled substances to "alleviat[e] pain or discomfort in the usual course of professional practice" is a "legitimate medical purpose"

under the Controlled Substances Act, 21 U.S.C. § 841 et seq., "even if the use of such a substance may increase the risk of death." Because a physician who acts with a "legitimate medical purpose" is acting in compliance with the Act,[1] H.R. 2260 effectively creates a "safe harbor" against administrative and criminal sanctions when controlled substances are used for palliative care. Sections 102, 201 and 202 amend the Controlled Substances Act and the Public Health Service Act (42 U.S.C. § 299 et seq.) to authorize the Attorney General, the Administrator of the Agency for Health Care Policy and Research, and the Secretary of the Health and Human Services Department to conduct research on palliative care, collect and distribute guidelines for the administration of palliative care, and to award grants, cooperative agreements, and contracts to health schools and other institutions to provide education and training on palliative care.

The Department fully supports these measures. Ambiguity about the legality of using controlled substances to alleviate the pain and suffering of the terminally ill can inhibit physicians from prescribing adequate pain medication for these patients. H.R. 2260 would eliminate this ambiguity and remove the threat of administrative and criminal sanctions in this context. This will allow physicians to act according to their professional judgment in caring for the terminally ill, who are often in the most extreme pain.

We understand that the American Medical Association is advocating an amendment to section 102 of the bill that would curtail the Department's discretion in enforcing the Controlled Substances Act by subjecting the enforcement authority of the Drug Enforcement Administration (DEA) to any guidelines that the Health and Human Services Department promulgates on the proper use of controlled substances for palliative care purposes. While we agree that clear, easy-to-follow guidelines are important, we do not think it is good policy to have an agency not charged with the administration of the Controlled Substances Act tie the hands of the agency that is charged with enforcing the Act. Nor is such a provision necessary since DEA agents would already be required by H.R. 2260 to take HHS guidelines into account in deciding whether to proceed. Accordingly, we would oppose such an amendment to section 102.

As currently written, however, the portions of H.R. 2260 addressing palliative care have the Department's support.

Physician Assisted Suicide

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[1] See, e.g., 21 C.F.R. § 1306.04(a) (authorizing prescriptions only for "legitimate medical purposes").

Section 101 amends section 303 of the Controlled Substances Act to add subsection (i), providing that "[n]othing in this section authorizes intentionally dispensing, distributing, or administering a controlled substance for the purpose of causing death or assisting another person in causing death."

This language could be read to curtail the Attorney General's authority under the Controlled Substances Act and to subject physicians to administrative and criminal sanctions in the event they prescribe controlled substances to assist a suicide. Because the proposed amendment refers to "this section" – and not merely to the newly added subsection (i) - the amendment would apply more broadly to all of section 303, which is the section that directs the Attorney General to register individuals to authorize them to manufacture and dispense controlled substances under certain circumstances. By modifying the entire section, H.R. 2260 would restrict the scope of the registration granted by the Attorney General under section 303 of the Controlled Substances Act, by providing that no registration allows a physician to dispense controlled substances for the purpose of assisting in a suicide.

Because a physician's registration under 21 U.S.C. § 824 may be revoked based on an applicant's failure to comply "with applicable State, Federal, or local laws relating to controlled substances," this reading of H.R. 2260 would also appear to give the Attorney General the power to revoke or suspend registrations of physicians who have prescribed controlled substances for the purpose of assisting in suicides. H.R. 2260 might also authorize criminal prosecution because the Controlled Substances Act makes it a crime "for any person knowingly or intentionally" to dispense a controlled substances "[e]xcept as authorized by this subchapter."[2] If a physician's registration did not permit dispensing for the purpose of assisting a suicide (as it would not under H.R. 2260), then such dispensing would not be "authorized by this subchapter."[3]

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[2] 21 U.S.C. § 841(a); see also 21 U.S.C. § 822(b) ("Persons registered by the Attorney General under this subchapter . . . are authorized to . . . dispense such substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter.") (emphasis added).

[3] The net effect of this amendment is essentially to checkmate state laws, such as Oregon's Death with Dignity Act, that authorize physician-assisted suicide, because physicians who comply with mandated state procedures may nevertheless lose their DEA registrations or be subject to federal criminal prosecution. Physicians under an Oregon-like scheme cannot prescribe controlled substances to assist suicide under the guise of alleviating pain because the state law requires a paper trail

H.R. 2260 further provides that the policies of the States on physician assisted suicide would be of no consequence when the DEA assesses whether to bring administrative actions against a physician for assisting a suicide using controlled substances. Section 101 would add a new subsection (i)(2) to section 303 of the Controlled Substances Act, which would provide that "in determining whether a registration is consistent with the public interest under this Act, the Attorney General shall give no force and effect to State law authorizing or permitting assisted suicide or euthanasia." The "public interest" is a touchstone inquiry in a registration revocation proceeding under 21 U.S.C. § 824(a). H.R. 2260 would therefore undermine the Attorney General's prior position that the Controlled Substances Act did not authorize administrative action against a physician who assisted a suicide pursuant to a state law authorizing such assistance, such as Oregon's Death with Dignity Act.[4]

Like proposed subsection (i)(1), discussed above, this subsection does not affirmatively prohibit physician-assisted suicide. It is a neutral statement that state policies should not influence federal policy. If the goal of these two amendments is to establish a clear federal policy against physician-assisted suicide, they serve this goal poorly.

More fundamentally, the Department does not believe that the Controlled Substances Act is an effective or appropriate vehicle for establishing a federal policy on physician-assisted suicide. The Act is a complex regulatory system, supported by criminal, civil and administrative penalties, designed to keep legally available controlled substances within lawful channels of distribution and use, and to prevent their diversion to illicit channels. See S. Rep. No. 91-613, at 3 (1969). The particular drug abuse that Congress intended to prevent in the Act was the abuse deriving from stimulant, depressant, or hallucinogenic effect on the central nervous system of controlled substances. The Controlled Substances Act is therefore ill-suited to be the platform for the articulation of national policy on physician-assisted suicide because physician-

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documenting the intent to assist in the requested suicide. See, e.g., O.R.S. § 127.855 (specifically requiring a physician in Oregon to "document[] or file[]" evidence of compliance with the Oregon Act's notice and waiting period requirements in the patient's medical record, and "indicat[e] that all requirements under [the Oregon law] have been met"). A physician who does not leave such a trail risks criminal prosecution by the State. See, e.g., id. § 127.885 (exempting physicians from criminal prosecution only if they comply with the Act).

[4] Letter from Attorney General Janet Reno to Sen. Orrin Hatch (June 5, 1998).

assisted suicide does not involve either the issue of diversion of drugs to illicit channels or the issue of drug abuse for psychoactive effects. Nor does it make sense to charge the DEA with interpreting federal policy regarding the "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide,"[5] simply because such suicide may involve the use of controlled substances. Furthermore, addressing an issue as charged as physician-assisted suicide in this way obfuscates the importance of discussion and debate about the wisdom of such a policy, and may hinder Congressional accountability for the policy, which is a valued aspect of our system of government.

The Controlled Substances Act is also an ineffective tool for banning physician-assisted suicide. It is our understanding that in the most common "prescription" for death, controlled and non-controlled substances are used in combination; in such cases, the controlled substance is used as a sedative while the non-controlled substances is the actual cause of death. Because H.R. 2260 bans only the use of controlled substances, it is probable that at least some patients and physicians in states with authorized physician-assisted suicide procedures would forego the controlled substance sedative, resulting in more painful deaths for the patients.

We are not, however, suggesting a federal law prohibiting physician-assisted suicide. We are not convinced that this would be a wise policy at this time. Such a law would, for example, clearly overturn the judgment of Oregon voters that physician-assisted suicide is appropriate under certain conditions and after certain procedures have been met.

The moral and ethical issues surrounding the propriety of physician-assisted suicide are difficult and are currently being debated in State legislatures all across the nation. The Supreme Court in Washington v. Glucksburg declined to cut short this debate by precluding States from banning physician-assisted suicide, and we think it may be similarly advisable not to curtail the debate by precluding States from authorizing physician-assisted suicide. As many Justices noted in Glucksburg, this is the type of issue best left to the laboratory of the States in the first instance.[6]

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[5] Washington v. Glucksburg, 117 S. Ct. 2258, 2275 (1997).

[6] Glucksburg, 117 S. Ct. 2258, 2274 (noting that debate over physician-assisted suicide is underway in the States, "as it should in a democratic society"); id. at 2303 (O'Connor, J., concurring) (endorsing majority's result, which left "the . . . challenging task of drafting appropriate procedures for safeguarding . . . liberty interests . . . to the `laboratory' of the States"); id. at 2293 (Souter, J., concurring) (emphasizing that, in light of current state experimentation, "[t]he Court

For these reasons, we think the time is not yet ripe for federal intervention.

Thank you for this opportunity to present our views. The Office of Management and Budget has advised use that from the standpoint of the Administration's program, there is no objection to submission of this letter. Please do not hesitate to call upon us if we may be of further assistance.

Sincerely,

Jon P. Jennings
Acting Assistant Attorney General

cc: Honorable John Conyers, Jr.
Ranking Minority Member

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should stay its hand to allow reasonable legislative consideration [of this difficult issue]").

HR 2260 IH

106th CONGRESS

1st Session

H. R. 2260

To amend the Controlled Substances Act to promote pain management and palliative care without permitting assisted suicide and euthanasia, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

June 17, 1999

Mr. HYDE (for himself, Mr. STUPAK, Mr. ADERHOLT, Mr. BAKER, Mr. BALLENGER, Mr. BARCIA, Mr. BARTON of Texas, Mr. BLUNT, Mr. BRYANT, Mr. BURR of North Carolina, Mr. BURTON of Indiana, Mr. CANADY of Florida, Mr. CHABOT, Mr. COBURN, Mr. COLLINS, Mr. CUNNINGHAM, Mr. DICKEY, Mr. DOOLITTLE, Mr. DOYLE, Mrs. EMERSON, Mr. EVERETT, Mr. FOSSELLA, Mr. GRAHAM, Mr. GOODE, Mr. GOODLATTE, Mr. HALL of Texas, Mr. HAYES, Mr. HERGER, Mr. HOEKSTRA, Mr. HUTCHINSON, Mr. ISTOOK, Mr. JOHN, Mr. KING, Mr. KNOLLENBERG, Mr. LAFALCE, Mr. LAHOOD, Mr. LARGENT, Mr. LEWIS of Kentucky, Mr. LUCAS of Kentucky, Mr. LUCAS of Oklahoma, Mr. MCINTYRE, Mr. MILLER of Florida, Mrs. MYRICK, Mr. NUSSLE, Mr. NETHERCUTT, Mr. PETERSON of Pennsylvania, Mr. PETERSON of Minnesota, Mr. PHELPS, Mr. PICKERING, Mr. PITTS, Mr. PORTMAN, Mr. RAHALL, Mr. ROGAN, Mr. ROGERS, Mr. SALMON, Mr. SCHAFFER, Mr. SENSENBRENNER, Mr. SHIMKUS, Mr. SHOWS, Mr. SKELTON, Mr. SMITH of Texas, Mr. SMITH of New Jersey, Mr. SPENCE, Mr. STEARNS, Mr. TANCREDO, Mr. TERRY, Mr. WALSH, Mr. WAMP, and Mr. WELDON of Florida) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Controlled Substances Act to promote pain management and palliative care without permitting assisted suicide and euthanasia, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the `Pain Relief Promotion Act of 1999'.

TITLE I--USE OF CONTROLLED SUBSTANCES CONSISTENT WITH THE CONTROLLED SUBSTANCES ACT

SEC. 101. REINFORCING EXISTING STANDARD FOR LEGITIMATE USE OF CONTROLLED SUBSTANCES.

Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

`(i)(1) For purposes of this Act and any regulations to implement this Act, alleviating pain or discomfort in the usual course of professional practice is a legitimate medical purpose for the dispensing, distributing, or administering of a controlled substance that is consistent with public health and safety, even if the use of such a substance may increase the risk of death. Nothing in this section authorizes intentionally dispensing, distributing, or administering a controlled substance for the purpose of causing death or assisting another person in causing death.

`(2) Notwithstanding any other provision of this Act, in determining whether a registration is consistent with the public interest under this Act, the Attorney General shall give no force and effect to State law authorizing or permitting assisted suicide or euthanasia.

`(3) Paragraph (2) applies only to conduct occurring after the date of enactment of this subsection.'.

SEC. 102. EDUCATION AND TRAINING PROGRAMS.

Section 502(a) of the Controlled Substances Act (21 U.S.C. 872(a)) is amended--

(1) by striking `and' at the end of paragraph (5);

(2) by striking the period at the end of paragraph (6) and inserting `; and'; and

(3) by adding at the end the following:

`(7) educational and training programs for local, State, and Federal personnel, incorporating recommendations by the Secretary of Health and Human Services, on the necessary and legitimate use of controlled substances in pain management and palliative care, and means by which investigation and enforcement actions by law enforcement personnel may accommodate such use.'.

TITLE II--PROMOTING PALLIATIVE CARE

SEC. 201. ACTIVITIES OF AGENCY FOR HEALTH CARE POLICY AND RESEARCH.

Part A of title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended by adding at the end the following section:

`SEC. 906. PROGRAM FOR PALLIATIVE CARE RESEARCH AND QUALITY.

`(a) IN GENERAL- The Administrator shall carry out a program to accomplish the following:

`(1) Develop and advance scientific understanding of palliative care.

`(2) Collect and disseminate protocols and evidence-based practices regarding palliative care,

with priority given to pain management for terminally ill patients, and make such information available to public and private health care programs and providers, health professions schools, and hospices, and to the general public.

`(b) DEFINITION- For purposes of this section, the term `palliative care' means the active total care of patients whose prognosis is limited due to progressive, far-advanced disease. The purpose of such care is to alleviate pain and other distressing symptoms and to enhance the quality of life, not to hasten or postpone death.'.

SEC. 202. ACTIVITIES OF HEALTH RESOURCES AND SERVICES ADMINISTRATION.

(a) IN GENERAL- Part D of title VII of the Public Health Service Act (42 U.S.C. 294 et seq.), as amended by section 103 of Public Law 105-392 (112 Stat. 3541), is amended--

(1) by redesignating sections 754 through 757 as sections 755 through 758, respectively; and

(2) by inserting after section 753 the following section:

`SEC. 754. PROGRAM FOR EDUCATION AND TRAINING IN PALLIATIVE CARE.

`(a) IN GENERAL- The Secretary, in consultation with the Administrator for Health Care Policy and Research, may make awards of grants, cooperative agreements, and contracts to health professions schools, hospices, and other public and private entities for the development and implementation of programs to provide education and training to health care professionals in palliative care.

`(b) PRIORITIES- In making awards under subsection (a), the Secretary shall give priority to awards for the implementation of programs under such subsection.

`(c) CERTAIN TOPICS- An award may be made under subsection (a) only if the applicant for the award agrees that the program carried out with the award will include information and education on--

`(1) means for alleviating pain and discomfort of patients, especially terminally ill patients, including the medically appropriate use of controlled substances;

`(2) applicable laws on controlled substances, including laws permitting health care professionals to dispense or administer controlled substances as needed to relieve pain even in cases where such efforts may unintentionally increase the risk of death; and

`(3) recent findings, developments, and improvements in the provision of palliative care.

`(d) PROGRAM SITES- Education and training under subsection (a) may be provided at or through health professions schools, residency training programs and other graduate programs in the health professions, entities that provide continuing medical education, hospices, and such other programs or sites as the Secretary determines to be appropriate.

`(e) EVALUATION OF PROGRAMS- The Secretary shall (directly or through grants or contracts) provide for the evaluation of programs implemented under subsection (a) in order to determine the

effect of such programs on knowledge and practice regarding palliative care.

`(f) PEER REVIEW GROUPS- In carrying out section 799(f) with respect to this section, the Secretary shall ensure that the membership of each peer review group involved includes one or more individuals with expertise and experience in palliative care.

`(g) DEFINITION- For purposes of this section, the term `palliative care' means the active total care of patients whose prognosis is limited due to progressive, far-advanced disease. The purpose of such care is to alleviate pain and other distressing symptoms and to enhance the quality of life, not to hasten or postpone death.'.

(b) AUTHORIZATION OF APPROPRIATIONS; ALLOCATION-

(1) IN GENERAL- Section 758 of the Public Health Service Act (as redesignated by subsection (a)(1) of this section) is amended in subsection (b)(1)(C) by striking `sections 753, 754, and 755' and inserting `section 753, 754, 755, and 756'.

(2) AMOUNT- With respect to section 758 of the Public Health Service Act (as redesignated by subsection (a)(1) of this section), the dollar amount specified in subsection (b)(1)(C) of such section is deemed to be increased by $5,000,000.

SEC. 203. EFFECTIVE DATE.

The amendments made by this title take effect October 1, 1999, or upon the date of the enactment of this Act, whichever occurs later.

END

Bill Summary & Status for the 106th Congress

NEW SEARCH | HOME | HELP | ABOUT STATUS

H.R.2260
SPONSOR: Rep Hyde, Henry J. (introduced 06/17/99)

STATUS: Detailed Legislative Status

House Actions

Jun 17, 99:
Referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.
Referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.