AMERICAN PAIN FOUNDATION℠

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Testimony by the American Pain Foundation

Senate Health, Education, Labor and Pensions Committee Hearing to Examine the Effects of the Painkiller OxyContin, Focusing on Risks and Benefits

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Summary

The American Pain Foundation agrees with the Drug Enforcement Administration, hundreds of pain management experts and thousands of patients that no additional legislation is needed to attack the diversion and abuse of all opioid pain medications, including OxyContin.

The Food, Drug & Cosmetic Act, and particularly the Controlled Substances Act, provide the DEA, state licensing boards, other law enforcement and regulatory entities, and the medical profession with the tools necessary to fight illegal use and abuse of all opioids while maintaining access to these medications for legitimate medical use by people suffering serious chronic pain.

Introduction

The American Pain Foundation (APF) is the nation's leading nonprofit consumer advocacy organization devoted exclusively to serving the needs of people with pain through information, education and advocacy. Our mission is to improve the quality of life for people with pain by raising public awareness, providing practical information, promoting research, and advocating removing barriers and increasing access to effective pain management. Our Board of Directors is composed of several of the nation's leading academic and clinical experts on pain management, along with consumer representatives.

FDA-approved Opioids are Safe and Effective Pain Medications

OxyContin is one of many opioids — strong medications used to treat people suffering with moderate to severe pain — that have been approved by the FDA as safe and effective when taken as prescribed, but are also classified under the Controlled Substances Act, Schedule II, as having the potential for abuse. As such, virtually all opioids have been the subject of some level of diversion and abuse. However, their acceptance by federal regulators and the medical community has slowly grown as their benefits have become known. That is because when taken as prescribed, under the direction of a physician for pain relief, opioids are safe and effective, and only in rare cases lead to addiction. When properly used, these medications rarely give a "high" — they give relief. And most importantly, they allow many people to resume their normal lives.

Recently, OxyContin abuse has been front-page news in several communities. While these often-sensationalized stories have focused primarily on the illegal and dangerous use of this medication by drug abusers, they have often failed to balance the problem of abuse with the real news about the whole class of opioid pain medications: that they provide valuable relief for millions of people suffering with significant, often disabling, chronic pain. The danger of these stories is that they perpetuate long-standing myths and misconceptions about opioids. Moreover, they have the potential to chill the legitimate medical use of opioids by people with pain for whom opioid therapy is appropriate.

Existing Laws Provide Sufficient Tools to Combat Illegal Opioid Use

The American Pain Foundation is extremely alarmed that media reports about the abuse of OxyContin have created a volatile situation with the potential for overreaction by federal lawmakers. Some solutions that have been proposed could end up reducing access to ALL opioid analgesics, not just OxyContin. The American Pain Foundation fully agrees with the statements made last fall by the Administrator of the Drug Enforcement Administration (DEA) that no new legislation is needed to address the abuse of *any* prescription medication, including OxyContin.

In an effort to stop OxyContin abuse, many policy-focused solutions would call on the DEA to take steps that will inadvertently hurt consumers who use any opioid for legitimate pain relief. Virtually all of the calls for tightening federal statutes and regulations fail to consider the OTHER side of the story: that millions of Americans suffer serious chronic pain, yet many go untreated or undertreated, especially the elderly, people of color and the poor. (*For more on the scope of the undertreatment of pain in the U.S., please see the attached background sheet on pain.*)

DEA Seeks to Balance Law Enforcement While Preserving Patient Access

In October 2001, the American Pain Foundation joined the DEA and 20 other health and medical organizations in releasing a "Consensus Statement" on prescription pain drugs that called for a balance between promoting patients' access to proper pain relief medication and preventing drug diversion and abuse. This was the first public event in which the DEA joined hands with virtually the entire pain management community to demonstrate their strong interest in preserving access to pain medications as they implement their law enforcement mandate.

DEA acknowledged that achieving the "balance" called for in the Consensus Statement would take a lot of work on both its part and the part of the pain management community. Congress would undermine this growing effort and short-circuit it by implementing additional mandates now. Even with the best of intentions, Congress runs the great risk of harming people with pain and impeding proper, patient-centered pain management practice.

Improving Pain Management: Still a Long Way to Go

Pain management practice is finally *starting* to achieve the status it deserves in the healthcare setting. Medical professionals, policy makers, the public and the media are becoming more aware of the undertreatment of pain and are beginning to take steps to address the problem. For example, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the largest accrediting body in the United States, released new pain management standards in the January 2001. These standards now require all of its 19,000 hospitals, nursing homes, and other healthcare facilities to assess and treat pain, and

inform patients about their right to effective pain care. If they do not comply, they can lose their accreditation.

In spite of these advances, over 50 million Americans still live with malignant or non-malignant chronic pain. Although most pain can be managed, it often goes untreated, improperly treated, or undertreated. For example, studies show that while cancer pain can almost always be relieved, more than 40% of cancer patients are undertreated for pain. Why? One reason is a false fear that opioid medications taken for pain are dangerous or addictive.

A recent study published in the Journal of the American Medical Association found that 24% of nursing home patients with a terminal illness who were in significant pain received nothing, not even an aspirin, to relieve their pain.

Obviously, we have a long way to go before every American gets adequate pain care.

Congress: Do Not Turn Back the Clock on the Little Progress We Have Made

In its efforts to "do something" about OxyContin, Congress must not take actions that would cause significant harm to people with pain and set a dangerous precedent for *all* opioid medications. Several proposals have been thrown out. We particularly oppose the following as the most fraught with dangerous "unintended consequences"

No. 1: Do not reduce the quota of oxycodone. Cutting the national supply of the active ingredient in OxyContin (oxycodone) is a classic law enforcement tactic for *illegal* drugs. But you cannot repeal the law of supply and demand, so the supply for the *legitimate* production of opioids must go down and their price must go up. As a result, many patients, especially the uninsured, will get less effective alternatives or nothing at all. Street prices will also rise, which can lead to more crime as dealers fight over profits and addicts steal more to support their "habit".

No. 2: Do not restrict prescribing privileges to pain specialists. No one agrees on the definition of a "pain specialist." Even with a liberal definition, only two to five percent of physicians would qualify. It would be physically impossible for them to treat all legitimate consumers. The poor, people of color, people with disabilities, the elderly, children and rural citizens would be harmed disproportionately, as they have the least access to such specialists. General practitioners *already* underutilize opioids. They need more education and more assurance that they will not be wrongly targeted by law enforcement, not have more restrictions placed on their professional judgment.

No. 3: Do not limit distribution to centralized pharmacies. This measure would deter access to effective pain care by many living in rural and underserved

communities, and those with limited mobility. Using the mail as an alternative only moves the site of potential crime from a pharmacy building with *some* security to a consumer's mailbox. Instead, we must educate pharmacists on current laws and policies and ways to improve existing security.

No. 4: Do not limit the indication to pain from certain diseases. FDA intensely scrutinizes *every* opioid for appropriate indications. Narrowing an indication to only "sympathetic" conditions, such as cancer or sickle cell, because of actions by *illegal* users contradicts sound medical science. Millions of Americans living with non-malignant chronic pain who effectively use opioids provide the best data that the original indications were right.

We Must Balance the Need for Law Enforcement with the Need of Patients

Doctors and pharmacists must remain vigilant to keep opioids out of illegal hands. Law enforcement officers should be tough in combating illegal diversion of opioids. Patients should safeguard their prescription medications to assure that they are not stolen and misused.

Nevertheless, all this must be done in a balanced way that does not discourage the legitimate use of prescribed pain medications. Congress should be wary of "quick-fix" proposals, because they often backfire.

In its desire to respond to a criminal problem, Congress must not turn the War on Drugs into a "War on Pain Patients."

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Background Information on Pain

I. Magnitude of the Pain Problem

Serious chronic pain is arguably the most widespread health problem in the American adult population. Because so little federal research dollars are devoted to pain, we have no exact figures, but best estimates are that:

- **Up to 75 million Americans suffer serious pain annually: 50 million** of those endure serious chronic pain annually (pain lasting 6 months or more), and another **25 million** experience acute pain (from injuries, accidents, surgeries, etc.)

That is more than diabetes, heart disease, asthma and stroke combined.

Other basic facts:

- Pain is the No. 1 reason for doctor visits. One study found that *80%* of physician visits were for pain
- Pain disproportionately affects women
- Headache, lower back pain, arthritis and other joint pain, and peripheral neuropathy are the most common forms of chronic pain
- Over 26 million adults experience frequent back pain, and 2/3 of Americans will have back pain during their lifetime
- 1 in 6 Americans suffers from arthritis
- Close to 4 million Americans -- mostly women -- suffer from fibromyalgia, a complex condition involving widespread pain and other symptoms
- The seminal SUPPORT study found that fully half of all hospitalized patients have moderate to severe pain in their last days of life

Because we know of no recent study on the pain problem in the State of Maryland where we are based, the American Pain Foundation is undertaking a survey on the extent of the problem and barriers to effective treatment, which we hope to have completed by early March.

II. The Gross Undertreatment of Pain in America

Although the medical knowledge and treatments are now available to relieve or greatly ease most pain, pain is still arguably the most untreated, undertreated and mistreated serious health problem in the U.S. Some startling examples:

- A 1999 study, Chronic Pain in America, found that only 1 in 4 of those with pain received adequate treatment
- An estimated *70%* of those with cancer experience significant pain during their illness, yet in an early study of cancer pain fewer than half received adequate treatment for their pain
- A recent study (published in JAMA) of nursing home patients with cancer found that 24% of patients with significant pain received nothing stronger than aspirin
- Another study recently published in JAMA found that 41% of nursing home patients who were admitted with moderate to severe pain still had approximately the same level of pain 6 months later
- Numerous studies have shown that people of color receive even worse pain care than the population at large.

III. The Cost of Pain

Pain exacts a terrible toll not only on the individual but society as well. People who endure chronic, unrelieved pain are more likely to --

- suffer from depression and anxiety,
- have trouble sleeping,
- have other physical ailments and take longer to recover from them,
- lose time at work,
- lose their job and have other financial problems,
- have more difficulty conducting everyday tasks,
- have difficulty caring for children and other dependents, and
- suffer deteriorated relationships with family and friends.

The overall impact of pain, while largely hidden, is enormous:

- Pain is the No. 1 cause of disability
- The National Institute on Health estimates that pain costs us over **$100 billion/year** in medical expenses, lost wages and other costs
- Another study found that 50 million workdays were lost to pain in 1995
- The same study revealed that untreated pain results in lower productivity, greater employee absenteeism, and higher insurance premiums

IV. Why is Pain So Often Untreated, Undertreated or Mismanaged?

There are, unfortunately, numerous reasons that lead to pain being so poorly treated in this country.

A. Public Attitudes About Pain

The public still harbors many outdated myths and misconceptions about pain. It is still often stigmatized, just the way mental illness has been until recently. Most common misperceptions are:

- Without obvious physical injury, the pain must "just be in your head."
- Pain is just something one has to "live with," that it is "inevitable" as one grows older, and that there is little help out there.
- Many Americans do not want to be perceived as weak or not able to "tough it out." Thus it was no surprise that in a 1999 Gallup survey 64% of Americans seek a doctor's help only when their pain has become "unbearable."

B. Fear of Medications

While there are many drugs, medical procedures, and complementary/alternative ways to treat pain, powerful pain medications called opioids are often the best (and sometimes only) treatment for severe pain that has not responded to more common techniques. Patients (and surprisingly, many health care professionals) lack even basic knowledge about these options and fear that powerful pain drugs will:

- Cause addiction. (One survey found 86% of Americans agreed with this statement, while most studies show that less than 1% of patients become addicted, which is medically different from becoming physically dependent.)
- Wear out or lose their effectiveness over time.
- Have unbearable side effects.
- Indicate that the person is "getting worse" or is "going to die."

C. Lack of Adequate Training of Medical Professionals

It is no secret that physicians, nurses, pharmacists and medical social workers traditionally did not get as much training in pain management as they needed. While this is *starting* to change, the picture is still bleak. For example:

- A 1997 National Institutes of Medicine report found that most physicians still do not get adequate training in pain and symptom management in end of life care.
- A 1999 study found that only 1 of 126 medical schools surveyed offered a full and separate course in pain management.
- A survey of 305 accredited baccalaureate nursing programs found that 48% of them spent 4 hours or less discussing the treatment of pain.
- Most states do not require health professionals to take pain management courses to fulfill their continuing education requirements.

D. Resulting Fears and Myths Among Health Care Professionals

Given the lack of widespread training in pain management, many health care professionals do not adequately assess pain. Furthermore, because many harbor the same unfounded concerns as patients, they often undertreat pain. Specifically, many health care professionals:

- Do not fully evaluate a patient's pain, take their complaints seriously, or conduct follow-up to see if their recommended course of treatment is working.
- Do not understand the differences among tolerance, physical dependence and addiction regarding prescription pain medications.
- Fear that opioids will hasten death by depressing respiration.
- Worry that prescribing controlled substances for pain will draw unwarranted scrutiny from state regulatory bodies and the DEA. (A confidential survey of N.Y. State physicians found that over 1 in 4 admitted to prescribing a lower dose or shorter course of an opioid than they believed necessary because of fears of being investigated.)
- Are not familiar with the safety and efficacy of many alternative pain treatments that have been shown effective for *some* patients, such as acupuncture, massage therapy, relaxation techniques and chiropractic.

Conclusion

There are *many* other reasons why pain is so poorly treated in this country, including:

- Lack of up-to-date requirements and policies among state medical boards, nursing boards and pharmacy boards,
- Lack of reimbursement for many effective pain medications and treatments, and
- Outdated regulatory policies

The bottom line, then, is that much needs to be done, and the American Pain Foundation is committed to working with Congress, the Administration and all others interested in pain management issues on solutions to tackle this problem in our nation.

Who We Are

The American Pain Foundation: (APF) is the nation's leading nonprofit organization devoted exclusively to serving the needs of people with pain through information, education and advocacy. Our mission is to improve the quality of life for people with pain by raising public awareness, providing practical information, promoting research, and advocating to remove barriers and increase access to effective pain management.

APF was founded in 1997 by three of the nation's leaders in pain management: Dr. James Campbell, Director of the Blaustein Pain Treatment Center at Johns Hopkins Hospital; Dr. Kathleen Foley, Pain & Palliative Care Services at Memorial Sloan

Kettering; and Dr. Charles Cleeland, Director of the Pain Research Group at M.D. Anderson Cancer Center.

They recognized that while a few professional societies existed for physicians, nurses and other professionals specializing in pain management, there was no national nonprofit, grassroots organization dedicated entirely to serving and representing pain patients. From a single staff person, we have grown to a staff of 10 professionals with a solid funding base.