James A. Baker III Institute for Public Policy
Rice University

Moving Beyond the "War on Drugs"

The Impact of Government Regulation on The Medical Treatment of Pain

C. Stratton Hill
Professor Emeritus of Medicine, University of Texas
M.D. Anderson Cancer Center

PRESENTED AT THE DRUG POLICY CONFERENCE
RICE UNIVERSITY - APRIL 10-11, 2002

These papers were written by a researcher (or researchers) who participated in a Baker Institute research project. Whenever feasible, these papers are reviewed by outside experts before they are released. However, the research and the views expressed in these papers are those of the individual researcher(s), and do not necessarily represent the views of the James A. Baker III Institute for Public Policy.

Abstract

The thesis of this presentation is that the current therapeutic milieu created by government regulatory bodies and law enforcement agencies for physicians treating chronic pain patients using opioids (narcotics) is threatening, both administratively and criminally, which results in unnecessary pain and suffering and a diminished quality of life for the patient.

The Case for Opioid Use for the Treatment of Pain

The use of opium was recorded at least 3,400 years before the birth of Christ. Though appreciated for its euphoric effects—the Sumerians called it the "joy plant"—its usefulness in relieving pain and improving quality of life has long been recognized. In the fifth century B.C.E., Hippocrates, the "Father of Medicine," acknowledged its usefulness as an analgesic. In the 17th century, Thomas Sydenham (the English Hippocrates) wrote, "Among the remedies which it has pleased Almighty God to give to man to relieve his suffering, none is so universal and efficacious as opium." In 1931, Albert Schweitzer wrote, "We must all die. But that I can save him from days of torture, that is what I feel as my great and ever-new privilege. Pain is a more terrible lord of mankind than even death itself."

Despite the acknowledged usefulness of opioids (the term currently used for purified derivatives of opium), their potential for abuse has led to extensive efforts to control their use, with serious consequences for medical practice. After the acquisition of the Philippines following the Spanish-American War, the United States began a long series of efforts to control certain drugs. The Pure Food and Drug Act was passed in 1906 and required simply that the ingredients of foodstuff and medicine be listed on the label. The Harrison Narcotic Act of 1914 was the first attempt by the United States to control the distribution of opioids (narcotics). Debate on the Senate floor concerning this major step in policy change was prophetic. On August 15, 1914, Senator Atlee Pomerene (D–Ohio) proclaimed,

"We must have a cure for the drug habitué, but we must not forget the innocent sufferer on his or her bed of sickness and pain. Let us protect the country from the physician or druggist who is encouraging the drug habit for purely commercial purposes; but let us not, by too much red tape, hinder the physician in the proper practice of his profession. We can prevent the abuse of the drug without unduly hampering its proper use."

The currently operative Controlled Substance Act of 1970 superseded the Harrison Narcotic Act. Neither of these acts contains any restrictions on the use of opioids for legitimate medical purposes.

Today, states retain the authority to regulate the practice of medicine. Drug regulation is contained in Medical Practice Acts or their equivalent in the various states. In most states, these acts do not specifically recognize that opioids (narcotics) have a legitimate medical use. Reference to narcotics in these acts was always in the context of their potential for abuse and warnings to practitioners not to prescribe them to addicts. Although there is no recognition of a legitimate medical use for opioids in state medical practice acts, there are also no restrictions to their use.

If both federal and state laws and regulations contain no restrictions against the use of opioids for legitimate medical purposes, what is the problem? Let me describe two that I see as particularly significant.

The first of these problems derives from the interpretation of language–specific phrases in statutes in light of the societal and cultural image of opioid use. Phrases commonly found in state statutes and requiring interpretation by government boards and agencies include the following: "legitimate medical purpose," "prescribing for non-therapeutic purpose," "prescribing that is not in the best interest of the public health and welfare," "practicing medicine that is not in the best interest of the public health and welfare," and "prescribing to a known drug abuser or someone the physician should have known was a drug abuser." The ambiguity of these phrases and the subjectivity involved in determining what is "in the best interest" and what a physician "should have known" can

have serious consequences for both patients and physicians. The use of opioids for legitimate medical purposes must "compete" with their image as "drugs of abuse." Their abuse image dominates in society at large, thus stigmatizing patients who must be treated with them variously as "drug abusers," "persons with weak morals or characters," or "addicts." As a result, patients whose quality of life would be enhanced by pain relief with opioids are reluctant to take them, for fear of such characterization and stigmatization by society. In keeping with these widespread attitudes, government boards and agencies generally assume, prima facie, that the relationship between the physician prescribing opioids and the patient requiring them is not based on a valid doctor/patient relationship of trust and honesty. Misinformation and ignorance among physicians, healthcare professionals, and society regarding the effects of opioids on pain patients accounts for misinterpretation of the phrase, "treatment for a legitimate medical purpose," thus allowing the abuse image of opioids to prevail.

A second, closely-related problem stems from equating the societal opioid abuse problem with legitimate medical use of opioids. Allowing opioids to be seen primarily as drugs of abuse rather than as valuable substances for the treatment of legitimate pain deprives millions of patients who suffer daily pain from achieving their deserved quality of life. Further, allowing the image of abuse of opioids to overshadow their legitimate use may result in criminal charges being levied against the prescribing physician for "illegal delivery of a controlled substance." Government agencies attempt to "achieve a balance" between making adequate quantities of opioids available for patients who need them for legitimate medical purposes and preventing their diversion to illegal use. Unfortunately, "balance" typically tilts toward greater concern with drug abusers and away from patients in pain. The incidence of serious consequences of abuse by non-patient, recreational drug users is consistently the subject of hyperbole by law enforcement officials and the media, resulting in efforts to restrict availability of the drugs that can be subjected to abuse. Restricting availability of drugs through legitimate channels by a variety of capricious, administrative edicts has resulted in denying drugs to patients who need them for legitimate medical purposes, while having insignificant effect on the availability of drugs to abusers. Legitimate users of these drugs are therefore "held

hostage" by ineffective government laws and policies directed toward restricting availability to abusers. Physicians and other prescribers of opioids are frequently distrustful and skeptical of drug policy proposals that cite legitimate medical uses for opioids as justification for unrestricted availability. This distrust and skepticism results in inadequate prescribing, despite assurances by authorities that physicians are free to prescribe what they deem to be in the best interest of their patients. Medical Boards often require physicians to assume the role of a law-enforcement official by distrusting their own patients, which intrudes and potentially destroys the relationship of trust and honesty between the doctor and his or her patient. Assuming this law-enforcement role places the physician in the position of "interrogating a suspect" rather than obtaining a traditional medical history from the patient.

Conclusion

Currently, patients who experience chronic pain whose relief requires treatment with opioids continue to demonstrate a severely diminished quality of life, in part because of governmental barriers to appropriate opioid use. Only a prevailing societal distinction between recreational, non-patient opioid abuse and the legitimate medical patient use of opioids, plus a demand for adequate pain treatment, will bring about the desired result: an optimum quality of life for chronic pain sufferers relieved of their pain by opioids.