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WHY NOT HEROIN? THE CONTROVERSY SURROUNDING THE LEGALIZATION OF HEROIN FOR THERAPEUTIC PURPOSES

INTRODUCTION

"Right now, in America, we know of a drug which is the most potent, effective, soluble, and rapidly active narcotic ever created. It is not available. I do not understand this."1

A noted oncologist testified before a House Subcommittee to encourage the legalization of heroin for the purpose of easing the pain experienced by many terminally ill cancer victims.2 The issue is an emotionally charged one in which medical, legal, ethical, personal, and societal values collide. Proponents of limited legalization of heroin are led by the relatives of cancer victims and their legal and medical advocates.3 Among them are many distinguished members of the medical and research communities who maintain that heroin is the most soluble and potent narcotic for pain relief,4 that it clearly works for some patients for whom all else fails,5 and that its therapeutic use presents no appreciable risk to the community.6

Legal advocates of heroin's therapeutic use contend that the judicially recognized constitutional right of privacy extends to the relevant medical deci-


2. Dr. Mondzac has been an oncologist for fifteen years, chairs the Cancer Committee of the D.C. Medical Society, serves as Clinical Associate Professor of Medicine at George Washington University, and is a member of the board of Directors of the National Committee on the Treatment of Intractable Pain. Hearings, supra note 1, at 546.

3. The National Committee on the Treatment of Intractable Pain (NCTIP) is an advocacy group formed in 1977 to lobby for congressional action to legalize heroin for limited therapeutic use. Its members and Board include medical and legal professionals as well as families of cancer victims. The organization has 6,000 members. National Committee on the Treatment of Intractable Pain, P.O. Box 9553, Friendship Station, Washington, D.C. 20016 (301) 983-1710. Judith H. Quattlebaum, President.


sion,⁷ that the prohibition of heroin for therapeutic purposes represents a deprivation of due process for cancer victims,⁸ and that, in some instances, the common law defense of necessity justifies the use of illicit drugs.⁹

Opponents are equally vocal. They include the institutional regulators of licit and illicit drugs: the Department of Health and Human Services (HHS) and its specialized arm, the Food and Drug Administration (FDA), and the Drug Enforcement Administration (DEA), which is responsible for categorizing drugs into one of five levels of abuse potential.¹⁰ Upon recommendation from HHS, the DEA scheduled heroin into Schedule I. This is the most restrictive class, and prohibits all use except for closely controlled research.

Official government sources now maintain that heroin is not preferable to morphine for pain relief¹¹ and that the advent of new synthetic narcotics makes the heroin issue moot.¹² Representatives of the medical profession, including the American Medical Association, report that more efficacious drugs exist for the same purpose and that ineffective pain management techniques are the problem for cancer patients, rather than the prohibition of a pain-killing drug.¹³ Finally, law enforcement officials as well as pharmacists and many citizens are fearful that heroin will be diverted from the pharmacy to the street.¹⁴

The American debate over the medicinal use of heroin has raged for over sixty years, but its current focus is more refined than ever before: Should heroin be available in hospital and hospice pharmacies to provide analgesic alternatives for patients experiencing severe pain from terminal cancer?¹⁵ It is estimated that eight thousand to forty thousand Americans suffer every year from pain so profound that no currently available medication is effective.¹⁶ For them, the modern link between cancer and heroin may be the

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7. Shapiro, supra note 5, at 56.
11. Hearings, supra note 1, at 454. (statement of Edward N. Brandt, Jr., M.D.).
13. Hearings, supra note 1, at 560, 599 (statement of Kathleen Foley, M.D.).
15. H.R. 5290 was amended to provide heroin only to terminally ill patients.
avenue to relief. For others, the cancer-heroin association ironically pairs America's most feared disease with its most feared drug of abuse.

Because the heroin dilemma strikes a nerve in the American public, the legalization of heroin for therapeutic purposes has become a focal point in the lay press as well as for legal and medical experts. Americans are acutely aware that one of every four people will be afflicted with some form of cancer during his lifetime and that nearly everyone will be affected by the impact of the disease on family members or friends. In this context, congressional initiatives to legalize heroin for specific therapeutic purposes have sparked greater public interest than similar bills in the past. The Compassionate Pain Relief Act was, however, defeated during the closing days of the 98th Congress.

This note will demonstrate a two-pronged approach to the legalization of heroin for therapeutic purposes. The first approach requires a more favorable judicial interpretation of the right of privacy as inclusive of the medical choice to take unauthorized or illicit drugs to alleviate intractable pain in dying patients. Parallels to the laetrile controversy offer guidance as to how heroin will fare in the courts: the choice to elect heroin therapy as a function of the right of privacy is likely to fall victim to compelling state interests. Still, the right of privacy is the best judicial ground upon which to establish a basis and seek future inroads.

The second and more promising approach is through congressional action. Public policy demands that all available effective cancer treatments be part of the physician's armamentarium to fight the disease. Congress can bypass the administrative logjam of the FDA's "new drug" procedures and provide for limited access for those patients whose conditions justify the use of heroin.

Furthermore, this note will trace the history of heroin's prohibition in this country and the medical issues at stake in the current controversy. It will proceed to explore the constitutional basis for legalizing heroin on a limited basis. Finally, it will focus on congressional efforts to provide a compassionate response to a profoundly human dilemma and conclude that the advocates of heroin's medical use still face major obstacles in their efforts to gain limited legal status for the controversial drug.


18. The bill was defeated by a vote of 355 to 55 on September 19, 1984. 130 CONG. REC. 9791 (1984)
THE HISTORY

In 1914, the Harrison Narcotics Act banned the recreational use of heroin in the United States in conjunction with an international initiative to stem the growing number of opium addicts.\textsuperscript{19} While the Act specifically prohibited the recreational use of the drug, it left the door open for the prescription of heroin by doctors “in good faith” and “in the legitimate practice of (the) profession.”\textsuperscript{20}

The physician’s right to prescribe heroin, however, was soon proscribed by two significant Supreme Court decisions. In 1918, the Court held in \textit{Webb v. United States}\textsuperscript{21} that it was never appropriate for a doctor to prescribe heroin to addicts. In \textit{United States v. Behrman},\textsuperscript{22} four years later, doctors were held strictly liable for prescriptions which “could only result in the gratification of a diseased appetite for those pernicious drugs.”\textsuperscript{23} While the statute in question in \textit{Behrman} specifically excluded physicians from its prohibition against drug dealing, the government charged “facts sufficient to show that the accused was not within the exception.”\textsuperscript{24} The Court concluded that the defendant physician was in violation of the Act because he indiscriminately prescribed the drug to a known addict.

In 1924, the House Ways and Means Committee held hearings to amend the Harrison Act, whose intent was to further restrict the importation of opium for exclusively medicinal purposes.\textsuperscript{25} Public concern about growing addiction problems and criminal conduct associated with the drug fanned the furor in favor of the simply worded amendment: “Provided, that no crude opium may be imported for the purpose of manufacturing heroin.”\textsuperscript{26} Testimony from the American Medical Association (AMA) and the then United States Surgeon General illustrated the low regard into which heroin had fallen. The Surgeon General alleged that the drug erased all moral sense while the physician speaking for the AMA indicated that codeine was a good substitute for heroin.\textsuperscript{27} In short, the medical testimony was more sensa-

\textsuperscript{19.} \textit{NATIONAL COMMITTEE ON THE TREATMENT OF INTRACTABLE PAIN, Authorizing the Medical Prescription of Heroin for Terminal Cancer Patients Under Controlled Circumstances} 1-3 (1979).
\textsuperscript{20.} \textit{Hearings, supra note 1, at 3 (statement of Arnold Trebach, J.D., Ph.D.).}
\textsuperscript{21.} \textit{Webb v. United States}, 249 U.S. 96 (1918).
\textsuperscript{22.} \textit{United States v. Behrman}, 258 U.S. 280 (1922).
\textsuperscript{23.} \textit{Id.} at 289.
\textsuperscript{24.} \textit{Id.} at 287.
\textsuperscript{25.} \textit{Hearings Before the Committee on Ways and Means, House of Representatives, on H.R. 7079, A Bill Prohibiting the Importation of Crude Opium for the Purpose of Manufacturing Heroin}, 68th Congress, 1st Sess. (1924).
\textsuperscript{26.} \textit{Id.} at 1.
\textsuperscript{27.} \textit{Id.} at 32, 13.
tional than it was substantive and the ban on heroin reflected its growing disrepute in the medical community.

The diversion question was also confused by the emotion and tenor of the testimony. While evidence was introduced that, of ten thousand addicts in New York State, only two per cent could trace their addiction to medical treatment, the momentum to outlaw all heroin use was underway. Testimony that seventy-six thousand ounces of heroin were sold on New York's black market, while only fifty-eight ounces were prescribed by all of the physicians in the state during the same period, was disregarded by those calling for the complete abolition of the drug.

One commentator has suggested that the 1924 hearings were a miscarriage of justice resulting in a deprivation of due process for many Americans from that time until the present. In testimony before the House Subcommittee on Health and the Environment in 1984, Arnold Trebach, author of The Heroin Solution, said of the early hearings, "No original or empirical evidence was introduced to demonstrate that there was a connection between the creation of addicts and the presence of this drug in medical practice."

In 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act which repealed the Harrison Narcotics Act and provided a new framework of drug enforcement. Title II of the new Act mandated the establishment of five schedules of drugs based on degree of abuse potential, known effects, harmfulness, and level of accepted medical use. Heroin was classified in Schedule I, the most restrictive category, and has remained there despite congressional attempts to reschedule it to allow more latitude in testing and medical use.

Schedule I criteria are identified as follows:

1. The drug or other substance has a high potential for abuse.
2. The drug or other substance has no currently accepted medical use in treatment in the United States.
3. A lack of accepted safety precautions for use of the drug or other substance under medical supervision.

During the 1980 hearings by the House Select Committee on Narcotics

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28. Id. See also Hearings, supra note 1, at 571 (statement of Arnold Trebach, J.D., Ph.D.).
29. Hearings, supra note 1, at 571.
32. Legislation in the 97th Congress (H.R. 2642) focused on re-scheduling heroin, rather than establishing a government administered program such as proposed in the latest heroin legislation.
Abuse and Control, the scheduling dilemma of substances such as heroin and specifically marijuana (also Schedule I) was dramatized in a dialogue between Congressman Stephen Neal and a panel of cancer researchers:

Mr. Neal: Well, just for the record, it's my understanding . . . that the assumption for a drug to be in Schedule I is that it has no medical use. And just for the record, I want to make it clear that you all, the three of you, are saying there are very definite medical uses for these substances.

Dr. Sallan: Most definitely.

Dr. Garb: Sir, I would add there are a lot more than three of us . . . .

Mr. Neal: Well, now, would you say this about THC only, or about THC and marijuana?

Dr. Sallan: I would say it about both, but I have much less certainty about marijuana because it doesn't have the same scientific rigor in the study at this time.

Mr. Neal: Well, then, we need more study, but to get the study, we need a substance available to you to study, but as long as it's under Schedule I, it will not be available, because the assumption will be that there is no medical use. It's a Catch-22 situation, it seems to me.\(^3\)

While Congressman Neal fairly characterized the “no medical use” irony, the United States government did make accommodations for two testing situations to analyze the effectiveness of heroin in medical use. These two studies, the Memorial Sloan Kettering Study and the Georgetown Study, will be discussed in the following section.

The United States experience with heroin contrasts sharply with that of the United Kingdom. Over ninety-five per cent of all licit heroin is prescribed in England where the drug has been widely used in hospices for pain control.\(^35\) Currently, heroin is used in a 3:7 ration with morphine. Its status as the medication of choice in severe pain situations has increased over the decades.\(^36\)

In addition to England, twenty-six nations specifically allow for medical


\(^36.\) Hearings supra note 1, at 10 (statement of Arnold Trebach, J.D., Ph.D.).
channeling of heroin by qualified physicians.\textsuperscript{37} Eleven more apply the same restrictions to heroin use as other narcotic analgesics and ten more nations have given specific government approval to the use of heroin.\textsuperscript{38} The United States, however, allows morphine a relatively favorable Schedule II classification in spite of its heroin-like narcotic properties while classifying marijuana as a Schedule I drug along with heroin. Clearly, the United States maintains a model of drug control more suited to law enforcement than to medical concerns. In spite of the positive experience of doctors and patients in twenty-seven other nations, many American lawmakers, doctors, and citizens still fear that the controlled introduction of heroin into medical practice would undermine the American system of drug enforcement and implicitly condone drug production and trafficking on an international scale.\textsuperscript{39}

\section*{The Medical Controversy}

Pain as a symptom involves at least fifty per cent of cancer victims and may become a serious management problem for at least fifteen to twenty per cent of those individuals.\textsuperscript{40} It is this proportion of cancer patients for whom heroin would provide an essential pain-killing alternative. Dr. William Beaver, who conducted the most recent government-sponsored study of heroin's therapeutic value at Georgetown Medical Center, noted: "There will be individual patients who respond better to heroin for reasons we do not understand."\textsuperscript{41} Since no two analgesics have properties that are identical, patients with different reactions may tolerate one analgesic and not another. "This fact alone justifies a variety of alternative drugs available."\textsuperscript{42}

Comparisons between heroin, morphine, and other analgesics usually break down into several distinct categories:

1. \textbf{POTENCY} — Heroin is highly potent (2.7 times more potent than morphine) thus allowing smaller doses to be administered to produce equivalent pain relief. This consideration is extremely important when administering a drug to patients with wasted muscle mass.\textsuperscript{43} Those who oppose heroin's use cite a new strong form of Dilaudid as being equally

\begin{thebibliography}{99}
\bibitem{37} J. Quattlebaum, \textit{Information on Medical Uses of Heroin in Other Nations} 4 (1983).
\bibitem{38} \textit{Id.}
\bibitem{40} \textit{Hearings, supra} note 1, at 1 (statement of William Regelson, M.D.).
\bibitem{41} \textit{Hearings, supra} note 1, at 4 (statement of Betsy Hague, R.N., M.S.N., quoting Dr. William Beaver, "Are Synthetic Narcotics Adequate Substitutes for Opium-Derived Alkaloids?").
\bibitem{42} \textit{Id.}
\bibitem{43} Satchell, \textit{When Heroin is the Right Drug}, \textit{Parade Magazine}, May 16, 1982, at 12.
\end{thebibliography}
2. **ONSET** — Heroin’s action is rapid and produces relief quicker than other drugs. Again, critics maintain that more effective pain management would offset this advantage.\(^4\)

3. **ATTITUDE** — Heroin produces euphoric feelings in most patients rather than the depression and anxiety that often follow morphine intake. Mood elevation differences, however, were not perceived as significant in the latest two studies of the drug.\(^5\)

In the Beaver study, conducted at Georgetown University Vincent T. Lombardi Cancer Research Center, fifty-two patients with incurable cancer received one injection of heroin and another of morphine to combat pain. The results indicated heroin to be more potent, more soluble, and faster-acting.\(^6\)

The Sloane Kettering study, conducted by Dr. Raymond Houde, treated post-operative pain in cancer patients.\(^7\) Results indicate that heroin was about twice as potent as morphine, that it provided a peak effect earlier than morphine, that doses with equal analgesic effects provided comparable improvements in various elements of mood, but that the peak arrived sooner with heroin. Furthermore, pain relief and mood improvement were less sustained after heroin at equal doses and in the researcher’s opinion, heroin had no unique advantage for the relief of pain in patients with cancer.\(^8\)

It is clear that the medical controversy over heroin’s therapeutic use would not exist but for the criminal aspects of heroin’s identity. Even its detractors find that heroin is neither more advantageous nor disadvantageous than other legal alternatives for the relief of pain. Where the issue of addiction is moot, as in the case of terminally ill patients, unwillingness to include heroin as a therapeutic option is a reaction to its character as a potentially addicting drug.

According to oncologist Allen Mondzac, “With each patient, there is a potential for using up all of the existing drugs.”\(^9\) The availability of heroin

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44. See *supra* note 12.
46. *Id.*
47. Dr. Beaver commented, “[t]here’s no point in doing more research. In fact, we knew pretty much before we started this study what we would find out.” *Supra* note 43, at 12.
48. There has been disagreement in the medical community over the validity of comparisons between post-operative patients, as in the Houde study, and those suffering chronic cancer pain, as in the Beaver study. It is the chronic and terminally ill sufferers for whom the legalization effort is being waged. See *Hearings, supra* note 1, at 2 (statement of William Regelson, M.D.).
50. *Hearings, supra* note 1, at 547. (statement of Allen Mondzac, M.D.)
would extend the physician’s potential pain-killing remedies to one more effective therapy. Heroin’s current outlaw status denies doctors and patients that alternative.

**THE LEGAL ISSUES**

*The Right to Privacy -- Griswold v. Connecticut*

The decision to use heroin to mitigate the agony of cancer pain enjoys no explicit constitutional protection. The complicated interplay of personal autonomy, illicit drug use, human suffering, and medical necessity creates a legal paradox that is at once intensely intimate and starkly public in nature. The question is basic: whether a person’s choice to use heroin should be fundamentally protected against coercion by law.\(^\text{51}\) The answer lies in the developing right of privacy which has been held to encompass something beyond the issues of marital choice, procreation, conception, and child-rearing and to embrace “an interest in independence in making certain kinds of important decisions.”\(^\text{52}\) No decision can be more profound than that implicit in the heroin dilemma.

The right of privacy was first judicially recognized in *Griswold v. Connecticut* in 1965.\(^\text{53}\) *Griswold* raised the question of whether a married couple living in Connecticut could be imprisoned for using birth control. Under the operative state statute, the use of any device to prevent conception was criminal. The Supreme Court struck down the statute, declaring that “marriage is... intimate to the degree of being sacred,”\(^\text{54}\) and is subject to constitutional protections under a privacy right “older than the Bill of Rights.”\(^\text{55}\) Justice Douglas, speaking for the majority, located substantive protection for marital intimacy in a “zone of privacy” created by several fundamental guarantees emanating from penumbras of the first, third, fourth, fifth, and ninth amendments.\(^\text{56}\)

Justice Goldberg’s *Griswold* concurrence identified the source of the privacy right in the ninth amendment and defined a test to determine whether a fundamental right worthy of constitutional protection exists. He directed judges to look to the “collective conscience of the people” to find whether a principle is so firmly rooted as to be ranked fundamental. The inquiry explored whether the right involved is of such a character that it cannot be

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52. Id. at 886.
54. Id. at 486.
55. Id.
56. Id. at 485.
denied without violating those "fundamental principles of liberty and justice which lie at the base of all of our civil and political institutions." 57 With the same breadth of philosophical conviction, Justice Harlan located the privacy right among those "basic values implicit in the concept of ordered liberty," 58 and suggested a fourteenth amendment due process analysis to determine whether such a right has been violated.

The Griswold Court concluded that a married couple's right to use contraceptives is fundamental and protected by the constitutional right of privacy, however abstract and circuitous the route to that protection. Seven years later, the same right was extended to unmarried persons in Eisenstadt v. Baird. 59

As the court construes the right to privacy, its decisions rest on a recognition of values implicit in our way of life and philosophy as a nation, rather than on any strict construction of a concept. The celebrated Brandeis statement in Olmstead v. United States 60 conveyed the tone that would underlie so many future decisions:

The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and sensations. They conferred, as against the Government, the right to be let alone — the most comprehensive of rights and the right most valued by civilized men. 61

The distance between the subjective recognition of collective and natural values and a concrete source for the protection of those values led the Griswold Court to explore several constitutional constructions. It is that same distance, still untraveled, that deprives the current heroin issue of a humane solution.

Development of the Right of Privacy

The evolution of the privacy right continued in the famous "abortion cases" of 1973: Roe v. Wade 62 and Doe v. Bolton. 63 In Roe, the Court con-

57. Id. at 493.
58. Id. at 500.
61. Id. at 478 (Brandeis, J. dissenting).
cluded that the right to personal privacy includes the right to an abortion but that "this right is not unqualified and must be considered against important state interest in regulation." The balancing test of a fundamental right versus a compelling state interest became the hallmark of personal health and privacy decisions in the courts. In his Roe concurrence, Justice Douglas explicitly includes within the term "liberty" in the Fourteenth Amendment "the freedom to care for one's own health and person . . . subject to regulation on a showing of 'compelling state interest'." His observation is a forerunner of the complex health and enforcement questions that characterize the heroin dilemma today.

The balancing test of Roe v. Wade is operative in Whalen v. Roe four years later. Whalen clearly establishes the state's right to regulate dangerous drugs in the face of individual privacy interests. The Court upheld a New York statute requiring the registration of all medical prescriptions for addictive drugs to control abuse. The Court distinguished the state's interest in record keeping from the individual's right to decide what drugs to take: "within dosage limits . . . the decision to prescribe, or to use, is left entirely to the physician and the patient." Yet, while acknowledging the "individual interest in avoiding disclosure of personal matters," the Court nonetheless upheld the right of the state to maintain the names of those selecting certain substances. In the view of the Court, the state's interest in record-keeping, while compelling disclosure, was justified and fell short of invading an individual's liberty right. Thus, the Court recognized relative levels of intrusion into personal decision-making, further emphasizing the less than absolute nature of the fundamental right of privacy.

**Choice of Treatment**

The choice of treatment as an element of the right of privacy may be considered in three separate contexts. The first is the right to choose from among approved methods of treatment, a well-established legal right which threatens no state interest and implies informed consent on the part of the patient.

The right to refuse treatment is the second and more complex issue. It was tested as early as 1904 when a man named Jacobsen refused a smallpox vaccination on the basis of every man's right to control the sanctity of his

64. Roe, 410 U.S. at 154-55.
65. Id.
67. Id. at 603.
68. Id at 599.
69. Id. at 598-606.
body. The Court held that the state's interest in preventing the spread of disease overrode Jacobsen's personal right to refuse treatment. The Court implied that the right to refuse treatment would be upheld only when the individual's choice is informed, and society's interest would not be harmed.

In In re Quinlan, the court's focus was limited to the right to decline life-prolonging treatment when the patient had no realistic hope of returning to "any semblance of cognitive or sapient life." The issue was further complicated by the patient's comatose state and her subsequent inability to represent her own interests before the court. The court held that her father could decide to cease life-prolonging activity in order to safeguard her right to die with dignity. The constitutional law commentator Laurence Tribe pointed out the inherent irony in the court's decision: that given the vegetative state that alone justified the court's holding, "attributing 'rights' to the patient at all was problematic." The decision more realistically concerned the desires of parents and society to allow freedom of medical decision-making when individuals without consciousness linger only through extraordinary life-prolonging means. The Quinlan case did not confer the right to terminate care to those who are conscious and for whom death is not imminent. In effect, the court recognized that a balancing of state and individual interests in the context of life-prolonging medical care is affected by the degree of illness suffered by the victim and the fading hope of a cure.

The third choice of treatment situation — the right to choose a medical treatment that is not approved by the state — has led to a number of decisions surrounding the drug laetrile and has loomed at the center of the marijuana controversy. Judicial resolution of this third category of decision-making may well determine the future of heroin as a therapeutic agent. The leading case in the area is Rutherford v. United States.

72. Id. at 39, 355 A.2d at 663.
73. Id. at 41-42, 355 A.2d at 664.
74. See supra note 51, at 936.
75. Id.
76. Quinlan, 70 N.J. at 41, 355 A.2d at 664.
78. Cooper, Therapeutic Use of Marihuana and Heroin: The Legal Framework, 35 FOOD DRUG COSM. L.J. 68 (1980).
79. Rutherford v. United States has the following judicial history: Rutherford v. United
Rutherford v. United States

In Rutherford, several terminally-ill cancer patients sued to enjoin the United States from interfering with their access to laetrile. The United States District Court for the Western District of Oklahoma issued an injunction against the Food and Drug Administration (FDA) on the basis that patients were denied freedom of choice and were deprived of life, liberty, or property without due process of law. The court held that the FDA's licensing requirements for new drugs made it virtually impossible for laetrile to become legally accessible.

On appeal, the United States Court of Appeals for the Tenth Circuit looked closely at FDA procedures and focused on the approval process for "new" drugs and the grandfather clause exemptions under the Food and Drug Act. Its inquiry raised the following questions: 1) Was laetrile marketed on October 9, 1962, as a cancer drug and was it then generally recognized as safe? 2) Was laetrile recognized or used as a cancer drug under the same conditions of present use during the period when the Food and Drug Act of 1906 was in effect from June of 1906 until June of 1938? If either question could be answered affirmatively, laetrile would be exempt under the grandfather clause.

The tenth circuit remanded the case to the Food and Drug Administration in order to produce an administrative record supporting its determination that laetrile was a “new” drug, though it did not explore the constitutionality of the “new” drug procedures. In 1977, in response to the court’s order, the FDA released its findings that laetrile was not generally recognized as safe and effective or exempt under the 1962 grandfather clause.

On appeal, the district court ruled that the FDA’s classification of laetrile as a “new” drug was “arbitrary, capricious, and an abuse of discretion, and,
as a matter of law, unsupportable."83 The judges noted that laetrile had been used and sold commercially in the United States for over twenty-five years and had been generally recognized as safe.84

As to the constitutional aspects, the court looked to the "abortion cases"85 for the premise that a right of privacy exists under the Constitution. As Douglas said in Doe, "that right has no more conspicuous place than in the physician-patient relationship."86 The district court determined that fundamental civil liberties were at issue in Rutherford, and that the choice to use laetrile, regardless of its correctness, should be the sole prerogative of the person whose body was being ravaged by disease.87

Again, the United States appealed the decision of the district court to the tenth circuit which sustained the district court's injunction, thus allowing the interstate sale and use of laetrile for terminally ill patients to continue.88 The appeals court did not directly address the constitutional issue. On appeal to the Supreme Court, the tenth circuit was reversed and the case remanded for further proceedings on those issues.89

In its opinion, the Supreme Court dealt with the relationship between the FDA's protective procedures and terminally ill patients. The Court held that the Congress could reasonably have intended to shield terminal patients from ineffectual or unsafe drugs, and that any other interpretation of the FDA regulations would substitute the opinion of the Court for that of Congress. "For the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit."90 The Supreme Court did not address the privacy issue.

On remand, the Tenth Circuit revived the balancing test to weigh the "protected right" to select a medical treatment against the governmental interest in protecting public health. The court found that the state's interest outweighed such personal medical decisions. The constitutional conflict was thus temporarily resolved.91

Rutherford represents a weakening of the individual's privacy interest in choosing medical treatment. Unlike the early Jacobsen case,92 no public
danger existed in granting laetrile's commerce. Unlike the "abortion decisions," other lives would not be affected by an individual's choice of treatment. Only victims of cancer themselves would be affected by the prohibition on laetrile's use. The compelling state interest could be construed only as protecting terminally ill patients from their own informed choice. Thus, while it has been held that an individual can refuse treatment to sustain life, he is not yet free to select an unauthorized treatment in the face of death.

**People v. Privatera**

*People v. Privatera,* a California Supreme Court decision, reaches the same conclusion. The California court determined that the right to use laetrile is not governed by the fundamental right of privacy because it is not among those decisions enumerated in the "privacy cases." As such, the court had only to find a rational basis for the statute proscribing laetrile's use, which it fulfilled by citing a history of misleading representations about cancer cures.

In a dissent more remarkable than the decision, Chief Justice Rose Bird asserted that "choice of treatment is one of the most important decisions a person may ever make, touching intimately on his or her being." Her opinion and that of the district court in *Rutherford* represent the eloquent dissent in a line of decisions that subordinate the individual's freedom of choice in medical decisions to the state's perceived goals.

Thus, the prevailing tone of judicial decisions leads to negative assumptions about the future of heroin therapy via the judiciary. Because heroin's status is not just unauthorized, but forbidden, the recognition of a fundamental right to use the drug for medical reasons would conflict with the state's interest in prohibiting its existence on nearly every occasion. Only a contention that the current prohibition is overbroad would prevent the state's interest from outweighing every personal consideration.

**The Marijuana Connection**

"It isn't absolutely necessary to be a masochist to do research on marijuana today, but it certainly helps." Marijuana, like heroin, is a Schedule I drug. Under federal law, it is

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94. The court referred to marriage, procreation, contraception, family relationships, child rearing, and education. 23 Cal. 3d at 702, 591 P.2d at 922, 153 Cal. Rptr. at 434.
95. 23 Cal. 3d at 711, 591 P.2d at 927, 153 Cal. Rptr. at 439 (Bird, C.J., dissenting).
deemed to have no medical usefulness while having high potential for abuse. It is subject to the following restrictions:

- The DEA has established quotas on lawful production of marijuana and its active ingredient THC.
- The drug may be manufactured only by an individual or company registered with the DEA.
- A researcher seeking to study the drug must obtain registration from the DEA.
- The drug must be kept in a vault.
- Record keeping is required.
- Trafficking the drug is a felony.
- The drug is available for research only and may not be prescribed.

In addition, marijuana falls under FDA’s “new drug” category and is subject to its regulatory provisions.

Marijuana and THC are currently being tested for their ability to relieve pain, insomnia, anxiety, asthma, epilepsy, glaucoma, and the side-effects of chemotherapy. In addition, the National Cancer Institute’s Division of Cancer Treatment now provides THC to physicians for use in controlled situations. As such, the Schedule I classification has become a contradiction in terms. The proven medical uses for marijuana are growing every day.

Hearings in Congress have focused on the subject of down-scheduling marijuana to conform with current knowledge about the drug’s effectiveness. Marijuana progress bears watching by advocates of heroin’s legalization. While the public’s response to marijuana continues to be volatile, public fear is less profound than with the use of heroin and the potential beneficiaries of therapeutic marijuana use are more numerous. Nevertheless, according to former FDA Chief Counsel Richard Cooper,

[the medical future of both THC and heroin is not entirely clear . . . . A potential manufacturer will have to gather the relevant data and organize them into new drug applications that meet the FDA standards. It may turn out that the biggest obstacle to the therapeutic use of marijuana and heroin is the lack of interest in the drug on the part of drug companies.]

97. Ironically, severe dependence liability is a criterion for Schedule II and not Schedule I.

98. Cooper, supra note 78, at 70.

99. Cohen, supra note 96, at 60.


101. Cooper, supra note 78, at 82.
Medical Necessity Defense

Federal courts have consistently held that possession and sale of marijuana are not protected by the right to privacy. However, the common law defense of necessity has been held to extend to medical necessity in the case of a Washington, D.C., man who used marijuana to treat his deteriorating glaucoma condition.

In 1975, Bob Randall was arrested and charged with unlawful possession of marijuana. He sought acquittal on the strength of a medical necessity defense. The District of Columbia Superior Court dismissed the charge, stating that a person whose use of marijuana is a matter of medical necessity is not criminally liable for its unlawful possession. While the necessity defense historically depended on an immediate threat to life, a fear of deteriorating health was later considered to be a justifiable ground for the defense.

The court stated that “necessity is the conscious, rational act of one who is not guided by his own free will. It arises from a determination by the individual that any reasonable man in his situation would find the personal consequences of violating the law less severe than the consequences of compliance.” The court noted that the defense is not available to one who has brought the circumstances upon himself. Thus, a heroin addict who would argue the defense of necessity would be unlikely to prevail. In addition, if there was a less stringent alternative, the defense would fall. Finally, the harm avoided must be more serious than what is performed to escape it.

The D.C. court’s analysis focused on a balancing of interests between Randall’s desire to preserve his sight and the government’s interest in main-
taining its regulation of marijuana. Noting "how far-reaching is the right of an individual to preserve his health and bodily integrity," the court concluded that blindness is a greater evil than breaking the prohibition on marijuana. In dismissing the case, the court also noted that no innocent party was injured and Randall had not brought his condition upon himself. The United States did not appeal.

The court's acceptance of Randall's defense is significant as a qualified affirmation of the right to protect one's health. Within the context of the case, an analogy between the use of marijuana and the use of heroin is a logical one. If the only means to combat intractable pain is heroin, then the medical necessity defense successfully employed by Randall might prevail for one who breaks the prohibition on heroin due to an advanced condition of cancer. However, the defense is limited to individuals caught in the medical-legal bind. It is no answer to the larger question of legalization that must be confronted by lawmakers if any true progress is to take place.

**Congressional Action**

While the courts have only addressed the heroin conflict by implication, Congress has squarely dealt with the issue. The Compassionate Pain Relief Act, H.R. 5290, was designed to establish a temporary program under which "parenteral diacetylmorphine (heroin) would be made available through qualified pharmacies for the relief of intractable pain due to cancer." The bill was introduced by Congressman Henry Waxman of California, Chairman of the Subcommittee on Health and the Environment of the Committee on Energy and Commerce. It was defeated by a vote of 355 to 55 on September 19, 1984, after several hours of passionate debate. According to Congressman Waxman, the lopsided vote was a consequence of political timing:

"People were afraid to vote in any way, shape or form for anything that sounded like legalization of heroin. They were afraid they would be campaigned against on the issue."

H.R. 5290 was not the first congressional attempt to deal with the availability of heroin for therapeutic purposes. In 1980, Congressmen Waxman of California and Congressman Madigan of Illinois jointly and separately introduced legislation to make heroin available on a limited basis. Hearings were

111. *Id.* at 2253.
held before the Subcommittee on Health and the Environment of the Interstate and Foreign Commerce Committee.\(^{115}\) Again in 1983, Waxman introduced legislation which was the subject of more hearings and was subsequently reintroduced as the clear bill which the House defeated in September, 1984. Its Senate companion, S. 209, was introduced by Senator Inouye of Hawaii and never reached a vote on the Senate floor.

The Waxman bill was a model of qualified legalization. H.R. 5290 would have required the Secretary of Health and Human Services to establish a temporary four-year research program during which heroin would be provided to terminally ill cancer patients through a limited number of pharmacies upon the written prescription of a licensed physician. The program would be monitored by the Government Accounting Office (GAO). An amendment by Congressman Hughes of New Jersey would have tightened the bill even further by requiring that the patient for whom heroin is prescribed would not respond to any other available drug, that a physician's decision to prescribe heroin be reviewed by a medical panel, and that the program be drawn into the system of regulation of the Controlled Substances Act. The Hughes Amendment was not passed.\(^{116}\)

The politics of the Compassionate Pain Relief Act were unusual and embittered. The Reagan administration opposed the bill, stating that equally potent drugs were available and diversion was a real and present danger.\(^{117}\) The American Medical Association opposed the bill while the American Nurses' Association favored its passage.\(^{118}\) Rhetoric on the House floor volleyed between calls for compassion and warnings of dire consequences if the bill were to become law.\(^{119}\) One opposing legislator even suggested that "we are going to have many pushers telling young kids, 'Look, this (heroin) cannot be that bad for you. After all, doctors and hospitals are using it all over the country.'"\(^{120}\)

Opponents also decried the fact that H.R. 5290 bypassed the Food and Drug Administration's "new drug" approval process by providing for government manufacture and distribution of the drug. Advocates maintain that so few patients are potentially involved that no drug company is likely to undertake the major effort and expense to meet the FDA regulations, espe-


\(^{117}\) Hearings, supra note 1, at 462.

\(^{118}\) Hearings, supra note 1, at 603.


cially in light of heroin's unsavory reputation.\textsuperscript{121}

It was the criminal identity of heroin and the threat of cross-over from pharmacy to "street" and from "street" back to the sick and dying that emerged as the focus of the debate in an election year. Chairman Rangel of the Select Committee on Narcotics Abuse and Control led the opposition suggesting that "a lot of people . . . would openly advocate that we just take the profits out of heroin and just start legalizing the entire illicit drug manufacturing and transactions in the United States."\textsuperscript{122} A letter from Secretary of Health and Human Services Margaret Heckler was quoted, emphasizing the Reagan administration position that legalization would pose serious public safety, enforcement, and security problems and that health care professionals would be placed in jeopardy by the direct link to criminal activity.\textsuperscript{123}

Chairman Dingell of the Energy and Commerce Committee that reported favorably on the bill disposed of the Administration's major objection metaphorically.

\textit{Let us take a little bit of a look at the question of diversion: 4.3 tons of illegal heroin come into this country. That is the equivalent to two elephants in weight. If you were to take the entire amount of heroin that is going to be coming into this country under carefully controlled conditions to meet the needs of the hopelessly dying cancer patients, you would probably have the equivalent of a pimple on the posterior of one of those elephants.}\textsuperscript{124}

The fact that the illicit heroin supply would not be significantly increased even in the worst case analysis did not prove persuasive to a majority of voting members. The debate had an evangelical tenor that had less to do with facts than with the emotional impact of heroin on the American psyche. According to one Waxman staffer, the "all-out-attack" waged by the administration not only helped to create a fervor among the bill's detractors, but also cost the proponents five months that proved strategically devastating.\textsuperscript{125} Allegations that the administration used illegal lobbying techniques to defeat the bill are now under investigation by the Office of the Inspector General.\textsuperscript{126}

\textsuperscript{121} Government manufacture of heroin might compete with the marketing of hydromorphone (trade name "Dilaudid"), a domestic drug. Dilaudid is currently the drug of choice for the treatment of severe, intractable pain. Although both Dilaudid and heroin are effective analgesics, the controversy centers on the availability of heroin for use in those cases where Dilaudid has proved ineffective.


\textsuperscript{123} \textit{Id.} at H9764.

\textsuperscript{124} \textit{Id.} at H9771.

\textsuperscript{125} Revealed in a conversation with Health Subcommittee staffers after defeat of the bill.

\textsuperscript{126} 130 Cong. Rec. 118, H9771-72 (daily ed. Sept. 19, 1984). Chairman Dingell placed in
The lay press rallied behind the Compassionate Pain Relief Act. *The Washington Post* headlined its September 22d editorial *Cruel Cowardice* and commented that "demagoguery carried the day."\(^{127}\) *The New York Times* editorialized that Congress preferred symbolic action, "no matter how cruel the effect on the dying."\(^{128}\) Papers from *The Fort Lauderdale News* to the *San Jose Mercury News* had endorsed the measure in weeks and months preceding the vote.\(^ {129}\) In an acerbic commentary on the subject, Editor Smith Hempstone of *The Washington Times* wrote, "[t]he absolute medical ban on heroin makes about as much sense as denying a man about to be electrocuted a cigarette on the grounds that the Surgeon General has determined smoking is injurious to the health."\(^ {130}\)

Proponents of the Compassionate Pain Relief Act are hopeful that more favorable timing, public support, and an off-election year will improve prospects for the bill's passage during the 99th Congress.\(^ {131}\)

**CONCLUSION**

The forty-thousand Americans who could benefit today from heroin's legalization cannot afford to wait for a broader judicial interpretation of the right to privacy. Even as the courts affirm the fundamental nature of decisions affecting one's health and well-being, they qualify the conditions and circumstances under which these decisions may be made. The strict scrutiny accorded to fundamental-right analyses seems more easily satisfied in the privacy context than where other fundamental rights are concerned: the balancing test is slanted toward compelling state interest. The persistent judicial perception that the state's interest in drug regulation overrides individual fundamental rights assures that courts will continue to defer to the authority of the FDA and DEA in the scheduling and control of heroin's use in this country.

Only a re-evaluation of the government's interest could alter this judicial posture. A closer look at the actual dangers of heroin's diversion from pharmacy to street use would reveal an exaggerated fear of expanded illicit trade. A recognition that the addictive potential of heroin is no issue for the dying would undermine the contention that its use is deleterious to the target pop-

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\(^{130}\) The Washington Times, March 28, 1984, at 1c, 2c, col. 1.

\(^{131}\) Conversation with Health Subcommittee staffers following bill's defeat.
ulation. But the courts will not re-define the nature of the government's interest in the sweeping prohibition on heroin. The judicial system will not substitute its judgment for the will of Congress so clearly demonstrated in 60 years of legislative history.

The only imminent hope for cancer victims lies with the Congress and not the courts. The dramatic defeat of the Compassionate Pain Relief Act of 1984 is a major setback which, according to Judith Quattlebaum of the National Committee on the Treatment of Intractable Pain, is "impossible to explain to cancer patients."132 Congressional advocates have, however, reintroduced the measure in the 99th Congress with an eye toward more advantageous timing.133

It is time for Congress to mitigate the law enforcement message of the past decades and offer a new perception of a compassionate, balanced, and hopeful drug policy for this nation. The quality of American lives depends on it.

*Suzanne Marcus Stoll*