Congressional Research Service
The Library of Congress

Washington, D.C. 20540

HEROIN: LEGALIZATION FOR MEDICAL USE

Blanchard Randall IV
Analyst in Social Sciences
Science Policy Research Division
March 14, 1984

ABSTRACT

The limited legalization of diacetylmorphine (heroin) for use in the medical treatment of intractable pain is discussed in a white paper which attempts to present pros and cons on the issue as well as information on pending legislation. The paper also provides a comparison of heroin's analgesic qualities to those of currently available and equivalent pharmaceutical alternatives.

HEROIN: LEGALIZATION FOR MEDICAL USE

Over the past few years a great deal of attention has focused on the emotionally charged issue involving the legalization of heroin for medical purposes, especially for the terminally ill suffering from intractable pain. Heroin, an opiate derivative, is subject to control under Schedule I of the Controlled Substances Act (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970). Drugs placed in this schedule meet the following criteria: (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; and (3) there is a lack of accepted safety for use of the drug or substance under medical supervision. Proponents of the legalization of heroin (i.e., having heroin rescheduled, probably down to Schedule II) most often argue that, contrary to the second scheduling requirement of Schedule I (no currently accepted medical use), the substance does have a place of benefit in our armamentarium of drugs to relieve pain.

The principal argument in favor of the use of heroin as an analgesic is that it is more potent and therefore can be administered in smaller doses than most other narcotic analgesics, including morphine. This may be true for early effects in that heroin passes the blood-brain barrier more rapidly than does morphine. However, heroin is then rapidly hydrolyzed to morphine in the body and acts thereafter as morphine does in pain control. 1/ Further research may

---

1/ Jaffe, Jerome H., and William R. Martin. In Goodman and Gilman, The Pharmacological Basis of Therapeutics [6th ed.]. New York, MacMillian, 1980. p. 506-507.

uncover subjective or heretofore unknown benefits that may alter this explanation of heroin's mechanism of action.

The following arguments have been made against a change in Federal law to permit the use of heroin to control pain:

1. On an international level, the United States is party to the 1961 Single Convention on Narcotic Drugs, which restricts the use of opium and its derivatives.
2. The United States is also party to a World Health Organization agreement (WHO Assembly Resolution No. 14) to discontinue the medical use of heroin because of its addiction producing qualities, and because other, less harmful drugs are available for such medical purposes.
3. The action of morphine in larger doses is generally equivalent to that of heroin and in either case dosage must be below that which would produce respiratory arrest.
4. Narcotics control authorities do not want addictive heroin in legal use in the United States as this would require careful surveillance in lockup cabinets in American hospitals.
5. Drugs many times more potent than heroin or morphine are being developed for pain control, the attention being focused on decreased tolerance and on an acceptable level of safety and effectiveness. In 1980, the National Cancer Institute developed a form of freeze-dried morphine that is very soluble and as a result allows high doses to be administered in less than one milliliter (one milliliter equals approximately one-quarter teaspoon).

6. Unlike morphine, heroin is unstable in solution and may have to be mixed daily.

7. In some cases, the better solution to terminal intractable pain is a cordotomy, a procedure performed by a neurosurgeon in which the appropriate pain nerve is severed.

In order to determine the possible value of heroin compared to other powerful analgesics, the U.S. Government has supported controlled studies conducted by the Vincent T. Lombardi Cancer Research Center at Georgetown University in Washington, D.C., and by the Memorial Sloan-Kettering Cancer Center in New York. The Sloan-Kettering study was designed to determine the relative potency of intramuscular heroin and morphine in cancer patients with postoperative pain. 2/ The investigators reported the following conclusions:

(a) heroin was about twice as potent as morphine;

(b) heroin provided an analgesic peak effect earlier than morphine;

(c) doses with equal analgesic effects provided comparable improvements in various elements of mood;

(d) peak mood improvement occurred earlier after heroin;

(e) both analgesic and mood improvement were less sustained after heroin at doses providing equal peak analgesic effects;

(f) sleepiness was the most frequent side effect after both drugs; and

(g) heroin has no unique advantages or disadvantages for the relief of pain in patients with cancer. 3/

2/ Kaiko, Robert F., et al. Analgesic and Mood Effects of Heroin and Morphine in Cancer Patients with Postoperative Pain. The New England Journal of Medicine, v. 304, June 18, 1981. p. 1501-5.

3/ Ibid., (research article abstract).

The Sloan-Kettering study has been criticized because it was carried out with cancer patients who were experiencing pain following surgery. 4/ By comparison, the Georgetown University study was conducted with terminally ill patients with moderate and severe pain. The medical team at Georgetown also found morphine and heroin to be equally effective, but they noted that heroin, having greater potency and solubility, would be very useful in treating patients who have developed a high level of tolerance to other drugs. 5/

From a pharmacological standpoint, it appears that heroin has no analgesic superiority over morphine or even some other powerful narcotics such as hydromorphone (Dilaudid) or methadone (Dolophine, etc.). In addition, the Food and Drug Administration has recently (January 11, 1984) approved a new high potency formulation of hydromorphone named Dilaudid HP. FDA noted in its press release that the drug "will provide pain relief as great as can be obtained with any other narcotic, including heroin, and can be delivered in a very small volume."

The policy question that remains is whether or not heroin should be rescheduled as a controlled substance, and be made available along with other opiate analgesics to treat intractable pain, especially pain so often encountered by patients with terminal illnesses such as cancer. During the 1981 annual meeting of the American Medical Association, the AMA House of Delegates adopted the following resolution:

> Resolved, that the American Medical Association endorsed the principle that the management of pain relief in terminal cancer patients should be a medical decision and should take priority over concerns about drug dependence. 6/

4/ Quattlebaum, Judith H. Letter to the Editor. The Washington Post, July 3, 1981. p. A30.

5/ Personal communication with Dr. William Beaver. Department of Oncology, Georgetown University, July 7, 1981.

6/ Resolution introduced by Dr. Roger J. Smith, Delegate, American Psychiatric Association, and adopted by the American Medical Association, June 9, 1981, during their annual meeting.

Although this resolution avoided mentioning any specific drugs for pain relief, heroin or otherwise, it coincided with various legislative initiatives introduced in the Congress related to the use of heroin for pain. In the 96th and 97th Congresses, Representative Edward Madigan introduced legislation to authorize the use of heroin for terminally ill cancer patients, and a hearing was held by the House Committee on Interstate and Foreign Commerce, Subcommittee on Health and the Environment on September 4, 1980. Similar legislation was introduced by Representative Henry Waxman in the 97th Congress and referred to the House Committee on Energy and Commerce. Although the language of the two bills differed, the intent of each was to amend the appropriate statutes to permit the dispensing of heroin for pain relief only to individuals with terminal cancer. Senator Daniel K. Inouye also introduced a heroin bill in the 97th Congress that would amend the Controlled Substances Act and direct the Secretary of Health and Human Services to establish a temporary heroin program under which confiscated heroin would be made available to pharmacies of qualified hospitals for dispensing to cancer patients for the relief of pain. The bill was referred to the Committee on Labor and Human Resources, and requests for executive comment were sought from the Department of Health and Human Services and the Office on Management and Budget.

Thus far, in the 98th Congress, two bills have been introduced in an effort to make heroin available under limited circumstances. On January 26, 1983, Senator Inouye reintroduced his legislation (S. 209) from the previous Congress. On February 6, 1984, Representative Waxman introduced H.R. 4762 which would direct the Secretary (DHHS) to establish a 60-month program under which heroin would be made available by prescription through qualified pharmacies. Hearings on Representative Waxman's proposal were held on March 8, 1984, by the Committee on Energy and Commerce, Subcommittee on

Health and the Environment. By narrowing the field of potential patients that might require strong pain relief (i.e., those terminally ill with cancer), these legislative efforts would allow limited use of heroin in medical practice, and as a result reduce the opportunities for potential illicit diversion.