

Introduction: Legal and Regulatory Issues in Pain Management

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The capacity to treat pain has never been greater; but, as you will read in the articles that follow, the problem of undertreated and neglected pain in the United States persists. Deep-seated perceptions and practices undergird this strong and well-documented pattern of neglect. Among the reasons frequently noted for the inadequacy of treatment for pain, however, is that the legal system actually penalizes effective interventions to relieve pain while it leaves neglect of pain unthreatened. It is the mission of the American Society of Law, Medicine & Ethics (ASLME) to explore areas, such as this one, where developments in medicine directly encounter the law and, in turn, create ethical issues for clinicians, regulators, patients, and lawyers.

This special issue of the *Journal of Law, Medicine & Ethics* is part of a multi-year project in which ASLME, with the wonderful support of the Mayday Fund, has worked to address legal and regulatory barriers to effective pain relief. The focus of the project, in line with ASLME's mission, has been on the impact of the legal system rather than on other factors such as professional training, institutional organization, or social constructs.

The first ASLME project on pain management, funded by the Mayday Fund and the Emily Davie and Joseph S. Kornfeld Foundation in 1995, was both a research and an educational project. In 1996, the project produced an interdisciplinary National Meeting on Legal, Ethical, and Institutional Issues in Pain Relief and a special issue of the *Journal of Law, Medicine & Ethics* that reported the research of the project itself, including a model Pain Relief Act and other influential articles. Completed in 1997, the first Mayday project at ASLME revealed other areas in which

legal constraints or fears of legal sanctions may negatively affect practice in pain management. The project also brought to light the need for development of experts who could participate in public policy and educational efforts relating to the law and pain management.

In 1997, the Mayday Fund provided a substantial grant to ASLME for the Mayday Scholars Program. Building on what was accomplished in the original project, the Mayday Scholars Program had two goals: (1) to support efforts to disseminate the results of the first project through training programs for lawyers and others and through consultation with policy-makers, professional associations, and individual professionals; and (2) to fund researchers who would contribute importantly to new scholarship on legal and regulatory issues. The program expanded the scope of the original effort to include payment issues as well.

The Mayday Fund's commitment to dissemination of the results of the first project has had significant impact. Educational sessions were provided to many key groups, including state and federal judges and state medical board investigators and executive directors, among others. One of the most significant consultation efforts was the work done with the Federation of State Medical Boards (FSMB). FSMB recently issued Model Guidelines on the use of opioids in pain management. These guidelines clearly recognize the legitimacy of the use of opioids in the management of chronic pain, reject quantity and chronicity of medication as proof of inappropriateness, and identify outcomes in terms of relief and function as the major indicators of a successful treatment regimen.

The Mayday Scholars Program also stimulated significant research in unaddressed areas. This special issue of the *Journal of Law, Medicine & Ethics* publishes the work of some of the Mayday Scholars.

Payment systems may control access to any health care

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services, including access to effective pain management. The first two articles in this issue present the results of the first in-depth research efforts to examine current policies in payment for pain relief. In the first, Diane Hoffmann analyzes the practices and policies of Blue Cross Blue Shield Plans in relation to payment for pain management services. In the second, Timothy Jost examines the policies of the Medicare and Medicaid programs.

Pain relief has become a central issue in quality care for the dying and in the debate over assisted suicide. Although there have been substantial efforts to assure that dying patients receive adequate pain relief, there is a perception that providing pain medication at the end of life may present a risk of prosecution. In her paper, Ann Alpers examines criminal investigations and prosecutions of physicians and nurses in relation to pain treatment for patients at the end of life.

The Mayday Fund projects at ASLME began with an examination of the standards used in disciplinary actions against physicians for the use of controlled substances in pain management. Although the ASLME project emphasized reducing the threat of disciplinary action against physicians who appropriately treat pain, some have called for

state medical boards to discipline physicians who undertreat. Ann Martino's paper examines the issues that arise should a state medical board take the step of viewing neglect or undertreatment of pain as cause for disciplinary action. David Haddox and Gerald Aronoff's response to that proposal raises further issues.

ASLME is grateful to the board of directors of the Mayday Fund for its long-term support of the Mayday project and the Mayday Scholars Program. We appreciate its commitment to improving the treatment of patients in pain. We have also benefited greatly from the special support of Fenella Rouse, executive director of the Mayday Fund, for her guidance, wisdom, and encouragement throughout. For myself, it has been one of the most satisfying professional experiences to serve as co-principal investigator with Nancy Dubler and Robert Levine for the first Mayday project at ASLME and then as principal investigator of the Mayday Scholars Program. The Mayday Fund has my great gratitude for its support and for its call to make a difference; and the leadership and staff of the ASLME, in particular Benjamin Moulton and Michael Vasko, for their commitment to working in that uncomfortable borderland among the disciplines.