FOSTERING CHANGE IN THE PAIN POLICY ENVIRONMENT

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SITUATION ANALYSIS

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

Given that effective pharmaceutical treatments for pain are available, medical experts believe that essentially no patient should 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 interventions is widely acknowledged by pain specialists).

Evidence gathered from studies on malignant pain treatment clearly demonstrates the potential for highly favorable outcomes from long-term opioid therapy. Studies reveal that long-term opioid therapy provides acceptable relief (thereby improving quality of life) in 70–90 percent of people experiencing malignant pain. As a result, long-term treatment with opioids is strongly advocated by pain specialists, as well as 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.[2]

Despite studies that demonstrate the efficacy of opioids in the treatment of pain, many legal, educational, historical and social barriers exist that often preclude patient use and physician administration of these drugs.[3] These barriers include, but are not limited to, the following:

1. ***Burdensome state laws and regulations***
   Laws and regulations that are intended to reduce the misuse and abuse of opioids impede (perhaps unintentionally) the legitimate use of these drugs. Studies reveal that in states where triplicate prescription forms are mandated by law, a 40–60 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.[4] There is an overall deficiency of training on issues related to pain 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 regarding 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 are criminally prosecuted in the state for prescription drug offenses. These unwarranted provider concerns need to be addressed.
4. ***Societal attitudes***
   There are pervasive societal myths related to opioid therapy that should 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.[5] 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 policymakers, consumer groups, purchasers and health care providers on issues related to pain treatment. 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.[6]

The Federation of State Medical Boards drafted model guidelines for prescribers and hopes they will be adopted universally. Pain policy analysts we spoke with argue that a nonlegislative approach to effecting change (*i.e.*, adopting practice guidelines) is better than a legislative approach because guidelines are easily modified as the practice of pain treatment 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 treatment with whom we spoke believe strongly that appropriate enforcement is linked inextricably with the state medical boards' members and staff's level of knowledge about pain treatment. 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 the 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 treatment and must encourage them to train medical board investigators and attorneys so accurate decisions are made about possible misconduct.[7]

OPPORTUNITIES

There is much activity at the state and federal levels directed toward improving pain treatment. Individuals from a variety of fields are working together to show policymakers and the general public the necessity of removing obstacles to provide good care.

As part of this movement for improved care, several foundations and research organizations, including the Midwest Bioethics Center (Kansas City, Mo.) and the Pain & Policy Studies Group (Madison, Wis.), are committed to studying public policy in relation to pain treatment. In addition, large research projects are underway (funded through organizations such as the Robert Wood Johnson Foundation and the Commonwealth Foundation) with the goal of generating useful information on this topic for physicians, regulators and patients alike.

An example of such a project 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 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 treatment policy. Grant recipients will be announced in December 1998. The Foundation encouraged grant applicants to include programs that address the need for state medical, nursing and pharmacy boards to develop and disseminate guidelines that promote effective pain treatment. In addition, the need for nursing home regulations regarding pain and symptom treatment, as well as programs to ensure that academic health centers train future health professionals adequately, were mentioned. There was an overwhelming response to the Foundation's request for proposals with 47 of the 50 states submitting programs.

To effect substantial change in the treatment of pain, comprehensive system change must occur. The state-based initiatives that will be successful in promoting system change will be those employing a multifaceted strategy focusing not only on the structures, processes and outcomes of care, but also on the environmental factors — financing mechanisms and educational programs — that impact the delivery of care.[8]

KEY ELEMENTS TO FOSTERING CHANGE

I. Strategically analyze key states and federal initiatives to determine the best environment to impact change.

II. Develop programs that leverage existing resources.

III. Implement pilot programs to effect pain policy.

FOSTERING CHANGE

I. Strategically analyze the best opportunities to impact change

Clearly, momentum is building to address and affect pain treatment policies and practices. While a myriad of opportunities exists, it is critical to choose wisely. Any effort undertaken can and should include a long-term marketing objective. For this reason, we recommend conducting a strategic and thorough analysis of the current key players, issues and alliances in the pain policy arena. Doing so will allow us to develop a program that meets Purdue Pharma's objectives and utilizes the company's resources in the most effective manner.

This analysis will profile the dynamics of individuals and groups involved in supporting or opposing pain legislation; analyze the status of legislation/regulations and professional guidelines; detail the barriers to success; and recommend the most effective and cost-efficient method for Purdue Pharma to participate in pain treatment public policy development.

Congress and the courts are deferring the specific policy-making regarding pain treatment to the state level. Although there will be opportunities to effect change at the federal level, most of the immediate opportunities will be at the state level.

State Level Efforts

Without a doubt, state policies directly affect how physicians prescribe pain medication. Many states have begun to recognize this and, as a result, have appointed end-of-life or pain commissions and enacted intractable pain legislation and guidelines for pain treatment. The next two years should bring intense activity in pain policy at the state level, involving medical boards and state legislatures among others. It is important to understand the importance of both state legislation and medical board policies. While legislation is often broadly drafted, medical board policies specifically address what physicians may or may not do. Both play a critical role in influencing change.

Key States. Seven states currently have multiple 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.[9] The major indicators for a state's progress in pain treatment policy are how it requires physicians to record and monitor Schedule II drug prescriptions. This is done either through state medical board adopted guidelines on pain treatment or through 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 was the oldest in the country, taking effect in 1940. However, recently Governor Wilson signed a bill that excludes the use of triplicate forms for terminal patients whose treatment is no longer curative but palliative. There also is a pilot program underway testing electronic data transfer systems for Schedule II drugs. California was 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**. Hawaii utilizes both a duplicate prescription form, as well as electronic data transfer. There are no state medical board guidelines and no intractable pain statutes or regulations. The state 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 treatment became mired in politics, and the task force disbanded. Members of the task force currently are trying to regroup.
- **Idaho**. Idaho mandates the use of duplicate prescription forms. The state medical board adopted guidelines for treating intractable pain, but there are no intractable pain statutes or regulations.
- **Illinois**. Illinois requires that its physicians use a triplicate prescription form. There are no state medical board guidelines for intractable pain. In addition, there are no intractable pain statutes or guidelines. State Senator John Maitland is the champion in the legislature for creating an end-of-life task force. His plans are to bring this before the legislature in 1999.
- **Michigan**. Michigan uses a special prescription form in addition to electronic data transfer. There are no state medical board guidelines for intractable pain and no intractable pain statutes or regulations. There is concern that Geoffrey Fieger's candidacy for governor will force the focus of end-of-life and pain treatment 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 three physicians to 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. There is concern that this issue has clouded the environment for pain policy changes and it may take some time for advocates to reemerge.

- **New York**. New York does not have state medical board guidelines for intractable pain. In addition, it does not have any intractable pain statutes or guidelines. However, in August the governor signed a bill that eliminated the triplicate form 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 which will alleviate some of the physicians' fears of scrutiny when they are prescribing Schedule-II drugs for chronic pain.
- **Texas**. Texas has triplicate prescription laws but is considering transferring to electronic data transfer. In 1989, Texas was 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 adopted guidelines that permit physicians to prescribe Schedule II drugs for intractable pain. Texas has both statutes and regulations on intractable pain.

Federal Level Initiatives

While there are immediate opportunities to impact pain treatment policy at the state level, there also are patient pain initiatives at the federal level. As health care legislation moves through Congress, it will be critical to monitor and assess opportunities that could impact pain treatment policy. For example, opportunities may exist as the Lethal Drug Abuse Prevention Act moves through Congress. While we recognize Purdue Pharma's reluctance to champion this issue, monitoring the legislation may provide insight into possible program ideas for the future.

In addition, there may be opportunities for Purdue Pharma to effect change through the development of relationships with The White House Office of National Drug Control Policy, Health Care Financing Administration, the Drug Enforcement Agency and national patient and professional organizations, among others. At the same time, analyzing what other pharmaceutical companies are doing at the federal level (either on their own or through association with federal agencies and national organizations) will be helpful to Purdue Pharma in selecting programs to undertake in this arena.

Work at the state level will undoubtedly lead to insights on federal issues; however, to determine specific opportunities for Purdue Pharma, Fleishman-Hillard recommends conducting a strategic evaluation of the issues relevant to pain treatment that are currently being discussed at the federal level. This will include an assessment of current federal level initiatives, an evaluation of opportunities to impact change, identification of groups or individuals championing pain treatment initiatives and recommendations on how best to leverage these activities to Purdue's advantage.

Timetable

A thorough analysis of the current situation at both the federal level and within the seven target states can be completed in three months. After the analysis is completed, Fleishman-Hillard would like to present our findings to the Purdue Pharma team. At this meeting, Fleishman-Hillard will provide a comprehensive written report detailing the strategic opportunities for Purdue Pharma to effect change at both the federal and state levels. The report will identify the key obstacles to achieving public policy change within each state. The most important influencers in each state and background on their respective grassroots initiatives will be included. At this strategy session, a plan will be established for how to proceed with our state and federal programs.

Monitoring Services

Since many states beyond the seven key states are implementing changes in their respective pain treatment environments — some faster than others, and all at varying degrees — tracking this information would be valuable to Purdue Pharma in evaluating opportunities for involvement in other state-based pain treatment initiatives.
And because much of the ongoing state-based activity is inextricably linked to activity at the federal level, it is critical to track the policy initiatives in Washington, D.C. The relationships cultivated in these states and at the federal level will be useful for future initiatives. In addition, monitoring these changes at the state and federal level presents a unique opportunity to provide a value-added service to the Partners Against Pain Web site and position the company as a resource for up-to-date information on pain policy initiatives.

Timetable

Gather initial data:	Three months
Monthly updates begin:	The fourth month

II. Develop state-specific and federal pilot programs based on research and analysis

After speaking with key policy makers, regulators, physicians, pharmacists and patient advocates (among others), and after conducting a thorough analysis of the ongoing activities within the eight states that currently have multiple prescription requirements, Fleishman-Hillard will outline strategic opportunities for Purdue Pharma to foster change in the pain treatment environment in three pilot states and at the federal level.

Using Purdue Pharma's corporate objectives as a guideline, we will work with the Company to develop a comprehensive communications program that best leverages these opportunities. This plan will support existing state efforts, such as the Robert Wood Johnson Foundation's Community-State Partnership Program, which will put tremendous dollars and influence behind reworking pain treatment guidelines and legislation. Our preliminary assessment is that this program presents strong opportunities for alliance building for Purdue Pharma.

Our initial research indicates that influencing a physician's prescribing behavior is a two-part process. First, the regulatory environment, both at the state and federal level, must allow physicians to prescribe Schedule II drugs to treat intractable pain with few restrictions and without fear of prosecution. Second, laws, regulations and guidelines must be clearly and effectively communicated to providers, regulators and the general public. Both are critical to effecting positive changes in physician prescribing behavior.

Each program will embrace three objectives:

- Strategically foster public policy changes that facilitate the use of opioids for pain treatment.
- Impact the prescribing environment in which opioids are used for responsible pain treatment.
- Position Purdue Pharma with key stakeholders in a manner that will be helpful to future product launches.

Timetable
A public affairs/communications plan on three target states and the federal level will be presented to Purdue Pharma a month following the presentation of the first phase of research to the Company.

III. Roll-out of pilot programs (state-specific and federal level)

With Purdue Pharma's corporate objectives in mind, the pilot programs will be implemented. Drawing on our vast experience with product launches, we will seek to develop a network of individuals and organizations at the state and federal levels that will be helpful to the company both in the short- and long-term. (Fleishman-Hillard is cognizant of the fact the Company has several pain treatment products in development.)

While specific tactics will be determined only after completing a comprehensive review of each, a potential program could include the following:

- **Develop educational brochure: "The Seven Myths of Pain Treatment."** There is a considerable amount of misinformation about pain treatment. As a result, there is a real need for a concise, educational piece that can be used to inform important decision-makers and opinion leaders, such as elected/appointed officials and the media, about issues related to the responsible treatment of pain. We recommend developing an educational brochure tentatively titled "The Seven Myths of Pain Treatment" that addresses the key concerns legislators, professionals and the public have about treating chronic pain with opioids. We would use Purdue Pharma research to show the reality of effective pain control, which would position Purdue Pharma as an authority on pain treatment. This brochure would be used as an educational piece for legislative decision-makers, opinion shapers and consumers could also be available on the Partners Against Pain Web page and used by the sales force.

- **Build alliances with key influencer groups.** Once we have identified the key national or state organizations that will provide the greatest benefit for Purdue Pharma, we will carefully evaluate the benefit of building alliances with them. These alliances could allow Purdue Pharma to work toward the common goal of improving the pain policy environment. These alliances will become vehicles for offering a series of educational campaigns targeting legislators. The backing of third-party groups will greatly increase the credibility of the message, thereby hastening the process.

- **Partners Against Pain media education effort**. The media will be an important third-party influencer to legislators and regulators. A campaign of editorial boards, desk-side briefings, one-on-one interviews and research-based media materials are some of the options.

- **Consensus Conferences**. Bringing together legislators and advocates for effective pain treatment will be important in raising the profile of the issue among state legislatures as well as state medical boards.

- **Speakers Bureaus**. Identifying champions and putting real faces on the issue is an effective education tool for policy makers. Through public testimony and other speaking opportunities "real people" can have a powerful impact.

These tactics are very preliminary and just a surface look at some of the opportunities that might exist. Each state will have it's own unique and creative program.

Timetable: Implementation will begin following program approval by Purdue Pharma.

Budget: To be developed for each state and federal program.

[1]Endnotes

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[2] R. Portenoy, *Journal of Law, Medicine & Ethics*
[3] Portenoy, 1996
[4] Institute of Medicine Report
[5] *Home HealthCare Consultant*, October 1997
[6] Institute of Medicine
[7] Chris Stern Hyman
[8] Institute of Medicine
[9] The Center to Improve Care of the Dying, The George Washington University