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PURDUE PHARMA, L.P.
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SITUATION ANALYSIS

It has been well documented that pain, including end-of-life pain, surgical pain and chronic pain, is not adequately treated in the United States.

Given that effective pharmaceutical treatments for pain are available, pain experts believe that essentially no patient should be required to suffer pain. In fact, some physicians have stated that not relieving pain optimally is tantamount to moral and legal malpractice.

The treatment of both malignant and nonmalignant pain depends predominantly on opioid analgesics (although the need for both pharmacological and nonpharmacological is clear).

Evidence gathered from studies on malignant pain management clearly demonstrates the potential for highly favorable outcomes from long-term opioid therapy. (R. Portenoy, *Journal of Law, Medicine & Ethics*). Many studies have demonstrated that long-term opioid therapy provides acceptable relief (thereby improving quality of life) in 70 percent to 90 percent of people experiencing malignant pain. As a result, long-term treatment with opioids has been strongly advocated by pain specialists, national and international medical groups.

However, there is much discussion and research concerning the role of opioids in the treatment of chronic, nonmalignant pain. It is generally agreed among specialists that a select subpopulation of patients with chronic nonmalignant pain can attain favorable outcomes for prolonged periods using opioid drugs (R. Portenoy, *Journal of Law, Medicine & Ethics*).

Despite studies that demonstrate the efficacy of opioids in the management of pain, many legal, educational, historical and social barriers exist that often preclude patient use and physician administration of these drugs (Portenoy, 1996). These barriers include, but are not limited to the following:

1. ***Burdensome state laws and regulations***

   Laws and regulations that are intended to reduce misuse and abuse of opioids have impeded (perhaps unintentionally) the legitimate use of these drugs. Studies demonstrate that in states where triplicate prescription forms are mandated by law, a 40 percent to 60 percent drop in the prescribing of Schedule II drugs is noted. Though research findings are inconclusive, some experts believe that in these states, the quality of care decreases because physicians substitute less

effective medication. A balance needs to be achieved between properly regulating these drugs and protecting the patient's right to palliative care.

2. ***Inadequate training of providers***

The experts we spoke with believe the more fundamental problem is the lack of adequate skills among health professionals. The education and training of physicians and other health care professionals fails to provide them with the appropriate knowledge, skills, and attitudes required to administer appropriate palliative care (Institute of Medicine Report). There is an overall deficiency of training on issues related to pain that is noted at the undergraduate, graduate, and continuing education levels. Because of this, there is relatively no mentoring of young physicians about palliative care.

3. ***Provider concerns***

Some physicians are reluctant to prescribe opioid analgesics due to unfounded concerns about addiction and a fear of being investigated for violating drug abuse-related laws and regulations. In addition, some pharmacists are reluctant to fill prescriptions because of underlying concerns related to possible disciplinary action. These fears are exaggerated. For example, there are approximately 75,000 licensed physicians practicing in California. From 1990 to 1995, the California State Medical Board disciplined 120 physicians for prescription-related violations. In addition, no more than 20 doctors, dentists and pharmacists per year have been criminally prosecuted in the state for prescription drug offenses. These unwarranted concerns need to be addressed.

4. ***Societal attitudes***

There are pervasive societal myths related to opioid therapy that need to be replaced by fact. We live in a society that is sensitized to endemic drug abuse; therefore it is not surprising that many health care providers view opioid drugs with hypervigilance and distrust (*Home HealthCare Consultant*, October 1997). Until providers and the general public understand the relevant facts, this climate of uncertainty and fear will prevail.

5. ***Poor coordination***

There is very little dialogue among policy makers, consumer groups, purchasers and health care providers on issues related to pain management. Although individual providers must act to improve care at the end of life, there must be changes in systems of care to support such action. System change requires the involvement of public and private purchasers of care, regulators, and others whose policies and practices may create incentives for inappropriate care and barriers to excellent care. (Institute of Medicine).

The Federation of State Medical Boards has drafted model guidelines for prescribers, which the Federation hopes will be adopted universally. Pain policy analysts we spoke with argue that a non-legislative approach to affecting change (*i.e.*, adopting practice guidelines) is better than a legislative approach because guidelines are easily modified as

the practice of pain management changes. In addition, many times, the interpretation of legislative solutions can be more limiting than intended.

Although statutes and regulations can provide reassurance for some physicians, the national thought leaders in the field of pain management that we spoke with believe strongly that appropriate enforcement is linked inextricably with the level of knowledge about pain management of the state medical boards' members and staff. Educating them is important, but it can be difficult due to the change in membership as terms expire.

Many experts argue that the most effective deterrent to physicians' fear of prescribing opioids is to ensure that state medical boards and DEA are not investigating and disciplining physicians who appropriately treat pain. In addition, state medical boards must enlist the expertise of those physicians who are knowledgeable about pain management and must encourage them to train medical board investigators and attorneys, so that accurate decisions will be made about possible misconduct (Chris Stern Hyman).

OPPORTUNITIES

There is much activity at the state and federal level directed toward improving pain management and treatment. Individuals from a variety of fields have joined together to direct the attention of policy makers and the general public to the need to remove the obstacles to providing good care.

As part of this movement for improved care, several foundations and research organizations including, the Midwest Bioethics Center (Kansas City, Missouri) and the Pain & Policy Studies Group (Madison, Wisconsin), have made commitments to study public policy in relation to pain management. In addition, large research projects have been funded (through organizations such as The Robert Wood Johnson Foundation and the Commonwealth Foundation) with the goal of generating useful information on this topic to physicians, regulators, and patients alike.

An example is the $11.25 million program, Community-State Partnerships to Improve End-of-Life Care. Under this program, which is funded by The Robert Wood Johnson Foundation, and is being administered by the Midwest Bioethics Center, grants will be awarded to state- and community-based groups that will work toward improving the quality of care for the dying, particularly in the area of pain control. Grant recipients will be announced in December 1998. The Foundation encouraged grant applicants to include programs addressing the need for state medical, nursing, and pharmacy boards to develop and disseminate guidelines that promote effective pain management. In addition, the need for nursing home regulations regarding pain and symptom management, as well as programs to ensure that academic health centers train future health professionals adequately were mentioned. There was an overwhelming response to the RFP — 47 of the 50 states submitted programs.

In order to effect substantial change in the management of pain, comprehensive system change must occur. Those state-based initiatives that will be successful in promoting system change will be those that employ a multifaceted strategy that focuses not only on the structures, processes, and outcomes of care, but also on the environmental factors – such as financing mechanisms and educational programs – that impact the delivery of care (Institute of Medicine).

PROGRAM OBJECTIVES

- To strategically foster public policy changes in the use of opioids for pain management.
- To impact the prescribing environment in which opioids are used for responsible pain management.
- To position Purdue Pharma with key stakeholders in a manner that will be helpful to future product launches.

STRATEGIES

Phase I: Analyze the best opportunities to impact change

Clearly, momentum is building to address and affect pain management policies and practices. While a myriad of opportunities exist, it is critical to choose wisely. Any effort undertaken can and should include a long-term marketing objective. For this reason, we recommend a thorough analysis of the players, issues and alliances in the current pain management. Doing so will allow us to develop a program that meets our objectives and use our resources in the most effective manner.

This evaluation will: profile the dynamics of individuals and groups involved in supporting or opposing pain legislation; analyze the status of legislation and professional regulations; evaluate the obstacles to success, and recommend the most effective and cost-efficient method for Purdue Pharma to participate in pain management public policy development.

Congress and the courts are deferring the specific policy making regarding pain management to the state level. Although there will continue to be opportunities at the federal level. However, most of the immediate impact will more than likely occur in the states.

State Level

Without a doubt, state policies have a direct affect on how physicians prescribe pain medication. Many states have begun to recognize this role, and they have appointed pain commissions, enacted intractable pain legislation and considered medical guidelines for intractable pain. The next two years should bring intense activity in pain policy at the state level, both by medical boards and state legislatures. It is important to remember the dual role of legislation and medical board policies. While state legislation is often broadly drafted, regulations can more specifically address what physicians may or may not do. Both play a critical role.

Key States. Seven states currently have triplicate-copy prescription requirements. Studies demonstrate that the prescribing of Schedule II opioids decreases in those states with a corresponding increase in less heavily regulated analgesics, which are not as strong or effective at managing moderate or severe pain. (The Center to Improve Care of the Dying, The George Washington University)

The major indicators for a state's progress in pain management policy are how it requires physicians to record Schedule II drug prescriptions, whether the state medical board has adopted guidelines on intractable pain treatment and whether there are any state statutes or regulations regarding the treatment of intractable pain. The following is a summary of those indicators in key states:

- **California.** California's triplicate prescription system had been the oldest in the country, taking effect in 1940. Currently the state is in the process of switching to an electronic data transfer system for Schedule II drugs. It became the second state to pass an Intractable Pain Act, mainly because of the support from patient and physician groups. The state medical board has adopted guidelines for treating intractable pain.
- **Hawaii.** Uses both a duplicate prescription form as well as electronic data transfer. No state medical board guidelines. No intractable pain statutes or regulations. Has an end-of-life task force but it became politicized when the Governor asked the task force to study physician-assisted suicide. As a result the task force's work on pain management became mired in politics an the task force disbanded. The task force is trying to regroup, but it will take some time.
- **Idaho.** Uses triplicate prescription form. State medical board has adopted guidelines for treating intractable pain. No intractable pain statutes or guidelines.
- **Illinois.** Uses triplicate prescription form. No state medical board guidelines for intractable pain. No intractable pain statutes or guidelines. State Senator John Maitland has been the champion in the legislature for creating an end-of-life task force. His current plans are to bring this before the legislature in 1999.

- **Michigan.** Uses special prescription form in addition to electronic data transfer. No state medical board guidelines for intractable pain. No intractable pain statutes or guidelines. There is concern that Geoffrey Fieger's candidacy for governor will force the focus of end of life and pain management policy onto physician-assisted suicide because of Fieger's former relationship as Jack Kevorkian's attorney,
- **New Jersey.** Recently the Board of Medical Examiners enforced an outdated statute pertaining to do not resuscitate orders. The policy, which requires that three physicians witness such an order, was not being enforced and the medical community asked that it be rescinded. A firestorm ensued and despite strong opposition from the medical and bioethics communities, the policy was maintained and now may be enforced with renewed vigor.
- **New York.** No state medical board guidelines for intractable pain. No intractable pain statutes or guidelines. However, in August the governor signed a bill that eliminated the triplicate forms in favor of a single form and an optional electronic data transfer at the pharmacy level. This was the result of a consolidated effort of patient, medical and drug associations taking on the triplicate law. In addition, the legal definition of an addict was changed to allow the legal prescribing of pain medications for pain relief..
- **Texas.** Uses triplicate prescription laws, but is considering transfer to electronic data transfer. In 1989, Texas became the first state to enact an Intractable Pain Act. That act authorizes physicians to prescribe Schedule II drugs for intractable pain. In addition, the state medical board has guidelines in place that permit physicians to prescribe Schedule II drugs for intractable pain. Has both statutes and regulations on intractable pain. .
- **Washington.** Uses triplicate forms for disciplinary purposes only. State medical board has guidelines for intractable pain. No intractable pain statutes or guidelines.

Pilot Programs: While every state has the potential to bring about progressive change in pain management policies, initially, Purdue Pharma should focus on three states. We recommend beginning Phase I in California, New York and Texas. Because of recent policy changes and the current political environment, these three states have the greatest need for broad-based education efforts. They also have solid organizations leading the efforts for changes in pain management policies. Working through these organizations there is a tremendous opportunity to position Partners Against Pain as a resource in any pain management education and outreach effort. In the process, Purdue Pharma will: build on existing relationships, such as the program in California that is educating physicians about the change in prescription procedures; establish relationships with *the* authorities in each state on pain management issues, both which will serve as a foundation for future pre-launch programs.

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