The War on Drugs v. the War on Pain: Do Controlled Prescribing Laws Have a Role?

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THE WAR ON DRUGS V. THE WAR ON PAIN:
DO CONTROLLED PRESCRIBING LAWS
HAVE A ROLE?

by

Susanne F. Homant

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THE WAR ON DRUGS V. THE WAR ON PAIN: DO CONTROLLED PRESCRIBING LAWS HAVE A ROLE?

Susanne F. Homant, D.P.A.
Western Michigan University, 2006

The illegal use of prescription drugs and the under-treatment of chronic pain are both considered serious public health issues in this country. Strong medicines classified as controlled substances by the DEA are often used to treat chronic pain conditions and are also known to be diverted to non-medical uses, thus a solution to one problem may happen at the expense of the other. Prescription Monitoring Programs (PMPs) are public policies that are felt by many to address diversion of controlled substances, and are generally welcomed by law enforcement as an excellent tool in the war against drugs. A number of pain management advocates, however, claim that the oversight included in PMPs discourages the prescribing of controlled substances by physicians and thus reduces the quality of pain management.

This study reviewed the effect of PMPs on drug diversion—as a subcategory of drug abuse—using a multiple regression analysis. Fifteen states were included in the regression statistics, seven of which had PMPs in place and eight states that operate without a PMP. The regression did not show a relationship between a change in the amount of drug diversion and the presence of a PMP.
The research also included a case study consisting of 30 in-depth interviews of physicians, pharmacists, and law enforcement officers, 15 in Michigan and 15 in Florida. The interviews provided professional opinions on what affects pain management and drug diversion, and the impact of PMPs on both issues. The case study generally supported the conclusion of the regression in relation to the effect of a PMP on drug diversion. It also provided additional insights into the best means of addressing a reduction in drug diversion and improvements in pain management. Education of clinicians and the general public was deemed critical by nearly every interview subject, as was attention to better and more accessible treatment for addictions. Physicians and pharmacists indicated they would welcome a prescription database as a patient-care tool if it were not accessible to law enforcement. All subjects seemed resigned to the presence of drug abuse in our society, regardless of the nature of public policy.
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The journey from my decision to pursue a doctoral level degree to the completion of this paper took slightly over eight years. Those years included working full time at intense and time-consuming positions in healthcare policy arenas. It also included the pleasure of working with several different professors and staff at Western Michigan University. This learning experience has been the best of my life: my professors and fellow students helped me to fully understand the value of questioning everything, to seek the truth, and to be able to deliver information in a clear, fact-filled, and unprejudiced manner. I will be forever grateful for this long and rewarding journey, and to those who helped me along the way.

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Acknowledgments—Continued

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Susanne F. Homant
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CHAPTER I

INTRODUCTION

Overview

The national concern over abuse of drugs and the consequences to individuals and to society as a whole have long been a public issue and a public health issue. The potential consequences of drug abuse range from a person’s inability to function normally with subsequent effects on personal, work, and family relationships, to criminal activity that may include harm to others and self. People who continuously abuse potent drugs, legal or illegal, will almost surely meet an early death, either from drug-related medical problems or suicide. Illegal use of drugs takes many forms, one of which is the diversion of legal prescription drugs to recreational use or use that is otherwise significantly against medical advice or the intended prescribed purpose of the medication. This research addresses public policy intended to help reduce illegal drug use, and it focuses on the diversion of drugs that are classified as legal drugs in the controlled substances schedules of the federal Controlled Substances Act. These schedules include highly potent medications such as opioids and benzodiazepines.

The treatment of chronic pain conditions nearly always includes the prescribing of drugs within the controlled substances schedules. Like drug abuse, chronic pain is also considered by many to be a significant public health issue, with the under-treatment of pain a factor in significant individual dysfunction. This includes
consequences to the individual and family health, as well as drug-seeking behavior for many if the condition is not managed. Drug-seeking behavior can include pursuit of illegal drugs as well as prescription drugs and excessive use of over-the-counter drugs such as alcohol. From the perspective of the diversion of controlled substances which is the subject of this research, a logical tension exists between controlling diversion and assuring access to the right pain medications. For decades, such concerns have resulted in the implementation of public policies that hope to address the diversion of legal drugs, while maintaining access to treatment for chronic pain conditions. One such type of policy and the focus of this study is a prescription monitoring program, or PMP. Those seeking more diversion control have encouraged the implementation of PMPs on a national basis. According to the Alliance of States with Prescription Monitoring Programs' goals statement, PMPs are a very important tool in containing diversion.

Diversion of controlled substances and other pharmaceuticals is generally recognized as a serious problem throughout the United States. . . States have found that prescription monitoring programs are among the most effective tools available to identify and prevent drug diversion at the prescriber, pharmacy and patient levels. (Alliance of States with Prescription Monitoring Programs, n.d.)

Those concerned over access to good pain management often feel such policies create treatment barriers for physicians. Sandra Johnson. J.D., LL.M. of the Saint Louis University School of Law and an active researcher on this topic stated:

In pain management, both real and perceived obstacles can have a powerful negative effect. If physicians and health care institutions believe, even wrongly, that they cannot do what needs to be done for their patients—for example because the providers believe that they will be at risk for discipline or
prosecution or because payment will be denied—it seriously decreases the likelihood that patients will receive the care they need. (Johnson, 2003, p. 15)

Because a tension exists between the desire to control diversion while allowing full medical access to drugs that are often diverted, this study was developed to look at whether PMPs are an effective tool in the goal of decreasing diversion while not limiting the quality of pain management. Such policies are now in place in 22 states with a national movement to encourage more states to enact such policies.

This research compares regulatory policies, specifically controlled substance prescribing laws or PMPs in 15 selected states to determine the effect those laws, or the absence of such laws, have on decreasing diversion. During the time frame of this study, 7 of the states in the study operated under state-authorized controlled substance prescribing restrictions, and 8 states did not. In addition to a quantitative analysis using the 15-state sample, this research also includes a qualitative study. That case study looks at the effect that laws such as PMPs may have on good pain management practices in two selected states: Michigan (which had controlled prescribing laws during the time period of the study) and Florida (which did not have such laws during the study period). The qualitative research was developed to determine if a balance between diversion control and pain management is possible, or if the success of one effort may only come at the expense of the other.

No specific study of the effectiveness of PMPs in states operating under different controlled prescribing laws was found in an extensive literature search incorporating journal articles and research reports, websites, books, and a variety of media and other research resources over the past three years. Examples include Drug
Enforcement Administration (DEA) reports and website, SAMHSA publications, OIG reports, the *Journal of Law, Medicine, and Ethics*, several pain and other medical journals, the Hospice News Network, University of Wisconsin Pain Policy website and reports, the National Association of State Controlled Substance Authorities, Google and other public search engines, the American Association of Cancer Pain Initiatives, the National Institutes of Health, and medlineplus, among others.

Based on this search, it was thus assumed that no such study exists. However, the results of such a study are likely to have significant impact on the identification of effective means of controlling diversion while assuring that patient care is not compromised in the process. Controlled prescribing laws may indeed be the best way to manage diversion of controlled drugs. However, if such laws are not the answer but are adopted by states, the perceived effectiveness of such laws has the potential to create a barrier to the identification of other, better solutions to the reduction of diversion activity while assuring the availability of drugs for medically recognized purposes. Stated differently, government and the public may want to so strongly believe that controlled prescribing laws are effective, that they may decrease efforts to find a better means of addressing the drug diversion problem.

The following three stories illustrate some of the real and ongoing issues that affect the public in relation to control of illegal use of legal drugs and the management of chronic and terminal pain conditions. They are presented as real-life examples of the dilemma that exists as government attempts to address the many problems
surrounding the illegal use of legal drugs, and a desire to remove barriers to
appropriate pain management for those who suffer from chronic, terminal or other
pain conditions.

Mattie Howard, a 54-year-old high school teacher, was diagnosed with
breast cancer. After surgery, she remained in remission for a year and a half
before the cancer reappeared in bone metastases. The disease and medical
treatments caused a great deal of pain, nausea, and fatigue. Her doctor
prescribed pain medications, but they did little to help her pain and nothing
for her other symptoms. Fearful of being accused of over prescribing
narcotics, he refused to provide more medications. Finding her situation
unbearable, Ms. Howard began to beg her daughter for help in taking her
own life. (Merritt et al., 1998, p. 9)

********

In remission from Ewings Sarcoma cancer, Solomon’s 6-year-old son Nathan
started feeling pain in his legs and tailbone in the spring of 2001. Doctors
took an X-ray of Nathan’s lower body and pronounced him fine. The pain
worsened.

In April, mother and son, who live in the Southern California city of
Fontana, returned to the doctor, who had just received the results of
Nathan’s yearly blood tests. They boy had been throwing up all night. The
doctor walked into the sterile office where Solomon and Nathan were waiting.
“He said, ‘Well, the cancer is back, and it doesn’t look good,’ then he
walked out,” Martha Solomon recalled. “It was just like, ‘Boom.’”
The cancer had spread all over Nathan’s body. He died three weeks
later.
“We were robbed of precious time because (the doctors) didn’t take
(Nathan’s pain) seriously,” Solomon said, believing her son might have lived
a few months longer if the doctors had caught the cancer recurrence earlier.
But it gets worse. The night of Nathan’s death . . . Nathan was in extreme
pain.
“My son, he was just—his teeth were just clenched together and there
was nothing I could do,” his mother said crying softly at the memory. “I had
no more medicine to give him. And he was like, ‘More pain medicine,
please.’ He was just so dang polite.”
The nurse would not administer more pain medicine because doctors
said it would slow Nathan’s breathing.
“The look on his face when he died, he looked like he was in agony—
absolute, complete agony—and that is something I can never forget,”
Solomon said. “I could live with myself so much easier if he had died
(without pain). It is gut-wrenching to have to imagine . . . It's been a year-and-a-half, and it's like it just happened.” (Harlick, 2002, p. 2)

In a steel-mill suburb northwest of Pittsburgh, the leader of the second wave of OxyContin apostles was Curt, a young man, who in 1998 at the age of 23, found himself kicked out of the Air Force and living back in his hometown. He worked the midnight shift running cranes at the mill, and he dealt a little marijuana during the day. He was part of a “drug community” as he calls it, 20 or so people who worked together, hung out together, went to parties and concerts and smoked a lot of pot. Every couple of months someone would land a prescription for Percocet or Vicodin, and they’d sell the pills to friends for $5 apiece, a cheap and mild high.

In April 1999, someone in his circle was prescribed OxyContin. Curt assumed that it was just like any other pain pill. “Everyone thought at first that they were like a Percocet,” Curt says. “Nobody understood how many milligrams were really in these things. People were selling them like an expensive Percocet”—for $10, in other words, instead of $5—and swallowing them whole. At a party, Curt figured out the trick of crushing the pill and snorting the powder, and he quickly spread the word. “I showed a lot of people,” Curt says. “At first they were like, 'You're crazy.' But then they'd do it, and that would be it. People tell me now, 'Yeah you're the one who showed me how to snort this thing.'”

. . . Oxsy quickly became very popular in Curt’s circle of friends, and Curt found a comfortable niche for himself between supply and demand.

. . . Before long he had 10 people giving him their pills to sell, mostly women in their 30’s and 40’s on welfare or disability. (Patients on Medicaid pay just a dollar for a $250 OxyContin prescription.)

. . . One of the most valuable—and closely guarded—resources in the local OxyContin economy was a doctor who was willing to write an OxyContin prescription without asking too many questions. “It’s a slow process, breaking a doctor in,” Curt explains. “You’ve got to know how to work him. I’d say, ‘I can’t take the Vicodins and the Percocets because they’re hurting my stomach. Do you have anything that’s, like, time released?’ The doctor goes, ‘Oh, you know what, they’ve got this new stuff called OxyContin.’ And I’d say, ‘Oh, yeah? Wow, how’s that work?’” Some local doctors, Curt says, knew exactly what was going on, but they needed the business. One started handing out month-long OxyContin prescriptions every two weeks. (Tough, 2001, pp. 33-37, 52, 62-63)

These are three of many such stories which help to illustrate how the public is significantly affected by policy and law enforcement decisions that aim to strike a
balance between pain management and the control of legal drugs diverted for illegal use. Drugs that are appropriate and most effective for the treatment of severe pain are also addictive for some. Furthermore, they are sometimes used for recreational drug purposes, an activity which has a significant effect on individual lives and communities. In a comprehensive study on state pain policies, Jorenson and colleagues of the University of Wisconsin Pain and Policy Studies Group found that identifying the right balance between diversion control and the ability of medical professionals to treat severe pain conditions remains a dilemma throughout the country (Jorenson, Gilson, Ryan, et al., 2003).

Statement of the Problem

The management of pain, and indeed the under-treatment of pain, is a major public health problem in the United States, as is drug diversion. Researchers at the Center for Work and Health at AdvancePCS in Hunt Valley, Maryland concluded that pain is the most widespread health condition affecting the U.S workforce, and most costly in terms of productive work time. (Stewart, Ricci, Chee, Morganstein, & Lipton, 2003.) Dr. Kathleen Foley (Eisner, 2000, p. 1), a nationally recognized neurologist at the Memorial Sloan-Kettering Cancer Center in New York, stated, “Every bit of data we have says that pain is under-assessed and undertreated [sic].” Others, like Foley, who advocate for better pain control, universally agree that pain management in this country is in need of a fix. At the same time there is agreement
that sufficient medical knowledge exists to relieve pain in the vast majority of patients, through drug therapies and other treatments.

As the movement to improve pain management continues its journey, an equally strong movement exists to address the dangers of abuse of drugs, both prescription drugs and illegal drugs, and the cost that brings to society. Drugs such as oxycodone and other controlled substances produce a powerful high, a euphoric effect that can and does lead to abuse and addiction when used inappropriately. Regulators such as the DEA and state drug enforcement officials recognize the potential for diversion of drugs for recreational purposes, and in fact have watched the use of such drugs for non-pain purposes grow at what some refer to as an alarming rate in this country. Such abuse causes immense suffering—loss of productive lives, broken families, poverty, and criminal behavior. This occurs when drugs are diverted from their intended use, or when prescriptions are illegally obtained, forged, or written for non-medical purposes by those with prescribing authority—generally physicians. The age group most affected is young people—from preteen to age 30. A highly visible example occurred in 2002, when Noell Bush, daughter of Florida’s Governor Jeb Bush, was arrested and convicted of forging a prescription for Xanax, an anti-anxiety drug from Controlled Substance Schedule IV. In addition, radio personality Rush Limbaugh has made national news for his addiction to controlled substances, including oxycodone—an opioid in Schedule II.

The existence and easy availability of strong pain-relieving medicines has thus become a blessing and a curse, with several states responding with the enactment of
laws that closely monitor certain prescription drugs, beyond the monitoring required by the federal government. These programs, often referred to as PMPs (Prescription Monitoring Programs) are touted by their supporters as an effective means of addressing diversion of controlled substances, and as a useful tool for prosecuting criminals who engage in such illegal activities. Pain management advocates, on the other hand, claim that such programs are costly, do not result in a significant reduction of diversion activity, and harm the public by exerting a negative or “chilling” influence on the proper prescribing of effective pain medications. This creates physician fears of overly aggressive oversight and investigation, which can lead them to under-prescribe pain medicines or substitute a less potent drug. Such activity, they claim, perpetuates the mismanagement of pain and makes it difficult for citizens in those states to receive proper treatment.

Significance of the Problem

Prescription monitoring programs are a response to the public pressure on government to address the problem of drug abuse in this country. Within the law enforcement community, many feel that such programs are extremely effective in deterring diversion activity as well as illegal drug trafficking, and that they provide a valuable tool for the investigation of such activity when it is suspected. Advocates of pain management claim that such programs are not significantly effective in addressing diversion, that diversion is not the primary cause of drug abuse, and that such laws produce the mentioned chilling effect on the proper prescribing of pain
medications which leads to significant under-treatment of pain. Since pain is the primary reason that most people seek medical help, any activity that is suspected of generating barriers to pain relief is a major concern to the medical community. People in severe pain are incapable of leading normal lives, with the pain taking over every activity and the search for relief becoming the primary focus. The negative effects on quality of life and productivity as a member of one’s community are readily apparent.

Both drug diversion and inadequate pain management reputedly cost billions of dollars annually. The costs of drug diversion include not only the regulatory and investigative activities which address diversion, but also the funds which are spent to purchase legal drugs for illegal use. There is also a tremendous cost to society of the dysfunctional and often dangerous activity that occurs with the illegal use of drugs. Similarly, inadequate pain management causes approximately $85–$90 billion in lost productivity in the U.S. Billions of dollars are used to purchase medications and therapies to address the pain, and about 50 million people are partially to totally disabled due to chronic pain—another great cost to society (EPIC MRA, 1997). Pain is the single most common reason for seeking treatment in hospital emergency departments, and patients whose pain is not resolved are frequent utilizers of emergency department services. (Todd, 2006) The problems are significant in terms of dollars and the people affected, and they are far-reaching, touching lives everywhere.

Thus, when studying policies such as PMPs, it is important to determine the effect on diversion and on access to medical help for pain relief. For public health
reasons, it is necessary to work towards finding the right solution to both problems. If public policy is created without some certainty that the policy will be successful in addressing the problem, there are two tremendous risks. One is that the policy will require administrative resources and tax dollars that will be wasted. The other, more significant risk is that ineffective policy will likely convince citizens that a problem has been solved, and government will thus cease to work on the real causes of drug abuse.

Research and commentary has been conducted by groups on both sides of the drug diversion/pain management debate. As a general statement, those in favor of a strong state regulatory approach to reducing drug diversion concentrate their studies and reports on how laws and regulations lead to identification, arrests, and successful prosecution of those who divert drugs to illegal use. Those in favor of allowing the system to be freer of regulatory restrictions on prescribing generally study and present results that showcase the extent of under-treated or untreated pain, and how these undesirable results may be caused by prescribing laws. This group often contends that PMPs are not satisfying their diversion control intent and instead may create a significant barrier to good pain management.

Current research does not take a look at the state of drug diversion activity in a group of states operating with and without PMPs, so this study will take a more comprehensive and comparison approach to the diversion issue. As Fishman, Papazian, et al. (2004) stated, “Very few PMPs have been adequately evaluated to determine their impact on the availability of controlled substances for legitimate
Recommendations as a result of this research may help to guide the development and refinement of future related public policy.

Background

The federal law at the foundation of drug oversight is the Controlled Substances Act of 1970 (CSA), which established schedules of drugs ranked from Schedule I (illegal drugs) to Schedule V, classified based on the drugs' addictive, abusive, and dependence properties. The CSA gives the DEA Office of Drug Control the authority to regulate the sale and distribution of these controlled substances at the manufacture and wholesale levels. The Government Accountability Office (GAO) summarizes the controlled substances as follows.

Schedule I drugs—including heroin, marijuana, and hallucinogens such as LSD and PCP—have a high potential for abuse and no currently accepted medical use. Schedule II drugs—including methylphenidate (Ritalin) and opiates such as hydrocodone, morphine, and oxycodone—have a high potential for abuse and may lead to severe physical dependence, but have a currently accepted medical use. Drugs on Schedules III through V have medical uses and successively lower potentials for abuse and dependence. Schedule III drugs include anabolic steroids, codeine hydrocodone in combination with aspirin or acetaminophen, and some barbiturates. Schedule IV contains such drugs as the anti-anxiety medications diazepam (Valium) and alprazolam (Xanax). Schedule V includes preparations such as cough syrups with codeine. All drugs but those in Schedule I are legally available to the public with a prescription. (U.S. General Accounting Office [USGAO], 2002, p. 5.) [Editor's note: OxyContin is a sustained-release, manufactured form of oxycodone.]

The CSA also regulates the distribution of controlled substances. All physicians who prescribe controlled substances are required to register with the DEA.
and have a registration number assigned. All pharmacies are also required to register and maintain accurate records of controlled substances that are handled by them, and to secure the storage of controlled substances.

In addition to the federal legal controls on the manufacture and wholesaling of controlled substances and as already noted, 16 states had enacted prescription drug monitoring programs during the time period of this study, with the objective of addressing the issue of diversion through regulation of the practice of medicine and pharmacy. The various state PMPs differ in scope, design, and objectives, and are generally put in place to help state officials (and the DEA) identify diversion activities. During the time period of the study, there were 34 states that operated without drug monitoring programs. No study has been done to compare the diversion activity between states with PMPs to states without PMPs with the specific objective of determining if PMPs are effective in decreasing diversion. Conclusions such as those reported in a May 2002 GAO study indicate that states with PMPs experience a reduction in time in investigating possible drug diversion cases, but do not boldly state that such programs are the reason for any decreases in drug diversion (USGAO, 2002, p. 15.) In fact, the study suggests that PMPs may just drive drug diversion across state borders. Or, such laws may move the diversion activity to another classification of drugs, such as from Schedule II drugs like OxyContin, to Schedule III drugs like Vicodin and Lortab, which are not monitored in many states.

Drug abuse statistics are gathered by several sources, one of which is the Drug Abuse Warning Network (DAWN) which monitors the incidence of drug abuse.
through reports of such abuse in emergency department visits. DAWN is operated under the Office of Applied Studies, Substance Abuse and Mental Health Services Administration (SAMHSA). The October 2002 issue of the DAWN Report (last year of this research) stated that the most frequently reported drug of abuse was cocaine, followed by marijuana and heroin (Ball & Kissin, 2002, p. 3). Methamphetamine, a Schedule II stimulant, was a very distant fourth. Prescription opioids such as OxyContin did not make the list of the top four. The 2003 DAWN Report produced similar results. According to the statistics gathered by DAWN, the critical drug abuse problem is one of use of illegal drugs, not of diversion of legally available and legally prescribed drugs.

The seven states in this study that have operating PMPs had additional information on the results of their monitoring programs, with the depth of such resources varying from state to state. Most of the seven selected states have had PMPs in place for several years, California as early as 1940. However, all states in the study have made changes in the 1990s in their prescription monitoring programs, generally towards creating electronic tracking systems.

Ultimately, any PMP should also be considered in the context of its effectiveness against drug abuse in a comprehensive sense, not as patchwork for a piece of the problem. This argument is often raised by pain management advocates who claim that PMPs can cloud the real issue of drug abuse while creating barriers to pain management.
Since this research also includes a qualitative research section comparing drug diversion and pain management in two states, one without a PMP (Florida) and the other with a PMP (Michigan), background on these two states is provided here.

Michigan, pressured by its citizens when the war on drugs was at its peak in the 1980s, enacted its Official Prescription Program (OPP) in 1989, with strong leadership and sponsorship in both the Michigan House and Senate. The original OPP tracked Schedule II drugs, requiring all physicians who prescribed such drugs to obtain a special prescription pad, and to write all such prescriptions in triplicate. It thus created an extra administrative burden for both physicians and pharmacists. The OPP changed to a single prescription form in 1993 due to a wave of complaints from physicians, and eliminated methylphenidate (Ritalin) from the reporting requirements. Many physicians were not receptive to the extra reporting and expressed their concerns by refusing to register for and obtain the special pads, thus eliminating their ability to prescribe opioids for pain. This raised concerns and created problems for those in need of strong pain medication to such an extent that the Governor appointed two groups to study the issues. It is important to note that Michigan’s PMP cost the state approximately $750,000 annually to maintain, and was never a primary factor in any convictions for diversion.

As a result of the recommendations of one of the groups, the Michigan Commission on End of Life Care (Thomason, 2001), the OPP was eliminated and replaced with an electronic monitoring system or PMP in 2003. The new program was welcomed by the medical community. At the same time it was recognized that
much physician education would be necessary to equip the many physicians who originally elected out of the OPP with the expertise to once again use Schedule II drugs and become effective in developing good pain management care plans for their patients.

Florida does not currently have a PMP, but has been reviewing the need for such a program for at least the past two years. In 2002, Senator Burt Locke, then a candidate for Florida’s Attorney General, introduced a bill designed to reduce the diversion of legal drugs, but that bill failed to pass during the 2002 session. Early promotion of a pending bill for 2003 occurred at a Statewide Summit on Prescription Drug Abuse in Tallahassee, Florida, January 22, 2003. The Summit was hosted by Governor Jeb Bush and his wife Columba, and included Senate sponsor Mike Fasano, House sponsor Gayle Harrell, Attorney General Charlie Crist, Office of Drug Control Director Jim McDonough, Commissioner Moore of the Florida Department of Law Enforcement and Secretary of Health John Agwunobi, among others. A bill was subsequently introduced, but died on the calendar. In 2004, House and Senate bills nearly identical to the 2003 bill were introduced, but again the proposed law did not pass. Senator Burt Saunders has introduced a similar bill to be considered by the 2006 legislature.

The Research Questions

The goal of this research was to determine, through comparison of the presence or absence of prescription monitoring policies in 15 states, whether PMPs
are likely to reduce diversion of Scheduled drugs. If drug diversion is lower in states with PMPs, is the reduction a result of the regulatory climate, specifically laws such as PMPs, or might other factors influence the level of diversion? If PMPs are effective in reducing diversion, does the amount of reduction justify the cost of the programs in dollars? In addition, this research attempted to determine if there is a difference in the effective treatment of pain between Michigan, with its PMP, and Florida, which currently does not have a PMP. This part of the research is important because it addresses one perceived “human” cost of PMPs—the tendency of such laws to raise concerns within the medical community about potential DEA investigations and thus serve to discourage the prescribing of strong pain medications. This hesitancy to prescribe those drugs classified as controlled substances has been called the “chilling effect” of PMPs in many studies and commentaries about such laws. Is it an acceptable compromise to have less effective pain management, if such a result produces a reduction in illegal use of legal drugs? The study of the effect that PMPs have on addressing drug diversion in the 15 states and of the responses from medical professionals in the two states in the qualitative portion of the research produced recommendations that will assist other states in determining whether to adopt a PMP, or to modify or eliminate an existing PMP and seek other means of addressing the drug abuse and diversion problem in their states.

This research thus addresses the following questions:

1. Do state controlled substance laws (PMPs) help to contain drug diversion activities of Scheduled drugs, particularly Schedule II drugs? In particular, did the
existence of such laws in seven states significantly reduce such diversion as compared
to eight other states, which do not have such laws in place?

2. Do PMPs and the regulatory climate limit access to good pain
management? Is access to pain management greater in Florida than Michigan? Did
Michigan’s PMP pose a significant barrier to adequate pain management?

In the report that follows, Chapter II contains the literature review that was
conducted for the study. Seminal studies on drug abuse, drug diversion, prescription
monitoring programs and related pain management issues are presented in that
section. Chapter III describes the methodology used to conduct the research. A
description of the quantitative study and the search for variables is included in this
chapter. A description of the qualitative methodology is also included. Chapter IV
contains details on the development of the multiple regression used to determine if
there is a statistically significant difference in drug diversion between states with and
without PMPs. The results of the multiple regression are presented in Chapter IV.

Chapter V reports the results of the case study between Michigan and Florida.
The concluding pages of that chapter contain two summary tables of key findings.
Chapter VI contains the conclusions and recommendations of the research. There are
seven conclusions, four recommendations, and three suggestions for further research.
CHAPTER II

LITERATURE REVIEW

This chapter discusses a number of studies, reports, and other documents related to the three primary subject areas of this dissertation. Analysis and commentary are grouped into the categories of pain management, Prescription Monitoring Programs, and drug diversion. The background provided by the literature review helps to identify the primary issues under consideration in this study, along with problems and concerns with the current state of analysis of the effectiveness of PMPs in the control and prevention of drug diversion.

The literature on all three of the subject areas is extensive, which supports the statement that pain management, drug diversion, and the larger arena of drug abuse are important topics to the medical and policy-making communities, as well as of high interest to the general public. In the review of studies and commentaries in the areas that follow, it is noteworthy that individual stories of problems and concerns were far more prevalent than actual, statistically significant studies of the referenced issues. It is not uncommon to find articles that reach conclusions, even in highly respected journals, that use a few isolated incidences in the analysis, without alluding to the need for further study. One of the difficulties is the inability to quantify drug diversion as an activity separate from drug abuse.
Pain Management

The National Institutes of Health report that pain is the most common reason for medical appointments in the United States. Visits to medical professionals for the treatment of pain exceed 40 million annually (Partners Against Pain, 2003, p. 3). Other sources state that pain is the second most common issue brought to the physician’s office (Dean, 2004, p. 1). Regardless of pain’s number one or number two position, the treatment of pain and the provision of quality pain management clearly deserve serious attention. Pain is well studied and researched, with one report indicating that over 105,000 articles had been categorized with the keyword “pain” in the years 1990-1999, an increase of 175% over the previous decade, and 350% more than the decade before that (Fishman, Gallagher, et al., 2004, p. 282).

Pain and its intensity is very individual, with subjective differences in the severity of pain generally related to each person’s tolerance plus other physical and psychosocial issues affecting their well being. According to the Oxford Dictionary, pain is “an unpleasant feeling caused by injury or disease of the body.” Webster’s adds that pain is caused by the stimulation of nerves. McCaffrey, in his pain manual stated that pain is subjective; it is “whatever the experiencing person says it is, existing whenever he/she says it does” (McCaffrey & Pasero, 1999, p. 4; Maroney, Litke, Fischberg, Moore, & Morrison, 2004, p. 448). Pain is generally described as either “acute,” lasting for a relatively short period of time, and relieved when the underlying pathology is resolved or chronic, extending for a longer period, generally worsening.
with time, more difficult to diagnose and treat, and having a more lasting effect on a patient’s life.

Regardless, for those people who live with a pain condition on a daily basis, especially one that is severe, it is more than an unpleasant feeling. Instead it is something urgently in need of hopefully permanent relief, and of quick and accessible relief. For the millions of people who suffer from a severe or persistent pain problem, good pain management is essential for well being and a decent quality of life. Because this issue has been with us since life began and is likely the oldest medical problem, the treatment and management of pain has a lengthy history.

Early physicians did their best to relieve pain, making use of opium and opium mixtures such as laudanum, which combined opium with sherry. But pain was not viewed as "bad" for everyone, and for a time was viewed as a sign of life force. At one time there was debate over whether pain relief might slow the healing process (Meldrum, 2003, p. 2470). Medical discussions and approaches to pain evolved in three general areas: relief of acute pain; palliation of severe pain for those patients in a terminal condition; and treatment of chronic, intractable pain, all of which incorporated the use of strong medicines in the plan of treatment. In the United States, the ability to deliver morphine to soldiers who were injured or suffering was considered a very desirable option, and dates back at least to the Civil War. Opiates became the standard of treatment for pain, with production of morphine beginning in Europe and spreading to the U.S. in the 19th and 20th centuries. In 1898, The Bayer Company of Germany began to market a derivative of morphine under the trade name
of Heroin as a cough medicine (Meldrum, 2003, p. 2471). At one time, morphine, heroin, and other such pain medicines could be obtained over the counter and even ordered from the Sears, Roebuck Catalog (Henningfield, 2004, p. 4). However, by the early 1900s, the potential for addiction to such medications began to frighten the public as well as concern the medical community, and physicians often withheld treatment because of fears of addiction. The U.S. Government started to pass laws to control the availability of such medicines in the early 1900s, culminating nationally with the passage of the Controlled Substances Act in 1970. This Act placed strong drugs in one of five categories or schedules, depending on their potency and risk of producing psychological or physical dependence.

Medical schools originally taught the “specificity theory,” that true pain was a result of a direct response to a specific stimulant. It took a while for psychological factors to be considered as part of the pain condition. Patients suffering with unexplained pain, or pain that could not be resolved were often considered as “maligners” or drug abusers. It was not until the mid to late 20th century that pain began to be considered the result of sensory, affective, and cognitive components (Dean, 2004, pp. 2-3). However, to this day many physicians have continued to be conflicted between the need for relief of pain and the concern over abuse of and addiction to pain medicines, especially with the treatment of chronic pain, and with the possible exception of acceptable use when patients were close to death.

Pain management gradually has come to be understood, but not necessarily handled, as a multi-disciplinary system of treatment, through the persistent and often
ignored work of several noted physicians in the 20th century. The difficulty in relieving pain conditions, especially chronic pain, continues to plague the medical profession. Concerns over addiction, the public outcry over drug abuse, and the sheer complexity of treating someone with a persistent and severe pain condition have often resulted in poor pain management, with significant personal and public consequences.

Current State of Pain Management

In reviewing the literature on the state of pain management, it is common to see statements such as, “Inadequate pain relief continues to be a serious public health problem in the U.S.” (Pain & Policy Studies Group [PPSG], 2003a, p. 1). In an FAQ document jointly supported by the Pain and Policy Studies Group, University of Wisconsin, the Drug Enforcement Administration (DEA) and Last Acts Partnership (Good et al., 2004), the organizations together agreed that “Uncontrolled pain is an enormous public health problem in the United States.” The DEA support of this document was subsequently withdrawn.

David Jorenson, Director of the Pain and Policy Studies Group and internationally-recognized expert on policy issues related to pain testifies and writes frequently about the seriousness of under-treated pain and its effect on the public good (Jorenson & Dahl, 1989; Joranson & Gilson, 1994, 1998; Joranson, Carrow, et al., 2002; Joranson, Gilson, Dahl, & Haddox, 2002; Joranson, Gilson, et al., 2003). Joan Teno, M.D., practitioner, professor, and health care researcher states that pain under-treatment is “a strikingly large problem,” and upon learning that a large number
of cancer patients receive inadequate treatment stated, "A person with cancer pain should receive treatment. I find this outrageous, shocking, and scandalous" (Matesa, 1999, p. 2). Karen Orloff Kaplan, former President and CEO of Last Acts Partnership, stated, "Under treatment of pain is a major public health issue in the United States" (Kaplan, 2004, p. 1).

The problem has been acknowledged by several other groups, including the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) which evaluates hospitals and other provider groups. JCAHO added an evaluation module on pain management to its accreditation process in 2000. Dennis O'Leary, M.D., President of JCAHO, stated, "Research clearly shows that unrelieved pain can slow recovery, create burdens for patients and their families, and increase costs to the health care system" (JCAHO, 1999, p. 1). The Veterans Administration initiated a Joint Collaborative with the Institute for Healthcare Improvement in 2000 to improve the delivery of pain management for veterans (Cleeland et al., 2003, p. 298). The hospice movement has continually campaigned for and adopted a strong approach to pain management for the terminally ill. Even the U.S. General Accounting Office (GAO) recognized reports that "inadequate treatment of cancer and non-cancer pain is a serious public health concern" (Kaplan, 2004, p. 3) However, in spite of all of the attention to the need for better pain management, pain remains under treated and often not treated at all, for significant numbers of patients.
Extent of the Problem

A number of studies have been conducted in an attempt to quantify the seriousness of the issues. In survey results released in 1993, 86% of 897 physician respondents reported that patients are under-medicated when experiencing cancer pain (Von Roenn, Cleeland, Gonin, Hatfield, & Randya, 1993, p. 121). A seminal study (Bernabei et al., 1998) of 13,625 cancer patients in nursing homes by the SAGE Study Group (a database established and maintained by Brown University) concluded that “Daily pain is prevalent among nursing home residents with cancer and is often untreated, particularly among older and minority patients” (p. 1877). In that study, more than a quarter (26%) of patients in daily pain received no analgesic agent at all. The study also found “a strong inverse correlation between the presence of pain and increasing age and an equally strong relationship between pain and belonging to minority groups” (Bernabei et al., 1998, p. 1880). Some of the members of the SAGE group are faculty at Brown University, which has conducted other extensive research related to the under- and non-treatment of pain among the elderly in nursing homes in the U.S. and rated excruciating pain among persons in U.S. nursing homes, in two separate analyses. The investigators determined that over 41% of nursing home residents who had reported moderate or excruciating daily pain at their first assessment, reported it as still present 60–180 days later. Other researchers, providers, and interested organizations have identified many “pockets of under-treatment” of pain, which may include age barriers related to the inability of the elderly to communicate due to dementia and confusion issues, as well as language
barriers in treating patients in different ethnic groups (Freeman, 2000, p. 1045; Morrison, Wallenstein, Natale, Senzel, & Huang, 2000, p. 1023). Limitations of this frequently cited study include the use of the Minimum Data Set (MDS), a federally required case management database, as the primary measure of pain. The reports on pain in nursing home patients as recorded on the MDS are often observations of nurses, and not direct reporting of the patients themselves. In addition, this study limits its analysis to the first 7–15 days of a nursing home stay, and does not reflect on any improvement in pain conditions beyond that time frame. The study also only includes nursing home patients, so the projection of its results beyond that population is not supported.

A statewide survey of a random stratified sample of 1,500 Michigan adults conducted in 1997 determined that 20% of Michigan adults (approximately 1.2 million people) were experiencing some form of chronic pain, and 77% of those individuals stated they had been suffering for over a year, with 40% of those individuals stating that pain was constant and had a major impact on their lives (EPIC MRA, 1997, p. 1). Responses to a 2003 Florida survey projected that up to 75% of Floridians suffer pain on at least a monthly basis and importantly, more than a third of them described their pain as moderate or severe (MacManus & Schuler, 2003, p. 50). A 2004 survey of 800 chronic pain sufferers revealed that nearly 50% do not have their pain under control—it is “ever present” (American Pain Foundation, 2005, p. 11). The 2003 Pain in America Survey found that 57% of adults in this country
have experienced chronic or recurrent pain in the last year (American Pain Foundation, 2005, p. 8).

**Barriers to Quality Pain Management**

Many of the noted studies cite other research, which all verify that the treatment of pain has been an issue for a long time and affects significant numbers of people. Furthermore, the alleviation of pain is often elusive as well as frustrating to patients and medical professionals alike. The World Health Organization (WHO) developed a treatment “ladder” in 1982 for drug administration to cancer patients to respond to this dilemma, and although the method has wide acceptance, the presence of a good method of drug treatment has not resulted in a meaningful reduction of the numbers who suffer in pain. There are several barriers to good pain management that have been identified, beginning with the minimal training medical professionals receive about pain management.

Medical schools do not routinely include pain management courses in the required curriculum, and most medical schools do not even offer a pain management elective (IOM 2001 study as cited in Kaplan, 2004, p. 3). Instead, the student is expected to “pick up” the skills to manage pain from information presented within required courses, and from practicing physicians as he or she completes rotations and internship. The 2001 Institute of Medicine study showed that medical schools in the U.S. provide little or no required, formal education in pain treatment and palliative care. There is no recognized discipline of pain management, so it cannot be classified
as a specialty (Fishman, Gallagher, et al., 2004, p. 281). The same lack of education on pain management is present in nursing schools and schools of pharmacy. Medical professionals are not generally required to obtain continuing education in pain management to maintain their licensure; thus, there is no incentive to pick up the knowledge after graduation. This means that the practice of pain management is hampered by a fundamental lack of knowledge for the vast majority of medical professionals. In practice, it also means that a chronic pain patient is often referred to a series of physicians as an attempt is made to obtain relief (Fishman, Gallagher, et al., 2004, p. 282).

Nearly all pain management care plans contain at minimum a drug regimen which often includes the use of opioids. Opioids are considered a basic treatment for a number of severe pain conditions and are accepted as a standard of practice throughout the world. They are strong medicines and because some patients may become addicted to the drugs, there is a concern among many medical professionals regarding potential addiction issues for their patients. These concerns are fueled by drug abuse issues and fears of sanction if a patient becomes dependent, addicted, or abuses his or her drugs.

The difference in the concepts of physical dependence, addiction, and tolerance are not well understood (Savage et al., 2003, p. 655). Physicians without a level of comfort in prescribing for pain conditions, especially persistent pain, are often fearful of regulatory action that has, for some, resulted in prosecution for over-prescribing or prescribing for non-medical purposes (recreational use or resale of the
drugs). A study of 2,000 physicians revealed that 5% would not prescribe opioids at all for cancer pain, and nearly 80% would avoid the use of opioids for severe back pain (Zickler, 2001, p. 3). In addition, regulatory action taken against physicians over opioid prescribing has created a “chilling effect” on the use of strong medicines in the treatment of severe, persistent pain, with many physicians restricting the use of opioids or not using them at all, to avoid any adverse interaction with law enforcement. Although the number of physicians actually prosecuted for drug diversion is very small, the few public prosecutions of physicians have resulted in widespread concerns over investigation, trial, loss of license and even criminal penalties (Merritt et al., 1998, pp. 11-12). Congressman Ron Paul of Texas even posted “The War on Drugs is a War on Doctors” on his website and indicated that law enforcement was applying laws intended for drug dealers on doctors (Brushwood, 2004, pp. 1-2). Attempts to counter this “chilling effect” have included the development of state standards and guidelines, acknowledgment of the need for balance in regulatory oversight, and assurances by the DEA that physicians would not be prosecuted for proper prescribing. Those activities have not removed the “chilling effect” on opioid prescribing, and there have been numerous articles and testimonials about the fear of regulatory scrutiny and how it contributes to inadequate pain management (Brushwood, 2003; Joranson & Gilson, 1998; Joranson, Carrow, et al., 2002; Ziegler & Lovrich, 2003).

Inconsistent access to opioids and other strong drugs also limits the delivery of good pain management in some areas. It is not uncommon to find that some
pharmacies stock only certain strengths of opioids, for example, limiting oxycodone dosages to 40 mg, and refusing to stock higher doses, or too frequently, not stocking opioids and other Schedule II drugs at all. One study reported that 51% of New York City pharmacies did not stock sufficient opioids to treat patients with severe pain (Morrison et al., 2000, p. 1023). That study, along with others, also establishes a racial injustice in pain treatment for black and Hispanic patients (Freeman, 2000, p. 1045). This inequity in treatment has been studied extensively with results reported in several articles (Cleeland, Gonin, Hatfield, et al., 1994; Cleeland, Gonin, Baez, Loehr, & Pandya, 1997).

Another barrier that needs to be recognized is the patient’s refusal or perceived lack of need to obtain treatment. People often do not seek medical help for pain conditions that they consider minor (MacManus & Schuler, 2003, p. 5; Maroney et al., 2004, p. 446). This issue needs to be addressed in considering the extent of the pain problem, since it is likely, and evidence exists to indicate, that people who self-select non-treatment are still included in statistics that define under-treated pain. Because people who choose to forego treatment are often included in pain studies, the credibility of the extent of unmanaged pain is sometimes questioned.

Consequences

The research verifies that nationally, the treatment of pain is inconsistent, fragmented, and in some cases, non-existent. The failure to manage pain effectively results in unnecessary suffering, higher health care costs in both the long and short
term, and has a tremendous impact on a pain patient’s life. Untreated or under­
treated, the patient becomes less productive at work if he or she is able to work at all.
Chronic pain is estimated to cost anywhere from $16 billion to over $70 billion per 
year in lost workdays, diminished productivity, compensation, and health care costs 
(Dean, 2004, pp. 1-2; Stewart et al., 2003, p. 2443). Patients face financial hardships 
if unable to remain fully employed while seeking relief, thus adding the loss of income 
to the cost of care. For those who cannot get relief from persistent pain conditions, 
the road often leads to unemployment, financial devastation, no health care coverage, 
compromised or destroyed relationships, drug-seeking behavior, and for some, suicide 
(American Pain Foundation, 2005; Dean, 2004; EPIC MRA, 1997; Fishman, 
Gallagher, et al., 2004; MacManus & Schuler, 2003). Research America reports that 
early 40% of chronic pain sufferers have had to make major adjustments in their 
lives, including disability leave, job changes, help with activities of daily living, or 
moving to different housing (Research America, 2003, p. 1). The impact on family 
members is significant. One study showed that 78% of family or household members 
indicated that relationships with family members were hurt due to a family member’s 
pain (MacManus & Schuler, 2003, p. 50).

In the analysis of the extent of the pain problem, the fact that most pain is 
treatable and preventable is often diminished or not mentioned at all. There are 
pockets of excellence, perhaps most notably the hospice movement, with the 
comment often heard that pain is manageable, but the patient has to be dying to get 
relief (Miller, Mor, Wu, Gozalo, & Lapane, 2002, p. 507).
In addition to the costs to the patient, business pays a cost in lost productivity and the rising costs of health care coverage, as employees with severe pain conditions make extensive use of their health care plan. The 1996 study of Pain and Absenteeism in the Workplace found that 14% of all full-time employees took sick days in 1995 due to pain conditions, resulting in more than 50 million work days. This translated into more than $3 billion in lost wages due to pain conditions (American Pain Foundation, 2005, p. 1). Another study reported that 36% of pain sufferers that were employed missed work due to that pain (EPIC MRA, 1997, p. 1). Significant diminished productivity issues were highlighted in the report from the Stewart study on lost productive time and costs (Stewart et al., 2003, p. 2446). The National Institutes of Health estimates the financial burden of untreated or under-treated pain is in excess of $100 billion annually, in medical costs, lost wages, and business productivity (National Institutes of Health, as cited in Partners Against Pain, 2003).

Poor pain management has a public cost as it affects the budget for the Medicare and Medicaid systems, as well as managed care organizations and private health insurance (O'Leary, as cited in JCAHO, 1999, p. 1). As these costs continue and even rise with the aging of America, they drive up the costs of health care for everyone, as health coverage premiums continue to increase. Thus, the cost burden of unresolved or poorly resolved pain is everyone's cost problem. The consequences of poor pain management reach every corner of the nation, and any barriers—real or perceived—should be addressed and resolved.
Prescription Monitoring Programs

In order to address the associated issues of the diversion of legal drugs and related substance abuse, several states have implemented a variety of laws and policies that supplement federal controlled substance laws. One type of such policies is a Prescription Monitoring Program or PMP. In general, PMPs are state laws which are designed to fight drug diversion at the state level. By the end of 2001, there were 16 states with PMPs, leaving 34 states operating without PMPs. The PMPs vary in their content and regulatory authority by state; however, all contain more restrictions on the prescribing of controlled substances than are present in federal law. Although the federal government through the FDA and the authority of the Uniform Controlled Substances Act has placed all legal prescription drugs in either Controlled Substance Schedules II–V or deemed them to be non-scheduled drugs, various states have reclassified some of the controlled substances because the states feel some drugs have a potentially more dangerous effect than that determined by the federal government. Some of the history, background, and basic information regarding the selection and regulation of controlled substances was presented in the first chapters. This section presents additional background and studies related to the benefits, limitations, and other commentary on the effectiveness of PMPs.

History and Definition of PMPs

The sole purpose of prescription monitoring programs is to reduce diversion of prescription drugs in one or more controlled substance categories. Additionally,
PMPs are only designed to detect and address diversion from one source, health professionals' prescribing of medications to patients. A division of the U.S. Department of Justice (USDOJ) stated on its website, “Prescription monitoring programs help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level . . .” (USDOJ, 2003, p. 1). The Pain and Policy Studies Group (PPSG, 2003b) of the University of Wisconsin offers the following definition: “PMPs collect prescribing and dispensing data from pharmacies, conduct review and analysis of the data, and make it available under certain circumstances to regulatory and law enforcement agencies . . ." (¶1)

The first continuously operating prescription monitoring program was implemented in California in 1939 and applied to limited drugs such as opium, cocaine, and marijuana—all drugs that subsequently became illegal to prescribe. In 1914 the state of New York became the first state to place controls on prescribing through special prescription pads for certain potent drugs, but that was not a continuous effort. New York did not adopt continuous controlled substance prescribing controls until 1972 (Fishman, Papzian, et al., 2004, pp. 312-314). All seven states included in this study that have experience with a PMP began their efforts with some sort of special prescription pad, all with triplicate copies, except Massachusetts. That state met with heavy resistance to a required special prescription pad from the medical community, and opted to begin its PMP as an electronic data monitoring system (EDT). Of the nine states that started their PMP with special prescription pads, only New York and Texas currently (as of 2004) require a special
form for full monitoring, and it is a single copy form. All other states have now converted to an EDT program. The State of Washington has maintained a special triplicate form for disciplinary purposes only, and not for prescription monitoring. The drug schedules monitored by the programs differ from state to state, with every state monitoring at least Schedule II substances (Alliance of States with Prescription Monitoring Programs, 2005), the category of drugs deemed by the DEA to have the most potential for dangerous side effects, abuse and addiction. As of 2001, nine states included the monitoring of other Scheduled drugs in their PMP. See Table 1 on the next page for a summary of each state’s program, as of 2001.

As national concerns increased over the diversion of legally available drugs, more states considered and several have adopted PMPs; all now are EDTs except the noted states. By the end of 2001, the last year of this study, there were 16 states with some type of monitoring program for prescribed drugs in various combinations of the five controlled substance schedules, with the state of Washington included as a 17th state although its monitoring was limited. In general, the primary reason most of the states have converted to an EDT system from a special prescription pad program is the cost of a paper system, although resistance by the medical community to the requirement of a special prescription pad continues to be a strong force. The federal government is supporting the development of PMPs as evidenced by its 2003 grant funding to assist states in the development of PMPs. (USDOJ, 2003, p.1.)

Throughout the history of the development of PMPs in the various states, the proponents—generally state agencies and law enforcement personnel—have argued
### Table 1

States With Prescription Monitoring Programs

<table>
<thead>
<tr>
<th>State</th>
<th>Year Enacted</th>
<th>Monitoring System</th>
<th>Drug Schedules and Groups Monitored</th>
<th>Managing Agency Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>California</td>
<td>1939</td>
<td>Triplicate + electronic (1996)</td>
<td>C-II</td>
<td>Justice Department</td>
</tr>
<tr>
<td>Hawaii</td>
<td>1943</td>
<td>Duplicate and Electronic</td>
<td>C-II (Dup.) and C-II, III, IV (elect.)</td>
<td>Public Safety Department</td>
</tr>
<tr>
<td>Idaho23</td>
<td>1967</td>
<td>Duplicate and Electronic</td>
<td>C-II (Dup.) and C-II, III, IV (elect.)</td>
<td>Pharmacy Board</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>1992</td>
<td>Electronic</td>
<td>C-II</td>
<td>Health Department</td>
</tr>
<tr>
<td>Nevada</td>
<td>1995</td>
<td>Electronic</td>
<td>C-II, III, IV</td>
<td>Pharmacy Board</td>
</tr>
<tr>
<td>New Mexico</td>
<td>1994</td>
<td>Electronic</td>
<td>C-II</td>
<td>Pharmacy Board</td>
</tr>
<tr>
<td>Oklahoma</td>
<td>1990</td>
<td>Electronic</td>
<td>C-II</td>
<td>Narcotics &amp; Dangerous Drugs Control Bureau</td>
</tr>
<tr>
<td>Rhode Island</td>
<td>1978</td>
<td>Electronic</td>
<td>C-II, III</td>
<td>Pharmacy Board</td>
</tr>
<tr>
<td>Utah</td>
<td>1995</td>
<td>Electronic</td>
<td>C-II, III, IV</td>
<td>Professional Licensure Division</td>
</tr>
<tr>
<td>Washington</td>
<td>1984</td>
<td>Triplicate for discipline only (not a true PMP)</td>
<td>C-II, III, IV, V</td>
<td>Pharmacy Board</td>
</tr>
<tr>
<td>West Virginia</td>
<td>1995</td>
<td>Electronic</td>
<td>C-II</td>
<td>Pharmacy Board</td>
</tr>
</tbody>
</table>

**Note.** Information as of March 2001 per NASCSA website.
that such programs decrease drug diversion while still allowing legitimate medical use, which is very important to proponents of accessible, high quality pain management. One of the arguments used to support the absence of prescribing barriers in policies such as PMPs is that the prescribing of scheduled drugs, with an emphasis on Schedule II drugs, has continued to increase overall. It is thus concluded that the presence of a PMP is not affecting prescribing patterns for pain management. While using statistics such as increased consumption, some regulators cite the data compiled by the DEA to indicate the growing problem of drug abuse in the U.S. The Drug Enforcement Agency has a variety of statistics and information on its website, www.dea.gov. Opponents of PMPs—generally medical groups and pain management advocates—acknowledge the drug abuse problem, but argue that the mere increase in use of a class of drugs does not indicate that optimum pain management is occurring, unfettered by policies such as PMPs. These opponents cite other factors that could lead to increased consumption with or without a PMP, such as increases in population, technology changes, and the discovery of better drugs, to name a few. Opponents also caution that laws such as PMPs may encourage physicians to prescribe drugs from a lower schedule of drugs that is less potent, thereby not adequately addressing pain problems and setting the stage for undesirable side effects of such less effective drugs (Joranson & Gilson, 1998, p. 160; Wastila & Bishop, 1996, p. 4).
Benefits and Limitations of PMPs

One of the seminal studies on the use of state prescription monitoring programs was conducted by Susan Peine of the Office of Diversion Control of the DEA, USDOJ in 1998–1999. Entitled “A Closer Look at State Prescription Monitoring Programs” (USDOJ DEA, 2000), one of the four goals of the study was to determine the effectiveness of PMPs. In the introductory comments to this study, the authors stated:

For many years states have struggled with the knowledge that the diversion and abuse of pharmaceutical controlled substances exists and the extent of the problems is much worse than known by the public (p. 3). They added, Major benefits of prescription monitoring programs whether they are multiple copy, electronic data transmission (EDT) or EDT with a single-serialized form, include diversion prevention and deterrence, increasing the probability of catching culpable practitioners when diversion does occur, reducing the consequences of abuse (accidents, injuries, lost productivity), and reducing unnecessary expenditures for health care services. (p. 7)

The study reports the increasing number of states that have implemented PMPs of some type, beginning with California in 1939 and including 16 states at the time of the research (USDOJ DEA, 2000, p. 11). The study acknowledges the controls imposed on all states by the Controlled Substances Act of 1970, and supports the additional controls imposed by states through PMPs. Diversion activity in each PMP state was reviewed using both statistics and anecdotal commentary, with the caveat that the full extent of the problem cannot be quantified because so much of the diversion problem goes unreported. This point is a limitation of the study, as it leaves no measurable means of determining if PMPs actually played a role in decreasing drug diversion. However, a few states were able to provide some data to
support PMPs. For example, after Indiana discontinued its PMP in the mid 1990s, the Indiana State Police reported an increase in the number of patients from Michigan (which had a PMP) who traveled to Indiana to obtain Schedule II drugs (p. 19). No evidence was provided to indicate that such drugs were then diverted to illegal use, which is another problem with the study. In Oklahoma, the number of undercover purchases of controlled substances went from 715,000 over a 5-year period before the implementation of Oklahoma’s PMP, to 281,383 purchases during the 5 years after the PMP went into effect (p. 22). However, no information was provided to indicate whether this was caused by a change in law enforcement resources or priorities during that same period. In Michigan, reduced prescribing of Schedule II drugs occurred after the implementation of its PMP, and was cited as evidence that diversion of such drugs was thus addressed (p. 32). Opponents of PMPs would use the same statistics to indicate that the reduced prescribing indicated that pain patients were not being properly treated.

Throughout this often-cited study which remains on the DEA website as evidence of the effectiveness of PMPs, there are many examples of drug diversion and the extent of the problem. The study does a very good job of providing evidence that the diversion of legal drugs to illegal use is a problem in the U.S. It also provides some evidence that the information collected using PMPs is a valuable tool in the investigation and arrest of those suspected of diverting drugs. In Indiana, the PMP was credited for more than 41 arrests during an unspecified period (USDOJ DEA, 2000, p. 30). In Illinois, a few examples were provided that connected fraudulent
prescribing practice discoveries to its PMP. However, in the 15-year period of
Illinois' PMP, referrals from its PMP only contributed to disciplinary actions against
25 medical providers, less than two per year (p. 29). In Michigan, the study estimated
that the absence of its PMP would have put over 2 million dosage units of Schedule II
drugs on the streets each year—with a street value of up to $50 million (p. 32). The
study claims the PMP has “virtually eliminated” this problem, in spite of the fact that
in 10 years, no legal action against any physician was initiated due to the existence of
Michigan’s PMP. The section on New York states that the forgery and counterfeiting
of Schedule II prescriptions was virtually eliminated due to its PMP. Again, no data
were provided to substantiate those statements. In Texas there was only one
conviction by the Texas Department of Public Safety (DPS) of an individual for drug
diversion prior to the implementation of its PMP. After implementation, the DPS
indicted 18 medical practitioners over an 18-month period, with another 17
practitioners surrendering their rights to prescribe Schedule II drugs. This was a
supported statistic; however, it is not known what other factors might have
contributed to the increase in legal actions in Texas. For example, the DPS might
have increased or reassigned its law enforcement officers during the same period. And
of course, an indictment is not a conviction, so the example is not as meaningful when
making a case for the benefits of a PMP in the prevention of drug diversion in Texas.

However, this report does provide some excellent examples of the extent of
drug diversion, the advantages of the availability of PMP data in specific cases, and
the desirability of such programs on the part of law enforcement officials. It fails to
draw a credible correlation between PMPs and a significant reduction in drug
diversion, and it does not control for other confounding factors such as population
changes, increases or decreases in law enforcement resources, changes in disease
prevalence, and the availability of new medications for the treatment of chronic pain
conditions. The study also uses some examples to justify activities that are then
contradicted in other areas of the study. For example, in Illinois the prescribing of
Schedule II drugs increased after the state PMP was implemented, a fact that was
used to indicate there was no “chilling effect” on proper prescribing. In other areas of
the report, similar increases in prescribing were used to support the extent of the drug
diversion problem. Opponents of PMPs might argue that this was evidence that the
PMPs might not be working. And the statistics presented for some states such as
Michigan which showed reduced prescribing of Schedule II drugs could be
interpreted to mean that the PMP was working, or that prescribers were more
cautious in their prescribing and thus pain patients were not receiving the drug
therapies needed. There were several examples of using the same information to
support opposing arguments throughout the study. There was no conclusive evidence
presented to indicate that PMPs significantly reduced drug diversion after
implementation. In fact, in the opening comments, the authors stated, “It was
determined that due to the many factors that affect the collection of the data by each
state, a purely scientific statistical analysis would be an impossible task” (USDOJ
DEA, 2000, p. 4). This issue and the lack of adequate studies were included in the
American Alliance of Cancer Pain Initiatives (AACPI) Statement on Prescription

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Monitoring Programs that was released in June, 2002 (AACPI, 2002, ¶1). In general the methodology used to support the existence and growth of state PMPs was limited to reporting individual state incidences and general statistics, without any scientific data that was consistently measured from state to state.

One of the study's conclusions was a commentary on the difference from state to state in the structure of PMPs. Stating that "no two programs are alike," the variables differentiating between state PMPs were reported as significant and make outcome and program evaluation very difficult. This supports the report's initial comments on the difficulty in determining how effective PMPs are in controlling drug diversion.

Brushwood (2003, p. 42) agreed with that conclusion, stating that there are no national standards for PMPs; there is a lack of accuracy, a lack of national integration (abusers can cross state lines to obtain their drugs); and the issue of confidentiality is problematic. He states:

It may be difficult for researchers to find a direct correlation between the ultimate outcome of reduced substance abuse and the implementation of electronic prescription monitoring programs, even if such a correlation exists. Yet, despite the difficulty of outcomes research, it is outcomes to which the health care community has turned for meaningful program evaluation. (p. 45)

He further states, "it is not unreasonable to provide clear evidence of positive outcomes from their programs."

In another study, Wastila and Bishop (1996) determined that the presence of a PMP in the form of a multiple copy prescription program (MCP) did reduce prescribing of Schedule II drugs, but that was done by merely changing prescribing
patterns to a less potent drug from within the Schedule III classification. They stated, "These patterns suggest that less potent drugs are substituted for Schedule II analgesics in MCPP states. This study finds that MCPPs alter analgesic utilization patterns, which has implications for physician practice patterns and patient access to analgesic therapy" (p. 4). They also point out the difficulties in studying the issue from a statistically significant viewpoint, indicating that "all studies to date fail to incorporate in a multivariate model other potential confounding and explanatory variables, including patient diagnostic information, physician specialty, and other related prescribing and reimbursement factors" (p. 6).

This reinforces the comments made in the DEA study and the Brushwood article. There is a presumption that there could be (or could not be) a correlation between PMPs and a reduction in drug diversion; however, no study has been done to verify that presumption. In fact, the Wastila and Bishop study provides some evidence that the presence of a PMP for the period of their study actually did reduce the prescribing of Schedule II drugs, which some would argue means a reduction in drug diversion—a conclusion that cannot be drawn from the research. The study also reports an increase in the prescribing of Schedule III drugs, perhaps indicating that patients may be receiving a less potent drug than desirable, reducing the quality of their pain treatment. Others would argue this is evidence of a decrease in drug diversion. Thus, the conclusions can be misinterpreted and misapplied. Limitations of the study include the inability to account for variations in PMP programs and length
since implementation across states. In addition, the medical environment of the states in the study vary.

The fact that laws and policies such as PMPs might have the potential to cause some physicians to under-prescribe for pain conditions was a caution issued early by several pain treatment proponents, most notably Joranson and Dahl of the University of Wisconsin Pain and Policy Studies Group (Joranson & Dahl, 1989, p. 202). Cautions without significant supporting studies, however, did not prevent the continuing growth of PMPs, although the structure and design has changed over time.

It is interesting to note that studies which imply that PMPs decrease drug diversion do not address the confounding factors of activities other than prescription fraud by which drugs are diverted, such as pharmacy theft, nursing home, hospital and clinic theft, and the movement of diversion activity across state and national borders. PMP studies place an emphasis on controlling prescribing activity that results in drug diversion. This fails to address the global problem and for critics is viewed as a “band-aid” approach to a significant issue.

PMPs, as indicated, take many forms in the states under study as well as the other states not a part of this study. Since they seek to identify prescribing that is illegal, fraudulent, or in a pattern that is outside the norms for the area of enforcement or physician specialty, they are subject to errors in determining “normal prescribing.” Thus, if area physicians in a particular specialty are under-prescribing for pain conditions, then a physician who is providing optimal pharmaceutical care for pain patients would be suspect, if the area averages were used as the norm. Several articles

The methods used by boards/agencies to determine standards of practice for opioid use result in interpreting the language in these regulations based on myths, prejudices, and misinformation about opioids, and the unexamined belief that mere exposure of patients to these drugs causes psychological dependence (addiction) on them to all patients in all instances. (p. 288)

He further states, “Therefore, practitioners who prescribe adequate doses for proper time intervals and who provide adequate quantities of opioids to the patient for a reasonable number of days are often considered, *prima facie*, outside the standard of practice” (p. 291).

Another limitation of PMPs is the delay in data collection and disbursement. Although most states with PMPs are now collecting data electronically and have discontinued the use of special pads, using PMP data to control drug diversion is addressing the issue after the fact. In a typical electronic PMP process, a prescription is electronically sent to the data collection agent (often a state department) and is maintained there until data are requested. Thus, a series of illegal prescriptions could be recorded, but until someone retrieves and reviews the data, there would be no knowledge of the activity. States with electronic PMPs do not (and will not, given current HIPAA laws) allow *carte blanche* access to the prescription database; thus, the ability to use the information is limited in its usefulness. One could argue that such regulatory policies are thus not truly preventive in nature. This limitation was mentioned in the interviews which are a part of the qualitative research conducted for this study.
Prescribing Patterns and Control of Drug Diversion

The “chilling effect” mentioned earlier has been reported by nearly all those who study and report on the negative effects of PMPs as an undesirable consequence of such laws. On the other side are law enforcement officials who generally claim that no chilling effect occurs, and that the changes in prescribing are evidence that the PMPs are working. A 1997 Michigan report by the Michigan Board of Pharmacy presented statistics indicating that although the use of oxycodone, hydromorphone, and meperidine prescriptions (all Schedule II drugs) declined from 1990–1995, prescriptions for Fentanyl and morphine (also Schedule II drugs) increased. They claimed that those statistics indicated no chilling effect (Baran, 1997). The same report included numbers that showed the disciplinary actions of medical doctors and doctors of osteopathy to be exactly the same (76) in 1994 and 1995, which is less than one quarter of 1% of all licensed physicians (over 35,000 each year) in the state. Opponents of PMPs state the low number of enforcement actions indicates the PMPs are thus not necessary. (Brushwood, 2003, p. 46; Johnson, 1996, p. 320; Skelly, 1994, p. 19; Szalavitz, 2004, p. 7). Johnson also refers to the chilling effect of such laws:

Doctors’ fears of disciplinary action and criminal prosecution are justified. There is no evidence that large numbers of physicians are sanctioned for their treatment of patients in pain, but the impact of the process on those physicians who are only investigated, or only charged but not disciplined, or only warned or cautioned but not penalized is severe. (p. 320)

The Reasononline website (2004) provides details on physicians whose practice and indeed personal and economic life were devastated by regulatory activity.
directed at decreasing drug diversion, and how such public exposure can cause other physicians to change their prescribing decisions. The October 2004 web article states, "While the OxyContin panic does not seem to have deterred addicts, it has scared doctors. Every time there is one of these trials . . . another 50 to 60 doctors drop off from prescribing" (p. 5). Statements like this are not uncommon in anti-PMP articles; however, no substantive study has occurred to indicate that physicians are actually changing prescribing patterns because of PMPs.

Some studies and data are available to indicate that fewer physicians prescribe Schedule II drugs when a PMP is implemented. For example, in California, 69% of physicians responding to a survey indicated that the potential for disciplinary action made them more conservative in prescribing opioids (Skelly, 1994, p. 15). A review of Michigan records on special prescription pad licenses for Schedule II drugs indicated a significant decrease in the number of physicians applying for such privileges after a PMP was implemented in Michigan, resulting in significantly fewer physicians able to prescribe the most effective pain medications. Proponents of PMPs say this means that unethical physicians have ceased to prescribe—that the "bad" doctors voluntarily elected non-renewal of their prescribing rights for Schedule II narcotics. Opponents of PMPs state this means that physicians feel the extra work required to prescribe and the threat of extra oversight are too much hassle, so they elect non-renewal. This is another example of the use of the same statistic to support opposing assumptions.
In his continuing analysis of regulatory effects on prescribing controls on physicians, David Brushwood of the University of Florida collected data from several states to determine the number of criminal prosecutions of physicians for offenses related to prescribing opioid analgesics from 1998 through 2003. Of the 27 states in his report, 124 physician prosecutions were reported, with 64 of those either pleading guilty or being convicted. Of the more than half million physicians licensed in those states, the prosecutions represent a miniscule portion, less than 1% of all physicians. Of the states in the Brushwood report, 12 had PMPs of some sort in force during at least a part of the 6-year summary, and included 39 of the prosecutions. Thus, 44% of the states in the report had 31% of the prosecutions. Proponents of PMPs would infer that meant the PMPs were working—that the number of prescription diversion crimes was less in the PMP states. Opponents of PMPs might infer otherwise, namely that the statistics showed the ineffectiveness of PMPs. It could be argued that there should actually be more prosecutions with the extra law enforcement data tool of the PMPs, and that the numbers were too small to draw any conclusion.

A study of four states by the USDOJ showed a 50% or greater reduction in the prescribing of Schedule II substances after the implementation of a multiple copy PMP (Angarola & Joranson, 1992, p. 10). Statistics compiled by the USDOJ indicate that the five states with the lowest number of OxyContin prescriptions per capita have PMPs and have reported few diversion problems with the drug. Conversely, the five states with the highest OxyContin prescriptions per capita do not have PMPs and have reported diversion and abuse. Although one study can infer that PMPs are
effective, very often the same study infers that PMPs may have little to do with diversion of controlled substances. As mentioned, most of the studies to date have failed to control for other factors; thus, a clear conclusion has not been possible.

An additional concern expressed about the effect of PMPs is the potential decrease in access to strong pain medications because of a reduction in pharmacy inventory. Owners of pharmacies are likely to limit their inventory of drugs that have little demand due to physician reluctance to prescribe or due to fear of investigation. Angarola (1994) states, "Some pharmacies are so concerned about drug diversion and the possibility of DEA investigation that they do not stock Schedule II and other controlled substances" (p. 32). A subsequent study by Cleeland as noted earlier, indicates that access related to low pharmacy inventory in ethnic neighborhoods also continues to be an issue. This limited access in some areas enhances the "substitution effect" or the prescribing of weaker drugs in PMP states to avoid scrutiny—drugs that are less efficacious, with more side effects when heavier doses are needed. (Angarola & Bormel, 1996, p. 53). Although this study established the existence of the substitution effect, there was no evidence that such change in prescribing patterns actually lowered the quality of pain management.

A more recent, although selective, study of analgesic prescriptions for musculoskeletal pain does provide some statistical evidence that the prescribing of opioids and NSAIDS for this type of chronic pain has increased, in spite of additional regulatory activity. This study might support the argument that PMPs produce no chilling effect. The study was substantial and included a comparison of prescribing as
a result of office visits in various areas of the country in 1980 and 1999 to determine changes in prescribing preferences. The researchers found that prescribing for both NSAIDS and opioids as a percent of office visits increased significantly over the study period. The data were collected by examining the results of the National Ambulatory Medical Survey, which compared 89,000 visits in 1980-1981 to 45,000 visits in 1999-2000. Physician participants were randomly selected. The study was done to look at prescribing pattern changes for acute and chronic pain conditions, but it also makes a statistical case against the chilling effect. Limitations of the study include not controlling for increased public awareness of the pain treatments available, the fact that NSAIDS were only available by prescription in 1980 and many were available over the counter by 1999, and the introduction of new and better pain medications. The numbers do, however, indicate that physician reluctance to prescribe for musculoskeletal pain conditions has not increased during the period of growth of PMPs (Caudill-Slosberg, Schwartz, & Woloshin, 2004, p. 514).

**Effect on Drug Diversion**

Since the primary purpose of PMPs is to reduce drug diversion, it would seem logical that evaluations at the various state levels would have been completed, to determine the impact on drug diversion and to ascertain the cost-effectiveness of such policies. If one removes the quality of pain management from the argument for or against PMPs and concentrates on subsequent reduction in drug diversion after a PMP is implemented, at least that objective could be tested. In fact, drug diversion
continues to increase in the United States, according to the DEA website and other sources: A wealth of information is found on these websites: www.DEA.gov, continuous reports; www.drugabusestatistics.samhsa.gov, continuous reports; and www.NASCSA.org. The Florida Office of Drug Control also published an extensive report on the increase in drug diversion in Florida in its document, *Florida Drug Control Strategy, 1999-2005* (Florida Office of Drug Control, 1999).

As previously mentioned, one of the challenges in establishing a correlation between reducing drug diversion and PMPs is the fact that PMPs are only designed to address diversion by prescribers, and such diversion is difficult or impossible to separate from other sources of diversion which notably include theft and loss from pharmacies and facilities that store an inventory of drugs such as hospitals and nursing homes, not to mention the growing concern with diversion through purchases from internet pharmacies. The pain community continues to acknowledge that drug diversion and drug abuse is a growing concern as publicized in a statement released October, 2001 by 21 health care organizations (American Alliance of Pain Initiatives, 2001, p. 1). The DEA and various law enforcement organizations believe they have statistics to verify that drug diversion is less in states with PMPs. The pain community does not necessarily dispute that such laws have an effect on drug diversion; the concern is that the effect may be so small on diversion using prescribed drugs, as not to be worth the resources expended. There is also a fear that pain management is not as good in those states with PMPs.
One of the indicators used by regulators and others to determine the extent of drug abuse is the DAWN data, which is used in the quantitative portion of this research. These statistics are obtained from the records of selected, large metropolitan hospital emergency department medical records to monitor national drug abuse trends (www.dawninfo.samhsa.gov, ongoing.) These statistics indicate increasing drug abuse; however, the majority of abuse problems are associated with illegal (non-prescription) drugs and alcohol in combination with drugs, so the projections are not conclusive for the diversion of legal drugs. In its 1994-2002 report, DAWN statistics showed a 120% increase in mentions of narcotic/analgesic combinations at DAWN sites nationally, an increase greater than the 11% population growth for that same period (U.S. Department of Health and Human Services, 2003, pp. 62-63). DAWN statistics from PMP states will be used as the dependent variable in the quantitative analysis section of this research to determine if such increase is greater or less in PMP states. Limitations of the DAWN statistics will be discussed in that analysis.

The existence of PMPs has not had a significant effect on addressing drug diversion through legal actions. The Reasononline website reports the following national arrest numbers of physicians for drug diversion for 3 years of this study: 1999, 81 arrests; 2000, 83 arrests; and 2001, 78 arrests (Szalavitz, 2004, p. 7). The number of arrests has remained relatively stable over the 3-year period and does not appear excessive, given the number of licensed physicians, and given that the number of PMPs has steadily increased. It should also be noted that the number of arrests is
hardly the same as the number of actual convictions. This might suggest that PMPs on a national basis are having little effect on successful prosecutions of drug diverters.

The literature as a whole thus remains inconclusive regarding the effects of PMPs on drug diversion. Although the pain community concedes the growing problem of drug diversion and the related drug abuse, it does not feel that PMPs should be implemented if that is done at the expense of good pain management. The law enforcement community concedes that untreated pain is a social and public health problem, but contends that PMPs and other regulatory means of addressing drug diversion do not interfere with access to quality pain management and are necessary for public safety. They stress the use of PMPs as a tool for physicians to use in assessing the credibility of their patients.

Pharmaceutical companies, which have a stake in the issue, tend to take the best political path in each state. For example, in Michigan several pharmaceutical companies worked with health care organizations to eliminate Michigan's PMP laws, citing the "chilling effect" on prescribing. In contrast, in Florida, one pharmaceutical company offered the state $2 million to start a PMP, to assist the Office of Drug Control and provide a tool for physicians.

In conclusion, there is no clear evidence from current studies that PMPs are effective policies in the war on drug diversion, nor is there clear evidence that PMPs serve as a barrier to good pain management. In light of this, the AACPI issued the following statement: "However it (AACPI) believes that no new PMPs should be established until and unless existing information sources have been fully utilized"
(American Alliance of Cancer Pain Initiatives, 2002, p. 1.) The AACPI goes on to define an ideal PMP, when and if such a policy were deemed effective. Varied opinions and measurements of effectiveness and a lack of conclusive studies indicate that we do not know if PMPs achieve their stated goals—and may never know. This fosters concerns over the cost of such programs (Michigan reported costs in the range of $750,000 per year just to collect the data) and provides the incentive for further study before additional PMPs or a national PMP are put in place.

Drug Diversion

The literature specific to drug diversion, as distinguished from the larger topic of drug abuse, is very limited and there were no studies of a strictly academic nature that were identified for review. There were, however, a number of reports and analyses which relied on anecdotal evidence combined with some statistics, which were used to formulate conclusions regarding drug diversion in a number of reports.

The public is naturally opposed to drug diversion and drug abuse as such activity creates situations that are dangerous and even fatal to individuals and society as a whole. The reports and articles that support public opposition to illegal drug use are numerous and contemporary. The prevention of drug abuse and drug diversion has strong public appeal, especially since such actions address activities that are known to be harmful to children and young adults. Additionally, crimes by drug cartels and gangs are often horrific and well publicized. The war against drug
diversion and abuse is a popular political platform, embraced by public officials and those who wish to be or remain public officials.

In the studies noted in this section, there is an inherent assumption that drug abuse and drug diversion can indeed be prevented. There is also an orientation in most of the studies to use the terms *drug abuse* and *drug diversion* interchangeably. That is incorrect, as drug abuse can be facilitated by the diversion of drugs, but it is not the same thing. As stated earlier in this study, drug diversion is defined to mean the illegal use of legal drugs. Drug abuse occurs when both legal and illegal drugs are used for non-medical purposes. Drug diversion is thus a part of the drug abuse picture, but should be viewed as one of many avenues to drug abuse. To illustrate, drug abuse occurs when illegal drugs such as heroine or marijuana are used; it also occurs when alcohol (an “over the counter” drug) is misused; and it occurs when legally prescribed drugs like Xanax or OxyContin are used for non-medical reasons. Only this last case is considered an example of drug diversion, because the drugs were diverted from their intended and FDA-approved use for another purpose (to get “high” or self-medicate in dealing with some other problem).

*Seminal Studies*

An annual and oft-quoted study of drug abuse and diversion is the annual National Survey on Drug Abuse (NSDA), which was entitled the National Household Survey on Drug Abuse prior to 1999. This study has been called “The primary source on the use of illicit drugs, alcohol, and tobacco by the non-institutional population”
This study provides annual estimates of such illicit use, the results of an extensive and representative study of U.S. households. In general, over 70,000 individuals are interviewed for the survey each year. The study has been conducted since 1971 although it was re-designed for the 2002 survey, which makes following current trends difficult except for a limited number of variables. Study results are posted on the SAMHSA website and extensively reported and quoted elsewhere. The statistical significance of the results is well documented. However, in the reporting, statistics are often selectively quoted, which can give a more extensive meaning to the results than the survey data can actually support. For example, the National Institute on Drug Abuse in its July 2001 Research Report, quoting the NSDA, states that “An estimated nine million people aged 12 and older used prescription drugs for non medical reasons in 1999” (Leshner, 2001, p. 1). Later in the same report, the author states that in 1999 “an estimated four million people were currently (use in the past month) using certain prescription drugs non-medically” (p. 4). The study does not appear to distinguish regular use from occasional use in the reporting of survey results, and the 9 million study result is the statistic of choice for many articles and other commentaries. In this referenced comment, reported survey results first cited the larger number of users, even though there is a distinct difference between current users and non medical use in the past year. The reported results also do not distinguish between regular use and a one-time occurrence. Thus it is very likely that a number of one-time, fairly harmless and innocent uses of a prescription drug are included in the 9 million and 4 million figures above. Examples of such
innocent use are easily conjectured: taking a friend’s pain medicine for a headache, older couples sharing a blood pressure medicine, and so on. These activities are, by the letter of the law, drug diversion, but certainly not the diversion that concerns law enforcement and the public. However, such ambiguity can disguise the actual incidence of drug diversion implied by the NSDA. Thus, the survey results should not be considered a reliable, quantifiable measure of the growth in illegal and harmful diversion of prescription drugs, and indeed does not make such claims, although the results are often used to that purpose.

With the above limitations noted, the existence of an increase in the diversion of legal prescription drugs was supported by NSDA study results. A review of the press releases for the study years 1998–2001 shows no mention of diversion of legal drugs in 1998—meaning the issue was not deemed significant enough to be reported to the press. By 2000, the NSDA reported 4 million people used legal drugs for non-prescribed reasons at some time in the past month—a “current” user. In 2001, there were 6.2 million current users. Clearly the increase in sheer numbers would be enough to cause public concern and indicate a problem, even though it appears that someone could be classed as a current user if the person only used another’s medicine once in the past month. Thus, in spite of some questionable use of the results, the NSDA study results still support the claim that the diversion of legal drugs to illegal use is increasing. The study results should, however, be considered in total. Of note is the fact that the most commonly used illegal drug identified by the NSDA in 2003 is marijuana (6.2% of the population) and the most commonly abused legal drug is
alcohol (54% had participated in binge drinking in the past month—23% of the population). In the same year, 2.7% of the population used prescription medications non-medically (U.S. Department of Health and Human Services, 2004, pp. 2-3). It is important to keep this in mind as anti-drug abuse policies and laws are considered, and attempts are made to quantify the level of diversion of prescription drugs using drug abuse statistics as justification.

The U.S. General Accounting Office (GAO) published a federal report in May, 2002 entitled *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*. The GAO refers to DEA statistics in its assertion that drug diversion is a growing problem. The report is intended to review the effectiveness of PMPs in deterring drug diversion and the positive effects of such policies in the states with PMPs. The report studies both benefits and challenges of PMPs and concludes that “States with PDMPs have realized benefits in their efforts to reduce drug diversion” (p. 3). This study looks at the different anti-diversion objectives of PMPs, and states that the anti-diversion effectiveness depends on the objectives of such a program as well as the funding allocated to the program. The researchers for the study reviewed information from several sources, including the DEA, the DOJ, and the National Alliance for Model State Drug Laws, as well as the National Association of State Controlled Substance Authorities. The researchers also studied PMPs in three states—Kentucky, Nevada, and Utah. They found that PMPs shortened investigation time in some diversion cases, and their mere existence had a deterring effect on potential diverters (p. 3). PMPs were also found to be useful in alerting
physicians to potential diversion activity in Nevada and Utah. The Nevada program also encourages referral of drug diverters to pain clinics and addiction clinics (p. 10).

In the above study, challenges to the implementation of a PMP were centered on public education and acceptance, especially the confidentiality issue that must be addressed, and the costs of start-up and operation of such a program. In Kentucky, the start-up costs and first year operating expenses approached $1 million (U.S. General Accounting Office, 2002, p. 3). In addition, most programs were reported to operate reactively, meaning they were not structured to prevent drug diversion, but to identify such activities after they occurred, in the form of prosecution or other actions (p. 10). To make PMPs truly effective in quantifying and preventing drug diversion, they would need to be restructured to provide same day information, which was viewed as cost prohibitive. The study also indicated that PMPs may not necessarily prevent drug diversion; they may just move such activity across state borders. “The presence of a PDMP helps a state reduce its illegal drug diversion, but diversion activities may increase in contiguous states without PDMPs” (p. 15). Throughout the GAO study, several comments were made regarding the growing problem of drug diversion. However, even this government-ordered study was unable to quantify the level of drug diversion and the actual growth trend. Instead, it simply concluded with a general belief that PMPs have a role in detecting and deterring drug diversion.

In 2002, the Office of Inspector General was asked to review the DEA’s efforts to investigate cases of controlled pharmaceutical diversion (Office of Inspector General, 2002). The report accepts the DEA contention that drug diversion is
occurring, stating, “although the quantity of controlled pharmaceuticals diverted is unknown, controlled pharmaceuticals account for 30 percent of all reported deaths and injuries associated with drug abuse” (p. i). A footnote to this comment states, “The data available for our analysis does not specifically identify what percentage of the problem is attributable to diversion of controlled pharmaceuticals versus the abuse of legally obtained prescriptions” (p. i). This report, while acknowledging the existence of a drug diversion problem, was also unable to cite sources that could verify the extent of the problem, and suggested that the DEA should be responsible for more activity to address this problem. The OIG report concluded with four recommendations to the DEA to increase its impact on diversion of prescription drugs: (a) to increase DEA investigative resources for diversion problems, (b) to clarify the roles of diversion officers, (c) to ensure adequate training for DEA agents, and (d) to fully implement a proposed online project (p. iii). The report does not include any reference to assistance from states in the form of laws and policies to prevent and control diversion. The report implies that diversion of legal drugs may not be an important enough issue to the DEA to devote resources and training, which again suggests that the extent of diversion may be exaggerated. This is another study without supporting statistics related to diversion.

DAWN Data as a Measure of Drug Diversion

Much of the current concern over drug diversion was initiated when the abuse of OxyContin became a national story. OxyContin, manufactured by Purdue Pharma,
is a controlled release Schedule II medication used primarily for severe pain conditions. It is a very effective drug when used as recommended for such conditions; however, abusers have discovered that crushing the tablets and using OxyContin in its crushed state can provide a heroin-like "high," thus creating a market for diversion of the drug. The illegal use of OxyContin became widely reported, as stories emerged in many economically depressed areas and eventually other areas, and deaths from overdoses began to be reported in the media (Gallop, 2003; Meier, 2001; Police haul, 2003; Rippel, 1998; Satel, 2003, 2004; Silver, 2001; Smith, 2003; Thomas, 2003, p. 42; Tough, 2001, p. 33).

The Drug Abuse Early Warning Network (DAWN) statistics, which report on emergency department visits for drug-related reasons, supported the claimed increasing presence of oxycodone, though not specifically OxyContin, since brand names cannot be identified by lab test. DAWN reported that the number of emergency department "contacts" identifying oxycodone in the blood increased from 1,178 in 1999 to 14,087 by 2002—an increase of over 1000% (Meyer, 2004, p. 4).

Purdue Pharma, the manufacturer of OxyContin, and other researchers studied the relationship of OxyContin use in such reported deaths, and published a report with its findings in March of 2003 (Cone et al., 2003). The report studied 919 drug abuse cases which resulted in death, according to DAWN statistics. The report concluded that multiple drug use was found in nearly all (96.7%) of the deaths (p. 56). The most common combinations included alcohol, cocaine, marijuana, benzodiazepines, other narcotics, and other depressants. The report makes the case that while oxycodone
may be present in the body at the time of death, death can rarely be attributed to oxycodone alone, and drug combinations may be the culprit, not any particular drug. Since this study was funded by Purdue Pharma, there may be some concerns with credibility and conflict of interest issues. Cases used in the study were reported voluntarily; thus, the credibility provided by randomization was not present. Furthermore, only deaths with oxycodone present were studied and only from areas that had media reports of overdose deaths involving OxyContin, which limits the study conclusions to only some parts of the country. The study also expressed concern about the use of DAWN data in studying polydrug deaths, since DAWN currently only lists up to six of the potentially contributing drugs in mortality cases. Some abusers exceed this amount of drugs in their abuse patterns (p. 65). The study does, however, support the use of DAWN data as a means of measuring drug diversion, in lieu of any better source of quantifiable events currently available. It cites the DAWN system as the “largest and most standardized system for reporting drug abuse morality data in the United States” (p. 65). Interestingly, alcohol was present in over 25% of the cases studied, supporting other statistics related to the role that alcohol may be playing in polydrug use and deaths (Best et al., 2000, pp. 319-321; Florida Office of Drug Control, 1999, Chapter 2; Office of Applied Studies, 2005a, pp. 1-2).

Actual DAWN statistics and the use of the DAWN data will be covered in the quantitative section of this study. However, it should be noted here that DAWN reports do verify an increasing trend in drug-related emergency department visits in
the metropolitan areas that are part of the DAWN system. Reviewing DAWN reports online (www.Dawninfo.net), the percentage increase in drug-related emergency department visits was 77% from 1995–2000, and 153% from 1995–2004. During this time, the population increase was just under 10%. Although there are limitations to DAWN data, there appears to be enough evidence from these statistics to support the conclusion that there is an alarming increase in drug abuse. Since diversion of legal drugs is included in the definition of drug abuse, the DAWN statistics provide another argument for continued attention to programs and policies that address diversion issues. It should be noted, however, that DAWN statistics do not provide clear evidence that the diversion of legal drugs increased at the same rate as its entire category of drug abuse.

The issue of distinguishing between drug abuse and the subset of drug diversion was and is a focus of the National Association of Attorneys General (NAAG). A group of 29 Attorneys General sent a letter to DEA Administrator Karen Tandy in early 2005, asking the DEA to “find ways to prevent abuse and diversion without infringing on the legitimate practice of medicine.” Supporting another approach, former NAAG Chair Drew Edmundson further stated, “We should concentrate on drugs that are illegally on the streets and work backwards to find out how they got illegally on the streets,” he said. “It should not be the other way around looking at doctors” (Robeznieks, 2005, pp. 1-2).
Other Studies and Testimony

In February of 2002, Dr. Donald Meyer of the FDA expressed the concerns of the FDA over the diversion of legal drugs (Meyer, 2004, p. 3). Citing DAWN statistics and the NSDA survey as sources for FDA concerns, Dr. Meyer reported on the responsibility of the FDA to address diversion potential. This includes a responsibility in the drug approval process to make sure that any approved drug is safe and effective for label uses, that any necessary warnings are on the label, and that the drug is properly placed on a controlled substance schedule if so indicated. Dr. Meyer stated, "Most approved controlled-release, high strength opiates contain a 'black box' warning, indicating that a serious risk has been identified" (p. 8). This type of warning is thus generally found on all Schedule II drugs, including OxyContin.

The FDA also monitors pharmaceutical company advertising for false and misleading statements that could lead to abuse. However, the penalty for such violation may be minimal. In the case of Purdue Pharma's questionable advertising of OxyContin at one point in time, the punishment was to correct the advertisements.

In his testimony to the Subcommittee, Dr. Meyer indicated that several activities were necessary to address the growing problem of drug diversion. Collaboration with other government agencies was stated as a primary means of developing successful initiatives. In addition, physician education, PMPs ("strongly supported" by the FDA), federal-state task forces, new product assessment for abuse potential, and FDA's Office of Criminal Investigation are all listed as activities that help to address the diversion problem (pp. 15-16). Collaboration with the DEA and
other law enforcement groups has produced legal action against diverters such as four clinicians in Indiana who dispensed controlled substances outside the scope of practice, and a physician involved with a web-based pharmacy (p. 17). From 1998 through early 2002, 46 criminal investigations were opened relating to OxyContin, with 24 of those cases successfully adjudicated (p. 15). There were no examples given in the testimony of successful actions to reduce drug diversion, other than the law enforcement collaboration which resulted in the enforcement actions reported above. And other than law enforcement collaboration, the testimony did not provide any documented examples of anti-drug diversion activities that were successful in slowing and preventing the growth of drug diversion.

Another study that looks at drug abuse by prescription drugs is conducted through the OAS within SAMHSA, a division of the U.S. Department of Health and Human Services (HHS). Reports based on information gathered through the Drug and Alcohol Services Information System (DASIS) in 2002 indicated that treatment admissions for prescription narcotics grew from approximately 12,500 in 1992 to 42,900 in 2002. Treatment admissions are those reported to SAMHSA's Treatment Episode Data Set (TEDS). In 2002 there were 1.9 million treatment admissions reported to TEDS, 4% of which cited prescription and OTC drugs as the primary substances of abuse (Office of Applied Studies [DASIS], 2005a). Although the DASIS reports are helpful in identifying some trends of drug abuse involving prescription drugs, the studies do not collect data on what portion of the drug abuse
statistics are directly due to drug diversion. The bulk of the TEDS admissions list the primary substances of abuse as illegal drugs and alcohol.

Testimony given by Dr. Ernest Cantley of the Stewart-Marchman Center in Daytona Beach, Florida, provided admission trends for the Center for Abuse of prescription drugs (Cantley, 2004). Statistics for the Center were used to substantiate Cantley’s statement that misuse and abuse of prescription drugs is increasing. Although his data showed a 260% increase in admissions for abuse of all prescription drugs between 2001–2003, the numbers are small (from 152 to 402 admissions). And although Dr. Cantley stated that “Our most significant problem is the abuse of prescription opiates in general and the drug OxyContin in particular,” the admission numbers do not support his characterization of a “significant problem.” Admissions to the Center with OxyContin as the primary problem were zero in 2001, 6 in 2002 and 26 in 2003, not large enough numbers to be significant, although Cantley testified that this was a “disturbing trend.” As mentioned in other studies in this chapter, the Center’s admissions do not distinguish between drug abuse and drug diversion. In addition, the statistics were not controlled for increased marketing of the Center, cost/reimbursement issue improvement for such admissions, and a decrease in such admissions in other nearby treatment locations. Once again the data presented have limitations when used to discuss the extent of the drug diversion problem.

One of the concerns with the collection and reporting of data related to drug diversion is the inconsistent collection of such data across the United States. No national parameters for such collection have been established, and even the DAWN
data which have been collected for several years point to inconsistency in the reporting of cause of death from drug abuse. The practice standards for attributing cause of death to drug abuse can vary from state to state and even county to county, since cause of death is a decision of the medical examiner or coroner. Narrowing the cause of death to distinguish diversion of prescription drugs is not even attempted.

The state of Florida, which publishes an annual Report on Drugs through the Medical Examiners Commission and the Florida Department of Law Enforcement, stated in its 2000 Report that “A drug was listed as having “caused” death [italics mine] when the medical examiner, after considering the circumstances, autopsy findings and toxicology findings, made the opinion that the drug was intoxicating” (Florida Department of Law Enforcement, 2003, p. ii). Thus, the cause of death is an educated opinion, based on some pre-set standards, which may or may not apply to the individual involved. As a result of these difficulties in identifying accurate drug abuse statistics, it appears to be much more difficult to identify drug diversion, a subset of drug abuse, with any accuracy.

However, even in the absence of clear guidelines, there is evidence as indicated in this section, that drug diversion is occurring, and probably increasing. Florida, through its Office of Drug Control (FODC) is one of the few states with extensive studies on drug abuse and selected studies on drug diversion. The program to determine the extent of abuse and diversion in Florida began in 1999, and the data collection and analysis has become more refined each year since. Florida now requires medical examiners to more clearly identify drugs that cause death as differentiated
from deaths where drugs were present. The NSDA was expanded for Florida at the state’s request, to gain a better picture of drug abuse for those age 12 and over.

Florida has gathered an extensive set of statistics on drug abuse and developed a comprehensive plan to address drug abuse. The diversion of legal drugs is discussed in the plan, but the plan provides no clear statistics on the extent of drug diversion in Florida. Furthermore, it cannot specify a trend in diversion other than to state that “The illegal diversion of prescription drugs has become a significant problem in Florida” with no documentation provided (Florida Office of Drug Control, 1999, pp. U-31–U-32). Statistics used by the FODC to suggest an increasing trend in drug diversion are often related to the use of OxyContin and other Schedule II drugs, which may not support the claimed increase in diversion. For example, in 2002 Florida reported 589 deaths where oxycodone was in the system. Annualizing the first 6 months’ data for the same statistic in 2003 produces 584 deaths with oxycodone present, which is actually a slight reduction in oxycodone presence. This, however, is just a small snapshot of the issue of drug diversion, which has not been reliably measured by any study.

In testimony to the Subcommittee on Criminal Justice, Drug Policy and Human Resources, FODC Director McDonough stated that “Florida has a serious problem with illegal prescription drug diversion and abuse” (McDonough, 2004, p. 1). As with other reports already analyzed, the statistics used to verify drug diversion are generally those establishing drug abuse, but not necessarily abuse that is the result of drug diversion. Statistics used in McDonough’s testimony were not
linked to any studies for verification; however, statistics such as 3,324 deaths in Florida in 2002 were caused by prescription drugs, and 5 Floridians die per day solely from prescription drug overdoses were provided in the testimony, without any reference to the analysis generating such statistics. The testimony does concede the lack of clear data when it reports that the Florida Grand Jury Report on Medicaid recipient fraud indicated that "it is almost impossible to know the true extent of the prescription drug abuse problem because so much of the problem goes unreported" (McDonough, 2004, p. 4). The testimony also states that drug diversion activity is complex; diversion can be a simple resale of a prescription on the street to wholesale doctor shopping, pharmacy shopping, pharmacy theft, theft from nursing homes and other institutions, or doctor/pharmacist arrangements, to organized crime (McDonough, 2004, p. 3).

Director McDonough does cite a few cases of drug diversion that have resulted in criminal investigations and penalties. One physician case resulted in a conviction, another in an arrest, another in practice sanctions, and a fourth physician was charged with manslaughter as of the date of the referenced testimony. The conviction and arrest were both linked to oxycodone investigations. Also cited in the testimony was a series of articles by the Orlando Sentinel regarding fraudulent prescribing of drugs to Medicaid patients (McDonough, 2004, pp. 5-6). This series was also linked to oxycodone abuse and was often quoted, but the Sentinel was forced to retract its accusations directed at OxyContin at a later date. An interesting comment from McDonough’s testimony was related to other causes of drug abuse.
He stated "that it may not be illegal diversion alone that contributes to the extent of the problem. It may also be fed by inappropriate degrees of classification and education" (p. 6). He also stated, "according to the Florida Medical Examiner's reports, the majority of drug-related fatalities occur from a lethal cocktail of several drugs" (p. 7). It is noted that not all the drugs in the cocktail are prescription drugs, with alcohol being the most common drug in the mix across the cases. The testimony includes a final statement emphasizing that drug abuse has multiple causes, only one of which is diversion of drugs (p. 9).

In a study done for Michigan Governor John Engler in 2001, the Michigan Commission on End of Life Care presented its analysis of possible drug diversion problems from the perspective of how investigations of such activity might affect pain management. The Commission concluded that Michigan had policies and programs that "impaired the delivery of quality pain care for Michigan citizens," and named the Official Prescription Program (a PMP) as one of those programs. Further, the Commission found that this program, directed at reducing diversion of Schedule II drugs, was ineffective, and that the amount of drug diversion the program had identified in its 10-year history was minimal. The Report stated that of the 192,000 licensed medical practitioners in Michigan in 2000, only eight cases of drug diversion had occurred (Thomason, 2001, p. 22). No source was provided for that statistic. The Report, targeted at improving pain management at the end of life, did not feel the incidence of drug diversion was significant enough to warrant the continuation of policies such as Michigan's OPP.
The common theme in all of the literature reviewed on the specific topic of drug diversion was that it was difficult if not impossible to quantify, and the default quantifier was drug abuse, which is a much broader problem than drug diversion. Also and importantly, all studies that looked at both abuse and diversion reported concerns with polydrug use—the presence of more than one strong drug in the abuse mix. In spite of the inability to more clearly identify drug diversion, 16 states had implemented full PMP programs by 2001 to help reduce and even prevent diversion. In light of the lack of good statistics which identify a significant increase in drug diversion and studies that support the role of public policies in preventing such activity, the benefits of more research regarding effectiveness and cost justification of PMPs seem clear.

Summary

Although the issues of pain management, prescription monitoring programs and drug diversion are reviewed in separate sections in this chapter, the topics are clearly connected. Studies of one of the three topics often mention at least one of the other two areas, and sometimes both. In general, the studies agree that people with severe chronic and acute pain conditions deserve to receive the best treatment available. The studies and reports also tend to agree that the diversion of legal drugs to illegal use is increasing. More credibility is given to the fact that drug abuse is increasing. The definition of drug abuse includes but is certainly not limited to drug diversion. Finally, PMPs are believed by many to be effective, but there is little
evidence in the literature to support such a belief. PMPs are also believed to be a barrier to good pain management, another assumption without credible evidence.
CHAPTER III

METHODOLOGY

This research consists of a qualitative case study and a quantitative analysis in the form of a multiple regression, in the belief that both research methods will allow for stronger conclusions than either study alone. This chapter will describe the development of the two study processes and reveal some of the unexpected barriers to the research that were imposed by actors within the regulatory and health care system in finalizing the design of the study.

The desirable goals of prevention of drug diversion and abuse even while continuing to assure the availability of appropriate drug therapies for pain management appear to be incompatible to many. This inference could be drawn from much of the literature reviewed for this research. Stated simply, those in law enforcement who are addressing the prevention of drug diversion and the larger arena of drug abuse are focused on that issue, and by virtue of their profession, generally pay less attention to the delivery of good pain management treatment. Those in the business of treating pain often tend to consider laws and regulations that address drug diversion to be barriers to good pain management, and correspondingly find enforcement activities to identify and prosecute suspected diversion to be a problem. Although leaders on both sides of the argument have publicly indicated a desire to collaborate (American Alliance of Cancer Pain Initiatives, 2001), in actual practice
collaborative efforts are not widespread and there is no formal national plan for such collaboration. This research methodology was designed to provide a more in-depth look at whether prescription monitoring programs to track and prosecute the illegal diversion of legal drugs are an effective tool in addressing that goal, or if such policies are overrated in their effectiveness, and serve to create policy that consumes public and private resources with little effect on the problem. The research design also includes a qualitative component in the form of a case study to determine if such laws encourage the under-treatment of pain.

Quantitative Methodology

The quantitative analysis draws its conclusions from the review of selected statistics from 15 states, during the 4-year period, 1998–2001. Seven of these states operated controlled prescribing programs during the study period, all of which imposed state regulations on the prescribing and use of Scheduled drugs. The controlled prescribing programs for these 7 states were adopted and implemented by 1997, with one exception. The states selected for this group are California, Illinois, Massachusetts, Michigan, New York, Texas, and Washington. The other 8 states had no controlled prescribing laws operating during the study time period. Those states are Colorado, Florida, Georgia, Louisiana, Maryland, Minnesota, Missouri, and Pennsylvania. The population in these 15 states represents approximately 60% of the U.S. population over the study years; thus, a majority of the nation’s citizens are included in the states selected for study.
All 15 of the states are included in the DAWN network of data collection and reporting, a rich source of information on drug-related emergency department visits for a majority of the population in each of the selected states, and the source of data used as the dependent variable in the multiple regression analysis. DAWN statistics are used as the dependent variable for the study, and are covered in depth in that section of this chapter.

Initially, it was the intent to limit the quantitative analysis to the diversion of legal drugs classified under Schedule II of the DEA’s drug classification system. This decision was made for two primary reasons. First, because drugs in this class are the most addictive, they have the highest potential to be sought for recreational and other illegal purposes, and are thus the most regulated drugs. Second, this class of drugs contains opioids, which are the drugs of choice for the treatment of severe, hard-to-manage pain, widely recognized as such by the medical community in the United States and by the World Health Organization. Therefore, Schedule II drugs have a role in drug diversion as well as treatment of pain.

As the research progressed, it was determined that the study needed to include some discussion of drugs in other Scheduled classes, because the issues with drug diversion were far more complicated than would be apparent if the study were limited to an analysis of Schedule II drugs alone. For example, in some states the prescribing of Schedule III drugs increased when more regulations were imposed on Schedule II drugs (Wastila & Bishop, 1996, p. 4). In addition, the proxy selected to measure drug
diversion in the multiple regression included some Schedule III and IV drugs, and it would have been impossible to use that proxy without the inclusion of such drugs.

Identification of Dependent Variable

Several potential variables were reviewed for inclusion in the development of the multiple regression used in the quantitative part of the analysis. The first challenge was to identify a variable that would represent the level of drug diversion in the areas of study. As was evident in the literature review, there are no data available that clearly measure drug diversion, specifically on a state-by-state basis. Initially, several potential sources of data were considered for use in creating a variable that would be representative of drug diversion. Deaths caused by drug diversion were considered as one of the data pieces. However, the means of collecting and reporting such deaths varies from state to state, and even county to county, with no credible consistency across the geographic areas in the study. One of the difficulties with death statistics related to drug diversion is the fact that death from illegal use of prescription drugs seldom occurs in isolation. Most drug-related deaths report the presence of multiple drugs in the patient’s body, some of which may be illegal drugs (cocaine, marijuana, and similar substances) and legal drugs such as alcohol as well as prescription drugs. In fact, it may be the very combination of drugs that caused the death, not any single drug in isolation. Additionally, it was determined that the reporting of cause of death can be very inconsistent across counties and the country as a whole. A variable that
measures deaths caused by the diversion of prescription drugs was thus not available and received no further consideration.

Another factor considered in building the dependent variable was arrests and convictions for drug diversion activity. It was felt that an assumption could be made to connect the increase in such activity to an increase in drug diversion. The effort to obtain arrest and conviction information included seeking such data from the DEA, from local law enforcement records, and from state law enforcement files. Research into this statistic revealed that the attention to drug diversion activity varied extensively from location to location, and the state and local data were determined to be without consistent credibility. DEA statistics, however, were more consistently reported, so extensive efforts were made to obtain DEA statistics on arrests and convictions for drug diversion. Arrests were considered relevant, even if no conviction occurred, due to the practice of settling cases out of court. In considering the inclusion of arrests data, it was assumed that several arrests that did not result in a conviction were actually legitimate drug diversion cases, but a number of factors prevented the case from going to the full conviction stage.

The attempt to obtain arrest and conviction data from the DEA involved an interesting, lengthy process. There are 20 state DEA Field Offices plus a Field Office in Washington DC. Each Field Office covers several states or a large area. For example, the Detroit Field Office covers activity in Michigan, Ohio, and Kentucky. The Miami Field Office covers the Bahamas as well as Florida. In addition to the state offices, several states such as Florida have District Offices in other selected areas.
throughout the state. Eighteen of the DEA Field Offices are involved in the 15 states included in this study. A listing of the DEA Field Offices and coverage areas are included in Appendix D.

In addition to asking for arrest and conviction data for drug diversion from the DEA, data on pharmacy theft and loss were also requested as a probable indicator of drug diversion, to be either included as an independent variable or as a control in the multiple regression equation development. An increase in pharmacy theft and loss would logically result in an increase in drug diversion, since drugs are stolen for illegal (that is, diverted) purposes. In seeking this data, an assumption was made that pharmacy theft and loss resulted in diversion in the same state where the pharmacy was located. Pharmacy theft and loss data are required to be reported to the DEA, on DEA form 106, and are authorized by the Controlled Substances Act of 1970.

The process to request the arrests, convictions, and theft and loss data was made to the DEA on an informal basis in early July 2004, followed by a full Freedom of Information Act (FOIA) request on July 19, 2004. Through a lengthy process which included repeated contacts with DEA staff and requests for assistance from Florida’s Congressman Allen Boyd and Senator Bill Nelson, the DEA repeatedly refused to provide the requested information. However, one year of theft and loss data were provided by the DEA, probably accidentally, and will be discussed in the analysis and results chapters. During the FOIA process, each of the DEA Field offices was individually contacted by phone, or mail or email if requested, for arrest and conviction information, and three Diversion Program Managers provided the
requested data for four states, willingly and with little concern. However, as the remaining Diversion Control Managers were contacted, the flow of information was blocked, with one Manager reporting that the "word from DC" was that statistics could not be released by the Managers, and they were prohibited from releasing any data directly to the researcher. Subsequent contacts with the DEA confirmed that the statistics desired for the dependent variable would not be available in a timely manner for this study. DEA contact information is provided in more detail in Appendix D.

DAWN Data

Although certainly not ideal, it was finally concluded that the most reasonable data available for measuring drug diversion came from the set of statistics gathered and analyzed by the Drug Abuse Warning Network, or DAWN. As required under Section 505 of the Public Health Services Act, the federal Substance Abuse and Mental Health Services Administration (SAMHSA) is the agency responsible for DAWN, and collects data on Emergency Department (ED) visits induced by or related to substance abuse, which includes abuse of both legal and illegal drugs. The DAWN program relies on a sample of hospitals in 21 major metropolitan areas (MSA's or metropolitan statistical areas) to submit such information. DAWN has been collecting data using this design since 1988, with earlier data collected since 1972. DAWN collects and reports data both by Drug Episode and Drug Mention, as defined below.
**Drug Episode:** A drug-related ED episode is an ED visit that was induced by or related to the use of an illegal drug(s) or the non medical use of a legal drug for patients aged 6 to 97 years.

**Drug Mention:** A drug mention refers to a substance that was recorded ("mentioned") during a drug-related ED episode. Because up to four drugs (and alcohol) can be reported for each drug abuse episode, there are more mentions than episodes cited in this report. (U.S. Department of Health & Human Services, 2003, p. 25)

This is an important distinction when using DAWN statistics, since each drug episode by definition can contain more than one drug mention. One reported visit can thus include up to four drug mentions plus alcohol. Because this distinction is not always provided, the reporting of drug abuse can be misinterpreted. For example, one patient’s visit to the ED could be reported as five mentions if four drugs and alcohol were present. It should also be noted that some drugs are not reported at all, if more than four and alcohol are found in the examination, as only the four most dominant are then reported. In this research, drug episodes are used in the design of the dependent variable for the study—Drug Diversion (DD).

DAWN data are collected by a DAWN designated “reporter” in each selected hospital in an MSA. This reporter reviews the medical records for each reportable episode. The patient is not required to be interviewed for data collection purposes and in fact may be unconscious or deceased. The patient must meet five criteria to be included in the DAWN report. The patient must be between 6 and 97 years of age, receive treatment in the hospital’s ED, and indicate that the visit to the ED was induced or related to drug use. The episode must also involve the use of an illegal drug, or a substance used illegally, and the patient’s reason for using the substance(s)
must have been dependence, suicide attempt or gesture, or psychic effects. The data are reported by metropolitan area. It uses sampling weights and produces estimates representing all ED drug episodes and drug mentions in the total coterminous U.S.

Statistics from the DAWN data that were used to create the dependent variable, Drug Diversion, are the estimates of drug episodes and drug mentions for psychotherapeutic agents and for narcotic analgesics and narcotic analgesic combinations. These categories were selected due to the number of Scheduled drugs, especially Schedule II and III drugs that are included. DAWN does not report state statistics based on the Controlled Substances Act Schedules, so it was impossible to limit the quantitative portion of this study to Schedule II drugs. DAWN defines drugs in each of these categories as follows.

**Psychotherapeutic agents** are divided into the following categories:

- **Antidepressants**
  - MAO Inhibitors
  - SSRI antidepressants
  - Tricyclic antidepressants
  - Miscellaneous antidepressants
- **Antipsychotics**
  - Phenothiazine antipsychotics
  - Psychotherapeutic combinations
  - Thioxanthenes
  - Miscellaneous antipsychotic agents
- **Anxiolytics, sedatives, and hypnotics**
  - Barbiturates
  - Benzodiazepines – this category excludes the benzodiazepine flunitrazepam (Rohypnol), which was assigned to major substances of abuse.
  - Miscellaneous anxiolytics, sedatives, and hypnotics
- **CNS stimulants.** This category excludes the CNS stimulants that were assigned to major substances of abuse: amphetamines, methamphetamine, and MDMA (Ecstasy).
Narcotic analgesics and narcotic analgesic combinations—This category excludes heroin, which is classified as a major substance of abuse. This category includes drugs reported to DAWN simply as opiates. (U.S. Department of Health and Human Services, 2003, pp. 43-44)

Identification of Independent Variables

As with the design of the dependent variable, several statistics were considered as independent variables. The presence or absence of a PMP was included as an independent variable since it is a primary focus of this research. In addition, the availability of statistics reporting deaths from the use of scheduled drugs was sought. It was determined that such statistics were not maintained consistently across the states in this study, and they did not clearly identify Schedule II and other scheduled drugs. Furthermore, death statistics themselves were very limiting and unreliable in reporting cause of death, as indicated earlier in this chapter. Because identification of controlled substances in the body can occur only through lab tests, there are certainly unknown numbers of deaths where drug-related causes go unidentified. For example, an individual who dies in a car accident without other suspicious evidence is likely to be reported as death by accident, even if the accident may have been caused by excessive use of drugs. In this case, unless an autopsy or other testing occurred, the presence of drugs may never be revealed.

Another possible statistic was the use or availability of Schedule II drugs, as measured by the DEA through their quota and distribution monitoring system. This information was initially considered because review indicated that the more a controlled substance was used in practice, the more likely it would be abused. As
Angarola and Joranson (1992) put it, "Experience has shown that the more a controlled substance is used in medical practice, the more it will appear in monitoring systems such as the Drug Abuse Warning Network." Additionally, the statistics are available on a state-by-state basis. In considering these data, it was assumed that a statistically significant increase in availability of strong medicines would also produce an increase in drug diversion. Use data, however, were rejected for the regression, because of the inability to factor in loss and theft data, and because the data were reported differently from the data used for the dependent variable. Quotas and production allowances are maintained by specific drug and chemical names, and not in the categories used by the DAWN program.

An increase or decrease in disease prevalence was another factor considered to independently increase or decrease the availability of medications and thus the opportunity to divert and use such medicines illegally. Initially, an increase in hospice patients, traditional users of strong drugs in the Schedule II and III categories, was reviewed for use; however, such numbers were not available in a reliable manner for all of the sample states during all the years of the study. Changes in the prevalence of diseases and diagnoses of conditions likely to increase the usage of Scheduled drugs (pain conditions, severe mental illness, painful cardiovascular and respiratory conditions) were also considered for use as independent variables, but accurate data in these categories were either not available at all, or not available in a reasonable, consistent format and timely manner. It is also difficult and seemingly impossible to extract such information from medical records, because many people with a chronic...
illness have multiple medical problems and multiple physicians, and the prescribing of
drugs cannot always be assigned to a certain disease with any supportable accuracy.

Cancer statistics, however, were available by state for the study period, and
were selected as an independent variable as representative of disease increase or
decrease. Cancer pain is widespread among cancer patients, and drugs in the
controlled substances categories, especially Schedules II and III, are often used to
control cancer pain along with related symptoms and side effects. The American
Cancer Society maintains statistics by year and by state for a number of cancer-related
categories. For this study, the ACS statistics on new cancer case by state was used as
an independent variable.

Demographic data were considered in various combinations, including age,
income, and education. After review of the characteristics of drug diverters and
abusers, it was determined that such information was not a predictor of drug
diversion, as such activity occurs within a wide range of different population
characteristics. However, population growth or decline as a whole was considered a
reliable and relevant independent variable and is used in the regression equation. The
assumption incorporated into the use of population is that an increase in population
will result in an increase in diversion activity. Population statistics were obtained from
the U.S. government census website.

*Model Specification*

The regression equation is \[ y = a + biX_i + e, \] where
\[ y = \text{drug diversion}. \]

\[ X_1 = \text{POP}, \text{population as taken from the U.S. Census figures and interim estimates}. \]

\[ X_2 = \text{NEWCAN}, \text{new cancer cases per 100,000, as provided by the American Cancer Society, } \textit{Cancer Facts and Figures, 1998–2001}. \]

\[ X_3 = \text{Absence or presence of a state PMP. Those states with a PMP are coded as 1; those states without a PMP are coded as 2}. \]

A \( y \)-intercept is included in the equation, because it is assumed that there would always be some drug diversion occurring, regardless of any action by government and other factors. Each of these variables is discussed below, with the limitations and assumptions presented.

\textit{Dependent Variable—Drug Diversion}

In order to measure drug diversion in a format that was compatible with population and new cancer cases, it was necessary to re-configure the DAWN statistics for each of the 15 states in the study with reference to the number of visits. Each state’s MSA DAWN reports were analyzed for each of the years of the study, a total of 60 DAWN reports. It was determined that some assumptions would need to be made to estimate the number of drug-related ED visits for drugs relevant to this research, if the DAWN statistics were used. The assumptions are covered later in this section; however, in the development of DAWN “visit” statistics, it is helpful to know that it is assumed that only one visit per person occurred during each study year.

DAWN reporters collect data on a number of factors, including the number of episodes reported each year and the number of mentions per year. For each episode,
there could be up to four drugs recorded per patient plus alcohol. Since only the episodes in the MSA hospitals are included, it was necessary to convert the MSA episodes to an estimate of the number of visits to the ED projected for the entire state.

Using SAMHSA statistics for MSA populations and DAWN MSA “mentions” for the same year, “mentions per 100,000 population” for the MSA area were calculated. DAWN also reports raw data on “mentions” and “episodes” for all DAWN drug categories, not just the categories used in this study. The number of annual “mentions” of the study’s selected drugs for each state was divided by the number of episodes to obtain the average number of mentions per episode. Stated another way, these calculations provided the number of drugs present per ED visit. This statistic was then divided into the DAWN number for “mentions per 100,000 population in the MSA area” to obtain visits per 100,000 MSA population. The number of visits per 100,000 in the MSA area was then projected over the full state, using census figures for the years of the study. Tables 2–5 contain the statistics and calculations used to determine the estimate of ED visits related to psychotherapeutic agents and narcotic analgesics/combinations that were used as the dependent variable in the multiple regression. The first seven states in each table are states with a PMP operating during the study period. The other eight states did not have a PMP in place during those years.
### Table 2

1998 ED Visits for States—Selected Controlled Substance DAWN Categories: Psychotherapeutic Agents and Narcotic Analgesics/Combinations

<table>
<thead>
<tr>
<th>State</th>
<th>1998 mentions/100,000 pop - MSA only</th>
<th>1998 pop/100,000-state</th>
<th>1998 mentions/episode</th>
<th>Visits X C = total visits for state 1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>California (SF, LA, SD-averaged)</td>
<td>106</td>
<td>326.83</td>
<td>1.55</td>
<td>68.82</td>
</tr>
<tr>
<td>Illinois (Chicago)</td>
<td>104</td>
<td>120.70</td>
<td>1.84</td>
<td>56.52</td>
</tr>
<tr>
<td>Massachusetts (Boston)</td>
<td>189</td>
<td>61.44</td>
<td>1.82</td>
<td>103.85</td>
</tr>
<tr>
<td>Michigan (Detroit)</td>
<td>138</td>
<td>98.20</td>
<td>1.87</td>
<td>73.80</td>
</tr>
<tr>
<td>New York (NY &amp; Buf-averaged)</td>
<td>69</td>
<td>181.59</td>
<td>1.70</td>
<td>40.59</td>
</tr>
<tr>
<td>Texas (Dallas)</td>
<td>141</td>
<td>197.12</td>
<td>1.86</td>
<td>75.91</td>
</tr>
<tr>
<td>Washington (Seattle)</td>
<td>167</td>
<td>56.88</td>
<td>1.67</td>
<td>100.00</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>1,042.76</strong></td>
<td><strong>70,945</strong></td>
<td></td>
<td><strong>42,749</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>State</th>
<th>1998 mentions/100,000 pop - MSA only</th>
<th>1998 pop/100,000-state</th>
<th>1998 mentions/episode</th>
<th>Visits X C = total visits for state 1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorado (Denver)</td>
<td>105</td>
<td>38.91</td>
<td>1.76</td>
<td>59.66</td>
</tr>
<tr>
<td>Florida (Miami)</td>
<td>82</td>
<td>149.08</td>
<td>1.67</td>
<td>49.10</td>
</tr>
<tr>
<td>Georgia (Atlanta)</td>
<td>136</td>
<td>76.36</td>
<td>1.88</td>
<td>72.34</td>
</tr>
<tr>
<td>Louisiana (New Orleans)</td>
<td>156</td>
<td>43.63</td>
<td>1.90</td>
<td>83.68</td>
</tr>
<tr>
<td>Maryland (Baltimore)</td>
<td>152</td>
<td>51.30</td>
<td>1.71</td>
<td>88.89</td>
</tr>
<tr>
<td>Minnesota (Minneapolis)</td>
<td>107</td>
<td>47.26</td>
<td>1.87</td>
<td>57.22</td>
</tr>
<tr>
<td>Missouri (St. Louis)</td>
<td>118</td>
<td>54.38</td>
<td>1.88</td>
<td>62.77</td>
</tr>
<tr>
<td>Pennsylvania (Philadelphia)</td>
<td>204</td>
<td>120.02</td>
<td>1.89</td>
<td>107.94</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>580.94</strong></td>
<td><strong>42,749</strong></td>
<td></td>
<td><strong>13,256</strong></td>
</tr>
</tbody>
</table>

Table 3

1999 ED Visits for States—Selected Controlled Substance DAWN Categories:
Psychotherapeutic Agents and Narcotic Analgesics/Combinations

<table>
<thead>
<tr>
<th>State</th>
<th>1999 mentions/100,000 pop - MSA only</th>
<th>1999 pop/100,000-state</th>
<th>1999 mentions/episode</th>
<th>mentions/D =&quot;Visits&quot; 1999</th>
<th>Visits X I = total visits for state 1999</th>
</tr>
</thead>
<tbody>
<tr>
<td>California (SF, LA, SD-averaged)</td>
<td>113.33</td>
<td>331.45</td>
<td>1.51</td>
<td>75.05</td>
<td>24,875</td>
</tr>
<tr>
<td>Illinois (Chicago)</td>
<td>107.00</td>
<td>121.28</td>
<td>1.83</td>
<td>58.47</td>
<td>7,091</td>
</tr>
<tr>
<td>Massachusetts (Boston)</td>
<td>163.00</td>
<td>61.75</td>
<td>1.82</td>
<td>89.56</td>
<td>5,530</td>
</tr>
<tr>
<td>Michigan (Detroit)</td>
<td>133.00</td>
<td>98.64</td>
<td>1.87</td>
<td>71.12</td>
<td>7,015</td>
</tr>
<tr>
<td>New York (NY &amp; Buf-averaged)</td>
<td>81.50</td>
<td>181.97</td>
<td>1.72</td>
<td>47.38</td>
<td>8,622</td>
</tr>
<tr>
<td>Texas (Dallas)</td>
<td>123.00</td>
<td>200.44</td>
<td>1.58</td>
<td>77.85</td>
<td>15,604</td>
</tr>
<tr>
<td>Washington (Seattle)</td>
<td>159.00</td>
<td>57.56</td>
<td>1.64</td>
<td>96.95</td>
<td>5,580</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>1,053.09</strong></td>
<td></td>
<td></td>
<td><strong>74,317</strong></td>
<td></td>
</tr>
<tr>
<td>Colorado (Denver)</td>
<td>121.00</td>
<td>40.56</td>
<td>1.71</td>
<td>70.76</td>
<td>2,870</td>
</tr>
<tr>
<td>Florida (Miami)</td>
<td>82.00</td>
<td>151.11</td>
<td>1.70</td>
<td>48.24</td>
<td>7,290</td>
</tr>
<tr>
<td>Georgia (Atlanta)</td>
<td>137.00</td>
<td>77.88</td>
<td>1.91</td>
<td>71.73</td>
<td>5,586</td>
</tr>
<tr>
<td>Louisiana (New Orleans)</td>
<td>141.00</td>
<td>43.72</td>
<td>2.00</td>
<td>70.50</td>
<td>3,082</td>
</tr>
<tr>
<td>Maryland (Baltimore)</td>
<td>164.00</td>
<td>51.72</td>
<td>1.75</td>
<td>93.71</td>
<td>4,847</td>
</tr>
<tr>
<td>Minnesota (Minneapolis)</td>
<td>110.00</td>
<td>47.76</td>
<td>1.93</td>
<td>56.99</td>
<td>2,722</td>
</tr>
<tr>
<td>Missouri (St. Louis)</td>
<td>121.00</td>
<td>54.68</td>
<td>1.85</td>
<td>65.41</td>
<td>3,577</td>
</tr>
<tr>
<td>Pennsylvania (Philadelphia)</td>
<td>194.00</td>
<td>119.94</td>
<td>1.87</td>
<td>103.74</td>
<td>12,443</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>587.37</strong></td>
<td></td>
<td></td>
<td><strong>42,416</strong></td>
<td></td>
</tr>
</tbody>
</table>

Source: SAMHSA DHHS-OAS D-24

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Table 4

2000 ED Visits for States—Selected Controlled Substance DAWN Categories: Psychotherapeutic Agents and Narcotic Analgesics/Combinations

<table>
<thead>
<tr>
<th>State</th>
<th>2000 mentions/100,000 pop - MSA only</th>
<th>2000 pop/100,000-state</th>
<th>2000 mentions/episode</th>
<th>Visits X O = total visits for state 2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>California (SF, LA, SD-averaged)</td>
<td>112</td>
<td>338.72</td>
<td>1.64</td>
<td>68.29</td>
</tr>
<tr>
<td>Illinois (Chicago)</td>
<td>113</td>
<td>124.19</td>
<td>1.83</td>
<td>61.75</td>
</tr>
<tr>
<td>Massachusetts (Boston)</td>
<td>183</td>
<td>63.49</td>
<td>1.74</td>
<td>110.47</td>
</tr>
<tr>
<td>Michigan (Detroit)</td>
<td>141</td>
<td>99.28</td>
<td>1.92</td>
<td>73.44</td>
</tr>
<tr>
<td>New York (NY &amp; Buf-averaged)</td>
<td>93</td>
<td>189.76</td>
<td>1.74</td>
<td>53.45</td>
</tr>
<tr>
<td>Texas (Dallas)</td>
<td>131</td>
<td>208.51</td>
<td>1.83</td>
<td>71.58</td>
</tr>
<tr>
<td>Washington (Seattle)</td>
<td>219</td>
<td>58.94</td>
<td>1.71</td>
<td>128.07</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>1,082.89</strong></td>
<td></td>
<td></td>
<td><strong>77,721</strong></td>
</tr>
</tbody>
</table>

| Colorado (Denver)            | 117                                  | 43.01                  | 1.73                  | 67.63                                   | 2,909                                   |
| Florida (Miami)              | 101                                  | 159.82                 | 1.74                  | 58.05                                   | 9,278                                   |
| Georgia (Atlanta)            | 127                                  | 81.86                  | 1.97                  | 64.47                                   | 5,278                                   |
| Louisiana (New Orleans)      | 153                                  | 44.69                  | 1.97                  | 77.66                                   | 3,471                                   |
| Maryland (Baltimore)         | 155                                  | 52.96                  | 1.73                  | 89.60                                   | 4,745                                   |
| Minnesota (Minneapolis)      | 121                                  | 49.19                  | 1.94                  | 62.37                                   | 3,068                                   |
| Missouri (St. Louis)         | 137                                  | 55.95                  | 1.93                  | 70.98                                   | 3,971                                   |
| Pennsylvania (Philadelphia)  | 204                                  | 122.81                 | 1.90                  | 107.37                                  | 13,186                                  |
| **TOTAL**                    | **610.29**                           |                        |                       | **45,906**                              |

Source: SAMHSA DHHS-OAS D-24

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Table 5
2001 ED Visits for States—Selected Controlled Substance DAWN Categories: Psychotherapeutic Agents and Narcotic Analgesics/Combinations

<table>
<thead>
<tr>
<th>State</th>
<th>2001 mentions/100,000 pop - MSA only</th>
<th>2001 pop/100,000-state</th>
<th>2001 mentions/episode</th>
<th>mentions/D=&quot;Visits&quot; 2001</th>
<th>Visits X U = total visits for state 2001</th>
</tr>
</thead>
<tbody>
<tr>
<td>California (SF, LA, SD-averaged)</td>
<td>126</td>
<td>345.33</td>
<td>1.68</td>
<td>75.00</td>
<td>25,900</td>
</tr>
<tr>
<td>Illinois (Chicago)</td>
<td>150</td>
<td>125.17</td>
<td>1.77</td>
<td>84.75</td>
<td>10,608</td>
</tr>
<tr>
<td>Massachusetts (Boston)</td>
<td>233</td>
<td>64.00</td>
<td>1.77</td>
<td>131.64</td>
<td>8,425</td>
</tr>
<tr>
<td>Michigan (Detroit)</td>
<td>193</td>
<td>100.05</td>
<td>1.93</td>
<td>100.00</td>
<td>10,005</td>
</tr>
<tr>
<td>New York (NY &amp; Buf-averaged)</td>
<td>116</td>
<td>190.75</td>
<td>1.69</td>
<td>68.64</td>
<td>13,093</td>
</tr>
<tr>
<td>Texas (Dallas)</td>
<td>122</td>
<td>213.41</td>
<td>1.86</td>
<td>65.59</td>
<td>13,998</td>
</tr>
<tr>
<td>Washington (Seattle)</td>
<td>255</td>
<td>59.93</td>
<td>1.72</td>
<td>148.26</td>
<td>8,885</td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td>1,098.64</td>
<td></td>
<td></td>
<td>90,914</td>
</tr>
<tr>
<td>Colorado (Denver)</td>
<td>118</td>
<td>44.28</td>
<td>1.72</td>
<td>68.60</td>
<td>3,038</td>
</tr>
<tr>
<td>Florida (Miami)</td>
<td>103</td>
<td>163.55</td>
<td>1.79</td>
<td>57.54</td>
<td>9,411</td>
</tr>
<tr>
<td>Georgia (Atlanta)</td>
<td>99</td>
<td>83.94</td>
<td>1.88</td>
<td>52.66</td>
<td>4,420</td>
</tr>
<tr>
<td>Louisiana (New Orleans)</td>
<td>182</td>
<td>44.66</td>
<td>1.89</td>
<td>96.30</td>
<td>4,301</td>
</tr>
<tr>
<td>Maryland (Baltimore)</td>
<td>211</td>
<td>53.83</td>
<td>1.79</td>
<td>117.88</td>
<td>6,345</td>
</tr>
<tr>
<td>Minnesota (Minneapolis)</td>
<td>145</td>
<td>49.85</td>
<td>1.88</td>
<td>77.13</td>
<td>3,845</td>
</tr>
<tr>
<td>Missouri (St. Louis)</td>
<td>167</td>
<td>56.36</td>
<td>1.94</td>
<td>86.08</td>
<td>4,851</td>
</tr>
<tr>
<td>Pennsylvania (Philadelphia)</td>
<td>239</td>
<td>122.98</td>
<td>1.87</td>
<td>127.81</td>
<td>15,718</td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td>619.45</td>
<td></td>
<td></td>
<td>51,929</td>
</tr>
</tbody>
</table>

The above data were used to calculate the dependent variable, the proxy for drug diversion. The total number of visits for each category of states for each year is presented in Table 6.

Table 6
Visits for Each Category of States Per Year

<table>
<thead>
<tr>
<th>Category of States</th>
<th>1998</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMP States</td>
<td>70,945</td>
<td>74,317</td>
<td>77,721</td>
<td>90,914</td>
</tr>
<tr>
<td>Non-PMP States</td>
<td>42,749</td>
<td>42,416</td>
<td>45,906</td>
<td>51,929</td>
</tr>
</tbody>
</table>

The numbers in each column represent the estimate of total state ED visits for psychotherapeutic agents and narcotic analgesics and narcotic analgesic combinations as defined previously. The seven PMP states have a greater population than the eight non-PMP states, which might explain the raw increase in number of visits and which also supports the literature and the assumption that more people equals more drug diversion. For example, the seven PMP states had an estimated total population of approximately 110 million people in 2001 and a corresponding 90,914 ED visits in the selected categories. For the non-PMP states, the population for 2001 was approximately 62 million, with 51,929 ED visits.

It was necessary to make the following assumptions in using the DAWN statistics for the dependent variable:

1. Each episode or visit is unique. No individual visits the ED more than once per year for drug-related reasons. There are no statistics available that would identify
repeat visits by individuals in any given year for drug-related reasons. Intuitively, there are probably some repeat visits, but an additional assumption is made that repeat visits are small in number, are not significant, and would not significantly affect the conclusions of this study.

2. DAWN statistics are collected by “reporters” at the selected hospital EDs. Much of the information is collected by observation or review of records. Although patients can be interviewed for the reports, in general they are not; thus, the drugs mentioned in the selected categories may not be “diverted” to recreational use. Drugs found in the body at the ED could be there for legitimate medical reasons. Reports on patients who are unconscious or dead upon arrival at the ED can be obtained only from the medical records. Such records are subject to accurate recording by medical personnel. For this portion of the research, it is assumed that such records are accurate, and that the selected drugs as identified are present illicitly.

3. DAWN limited the number of drug mentions reported to four drugs plus alcohol during the period of this study. For this study, it is assumed that these drugs caused the ED visit. Furthermore, it is assumed that the prescription drugs that caused the visit were diverted from approved medical uses—either they were obtained illegally or used in larger doses than prescribed.

4. DAWN collects data only from selected MSAs, which are large urban areas. It is assumed that conclusions drawn for DAWN data also apply to the rural areas of the states in the study, and at the same levels.
Independent Variables—Population, New Cancer Cases, and PMP

Three categories of data were used as independent variables for the regression equation: population, new cancer cases, and the presence or absence of a PMP. Population figures were obtained from the U.S. Census Bureau and can be accessed from the Bureau’s website, www.census.gov. Population estimates were used for the years 1998, 1999, and 2001, with actual census count figures used for 2000. Estimates were used as calculated by the Census Bureau for July 1 of the study years. An assumption was made that the mid-year estimates and the actual numbers for the census count year of 2000 were statistically similar for use in this study.

The variable, New Cancer Cases, was obtained from the American Cancer Society’s (ACS) publication, Cancer Facts & Figures for the selected years. This statistic was chosen over the Centers for Disease Control’s (CDC) statistics on cancer case counts by state, because it was assumed that New Cancer Cases would not be duplicated in subsequent years, and that each new cancer case represented one new person. The CDC data would include cancer cases that continue to be counted over several years, with the inclusion of some of the same cancer patients in more than one year. The ACS cancer data include all new cases for all sites, except non-invasive cancers such as basal and squamous cell skin cancers and in-situ carcinomas except urinary bladder. Chronic pain conditions often accompany cancer; thus, this variable was added to the regression equation to measure the effect of changes in disease prevalence in the diversion of the selected medications. Unlike other chronic diseases, cancer statistics were available for the years of the study, on a state-by-state basis.
New Cancer Cases thus becomes the proxy for increases or decreases in disease conditions that require the use of controlled substances.

Table 7 on the next page contains the population data and New Cancer Cases by state for each of the years of the study.

The presence or absence of a PMP was included to measure the effect of this type of prescription monitoring policy on the changes in drug diversion. Each of the PMP programs for the seven PMP states in the study was considered to equally influence drug diversion in its state, even though the parameters of the programs differed somewhat from state to state. The primary differences were the controlled substance category or categories that were covered by the state’s PMP, along with the years the PMP had been in place. During the period of the study, the covered drugs for the PMP study-states are as follows:

- California: Schedule II, since 1939
- Illinois: Schedule II since 1961
- Massachusetts: Schedule II since 1992
- Michigan: Schedule II since 1989
- New York: Schedule II and Benzodiazepines since 1972
- Texas: Schedule II since 1981
- Washington: Schedules II, III, IV, V since 1984 (for disciplinary purposes only)

In the regression model, a state with a PMP was given a value of 1, and a non-PMP state was given a value of 2.
Table 7
Population and New Cancer Cases

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<td>Louisiana</td>
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<td>Pennsylvania</td>
<td>12,281,054</td>
<td>68,400</td>
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</table>

The statistical analysis of the variables was done using a multiple regression format, using the SPSS computer program. Tests of statistical significance were run to determine the effect of a PMP on drug diversion and to identify correlation issues and reliability of the regression and the variables used. The results and their implications are presented in the next chapter.

Qualitative Methodology

In addition to the quantitative analysis of the levels of diversion of controlled substances, using DAWN statistics for the selected states, this research also includes a qualitative case study to identify perceived effects of controlled prescribing laws on drug diversion and pain management in Michigan and Florida. Michigan has operated with controlled prescribing laws from 1989 to the present, with its laws modified in 2002. Florida has been without such laws, but the state's legislature has considered passage of a PMP for at least the last 3 years. In addition, the Florida Office of the Governor includes an Office of Drug Control, which is focusing many of its resources on the drug diversion issues in the state.

Seeking and comparing the opinions of professionals within these two states with distinctly different policies for addressing diversion was considered a necessary component of the study, to determine if the opinions and experience of those who deal with these topics were consistent with the regression results from the quantitative analysis. Additionally, the literature review indicated that the perceptions of barriers
to pain management, addiction potential, and attitude towards drug abuse were a factor in how these issues studied were addressed by clinicians in the states with and without PMPs. Although it was beyond the scope of this study to conduct interviews in all 15 states, the case study analysis provides some interesting insights and relevant suggestions for further study.

The qualitative study consists of interviews with physicians, pharmacists, and law enforcement officials in the two states. Thirty interviews were conducted over the months of July through December 2004, with 15 subjects interviewed in each of the two states. Of those subjects, 3 were pharmacists, 8 were physicians, and 4 were law enforcement professionals in each state. Seven of the interviews were conducted by phone, and 23 were conducted in person.

Subjects were selected based on my personal knowledge of the subjects, as well as for access and credibility reasons. Subjects who were sought and not known personally were referred to me by mutual professional friends. This method of selecting the participants was considered important in obtaining frank opinions and encouraging free discussion of the research subject matter. Nearly all of the originally contacted subjects agreed to be interviewed, and the interviews were conducted at times and places selected by the participants. The interviews generally lasted 30–45 minutes, with a few lasting over an hour. Participants were asked a series of open-ended questions, a copy of which they received prior to the interview. During the interviews, additional questions were often added to the list, based on the comments and responses provided. The interviews produced some very rich information on the
subject of drug abuse and pain management, and allowed for the addition of many
insights from the perspective of those who deal with the issues on a daily basis as a
part of their jobs.

The general questions that were either asked of each participant or answered
by the participant without raising the question are provided below:

1. (For physicians and pharmacists) What, in your opinion, is the state
   of pain management in your state?
   (For law enforcement) What, in your opinion, is the state of drug diversion
   in your state?

2. (For physicians and pharmacists) What influences prescribing
   patterns for pain conditions—both chronic and terminal?
   (For law enforcement) What influences prescribing that results in drug
   diversion?

3. (For physicians and pharmacists) What factors influence the quality
   of pain management in your state?
   (For law enforcement) What factors influence the amount of drug
   diversion of Scheduled drugs in your state?

4. (For physicians and pharmacists) How do laws and policy affect
   drug diversion in your state, especially that of Schedule II drugs?
   (For law enforcement) How does the activity to control drug diversion
   affect pain management in (Florida) (Michigan)?

5. How do you think a PMP will affect drug diversion and pain
   management if enacted in Florida?
   OR
   How does Michigan’s PMP affect drug diversion and pain
   management in Michigan?

6. What can be done to decrease the diversion of legal drugs to illegal
   use?

7. What can be done to improve pain management in (Florida)
   (Michigan)?
8. What data do we need to have available to address drug diversion and measure the quality of pain management?

9. Would you like to add anything else?

Physicians were included as interview subjects because they are the primary prescribers of controlled substances and are the main resource for those seeking treatment for pain. Physicians are thus prime contacts for the diversion of prescription medicines, and with the exception of drugs that are lost or stolen, are a key access point for drugs that are used illicitly. That may be innocent or intentional on the physician's part, but either way, they play an important role.

Pharmacists were interviewed to include perspectives on their role in helping their customers understand pain medications, and advise on use. These participants are also the final decision makers in filling prescriptions. Pharmacists are often in a position to determine whether a prescription is legitimate, or is likely to fall into the wrong hands, or is being obtained for illegal use. They can also tell whether a physician's prescribing patterns have changed significantly. One pharmacist with whom I spoke during the early development of this research stated that he had been in business long enough to know intuitively the prescribing patterns of physicians who sent patients to his pharmacy. If a prescription or a series of prescriptions were presented that were significantly out of the ordinary for a particular doctor, the pharmacist would be alerted, and either call the doctor or consider reporting him or her. Pharmacists were also important to this research because they are likely to help identify other issues that may affect diversion activity and good pain management.
Law enforcement officials are included in the case study, because they brought a perspective on the need to control drug diversion that was unlikely to be voiced by the physicians and pharmacists. The law enforcement community sees the effects of drug diversion much more frequently than most physicians and pharmacists, not only on the users, but also on the friends and families of the users and indeed on the entire community. The inclusion of law enforcement officials as participants brought an additional perspective to the research, necessary to balance the perceptions of the practitioner community concerned with restrictions on prescribing.

During the participant scheduling and interview process, only 2 subjects declined to participate, and 1 other did not return phone calls. Nearly all of the subjects willingly extended their comments beyond the 30-minute time frame requested for the interview, and all expressed interest in the results of the research.

**Analysis of Interviews**

The interviews were in-depth interviews of experts in their fields. The interviews were recorded and transcribed by the researcher herself, to lend additional understanding to the comments and perspectives provided. The transcribed interviews were reviewed several times in the process of analysis of the information. Categories of analysis based on the questions asked were used to group responses, as were emergent categories that resulted from the interviews. The second edition of *Designing Qualitative Research* by Catherine Marshall and Gretchen Rossman (1995) and the second edition of *Case Study Research Design and Methods* by Robert Yin
(1994) were consulted to help organize the data and structure the analysis of the interviews. The interviews were conducted as required by the Human Subjects Institutional Review Board (HSIRB) of Western Michigan University.

The results of the qualitative research are considered together with the quantitative findings in drawing conclusions from the research. The qualitative study results provide a perspective on pain management and drug diversion from professionals who work in PMP and non-PMP states. The results are presented anonymously as required by HSIRB protocols.

A limitation of the qualitative research is that the participants were selected by the researcher rather than randomly selected. Although this assured that participants had knowledge of the topics and were able to address the research questions, it may have created a bias. Another limitation, already mentioned, is that participants were selected from only 2 of the 15 states in the study, so the results of the case study cannot be projected to the other states.

Results of the quantitative and qualitative parts of this research are presented in the next chapters, as separate analyses and in combination to provide reinforcement and add credibility to the research conclusions.
CHAPTER IV

FINDINGS, QUANTITATIVE ANALYSIS

Development of Regression Components

In reviewing the results of the data analysis, it is important to note again that there are no data that accurately measure the level of drug diversion in any state or the country as a whole. Drug diversion is hard to quantify using currently available information. The definition of drug diversion is also repeated as a reference in reviewing the results of the quantitative analysis. For the purposes of this study, drug diversion is defined as the illegal use of legal prescription drugs. This activity is not easy to quantify, since much happens in clandestine settings which are never known, much less investigated. Data on the abuse of legal prescription drugs—even controlled substances—are not collected in a consistent manner across the country. There are many cases where legal drugs are used illegally that are not captured and may never be captured in any reasonably accessible manner, and it is logical to assume that there are cases of suspected and possibly prosecuted drug diversion that are in fact the legal use of a controlled substance that went awry due to drug interaction or other environmental or individual circumstances. Because of the difficulty in collecting data to measure drug diversion, the statistical analysis used to test the influence of independent variables on the proxy used for drug diversion did not
produce substantial conclusions. However, it did provide some interesting insights that were reinforced by the qualitative analysis that is also a part of this research.

The multiple regression mode of analysis was used to determine the potential influence and functional relationship of selected data on the prevalence of drug abuse in the 15 states chosen for the study. This type of analysis uses mathematical methods to determine the extent of such relationship between variables. Correlation analysis was also employed to determine possible associations between two sets of data. Correlation differs from regression analysis in that the finding of a correlation between sets of data or factors does not imply a functional relationship. This is an important distinction, because a functional relationship implies a "cause and effect" environment, which then suggests the possibility of control of that environment. On the other hand, data or factors that are correlated may not create an influence; they are just frequently found together. Using professional football as an illustration, great fan support is often associated with a winning football team. However, great fan support does not make a football team win. So even though the two factors are usually associated with each other, a high level of fan support does not function to make a winning team. There is no cause and effect of significance.

In the search for data to address the research question, it was hypothesized that there would be no significant difference in the amount of drug diversion in the 15 study states during the years of the study, regardless of the presence or absence of a prescription monitoring program (PMP), and that in fact the increase or decrease in drug diversion was not caused by the presence or absence of public policy designed to
influence diversion activity. The data search included a review of numerous variables and data sources, as already discussed in depth in the methodology section. The selected data for the 15 states over the 4 years of the study were entered on a table using the statistical analysis program SPSS version 8.0. They are presented in Table 8 on the following pages. The dependent variable entitled “visits” in the table is the proxy value for drug diversion, and was calculated from DAWN (Drug Abuse Warning Network) statistics for the 15 states during the years of the study (1998–2001). Visits refers to the number of drug-related individual visits to emergency departments during the time period of the study. Only drug-related visits for the specific, controlled substance categories of psychotherapeutic agents, narcotic analgesics, and narcotic analgesic combinations as described in the methodology chapter were used. Statistical analysis was done using a multiple regression program within the SPSS software program.

The initial regression computation was run using all three of the final selection of independent variables—population, new cancer cases, and the presence or absence of a PMP. Population was selected as one of the independent variables to determine the effect of a growth in population on an increase or decrease in prescription drug diversion. There is a belief by some that drug diversion is primarily a function of the number of people in the country. This will be discussed in the section which reports the findings from the interviews conducted as a part of this research. New cancer cases were selected as a proxy for an increase or decrease in disease prevalence. The treatment of cancer is likely to include strong pain medications, so an increase in
Table 8

Values—Dependent and Independent Variables,
15 Study States, 1998–2001 (N = 60)

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<tr>
<th>Visits (Dependent Variable)</th>
<th>Population</th>
<th>New Cancer Cases</th>
<th>PMP</th>
<th>State</th>
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<tr>
<th>Visits (Dependent Variable)</th>
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<th>PMP</th>
<th>State</th>
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<td>2.00</td>
<td>Florida</td>
</tr>
<tr>
<td>4,420</td>
<td>8,394,795</td>
<td>31,100</td>
<td>2.00</td>
<td>Georgia</td>
</tr>
<tr>
<td>4,301</td>
<td>4,466,001</td>
<td>21,700</td>
<td>2.00</td>
<td>Louisiana</td>
</tr>
<tr>
<td>6,345</td>
<td>5,383,377</td>
<td>23,500</td>
<td>2.00</td>
<td>Maryland</td>
</tr>
<tr>
<td>3,845</td>
<td>4,985,202</td>
<td>20,600</td>
<td>2.00</td>
<td>Minnesota</td>
</tr>
<tr>
<td>4,851</td>
<td>5,636,220</td>
<td>28,400</td>
<td>2.00</td>
<td>Missouri</td>
</tr>
<tr>
<td>15,718</td>
<td>12,298,363</td>
<td>68,400</td>
<td>2.00</td>
<td>Pennsylvania</td>
</tr>
</tbody>
</table>

*Population is total population for the state for the years indicated, per the U.S. Census figure. New Cancer Cases for the year, per the American Cancer Society. Existence (1) or non-existence (2) of a PMP.*
number of cancer cases was assumed to cause an increase in the amount of controlled substances in use. The variable PMP (prescription monitoring program) represents the presence or absence of specific public policy that is implemented with the belief that it will decrease drug diversion.

This model with three independent variables produced an $R^2$ of 85.1, indicating the model explained 85.1% of the variance in the dependent variable. This indicates that 85.1% of the variation in drug diversion is explained by the three independent variables. The relationship between the dependent variable and the independent variables was thus highly significant, indicating the variance is not likely to be due to sampling error. The results of the three-variable regression model are presented in Table 9, which reports the $R^2$ and the standard error of the estimate of 2,225, which is the amount of predicted error in the estimate of the dependent variable, drug diversion, that the regression equation produces. Table 9 below contains the model summary.

Table 9

<table>
<thead>
<tr>
<th>Model</th>
<th>$R^2$</th>
<th>$R^2$</th>
<th>Adjusted $R^2$</th>
<th>Standard Error of the Estimate</th>
<th>$F$ Change</th>
<th>$d/1$</th>
<th>$d/2$</th>
<th>Sig. $F$ Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.922</td>
<td>0.851</td>
<td>0.842</td>
<td>2,224.66</td>
<td>106.2</td>
<td>3</td>
<td>56</td>
<td>0</td>
</tr>
</tbody>
</table>

*Note. Predictors: (Constant), PMP, New Cancer Cases, Population per U.S. Census figures.*
Table 10 was developed to identify statistics for the independent variable coefficients and a value for the constant or y-intercept for the model. This analysis provides numerical coefficients for each of the three independent variables and assigns a positive or negative value to each variable's influence on the estimate of the dependent variable, drug diversion. Using the data provided in Table 10, the following regression equation was determined.

\[
\text{Visits (Drug Diversion) = 2189.928 + 7.134(POP/10,000) - 2.225(Newcan/100) - 504.166(PMP)},
\]

where "visits" is the proxy for measuring drug diversion in each of the states in the study.

<table>
<thead>
<tr>
<th>Model</th>
<th>Unstandardized Coefficients</th>
<th>Standardized Coefficients</th>
<th>t</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Constant)</td>
<td>2189.928</td>
<td>1339.257</td>
<td>1.635</td>
<td>.108</td>
</tr>
<tr>
<td>Population, per U.S. Census figures</td>
<td>7.134E-04</td>
<td>.000</td>
<td>1.012</td>
<td>.000</td>
</tr>
<tr>
<td>New Cancer Cases</td>
<td>-2.225E-02</td>
<td>.030</td>
<td>-.120</td>
<td>.459</td>
</tr>
<tr>
<td>PMP</td>
<td>-504.166</td>
<td>671.861</td>
<td>-.045</td>
<td>.456</td>
</tr>
</tbody>
</table>

*Note.* Dependent Variable: Annual Visits to ED departments per DAWN stats, for selected drug mentions. Predictors: (Constant), PMP, New Cancer Cases, Population per U.S. Census figures.

Review of the raw data showed that the number of new cancer cases generally increased when population increased, which means that the influence of population
and new cancer cases on drug diversion may overlap, with their individual influence being questionable as well as creating uncertainties with the regression equation as a whole. Therefore, the correlation of independent variables to each other and to the dependent variable were calculated, to test for multicollinearity and singularity concerns. Multicollinearity occurs when variables are highly correlated (0.90 and above) and singularity is when they are perfectly correlated. When multicollinearity exists in a regression matrix, the independent variables are interrelated, which makes the regression coefficients unreliable. The test for multicollinearity and singularity were run using the SPSS software, and are presented in Table 11.

The analysis shows that population and new cancer cases are indeed highly correlated, as might be expected. The correlation between population and new cancer cases is .946, verifying the very high interrelationship between the two variables. With this level of multicollinearity, the model does not allow for a determination of the separate effects of population and new cancer cases. With a multicollinearity over 0.70 statistical problems occur, with the independent variables interrelated, and yet affecting the dependent variable differently (Wulder, n.d.). The regression coefficients are unstable and unreliable.

In consideration of this finding, the regression was re-run twice. The variable population was removed from the first run, and new cancer cases from the second run to determine if the results would thereby improve. Both new runs thus contained two independent variables, one run with just population and PMP as the independent variables, and the other with new cancer cases and PMP as the two independent
Table 11
Correlations, Dependent and Independent Variables, 1998–2001 (N = 60)

<table>
<thead>
<tr>
<th>Dependent Variable: Annual Visits to ED departments per DAWN stats, for selected drug mentions</th>
<th>Population, per U.S. Census figures</th>
<th>New Cancer Cases</th>
<th>PMP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pearson Correlation</td>
<td>1.000</td>
<td>.920</td>
<td>.855</td>
</tr>
<tr>
<td>Dependent Variable: Annual Visits to ED departments per DAWN stats, for selected drug mentions</td>
<td>.920</td>
<td>1.000</td>
<td>.946</td>
</tr>
<tr>
<td>Population, per U.S. census figures</td>
<td>.855</td>
<td>.946</td>
<td>1.000</td>
</tr>
<tr>
<td>New Cancer Cases</td>
<td>−.493</td>
<td>−.492</td>
<td>−.416</td>
</tr>
<tr>
<td>PMP</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

variables. Both new runs provided less reliable results than the first run with all three variables. In both additional runs, the $R$ Square value was reduced but not significantly reduced, and the standard error of the estimate was increased. Thus, neither of the new runs was determined to be an improvement. Interestingly, new cancer cases as a variable is negatively correlated in the three-variable regression, but positively correlated in the two-variable analysis (Newcan and PMP). This confirms the concerns over instability in the three-variable equation and the strong and unreliable relationship between population and new cancer cases.
Some Observations

Although no significant conclusions can be drawn from the multiple regression results, there appears to be a positive association between an increase in a state’s population, an increase in new cancer cases and an increase in controlled substance-related visits to selected metropolitan area emergency departments. Such a connection makes sense. Importantly, the fact that drug diversion and population are positively related was suggested by several of the participants in the qualitative portion of this research. Comments such as “drug abuse will always be here” and “more people” or “more availability of drugs,” meaning an increasing supply of drugs available to more people, were mentioned in various interview contexts as predictors of drug abuse. At least some of the subjects interviewed for this research believed that drug abuse is simply a function of the number of people in an area. More information on that topic will be included in the interview results chapter. However, for statistical analysis purposes, the high correlation value suggests that the variables are redundant and may bring the same issue to the analysis. For that reason, although there is a clear association between variables, no functional relationship has been proven.

It would also seem logical that an increase in new cancer cases would be associated with an increase in population. Cancer is the second leading cause of death (CDC website, 2005, National Center for Health Statistics–Fast Stats) and a disease modality that requires extensive use of strong pain medications such as the controlled substances that are the subject of this study. The use of new cancer case statistics was thus considered a reasonable proxy for diseases that promote more extensive use of...
the subject medications and as a proxy for measuring increases and decreases for such need from a medical perspective. Unfortunately, the correlation with population is too high to make it a reliable variable, since the high correlation suggests that both variables are measuring much of the same thing. Stated another way, new cancer cases appear to also be associated with a growth in population, so population growth is probably included within the cancer variable as well as the population variable.

Limitations of DAWN Data as a Proxy for Drug Abuse

Some limitations of the use of DAWN data were mentioned in the methodology chapter. It is important to emphasize that “although DAWN is capable of detecting certain drugs of abuse before their appearance in other data systems, findings from DAWN alone cannot define an emerging drug abuse problem or quantify precisely the abuse potential of prescription drug products. Instead, DAWN identifies sentinel events—indications of a potential drug abuse problem . . .” (U.S. Department of Health and Human Services, 2003, p. 111).

In its review of the usefulness of DAWN data as a measure of drug abuse, SAMHSA (the Substance Abuse and Mental Health Services Administration) analysis provides some commentary as both limitations and in defense of DAWN as a tool (U.S. Department of Health and Human Services, 2003, pp. 106–111). Limitations include:

1. DAWN data were intended to be reported where “intent to abuse” was present. In reality, it is hard to distinguish such intent since intent is usually
inconsequential to care, subjective, and not a priority when an individual presents for treatment. Thus, intent was impossible to collect in all cases, and some visits may be missing from the DAWN data.

2. Some people may visit the ED more than once per year with a drug abuse problem. DAWN does not distinguish visits by person, so the numbers of individual visits may be overstated because of the research assumption that each visit is one different person. However, the extent of such overstatement was assumed to be insignificant for purposes of this study.

3. A report of opiates can include either narcotic analgesics (prescription opiates) or heroin, which cannot always be distinguished from a prescription analgesic due to chemical actions. Thus, the statistics for prescribed narcotic analgesics may include some use of illegal drugs.

4. DAWN statistics show only one dimension of drug abuse—those presenting at the ED departments of selected hospitals. Only a fraction of abuse cases are a part of DAWN statistics, which would imply that DAWN statistics understate the prevalence of prescription drug abuse. However, the DAWN statistics have been used over the years to verify claims of increases in drug diversion and abuse of prescription medications.

In defense of the use of DAWN statistics, SAMHSA offers these comments:

1. The DAWN data show an increasing trend in the abuse of “other substances”—the drugs that are the subject of this research. Over the period of 1995–2002, the use of narcotic analgesics increased 260%, and the use of benzodiazepines
increased 38%. Both categories are included in the controlled substance schedules. Thus, it was concluded, for purposes of this study, that the DAWN data’s ability to show increases and decreases provide a sufficient case for use as the dependent variable and proxy for drug abuse of controlled substances.

2. Although only 21 metropolitan areas are included in the DAWN information used for this study, those 21 areas are located in states that comprise the majority of the U.S. population.

3. SAMHSA analysts themselves state that “ED visits are one useful indicator of the drug abuse in communities” (U.S. Department of Health and Human Services, 2003, p. 110).

Conclusions

Although the quantitative model is not as reliable as desired, some conclusions can be proposed.

First, there does not appear to be a significant correlation between the presence or absence of a PMP and the number of controlled substance drug abuse cases, using DAWN statistics as the proxy for such abuse. In fact, the presence of a PMP is negatively correlated to the number of DAWN cases as presented in the analysis. This means that a policy such as a PMP may actually increase the recorded incidences of abuse. From an analysis perspective, this could mean a number of things. For example, on one hand it could be interpreted to mean that a PMP causes more attention to be placed on the potential for abuse, with more cases brought to the
ED and more attention to determining abuse by the DAWN reporters because of the heightened awareness that a state law would generate. On the other hand, it could mean that a PMP does not have anything to do with the incidences of abuse and the absence of such a policy may in fact be better for a state. One could speculate that law enforcement activity directed at identifying abusers is stronger in states without PMPs because there is no such law that can be relied on, thus “street” enforcement must be more focused. Or maybe less public attention is paid to abuse issues in states without PMPs; thus, it is not a publicly reinforced activity, or is not a priority for reporting. Regardless, this result of the regression does suggest the need for further study, since the implementation and annual costs of PMP policies can be substantial and are not justified if PMPs are ineffective.

Secondly, there is a clear connection between a sheer increase in numbers of people and the DAWN trends. This reinforces most instinctive and anecdotal evidence, but leaves policy makers with a dilemma. As the population of a state increases, should the government dedicate more resources (money and people) to the prevention of prescription drug abuse, or should it try to stem the trend by creating policies that might provide law enforcement with additional tools that would make the existing resources more efficient? And if additional policies are a choice, do they really work, or just create additional costs for the citizens? There are other issues that would need consideration before a simple answer is offered, such as public education needs, additional training for health care professionals, and a number of prevention
programs that might make a bigger impact on stemming abuse than the presence of additional policies targeted only at the law enforcement dimension of the problem.

The primary conclusion that can be drawn from the extensive efforts to quantify a response to the research question is that there is just not enough data available to justify or not justify the presence of a PMP. In all of the data that were analyzed for possible use in the regression, and in the limited data that were finally included in the regression, there is no evidence that PMPs have anything substantial to do with the trends related to abuse of controlled substances in the United States. Without further study, it would be unwise to recommend that state governments incur the costs of such policies, and it might be suggested that such activity would take the focus away from activities that might actually have more of an impact on reducing the illegal use of controlled substances, thereby delaying the implementation of a better solution.
CHAPTER V

THE CASE STUDY

Overview

The application of public policy and the delivery of health care services related to pain management happen at the point of service, when professionals incorporate their personal values and their interpretation of such policies into their interaction with the people they serve. When regulations differ between states, it is theorized that behaviors and perceptions would also be different. The purpose of including a case study in this research was to learn such behaviors and perceptions from the professionals involved in pain management and drug diversion issues, and to compare differences between two states. The case study includes direct interviews with 30 individuals, 15 working under Michigan laws and 15 working under Florida laws. The people selected for the interviews were grouped into three categories: law enforcement, pharmacists, and physicians. There were four law enforcement professionals, three pharmacists, and eight physicians interviewed in each state.

Interviews were conducted between July 15 and December 31, 2004. Twenty-three interviews were conducted in person and seven over the phone.

The 30 subjects had significant knowledge of the issues surrounding pain management, drug diversion, and prescription monitoring policies in their respective states, both individually and as a group. During the period of the study, Michigan had
a PMP, and Florida did not. However, legislators in Florida were considering the implementation of such a program as a means to control drug diversion. The PMP in Michigan was known as the Michigan Official Prescription Program (OPP) and during the time period of this study, required physicians to write all prescriptions for Schedule II drugs on a special prescription pad. This meant that physicians licensed to prescribe controlled substances had to carry two prescription pads if they wanted to prescribe Schedule II drugs. Those prescription forms were required to be forwarded after dispensing to a state agency for use in review of prescribing patterns and as potential evidence for investigation and prosecution of suspected drug crimes.

This caused an additional paperwork burden and created some fears of oversight, which caused much discontent within the physician community. Michigan eventually repealed the OPP program, and replaced it with the Michigan Automated Prescription System (MAPS), which eliminated the special prescription pad and requires electronic submission of prescriptions for drugs in Schedules II–V. Among other features, the MAPS allows physicians to query the MAPS database to determine the number of drugs a patient is obtaining from Michigan pharmacies. Florida legislators have considered passing laws to implement programs with characteristics of the OPP and MAPS for at least 3 years. Thus, the environment for prescribing and therefore for the availability of strong drugs was different in the two states. This case study was designed to identify how those differences translated into practice.
It is important to note that persons selected for the interviews were not chosen because of any particular national expertise in the research topic; rather, subjects were selected because they were able to speak on the issues from a point of service perspective. Individuals selected were either known to the investigator or selected based on recommendations by people who were familiar with the research topic.

The general interview structure and questions are presented in the Methodology Chapter. Early in the interview process, it was determined that some participants wanted to talk about the role of pharmaceutical representatives and companies in the delivery of medications for pain management, as well as the impact of internet pharmacies on the availability of Scheduled drugs. Thus, queries were added to the basic interview structure to assure that all participants were given an opportunity to discuss internet pharmacy and pharmaceutical representative influence, if such topics were not voluntarily mentioned. Nearly all of the subjects spoke passionately about the topics, with clear differences in emphasis depending on the profession of the participant. Distinctions in attitude or opinion between Michigan and Florida were not so clear. All of the interviews were 30 minutes or longer, with several individuals' participation much longer, in several cases up to an hour. The results of the interviews are presented by professional category, with differences between the two states noted.
Law Enforcement

Law enforcement participants included a sheriff from each state; two government bureaucrats, one from each state; one DEA representative; and three officers from state law enforcement divisions. Responses are reported by category of inquiry.

On Drug Diversion

One of the queries made of all interview participants was their opinion on the severity of the problem of drug diversion in their state. With one exception, all individuals in the law enforcement category indicated that drug diversion had increased in their respective state and continues to be a growing problem. Those interviewed in Florida made comments such as, drug diversion is “growing at an exponential rate,” “prescription drug abuse is far more of a problem than realized,” “illicit drug diversion is the most critical problem we have (in the area of drug abuse),” and “Florida is one of the most rapidly growing states for drug diversion—worse than other states.” One Florida participant made the strong statement that “It is a runaway problem, becoming an epidemic.” Comments from the Michigan participants included: “Drug diversion is a significant problem,” “has gone up quite a bit,” “Michigan has a larger than average problem with drug diversion than the rest of the country,” and (the exception) “drug diversion in Michigan has stayed the same for at least the past 3 years.”
Participants were asked how they formed such opinions. The responses were more varied, with some respondents making general statements of perception, and others actually citing some statistics. Florida law enforcement participants reported an increase in the number of cases “being made,” increased advertising by pharmaceutical companies which increases supply, population growth which also increases the supply, and an increase in the number of deaths with controlled substances in the deceased’s blood. A Michigan respondent stated he compared the current diversion of legal drugs to similar problems when he first began his law enforcement career, and reported that he felt there was much less diversion activity in the past. Other Michigan respondents used information from law enforcement activity such as jail bookings. Data sources cited by one respondent included ARCOS data and DAWN data, plus “general information” from coroners. There were two mentions (one from each state) of the dilemma caused by the presence of multiple drugs in the identification of actual cause of death.

Thus, while there appeared to be agreement that drug diversion was a growing problem, the information used to reach that conclusion was extremely varied, from a “gut feeling” based on experience and anecdotal evidence to an interpretation of actual statistics.

Respondents were questioned on what influences a physician to divert drugs or put a physician in a position where prescriptions are diverted. Interestingly, law enforcement participants from both states cited money as the primary influence—comments included “pure greed,” “it’s big money,” and “money for scripts kind-of
atmosphere.” A close second was addiction of the physician, with six of the subjects indicating that as an influence. Two participants cited instances of trading drugs for sex.

On Influencing Choice of Drugs

Of note here was the discussion centered around physicians who are perceived to be fooled by their patients into providing drugs that are then diverted, or who are not felt to be up-to-date on drugs. Some of the respondents talked extensively about physicians who are “duped” by their patients, or “too soft,” or victims of time pressures that prevent the needed interactions with patients—“production line medicine” was a phrase that was used. Two of the subjects talked extensively about the responsibility of the physician in learning more about available new drugs before prescribing, and one person stated that physicians should not be allowed to prescribe controlled substances without additional, post-medical school training.

Five of the subjects (four from Florida and one from Michigan) cited the influence of pharmaceutical companies on prescribing patterns and choice of drugs. Those who commented were not overly critical of pharmaceutical company representatives, recognizing the natural business activities of such companies. However, comments like “oversell new drugs,” “gonna make as many as they can sell,” and a discussion of company marketing techniques used were a part of the conversations.
Respondents were queried on how they felt pain management was affected by law enforcement activity. In general, the four participants from Florida have stronger feelings than Michigan respondents about the existence of a “chilling effect” on proper prescribing as a result of such activity. One stated that we “cannot let patients suffer because of diversion,” a comment that was supported by others in the study. However, he also stated, “by the same token, some doctors need to be arrested.” One felt a PMP would provide doctors with more information and thus reduce the chilling effect on proper prescribing. Another acknowledged that “many doctors are now stating [that they are] leery to prescribe certain medications . . .” However, an interesting statistic presented by one of the participants was that only 50 physicians had been arrested in the entire country in the previous year (2003).

Three of the four Michigan subjects did not acknowledge a chilling effect on pain management. The other stated that he had not seen any such effect on physicians who were pain management specialists. Another stated he never did get a lot of information on the failure of physicians to provide adequate pain management, and in fact Michigan had seen an increase in the prescribing of Schedule II drugs since Michigan’s new electronic prescription system (MAPS) went into effect, thereby indicating to him that pain management had improved. (A chilling effect could theoretically reduce the prescribing of strong, Schedule II drugs.) This same person felt that pharmacists should have a bigger role in the final choice of prescriptions for the patients. Another stated that a chilling effect, if one existed, might be beneficial.
and said, “Yeah, we may have a chilling effect on some of these doctors that are just borderline, but maybe that’s good.”

All of the law enforcement study participants talked about addiction problems at some time during their interviews, and all expressed a concern over such addiction and the physician’s role in addressing addiction to prescription drugs. Several incidences were cited in the course of the interviews, some describing physicians who prescribe without doing a medical exam or only a feeble attempt at an exam (“taking blood pressure through a winter coat”).

There was a clear concern over the wide reach of drug addiction, with one sheriff stating, “I’m of the belief that everything comes back to drugs. Anything to do with crime. . . . It always seems to get back there somehow.” He cited several crimes including homicides, all of which were committed over drug needs, but noted that such connection was not made on the arrest report. He said, “Unfortunately, when it comes time for sentencing, they’re sentencing the guy for armed robbery, for car jacking, or whatever. They’re looking at that as the violent crime.” He felt that such reporting diluted the statistics on the extent of drug crimes. It should be noted that he was referring to all drugs, both legal and illegal.

*On Influencing Prescribing–Pharmaceutical Issues*

Some commented on the role that pharmaceutical companies and pharmacies play in drug diversion. Two of the subjects indicated that pharmacy company representatives unduly influence some physicians’ choice of pain medications, but one
stated that the education provided to physicians by these representatives was good.
Six of the eight law enforcement officials indicated that criminal activity in pharmacies
was also a concern. In both states, laws were cited that require pharmacies to report
suspicious prescriptions; however, those laws are difficult to enforce. The concept
that pharmacies are in business to sell prescriptions, which can discourage such
reporting (by turning away business) was mentioned, but one Michigan respondent
did state that more pharmacists turn in drug diversion leads than physicians—about
four times as many. Two Florida respondents and two Michigan respondents reported
cases of illegal pharmacy activity and pharmacy thefts. One respondent referred to the
temptation to “Mom and Pop,” or locally owned operations, where the owners turn a
“blind eye” to a questionable prescription, as opposed to a chain operation where
databases and prescription histories can be reviewed, and financial incentives are not
as personal.

Four participants, two from each state, talked about the growing drug
diversion problems that are connected to internet pharmacies. Both states have laws
that make it illegal to sell drugs over the internet without a defined examination, but
again, those laws are hard to enforce. Although such pharmacies must be licensed in
the state of sale, comments included “hard to track,” “only catch by complaint,”
“running different websites,” a source of “dangerous diversion of prescription drugs,”
and “not enough investigators in Florida alone to handle internet pharmacy (activity).”

When asked about the role of pharmaceutical companies and their
representatives’ influence on diversion activity, none of the participants indicated they
felt the sales approach by pharmaceutical company staff encouraged criminal activity. Mentions were made of strong marketing techniques and the use of gifts to influence the use of their company's drugs, but no culpability was perceived.

Effect of Public Policy, Regulatory and Law Enforcement Activity

During the period of time assigned to the quantitative study (1998–2001), Michigan had an active prescription monitoring program, which was eliminated in 2003 in favor of an electronic database for Scheduled drugs. The prescription monitoring activity moved from a reporting of Schedule II prescriptions through a special prescription pad, to the electronic reporting of prescriptions for all legal Scheduled drugs, with no special form or pad required. This eased the administrative burden on physicians, but still captured prescribing patterns. Florida has never had a PMP or anything similar, but has attempted to pass legislation to implement a similar program during at least three legislative sessions. Comments on laws, policies and PMPs differed between the two states in this case study, because of the difference in the regulatory climate.

However, there was consistent appreciation for the benefits that a PMP would bring to the efforts against drug diversion. All eight law enforcement participants supported a monitoring program or some additional data collection that would assist in the identification of illegal prescribing. Interestingly, the Michigan respondents (where a PMP—the MAPS—is operating) were less passionate in their responses, with two of the four Michigan participants not even familiar with Michigan's MAPS.
One Michigan respondent stated that the laws on the books were fairly effective, but enforced inconsistently. That comment about inconsistent enforcement was supported by another participant who also stated that such laws should not be created to address specific events or specific drugs, but to prevent bad outcomes. The Michigan subjects were also more likely to feel the real beneficiaries of a PMP are the physicians and pharmacists who are able to use the MAPS to track prescription activity of their patients and those wanting to become their patients. However, those “real time” benefits are limited, because prescription records are generally not available on the database sooner than 30 to 45 days from the date of the sale, which means an inquiring physician can learn what drugs a patient obtained 30 to 45 days ago, but not last week.

The Florida participants were very supportive of implementing a PMP, making statements such as PMPs are “a fantastic tool,” and would “bring down the death rate” from illicit use of prescription drugs. Two others felt that a PMP would not exert a chilling effect on pain prescribing, but would actually make proper prescribing more possible, since physicians would be able to obtain a patient’s prescription history before finalizing treatment. (However, with the 30- to 45-day lag time that Michigan reported, the PMP would be unlikely to be of assistance during a patient’s visit.) One of the Florida participants also stated he would support a mandated special prescription pad for controlled substances, regardless of the passage of a PMP. Florida law enforcement participants were not optimistic about the passage of a
Florida PMP, stating that legislators, physician groups, and consumer rights organizations had opposed such laws when introduced in the past.

With one exception, all participants cited other problems with the environment that hindered the anti-drug diversion activity in their state. One from each state expressed concern over the cost of additional laws. Other issues included a concern over abuse of illegal drugs and of alcohol, which would not be addressed by a PMP; the need for more accountability; need for a national drug database as opposed to just state by state records; more physician education; more drug abuse treatment funding, more law enforcement officials; and better communications. There was no perceived indication that a PMP was or would be a key factor in the prevention of abuse of legal drugs. Rather it is a complicated problem, with no solution in sight.

*On Decreasing Drug Diversion and Improving Pain Management*

All participants provided ideas on activities and programs that would be likely to reduce drug diversion, outside of a PMP, and also what else can be done to address the perceived pain management problem. Comments were made regarding mandating forgery-resistant prescription pads, a need for more law enforcement investigators—"We're so far behind the eight ball now that it wouldn't help us if we got 100 more investigators throughout this county," a need for judges to be tougher in their sentencing, and more funding and better access to treatment for those who are users. Four of the participants indicated a need for more education. Interestingly, one felt the public needed the education, another thought education was lacking for law
enforcement officers, and the other two thought the education gap was with the physicians. One comment was made regarding the inevitability of crimes of drug diversion, given human nature, regardless of education and government activity to address the issue.

Nearly all of the participants were unable to provide additional solutions for the improvement of pain management. In general, most felt that pain management was taken care of already, and that skills and tools were in place to assure that needed pain treatments would be available. The implication was that improvements in pain management were the responsibility of the physicians, and that the medical profession needed to better apply the opportunities that were already in place. One participant did discuss the need for a specialty license for pain management physicians.

On Data Needs

There was no specific data identified by the eight law enforcement participants for collection, but there was agreement that additional statistical information would be helpful in their jobs. The need to connect data sources was mentioned at various points in the interviews, with participants stating that a central database of prescription activity would be helpful. When specifically questioned on data needs at the conclusion of the interviews, four of the participants mentioned the need to provide the available data in a more timely fashion. Examples of 1- and 2-year old data were mentioned as not being very helpful in investigations. Of note is that a need
for more and better data was mentioned by law enforcement participants in both the PMP (Michigan) and non-PMP state (Florida).

Pharmacists

Six pharmacists were interviewed for this study, three each in Michigan and Florida. Two of the Michigan pharmacists were with rural pharmacies, one being an owner. The other Michigan pharmacist was the head pharmacist for a small chain store operation. In Florida, one pharmacist practiced in a rural setting in a grocery store, one managed a drug chain store in an urban setting, and the other worked in private practice for a clinic.

On the State of Pain Management

All six of the pharmacists stated that pain management is not what it should be, with pharmacists from both states indicating that pain management specialists do a better job than general practice physicians. Florida participants did not agree on causes for the state of pain management in their areas, citing some physician concerns with aggressive investigations, patient fears of addiction and side effects of medicine, and lack of adequate training at the university level for clinicians. One respondent talked about the “warring factions”—law enforcement and physicians—that may have created further prescribing concerns on the part of physicians. This respondent also encouraged the use of alternative therapies with non-Scheduled drugs that may be appropriate for many pain patients.
All three Michigan participants stated that the quality of pain management depends on the individual practitioner. One stated that acute pain is better treated than chronic pain, which is "a lot of trial and error." Another indicated that hospice patients are better treated for pain than other pain patients. Another talked extensively about the cost of inadequate pain treatment: more time off work, can lead to depression, more clinical visits, and the family structure suffers. This Michigan participant also talked about the tendency of physicians not to prescribe outside of what they learned "years ago." She stated, "I see them using drugs like Darvocet and Demerol that basically in current standards of practice, you don’t use them anymore."

On Influencing Choice of Drugs

The pharmacy participants were asked their opinion on what influences a physician to prescribe certain drugs for pain management. Four of the six expressed a need for more education ranging from medical school training to better education from drug company detailing. One Florida subject talked extensively about the responsibility of drug companies to discuss the risks of controlled substances for certain patient populations, as well as the benefits. She stated the pharmaceutical companies “go out of their way to downplay the negatives and to up-play the positives.” She also indicated that the marketing is skewed toward patient norms, but pain patients are not the norm, and patients that have a history of substance abuse are not the norm, implying that education on treatment of these patient populations needs to be different. A Michigan participant also discussed the lack of clinical studies by
drug companies, to prove the long-range effectiveness of treatment for chronic pain patients who use their drugs.

All six subjects stated they felt that pharmaceutical companies, through their various retail and direct-to-physician marketing efforts are a major influence on physician prescribing patterns. The influence was perceived as both good and bad, with some concerns over aggressive marketing, but equal appreciation for the education that is provided. A Michigan subject commented, “The drug reps present them [physicians] with a clear, concise evaluation of their product, and if the doctor feels it’s appropriate, they’ve got dosing information, indications, and everything right there given to them. A big time saver for the doctor.”

Two of the participants (one from each state) felt the biggest influence on choice of drugs was the payer, or insurance company, and one other participant included that as one of his top three influencing factors in choice of drugs. Fear of prescribing certain drugs was mentioned by one subject in each state. Addiction concerns were discussed at length by a Florida participant.

The learning process for the use of Scheduled drugs was discussed in various ways, with one participant stating “peer to peer conversations,” another citing “trial and error,” another that the use of Schedule II drugs was not taught in medical schools, and another that continuing education is negatively affected by regulatory scrutiny.
Perspectives on Drug Diversion

All six pharmacists acknowledged drug diversion as being a problem in their respective states, and there was general agreement that drug diversion was also a problem throughout the country. Two of the Florida participants did not think more laws would cause drug diversion to decrease, with one stating that additional regulations would “just make the diverter more sophisticated.” The other Florida participant thought a PMP would help to reduce drug diversion, but at the expense of pain management. Two Michigan pharmacists stated the elimination of the special prescription pad for Schedule II drugs (repealed in 2003) makes drug diversion easier, but those same two individuals were more concerned over the diversion caused by addiction, and the lack of funding for addiction programs. One of the Florida participants also talked extensively about the need for addiction treatment, pointing to the significant reimbursement barriers to such treatment, but that is “where anti-drug diversion activity has to start.” A Michigan pharmacist called addiction treatment a “bigger bang for the buck” citing the alternative and perceived greater cost of repeated incarceration if diverters are not treated.

Several issues related to time constraints were mentioned by participants in both states, with involvement in arresting someone for drug diversion being very time-intensive from both a law perspective as well as a privacy perspective. Subjects gave examples of the many calls they would make (if they had time) to determine if a suspected prescription was legitimate, the need to catch someone actually exchanging drugs for money or the timing necessary to arrest someone at the point of sale. Other
comments included a concern for the safety of the pharmacist in such a process, and the refusal to fill a suspected prescription as the safest and most expedient solution for a pharmacist who suspects diversion. There also appeared to be some liability concerns over possible violation of HIPAA regulations if patients’ names and their medications were released.

On Laws, Policies, and PMPs (Prescription Monitoring Programs)

The responses to questions regarding the effect that laws and regulations had on pain management and drug diversion were very similar, in spite of the fact that Florida does not have a prescription monitoring program in place, and Michigan does. None of the six respondents felt that such programs were the solution to either issue, and all six also had policies within their own operations to address suspected drug diversion and interact with physicians on medication issues.

Florida participants in general felt that a PMP or similar laws would decrease the diversion of prescription drugs, but would have a corresponding negative effect on proper prescribing with the additional regulatory scrutiny. One pharmacist stated the solution to both issues needs to start with the physicians, as they “drive the care.” Another stated that more laws would increase the workload for already busy pharmacists. He also said, “The tighter and the more laws you pass, the less able health care professionals and patients are to work together to get what they need.” A third stated that monitoring laws can have a “great positive effect” if designed and implemented right, as such design would help physicians feel safer in their prescribing.
However, such design has to be done collaboratively with both health professionals and law enforcement, and then all who have access to such monitoring programs need to be “perfectly educated” on its use. Although this pharmacist supported a properly designed PMP, she was not optimistic that Florida could create such a program. She stated:

Right now, there’s only negative impact, because of the independence of everybody doing their own thing, everybody’s blaming the other person for their problems. The DEA, law enforcement, say it’s the physicians’ problems, they’re the ones at fault. The physicians are saying, well you know, if the DEA would stay out of it, we could actually manage pain. So there’s a lot of pointing fingers, I think right now with the legislators, with the law enforcement, and they come together only when they’re forced. And when they’re forced, there’s not much positive outcome—to date anyway.

Michigan participants talked about the PMP that is in place in their state, but did not feel that the PMP or other laws were significant in the efforts to decrease drug diversion or improve pain management. Two of the subjects felt the elimination of a special prescription pad for Schedule II drugs might make it easier to divert drugs. One participant stated that the necessary education that was promised with Michigan’s PMP change did not appear to be happening; thus its usefulness was limited. Another stated that such laws are more of a tool for state officials than health professionals. A third stated he had “no strong opinion” on PMPs and the information available; however, this participant did not know that the database was accessible for health care practitioners, which exemplified the lack of sufficient education this issue. Michigan participants had fewer comments regarding laws such as PMPs than the Florida participants, with little interest in the subject, and more interest in their
internal policies to deal with drug diversion and pain patients. None of the three indicated the PMP was a good tool for their operations.

*On Decreasing Drug Diversion and Improving Pain Management*

The pharmacists were asked what else could be done to decrease drug diversion and improve pain management, if they did not bring up the topic on their own. Three (two from Florida and the other from Michigan) specifically mentioned the need to treat addiction as a part of the war on drugs, with two of the three other participants mentioning addiction treatment issues when queried earlier in the interviews. A Florida pharmacist reported health insurance barriers to addiction treatment. One Michigan pharmacist stated she felt emphasizing education and addiction treatment was the key, but the system was "self-defeating," stating that law enforcement "counts convictions. That's how they look good, is how many convictions they've had, not on how many people they've sent to treatment. So there's no incentive for them to get people into treatment. They want that conviction, because that's how they're funded."

There was a sense that both drug diversion and improved pain management could be better addressed with more collaboration—between physicians, pharmacists, law enforcement officials, patients and others, depending on the respondent. Although stated a number of different ways, there was interest in more involvement between physician and pharmacists. Pain management improvement was felt to be a function of more education by two participants and a direct responsibility of physicians by two
others. One subject from each state talked extensively of the need to develop a shared or joint practice for chronic pain management, with many types of practitioners available for patient analysis and screening, and with the development of a joint treatment plan. One commented on the difficulty of treating pain, since it is hard to measure and thus assess the effectiveness of treatment. Another discussed the need to find treatment for chronic pain as early in the diagnosis as possible, since “Once that pain starts, that cycle of pain starts, it’s harder to get it under control.”

On the diversion-for-business subject, there was a general feeling that there was too much money involved in diverting prescription drugs to ever close down such activities.

On Data Needs

Five of the six pharmacists mentioned additional data that would be helpful in addressing drug diversion and under-treatment of pain conditions. One Michigan participant would like to compare Michigan before and after the MAPS to determine if the change in the laws actually changed anything in practice. Another thought outcomes would be helpful. The Florida participants discussed data needs a bit more in depth, citing the need for a central database on statistics ranging from knowing which patients are receiving a “large amount of narcotics,” to arrest data so clinicians would know of prior drug arrests when a patient visited their practice, to a PMP of some sort. One Florida pharmacist spoke at length about the need to identify the extent of diversion, so that can be compared with statistics on the extent of pain, to
determine the real effect on society of the two issues. She also suggested that families of patients who are arrested or overdose be interviewed to determine the existence of underlying causes such as addiction, unmanaged pain, and related psychiatric issues.

Physicians

Sixteen physicians were interviewed, using the same basic set of questions asked of the pharmacists and law enforcement participants. Eight physicians from Michigan and eight physicians from Florida were included in the interviews. Although not specifically asked, it was determined during the course of the interviews that all 16 had been practicing medicine for at least 10 years, with some practicing much longer. Their medical specialties included oncology, family practice, hospice and nursing home medical directors, pain management specialists and internal medicine. There was significant experience among these physician participants in dealing with patients in pain.

On the State of Pain Management

Florida physicians ranked their state’s health care professionals as providing poor to just average pain management. Michigan physicians were a little more positive, ranking Michigan as providing average to above average treatment for pain conditions, with one exception. Physicians based their opinions on their own experiences and that of their patients. One Florida physician stated that he felt the closer a pain patient lived to a major medical center, the more likely he or she was to
receive good pain management. He stated, "I think the farther you move away from universities and major treatment centers, the worse it gets." Physicians in large centers "understand the risks better." Another Florida physician commented that pain management is a little easier to provide than in the past; however, a lot of people are living in a state of pain. Three of the Florida doctors felt the state of pain treatment was poor—one even called it "horrible, simply horrible." One physician spoke passionately about the limitations imposed by the failure of the medical profession and the managed care companies to define and utilize pain specialists, which limits referrals to their expertise. He stated the reimbursement system favors certain treatments for pain conditions (such as physical therapy but no psychological counseling to help determine cause). He also stated that malpractice insurance rates for those who include pain treatment as a specialty of their practice are prohibitive, discouraging many physicians from extensive treatment of pain patients.

Michigan physicians were much more comfortable with the level of pain management in their state than Florida physicians, with some agreement that it was getting better. Michigan physicians talked more at length about the need for comprehensive pain management and a more holistic approach to the treatment of pain. One physician stated that "pain management isn’t just about prescribing drugs but that’s where it always starts and always ends." Although this physician ranked Michigan as average in pain management, he stated that if he were to consider the lack of access to treatment with alternative therapies, Michigan would be rated much lower. Another physician agreed, saying that doctors are much more comfortable
prescribing stronger medications now than in the past, but that the treatment of pain is "mish-mash." She stated that there is no structured approach to pain management, that "they understand that good pain care might be important, but they’re not sure how to get there." Another talked at length about the need to provide multi-disciplinary care if we are to really improve the lives of those in pain. However, this physician reported that the reimbursement system does not support such care, so there is and will be a "continual deficiency" in pain treatment.

Some physicians from both Florida and Michigan felt that pain management is much better within a hospice setting. A similar comment heard more than once was that terminal pain was treated better than chronic, non-malignant pain.

On Influencing Choice of Drugs

The 16 physicians were asked what factors influenced a physician’s choice of medications for their patients. If the participants did not mention sources of influence that were mentioned by a number of other physicians, they were asked for their opinion on those factors also. Seven of the Michigan physicians and four of the Florida physicians stated that education they received in medical school and continuing education under CME is a strong influence. Some talked about a "comfort level" with certain drugs, prescribing what they are "used to." “They teach you in medical school (that) you can’t know everything, but know a few drugs well.” A Michigan physician elaborated on the education issue, stating that the residency program is key to the practice of pain management. He said:
Because the best chance we have at changing practice patterns is not catching them at CME lectures after they’re out in the community; it’s affecting their practice patterns while they are still impressionable, while they’re in training. And it’s very hard to change practice once they’ve finished. Because most physicians practice what they learned in their residency programs.

Michigan physicians put education and knowledge at or near the top of the list of influencing factors in their prescribing. Another major influence for the Michigan contingent was managed care (MCO) company related. A variety of MCO policies such as drug formularies, incentives to treat with medications rather than more expensive therapies, and the cost of drugs to patients due to MCO rules was discussed by four of the Michigan physicians.

All Michigan physicians either mentioned pharmaceutical companies as a factor or were asked that questions directly. Interestingly, none of these physicians felt that pharmaceutical company representatives negatively influenced a physician’s choice of medications, and most felt that the knowledge gained from pharmaceutical representatives was acceptable to good. One stated, “Without their detailing, most drugs wouldn’t be used.” Another said that “leader docs” are not influenced by pharmaceutical marketing; another observed that such marketing exerted no influence on a doctor’s choice of drugs. Two Michigan doctors indicated they also considered what drugs are available in their patient’s geographic area, since not all drugs are stocked at every pharmacy. Two also felt that a fear of prescribing strong medications could influence some choices of drugs.

Among the Florida physicians interviewed, the commentary on influencing factors was less cohesive. Four Florida physicians had more concerns over addiction
and "risky patients," with one stating, "They'll tend to avoid using drugs that have a potential for addiction if they think that they're going to have a whole bunch of drug addicts on their hands." Pharmaceutical company influence was also inconsistent, with comments ranging from "little or no influence" to one doctor stating that many physicians rely solely on the knowledge dispensed by the pharmaceutical industry. Comments by others included reference to doctors being too busy to research drugs on their own and appreciating the studies done by drug companies. Two Florida physicians mentioned reimbursement and cost issues as a factor in selection of drugs for their patients.

Only one physician, a Florida participant, mentioned fear of DEA activity, stating DEA agents provoke pain physicians and monitor them excessively.

On What Affects the Quality of Pain Management

In addition to conversation on what influences prescribing patterns, physicians were asked what influences the quality of pain management for patients in their respective states. Education, training, and knowledge were mentioned again by nearly all physicians as the primary factor. One Florida physician commented on how difficult it is to handle pain patients, that pain is a difficult problem to diagnose and treat, and time consuming. He stated, "It's not hard to practice medicine without doing pain management," and inferred that any barriers will affect quality. Another Florida doctor said, "I don't know that many of my colleagues know the first thing about pain management."
Seven participants, four from Michigan and three from Florida mentioned fears and misconceptions about addiction and the use of strong medicines again when asked questions on this topic. Commentary included lack of understanding of the difference between addiction, physical dependence, and tolerance, and the fact that someone classed as an addict can also have a legitimate pain problem. Many of the participants talked at length regarding how they would handle a patient who was perceived or known to have an addiction problem, with some choosing to drop the patient, and others continuing to treat, but with limitations and even the use of "contracts" where the patient must make certain promises regarding treatment in order for the doctor to agree to continue to treat him or her.

Six physicians specified that the health insurance industry is a major influence on the quality of pain management, five from Michigan and one from Florida. Michigan doctors commented on the lack of earlier referrals to pain specialists, lack of reimbursement for some treatment procedures being limited or lacking, and inadequate payment for a full assessment, diagnostic testing and a comprehensive plan of care. A Michigan physician pointed out the cost inefficiencies of delayed pain management. He stated:

Reimbursement is still not coming forth from insurers or managed care organizations for comprehensive pain services. . . . And what managed care and health care reimbursers and businesses at this point have not yet come to understand is that in a high cost chronic illness such as pain, you're not gonna save money by limiting services early in the course of treatment.

He also commented on the development of more health problems—which he called preventable—if early treatment was not available for pain management, and
warned that the cost was not only a financial one, but also a social cost to the patients and their families as well. Another Michigan doctor talked about the limitations of a primary care physician in the treatment of chronic pain. He stated, "you know, what's in the average doctor's armamentary? Well, it's primarily drugs and physical therapy. When that doesn't work they do one of two things. Either they continue to write the patients drugs, or they punt." This same physician commented at length on the system that encourages drug use as the least expensive treatment route, rather than allowing physicians to fully diagnose and identify appropriate care. He gave this example:

We do have technologies now that can be done percutaneously to deal with certain types of disc problems, or some of the other structures in the back that generate pain, but yet because they're more expensive than writing 120 Vicodin a month, it oftentimes becomes difficult to get that stuff approved. . . . So the influence that HMO's have had on the one hand have probably increased the use of narcotics by the primary care doctor and it slows down the referral . . .

The lone Florida physician, a practicing pain specialist who commented on the role of health insurers in the quality of pain management, supported the Michigan comments on the influence of managed care companies. He stated that late referral to pain specialists is the common practice of health plans; that the pain specialist is the "doc of last resort." He commented on many workers compensation cases where patients were referred to chiropractic treatments and physical therapists and treatment by medication alone, and "when nothing else works," they are referred to his practice, when the funding has been exhausted. Based on his experience, he felt the poor pain management reimbursement and late referral systems of health plans are key factors in
the low quality of pain management, and the collateral damage is that this encourages
drug diversion, as some patients seek their own solutions.

Effect of Public Policy, Regulatory and Law Enforcement Activity

Participating physicians were asked their opinion on the effect of policy and
enforcement activity on pain management. At the time of the interviews, Michigan
had just ended a decade-long prescription monitoring program, which started in the
late 1980s as a triplicate prescription program for Schedule II drugs requiring
physicians to create three copies of each such prescription, with one copy going to the
state. Later, the triplicate requirement was repealed and replaced with a special,
numbered prescription pad for Schedule II prescriptions, which meant that physicians
who wrote such prescriptions had to carry two prescription pads. Because the
numbered sheets could be monitored, many physicians kept those pads in a safe place,
which created a prescribing barrier for physicians who practiced in a variety of
settings outside of their office. The special pad was eliminated in 2003, when an
electronic system call MAPS (Michigan Automated Prescription System) was passed
into law.

There has been no prescription monitoring system in place in Florida, but
there have been several attempts by the legislature to implement an electronic
monitoring system, efforts that have been resisted by the medical community and
others. Thus, the regulatory climate in the two states differs significantly. In spite of
that, the majority of physicians in both states agreed that regulatory oversight and fear
of practice sanctions produce a "chilling effect" on prescribing for pain management purposes, regardless of the reality that very few physicians are prosecuted for drug diversion.

Michigan physicians commented on the MAPS system now in place, and there was a general feeling that the program is a good one to have available, but only one of the physicians has ever used the MAPS to get information on a patient. One physician indicated he was relying on the pharmacy (rather than MAPS) to alert him if anyone is filling multiple prescriptions from his practice. Another stated that, although the MAPS program eliminated the special prescription pad barrier to good pain management, it still contains monitoring of all Scheduled drugs, which might tempt "doctors who don't want to be watched" to prescribe older, less effective drugs. He compared the experience in New York, when physicians were required to report prescriptions of Schedule IV drugs, and stated, "so you saw patients getting old drugs like Miltown and other things like that, that were horrible drugs, because they wouldn't be scrutinized." Another Michigan physician liked the inclusion of all Scheduled drugs, as this allowed a more comprehensive analysis of a patient's medications. A Michigan physician who spoke strongly in favor of the MAPS stated that the change in Michigan "enhances pain management" because a barrier (the special pad) has been eliminated. She stated that the data available through the MAPS allow for better decision-making.

However, education on MAPS for the physician and pharmacist community has not been done well, so the new system is still not used by many. The other
concern with the program, expressed by two physicians, was that the program could not handle volumes of requests (which may be a factor in the limited education that has occurred). One stated, “There’s two problems though. One is, nobody seems to know it exists, outside of a very few of us. And the second thing is, if people were to use it the way it is supposed to be used, the people in Lansing told me it would crash the system.” Another physician complained that, while he can obtain medication history for his patients, the MAPS system will not provide him with his own prescribing history, so he cannot check to determine if anyone is forging his name to obtain medications.

In general, physicians felt that the MAPS program could be a tool to improve patient care, without being as burdensome as former Michigan regulations. They did not, however, look upon the program as a tool in fighting drug diversion. One physician specifically commented that such programs do not have an effect on drug diversion. He said, “I think people who really want to get the drugs figure out a way to do it. It may have made people who really wanted to get at the drugs work harder to do it, but I don’t think that it made that much difference.”

Florida physicians had a much greater concern over the possibility of more regulations, including the development of an electronic database PMP, similar to MAPS. Florida physicians were more likely to view a PMP as a tool to fight drug diversion, and to create treatment access barriers for pain patients. One stated:

So to implement this type of legislation (a PMP) without any input from pain physicians is going to be an act to secure prosecutions. Pain physicians view this legislation as handing the DEA on a silver platter exactly what they’re
looking for. Unrestricted monitoring, information at their fingertips, to target whomever they wish at whatever time they wish.

Another stated that regulatory activities in Tallahassee and Washington keep pain management from getting better. However, this same physician said that more prescription data in an easily accessible database would be very helpful in the practice of pain medicine. She said, “You could almost cut it (diversion) out—99% of it overnight—if you just had that computer data tabulated and reviewed and enforced.”

Another felt that the movement to a PMP in Florida was not supported by evidence. He said, “the legislative response seems to be driven, as it often is, by horror stories and anecdotes that may or may not have anything to do really with the bulk of concerns and issues that we have.” This same physician would strongly support centrally maintained electronic medical charts available for medical care only, but would not support such electronic systems if the primary focus was on decreasing drug diversion. That feeling was supported by other Florida physicians, with three of them also stating that a PMP or other electronic tracking system would not solve the drug diversion problem.

One physician from Florida did not believe the cost of such a system was worth the benefits, stating:

I wonder about it [cost]. I mean, what’s the magnitude of the problem and the cost of catching that one person. What did we accomplish? To go through this expense, the prescribing, to check everybody, and 1 in 700—is it 1 in 10—I don’t know. I don’t know. I don’t know what the value is here.

Another commented on a related issue, the lack of knowledge of the actual extent of drug diversion:
I don’t think we know—we hear about these spectacular cases, we don’t hear about the huge problem of inadequate pain management nearly as often as the few cases of a few people selling drugs in the parking lot at doctors’ offices and that seems to be what drives public policy more than the bulk of the experiences.

Thus, there was some concern over cost-benefit issues related to the development of a PMP in Florida. Another physician summed up his feelings that the solution to drug diversion is far more complicated than passing laws can fix—"that just puts more people in jail."

Interestingly, none of the physicians interviewed had any personal experiences with DEA or law enforcement investigations of their practice, and few had even received an inquiry from any government agency about their prescribing patterns. In addition, none of them recalled any colleague who had been investigated, other than a cursory and rare call or letter. Their knowledge of such instances came from reading and hearing about cases from TV and radio coverage.

**Perspectives on Drug Diversion**

Study participants were asked for their perceptions about drug diversion in their state. Michigan physicians were not as sure that there was a big problem with drug diversion, although all acknowledged that drug diversion exists. Florida physicians as a group felt drug diversion was more serious. Several general comments were made about the need for more data to determine the true extent of the drug diversion problem. In lieu of good data, the perceptions of drug diversion varied from
not being sure there was a problem, to a sense that there is "a lot more diversion than we know about."

Three Michigan physicians stated that drug diversion happens primarily for monetary reasons, and made no comments on any other motivators. Four of the Michigan doctors stated that drug diversion will always be with us, with one stating:

But the amount (of prescription drugs) that slips out into the drug community is minor compared to what's already out there. So if you stopped all narcotic prescriptions, you'd have essentially the same amount of narcotics out on the street as you already have.

This same physician went on to state that it was not a prime concern of his to stop drug diversion. He said:

My job is to take care of the patient, and if I think the patient's being deprived because their family is selling some of their drugs, then we'll take care of it without stopping the care. Because my responsibility is really to the patient, not to the drug enforcement people.

Another commented that regulatory activity monitoring prescribing of one Schedule of drugs has only served to move drug diversion from that Schedule to another (such as from diverting Schedule II to diverting Schedule III drugs, if II's are being monitored). This just changed the drug of choice, not the amount of diversion.

Two Michigan physicians commented on other sources of drug diversion—pharmacy theft from all sources (pharmacy staff as well as outside thieves) and by nurses in nursing homes. The opportunity for medication theft is particularly tempting, since many patients are not as cognitively able to monitor their own medications. One other Michigan physician stated that the "incidence of drug diversion is much smaller than the hype," and compared the one third of Michigan
residents who have pain problems to the less than 1% of residents with a drug addiction problem (based on diagnostic codes for addiction treatment).

Florida physicians not only felt that drug diversion was more of a serious problem than Michigan physicians, but a couple of them even warned that the problem will get worse, that we are seeing the “tip of the iceberg.” Three of these physicians talked about drug abuse among other health care professionals—those that serve the patients. One indicated he had been involved in “four or five cases” of staff diverting drugs from patients. Another mentioned the diversion that occurred in two of her cases, where older relatives were used to obtain legitimate prescriptions, and the drugs were then stolen and sold or used. One commented on the statistics that report polydrug use, where more than one drug is identified, and the most common other “drug” is alcohol. She stated that using such statistics to support statements about the extent of drug abuse are wrong, since mixing alcohol with drugs is not drug diversion—it is non-compliance with medication instruction. Two physicians volunteered that money was the prime motivator for diversion, with one stating that diverting for sex was also an issue.

On Decreasing Drug Diversion

Participants were asked how they would suggest drug diversion be addressed. Both Michigan and Florida physicians commented again on the belief that improper drug use and thus drug diversion will always be present. There will always be a certain percentage of the population that is unable to control drug use. A Florida
physician stated, "I don't think the drug problem has probably changed in a century."
A Michigan doctor, different from the one mentioned in the preceding paragraph,
stated that we need to address the more serious drug problems of alcohol abuse and
illegal drug abuse first, and that has not happened for "a couple of thousand years."
His point was that extraordinary attention to diversion of prescription drugs would be
ignoring the real drug problem in this country.

Another Michigan participant talked at length about the relationship that the
media, regulators, and general public have drawn between strong medications and
addictions. She stated, "So we need the federal government to look at the true
positive and negative effects of medications. And none of these medications are
addicting, there's nothing addicting about any substance, there is the ability to be
addicted." She urged a change of mindset to get rid of the myths that opioids are
addicting. And she stated, "there are fewer opioid addicts in the state of Michigan
than there are benzodiazepine and alcohol and other medication addicts."

Michigan participants mentioned a need for greater general and unbiased
education on drug diversion. They also indicated that better record keeping and
information on use of drugs be developed so that the extent of the problem can be
identified before perceived solutions are put in place. There was a general belief that
the MAPS system might help drug diversion a little bit, but no strong statement that
the MAPS has or will have a major impact.

Four Florida physicians indicated they thought more data, even a central
database such as a PMP or something similar to the Michigan MAPS program would
help decrease drug diversion. One even called the concept "awesome," but only if law enforcement officials had very limited access. Another talked about the data that were already available by computer (Medicaid data, chain pharmacy data, and health plan data) but were not merged in any central database so that all the data could be used effectively by physicians and others. The issue of merging already existing databases was mentioned at other times in the interviews by most of the physicians in the study.

Two Florida doctors made a case for better use of pain specialists, who are believed by them to be better able to identify drug diverters because of their multidisciplinary approach to pain management, which also equips them to identify and treat addicts. Two mentioned more education as key to decreasing drug diversion, with one physician advocating for a change in culture, starting with the very young, so that people will grow up understanding what causes addiction and the consequences, as well as what promotes good health. One Florida physician echoed the Michigan statement regarding the bigger problem of alcohol abuse, stating that diversion of legal prescription drugs is a small problem in comparison.

On Improving Pain Management

The study participants were asked what could be done to improve pain management in their respective states. Nine physicians, five from Michigan and four from Florida, stated that education was the key, with several stating that all providers (physicians, pharmacists, nurses were mentioned) need more education in what makes good pain management. The educational setting varied between the study subjects,
with some emphasizing medical school, another supporting a role model program, and
another nursing school. Three of the Florida physicians favored mandated CME
courses on pain management, even though mandated education is usually resisted by
physicians. He said:

I hate to do this because I don’t like to be mandated—but you will get the
most bang for your buck if it’s mandated. . . . So I think in order to get
physicians to change how they treat pain, sorry to say, much as I don’t like it,
to be mandated to take education, would have a big impact.

Education of the general public on their right to pain management was
mentioned by one Florida physician and one Michigan physician. A Michigan
physician also thought that legislators and the “drug enforcement establishment”
needed more education about pain management. Four Michigan physicians talked
about things that could be done to improve the practice of pain management. One
favored the development of country-wide clinical practice guidelines, available on
computer for point of care use. Two others discussed the importance of proper
diagnostics, and three talked about the proper place for strong medications in the
treatment plan. One of these participants emphasized that physicians should avoid
treating pain just with drugs, while another stated that pain management doctors also
need to deal with “getting people off opioids,” and instead develop a comprehensive
plan of care with a variety of treatments, depending on the identified or perceived
causes of the pain.

In addition to emphasizing education, Florida physicians had other suggestions
for the improvement of pain management. One stated that the environment for
treating pain needs to change, that access to pain specialists must occur earlier in
treatment. Another agreed, stating that there is a need for good, thorough pain management specialists and specialties in Florida, and that there are good examples which can serve as models. One Florida physician was pessimistic and could not offer any suggestions for the improvement of pain management, stating that, absent any significant changes, there would be no effective pain management in five to ten years.

_On Data Needs_

The final question posed to the physicians was about data needs. They were asked what additional data and statistics are needed to better manage pain and to address drug diversion. Three of the Florida physicians had no suggestions. Three talked about the creation of a prescription-oriented database, with one mentioning that the data should be standardized first. One thought the database should contain information on known diverters, much like the information maintained on pedophiles. Another suggested doing a cost-benefit analysis of arresting and prosecuting diverters to determine if the benefits justify the costs. One suggested that patients be surveyed at the point of service in the physicians' offices and in hospital settings to determine their perceptions and needs.

Michigan participants took a different approach to this question without exception. Those who offered suggestions for additional statistics and data were very research-oriented, rather than database specific. Six of the seven physicians responding to this question talked about the need for much more research, with three citing the need for outcomes identification. Two stated that research is needed to
identify best practices so they can be imitated, and another recommended that the Support Study be done again, to determine if any improvements have been made. (The SUPPORT Study was conducted in the early 1990s to measure, among other things, the state of pain management in institutions.) One physician described the research he felt was needed. He stated:

There has to be honest data collection of consequence, diversion, addiction in the traditional sense, abuse, non-compliance, and long term value that's matched by observable changes in life. In other words, I don't want to just hear that it makes people feel better, I want to see that it's made them feel better. I want to see that they've not just become couch potatoes that feel better. I'd like to see some improvement in their ability to function at home, their ability to function as a partner in marriage if that's where they are, or perform in school or get a job.

Summary

As a general statement, there were some important differences in the opinions of all three categories of professionals and between the professionals in the two states and some interesting areas of agreement. The Tables 12 and 13 on the following pages summarize the findings. These tables summarize 30 interviews conducted in 2004 and 2005 in Michigan and Florida. The individuals participating in the interviews included 16 physicians, 8 law enforcement officers, and 6 pharmacists. It should be noted that the summaries contain the opinions, perceptions, and attitudes of only 30 individuals. However, those participating had extensive knowledge of either drug diversion or pain management issues, or both.
Table 12
Comparison of Key Points by Profession and Categories of Discussion

<table>
<thead>
<tr>
<th>Drug Diversion</th>
<th>Physicians</th>
<th>Pharmacists</th>
<th>Law Enforcement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All expressed a concern over drug diversion. Diversion control not their issue. Reasons for diversion by physicians were money, sexual favors, and with some, physician addiction problems.</td>
<td>General acknowledgment of a drug diversion problem. Need more funding for addiction treatment. New policies addressing diversion concerns are time consuming to implement.</td>
<td>Drug diversion increasing and the problem is significant. Drug company advertising direct to consumers is part of the problem. Physician involvement motivated primarily by money, also their own addiction and for sexual favors.</td>
</tr>
</tbody>
</table>

| Influencing Choice of Drugs | Physicians need more education to make good choices. Pharmaceutical company reps exert a major influence—good and bad. Payer formulary also exerts strong influence. | Pharmaceutical companies exert strong influence (but not necessarily bad). Lack of physician expertise on use of strong medicines—more education needed. |

| State of Pain Management | Pain management is poor. Based on knowledge of individual practitioners and on perception of barriers in regulatory environment. | Not much knowledge of pain management. Some acknowledged a chilling effect due to regulatory activity, but some disagreed. All expressed concerns over addiction. |

Drug use knowledge learned during medical school and from CME courses was major factor. Drug company reps influence, but not negatively. Addiction concerns with certain drugs. Payer formularies influence prescribing.

Ranked from poor to average—none above average. Pain management is a function of education. Addiction fears are a barrier. MCO formularies and late referrals to specialists a problem.
<table>
<thead>
<tr>
<th>Effect of Public Policy</th>
<th>Physicians</th>
<th>Pharmacists</th>
<th>Law Enforcement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory oversight produces a prescribing barrier. PMPs not a tool in fighting drug diversion. Lots of databases in place, need to be merged and reviewed for gaps before new policies are created.</td>
<td>Laws and policies are not a solution to drug diversion. All pharmacies had internal policies to address diversion issues</td>
<td>All supported a monitoring program. All felt drug diversion is a complicated problem that a PMP would not solve. PMP would provide another tool in the war on drugs.</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Decreasing Drug Diversion and Improving Pain Management</th>
<th>Physicians</th>
<th>Pharmacists</th>
<th>Law Enforcement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug diversion will always be present: address more serious problems of alcohol abuse and illegal drug use first. Education of all providers is needed. Earlier access to pain specialists needed to improve pain management.</td>
<td>Treating addiction must be a part of the solution to diversion. Pain management needs more collaboration between pharmacists and physicians.</td>
<td>Education gap on diversion exists for public, providers and law enforcement, but there will always be drug diversion. Pain management not a concern of officers interviewed.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Data Needs</th>
<th>Physicians</th>
<th>Pharmacists</th>
<th>Law Enforcement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Need for more data was supported: should be research-oriented, emphasizing outcomes and best practices. Quality of life improvement is an important outcome.</td>
<td>More data are needed, outcomes oriented. Use data for decision-making, not anecdotal information or arrests.</td>
<td>Unable to identify specific data needs, but should be consistent when collected. Also needs to be timely, to be useful to law enforcement.</td>
<td></td>
</tr>
</tbody>
</table>
Table 13
Comparison of Comments by State and Subject Area

<table>
<thead>
<tr>
<th></th>
<th>Michigan Physicians, Pharmacists, and Law Enforcement</th>
<th>Florida Physicians, Pharmacists, and Law Enforcement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug Diversion</strong></td>
<td>Drug diversion is a problem, physicians not as concerned about prescription drug diversion. Drug theft a concern, addiction treatments needed. Internet pharmacy concerns expressed. Money is prime motivator for diversion activity among health care professionals.</td>
<td>Felt drug diversion a growing to serious problem. Internet pharmacies are a factor. More laws not a solution. Addiction treatment attention needed. Diversion/theft of drugs by healthcare professionals a concern. Money is prime motivation, sexual favors second.</td>
</tr>
<tr>
<td><strong>Influencing Choice of Drugs</strong></td>
<td>Acknowledged pharmaceutical company influence, aggressive but not problematic. Direct advertising to consumers, education, experience and payer influence all cited as influencing physician drug choices. Medical school and CME education very important in choosing medications.</td>
<td>Acknowledged pharmaceutical company influence; aggressive, but only two expressed concerns. Education in medical school and CME offerings are major factors. Payer formularies also an influence. Addiction concerns over some drugs.</td>
</tr>
<tr>
<td><strong>State of Pain Management</strong></td>
<td>Average to above average rating for pain management, in Michigan and depends on practitioner, and his/her education and expertise. No one stated that enforcement activity created a barrier. Expressed concerns over addiction with strong drugs. Need more comprehensive treatment plans. MCO policies limit pain treatment choices.</td>
<td>Poor to average pain management rating for Florida. More education needed on pain management and addiction potential. Enforcement and regulatory activity can create barriers, but that is overstated to the public. Need to use pain management specialists more.</td>
</tr>
<tr>
<td>Table 13—Continued</td>
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<td>---------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Michigan Physicians, Pharmacists, and Law Enforcement</td>
<td>Florida Physicians, Pharmacists, and Law Enforcement</td>
</tr>
<tr>
<td>Effect of Public Policy: PMPs</td>
<td>Varied between professions interviewed, but some in all categories did support a PMP. Perception that PMP benefits physicians and pharmacists more than law enforcement. None interviewed believe PMPs were the solution to drug diversion activity - not timely enough. No personal investigations of physicians by law enforcement cited.</td>
<td>Law officers disagreed with physicians in Florida, with law enforcement supporting a PMP for drug diversion control, and physicians supporting them only if used for medical charts and records. All felt that PMPs are not the key to preventing drug diversion. Physicians and pharmacists also felt a PMP would create another barrier for pain patients. No personal experience with investigations were cited.</td>
</tr>
<tr>
<td>Decreasing Drug Diversion and Improvement Pain Management</td>
<td>The need for better education on both issues was cited by all. Sentencing, addiction treatment, and collaboration also very important. However, drug diversion won't be eliminated. Need more clinical practice tools for pain management improvement: pain patients deserve treatment even if they have a substance abuse problem. Law enforcement felt skills and tools were available for pain management, and responsibility of physicians, while physicians expressed concerns about education gaps in those skills and tools.</td>
<td>Need for more education on drug diversion expressed by law officers and physicians. Physicians also cited need for more pain management education—perhaps mandated CMEs. Treatment of addiction needs to be addressed, and more collaboration between professionals has to occur. Drug diversion will always be a problem. Need more pain specialists. Pain patients deserve treatment even if they have a substance abuse problem.</td>
</tr>
<tr>
<td>Data Needs</td>
<td>More data needed: physicians only group to define type of data, calling for research-based data collection, including outcomes and best practice identification. Should be timely and accessible. More interest in use of data for pain management than diversion control.</td>
<td>General desire for a PMP, with some physician exceptions. Data that would be helpful are beyond what a PMP can provide. Data collection comments were more oriented to diversion control than pain management from Florida participants.</td>
</tr>
</tbody>
</table>
There were differences and similarities in opinions expressed between professionals and between Michigan and Florida participants, and related comments are presented in detail in the Conclusions section of this report. Some key findings are noted below.

- Physicians and pharmacists were very supportive of a prescription database, as long as law enforcement did not have access to the information, and as long as it was used as a patient care tool. Law enforcement believed they should have access for drug diversion cases, and would not support a database for health care purposes only.

- Physicians were more concerned about PMPs as a barrier than either pharmacists or law enforcement officers.

- Michigan physicians rated the quality of pain management higher in Michigan than Florida physicians did in Florida.

- Data needed to address drug diversion and pain management were not easy to define, with physicians seeking outcome and best practices data, and law enforcement more concerned with timely data for oversight and investigations.

- Physicians in Florida seemed more concerned over diversion control than did Michigan physicians, who were more focused on patient care, as such concern related to data needs.

- All interviewed agreed that more education was needed for all professional who deal with pain management and drug diversion issues.
• There was emphatic agreement that much more attention needs to be paid to addiction treatment, in order to begin to address the growth of drug diversion.

Surprisingly, there was not much difference of note between the states, even though they were operating under different drug monitoring policy environments at the time of the interview.
CHAPTER VI

SUMMARY AND CONCLUSIONS

The purpose of this research is to test the belief that prescribing of controlled substances in the Schedule II federal classification of drugs is affected by state-based public policy that falls under the category of prescription monitoring programs. Schedule II drugs are the strongest category of drugs that can be obtained legally. Drugs are placed in this schedule because they are the most potent and have the highest potential for addiction. The research questions addressed two possible effects of public policy that imposes prescription monitoring controls: whether such monitoring has the power to decrease illegal diversion of prescription drugs, and whether such laws lower the quality of pain management.

Summary

The study was conducted using two methodologies. Data were gathered and analyzed for the 15 states in the study to determine if any conclusions could be drawn after conducting a quantitative analysis. Seven of the states operated with a prescription monitoring program (PMP) in place during the time period of the study, and 8 of the states did not have such laws in effect during that time. A case study analysis consisting of interviews of physicians, pharmacists, and law enforcement
officials in Michigan and Florida was also carried out to identify any differences in practice patterns and perceptions between a PMP and non-PMP state.

The research questions were:

1. Do state controlled substance laws referred to as prescription monitoring programs (PMPs) help to contain drug diversion activities of Scheduled drugs, particularly Schedule II drugs?

2. Do PMPs and the regulatory climate limit access to good pain management?

Drugs classified as Schedule II drugs were identified as the specific pharmaceuticals of interest in order to make the best connection to prescription monitoring programs in effect during the study period. Schedule II drugs are often the drugs of choice for treating chronic, severe pain. During the time of the study, there were 15 states with PMPs in place. All of those programs monitor Schedule II drugs, with 7 also covering Schedule III drugs, and 6 monitoring Schedule IV drugs as well.

The research included both drug diversion, a law enforcement issue, and pain management because they are connected, a fact supported by the literature. They are two different issues, but as stated by one of the physicians interviewed for the study, they are “intimately related.” In general, public policy has had an impact on the delivery of medical care for decades, with Medicare and the Social Security Act (1935) as benchmark laws along with Medicaid (1969) and the Controlled Substances Act (1970) being national policies that have had an influence in every state. States have also implemented additional controls over the practice of medicine through many
different government programs such as professional licensing requirements, professional boards, required education, and public policies such as the prescription monitoring programs which are addressed in this research. Noting the influence that laws, policies, and programs have on health care, it is clear that the practice of medicine is controlled to a great extent by such public policy. Thus, any analysis of public policy such as PMPs for law enforcement purposes should also study the effect of PMPs on the delivery of health care to the affected citizens.

As the research progressed from literature review and informal initial discussions with experts in the field and the actual research began, it became apparent that the public policy issues surrounding prescription drug diversion and the quality of pain management treatment relating to those issues were much more complicated than initially perceived. In fact, it became evident that diversion of Schedule II drugs does not exist in isolation from a number of other factors, such as the equally pursued diversion of drugs in other federal controlled substance Schedules, particularly Schedules III and IV. For example, in the two states where case studies were part of the research, Lortab and Vicodin are the most prescribed drugs, and were therefore believed to be the most diverted drugs. Both of these are brand names for hydrocodone combinations, generally Schedule III drugs which have a high potential for abuse and diversion. Other contributing factors include the use of legal and illegal drugs at the same time (poly-drug use), the role that alcohol plays in combination with other drugs, and the government’s way of handling addicts who become criminals. In fact, it was not possible to collect data on drug abuse for drugs
contained in only one controlled substance schedule; thus, the analysis of information and subsequent conclusions of this study generally relate to all legal controlled substances, not just those in Schedule II of the federal Controlled Substances Act.

The states with PMPs were compared to the states that have DAWN data available in order to help identify a set of states with both DAWN and PMPs, and a set with only PMPs. The DAWN program collects data on drug abuse episodes and drug mentions, drawn from cases that present at emergency departments in selected major metropolitan areas around the country. Although less than ideal, DAWN data as projected statewide for the states in the study were chosen as the proxy for drug diversion in the quantitative study because they were the best data available for all those states during the study period.

SAMHSA (the Substance Abuse and Mental Health Services Administration), the federal agency responsible for collecting data from emergency department (ED) visits related to drug abuse, also acknowledged the complicity in collecting data on drug diversion. Identifying single controlled substances for any study is difficult, since drug diversion and abuse range from poly-drug use (any combination of legal or illegal drugs), drug use in combination with alcohol, illegal drugs (Schedule I substances such as heroin and marijuana), and prescription drugs (Schedules II – IV and non-scheduled drugs). To illustrate this complexity, the breakdown of emergency department drug mentions for 2002 reveals that 81% of the drugs identified are from seven categories, only one of which contains legal controlled substances. SAMHSA reports:
Eight out of every 10 ED drug mentions (81%) come from only 7 categories: alcohol-in-combination, cocaine, heroin, marijuana, benzodiazepines, antidepressants, and analgesics. In 2002, alcohol-in-combination was a factor in 31 percent of ED drug episodes (207,395 mentions), cocaine in 30 percent (199,198) marijuana in 18 percent (119,472) and heroin in 14 percent (93,519). Collectively, the benzodiazepines, antidepressants, and analgesics constituted 359,266 ED mentions in 2002, or nearly 30 percent of total ED drug mentions. (U.S. Department of Health and Human Services, 2003, p. 25)

Since DAWN reports drug mentions and episodes in different drug categories than the Schedules in the federal Controlled Substance Act, it became apparent early in the search for data for the quantitative portion of the study that the research data could not be restricted to Schedule II drugs. The other salient issue affecting data collection was the realization that drug diversion would not be easy to quantify. Extensive data review, foiled requests for information that was not available on a consistent and comparable basis in the 15 states in the study, and many months of effort attempting to obtain drug theft data from the DEA forced a change from the original plan. The decision was made that research could not be restricted to the diversion of only Schedule II drugs. The conclusions and recommendations here thus refer to drug diversion in controlled substance Schedules II–IV.

Data were accumulated to quantitatively test the relationship between drug diversion, using DAWN data as the proxy for drug diversion as well as other independent variables. These independent variables, finally selected as a result of an extensive search for meaningful and consistent data across all 15 states in the study, were population, new cancer cases, and the presence or absence of a PMP. “New cancer cases” was used as a proxy for the prevalence of diseases that are likely to
require the use of controlled substances. States selected for the quantitative study included 7 with PMPs and 8 without PMPs. All 15 states had DAWN data and new cancer cases data available.

The other part of the study included a number of interviews with physicians, pharmacists, and law enforcement officials in both Michigan and Florida to determine differences in attitudes and perceptions in those states. During the study period, Michigan had a PMP for the monitoring of Schedule II drugs. Michigan has since replaced its triplicate PMP with an electronic PMP that covers all legal controlled substances, Schedules II–V. Florida has never had a PMP in place. Michigan and Florida were selected as the states of comparison because of the author’s familiarity with those states and ability to identify individuals for the interviews. Thirty interviews were conducted, 16 with physicians whose practice included a significant amount of pain management, 6 with pharmacists, and 8 with law enforcement officials. The interviews were designed to be 30 minutes in length, though several went longer. Some subjects expanded on their answers during the interview time voluntarily, providing specific examples of related issues from their own or a colleague’s practice, or venting their frustration with the system.

Analysis of the quantitative data was conducted using SPSS software. The interviews were recorded, transcribed, and then analyzed. In addition, key words were searched to identify similarities and differences in the responses to the interview questions.
Conclusions

In analyzing the research results and preparing conclusions of the study, it is noted that the qualitative results which are considered with the quantitative results were obtained from a small sample of professionals, as noted earlier in this chapter. The interview sample for the case study was limited to 30 individuals. However, the participants selected all had considerable expertise in drug diversion, pain management, or with both issues. The following seven conclusions may be drawn from this study.

1. **There does not appear to be a significant correlation between Prescription Monitoring Programs and an increase or decrease in drug diversion in the 15 states in the study.** The multiple regression analysis indicated that PMPs had no effect or may even be negatively correlated to instances of drug diversion as quantified using DAWN statistics. Although there are some concerns with the regression analysis, this conclusion was also supported during the interviews conducted for the case study.

The limitations of the regression analysis include the small number of independent variables and the presence of multicollinearity between two of those variables. Since there were only three independent variables in the regression, the extensive correlation between two of them generates concern over the results. While the regression suggests the above conclusion, such concerns support the need for additional study and more extensive availability of evaluation data. The regression equation was limited to three independent variables because there was a lack of consistent and reliable data from other sources to include other variables.
Interviewed subjects were asked their opinion on the causes of drug diversion in their state. The majority of those interviewed in all three professional groups acknowledged a concern with drug diversion. In general they stated that there was a problem, with law enforcement officials more likely to view diversion as a major problem. The extent of the problem was substantiated when the increase in drug episodes and mentions in the DAWN data were compared to the increased size of the general population. During the 4 years of the study, the population for the country increased by 5.4%. Drug diversion, as measured by the DAWN data, increased 28% for the seven states with a PMP and 21% for the eight non-PMP states. Although such statistics were not tested for other influencing factors, the increase in reported data from drug-related visits to emergency departments would suggest that there has been a sizable increase in diversion. The data support the belief that such diversion is a growing problem.

There was unanimous agreement among the 30 participants that the primary motivation for drug diversion activity was money—with one subject referring to it as "big money." There was also a general acceptance of the view that drug diversion "will always be with us." This was a majority opinion of those interviewed and supported the conclusion that public policies such as prescription monitoring programs were not likely to be the solution, and indeed there may be no solution. There was general consistency among the doctors, pharmacists, and law enforcement officers on these points. They agreed that PMPs are at best a tool that can be used in the war on drugs, but should not be considered a major factor in such activity.
Comments from the four Florida law enforcement participants were an exception to this response, with those individuals stating that a PMP would be of significant help in addressing drug diversion in Florida.

There is support for this conclusion in the literature reviewed. A study by the U.S. Department of Justice (2000) alleged a connection between PMPs and the level of drug diversion, but admitted that such a connection could not be quantified. A study by Brushwood (2003) referred to the inconsistencies between data available in different states, further implying an inability to verify any influence of PMPs on drug diversion. He stated that such lack of consistent data makes program evaluation difficult, further confounding the ability to make a correlation. Data also used by a USDOJ report from states with PMPs to correlate the existence of a PMP with a reduction in drug diversion were not conclusive and very assumptive. For example, that report used statistics such as the decline in arrests for drug diversion to make a case for a decrease in drug diversion, without addressing other factors that might influence the arrest numbers. In fact, one source, Reasononline.com, reported that arrests for drug diversion in the country remained stable (not in decline) over a 3-year period of this study, even though the number of PMPs increased during that time. Based on such inconclusive information and lack of a reliable connection between PMPs and a decline in drug diversion, the American Alliance of Cancer Pain Initiatives recommended that no new PMPs be implemented until "existing information sources have been fully utilized" (American Alliance of Cancer Pain Initiatives, 2002).
There is also some logic to this statement, upon reflection. PMPs collect data that are retrospective. Data are reported after the diversion has occurred, which questions the effectiveness of PMPs as a preventive tool. Law enforcement officials claim that PMPs do have a preventive role, but no such quantifiable evidence was presented in any study. In the case of the Michigan PMP, even in the preferred electronic program, the data could have a lag time of up to 45 days. This might render the data useful in investigations, but does not suggest that PMPs have a strong influence on prevention of drug diversion.

2. Drug diversion problems and drug abuse are not likely to be eliminated.

The data compiled for the regression analysis indicated an increase in drug diversion, and the participants in the case study as a whole were resigned to the continuing existence of diversion and drug abuse. The regression results suggested that drug diversion may simply be a function of the number of people and the prevalence of diseases that require the use of controlled substances in the treatment plans. The cycle of more people, a corresponding increase in chronic diseases with the consequent production of more drugs and thus the presence of more controlled substances in the marketplace was mentioned by several study participants. These trends would lead to an inevitable increase in diversion. When participants in the case study were asked their opinions on possible activities that could slow the growth of illegal use of prescription drugs, education and addiction treatment were mentioned most often, along with the need for more law enforcement resources dedicated to the entire drug abuse problem. This could imply that public policy to address diversion would be
better directed towards developing and funding programs that address education needs, addiction treatment funding, and putting more diversion-trained officers on the street. These issues are covered in other recommendations.

There was no indication from any of the research efforts that drug diversion can be eliminated, even with an expansion of public policy such as PMPs. Regardless of the professional category of those interviewed for the qualitative portion of this research, there was universal agreement that diversion of legal drugs would always be an issue and a sub-category of the larger problem of drug abuse. This belief was also supported by the literature. An extensive DEA Report for 1998-99 made that conclusion, as do ongoing reports on the DEA website. Members of the pain community also acknowledge the ongoing nature of drug diversion and its growth, but stop short of suggesting that PMPs are the solution or that there is any solution. The NSDA surveys report a continuing increase in abuse and diversion, in spite of an increase in the number of PMPs.

There was, however, some optimism among those interviewed that the growth in drug diversion and drug abuse could be slowed, but current policies were not identified as a major weapon in that effort. Rather, the bigger issue of drug abuse probably needs to be addressed from a global perspective, with other causes—theft, Internet pharmacies, border access and others—incorporated into the search for an effective resolution.

The entire subject of how much drug diversion could be attributed to physician involvement needs a full assessment. It appears that a very small percent of
physicians are knowingly involved in drug diversion, with one source stating that only 50 physicians had been arrested in the country in 1 year (averaging 1 per state). Furthermore, the study by Brushwood confirmed the small number of physician prosecutions over a 6-year period—less than one-thousandth of a percent of all physicians. However, those physicians who are arrested often make national headlines and prosecutions are very public, so the extent of the drug diversion problem as it relates to physician involvement may seem larger than it is.

Of consideration here is the cost of programs such as PMPs. If indeed they are not proven effective, then the cost to taxpayers of such programs is wasteful. A study by the GAO reported such programs cost state governments up to a million dollars per year, funds that are clearly better spent elsewhere until the effectiveness of policies to stem the growth of drug diversion is better identified.

3. Prescription Drug Programs or related policies may be desirable and very useful to physicians and pharmacists in patient care design and delivery. This conclusion was based on interview discussions and a few studies of the effectiveness of information available through prescription databases. It was also an unanticipated conclusion, given the widespread concerns over the "chilling effect" on prescribing controlled substances that is reported by several articles and reports. Students of the chilling effect phenomenon such as Brushwood, Johnson, and Skelly believe that PMPs that allow access to law enforcement will serve to limit physician willingness to prescribe controlled substances. However, databases similar to PMPs may be
supported by the medical community if their purpose does not include oversight and investigation of medical professionals.

Of note in the discussions regarding drug diversion was an interest on the part of the physicians in the study to have access to a prescription database that could be used exclusively for patient care, with availability only to physicians and perhaps other clinicians. In fact several participants, including some pharmacists, lamented that there are current prescription drug databases (private insurances, pharmacy chains, and Medicaid) that could and should be merged and “talk to each other” so that providers can get a better picture of the prescription drug history of their patients. Several study participants indicated that the databases available within pharmacy chains were already used on an informal basis as pharmacists and physicians stayed in touch regarding patients considered potential risks for drug diversion. These participants felt the available information was very useful, but not extensive enough. Pharmacists within a chain operation have access to their own company’s database, so useful prescription history is available from within their operations. Physicians who were dealing with a suspicious patient but were committed to his or her care sometimes called several local pharmacies in an attempt to determine whether prescription problems were present.

Using the sources currently available, providers of health care are already using existing databases to help make good treatment decisions for their patients. Thus the availability of a comprehensive database on prescription drug use would be a significant improvement on the informal sharing system already in place. The
difference between that informal system and the typical PMP is that only providers can access the informal system, but PMPs are generally accessible to law enforcement too.

Michigan physicians felt the electronic prescription program that replaced the original PMP in Michigan (the Michigan Official Prescription Program or MOPP) was more useful or potentially more useful to the care of their patients than the previous policy, but it is still a monitoring program, accessible to law enforcement. Few had used it for patient care as of the date of their interview. Physicians did feel that public policy intended primarily to monitor physician prescribing was a potential barrier to good pain management. Michigan physicians were less concerned about such policy than Florida physicians. However, at the time of the interviews, Michigan had just replaced its PMP with a "softer" law, and Florida physicians were reacting to the potential for such a proposal in their state. The political environment was thus felt to be a factor in the divergent responses. Also in another study, physicians in Utah and Nevada reported their state's PMP alerted them to potential diverters, and that was deemed valuable.

Pharmacists talked more about their own internal checks and balances, and the ability of their payers' databases to check for multiple prescriptions from various providers. More data rather than less were deemed to be important, but the use of the data should be identified and agreed upon before new programs or policies are implemented.
In spite of deep concerns from clinicians regarding the presence of a PMP or related regulatory policy, there was support from both physicians and pharmacists for a patient database that could be used by the medical community to obtain information about a patient's prescription drug history and physician encounters. The physicians interviewed indicated that they would not be inclined to use such a database very often due to time constraints, but it would be valuable for patients of concern, especially if the data were timely. None of the providers felt that such a database should be accessible to law enforcement. If such a database were to be most useful, it should produce information that fills an important gap in the health care system. As one physician so clearly stated, it was his job to take care of patients, not to fight the war on drugs. If a database becomes a tool solely to improve patient care, it would likely be welcomed.

4. Addiction to prescription drugs and the lack of adequate attention to addiction treatment were identified as major drug diversion issues by the participants in the case study. There was a general and strong expression of support for much more in the way of addiction treatment, if drug abuse is to be effectively addressed. Study participants from both Michigan and Florida stated that treatment for addiction, education regarding addiction, and better management of addiction from a health care perspective are probably a better way to slow the growth of drug diversion and drug abuse in general. As one pharmacist put it, "a bigger bang for the buck." Although examining the effect of greater attention to addiction treatment was not a part of this study, there was a fairly clear message from the study participants.
that the war on drugs needs to include more in the way of identification and adequate
treatment of drug addicts, whether they are addicted to prescription drugs, illegal
drugs or alcohol.

Discussion included the need for such care in all settings, not just the
physician’s office. A Florida law enforcement officer and a Michigan sheriff talked
extensively about untreated addiction problems for jailed individuals, who are denied
drugs while in jail but with no treatment are likely to commit drug-related crimes
upon release. Recidivism here is virtually inevitable, according to the law enforcement
officers interviewed. Physician participants were also concerned with the ability of the
medical community to adequately treat patients in pain when the patient might also
have addiction problems. For some, it may be easier to avoid prescribing the right
drugs, rather than deal with addiction or the potential for addiction in their patients.

Addiction to strong medicines was recognized as a potential problem long
ago, with the Controlled Substances Act of 1970 categorizing drugs into Schedules
partially based on their potential for addiction. Unfortunately, addiction is not well
understood as reported in studies such as those by Savage and Zickler, where reduced
prescribing of strong medications was a consequence of such misunderstandings.

More attention to treatment for those addicted to prescription drugs or any
other drug makes sense, since any decrease in drug-seeking behavior is likely to
decrease prescription drug diversion. In addition, adequate reimbursement for
addiction treatment should improve access and encourage such care. Greater
awareness and improved access may also remove some physician fears over treating
what one referred to as “risky patients,” and thus foster a climate for improved pain management. Although it was outside the scope of this research to test the effect of good addiction treatment resources on the incidence of drug diversion and abuse, the issue was mentioned and discussed enough by several study participants to suggest further study.

5. There is a need for more education of health care professionals on both drug diversion issues and the treatment of patients with chronic pain conditions. This conclusion was expected, based on the literature, especially the literature on the quality of pain management. A lack of sufficient knowledge of strong medicines, addiction issues, and the treatment of chronic pain conditions were mentioned most often by the case study participants from the two states, both in the context of what needs to be done to decrease diversion and what needs to be done to improve the quality of pain management. Many of the participants felt that medical school training on the use of controlled substances was not sufficient to address the treatment of patients with severe, chronic pain conditions that they might see during the years of their professional practice. This was supported by an Institute of Medicine study (Kaplan, 2004), which reported that specific education on pain management is not routinely included in medical school training. The same dearth of education was reported for nursing schools and schools of pharmacy. According to Fishman and Gallagher (2004), no state licensing boards mandate CMEs in either pain management or drug abuse, so additional knowledge on these subjects is optional for physicians and other medical professionals. Several of the interviewed physicians stated that the
drugs learned in medical school become the primary medication choices, with additional knowledge of new drugs obtained mostly through interaction with pharmaceutical company representatives and perhaps some voluntary CME courses.

The physician education obtained through pharmaceutical company representatives was determined to be an important source of knowledge of the benefits of new pain management drugs. However, concerns were expressed that such education was limited in scope most of the time to accentuate the positive and to limit education on the dangers of new medicines. None of the participants felt that drug company education should be eliminated, just expanded in its scope. In particular, several of those interviewed said that pharmaceutical company education would be much more valuable if the presentations included full information on the medication risks, and provided assistance in identifying those populations of patients who are not suited for such new drugs. Nearly all of the subjects in the case study felt that pharmaceutical company information and education was extremely valuable, and there appeared to be no good substitute or alternate source for that knowledge. The concern was that the presentations were not comprehensive enough.

Education of the general public on the use of certain brand name prescription drugs using TV, radio commercials, and other media was not viewed as education by anyone in the study. Very little information can be delivered in a 30-second commercial, and public advertising is designed solely to increase demand for a product. Public advertising of new medicines was actually reported to be a problem by some of the physicians in the study, since patients demanding prescriptions for
advertised new drugs did not appear to be isolated incidents. It is important to note that continuation of such advertising, although a part of the fabric of business, is not considered health care education and is not a part of the conclusions related to education that are contained in this research.

Interestingly, a report by the OIG called for “more adequate training” of DEA agents. FDA head Dr. Donald Meyer also called for more physician education on drug diversion. Overall, there appears to be a significant gap in education and training on the related subjects of pain management and drug abuse.

6. Among those interviewed, PMPs and other related public policies were more of a concern as a potential barrier to good pain management to physicians than pharmacists or law enforcement officers. The majority of the physicians in both Michigan and Florida felt that regulatory oversight and fear of practice sanctions generated greater concern within the physician community than prescribing certain drugs that help to control pain. This perception is supported in the literature (Joranson, Angarola, Brushwood). This “chilling effect” was the subject of much discussion during the interviews, in spite of the fact that very few physicians are actually prosecuted for their involvement in drug diversion.

There did not appear to be a difference in that concern between physicians in the two states in the study. However, the Michigan contingent rated the quality of pain management somewhat higher than the Florida contingent. This might suggest that public policy does not, in practice, affect the quality of pain management, as Michigan has a controlled prescribing program and Florida does not. This was a
surprising finding, since the Michigan medical community had complained long and loudly in the past about the diminished quality of pain management due to the presence of a PMP. Perhaps the change in the PMP policy that went into effect in 2003 improved the treatment of pain, or at least the perception of such treatment.

Michigan physicians did state that there was more of a chilling effect before its monitoring program was modified to an electronic tracking system. It was not determined if this change in policy improved the treatment of pain, and in fact nothing in the interviews would suggest that such improvement had happened. No data were available, and no research is evident in Michigan to determine if the quality of pain management has improved since the change in policy.

Florida physicians, practicing in a state without a PMP, actually rated the quality of pain management lower than Michigan physicians. Certainly that could be due to issues other than policy, but what it suggests in this study is that policies such as PMPs are not a primary factor in the quality of pain management. That indeed was supported by the results of the multiple regression.

In fact, physicians from both states, many of the pharmacists, and even some of the law enforcement officials were more concerned with the lack of a comprehensive approach to pain management, the scarcity of pain management specialists, and the payer reimbursement barriers to the use of pain specialists. Payer concerns include late referrals to pain specialists and lack of reimbursement for the medications and therapies of choice early in the course of treatment for a chronic pain condition.
7. There is a lack of sufficient, accessible, consistent and reliable data to define and measure both the extent of drug diversion and the quality of pain management. Without such data, it is difficult to determine the magnitude of either problem, and impossible to know if activities to address such issues are of benefit. As noted earlier, months were spent trying to collect data that better measured prescription drug diversion than the DAWN statistics. A variety of data was collected from state to state and even county by county, but on an inconsistent basis, so combining data for analysis purposes was not possible. Access to some data, most notably drug theft data, was denied even after several months of contact with the DEA and proper application for such data through the Freedom of Information Act. Subjectivity in data collection was identified, particularly in the case of data related to causes of death.

Difficulties were also encountered when attempting to measure the state of pain management. Most of the information to measure the incidence of pain was collected through surveys that asked general questions about pain, rather than trying to quantify the consequences of poor pain management. There are inconsistencies with those studies that affect credibility. For example, a Florida survey of pain (MacManus & Schuler, 2003), reported that as many as 75% of Floridians suffered from unmanaged pain; a survey in Michigan (EPIC MRA, 1997) reported 20%, and a national survey (Office of Applied Studies, 2005a) reported 57%. Regardless of differences in the way the surveys were structured, the reported numbers are those stated which are too inconsistent to be useful. According to research conducted by
Dean (2004), pain was only recognized as a complicated medical problem in the late 20th century, so gathering data on the treatment of pain is a fairly contemporary and thus an evolving activity. Some studies such as the JCAHO pain assessment module for institutionalized patients and the SAGE study of pain in nursing home patients provide good information, but those studies are targeted at a small percent of the population, and rely to an extent on observations rather than improvements in quality of life. As one of the interview subjects stated, he doesn’t want to see “couch potatoes that feel better,” rather the measure of successful pain treatment is improvement in the ability to function at home, at school, on the job, as a partner in marriage or in other personal, social settings.

Physicians interviewed stated, in a number of different ways, that trusting what patients tell them about the state of their pain condition is simply not possible, much as they would like it to be.

So there needs to be good data collection including statistics on diversion, addiction, abuse, non-compliance, long-term life style improvements and good health outcomes to truly asses the state of pain management and determine improvements. Without such data, finding solutions will continue to be a trial and error effort.

Without benchmark data on both drug diversion and the state of pain management, there is no reliable way to make a case for any program or policy to change the current state of either issue. If drug diversion and the quality of pain management cannot be defined and measured, then the success or failure of a policy cannot be measured. Benchmark data also allow for the setting of goals for new
programs, such as targeting a 10% reduction in lost workdays due to pain, or a 5% reduction in hospitalizations due to uncontrolled pain, or an 8% reduction in thefts of controlled substances over a 2-year period, or a 5% reduction in deaths with controlled substances present. Without reasonable data, those who fund policies and programs to address drug diversion and improvements in the care of pain patients will never know what success should look like, and they are likely to eliminate funding after a short while. Worse, they could continue to fund programs that may be perceived to address the issues but do not, thereby preventing the identification of meaningful solutions.

Lack of good data is an insurmountable barrier to the identification and implementation of programs that work well. It is addressed as a recommendation of the research.

The research was designed to find answers to the following questions.

1. Do state controlled-substance laws referred to as prescription monitoring programs (PMPs) help to contain drug diversion activities of Scheduled drugs, particularly Schedule II drugs? In particular, did the existence of these laws in seven states significantly reduce such diversion as compared to eight other states, which do not have such laws in place?

2. Do PMPs and the regulatory climate limit access to good pain management? Is access to pain management greater in Florida than Michigan? Did Michigan’s PMP pose a significant barrier to adequate pain management?
The research found nothing to indicate conclusively that PMPs either help or hinder drug diversion activities. There is, however, some evidence that they are at best a minimal tool in such activity, but perhaps are not worth the cost of implementation and maintenance. Further, there was no evidence that the amount of prescription drug diversion in these states was a function of the presence or absence of a PMP.

It is likely that PMPs may create a barrier to good pain management for some physicians, but there is no way to measure the extent of such a barrier. Access to good pain management was not considered a function of laws or public polices—PMPs or other policies—in either Florida or Michigan.

Recommendations

In light of the conclusions in response to the research questions, four major recommendations are offered. The recommendations that follow all have an effect on public policy and its place in the war on drugs and the war on pain, with one exception. The education recommendation has an indirect effect on public policy, as mandated education is included in the commentary. There are also policy implications in the seven conclusions. Public policy has a cost, so there are costs connected to the recommendations that are a result of this research. However, there are also tremendous costs to implement policies that are not effective. The recommendations and conclusions are directed at containing additional costs for current policy while seeking better answers.
There were no research results which suggested that the current PMP policies are an effective use of public funds or human resources. In fact, there is some evidence that such policies may negatively affect pain management even if they do reduce drug diversion. Thus, there is no recommendation that additional states should implement PMPs, given the current level of information available on their effectiveness. The recommendations instead discuss a means of obtaining the information that can be used to make decisions on what policies will play a significant role in reducing diversion of legal drugs to illegal use, while doing no harm to the treatment of pain patients.

The four recommendations follow.

1. States should not implement a PMP or related public policy to address drug diversion until information is available to assure that such a policy's purpose is clear and that implementation is cost-effective. The goals of such a policy should be established and accepted by the public before implementation. The costs to start and maintain a PMP should be publicized to insure that the results justify the costs. In general, there was not sufficient evidence in this research to defend the creation of a PMP for drug diversion control purposes.

However, states may wish to consider proceeding with a PMP or related policy that is limited to assisting health care professionals in the delivery of good patient care. There was support for prescription databases that help physicians and pharmacists with information on patient prescription history, with no access by law enforcement except by subpoena. Such a prescription database would allow
physicians and pharmacists to access prescription drug information for patients who are a part of their practice, providing them with additional information to help identify problems or potential problems for treatment purposes. For example, a prescription history for a pain patient might indicate that the patient had seen several doctors for the treatment of his or her pain in the past few months, but after review of that history with the patient, it might be learned that the use of multiple doctors was a result of no relief for the pain. Or the physician might learn that the patient had a drug diversion or addiction issue, but still suffered from a pain condition, and needed more intense management of the treatment plan, such as prescribing smaller quantities of drugs, requiring a doctor–patient contract on the use of drugs, or including required drug testing as a part of the treatment plan. The physician might also decide after review that the patient’s condition cannot be treated at his or her office, and thus justifies an earlier referral to a pain specialist.

Thus, for purposes of earlier identification of the entire medical issue which should foster earlier comprehensive and preventative treatment, it is recommended that state governments considering PMPs do so for medical treatment reasons only, and not for drug diversion investigations. PMPs that go beyond such medical purpose should be thoroughly researched, not only for cost-effectiveness but also for their implications in the treatment of pain patients and to determine their real effect on decreasing diversion of prescription drugs.

2. Data identification and collection needs to be implemented on a large scale to better address both drug diversion and the quality of pain management. This

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should include benchmark data to set the stage for measuring the level of
effectiveness of activities designed to address problems in these two areas. The need
for better data and a means of measuring the extent of diversion of prescription drugs
and of measuring pain management efficacy was evident in both the search for useful
data in the development of the regression equation and with the subjects interviewed
for the case study. “Better” data were described by the physician community and
some of the pharmacists as needing to be research-oriented, with attention to best
practices and outcomes.

Suggestions for research went far beyond mere surveys or small focus groups,
and certainly extended beyond a few isolated incidences that might garner public
attention. They included research to identify best practices in both pain management
and addiction treatment, and the development of evidenced-based care plans as a
result of the research. Behavior studies were suggested, especially to better
understand the psychological bases for pain that is hard to control and also to better
understand addiction. More extensive research on the consequences of poor pain
management and lack of access to pain specialists and addiction treatment was
mentioned, along with studies of what earlier treatment of chronic pain means from
both a personal and economic perspective. A system to translate the research into
practice was mentioned as a critical component of any studies.

In the effort to collect data for the multiple regression in this study, the lack of
consistent information, the lack of accurate information, and sometimes the sheer
absence of data was the single most critical issue preventing a better look at how policies such as PMPs can change drug diversion patterns.

Interestingly, much of the data needed to improve the analysis of how policy affects diversion activity appears to be available; it is just either not accessible or not maintained in the same format. For example, it would have been enlightening to have drug theft data for the years of the study for all the study states. This information is available (required to be reported to the DEA by each pharmacy), gathered quarterly by DEA district offices, and then submitted to DEA headquarters in Virginia where it is stored. I was able to obtain only one year of drug theft data from the DEA before access was denied for such data for the other years in the study. An analysis of that year’s data indicated that drug theft from pharmacies probably constitutes a major proportion of prescription drugs that are diverted. If drug thefts from pharmacies are highly correlated with an increase or decrease in drug diversion, then it would be logical to take action to decrease pharmacy theft as a primary step in decreasing drug diversion. Public policy could then be directed at controlling pharmacy thefts, rather than directed at diversion that might be the result of prescribing activities.

Similarly, it would have been helpful to include data on the number of drug-related deaths in the states, with perhaps a reduction in such deaths suggesting a sign of improvement. However, death statistics are maintained differently from state to state, and there is no current way to take the death statistics for a number of states and use them statistically in their present format. Causes of death and secondary causes of death are sometimes verified and at other times not verified. It would be

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normal, for example, in a car accident for death to be recorded as death by accident, rather than a drug overdose, even if drugs were the cause, because autopsies to determine actual cause of death are the exception rather than the norm in most areas of the country.

Equally lacking is good data on the state of pain management and a means of measuring whether pain management is improving. Information used to discuss and quantify the state of pain management was generally available only through surveys that queried individuals on their opinion of their own pain and how they viewed its effect on their lives. Such studies were one-time assessments, and some of the questions used were of dubious value, since they often contained little that could be measured. For example, one study asked subjects if they had experienced pain in the past month, without clarifying the permanent or temporary nature of such pain (an occasional headache is different from chronic back pain). In order to assess properly the state of pain management and thus be able to determine the effect of public health policy on the treatment of pain, a means of collecting data that measures the quality of pain management must be identified. One of the physicians in the study said it well when he stated that improved pain management means a better quality of life: employment, family relations, social activities, and involvement in the community must be assessed to determine if there are barriers to effective treatment and when such barriers are being removed.
The need for better, more accurate, and accessible data is critical to making good policy decisions. It is recommended that such data collection proceed before any policies such as PMPs are implemented.

3. *Education on drug diversion and pain management should be a priority for physicians, pharmacists, law enforcement officers assigned to anti-drug activity, and managed care entities.* Every participant in the case study commented on the need for more and better education on pain management and drug diversion, with some commenting extensively on the subject. Managed care entities should be added to the list of those in need of additional education. Several of the case study participants stated that the payer’s policies exert the final influence on prescribing patterns and treatment plans for those in pain and those who may have a related drug abuse problem.

Education goals should be established to increase provider and law enforcement knowledge and understanding of drug diversion and addiction issues, including how best to manage those individuals. Education for providers and payers should be regularly available that will serve to increase the quality of pain management for those physicians and managed care companies who may have clients with a chronic pain condition. Although only 30 individuals were interviewed for the study, there was enough consensus on this issue to lend some credibility to the proposals that professionals be required to take some CME courses on both subjects in order to renew their licenses. Mandated education on specific topics is not embraced by the health care community, and there is evidence that CME education...
does not change practice behaviors. However, with pain being one of the primary reasons that people seek medical care and with the growth in drug abuse and drug diversion, I believe a case can be made to require some type of regular, unbiased education for health care professionals on both subjects.

4. A better means of addressing addiction should be identified that will reduce the number of individuals whose lives are controlled to some extent by the need to use drugs in a way that is against medical advice. Dealing with drug addicts in a positive way was the second most common topic of conversation among those interviewed. In addition, the literature supports better attention to addiction concerns as one of the critical components in any plan to reduce drug diversion. Although outside the scope of this study, comments made in some of the interviews suggest that data on addiction treatments available to the general public and to those addicts who are incarcerated should be incorporated into future statistical analyses of what influences drug diversion.

Improvement in addiction treatment will need additional funding from the government and through private insurers and managed care companies. Addiction treatment centers are often only available to those with private funds, or on a limited basis to those with a health plan benefit. Treatment for addiction and the provision of related support systems should continue for those affected for as long as necessary, as such practice is cost-effective and in the long run helps to assure the safety of the community and the individual, and improves quality of life.
Suggestions for Further Research

The extensive search for relevant independent variables and the rich conversations with the study participants revealed a number of areas that invite more study. However, three topics seemed to surface in the research more often during the months of the study, and are offered here as strong suggestions for further research.

1. Research should be conducted to identify a means of measuring drug diversion (alone or as part of a full drug abuse agenda) so that activities to combat these problems can be identified and then tested for effectiveness. The research should identify a method or system that would assure consistent data collection across regions and the entire country so that an accurate picture of the drug diversion problem is available. The research should be designed to allow comparison of drug diversion problems to the bigger issue of drug abuse to determine the areas of most concern. This will be very helpful in identifying priorities for public funding as well as the assignment of human resources. Without such research and the consequent ability to better define drug diversion, proposed solutions are not likely to be realistically based, and the results of such solutions cannot be tested for effectiveness.

2. Similarly, research is needed to identify a means of measuring the quality of pain management beyond general surveys of pain patients. Such research should go beyond soliciting opinions regarding just pain intensity or just duration of the painful condition. A higher quality of pain management will result in a better quality of life, which means improvement in functional abilities at home and on the job, school performance and social involvement—not just feeling better. Some studies have been
done to measure days lost from work due to pain problems and to translate the lost productivity into a cost to business. More such studies should be done to determine the cost of untreated or under-treated pain, so that the full effect on families and communities can be measured. This would then provide a means to determine if public or private activity was effective in improving the benchmarks.

3. Research is suggested to determine the cost-effectiveness of addiction treatment. Better attention to the medical treatment of drug addicts was mentioned repeatedly as is discussed in the recommendations section. Importantly, research to find a cost-effective means of treating addicts earlier in their disease is very critical, to limit damage to their future health. Untreated, drug addiction sadly often results in an early death. On the way, it can cause tremendous dysfunction in families and relationships, and once the addiction becomes a part of life, it is very hard to bring it under control. Addiction treatment research is particularly important for those who are incarcerated, because untreated addictions encourage recidivism upon release. Addiction research should thus be designed also to identify priorities for public funding of addiction treatment.
REFERENCES


classification scheme applied to an oxycodone postmortem database containing over 1000 cases. *Journal of Analytical Toxicology, 27*(2), 57-67.


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Appendix A

Prescription Monitoring Program States

205
# Alliance of States with Prescription Monitoring Programs

**States with Prescription Monitoring Programs**

<table>
<thead>
<tr>
<th>STATE</th>
<th>YEAR ENACTED</th>
<th>MONITORING SYSTEM</th>
<th>DRUG SCHEDULES AND GROUPS MONITORED</th>
<th>MANAGING AGENCY TYPE</th>
<th>WEBSITE</th>
</tr>
</thead>
<tbody>
<tr>
<td>CALIFORNIA</td>
<td>1939</td>
<td>Triplicate + Electronic</td>
<td>C-II</td>
<td>Justice Dept.</td>
<td><a href="http://caag.state.ca.us">http://caag.state.ca.us</a></td>
</tr>
<tr>
<td>HAWAI</td>
<td>1943</td>
<td>Duplicate Electronic</td>
<td>C-II, III, IV</td>
<td>Public Safety Dept.</td>
<td><a href="http://www.state.hi.us/icsd/psd/psd.html">http://www.state.hi.us/icsd/psd/psd.html</a></td>
</tr>
<tr>
<td>IDAHO</td>
<td>1967</td>
<td>Duplicate Electronic</td>
<td>C-II</td>
<td>Pharmacy Board</td>
<td><a href="http://www.state.id.us/bop">http://www.state.id.us/bop</a></td>
</tr>
<tr>
<td>ILLINOIS</td>
<td>1961</td>
<td>Electronic</td>
<td>C-II</td>
<td>Human Services Dept.</td>
<td><a href="http://www.state.il.us/">http://www.state.il.us/</a></td>
</tr>
<tr>
<td>INDIANA</td>
<td>1987</td>
<td>Single-copy + Electronic</td>
<td>C-II, III, IV, V</td>
<td>Public Safety Dept</td>
<td><a href="http://www.state.in.us/safetynet">http://www.state.in.us/safetynet</a></td>
</tr>
<tr>
<td>MASSACHUSETTS</td>
<td>1992</td>
<td>Electronic</td>
<td>C-II</td>
<td>Health Dept.</td>
<td><a href="http://www.state.ma.us/dph/dcp/">http://www.state.ma.us/dph/dcp/</a></td>
</tr>
<tr>
<td>MICHIGAN</td>
<td>1986</td>
<td>Single-copy, serialized + Electronic</td>
<td>C-II</td>
<td>Consumer &amp; Industry Services Dept.</td>
<td><a href="http://www.cis.state.mi.us">http://www.cis.state.mi.us</a></td>
</tr>
<tr>
<td>NEVADA</td>
<td>1995</td>
<td>Electronic</td>
<td>C-II, III, IV</td>
<td>Pharmacy Board</td>
<td><a href="http://www.state.nv.us/pharmacy/frame.htm">http://www.state.nv.us/pharmacy/frame.htm</a></td>
</tr>
<tr>
<td>NEW MEXICO</td>
<td>1994</td>
<td>Electronic</td>
<td>C-II</td>
<td>Pharmacy Board</td>
<td><a href="http://www.state.nm.us/pharmacy">http://www.state.nm.us/pharmacy</a></td>
</tr>
<tr>
<td>NEW YORK</td>
<td>1972</td>
<td>Single-copy, serialized + Electronic</td>
<td>C-II and Benzodiazepines</td>
<td>Health Dept.</td>
<td><a href="http://www.health.state.ny.us">http://www.health.state.ny.us</a></td>
</tr>
<tr>
<td>OKLAHOMA</td>
<td>1990</td>
<td>Electronic</td>
<td>C-II</td>
<td>Narcotics &amp; Dangerous Drugs Control Bureau</td>
<td><a href="http://www.state.ok.us/~obnnd">http://www.state.ok.us/~obnnd</a></td>
</tr>
<tr>
<td>State</td>
<td>Year</td>
<td>System Type</td>
<td>System Code</td>
<td>Board/Division</td>
<td>Website</td>
</tr>
<tr>
<td>---------------</td>
<td>------</td>
<td>------------------------------</td>
<td>-------------</td>
<td>---------------------------------------------------</td>
<td>----------------------------------------------</td>
</tr>
<tr>
<td>RHODE ISLAND</td>
<td>1978</td>
<td>Electronic</td>
<td>C-II, III</td>
<td>Pharmacy Board</td>
<td><a href="http://www.health.state.ri.us/hsr/pharmacy.htm">http://www.health.state.ri.us/hsr/pharmacy.htm</a></td>
</tr>
<tr>
<td>TEXAS</td>
<td>1981</td>
<td>Single-copy, serialized + Electronic</td>
<td>C-II</td>
<td>Public Safety Dept</td>
<td><a href="http://www.txdps.state.tx.us">http://www.txdps.state.tx.us</a></td>
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<tr>
<td>UTAH</td>
<td>1995</td>
<td>Electronic</td>
<td>C-II, III, IV, V</td>
<td>Professional Licensure Division</td>
<td><a href="http://www.commerce.state.ut.us/dopl/dopi1.htm">http://www.commerce.state.ut.us/dopl/dopi1.htm</a></td>
</tr>
<tr>
<td>WEST VIRGINIA</td>
<td>1995</td>
<td>Electronic</td>
<td>C-II</td>
<td>Pharmacy Board</td>
<td><a href="http://www.state.wv.us/sos/corp/proflicense.htm">http://www.state.wv.us/sos/corp/proflicense.htm</a></td>
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</tbody>
</table>

1 Information current as of March 2001.
2 Year original program enacted, does not reflect subsequent amendments.
3 May be different than original system type at time of original program enactment.
4 Listed state websites do not necessarily have information on prescription monitoring programs.
Appendix B

DAWN Data Sites
Welcome to the 
New Drug Abuse Warning Network (DAWN)
The Drug Abuse Warning Network (DAWN) is a public health surveillance system that monitors:
- Drug-related visits to hospital emergency departments (EDs) and
- Drug-related deaths investigated by medical examiners and coroners (ME/Cs).

In 2003, a new, redesigned DAWN expanded beyond drug abuse. New DAWN helps communities and member facilities identify emerging problems, improve patient care, and manage resources.

Metropolitan Areas in DAWN
Appendix C

Controlled Substances Schedules II-IV
## Controlled Substance Schedules > List of Controlled Substances > Schedule II

### Controlled Substances in Schedule II

This document is a general reference and not a comprehensive list. This list describes the basic or parent chemical and does not describe the salts, isomers and salts of isomers, esters, ethers and derivatives which may also be controlled substances.

<table>
<thead>
<tr>
<th>Substance</th>
<th>DEA Number</th>
<th>Narcotic</th>
<th>Other Names</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Phenylcyclohexylamine</td>
<td>7490</td>
<td>N</td>
<td>PCP precursor</td>
</tr>
<tr>
<td>1-Piperidinoctahexanes/borotriite</td>
<td>8603</td>
<td>N</td>
<td>PCC, PCP precursor</td>
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<tr>
<td>Alfentanil</td>
<td>9737</td>
<td>Y</td>
<td>Alfenta</td>
</tr>
<tr>
<td>Alphaprodine</td>
<td>9010</td>
<td>Y</td>
<td>Nisentil</td>
</tr>
<tr>
<td>Amobarbital</td>
<td>2125</td>
<td>N</td>
<td>Amytal, Talnal</td>
</tr>
<tr>
<td>Amphetamine</td>
<td>1100</td>
<td>N</td>
<td>Dextedrine, Adderall, Obetrol</td>
</tr>
<tr>
<td>Anileridine</td>
<td>9020</td>
<td>Y</td>
<td>Leritine</td>
</tr>
<tr>
<td>Benzoylecgonine</td>
<td>9180</td>
<td>Y</td>
<td>Cocaine metabolite</td>
</tr>
<tr>
<td>Benzphetamine</td>
<td>9040</td>
<td>Y</td>
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<tr>
<td>Benzylpiperazine dihydrobromide</td>
<td>9041</td>
<td>Y</td>
<td>Methyl benzoylecgonine, Crack</td>
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<tr>
<td>Codeine</td>
<td>9050</td>
<td>Y</td>
<td>Morphone methyl ester, methyl morphone</td>
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<tr>
<td>Codeine intermediate-A</td>
<td>9232</td>
<td>Y</td>
<td></td>
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<tr>
<td>Codeine intermediate-B</td>
<td>9233</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Codeine intermediate-C</td>
<td>9234</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Cocaine</td>
<td>9040</td>
<td>Y</td>
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<tr>
<td>Cocaine intermediate-A</td>
<td>9232</td>
<td>Y</td>
<td></td>
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<tr>
<td>Cocaine intermediate-B</td>
<td>9233</td>
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</tr>
<tr>
<td>Cocaine intermediate-C</td>
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<table>
<thead>
<tr>
<th>Substance</th>
<th>Code</th>
<th>Classification</th>
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<tbody>
<tr>
<td>Metazocine</td>
<td>9240</td>
<td>Y</td>
</tr>
<tr>
<td>Methadone</td>
<td>9250</td>
<td>Y Dolophine, Methadose, Amidone</td>
</tr>
<tr>
<td>Methadone Intermediate</td>
<td>9254</td>
<td>Y Methadone precursor</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>1105</td>
<td>N Desoxyn, D-decophedrine, ICE, Crank, Speed</td>
</tr>
<tr>
<td>Methylenediacetate</td>
<td>1724</td>
<td>N Concerts, Ritalin, Methylen</td>
</tr>
<tr>
<td>Methadone</td>
<td>9260</td>
<td>Y</td>
</tr>
<tr>
<td>Moraneide-$\text{intermedlata}$</td>
<td>9802</td>
<td>Y</td>
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<tr>
<td>Morphine</td>
<td>9300</td>
<td>Y MS Contin, Roxanol, Oramorph, RMS, MSIR</td>
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<tr>
<td>Naltrexone</td>
<td>7378</td>
<td>N Cesamet</td>
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<tr>
<td>Opium extracts</td>
<td>9610</td>
<td>Y</td>
</tr>
<tr>
<td>Opium fluid extract</td>
<td>9620</td>
<td>Y</td>
</tr>
<tr>
<td>Opium poppy</td>
<td>9650</td>
<td>Y Papaver somniferum</td>
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<tr>
<td>Opium tincture</td>
<td>9630</td>
<td>Y Laudanum</td>
</tr>
<tr>
<td>Opium, granulated</td>
<td>9640</td>
<td>Y Granulated opium</td>
</tr>
<tr>
<td>Opium, powdered</td>
<td>9639</td>
<td>Y Powdered opium</td>
</tr>
<tr>
<td>Opium, raw</td>
<td>9650</td>
<td>Y Raw opium, gum opium</td>
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<tr>
<td>Oxycodone</td>
<td>9143</td>
<td>Y OxyContin, Percocet, Endocet, Roxicodone, Roxicet,</td>
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<tr>
<td>Oxyphorphone</td>
<td>9652</td>
<td>Y Numorphan</td>
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<tr>
<td>Penobarbital</td>
<td>2270</td>
<td>N Nembutal</td>
</tr>
<tr>
<td>Phenazonine</td>
<td>9715</td>
<td>Y Narphen, Prinadol</td>
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<tr>
<td>Phenocidine</td>
<td>9711</td>
<td>N PCP, Sernylan</td>
</tr>
<tr>
<td>Phenmetrazine</td>
<td>1631</td>
<td>N Preludin</td>
</tr>
<tr>
<td>Phenylacetone</td>
<td>8501</td>
<td>Y P2P, phenyl-2-propanone, benzyl methyl ketone</td>
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<tr>
<td>Piminodine</td>
<td>9730</td>
<td>Y</td>
</tr>
<tr>
<td>Poppy Straw</td>
<td>9650</td>
<td>Y Opium poppy capsules, poppy heads</td>
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<tr>
<td>Poppy Straw Concentrate</td>
<td>9670</td>
<td>Y Concentrate of Poppy Straw, CPS</td>
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<tr>
<td>Racemethorphan</td>
<td>9732</td>
<td>Y</td>
</tr>
<tr>
<td>Racemorphan</td>
<td>9733</td>
<td>Y Dromoran</td>
</tr>
<tr>
<td>Remifentanil</td>
<td>9739</td>
<td>Y Ultiva</td>
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<tr>
<td>Secobarbital</td>
<td>2315</td>
<td>N Seconal, Tunal</td>
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<tr>
<td>Sufentanil</td>
<td>9740</td>
<td>Y Sufenta</td>
</tr>
<tr>
<td>Thebaine</td>
<td>9333</td>
<td>Y Precursor of many narcotics</td>
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## Controlled Substances in Schedule III

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<table>
<thead>
<tr>
<th>Substance</th>
<th>DEA Number</th>
<th>Narcotic</th>
<th>Other Names</th>
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</thead>
<tbody>
<tr>
<td>13Beta-ethyl-17beta-hydroxyprog-4-en-3-one</td>
<td>4000</td>
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<td>17Alpha-methyl-17beta-hydroxy-Salma-androstane</td>
<td>4000</td>
<td>N</td>
<td></td>
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<tr>
<td>17Alpha-methyl-3beta,17beta-dihydroxy-Salma-androstane</td>
<td>4000</td>
<td>N</td>
<td></td>
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<tr>
<td>17Alpha-methyl-3beta,17beta-dihydroxy-androst-4-ene</td>
<td>4000</td>
<td>N</td>
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<tr>
<td>17Alpha-methyl-4-hydroxyandrostane (17alpha-methyl-4-hydroxy-17beta-hydroxyestr-4-en-3-one)</td>
<td>4000</td>
<td>N</td>
<td></td>
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<tr>
<td>17Alpha-methyl-alpha-1-dihydrotestosterone (17beta-hydroxy-17alpha-methyl-Salma-androst-1-en-3-one)</td>
<td>4000</td>
<td>N</td>
<td>17-alpha-methyl-1-testosterone</td>
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<tr>
<td>19-Nor-4-androstenediol (3beta,17beta-dihydroxyestr-4-ene, 3alpha,17beta-dihydroxyestr-4-ene)</td>
<td>4000</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>19-Nor-4-androstenedione (estr-4-en-3,17-dione)</td>
<td>4000</td>
<td>N</td>
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</tr>
<tr>
<td>19-Nor-5-androstenediol (3beta,17beta-dihydroxyestr-5-ene, 3alpha,17beta-dihydroxyestr-5-ene)</td>
<td>4000</td>
<td>N</td>
<td></td>
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<tr>
<td>19-Nor-5-androstenedione (estr-5-en-3,17-dione)</td>
<td>4000</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>1-Androstenediol (3beta, 17beta-dihydroxy-androst-5-ene)</td>
<td>4000</td>
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<td></td>
</tr>
<tr>
<td>1-Androstenedione (androst-5-en-3,17-dione)</td>
<td>4000</td>
<td>N</td>
<td>4-AD</td>
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<tr>
<td>1-Androstenedione (androst-4-en-3,17-dione)</td>
<td>4000</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>4-Androstenediol (3beta,17beta-dihydroxy-androst-4-ene)</td>
<td>4000</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>4-Androstenedione (androst-4-en-3,17-dione)</td>
<td>4000</td>
<td>N</td>
<td></td>
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<tr>
<td>4-Dihydrotestosterone (17beta-hydroxyandrost-3-one)</td>
<td>4000</td>
<td>N</td>
<td>Anabolic steroids, Androlexim, Pescosan, Stanoldone</td>
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<tr>
<td>4-Androstenediol (4,17beta-dihydroxyestr-4-en-3-one)</td>
<td>4000</td>
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<td>4-Androstenediol (4,17beta-dihydroxyandrost-4-en-3-one)</td>
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<td>N</td>
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<tr>
<td>5-Androstenediol (3beta,17beta-dihydroxy-androst-5-ene)</td>
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</tr>
<tr>
<td>5-Androstenedione (androst-5-en-3,17-dione)</td>
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</tr>
<tr>
<td>Amobarbital &amp; noncontrolled active ingred.</td>
<td>2126</td>
<td>N</td>
<td></td>
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<tr>
<td>Anabolic steroid suppository dosage form</td>
<td>2126</td>
<td>N</td>
<td>&quot;Body Building&quot; drugs</td>
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<tr>
<td>Androstenedione (Salma-androst-3,17-dione)</td>
<td>4000</td>
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<tr>
<td>Aprobarbital</td>
<td>2120</td>
<td>N</td>
<td>Aurate</td>
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<tr>
<td>Barbituric acid derivative</td>
<td>2120</td>
<td>N</td>
<td>Barbiturates not specifically list</td>
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<tr>
<td>Benzphetamine</td>
<td>1228</td>
<td>N</td>
<td>Cidrex, Inapetyl</td>
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</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Schedule</th>
<th>N</th>
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<tbody>
<tr>
<td>Boldosterone (7α,17α-dimethyl-17β-hydroxyandrost-4-en-3-one)</td>
<td>4000</td>
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</tr>
<tr>
<td>Boldenone (17β-hydroxyandrost-1,4-diene-3-one)</td>
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<tr>
<td>Buprenorphine</td>
<td>9054</td>
<td>Y</td>
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<tr>
<td>Butabarbital (secbutabarbital)</td>
<td>2100</td>
<td>N</td>
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<tr>
<td>Butalbital</td>
<td>2100</td>
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<tr>
<td>Butobarbital (butethal)</td>
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<td>Calusterone (7β,17α-dimethyl-17β-hydroxyandrost-4-en-3-one)</td>
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<tr>
<td>Chlorhexadol</td>
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<td>N</td>
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<td>Chlorphenetermine</td>
<td>1645</td>
<td>N</td>
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<td>Closterone (7β,17α-dimethyl-17β-hydroxyandrost-4-en-3-one)</td>
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<tr>
<td>Codeine &amp; isoquinoline alkaloid</td>
<td>90 mg/d</td>
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<tr>
<td>Codeine combination product</td>
<td>90 mg/d</td>
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<tr>
<td>Dehydrocholoromethyltestosterone (4-chloro-17β-hydroxy-17α-methyl-1,4-dien-3-one)</td>
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<td>N</td>
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<tr>
<td>Deltal-dhydrotestosterone (17β-hydroxy-5α-androst-1-en-3-one)</td>
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<td>N</td>
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<tr>
<td>Dihydrocodeine combination product</td>
<td>90 mg/d</td>
<td>9807</td>
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<tr>
<td>Dronabinol in sesame oil in soft gelatin capsule</td>
<td>7369</td>
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<tr>
<td>Drostanolone (17β-hydroxy-2α-methyl-5α-androstan-3-one)</td>
<td>4000</td>
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<tr>
<td>Ethylmorphine combination product</td>
<td>15 mg/d</td>
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<tr>
<td>Fluoxymesterone (9-fluoro-17α-methyl-17β-hydroxyandrost-4-en-3-one)</td>
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<td>N</td>
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<tr>
<td>Formebolone (2-formyl-17α-methyl-17β-hydroxyandrost-1,4-diene-3-one)</td>
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<tr>
<td>Furazabol (17α-methyl-17β-hydroxyandrostan-2,3-c-furazan)</td>
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<tr>
<td>Gamma Hydroxybutyric Acid preparations</td>
<td>2012</td>
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<tr>
<td>Hydrocodeone &amp; isoquinoline alkaloid &lt;15 mg/d</td>
<td>9805</td>
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<tr>
<td>Hydrocodeone combination product &lt;15 mg/d</td>
<td>9806</td>
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<tr>
<td>Ketamine</td>
<td>7285</td>
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<tr>
<td>Lysergic acid</td>
<td>7300</td>
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<tr>
<td>Lysergic acid amide</td>
<td>7310</td>
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<tr>
<td>Mesterolone (17α-methyl-17β-hydroxy-5α-androst-3-one)</td>
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<tr>
<td>Mesterolone (1α-methyl-17β-hydroxy-5α-androst-3-one)</td>
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<td>N</td>
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<tr>
<td>Methandienone (17α-methyl-17β-hydroxyandrost-1,4-diene-3-one)</td>
<td>4000</td>
<td>N</td>
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<tr>
<td>Methandietol (17α-methyl-3β,17β-dihydroxyandrost-5-one)</td>
<td>4000</td>
<td>N</td>
</tr>
<tr>
<td>Methenolone (1-methyl-17β-hydroxy-5α-androst-1-en-3-one)</td>
<td>4000</td>
<td>N</td>
</tr>
<tr>
<td>Methyldienolone (17α-methyl-17β-hydroxyestr-4,9(10)-dien-3-one)</td>
<td>4000</td>
<td>N</td>
</tr>
<tr>
<td>Methyltestosterone (17α-methyl-17β-hydroxyandrost-4-en-3-one)</td>
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</tr>
<tr>
<td>Methyltestosterone (17α-methyl-17β-hydroxy-4,9,11-trien-3-one)</td>
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<td>N</td>
</tr>
<tr>
<td>Methyprylon</td>
<td>2575</td>
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<tr>
<td>Nandrolone (17α-methyl-17β-hydroxyestr-4-en-3-one)</td>
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</tr>
<tr>
<td>Morphone combination product 50 mg/100 ml or gm</td>
<td>8810</td>
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<tr>
<td>Norcodeine</td>
<td>9400</td>
<td>Y</td>
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<tr>
<td>Norbolethone (17α-methyl-17β-hydroxyestr-4-en-3-one)</td>
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<tr>
<td>Norbolethone (17α-methyl-17β-hydroxyestr-4-en-3-one)</td>
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<table>
<thead>
<tr>
<th>Substance</th>
<th>DEA Number</th>
<th>Narcotic</th>
<th>Other Names</th>
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<tbody>
<tr>
<td>Alprazolam</td>
<td>2882</td>
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<td>Xanax</td>
</tr>
<tr>
<td>Barbitol</td>
<td>2145</td>
<td>N</td>
<td>Veronal, Pexional, barbitone</td>
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<tr>
<td>Bromazepam</td>
<td>2748</td>
<td>N</td>
<td>Lexotan, Lexafin, Lexotanil</td>
</tr>
<tr>
<td>Butorphanol</td>
<td>9720</td>
<td>N</td>
<td>Stadol, Stadol NS, Torbogesic, Torbutrol</td>
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<tr>
<td>Camazepam</td>
<td>2749</td>
<td>N</td>
<td>Albeo, Limdolon, Paxor</td>
</tr>
<tr>
<td>Cathine</td>
<td>1230</td>
<td>N</td>
<td>Constituent of &quot;Khat&quot; plant</td>
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<tr>
<td>Chloral betaine</td>
<td>2450</td>
<td>N</td>
<td>Beta Chlor</td>
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<tr>
<td>Chloral hydrate</td>
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<td>N</td>
<td>Noctec</td>
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<tr>
<td>Chlordiazepoxide</td>
<td>2744</td>
<td>N</td>
<td>Librit, Librilab, Limbirtol, SK-Lygen</td>
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<tr>
<td>Clodazepam</td>
<td>2751</td>
<td>N</td>
<td>Uribadan, Urbanyl</td>
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<tr>
<td>Conazepam</td>
<td>2757</td>
<td>N</td>
<td>Klonopin, Clonopin</td>
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<tr>
<td>Cocarbazepate</td>
<td>2768</td>
<td>N</td>
<td>Tremene</td>
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<tr>
<td>Clofazepam</td>
<td>2752'</td>
<td>N</td>
<td>Trecalmo, Rize, Clozan, Veratran</td>
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<tr>
<td>Cloxazolam</td>
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<td>Aldon, Lubaliix, Ticacal, Sepazon</td>
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<tr>
<td>Delorazepam</td>
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<tr>
<td>Dexfenfluramine</td>
<td>1870</td>
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<td>Redux</td>
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<td>Dextropropoxyphene dosage forms</td>
<td>9278</td>
<td>Y</td>
<td>Darvon, propoxyphene, Darvocet, Propacef</td>
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<tr>
<td>Diazepam</td>
<td>2785</td>
<td>N</td>
<td>Valium, Diestat</td>
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<tr>
<td>Dichloralphenazone</td>
<td>2467</td>
<td>N</td>
<td>Middin, dichloralantipyrine</td>
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<tr>
<td>Diethylpropion</td>
<td>1610</td>
<td>N</td>
<td>Tenuate, Tepanii</td>
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<tr>
<td>Difenoxin 1 mg/25 ug AtSO4du</td>
<td>9167</td>
<td>Y</td>
<td>Motofen</td>
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<tr>
<td>Estazolam</td>
<td>2796</td>
<td>N</td>
<td>ProSom, Domnamid, Eurodin, Nuctalon</td>
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<tr>
<td>Ethylchlopyrilol</td>
<td>2540</td>
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<td>Pardiol</td>
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<td>Ethylmagnesium</td>
<td>2545</td>
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<td>Valmid, Valamin</td>
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<tr>
<td>Ethyl lofazepate</td>
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<tr>
<td>Fenamidactin</td>
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<td>Reactivan</td>
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<td>Fenfluramine</td>
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<td>Pondrin, Ponderal</td>
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<tr>
<td>Fenproporex</td>
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Norethandrolone (17alpha-ethyl-17beta-hydroxyestr-4-en-3-one)
Normethandrolone (17alpha-methyl-17beta-hydroxyestr-4-en-3-one)
Oxymetholone (17alpha-methyl-2-hydroxymethylene-17beta-hydroxy-5alpha-androstan-3-one)
Oxandrolone (17alpha-methyl-17beta-hydroxy-2-oxa-5alpha-androstan-3-one)
Oxymesterone (17alpha-methyl-4,17beta-dihydroxyandrost-4-en-3-one)
Oxymetholone (17alpha-methyl-2-hydroxymethylene-17beta-hydroxy-5alpha-androstan-3-one)
Pentobarbital & noncontrolled active ingred.
Pentobarbital suppository dosage form
Phendimetrazine
Secobarbital & noncontrolled active ingred.
Secobarbital suppository dosage form
Stanozolol (17alpha-methyl-17beta-hydroxy-5alpha-androst-1-en-3-one(3,2-c)-pyrazole)
Stenbolone (17beta-hydroxyl-2-methyl-5alpha-androst-1-en-3-one)
Sulfonmethane
Sulfonmethane
Sulfonmethane
Talbutal
Tetrabotive
Tetrahydrogestrinone (13beta,17alpha-diethyl-17beta-hydroxy gon-4,9,11-trien-3-one)
Testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone)
Testosterone (17beta-hydroxyandrost-4-en-3-one)
Tetrahydrogestrinone (17beta,17alpha-dimethyl-17beta-hydroxy-oxygen-4,9,11-trien-3-one)
Thiamyal
Thiopental
Thiopental
Thiopental
Tilenazepam & Zolazepam Combination Product
Trenbolone (17beta-hydroxyestr-4,8,11-trien-3-one)
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Appendix D

DEA Offices of Diversion Control
Offices and Directories > Field Office Locations

Field Office Locations

To access information on Field Offices, select a particular state on the map below or view the text list of states.

Legend
® Diversion Program Manager, Diversion Investigators, and Registrant Assistants
○ Diversion Investigators
* Diversion Investigators and Registration Assistants

ALABAMA
ALASKA
ARIZONA
ARKANSAS
NEBRASKA
NEVADA
NEW JERSEY
NEW HAMPSHIRE

http://www.deadiversion.usdoj.gov/offices_n_dirs/fielddiv/index.html

3/2/2006
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<tr>
<td>CALIFORNIA (Central)</td>
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<td>CALIFORNIA (San Diego &amp; Imperial Counties Only)</td>
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<td>MONTANA</td>
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Registration Support
Toll Free Number: 1-800-882-9539

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Diversion Program Managers

Select a Field Office Location:

Atlanta      Newark
Boston       New Orleans
Caribbean    New York
Chicago      Philadelphia
Dallas       Phoenix
Denver       St. Louis
Detroit      San Diego
El Paso      San Francisco
Houston     Seattle
Los Angeles  Washington D.C
Miami

DIVISION Atlanta
States NW Georgia
North Carolina
South Carolina
Tennessee
Name Howard W. Davis
Address 75 Spring Street, SW, Room 800
Atlanta, GA 30303
Telephone 404-893-7165
Fax 404-893-7138 (Diversion Program Manager)
404-893-7096 (Diversion Group)

Back to Top

DIVISION Boston
States Connecticut
Maine
Massachusetts
New Hampshire
Rhode Island
Vermont

<table>
<thead>
<tr>
<th>Name</th>
<th>Nancy Coffey</th>
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<tbody>
<tr>
<td>Address</td>
<td>JFK Federal Building</td>
</tr>
<tr>
<td></td>
<td>15 New Sudbury Street, Room 400E</td>
</tr>
<tr>
<td></td>
<td>Boston, MA 02203-0402</td>
</tr>
<tr>
<td>Telephone</td>
<td>617-557-2191</td>
</tr>
<tr>
<td>Fax</td>
<td>617-557-2130 (Dvision Prgram Manager)</td>
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**DIVISION Caribbean**

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<tr>
<td>Name</td>
<td>DPM - Marcellino Sustache</td>
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<td></td>
<td>P.O. Box 2167</td>
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<td>Suites 400 and 500</td>
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<td>Guaynabo, PR 00968</td>
</tr>
<tr>
<td>Telephone</td>
<td>787-775-1716</td>
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**DIVISION Chicago**

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<td>Minnesota &amp; North Dakota</td>
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<tr>
<td>Name</td>
<td>Acting DPM - James K. Portner</td>
</tr>
<tr>
<td>Address</td>
<td>Kluczynski Federal Building</td>
</tr>
<tr>
<td></td>
<td>230 S. Dearborn Street, Room 1200</td>
</tr>
<tr>
<td></td>
<td>Chicago, IL 60604</td>
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<tr>
<td>Telephone</td>
<td>312-353-8227 or 800-478-7914</td>
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<td>312-353-1236 or 800-478-7642    (Minnesota)</td>
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| States  | Oklahoma  
|         | North Texas |
| Name    | Michael Lewis |
| Address | 10160 Technology Blvd., East  
|         | Dallas, TX 75235 |
| Telephone | 214-366-6900 |
| Fax     | 214-366-6902 |

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| States  | Colorado  
|         | Montana  
|         | Utah  
|         | Wyoming |
| Name    | William C. Reinig |
| Address | 115 Inverness Drive, East  
|         | Englewood, CO 80112 |
| Telephone | 303-705-7300 |
| Fax     | 303-705-7423 |

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| States  | Kentucky  
|         | Michigan  
|         | Ohio |
| Name    | Acting DPM - James Geldhof |
| Address | 431 Howard Street  
|         | Detroit, MI 48226 |
| Telephone | 313-234-4307 |
| Fax     | 313-234-4041 (Diversion Program Manager)  
|         | 313-234-4149 (Diversion Group) |

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| States  | New Mexico  
|         | West Texas |
| Name    | G/S Benjamin Vinson |
| Address | El Paso Federal Justice Center  
|         | 660 South Mesa Hills Drive, Suite 2000 |

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El Paso, TX 79912
Telephone 915-832-6000
Fax 915-832-6302 (Diversion Program Manager)
915-832-6225

DIVISION Houston
States South Texas
Name Judett R. Black
Address 1433 West Loop South, Suite 600
Houston, TX 77027-9506
Telephone 713-693-3000
713-693-3634 (Group)
Fax 713-693-3661

DIVISION Los Angeles
States Central California
Guam
Hawaii
Nevada
Name Raymond Conner
Address 255 East Temple Street, 20th Floor
Los Angeles, CA 90012
Telephone 213-621-6711
Fax 213-894-5924 (Division Program Manager)
213-894-3946 (Division Group)

DIVISION Miami
States Bahamas
Florida
Name Barbara A. McGrath
Address 8400 N.W. 53rd Street
Miami, FL 33166
Telephone 305-994-4704
Fax 305-994-4293


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<tr>
<td>Name</td>
<td>Donald Hickman</td>
</tr>
<tr>
<td>Address</td>
<td>3838 N. Causeway Blvd., Room 1800, Metairie, LA 70002</td>
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<tr>
<td>Telephone</td>
<td>504-840-1100, 504-840-1100 (Group)</td>
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<tr>
<td>Name</td>
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<tr>
<td>Address</td>
<td>69 Tenth Avenue, New York, NY 10011</td>
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<tr>
<td>Telephone</td>
<td>212-337-1190, 212-337-1575 (Group)</td>
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<td>Name</td>
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<td>Address</td>
<td>80 Mulberry Street, 2nd Floor, Newark, NJ 07102</td>
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<tr>
<td>Telephone</td>
<td>973-776-1100, 973-776-1161/1171 (Group)</td>
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<table>
<thead>
<tr>
<th>Name</th>
<th>Ann L. Carter</th>
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</table>
| Address            | William J. Green Federal Building  
                     | 600 Arch Street, Room 10224  
                     | Philadelphia, PA 19106       |
| Telephone          | 215-597-9540           |
| Fax                | 215-597-3030           |

DIVISION Phoenix  
States Arizona  
Name G/S Barbara Roberts  
Address 3010 N. 2nd Street, Suite 301  
Phoenix, AZ 85012  
Telephone 602-664-5813  
Fax 602-664-5820

DIVISION St. Louis  
States Iowa  
Kansas  
Missouri  
Nebraska  
South Dakota  
South Illinois  
Name Acting DPM - Barbara Heath / Kansas City DO  
Address 317 South 16th Street  
St. Louis, MO 63103  
Telephone 913-825-4201 (KCDO)  
314-538-4600 (Group)  
Fax 314-538-4622

DIVISION San Diego  
States South California  
Name G/S Valencia B. Abrams  
Address 4560 Viewridge Avenue  
San Diego, CA 92123-1637  
Telephone 858-616-4100 (G/S)  
858-616-4100 (Group)  
Fax 858-616-4326

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<td>Alaska</td>
<td>District of Columbia</td>
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<tr>
<td>Name</td>
<td>William Davis</td>
<td>Alfred C. Cheeseman</td>
<td>Donetta Spears</td>
</tr>
<tr>
<td>Address</td>
<td>450 Golden Gate Avenue, 14th Floor</td>
<td>400 2nd Avenue West</td>
<td>Mailing Address: Techworld</td>
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<td></td>
<td>P.O. Box 36035</td>
<td></td>
<td>800 K Street, NW, Suite 500</td>
</tr>
<tr>
<td></td>
<td>San Francisco, CA 94102</td>
<td></td>
<td>Washington, DC 20001</td>
</tr>
<tr>
<td>Telephone</td>
<td>415-436-7900</td>
<td>206-553-5443</td>
<td>202-305-8137</td>
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<tr>
<td>Fax</td>
<td>415-436-7810</td>
<td>206-553-1576</td>
<td>202-305-8800 (Group)</td>
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Appendix E

EPIC MRA Michigan Pain Study—Executive Brief
EXECUTIVE BRIEF
“STATE OF PAIN”
MICHIGAN PAIN STUDY -- A STATEWIDE SURVEY

Sample: Random stratified sample of 1,500 Michigan adults (Error margin +/- 2.5%)

The "pain" facts in Michigan are that one in five Michigan adults are experiencing some form of chronic, ongoing or recurring pain, representing some 1.2 million people. This experience is not a passing problem, since 77 percent of these sufferers have been experiencing pain for well over a year, with 40 percent indicating the pain is "constant" and has a major impact on their lives.

Chronic pain not only impacts the lives of those suffering, but the rest of Michigan as well. Forty-two percent of respondents reporting pain said their pain has affected their relationships with spouses, family and fellow workers. For employers this means lost productivity, as 36 percent of pain sufferers missed some work last year. This accounts for some 400,000 workers; put another way, 12 percent of the Michigan work force did not show up for work some time in the last year because of pain (35 percent missing more than 20 days).

Hospital emergency rooms saw 21 percent of these chronic pain sufferers (representing approximately 252,000 adults) an average of four times, with two percent of these patients, approximately 24,000 in-pain adults, receiving treatment for overdoses of medication.

Solutions for this problem will not come easy. Seventy percent of chronic pain sufferers said they still experience pain after treatment. Thirty percent (representing approximately 360,000 adults) said they did not experience even a reduction in their pain after treatment; with 22 percent saying treatment "only makes it worse."

Looking for solutions for their pain has lead to five percent of chronic pain sufferers (representing approximately 60,000 adults) to drink alcohol, including 18 percent of whom admit to overdosing on their medication. Forty-eight percent report "getting depressed" about their pain and 29 percent report "losing sleep."

A final solution for some chronic pain sufferers is the contemplation of suicide. Ten percent of respondents experiencing chronic, ongoing or recurring pain said they have thought about committing suicide, representing 120,000 adults in Michigan.

Reduction in the number of chronic pain sufferers may come through education and access to drugs, procedures, medical devices and referrals to other health care professionals and pain centers. Thirteen percent of chronic pain sufferers said they have been denied such access. Half of pain respondents are unaware that Michigan has several pain centers or that there has been several advancements in the treatment of pain.

Currently, 42 percent of chronic pain sufferers either see no doctor on a regular basis or only see a family doctor. Sixty-five percent of these respondents have never seen a specialist or a professional who specializes in treating pain.
MEN & WOMEN -- PAIN

Men and women differ in their views of pain. While men appear to come to some form of resignation to their pain, women appear to more successfully acknowledge and incorporate pain into their daily lives. Twenty-two percent of men reporting pain and 34 percent of women reporting pain rate their quality of life "the best it can be" as a result of the effects of pain (on a scale of 0-10, with 8, 9 and 10 being considered "the best.")

Differences between men and women don't stop there. While 57 percent of men indicate they "under report" pain, 47 percent of women say they do so, and women also more quickly seek out help for their pain than do men. This difference can lead to dangerous consequences because men are not coping with their pain; twice as many men (14 percent) as women (seven percent) said they contemplate suicide because of their pain.

Men under age 50 were most likely to have pain that has persisted more than a year (86 percent), compared to 75 percent for men over 50, 79 percent for women over 50 and 69 percent for women under 50. Men under 50 were most likely to "under report" their pain. Women over 50 are the least comfortable about discussing pain with their doctors and men under 30 are by far the most likely to call in sick to work because of pain.

<table>
<thead>
<tr>
<th>Experienced chronic pain</th>
<th>17%</th>
<th>23%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain has a major impact</td>
<td>38%</td>
<td>42%</td>
</tr>
<tr>
<td>Pain has a significant impact</td>
<td>23%</td>
<td>20%</td>
</tr>
<tr>
<td><strong>SOURCE OF PAIN:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injury or accident</td>
<td>43%</td>
<td>20%</td>
</tr>
<tr>
<td>Ongoing condition</td>
<td>50%</td>
<td>71%</td>
</tr>
<tr>
<td>Pain has persisted more than a year</td>
<td>81%</td>
<td>75%</td>
</tr>
<tr>
<td><strong>WILL SEEK MEDICAL HELP:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If pain persists more than a day</td>
<td>5%</td>
<td>9%</td>
</tr>
<tr>
<td>If over-counter medicine doesn't work</td>
<td>8%</td>
<td>7%</td>
</tr>
<tr>
<td>Work impaired more than 20 days</td>
<td>34%</td>
<td>24%</td>
</tr>
<tr>
<td>When pain becomes unbearable</td>
<td>29%</td>
<td>32%</td>
</tr>
<tr>
<td>&quot;Pain makes me depressed&quot;</td>
<td>48%</td>
<td>48%</td>
</tr>
<tr>
<td>&quot;Pain makes me suicidal&quot;</td>
<td>17%</td>
<td>7%</td>
</tr>
</tbody>
</table>

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ADDITIONAL COMMENTS

1. One-in-five Michigan adults (20 percent) may have "chronic" pain, representing some 1.2 million adults. These numbers appear to be conservative, since half the respondents (51 percent) said they "underreport" pain. If that is true, then a number of respondents experiencing pain may not have made it through the survey screen, since they may have not indicated they have pain and thus were not interviewed.

2. Telling others they are in pain does not come easily to the survey respondents. Only seven percent report seeking help for pain "immediately," while 46 percent (representing approximately 552,000 adults) wait until it's "unbearable" or "interferes with other activities." Men more than women (26 percent to 16 percent) "wait for pain to pass on its own."

3. Above average numbers of people in pain can be found in Detroit and in northern Michigan. This is not unexpected, as other data in the survey shows that people who are older or of lower income status have higher reported incidents of chronic pain. Older women rank the highest in reporting chronic pain, at 31 percent.

4. Younger men report the main reason for pain is "the result of an injury or accident" (56 percent), while the rest of respondents report "ongoing conditions" as the primary reason for pain.

5. The reported pain is not short term, as 77 percent (representing approximately 924,000 adults) said their pain has been with them over a year and 85 percent saying over six months.

6. Forty percent (representing approximately 480,000 adults) said their pain is "constant" with another 27 percent indicating their pain is "daily." This totals to 67 percent of respondents reporting pain experiencing it on a regular daily basis. These numbers hold true across all generation groups.

7. A significant difference between those "under reporting" and those who don't, lies in the result that those under reporting report having constant pain by 45 percent opposed to the 37 percent of those in constant pain who don't under report.

8. Sufferers in their 6th to 12th month of pain appear to go through some kind of resignation or acknowledgment of their pain. This particular group attempts to "let pain pass on its own," with 35 percent of these respondents waiting for it to pass versus 19 percent of all respondents reporting pain. Further study is needed on this apparent phase of psychological adjustment - i.e.: Does this adjustment lead pain sufferers to refuse to seek or accept treatment? Is the success of treatment affected during this phase?

9. At risk respondents -- the survey indicates that 10 to 15 percent of pain respondents (representing approximately 120,000-180,000 adults) could be classified at risk. Overdosing on medication, severe depression, drinking alcohol, working on the job impaired by their pain and being unable to get help for their pain.
NOTES OF INTEREST

• 22 percent feel uncomfortable talking about their pain with their doctors.

• 22 percent don't have faith that the medical professionals they see have the knowledge or understanding needed to treat their pain.

• People with chronic pain spend about $1,118 out-of-pocket each year on medicine to relieve the pain and average four emergency room visits per year. Twenty-one percent say they have been hospitalized for their condition, for an average hospital stay of three days.

• 28 percent said their pain was severe enough to impair their ability to perform their job well that on more than 20 work days in the past year.

• Complaints of chronic pain are most common among people earning less than $30,000 a year.

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Michigan Pain Study -- News Conference Participants

Ed Sarpolus, Vice President, EPIC/MRA, Lansing, Michigan
Sarpolus is a leading pollster and public opinion analyst. His firm's studies focus on a wide range of social and political issues and receive national attention. Recent studies have addressed such topics as assisted suicide, aggressive driving and a variety of health and public health issues. Sarpolus is a frequent speaker and often-quoted source in interpreting public opinion.

Joel R. Saper, M.D., Chairman, Michigan Council on Pain
Director, Michigan Head Pain & Neurological Institute, Ann Arbor, Michigan
Dr. Saper is a board-certified neurologist recognized internationally as a leading pain expert and educator, and founder of the world's first comprehensive head pain treatment and research center. He was appointed by the Michigan Legislature to chair the Michigan Council on Pain and speaks nationwide on the causes and treatment of severe and chronic pain. Dr. Saper is chairman of the National Coalition for Patients in Pain and past president of the American Association for the Study of Headache. He is on the boards of the American Pain Society and American Association of Pain Medicine and is also past national chairperson of the American Council for Headache Education.

John Burrows, M.D.
Hospice Medical Director, Karmanos Cancer Institute, Southfield, Michigan
Dr. Burrows joined Karmanos Cancer Institute (the former Michigan Cancer Foundation) in 1973 and now directs one of the state's largest hospice programs. He is also a practicing oncologist. Dr. Burrows is responsible for establishing numerous cancer treatment and training programs at St. John Hospital in Detroit and elsewhere around the state. He is a frequent speaker on cancer patient care and is on the faculty of the Wayne State University School of Medicine.

John Jerome, Ph.D., Clinical Director, Sparrow Regional Pain Center, Lansing, Michigan
Dr. Jerome is a licensed psychologist with 23 years experience specializing in the treatment of the emotional effects of chronic pain. He recently authored chapters on pain management for the 1997 medical text, Foundations of Osteopathic Medicine, and is on the faculty of the College of Osteopathic Medicine at Michigan State University.

Todd Lininger, M.D., Vice Chairman, Department of Anesthesiology and Medical Director of Pain Management Services, North Oakland Medical Center, Pontiac, Michigan
Dr. Lininger is board-certified in anesthesiology and pain management with a special interest in reflex sympathetic dystrophy and neuropathic pain. He is a frequent national speaker on new advances in pain treatment and is on the faculty of the Wayne State University School of Medicine, Department of Anesthesiology.

Susanne Homant, Executive Director, Michigan Hospice Organization, Lansing, Michigan
Homant is responsible for operations of this statewide organization which is a leading advocate for quality hospice care in Michigan. She leads the organization's efforts in lobbying on public policy and legislative issues and manages the organization's statewide educational programs. Homant is a director and legislative chairperson of the Michigan Cancer Pain Initiative. She is completing a doctorate in public administration at Western Michigan University.
September 2, 1997

The Honorable Joe Palamara
State Representative
State Capitol, Rm. 315
Lansing, Michigan 48909-7514

Dear Rep. Palamara:

Dr. Joel Saper requested that I provide you with some information based on my research concerning the effectiveness of specialized treatment of patients with chronic pain. I hope that what I will summarize in this letter will be of some use to you and your committee.

It has been estimated that over 60 million Americans suffer from some type of persistent or recurrent pain. Not only does chronic pain adversely affect patients' physical and psychological well-being, chronic pain costs billions of dollars to society in lost productivity, health care expenditures, and disability compensation. In the past quarter century, specialized treatment facilities—Multidisciplinary Pain Centers (MPCs)—have been established to treat patients with recalcitrant pain problems. A recent survey identified over 400 pain centers and clinics devoted to the treatment of rehabilitation of these patients. In 1995, it was estimated that over 175,000 were treated at MPCs (MarketData, 1995).

Despite the growing number of MPCs, persistent skepticism has been voiced by third-party payers who frequently deny payment for treatment. The criticisms are of two general types: (1) it is suggested that there is no evidence that MPCs are successful in bringing about important outcomes, namely, returning people to work and other functional activities, reducing utilization of the health care system, and closure of disability claims; and (2) it is asserted that MPCs are not cost-effective. Despite the skepticism, there is a substantial body of published evidence that runs counter these two criticisms.

It is important to note that the patients treated at MPCs have long histories of pain (averaging over 7 years). These are the most difficult cases. These patients are heavy utilizers of the health care system with over 85% taking pain medication and the average patient having 1.7 surgical procedures prior to treatment (Flor et al., 1992) and on average spent over $13,000 on health care in the year prior to treatment (Simmons et al., 1988). In addition, over 30% of treated at MPC are receiving some form of disability at the initiation of treatment (Flor et al., 1992). Even though the patients treated at MPCs are among the most difficult, the results are quite impressive. I will highlight some of these.

Two meta-analyses (Flor et al., 1992; Cutler et al., 1994) concluded that MPCs are substantially more effective in helping return patients to work than conventional medical and surgical interventions. Based on over 65 published studies [3,089 patients], Flor et al. noted that from 45%-65% of patients treated at MPCs return to work following treatment. This can be compared to the 20% of patients who return to work. Following treatment at MPCs, patients required 1/3 the number of surgical intervention and hospitalizations compared to patients treated by conventional medical and surgical care. Treatment at MPCs resulted in closure of disability claims for ¼ of those receiving disability at the time of treatment.

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My colleagues and I (Turk & Gatchel, in press; Turk & Okifuji, 1997) have made extrapolations from the data included in the two meta-analyses cited above and more recent studies and concluded that not only are MPCs clinically effective, they are cost-effective. Using the 3,689 patients included in the Flor et al. meta-analysis, we estimated that even after factoring the cost of treatment at MPCs (average $8,100 based on a MarketData Survey in 1993) savings in excess of $20 million would be achieved based on reductions in health care utilization and indemnity costs during the first year following treatment. Considering the average age of the patients treated in the Flor et al. meta-analysis was 43, the savings until age 65 would exceed $348 million. If we used the same assumptions for the estimated 175,000 patients treated at MPCs, then the financial savings would exceed $11 billion in the first year following treatment alone. Of course these astronomical figures do not take into consideration the reduction in suffering and improvement in the quality of life of the patients and their families.

The data I have presented supports the clinical and cost-effectiveness of MPCs. To my knowledge, no health care intervention has been studied as extensively as MPCs nor have the outcomes for treatment been as great. These results are significantly better than any reported for conventional medical or surgical treatments for chronic pain. Yet, alternatives such as surgery are more readily covered by third-party payers. There seems to be a disparity in the evidence that is acceptable. Third-party payers should give greater attention to the available evidence as MPCs hold significant promise for reducing health care expenditures and disability compensation while improving the functioning and quality of life of a substantial proportion of chronic pain sufferers.

I hope that the information I have provided will be of some value to you and your colleagues who are examining the issue of appropriate treatment and rehabilitation of people suffering from chronic pain. I have included a list of references upon which I based my conclusions. Please let me know if I can provide any additional information or be of any further assistance.

Sincerely,

Dennis C. Turk, Ph.D.

DCT/jb

enclosure

cc: Joel R. Saper, M.D., PACP
Appendix F

Human Subjects Institutional Review Board
Approval Letter and Extension
Date: June 29, 2004

To: Peter Kobrak, Principal Investigator
    Susanne Homant, Student Investigator

From: Mary Lagerwey, Ph.D., Chair

Re: HSIRB Project Number: 04-05-26

This letter will serve as confirmation that your research project entitled “The War on Drugs V. The war on Pain: Do Controlled Prescribing Laws Have a Role” has been approved under the expedited category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note that you may only conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: June 29, 2005
APPLICATION FOR CONTINUING REVIEW or FINAL REPORT FORM

In compliance with Western Michigan University's policy that "the HSIRB's review of research will be conducted at appropriate intervals but not less than once per year," the HSIRB requests the following information:

I. PROJECT INFORMATION

PROJECT TITLE: The War on Drugs v. the War on Pain

HSIRB Project Number: 04-05-26

Previous level of review: □ Full Board Review X Expedited Review □ Administrative (Exempt) Review

Date of Review Request: 05/29/05 Date of Last Approval: 06/29/04

II. INVESTIGATOR INFORMATION

PRINCIPAL INVESTIGATOR OR ADVISOR
Name: Peter Kobrak, PhD
Department: PA&A Mail Stop: N/A Electronic Mail Address: Peter.kobrak@wmich.edu

(1) CO-PRINCIPAL OR STUDENT INVESTIGATOR
Name: Susanne F. Homant
Department: PA&A Mail Stop: N/A Electronic Mail Address: Suehospice@aol.com

(2) CO-PRINCIPAL OR STUDENT INVESTIGATOR
Name: 
Department: Mail Stop: Electronic Mail Address:

III. CURRENT STATUS OF RESEARCH PROJECT

Please answer questions 1-4 to determine if this project requires continuing review by the HSIRB.

1. The project is closed to recruitment of new subjects.
   □ Yes (Date of last enrollment: 12/5/04) □ No (Project must be reviewed for renewal.)

2. All subjects have completed research related interventions.
   □ Yes □ Not Applicable □ No (Project must be reviewed for renewal.)

3. Long-term follow-up of subjects has been completed.
   □ Yes □ Not Applicable □ No (Project must be reviewed for renewal.)

4. Analysis of data is complete.
   □ Yes □ No (Project must be reviewed for renewal.)

- If you have answered "No" to ANY of the questions above, you must apply for Continuing Review. Please complete numbers 5-12 on page 2. If you need to make changes in your protocol, please submit a separate memo detailing the changes that you are requesting.

- If you have answered "Yes" or "Not Applicable" to ALL of the above questions, please check the Final Report box below and complete questions 5-10 on page 2.

- If your protocol has been open for three years and you still want to collect or analyze data, you must close this protocol by filing a final report using this form and apply for approval of a new protocol using an Application for Initial Review. Please make a Final Report on your project by completing numbers 5-10 on page 2.

IV. XX Application for Continuing Review V. □ Final Report

Revised 7/03 WMU HSIRB
All other copies obsolete.
5. Have there been changes in Principal or Co-Principal Investigators? □ Yes XX No
   (If yes, provide details on an "Additional Investigators" form (available at the HSIRB web site, http://www.wmich.edu/research/compliance/hsirb/hsirb_2.html).)

6. Has the approved protocol been modified or added to with respect to:
   (If yes to any item below, provide the details on an attached sheet.)
   a. Procedures □ Yes XX No
   b. Subjects □ Yes XX No
   c. Design □ Yes XX No
   d. Data collection □ Yes XX No

7. Has any instrumentation been modified or added to the protocol? □ Yes XX No
   (If yes, attach new instrumentation or indicate the modifications made.)

8. Have there been any adverse events that need to be reported to the HSIRB? □ Yes
   (If yes, provide details on an attached sheet.)

9. Total number of subjects approved in original protocol: 30

10. Total number of subjects enrolled so far: 30
    If applicable: Number of subjects in experimental group: Number in control group:
    • If this is a FINAL REPORT you may stop here and return the form electronically.
    • If this is an APPLICATION FOR CONTINUING REVIEW continue with numbers 11-13 below.

11. Estimated number of subjects yet to be enrolled: None

12. Verification of Consent Procedure: Provide copies of the consent documents signed by the last two
    subjects enrolled in the project. Cover the signature in such a way that the name is not clear but there is
    evidence of signature. If subjects are not required to sign the consent document, provide a copy of the
    most current consent document being used.

13. If you are continuing to recruit subjects for this project, please remember to include a clean
    original of the consent documents to receive a renewed approval stamp.

   [Signatures and dates]

   Approved by the HSIRB:

   [Signature and date]

   Western Michigan University
   Human Subject Institutional Review Board – Mail Stop 5456

Revised 7/03 WMU HSIRB
All other copies obsolete.
ARCOS: Automation of Reports and Consolidated and Consolidated Orders system.

An automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture to point of sale at the retail level. Operated under the DEA.

Addiction: A chronic, relapsing disease, characterized by compulsive drug seeking and use and by neurochemical and molecular changes in the brain. (NIDA-NIH) A primary chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestation (American Academy of Pain Medicine). It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction (Fed of State Medical Boards-2004 Policy statement).

Pseudoaddiction: An iatrogenic syndrome characterized by a pattern of drug seeking behavior in pain patients who are receiving inadequate pain management. Pseudoaddiction can be mistaken for “drug-seeking” behavior and addiction.

Physical Dependence: An adaptive physiological state that can occur with regular drug use and results in withdrawal when drug use is discontinued.
**Tolerance:** A condition in which higher doses of a drug are required to produce the same effect as experienced initially. A state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug’s effects over time.

**Barbituate:** A type of central nervous system (CNS) depressant often prescribed to promote sleep (also anxiety, tension, seizures).

**Benzodiazeephine:** A chemical used in several types of CNS depressant prescribed to relieve anxiety; among the most widely prescribed medications, includes Valium, Librium, Vicodin and Lortab.

**Chilling Effect:** As used in this study, means the negative effect that public policies have on prescribing patterns for controlled substances. The chilling effect is present when a clinician prescribes differently due to concerns over regulatory oversight.

**CNS – Central Nervous System:** The brain and spinal cord. (#1)

**DAWN:** Drug Abuse Warning Network, a national data system that collects information on drug-related visits to emergency departments from a national sample of hospitals. Operated through the Office of Applied Studies of SAMHSA.

**DEA:** Drug Enforcement Administration, a division of the U.S. Department of Justice.

**Drug Diversion:** As used in this study, drug diversion is defined as the use of legal, controlled substance drugs for non-prescribed purposes.
Opioids: Controlled drugs or narcotics most often prescribed for the management of pain; natural or synthetic chemicals based on opium’s active component—morphine—that work by mimicking the actions of pain-relieving chemicals produced in the body.

Opiate: Drugs whose origin is the opium poppy, including codeine and morphine.

Policy: As used in this study, is a very broad term, and may be used to refer to laws, regulations, or guidelines.

Statute: Law created by a legislative body.

Regulation: An official rule or order issues by agencies of the branches of government. Regulations have the force of law and are intended to implement a specific statute.

Guideline: An official policy statement, which does not have the force of law. Although they do not have binding legal force, they often describe accepted standards of practice for those regulated by an organization or agency.

Pain: An unpleasant sensory and emotional experience associated with actual or potential tissue damage or chronic pathologic process that causes continuous or intermittent pain over months or years.
**Nociceptive pain:** May be visceral or somatic and is most often derived from stimulation of pain receptors. May arise from tissue inflammation, mechanical deformation, ongoing injury, etc. Arthritis, broken leg, etc. Usually responds well to standard analgesic treatments.

**Neuropathic pain:** Results from a pathophysiologic process that involves injury to the peripheral or central nervous system. Neuralgia, etc. Does not respond as well to conventional analgesic treatment.

**Mixed or unspecified pain:** Having unknown or mixed mechanisms. Migraine headaches, vasculitic pain syndromes. May require treatment trials.

**Psychogenic pain:** Pain caused by psychological factors, deemed to have a major role in the onset, severity or persistence of pain. Needs treatment with psychiatric interventions, does not respond to traditional medical pain interventions.

**PMP:** Prescription Monitoring Program

**Psychotherapeutics:** Drugs that have an effect on the function of the brain and that often are used to treat psychiatric disorders; can include opioids, CNS depressants, and stimulants.

**Substance Abuse:** The use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.