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A Death By Any Other Name: The Federal Government's Inconsistent Treatment of Drugs Used in Lethal Injections and Physician-Assisted Suicide

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A DEATH BY ANY OTHER NAME: THE FEDERAL
GOVERNMENT’S INCONSISTENT TREATMENT OF DRUGS
USED IN LETHAL INJECTIONS AND PHYSICIAN-ASSISTED
SUICIDE

COLIN MILLER¹

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I. INTRODCUTION

In 1985, in *Heckler v. Chaney*, the Supreme Court rejected a challenge by death row inmates to the Food and Drug Administration’s (FDA) failure to initiate enforcement actions against drugs used in capital punishment. Rehnquist’s majority opinion cursorily held that agency decisions not to institute such proceedings are unreviewable, and the Court has persistently upheld this principle in *Chaney’s* progeny. As important as this principle may be, even more important is why the FDA chose not to review the safety and efficacy of drugs used in capital punishment.

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First, the FDA argued that lethal injection was a distinctly minority practice affecting few prisoners and that scant empirical evidence existed that the drugs used in the procedure were dangerous. Second, it claimed that lethal injection constitutes the practice of medicine, and the FDA has a policy of non-interference with physician's professional treatment decisions. Finally, the FDA asserted that it has a policy of not initiating enforcement actions against state laws that are duly authorized and further legitimate state interests.

In 1997, the Supreme Court gave such authorization to states to experiment with physician-assisted suicide (PAS). Although the Court found no right to PAS, it explicitly delegated to states the power to legalize and regulate its practice. Based on this decision, Oregon enacted its Death with Dignity Act (DWDA) that same year, legalizing PAS for terminally ill patients. Later, Attorney General John Ashcroft -- usually a federalist -- challenged the DWDA under the federal Controlled Substance Act. A primary contention of his challenge was that PAS is subject to federal regulation because it does not constitute the practice of medicine.

Concurrently, lethal injection has become the primary, almost the sole, method of execution in this country. Despite frequently clandestine execution procedures, many observers have filed reports of "botched" executions based on improper dosages and combinations of drugs. Doctors who treat other prisoners frequently participate directly in these executions, and non-medical personnel often improperly inject the drugs, causing painful and prolonged deaths.

While the FDA is under no legal obligation to regulate the drugs used in executions, these recent developments certainly create a moral imperative requiring review. This paper will argue that the federal government cannot consistently refrain from regulating lethal injection drugs while arguing for prosecution of those prescribing drugs to be used by patients in assisted suicide.

Part II will look at the opinions in *Chaney* and the factors behind the FDA's decision not to regulate the drugs used in executions. Part III will look at Oregon's Death with Dignity Act and its authorization by the Supreme Court. Parts IV-VI will analyze how the justifications given by the FDA in the early 1980s, for not regulating the drugs used in executions, are no longer valid in 2003. Part IV will discuss how lethal injection now constitutes a serious public health issue. In the early 1980s, only two hundred prisoners were subject to lethal injection, and scant evidence existed of its dangerousness. Now, after two decades of botched executions and the ascendance of lethal injection as the near exclusive method of execution, it is evident that the process has caused serious damages.

Part V will look at the inconsistency in the federal government's classification of lethal injection as a legitimate medical practice that the FDA will not regulate and in its claim that PAS is an illegal state practice subject to federal nullification. It will argue that lethal injection is 1) more disfavored by medical groups, 2) less consistent with the Hippocratic Oath, 3) a more active form of killing for the physician, and 4) less consistent with the standard medical treatment model than PAS. Finally, Part VI will discuss how capital punishment is less of a duly authorized state practice than PAS. Specifically, capital punishment has been circumscribed severely by the Supreme Court based on doubts as to its constitutionality. Meanwhile, states have been given broad authority to implement PAS statutes. While there has been less time for challenges to PAS statutes, the key point is that the patients who desire PAS would never challenge such statutes as cruel and unusual.

II. *HECKLER V. CHANEY* AND THE FDA'S RELUCTANCE TO ACT

In 1981, eight death row inmates in Texas and Oklahoma “filed suit in the District Court seeking to compel the FDA to fulfill its statutory obligation to investigate and to regulate the unapproved use of approved drugs in human execution systems.”² The district court granted summary judgment to the FDA because courts presumptively cannot review agency decisions not to institute investigations.³ Because the FDA provided reasons for its failure to act, it “had not completely abdicated its statutory responsibilities,” and no basis for judicial review existed.⁴

The Court of Appeals reversed, arguing that judicial review of agency decisions not to act is proper only when no “law to apply” to agency nonenforcement exists.⁵ The Court found the requisite “law to apply” in a policy statement by the FDA: “Where the unapproved use of an approved new drug becomes widespread or endangers the public health, the Food and Drug Administration is obligated to investigate it thoroughly and to take whatever action is warranted to protect the public.”⁶

Having established the prerequisite for judicial review, the Court then found that the FDA's decision was arbitrary and capricious for two principal reasons. First, the FDA regulates drugs used in animal euthanasia and on prisoners in clinical investigations.⁷ This review precludes the argument that the FDA should not spend its resources regulating drugs inducing death and drugs used solely on prison populations. Second, the Court challenged the FDA Commissioner's assertion that state laws advancing legitimate interests “cannot, as a matter of law, pose ... a danger to the public.”⁸ Instead, “uncontroverted evidence ... shows that drugs used

²*Chaney v. Heckler*, 718 F.2d 1174, 1178 (D.C. Cir. 1983). The prisoners claimed that the use of barbiturates and paralytics in lethal injections “violated the ‘new drug’ as well as the ‘misbranding’ provisions of the Food, Drug, and Cosmetics Act” Timothy V. Kaufman-Osborn, Book Review, *Regulating Death: Capital Punishment and the Late Liberal State*, 111 YALE L.J. 681, 714 (2001).

³*Heckler*, 718 F.2d at 1178 (holding “that ‘decisions of executive departments and agencies to *refrain* from instituting investigations and enforcement proceedings are essentially unreviewable by courts’”) (emphasis in original).

⁴*Id.* at 1179.

⁵*Id.* at 1185 (construing *Dunlop v. Bachowski*, 421 U.S. 560 (1975)). If no law exists, regulating agency action (or inaction), the court has no standard under which to judge the reasonableness of a decision.

⁶*Id.*

⁷Kaufman-Osborn, *supra* note 2, at 714. This regulation also precludes the argument the FDA made early in the litigation that it lacked jurisdiction to regulate drugs used in lethal injections. As the prisoners correctly argued, the FDA “employed much the same logic [the prisoners used to argue the FDA can regulate lethal injection drugs] in affirming its authority to regulate drugs administered to prison inmates in experimental clinical investigations as well as drugs employed by veterinarians to put infirm and diseased animals to death.” *Id.*

⁸*Heckler*, 718 F.2d at 1190.

in lethal injections pose a substantial threat of torturous pain to persons being executed.”⁹

Judge Scalia’s dissent, in addition to arguing that judicial review was improper, held that the FDA’s decision to forgo regulating lethal injection drugs was not in clear error.¹⁰ He argued that no serious public health issue existed because only two hundred prisoners were on death row in states providing for lethal injection.¹¹ Scalia also challenged the inhumanity of lethal injections, claiming that the process is “the most ‘humane’ way of putting hopelessly crippled or diseased animals out of their misery.”¹² He asserted that the report revealing the dangers of lethal injection was outdated, based on “medical knowledge and technique thirty years ago”¹³ Scalia then charged the majority with misconstruing the dichotomy. He held that the comparison should not be made between unregulated and regulated lethal injection drugs but between unregulated lethal injection drugs and other forms of execution such as electrocution and the gas chamber.¹⁴ In this calculus, the use of even unregulated lethal injection drugs is, “*in all likelihood substitution of a lesser pain, since that is the principal purpose of the lethal injection statutes.*”¹⁵

Scalia’s final argument was that the FDA Commissioner had not said that a practice must be consistent with public health “*only by virtue of the fact that*” it is authorized by state law.¹⁶ Instead, he construed the Commissioner’s assertion as holding that the specific nature of lethal injection laws makes them immune from judicial review.¹⁷ Read one way, this argument could mean that the FDA legitimately found that the drugs used in lethal injections were safe and effective. In his Petition for Writ of Certiorari to the Supreme Court, however, the Solicitor General seemed to construe this argument as focused on the state interest in punishing offenders rather than on the safety and efficacy of lethal injection procedures. After citing Scalia’s above language, the Petition defended the FDA’s inaction because “[e]nacting laws to prevent and punish crime is among the most important powers of the states”¹⁸ Inherent in this argument was the belief that

⁹*Id.* (citing the ROYAL COMMISSION ON CAPITAL PUNISHMENT, 1949-1953 REPORT (1953)). In 1965, Great Britain abolished capital punishment, so there was no need for further reports. Deborah W. Denno, *Getting to Death: Are Executions Constitutional?*, 82 IOWA L. REV. 319, 373, n.313 (1997) [hereinafter Denno, *Executions*].

¹⁰*Heckler*, 718 F.2d at 1178 (Scalia, J., dissenting).

¹¹Kaufman-Osborn, *supra* note 2, at 716.

¹²*Heckler*, 718 F.2d at 1177, n.5 (Scalia, J. dissenting). What Scalia did not address is the fact that animals must be put to death by trained personnel such as veterinary surgeons, while prisoners are often killed by minimally trained corrections staff members. *See infra* note 155.

¹³*Id.*

¹⁴Kaufman-Osborn, *supra* note 2, at 716.

¹⁵*Heckler*, 718 F.2d at 1198 (Scalia, J. dissenting) (emphasis in original).

¹⁶*Id.* at 1177, n.6 (emphasis in original).

¹⁷*Id.*

¹⁸*Heckler v. Chaney*, No. 83-1878, *Petition for a Writ of Certiorari to The United States Court of Appeals for the District of Columbia* (Oct. 1983), available <http://www.usdoj.gov/osg/briefs/1983/sg830021.txt> (last visited Mar. 2, 2004).

“[t]he FDA’s decision ... was based upon a proper consideration for the principles of federalism.”¹⁹

In *Heckler v. Chaney*, the Supreme Court reversed the Court of Appeals, concluding that agency decisions against instituting proceedings are not subject to judicial review and not reaching the merits of the arbitrary and capricious argument.²⁰ Specifically, the Court found that the FDA’s policy statement²¹ was both vague and not a properly adopted agency rule.²² The Court also held that the enforcement provisions of the Federal Food, Drug, and Cosmetic Act did not abrogate the presumption that agency decisions are immune from judicial review.²³ Courts have universally adhered to *Chaney*’s precedent in failing to review agency decisions not to act, especially in the lethal injection context. For instance, a year after *Chaney*, the Fifth Circuit Court of Appeals rejected Randy Woolls’s argument that Congress’ failure to provide judicial review for the FDA’s refusal to regulate lethal injection drugs constituted cruel and unusual punishment.²⁴ “Only [s]ix days after his challenge, Woolls’s execution was botched.”²⁵

III. WASHINGTON V. GLUCKSBERG AND OREGON’S DEATH WITH DIGNITY ACT

In 1997, the Supreme Court found that terminally ill patients did not have a right to physician-assisted suicide (PAS) in *Washington v. Glucksberg*.²⁶ Rehnquist’s majority opinion acknowledged that the Court’s decision did not foreclose the ability of states to pass laws legalizing assisted suicide. In fact, he concluded by indicating that “[o]ur holding permits this debate to continue, as it should in a democratic society.”²⁷ Justice Souter’s concurring opinion was more explicit, concluding that “[l]egislatures are not so constrained.”²⁸ He even acknowledged that state “experimentation ... is entirely proper, as well as highly desirable, when the legislative power addresses an emerging issue like assisted suicide.”²⁹ Souter basically gave states carte blanche, declaring that “[t]he Court should accordingly stay

¹⁹*Id.*

²⁰470 U.S. 821, 837 (1985).

²¹*See supra* note 6 and accompanying text.

²²*Heckler*, 470 U.S. at 836.

²³*Id.* at 837.

²⁴*Woolls v. McCotter*, 798 F.2d 695 (5th Cir. 1986).

²⁵Deborah W. Denno, *When Legislatures Delegate Death: The Troubling Paradox Behind State Uses of Electrocuting and Lethal Injection and What it Says About Us*, 63 OHIO ST. L.J. 63, 102 (2002) [hereinafter Denno, *Paradox*]. Woolls had been a drug addict, so executioners had difficulty selecting a proper vein for insertion; eventually, “Woolls had to assist execution technicians to find an adequate vein.” Denno, *Executions*, *supra* note 9, at 431.

²⁶521 U.S. 702 (1997).

²⁷*Id.* at 735.

²⁸*Id.* at 789 (Souter, J. concurring).

²⁹*Id.*

its hand to allow reasonable legislative consideration.”³⁰ Justice O’Connor further concurred that “the ... challenging task of crafting appropriate procedures for safeguarding ... liberty interests is entrusted to the ‘laboratory’ of the States ... in the first instance.”³¹

Oregon made its first attempt at legalizing PAS in 1994. The Oregon Death with Dignity Act (DWDA), or Measure 16, was “voted into law by fifty-one percent of Oregon’s voters.”³² Soon thereafter, however, the Act was challenged in district court, and the court enjoined physicians from assisting in suicides.³³ Two years later, the court re-affirmed its temporary restraining order,³⁴ but the Ninth Circuit eventually directed the district court to dismiss the complaint for lack of jurisdiction.³⁵ After this ruling, in 1997, “the Oregon electorate voted to reestablish the Oregon Death with Dignity Act with a firm belief that the Act would receive the support of the U.S. Supreme Court based on its holdings in *Vacco* and *Glucksberg*.”³⁶

As practiced in Oregon, PAS involves a physician prescribing a lethal dosage of drugs to a patient, who then ingests the drugs herself to hasten death.³⁷ Under the DWDA, only an adult “suffering from a terminal disease”³⁸ may be a candidate for PAS. The Act defined a terminal disease as “an incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, produce death within six (6) months.”³⁹ Before a patient may receive assistance,

³⁰*Id.* Souter would not even foreclose the possibility of finding a right to assisted suicide in the future, indicating, “I do not decide for all time that respondents’ claim should not be recognized” *Id.* He also “acknowledge[d] the legislative institutional competence as the better one to deal with ... [PAS] ... at this time.” *Id.*

³¹*Id.* at 737 (O’Connor, J. concurring).

³²Carol A. Pratt, *Efforts to Legalize Physician-Assisted Suicide, New York, Washington, and Oregon: A Contrast Between Judicial and Initiative Approaches - - Who Should Decide?*, 77 OR. L. REV. 1027, 1082 (1998).

³³*Lee v. Oregon*, 869 F. Supp. 1491 (D. Or. 1994).

³⁴*Lee v. Oregon*, 891 F. Supp. 1439 (D. Or. 1995).

³⁵*Lee v. Oregon*, 107 F.3d 1382 (9th Cir. 1997).

³⁶Alan D. Lieberman, *Issues of Concern When Drafting a Physician-Assisted Suicide Statute*, 2 QUINNIPIAC HEALTH L.J. 149, 149 (1999). In *Vacco v. Quill*, the Supreme Court found that New York’s legalization of the withdrawal of life support, while it continues to prohibit PAS, does not “violate[] the Equal Protection Clause of the Fourteenth Amendment.” See *infra* note 143 and accompanying text. 521 U.S. 793, 796-97 (1997). The second time voters approved the DWDA, the vote was “60% to 40%.” Lindsay R. Kandra, *Questioning the Foundation of Attorney General Ashcroft’s Attempt to Invalidate Oregon’s Death with Dignity Act*, 81 OR. L. REV. 505, 511 (2002).

³⁷See David Orentlicher, *The Legalization of Physician Assisted Suicide: A Very Modest Revolution*, 38 B.C. L. REV. 443, 448 (1997) [hereinafter Orentlicher, *Legalization*] (recognizing that “because the patient must *self-administer* the drug, the patient brings about his or her own death.”).

³⁸OR. REV. STAT. § 2.01 (1997).

³⁹*Id.* at § 1.01.

“[t]he patient must make one written request and two oral requests to his or her physician, and the two oral requests must be separated by at least 15 days.”⁴⁰ Before a patient may receive her prescription, “[t]he physician and a consultant must confirm the diagnosis of a terminal condition, determine that the patient is competent to make the decision, and refer the patient to counseling if either believes the patient’s judgment is impaired by depression or another psychiatric or psychological disorder.”⁴¹ Finally, “[t]he prescribing physician must inform the patient of alternatives including palliative care, hospice and pain management options.”⁴²

Less than a year after the Act passed, Attorney General Janet Reno actively supported it, finding no grounds for adverse action against physicians assisting in suicide under the Controlled Substances Act (CSA).⁴³ The CSA is administered under the Drug Enforcement Administration (DEA), and its stated purpose is to serve as “the legal foundation of the government’s fight against the abuse of drugs and other substances.”⁴⁴ Reno first argued that the purpose of the CSA was to prevent illicit drug abuse and its concomitant “stimulant, depressant, or hallucinogenic effect on the central nervous system,”⁴⁵ presenting was no indication it was intended to cover terminal sedation, by definition, a single use situation. Reno then argued that the CSA must be read as consistent with federalism and particularly the state’s determination of what constitutes the practice of medicine.⁴⁶

Congress, however, was not as hospitable. In 1998, it attempted to proscribe the DWDA through “the Lethal Drug Abuse and Prevention Act and again in 1999 with the Pain Relief Promotion Act”⁴⁷ While the first Act failed in the House, “[t]he second bill passed the House but failed to reach a vote in the Senate.”⁴⁸ Two years

⁴⁰Andrew I. Batavia, *So Far So Good: Observations on the First Year of Oregon’s Death with Dignity Act*, 6 PSYCHOL. PUB. POL’Y & L. 291, 295 (2000).

⁴¹*Id.*

⁴²Christina E. Manuel, *Physician-Assisted Suicide Permits Dignity in Dying*, 23 J. LEGAL MED. 563, 577, n.118 (2002). The Act also has other safeguards, such as requiring that the physician request that the patient inform her next-of-kin of her decision. A full list of the safeguards can be found, *Death With Dignity National Center, Safeguards of the Law*, at <http://www.dwd.org/law/index.asp?IDW590> (last visited Mar. 2, 2004).

⁴³*Statement of Attorney General Reno on Oregon’s Death with Dignity Act* (June 5, 1998), available at http://www.dwd.org/pdf/reno_letter.pdf (last visited Mar. 2, 2004) [hereinafter *Statement*]. Reno specifically argued that “adverse action against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the CSA.” *Id.*

⁴⁴U.S. Drug Enforcement Administration, *Controlled Substances Act*, at <http://www.usdoj.gov/dea/agency/csa.htm> (last visited Mar. 2, 2004).

⁴⁵*Statement*, *supra* note 43.

⁴⁶*See id.* (stating that “[t]here is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession or to override a state’s determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice”).

⁴⁷Lindsay F. Wiley, *Ashcroft Appeals Assisted Suicide Decision* (May 24, 2002), available at www.painandthelaw.org/palliative/ashcroft_053002.php (last visited Mar. 2, 2004).

⁴⁸*Id.*

later, new Attorney General John Ashcroft — a staunch supporter of federalism on most issues⁴⁹ — decided to contradict Reno's position and attempted to nullify the DWDA. In an order entitled "Dispensing of Controlled Substances to Assist Suicide," Ashcroft asserted that "assisting suicide is not a 'legitimate medical purpose' within the meaning of" the CSA.⁵⁰ Ashcroft explicitly disregarded federalism concerns, arguing that his "conclusion applies regardless of whether state law authorizes or permits such conduct by practitioners"⁵¹

Oregon responded to Ashcroft's order by immediately filing "suit in federal district court requesting a temporary restraining order, which was granted on November 7, 2001, and then extended until further notice on November 20, 2001."⁵² In April of 2002, the district court entered a permanent injunction preventing the federal government from "enforcing, applying, or otherwise giving any legal effect to the Ashcroft directive"⁵³ The principal ground for this decision was that no basis was established in the legislative history, language, or application of the CSA to support the conclusion that the federal government could override state decisions about what constitutes legitimate medical practice.⁵⁴ Ashcroft then appealed to the Court of Appeals for the Ninth Circuit, and a three-judge panel heard oral arguments in Portland, Oregon, on May 7, 2003.⁵⁵

While the ultimate disposition in this case is highly relevant to citizens in Oregon, and particularly to those terminally ill patients seeking PAS, whether the Court upholds the DWDA should be irrelevant as to whether the FDA should regulate the drugs used in capital punishment. The federal government has clearly indicated that it feels an agency such as the DEA has the ability to nullify state law and should proscribe the use of drugs in what it feels is not a legitimate medical practice. If the federal government feels that this is a practical use of resources, the FDA should also choose to regulate the drugs used in lethal injections unless the justifications cited for abstaining in 1983 remain valid today or if stronger reasons exist for proscribing PAS. The following three sections will argue that these

⁴⁹Jonathan Turley, *It's Not the Cannabis, It's the Constitution*, L.A. TIMES, Aug. 5, 2002, available at <http://www.dutch-passion.nl/news/2002/August/US-%20It's%20Not%20the%20Cannabis,%20It's%20the%20Constitution.txt> (last visited Apr. 28, 2003).

⁵⁰Att'y Gen. Order No. 2534-200121 C.F.R. 1306 (Nov. 9, 2001), available at http://www.dwd.org/pdf/ashcroft_letter.pdf (last visited Mar. 2, 2004).

⁵¹*Id.*

⁵²Manuel, *supra* note 42, at 583.

⁵³Oregon v. Ashcroft, 192 F. Supp. 2d 1077, 1080 (2002).

⁵⁴*Id.* at 1088-92.

⁵⁵Laurence M. Cruz, *Appeals Court to Rule First on Assisted Suicide: The Justice Department Wants to Overturn Oregon's Twice-Affirmed Law*, STATESMAN J., March 6, 2003, available at <http://www.worldrtd.org/AppealsCrt2Rule1.html> (last visited Mar. 2, 2004). According to at least one source, the panel was skeptical about the ability of Ashcroft to punish physicians under the CSA. Bob Egelko, *Court Hears Suicide-Law Case: Appellate Judges Grill Federal Lawyer Over Strategy in Oregon*, S.F. CHRONICLE, May 8, 2003, available at <http://www.sfgate.com/cgi-bin/article.cgi?file=/c/a/2003/05/08/MN232980.DTL> (last visited Mar. 2, 2004). For instance, Judge Tallman argued that the CSA was "was intended to curb narcotics trafficking, not medical practice." *Id.*

justifications for inaction are no longer valid and that the federal government cannot consistently maintain that it can and should prosecute physicians prescribing PAS drugs while it fails to regulate lethal injection drugs.

IV. THE EMERGENCE OF LETHAL INJECTION AS THE SOLE METHOD OF EXECUTION

A. *Lethal Injection's Rise to Exclusivity*

When the prisoners challenged the FDA's inaction with regard to lethal injection drugs in 1981, only four states (eight percent of all states) allowed lethal injection.⁵⁶ Further, when the Court of Appeals rendered its decision, only one individual had been executed by lethal injection: Charles Brooks, Jr. in 1982.⁵⁷ As Scalia noted in his dissent,⁵⁸ in 1983, only 200 prisoners were on death row in states that allowed lethal injection, while only 1,100 total prisoners were on death row generally.⁵⁹ Thus, only about eighteen percent of death row inmates faced the possibility of lethal injection.

In 2003, thirty-seven (seventy-four percent of all states) of thirty-eight death penalty states authorized lethal injection as a method of execution,⁶⁰ thus over ninety-seven percent of death row prisoners could be injected with drugs unapproved for causing death. Of the thirty-seven lethal injection states, twenty-seven have lethal injection as the sole method of execution.⁶¹

When the Supreme Court handed down its *Chaney* decision in 1985, electrocution remained a practical alternative to lethal injection. In the ten years since 1976, when the Supreme Court lifted the moratorium on capital punishment in

⁵⁶*Chaney v. Heckler*, 718 F.2d 1174, 1178 (1983).

⁵⁷FREDERICK DRIMMER, *UNTIL YOU ARE DEAD: THE BOOK OF EXECUTIONS IN AMERICA* 78 (1990). The non-medical personnel took a long time finding a suitable vein for injection because Brooks had been a drug addict, and it took seven minutes for him to die from a sodium thiopental overdose. Jeff Stryker, *The Role of Professions in the Execution Process*, RECORDER, Apr. 23, 1992, at 6. Other severe complications occurred during the procedure. One witness stated that, during the execution, Brooks "moved his head as if to say 'no.' Then he yawned and his eyes closed, and then he wheezed. His head fell over toward us, then he wheezed again." Robert Reinhold, *Execution by Injection Stirs Fear and Sharpens Debate*, N.Y. TIMES, Dec. 8, 1982, at A28. The general consensus among witnesses was that Brooks "had not died easily." DRIMMER, *supra*, at 75.

⁵⁸*See supra* note 11 and accompanying text.

⁵⁹*Heckler*, 718 F.2d at 1197 (Scalia, J., dissenting).

⁶⁰Denno, *Paradox*, *supra* note 26, at 116 (2002). The only aberration is Nebraska, which only has electrocution. In 2002, Alabama became the latest state to adopt lethal injection, holding that "lethal injection will be used unless an inmate requests the electric chair." *Methods of Execution*, at <http://www.deathpenaltyinfo.org/article.php?scid=8&did=245> (last visited Mar. 2, 2004).

⁶¹Denno, *Paradox*, *supra* note 25, at 129, tbl. 1. New Hampshire and Washington provide for either lethal injection or hanging, while prisoners in Idaho and Utah have the choice of lethal injection or firing squad. *Id.* Electrocution remains an option in Alabama, Florida, South Carolina, and Virginia, and lethal gas is authorized as an alternative in California and Missouri. *Id.*

*Gregg v. Georgia*⁶² states had electrocuted thirty-four prisoners compared to thirteen cases of lethal injection.⁶³ In 1999-2001, however, 240 lethal injections occurred, but only 8 electrocutions (the only eight executions not by lethal injection).⁶⁴ Almost ninety-seven percent of executions were by lethal injection, making it constructively the only form of execution in this country.⁶⁵ In 2001, all of the sixty-six executions in this country were by lethal injection.⁶⁶ When this is combined with the fact that “no state has moved from lethal injection to another form of execution . . . , there appears to be a national consensus rejecting all methods of execution except lethal injection.”⁶⁷ Internationally, “execution by electrocution is practiced in no other country in the world.”⁶⁸

This near categorical acceptance of lethal injection as the only proper form of capital punishment undermines the validity of Scalia’s dichotomy. The FDA can no longer use the straw man of other execution procedures to claim that lethal injection is the “substitution of a lesser pain,”⁶⁹ or a lesser evil. In practice, other execution procedures have been proscribed, and “it is likely that electrocution will soon be extinct.”⁷⁰

Even if this is not the case, Scalia still improperly concluded that the choice is between the lesser pain of lethal injection and the greater pain of other execution procedures. While the purpose behind the prisoners’ challenge to the FDA’s inaction in *Chaney* may have been for lethal injection drugs to be confiscated as misbranded, such drastic action is unnecessary. The FDA could merely require that manufacturers submit these drugs for approval so that universal standards can be established regarding which drugs should be used, their dosages and instructions for use.⁷¹

⁶²428 U.S. 153 (1976).

⁶³Denno, *Paradox*, *supra* note 25, at 129, tbl. 4. In the year of the Court’s decision, eleven executions and seven lethal injections occurred. *Id.*

⁶⁴*Id.*

⁶⁵See *Lethal Injection*, at <http://www.richard.clark32.btinternet.co.uk/injection.html> (last visited Mar. 2, 2004) (stating that “[l]ethal injection is now virtually the universal method of execution in the United States. . .”).

⁶⁶Denno, *Paradox*, *supra* note 25. All except for one of the seventy-one executions in 2002 were by lethal injection. *Lethal Injection*, *supra* note 65.

⁶⁷Kenneth Williams, *The Deregulation of the Death Penalty*, 40 SANTA CLARA L. REV. 677, 700 (2000).

⁶⁸Provenzano v. Moore, 744 S.2d 413, 436 (Fla. 1999) (Shaw, J, dissenting).

⁶⁹See *supra* note 15 and accompanying text.

⁷⁰Denno, *Paradox*, *supra* note 25, at 85.

⁷¹While obviously double blind studies with placebos cannot be conducted when the purpose of a drug is to cause death, the FDA could impose less strict guidelines for approving lethal injection drugs. It could look to the data collected in Oregon regarding the safety and efficacy of the drugs used in PAS. Additionally, it could look to foreign countries such as the Netherlands where euthanasia is legal to determine what dosages are proper for causing the quickest and least painful death. Finally, the FDA could allow studies to estimate lethal dosages for humans based on studies previously submitted to the FDA for approval of drugs

Opponents of regulating lethal injection drugs could finally argue that lethal injection is still the least harmful method of execution, so the FDA should not be concerned with its regulation. Such a position, however, is fundamentally inconsistent with FDA practice. An example of this is the FDA's failure to approve biliary lithotripters — machines intended to remove gallstones nonsurgically.⁷² When the FDA initially failed to approve these machines, the most common (and only viable) alternative treatment was cholecystectomy: “the complete removal of the gallbladder” leading to trauma, incapacity for several weeks, weakness for longer, and the necessity of following a low-fat diet for the rest of the patient's life.⁷³

While some issues with side effects existed — such as debris clearance — the lithotripters were “the only nonsurgical technique to provide rapid and ongoing symptomatic relief from the severe pain caused by gallstone disease.”⁷⁴ Despite the fact that use of the lithotripters would be a “substitution of a lesser pain,” the FDA did not approve them because of the concerns about side effects.⁷⁵ Properly understood, then, the FDA's review of drugs and devices is largely insulated from the quality of existing treatments. If a treatment presents serious public health issues, the FDA should and does regulate it, regardless of the safety and efficacy of other treatments.

B. Lethal Injection's Effect on All Prisoners

As previously noted, in 1983, during the *Chaney* litigation, only 200 prisoners were on death row in lethal injection states.⁷⁶ By 2001, the population on death row had grown to 3,581, with prisoners in every state but Nebraska subject to lethal injection.⁷⁷ This means that the number of prisoners who can suffer from unregulated lethal injection drugs has increased by over 1600% since the FDA held that the low number of prisoners subject to lethal injection did not constitute a public health problem.

Conversely, PAS — which Ashcroft found to be enough of a public health problem to proscribe — is only legal in one state: Oregon. In 1999-2002, only 27,

used in animal euthanasia. This is essentially what Fred Leuchter did when he was originally creating execution machines, but he was later discredited as lacking scientific credentials. See *infra* note 115 and accompanying text.

⁷²Lawrence S. Makow, Note, *Medical Device Review at the Food and Drug Administration: Lessons from Magnetic Resonance Spectroscopy and Bilateral Lithotripsy*, 46 STAN. L. REV. 709, 723 (1994).

⁷³*Id.* Other techniques existed, “[b]ut serious limitations ma[d]e these techniques less attractive” *Id.* Laparoscopic cholecystectomy, a more viable alternative, was eventually approved by the FDA, but it did not exist when the lithotripters were initially being reviewed. *Id.* at 725.

⁷⁴*Id.* at 724.

⁷⁵*Id.*

⁷⁶See *supra* note 58 and accompanying text.

⁷⁷Curt Anderson, *Death Row Population Drops in U.S. for First Time Since 1976*, Dec. 16, 2002, available at http://www.lfexnews.com/1998/2002/texas/texas_Death_row1216.html (last visited Mar. 2, 2004).

27, 21, and 38 deaths occurred by PAS, respectively.⁷⁸ While some may attempt to compare these numbers with the 66 executions in 2001, the comparison would be incorrect. All of the over 3,500 prisoners on death row in lethal injection states live in the shadow of an involuntary execution by drugs unapproved for causing death. Terminally ill adults in Oregon who do not want to hasten their deaths are in no way subject to being involuntarily exterminated.⁷⁹

The harm caused by lethal injection, however, can not be limited to death row prisoners.⁸⁰ Physicians assisting in executions “have a doctor-patient relationship with all ... inmates ...”⁸¹ Consequently, all prisoners are in an awkward position with regard to the physicians whom they view as both healer and killer, and “the prison physician’s participation causes a deleterious effect on the physician’s relationship with other inmates.”⁸² Of course, this damage is the greatest for death row inmates because these “inmates perceive the physicians ... as people who will kill them someday ...”, [l]eading to “complain[ts] about this conflict since they must submit to care by the same prison physician.”⁸³

⁷⁸Oregon Department of Health and Human Services, *Fifth Annual Report on Oregon’s Death with Dignity Act*, available at <http://www.ohd.hr.state.or.us/chs/pas/arresult.cfm> (last visited Mar. 2, 2004) [hereinafter *Report*].

⁷⁹Critics may argue that the practice of PAS will lead to involuntary euthanasia, jeopardizing the lives of patients who do not want to hasten their deaths. This is a point that can be legitimately argued, but there is an equally valid argument that more risk of abuse exists where PAS is illegal and practiced in a clandestine, unregulated manner. By legalizing the procedure and establishing safeguards, other terminally ill patients may actually be safer. Critics of legalizing PAS often cite the Netherlands — where abuses involving assisted suicides have occurred — as a harbinger of a slippery slope when PAS is legalized. This analogy is fallacious because, until recently, “[i]n Holland, assisted suicide [was] officially illegal[] but [was] typically not prosecuted under certain specified circumstances.” Batavia, *supra* note 40, at 301. Conversely, “[i]n Oregon, assisted suicide is officially legal under specified circumstances and is illegal under all other circumstances.” *Id.* Thus, if anything, the previous non-prosecution policy in the Netherlands was more similar to current PAS policy in every state except for Oregon. In every other state, PAS is officially illegal, but no physician has ever been convicted of assisting in a suicide. For instance, Jack Kevorkian was acquitted several times for assisting in suicides before he was finally convicted of euthanizing a patient. Liz Townsend, *Kevorkian’s Nine-Year Euthanasia Crusade Leads to Murder Conviction*, NAT’L RIGHT TO LIFE NEWS, Apr. 8, 1999, available at <http://www.nrlc.org/news/1999/NRL499/kev.html> (last visited Mar. 2, 2004).

⁸⁰Conversely, it can be argued that the benefit of PAS is not limited to those patients electing to receive a lethal prescription of drugs. See, e.g., David Orentlicher, *The Alleged Distinction Between Euthanasia and the Withdrawal of Life-Sustaining Treatment: Conceptually Incoherent and Impossible to Maintain*, 1998 U. ILL. L. REV. 837, 845-46 (1998) (stating that legalization of PAS has the potential to benefit all terminally ill patients because being told that such an option exists “can alleviate their anxiety about what lies ahead”).

⁸¹Stacey A. Ragon, *A Doctor’s Dilemma: Resolving the Conflict Between Physician Participation in Executions and the AMA’s Code of Medical Ethics*, 20 DAYTON L. REV. 975, 985 (1995).

⁸²*Id.*

⁸³*Id.*

While some may (speciously) argue that the lives and rights of prisoners are not as important as those of law-abiding individuals, “[o]nly a callous mind would claim that this is not a serious danger to public health.”⁸⁴ While “the public perception of physicians focuses on the general public . . . , the relationship of trust is equally important in treating inmates because that relationship serves the same purposes.”⁸⁵

Ashcroft would have us believe that legalization of PAS creates a similar strain in doctor-patient relationships, but, logically, physician assistance in suicide should cause substantially less mistrust. When a physician assists in a suicide, she is obeying the wishes of a patient using informed consent. In executions, the physician is working decidedly against the prisoner’s interests and consent. The “trust . . . threatened by physician participation in executions is the trust[] that physician[s] will work for the benefit of their patients.”⁸⁶ This trust is implicated to a lesser degree when the physician supports and assists in what the patient and she believe to be in the patient’s best interests. This theory has empirical support. In one “survey of adult patients, researchers found that 90.5% of patients would consider a physician who assisted in suicides to be as trustworthy as other physicians in providing care to critically ill patients.”⁸⁷

Another reason patients are less likely to be worried about PAS is that withdrawal of life support is already legally recognized and widely practiced. Withdrawal of life support involves a physician removing a patient from a machine keeping that patient alive (and often hastening death through drugs) while, as already noted, PAS merely involves a physician prescribing drugs to a patient who self-ingests the drugs.⁸⁸ While the Supreme Court has held that these practices are legally distinct, “from the perspective of the lay public, a doctor’s pulling of the plug and precipitating death may seem as much a killing as provision of a prescription for poison.”⁸⁹

⁸⁴Chaney v. Heckler, 718 F.2d 1174, 1190, n.44 (1983).

⁸⁵Ragon, *supra* note 81, at 1000.

⁸⁶*Id.*

⁸⁷Orentlicher, *Legalization*, *supra* note 37, at 452, n.43 (citing Mark A. Graber et al., *Patients’ Views About Physician Assisted Suicide and Euthanasia*, 11 J. GEN. INTERNAL MED. 71, 73 (1996)) (studying 228 patients at a single university-based family practice program); *see also* University of Washington School of Medicine, *Ethics in Medicine: Physician-Assisted Suicide*, at <http://eduserv.hscer.washington.edu/bioethics/topics/pas.html> (last visited Mar. 2, 2004) [hereinafter *Ethics*] (“Surveys of patients and members of the general public find that the vast majority think that PAS is ethically justifiable in certain cases . . .”).

⁸⁸*See supra* note 37 and accompanying text.

⁸⁹Norman L. Cantor & George C. Thomas III, *The Legal Bounds of Physician Conduct Hastening Death*, 48 BUFF. L. REV. 83, 155 (2000); *see also* *Vacco v. Quill*, 521 U.S. 793, 809 (1997) (Stevens, J. concurring) (holding that the Court’s “traditional view of the physician’s role” is simply inapplicable in an age where “physicians are already involved in making decisions that hasten the death of terminally ill patients - - through termination of life support, withholding of medical treatment, and terminal sedation”); Stephen A. Newman, *Euthanasia: Orchestrating “The Last Syllable of...Time,”* U. PITT. L. REV. 153, 166 (1991) (“[I]n the modern medical setting, these terms and distinctions are ephemeral. The concept of natural death in the hospital has lost its meaning.”).

In fact, patients may be less trustworthy of physicians declining to participate in PAS. For these “patients, it would be a physician’s refusal to dispense medication to ease their suffering and make their death tolerable and dignified that would be inconsistent with the healing role.”⁹⁰ Many “[p]atients fear that when they are suffering intolerably, they will be denied the drugs that are necessary to end their suffering.”⁹¹ Most Americans are more concerned that modern medical technology will artificially prolong lives than with the idea of PAS.⁹²

Some have even argued that “it is clear ... trust cannot survive in the present context surrounding dying.”⁹³ These critics doubt that “the public [can] place much faith in a process that involves ... ‘long, drawn out months to years of increasingly complicated illness that can require an array of specialists, confusing choices, false hopes, loss of control and dignity, misery and pain.’”⁹⁴ When we “[a]dd to this enormous costs and the propensity of certain doctors to block out others’ suffering, to avoid contact with the dying, and to neglect available measures for pain relief, ... the picture of an ailing doctor-patient relationship becomes complete.”⁹⁵

Patients with terminal illnesses primarily fear “doctor neglect and abandonment.”⁹⁶ “[T]he present system fosters [this neglect] by allowing an inordinate amount of suffering to continue for months, leading many caregivers to simply block it out.”⁹⁷ When the physician cannot assist in the suicide of a patient in great suffering, it is often difficult for her to face the patient, making avoidance the only possible response. “By avoiding the hopeless patient and the family, the doctor learns to live with the brutality of prolonged suffering by disregarding it.”⁹⁸ Worse, “a doctor’s refusal to hasten death ‘may be experienced by the [dying] patient as an abandonment, a rejection, or an expression of inappropriate paternalistic authority.’”⁹⁹

Allowing PAS may “foster a deeper dimension to some doctor-patient relationships.”¹⁰⁰ Legalization of PAS “moves it into the arena for open discussion

⁹⁰*Quill*, 521 U.S. at 809 (Stevens, J. concurring); see also Susan Block & J. Andrew Billings, *Patient Request to Hasten Death*, 154 ARCHIVES INTERNAL MED. 2039, 2045 (1994).

⁹¹Orentlicher, *supra* note 37, at 452.

⁹²See Newman, *supra* note 89, at 171 (stating that “[t]he public seems to fear the dying process now because it believes doctors’ efforts will prolong, not relieve suffering”).

⁹³*Id.* at 172

⁹⁴*Id.* (quoting *Should Physicians Perform Euthanasia?*, AM. MED. NEWS 12, 15 (Jan. 7, 1991)).

⁹⁵*Id.*

⁹⁶*Id.* at 176.

⁹⁷*Id.*

⁹⁸*Id.*

⁹⁹*Vacco v. Quill*, 521 U.S. 793, 809 (1997) (Stevens, J. concurring) (quoting Block & Billings, *supra* note 90, at 2045).

¹⁰⁰*Id.*

and consideration.”¹⁰¹ Consequently, “a process of conversation, explanation and negotiation may ensue between doctors and patients requesting help in ending life.”¹⁰² Some have argued that “[d]ying is one of life’s most profound experiences. To share this ... with another who is willing to understand and acknowledge this type of suffering, and to act on it, surely must create one of the most trusted bonds that can be possible.”¹⁰³

While some may argue that it is hyperbole to claim that legalizing PAS would actually improve the doctor-patient relationship, it is at least an argument that can be rationally made and supported. Conversely, there are no legitimate grounds upon which one can argue that physicians participating in the involuntary executions of prisoners will do anything but harm their relationships with these and other prisoners.

C. Botched Executions

From the first lethal injection in 1982 through 2001, there have been 31 reported botched executions by lethal injection.¹⁰⁴ In reality, this number is probably substantially higher, but we cannot be certain of this for two reasons. The first reason is that many states have clandestine execution procedures. Some states allow witnesses to view executions, and these witnesses often become the reporters of botched executions.¹⁰⁵ In other states, however, such as New York, witnesses are not allowed to see the inmate die.¹⁰⁶

Second, because of the drugs used in lethal injections, witnesses may not be able to observe that a prisoner is in severe pain. In most states, three drugs are used in lethal injections. The physician first uses sodium thiopental¹⁰⁷ to cause the patient to lose consciousness.¹⁰⁸ The second drug administered is pancuronium bromide,

¹⁰¹Newman, *supra* note 89, at 171. Currently, however, “[m]aking the practice illegal discourages discussion. One must be very sure of others’ reactions before confiding in them. The useful deliberation that comes from sharing ideas and perspectives is thereby lost.” *Id.* at 177.

¹⁰²*Id.* at 172

¹⁰³*Id.* (quoting *Should Physicians Perform Euthanasia?*, AM. MED. NEWS 12, 15 (Jan. 7 1991)).

¹⁰⁴Denno, *Paradox*, *supra* note 25, at 139, tbl. 9. While it is difficult to define what constitutes a “botched” execution, a fair standard seems to be an execution where the patient takes longer to die than expected or suffers from severe pain. Others have claimed a much higher rate of error. See, e.g., Edward Brunner, M.D., Ph.D., *Many Lethal Injection Executions are Bungled*, BALT. SUN (2001) [hereinafter *Bungled*], available at <http://www.lairdcarlson.com/celldoor/00302/SW00302LethalInjectionBungled.htm> (last visited Mar. 2, 2004) (stating that “in about 40 percent of cases where lethal injection has been used, there has been misuse in one way or another”).

¹⁰⁵*Id.* at 123-24.

¹⁰⁶*Id.* at 124-25.

¹⁰⁷PHYSICIAN’S DESK REFERENCE 835 (55th ed. 2001) [hereinafter REFERENCE].

¹⁰⁸Patrick Malone, *Death Row and the Medical Model*, 9 HASTINGS CTR. REP., Oct. 1979, at 6.

which temporarily paralyzes the lungs and diaphragm to stop breathing.¹⁰⁹ The third drug — which actually induces death — is potassium chloride, which permanently stops the inmate's heart from beating."¹¹⁰

According to studies, when the executioner makes a mistake — “for example, pancuronium bromide is administered first — there is near certainty that the inmate will experience excruciating pain during a lethal injection even without the outside appearance of pain because the pancuronium bromide paralyzes him.”¹¹¹ The prisoner's suffering begins with “an extremely painful sensation of crushing and suffocation” while the prisoner is “unable to move or communicate in any way”¹¹² Later, as “potassium chloride is administered, the prisoner will experience an excruciating burning sensation in his vein ... equivalent to the sensation of a hot poker being inserted into the arm”¹¹³

Three main causes of botched executions exist. The first is that there is wide variance in the drugs and dosages used in different states. To begin, when Fred Leuchter — the original creator of most execution equipment in this country — was deciding on the proper dosage of potassium chloride to kill a patient, “the medical literature did not have articles specifying what dosages of the drugs were adequate to be lethal”¹¹⁴ Consequently, Leuchter relied on the information that was available for pigs and estimated accordingly.¹¹⁵ This imprecision still permeates the practice of lethal injection.

A few states such as North Carolina and New Jersey do not use the standard three drugs mentioned above while other states keep the drugs they use confidential.¹¹⁶ Moreover, an “inordinate variation” exists in the dosages used among lethal injection states.¹¹⁷ Montana is probably the worst because “the amount of sodium pentothal is not a lethal dose; it is one-fourth or less than that used in other states.”¹¹⁸

¹⁰⁹REFERENCE, *supra* note 107, at 1193.

¹¹⁰Malone, *supra* note 108, at 6.

¹¹¹Denno, *Paradox*, *supra* note 2, at 109.

¹¹²*Id.* at 109, n.321.

¹¹³*Id.*

¹¹⁴*Id.*

¹¹⁵*Id.* at 100. Significantly, Leuchter's qualifications were later severely criticized when he was asked by neo-Nazis to prove that the Holocaust never happened. Leuchter complied and fallaciously concluded that concentration camps did not hold executions because no evidence of lethal gas could be found in the walls. It turned out that Leuchter's only qualifications were college classes in chemistry and physics while studying for a B.A. These events were thoroughly reported in the Errol Morris documentary, MR. DEATH: THE RISE AND FALL OF FRED A. LEUCHTER JR. (Universal 1999).

¹¹⁶Denno, *Paradox*, *supra* note 25, at 145, tbl. 11. North Carolina only uses sodium thiopental and pancuronium bromide while New Jersey uses combinations of saline with potassium chloride and saline with sodium thiopental. *Id.*

¹¹⁷*Id.* at 120.

¹¹⁸*Id.*

Similar improper dosages have caused several executions to be botched. In 1989, executioners in Texas gave Stephen McCoy an insufficient dosage of drugs, resulting in “chok[ing] and heav[ing]” near the end of his execution.¹¹⁹ Even the Attorney General of Texas had to admit that “[t]he drugs might have been administered in a heavier dose or more rapidly.”¹²⁰ A year later, in Illinois, Charles Walker was executed, and “[t]here was some indication that the first chemical may have worn off before Walker became unconscious. ‘If this occurred...Walker would have slowly strangled and suffered excruciating pain while remaining completely immobile.’”¹²¹ Unfortunately, witnesses could not see exactly what happened because “corrections officers ‘panicked’ and ordered that the blinds to the execution room be closed.”¹²²

A second problem is that many states do not provide adequate instructions for executioners; for instance, “[t]he high percentage of botches in Texas appear[s] to be partly attributable to the dearth of written procedures provided to executioners concerning how to perform an execution.”¹²³ This problem is compounded by the last problem: “untrained executioners.”¹²⁴ The dearth of training for these individuals will be discussed further in *infra* section IV.C., but for now it will suffice to say that executioners have difficulty finding proper veins for injection and often insert catheters incorrectly.¹²⁵

In the lethal injection of Raymond Landry, executioners searched for a vein for forty minutes,¹²⁶ and, later, the syringe fell out, “spewing deadly chemicals toward startled witnesses.”¹²⁷ The execution of Joseph Cannon was suspended when “Cannon’s vein collapsed and the needle popped out after the first injection. These events caused him to make a second final statement and be injected a second time behind closed curtains.”¹²⁸

When judges last reached the merits of the FDA’s inaction with regard to lethal injection drugs, the only significant evidence indicating the process was dangerous was a British report from the 1950s. Now, this country has over three decades of experience with botched lethal injections causing prisoners inordinate suffering. In fact, some sources have argued that lethal injection “is the most commonly botched execution in the United States”¹²⁹ making it more harmful than other execution

¹¹⁹Dawn M. Weyrich, *Grotesque Blunders; Botched Execution Spurs New Death Row Challenge*, WASH. TIMES, June 7, 1990, at A1.

¹²⁰*Witness to an Execution*, HOUSTON CHRONICLE, May 27, 1989, at 11B.

¹²¹Denno, *Executions*, *supra* note 9, at 433.

¹²²*Id.* at 434.

¹²³Denno, *Paradox*, *supra* note 25, at 111.

¹²⁴*Id.* at 110.

¹²⁵*Id.*

¹²⁶Michael deCourcy Hinds, *Making Execution Humane (Or Can It Be?)*, N.Y. TIMES, Oct. 14, 1990, at 1.

¹²⁷Weyrich, *supra* note 119.

¹²⁸Denno, *Paradox*, *supra* note 25, at 139, tbl. 9.

¹²⁹*Sims v. State*, 754 So. 2d 657, 667 n.19 (Fla. 2000) (quoting Professor Michael Radelet).

procedures in practice if not in principle.¹³⁰ It is important to note that the main problems of incorrect dosage and inadequate instructions for use are exactly the problems that would be solved by the FDA regulating lethal injection drugs as misbranded and as new uses for previously approved drugs.

V. THE PRACTICE OF MEDICINE EXCEPTION

During the *Chaney* litigation, the FDA argued “that state-sanctioned use of lethal injections comes within a commonly recognized exception to the Act’s broad and protective coverage: the ‘practice-of-medicine’ exception.”¹³¹ Under this policy, the FDA will not interfere with practices that involve the medical judgments of physicians in treating patients. The following four parts will discuss how lethal injection violates medical practice more than PAS.

A. Medical Association Views

When the Supreme Court rejected a constitutional right to PAS, it focused heavily on the fact that the American Medical Association (AMA) had declared in its Code of Medical Ethics that “[p]hysician assisted suicide is fundamentally incompatible with the physician’s role as healer.”¹³² What the Court failed to note is that the AMA’s “policy regarding PAS was not made binding upon its members”¹³³ and that other groups such as the American Women’s Medical Association (AMWA) support the practice.¹³⁴ Finally, despite the AMA’s “advisory” position, some studies indicate that at least half of all physicians support PAS in certain circumstances.¹³⁵

In contrast, the AMA has a much stricter mandatory policy against physician participation in executions, particularly those by lethal injection. This policy holds that “[a] physician, as a member of a profession dedicated to preserving life when there is hope of doing so, should not be a participant in a legally authorized

¹³⁰Others have contended that lethal injection is even the least humane execution procedure without considering mistakes. The main basis for this argument is that “[e]xecution by lethal injection takes much longer from start to finish than any other method, typically 30-45 minutes For the majority of this time the condemned person is fully aware of what is happening to them and able to experience their execution.” *Lethal Injection*, *supra* note 65.

¹³¹*Chaney v. Heckler*, 718 F.2d 1174, 1179 (1983).

¹³²*Washington v. Glucksberg*, 521 U.S. 702, 731 (1997).

¹³³W. Noel Keyes, *The Choice of Participation by Physicians in Capital Punishment*, 22 WHITTIER L. REV. 809, 814 (2001).

¹³⁴See American Medical Women’s Association, *Position Statement on Physician Assisted Suicide* (Nov. 1997), (“The AMWA supports the right of physicians to engage in practice wherein they may provide a patient with, but not administer, a lethal dose of medication and/or medical knowledge, so that the patient can, without further assistance, end his/her life.”). available at http://www.amwa-doc.org/publications/Position_Papers/suicide.htm (last visited Mar. 2, 2004).

¹³⁵One “survey published in the New England Journal of Medicine found that 56% of responding doctors in Michigan preferred legalizing assisted suicide to an explicit ban.” *Glucksberg*, 521 U.S. at 749, n.12 (Stevens, J., concurring); see also ETHICS, *supra* note 82 (“Surveys of individual physicians show that half believe that PAS is ethically justifiable in certain cases.”).

execution.”¹³⁶ In fact, “AMA policy is ‘to inform state medical licensure boards and certification and recertification agencies that physician participation in supervising or administering lethal injections is a *serious violation* of the ethical standards of the medical profession.’”¹³⁷ The AMA’s position “is particularly applicable to lethal injection, which requires relatively more medical skill [than other execution procedures] and has long been affiliated with the medical profession.”¹³⁸

The AMA is not alone in its position as “the World Medical Association, the Medical Societies of the Nordic Countries, and the American Psychiatric Association have all issued policy statements declaring that participation ... was both unethical and subject to sanction.”¹³⁹ Perhaps this stricter policy toward physician participation in executions reflects the fact that executions are more clearly violative of the Hippocratic Oath than PAS.

B. *The Hippocratic Oath*

The fundamental principle guiding physicians in the practice of medicine is the Hippocratic Oath. The Oath commands that physicians “shall do no harm.”¹⁴⁰ Under the Oath, “[t]he concept of choice creates a significant disparity between [PAS] and capital punishment.”¹⁴¹ Ideally, PAS “involves the decision of a terminally ill, mentally competent adult making a reasoned choice to die.”¹⁴² When a physician responds to this request and hastens the death of a cancer patient in severe pain with a few months to live, she could rationally be seen as not doing harm. The same argument cannot be made about a physician participating in the involuntary execution of a healthy prisoner.

C. *Physicians Play a More Active Role in Causing Death in Lethal Injection than in PAS*

In *Vacco v. Quill*, the Supreme Court found that New York’s legalization of the withdrawal of life support, while it continues to prohibit PAS, does not “violate[] the Equal Protection Clause of the Fourteenth Amendment.”¹⁴³ The Court held that these two groups of patients are not similarly situated because those requesting PAS

¹³⁶Council on Ethical and Jud. Affairs, AMA, Council Rep., *Physician Participation in Capital Punishment*, 270 JAMA 365, 365 (1993). The AMA’s more lenient position on PAS is partially based on the fact that there is less hope of preserving life in a terminally ill patient.

¹³⁷Keyes, *supra* note 133, at 811 (quoting Am. Med. Ass’n, Policy Compendium, H-140.974 (1997 ed. 1997)).

¹³⁸Denno, *Paradox*, *supra* note 25, at 113.

¹³⁹Keyes, *supra* note 133, at 809, n.2; *see also Bungled*, *supra* note 104 (stating that “[t]he whole spectrum of medical professional groups has condemned the participation of physicians in the process”).

¹⁴⁰David L. Katy, Perry v. Louisiana: *Medical Ethics on Death Row -- Is Judicial Intervention Warranted?*, 4 GEO. J. LEGAL ETHICS 707, 707 (1991) (citing the Hippocratic Oath).

¹⁴¹Ragon, *supra* note 81, at 1001.

¹⁴²*Id.*

¹⁴³521 U.S. 793, 796-97 (1997).

require a physician to cause death actively while physicians can merely remove life support and let a patient die of natural causes. While this dichotomy is suspect,¹⁴⁴ it does establish a legitimate criterion for determining whether an act constitutes the legitimate practice of medicine: the level of the physician's participation in actively causing death. This standard creates another argument against the federal government's inconsistency, because physicians play a more active role in directly causing death through lethal injection than through PAS.

Physicians in both cases prescribe a lethal dosage of drugs to be used in killing the patient, but the physician's role ends there in the case of PAS. This is "because [since] the patient must *self-administer* the drug, the patient brings about his or her own death."¹⁴⁵ In fact, the physician's act of prescribing the drug is not even always temporally close to the death of the patient. Often, a physician's lethal prescription will not be used until "a few weeks or months later in a suicide,"¹⁴⁶ if it is used at all.¹⁴⁷

This contrasts with capital punishment, where physicians are often present during the execution and contribute to bringing about death. In capital punishment, physicians have undertaken an amalgam of further duties such as "preparing for, participating in, [and] monitoring executions or attempting to harvest prisoners' organs for transportation."¹⁴⁸ This participation has even included physicians "inserting intravenous lines for lethal injections ..."¹⁴⁹ [and/] "administering ... injection drugs or their doses or types."¹⁵⁰ An example of this latter practice occurred in Illinois, where — before Governor Ryan placed a moratorium on executions¹⁵¹ — state law authorized physicians to kill prisoners by directly administering lethal injection drugs.¹⁵² Under *Quill*, this increased level of physician

¹⁴⁴As previously noted, under PAS, the physician merely prescribes a lethal dose of drugs that the patient self-administers. See *supra* note 37. Often, however, "[w]ithdrawal of life support requires physicians or those acting at their discretion physically to remove equipment and, often, to administer palliative drugs which may themselves contribute to death. *Quill v. Vacco*, 80 F.3d 716, 729 (1996), *rev'd* 521 U.S. 793 (1997).

¹⁴⁵Orentlicher, *Legalization*, *supra* note 37, at 448 (emphasis added).

¹⁴⁶*Id.*

¹⁴⁷For instance, according to the data reported from Oregon in the first year of the DWDA, "23 people received [lethal] prescriptions, 15 of whom used them in hastening death" Batavia, *supra* note 40, at 293.

¹⁴⁸Linda L. Emanuel & Leigh B. Bienen, *Physician Participation in Executions: Time to Eliminate Anonymity Provisions and Protest the Practice*, 135 ANNALS INTERNAL MED. 922, 922 (2001) (citing Robert D. Trogg & Troyen A. Brennan, *Participation of Physicians in Capital Punishment*, 329 NEW ENG. J. MED. 1346-50 (1993)); see also Denno, *Paradox*, *supra* note 25, at 115 (stating that "a substantial minority [of physicians] are involved in every possible stage" of executions).

¹⁴⁹Ragon, *supra* note 81, at 977.

¹⁵⁰*Id.*

¹⁵¹See *infra* note 170 and accompanying text.

¹⁵²Neil Farber et al., *Physicians' Attitudes About Involvement in Lethal Injection for Capital Punishment*, 160 ARCHIVES INTERNAL MED. 2912, 2912-13 (2000).

participation in actively causing death makes lethal injection more constitutionally suspect than PAS.

D. Lethal Injection Does Not Fit the Standard Model of the Practice of Medicine

Under the standard model of medical treatment, when physicians prescribe drugs, either the physician, a trained and certified medical professional, or the patient herself, eventually administers the drugs.¹⁵³ Some exceptions for drugs exist, such as insulin used for diabetics, but sodium “[t]hiopental is a controlled substance. To use it you need a special license, which the executioner doesn’t have and the warden doesn’t have.”¹⁵⁴ While physicians themselves sometimes administer lethal injection drugs, in most cases, minimally trained corrections staff members likely serve as executioners.¹⁵⁵ Unfortunately, “[t]he thirty-[seven] lethal injection states provide minimal information in their protocols on the quality or training of those individuals selected to execute an inmate.”¹⁵⁶ Only fourteen of these states even “mention ‘training’ or ‘competency’ or ‘preparation’ or ‘practice’ for the executioners”, and these states still give “little to no indication of what kind of preparation the department of corrections offers.”¹⁵⁷

In at least eight states, “[c]riteria for selecting or training executioners ... appear to be nonexistent.”¹⁵⁸ In Arkansas, executions are left in the hands of “unpaid volunteers.”¹⁵⁹ In other states, it is very likely that someone other than a physician must pronounce death.¹⁶⁰ This high level of participation by non-physicians or medical staff means that lethal injection differs substantially from the standard medical treatment model. To this extent, lethal injection is less defensible as the “practice of medicine” than PAS.

VI. DULY AUTHORIZED STATE PRACTICE

As previously noted there are at least three interpretations of the FDA Commissioner’s statement during the *Chaney* litigation that duly authorized state practices are not subject to judicial review.¹⁶¹ Under any of the interpretations,

¹⁵³Most states have statutes only allowing those with medical training and state certification to administer drugs. For instance, in Ohio, “[a] person needs a medical license or some other license with specific statutory authority to” administer drugs. The State Medical Board of Ohio, *Frequently Asked Questions*, at <http://www5.state.oh.us/med/faq/acup-02.htm> (last visited Mar. 2, 2004).

¹⁵⁴*Bungled*, *supra* note 104.

¹⁵⁵In other states, “a fully automated lethal injection machine is used” *Lethal Injection*, *supra* note 65. The later discredited Fred Leuchter created most of these machines. *See supra* note 111 and accompanying text.

¹⁵⁶Denno, *Paradox*, *supra* note 25, at 121.

¹⁵⁷*Id.*

¹⁵⁸*Id.* at 122.

¹⁵⁹*Id.*

¹⁶⁰*See id.* (holding that “in eight states, there is no mention that medical personnel are to participate in any way, even in pronouncing death”).

¹⁶¹*See supra* notes 7 & 16-18 and accompanying text.

however, it appears that a state practice should be more insulated the less it has been circumscribed by the courts. If the courts have found a law to be unconstitutional as applied in numerous situations, it seems fair to say that it is more constitutionally suspect than a practice that has not been so limited. Under any fair standard, capital punishment has been less duly authorized than PAS.

Beginning “[i]n the mid-1960s, [NAACP Legal Defense and Educational] Fund lawyers ... [/]attempted[/] to convince the Supreme Court to abolish the death penalty.”¹⁶² Eventually, “in 1972 the Supreme Court determined that the imposition of the death penalty, as then applied, was cruel an unusual punishment ... [and] struck down all death penalty schemes then operating in the United States”¹⁶³ in *Furman v. Georgia*.¹⁶⁴ The Court found both that “existing death penalty laws ... [were] administer[ed] ... in an arbitrary and capricious way ... [/]and that[/] racial discrimination infected the imposition of the death penalty, particularly for rape.”¹⁶⁵

Four years later, the Court effectively overturned *Furman* in *Gregg v. Georgia*,¹⁶⁶ holding that the death penalty was palatable when accompanied by “procedures intended to prevent [its] arbitrary imposition.”¹⁶⁷ Despite this holding, “studies of the application of these rewritten statutes show[] continued disparities in the use of the death penalty by race of the defendant and especially by race of the victim.”¹⁶⁸ Concurrently, the number of exonerated “former death row inmates continues to climb above 100.”¹⁶⁹ Responding to these concerns, governors in Illinois and Maryland recently imposed moratoria on imposition of the death penalty in their states.¹⁷⁰

Just last summer, the Supreme Court found that states cannot execute mentally retarded offenders¹⁷¹ and that judges, sitting alone, cannot determine the presence or absence of aggravating factors necessary for imposition of the death penalty after a

¹⁶²James S. Liebman, *The Overproduction of Death*, 100 COLUM. L. REV. 2030, 2033 (2000).

¹⁶³*Id.*

¹⁶⁴408 U.S. 238 (1972).

¹⁶⁵Liebman, *supra* note 162.

¹⁶⁶428 U.S. 153 (1976).

¹⁶⁷William J. Bowers, et al., *Death Sentencing in Black and White: An Empirical Analysis of the Role of Jurors' Race and Jury Racial Composition*, 3 U. PA. J. CONST. L. 171, 177, n.23 (2001).

¹⁶⁸*Id.* at 177.

¹⁶⁹National Coalition to Abolish the Death Penalty, Yet Another Innocent Person Freed from Florida Death Row; National Count of Wrongfully Convicted Continues to Grow, (Jan. 24, 2003), at http://www.ncadp.org/press_release_01_24_2003.html (last visited Mar. 2, 2004).

¹⁷⁰Robert Blecker, *The Death Penalty: Where Are We Now?*, 19 N.Y.L. SCH. J. HUM. RTS. 295, 296 (2003). When new Governor Robert L. Ehrlich Jr. took office, he lifted the moratorium in Maryland. Ivan Penn, *Death Penalty Foes Lobby Legislators*, BALT. SUN, Feb. 11, 2003 available at <http://www.baltimoresun.com/news/local/bal-md.penalty11feb11,0,7639003.story?coll=bal-local-utility> (last visited Mar. 2, 2004).

¹⁷¹*Atkins v. Virginia*, 536 U.S. 304 (2002).

jury finds the defendant guilty of first-degree murder.¹⁷² The conclusion from this evidence is that execution is not a duly authorized state practice but a punishment with numerous flaws that often fails constitutional scrutiny in particular factual circumstances. If the Court last summer determined that executions can violate the Bill of Rights based on who performs the execution and whom is executed, why should the FDA not question how the prisoner is executed?

On the other hand, there has been no circumspection of PAS. The only Supreme Court ruling discussing the legality of PAS was *Glucksberg*, where the Court gave states significant leniency in implementing PAS statutes.¹⁷³ Opponents can justifiably argue that there has been much less time for the DWDA to be challenged than centuries old death penalty statutes. Still, two points militate against this argument. First, all of the challenges against the DWDA have been premised on the belief that PAS is an illegitimate practice, not on the basis that it is unconstitutional as applied. The two congressional challenges and Ashcroft's order all argued that PAS was not a legitimate practice of medicine because its purpose is to hasten death.¹⁷⁴

In essence, then, the federal challenge to PAS is that it is *too effective* in causing death, not that it causes deleterious side effects to patients. The courts may very well find that PAS is unconstitutional in principle, but there have been no challenges to PAS as it is practiced in Oregon.¹⁷⁵ This means that the federal government has presented no reasons why federal agencies should engage in a fact-sensitive analysis of whether PAS is being applied properly.

Equally important is the fact that no challenges have come from the patients who are subject to the DWDA -- namely, terminally ill patients seeking to hasten their deaths. The point here is relatively straightforward: patients who want to hasten their deaths have no reason to challenge the legality of PAS statutes.

Of course, the mere fact that patients want to receive a particular medication does not insulate the statute authorizing that distribution from congressional challenge. In fact, just two years ago, the Supreme Court found that marijuana is subject to regulation under the CSA in *United States v. Oakland Cannabis Buyers' Coop.*¹⁷⁶

¹⁷²Ring v. Arizona, 536 U.S. 584 (2002).

¹⁷³See *supra* notes 27-31 and accompanying text.

¹⁷⁴Kandra, *supra* note 36, at 515. The second Congressional challenge and Ashcroft's order declared that PAS violated the CSA. *Id.* The first Congressional challenge would have barred the use of federal money for PAS. *Id.*

¹⁷⁵This does not mean that problems have not occurred with PAS in Oregon. The primary problem is that the drug secobarbital was used in ninety-one percent of assisted suicides between 1998 and 2001, but then "Eli Lilly stopped producing secobarbital." *Report, supra* note 77. Based in part on the consequent change in drugs, few problems occurred with assisted suicides in 2002. For instance, one patient "coughed and gagged for 10-15 seconds," another took 13 minutes to die, and a third died 2 hours later. *Id.* It is important to note, however, that these problems should have nothing to do with the CSA's authority to nullify state law. The CSA has authority to regulate the use of drugs to prevent addiction, not unintended side effects. At best, these problems would give the FDA authority to regulate PAS drugs. Such regulatory authority would be beneficial, because studies manufacturers would have to submit could then be used to make lethal injection drugs safer as well.

¹⁷⁶532 U.S. 483, 491 (2001).

The important point here, however, is that marijuana is exactly the type of drug the CSA was intended to regulate. As stated previously, the purpose of the CSA is to prevent the circulation of drugs that are abused, leading to depressant and other effects.¹⁷⁷ By definition, no possibility of drug abuse and addiction exists when a patient takes drugs to hasten her death under PAS.

Critics may argue that the flaw in this argument — and with this paper in general — is that the FDA has different goals in regulating drugs than does the DEA in enforcing the CSA. In reality, however, this distinction should make the argument for regulation of lethal injection drugs stronger. The question should be: Is there a stronger basis for federal proscription of state PAS laws based on the potential of drugs causing death also leading to drug abuse, or is there a better argument that the federal government should regulate drugs used in lethal injections based on questions about the humanity of the procedure as applied? If the United States Attorney General feels it is in the public interest to spend federal resources based on the tenuous link between PAS and drug abuse, why should the FDA continue to ignore empirical evidence that lethal injections are often botched because of improper drug combinations, dosages, and executioners?

VII. CONCLUSION

When the FDA defended its inaction with regard to lethal injection drugs, little data existed about this new, seldom used method of execution. As lethal injection has become the near exclusive method of execution in this country, it has become evident that fears about the safety of the procedure were justified. With Ashcroft's attack on physician-assisted suicide, it has become apparent that the federal government believes that it can and should challenge what states believe to be legitimate medical practices, even when a relatively small percentage of the population is at risk. Based on this position, the FDA can no longer consistently hold that it should not regulate the drugs used in lethal injections.

¹⁷⁷See *supra* note 45 and accompanying text.