

Testimony Presented to the Special Committee on Aging United States Senate

Field Hearing Jefferson City, Missouri January 19, 2016

The United States finds itself beset by two major public health crises that often are perceived as being interrelated, namely prescription drug abuse and chronic pain. Many people perceive a sort of "zero-sum game", in which efforts to resolve one of these two problems must, of necessity, worsen the other problem. Policymakers' efforts to address these problems, to date, have skewed largely toward preventing prescription drug abuse, and have often resulted in policies that are perceived by people with pain and the clinicians who care for them as restricting access to some pain medications. Unfortunately, there is evidence to support this notion—in particular, Florida's efforts to rein in "pill mills" have resulted in a dramatic decrease in overdose deaths related to prescription opioids, but they also have left many people with chronic pain unable to fill prescriptions for the opioid pain relievers that maximize their ability to function and their overall quality of life.

Prescription drug abuse and chronic pain share many similar characteristics. For instance:

- Both are highly prevalent
- Both are very costly, in economic and human terms
- Both highly stigmatized, and patients are blamed for having each condition
- Both involve tremendous suffering, both for patients and those who care about them
- Both are poorly understood by the medical profession, due to lack of content in training programs
- Both are under-resourced vis-à-vis treatment
- Both are very complex problems, with many moving parts
- Both are best treated with a multimodal, integrated, biopsychosocial approach

The writer H.L. Mencken is quoted as having said, "For every complex problem, there is a solution that is neat, simple, and wrong." Our view is that many of the policy solutions developed to address these two problems have been those "neat, simple, and wrong" solutions. Trying to solve problems as complex as these with simple policy changes results, we believe, in the "zero-sum" game outlined above, and creates negative unintended consequences. We will succeed in addressing both of these

problems only when we are able to conceptualize and implement solutions that match the problems in terms of complexity.

Complex Solutions for Complex Problems

The American Academy of Pain Management is the premier organization for all clinicians who care for people with pain. The Academy's 4200+ members include approximately 2200 MDs and DOs, with the remaining 2000 members representing 30 distinct healthcare disciplines, all of which provide pain care. Since it was founded in 1988, the Academy has espoused a model of integrated pain care, in which professionals from multiple disciplines come together as a team to provide the best, most comprehensive, care possible for each individual person with pain. As an organization, the Academy fosters the formation of these teams and supports the professional growth of individual team members through education, credentialing, publications, and advocacy.

Our policy advocacy efforts have, for the past several years, focused heavily on two areas: Increasing access to multidisciplinary, multimodal, team-based pain care; and minimizing the risk of prescription drug abuse through the implementation of balanced policies that provide for the ongoing needs of people with pain. This agenda has provided us the opportunity to participate in a wide array of national, regional, and statewide groups, and has enabled us to weigh in on several hundred individual policy proposals. Two policy issues that have been among our most frequently encountered are prescription drug monitoring programs (PDMPs) and adequate education for clinicians about both substance abuse and chronic pain.

Prescription Drug Monitoring Programs

PDMPs are state-based electronic database programs that collect, analyze, and distribute information about controlled substance prescriptions dispensed to that state's citizens. The first of these programs was established by California in 1939, while the most recently-established program is in the District of Columbia, which began operating its program in 2015. At this time, 49 states, the District of Columbia, and Guam all operate PDMPs (see attached map). Additionally, seven Canadian provinces currently operate programs and two more have programs in development, while Yukon Territory is linked to the Alberta PDMP. The only exception in the United States is the state of Missouri, where efforts to establish a PDMP over the past half-dozen years have failed.

Public Safety Uses of PDMPs

Many people recognize the public safety utility of PDMPs in deterring, detecting, and intervening in drug diversion activities. This was the original purpose of PDMPs, and it remains the purpose that carries the most weight in policymaking. By analyzing records collected by the PDMP, it is possible to identify individuals who obtain prescriptions from multiple prescribers, fill them at multiple pharmacies, using multiple payment methods, all in order to accumulate large supplies of controlled substances that they can sell, while avoiding detection by insurance companies, prescribers, and dispensers. These individuals, often referred to as "doctor shoppers" are rare, but can be quite prolific. One study found that they represented 0.7% of opioid purchasers in one state, but those individuals accounted for 1.9% of all controlled substance prescriptions and 4% of all opioids dispensed by weight. The Academy's Executive Director, Bob Twillman, also serves as chair of the advisory committee for the

Kansas PDMP, known as K-TRACS. Two of the most egregious cases encountered in K-TRACS are the following:

- A person who, in one years' time, filled prescriptions for various controlled substance written by 86 unique prescribers, using 65 unique pharmacies to do so. It should be noted that this individual received prescriptions from physicians, physician assistants, nurse practitioners, and a sizeable number of dentists.
- A person who, over the course of two years (730 days), filled prescriptions totaling 4000 doses of zolpidem (Ambien®), a sleep medication. (The presumption of the advisory committee is that this individual was selling or trading the medication to people using methamphetamine, who frequently have problems sleeping.)

These two individuals also illustrate another important consideration for PDMPs. Data in any individual state's PDMP are collected from pharmacies in those states, and from mail-order pharmacies that ship medications into that state. Thus, a Kansas resident who has a prescription filled in Kansas will have a record in K-TRACS, but if that same resident fills the prescription in Missouri, it will not be in K-TRACS, even if the prescriber practices in Kansas. Thus, someone intent on avoiding detection through K-TRACS could simply fill all of his/her prescriptions in Missouri. The first individual above lived in Johnson County, Kansas, and thus could easily be filling prescriptions in Missouri; thus, we believe it is likely that she actually obtained even more medication than indicated here. The second individual above actually was a resident of Kansas City, Missouri, so we believe it's very likely that she obtained more than the indicated amount of medication.

To combat this problem (which is especially acute in Missouri, whose two largest cities border other states), states have begun entering into agreements to share data across state lines. This program, operated by the National Association of Boards of Pharmacy, is known as PMPInterConnect. As of this date, 30 states are participating; another five have completed Memoranda of Understanding and are waiting to come online, and three more are in the process of completing their Memoranda of Understanding (see attached map). Many of the non-participant states will need to revise their PDMP statutes to allow interstate data sharing. Periodically, policymakers have called for a national PDMP, presumably operated by the federal government, but we strongly believe that the current model, with participation by all states in PMPInterConnect, would be superior.

Public Health Uses of PDMPs

Often overlooked are the public health benefits of PDMPs. Clinically, information contained in PDMPs can be of tremendous value. This value falls out into three categories:

• Reassurance to prescribers: Often, especially when seeing a new patient with chronic pain, prescribers will be uncertain about whether or not prescribing a controlled substance is a good idea. Patients whose backgrounds are unknown to prescribers cause this uncertainty, because the prescriber has no data on which to base a prescribing decision. Using the PDMP, the prescriber can view the patient's history of controlled substance use, and can make a decision on the basis of that history. In most cases (we estimate ~85% of the time), the prescriber will be reassured by the patient's PDMP record, and will be less anxious about prescribing. This

- benefits both the prescriber (who is less anxious) and the patient (who receives the medication he/she needs for pain).
- <u>Detection of substance abuse</u>: In some cases (we estimate somewhere around 10-12% of the time), the prescriber will find information in the PDMP that suggests the patient may have a substance use disorder (SUD). In these cases, the PDMP information should lead the prescriber to conduct an evaluation for the presence of an SUD, and to treat the patient according to the results. For patients whose evaluations reveal an SUD, referral to substance abuse treatment is appropriate. Without PDMP information, those diagnoses may not have been made, and patients potentially would have had their SUD exacerbated by the prescriber's continued prescription of controlled substances.
- Patient safety: Patients sometimes fail to communicate all of their current prescriptions to their prescribers. In some cases, this is intentional, as the "patient" is attempting to obtain multiple prescriptions for purposes of abuse or diversion. In other cases, the omission is unintentional, resulting from poor memory or a failure to consider certain medications as being medically relevant. Older patients, in particular, are vulnerable to these circumstances, as they often take numerous medications and may not be able to remember all of them. Additionally, older patients who are experiencing memory difficulties may have trouble remembering all of their prescriptions. In these cases, a review of the patient's PDMP record can reveal controlled substances originating with other prescribers, which, when combined with a new prescription from another prescriber, could create a potentially fatal drug-drug interaction. In these cases, a simple review of PDMP data can be life-saving.

Clinicians who use PDMPs on a regular basis tell us that they don't know how they managed to practice without them. There is so much clinically relevant information contained in a PDMP record, with such significant potential to affect the patient's course of treatment and risk of overdose, that regular PDMP queries are strongly recommended.

In many ways, Missouri's lack of a PDMP not only impairs the ability of its public safety agencies to properly police drug diversion, but it also places citizens with chronic pain at greater risk of misuse, abuse, diversion, addiction, and overdose. Each year that goes by without a PDMP in place sees numerous people die of overdoses that a PDMP could have prevented. Each year that goes by without a PDMP in place sees numerous Missourians receive inadequate pain care because their prescribers do not have access to their complete controlled substance prescription history. And each year that goes by without a PDMP in place exposes numerous Missourians to harms associated with prescription drug abuse, addiction, and potential overdose, resulting from both proper and improper use of those prescription drugs. Further delay in passing a PDMP bill is unconscionable.

Clinician Education

Numerous studies have documented the inadequacy of pain management education for physicians. These studies are summarized in the 2011 report from the Institute of Medicine, *Relieving Pain in America*. This report states that, in four years of medical school, medical students receive a median of nine hours of education on pain management—despite pain being the reason for half or more of all physician office visits. Similar studies regarding education about substance abuse reveal that the median amount received by medical students is four hours. Both of these are grossly inadequate, and

go a long way toward explaining the problems clinicians have in diagnosing and treating these two conditions.

Clearly, there is a need to substantially upgrade the amount of education student clinicians receive, related to both of these conditions. This education needs to begin in primary training experiences (e.g., medical school, nursing school, pharmacy school, etc.), but the historical inadequacy of this education means that substantial improvement in continuing education of practicing clinicians is also needed.

Some states have begun mandating continuing education for clinicians in one or both of these topic areas. Unfortunately, the state mandates tend to be for one to three hours of continuing education for every license renewal cycle (usually every two years), and the content requirements are often quite vague. Expecting one or two hours of education every two years to produce a substantial improvement in clinical practice is unrealistic.

When we encounter policy proposals establishing mandated continuing education, we look for the following components: 1) the amount required is substantial—as much as five hours every renewal cycle; 2) the required components include both good pain management practices and the diagnosis and treatment of substance use disorders; and 3) the pain management education component must include more than just controlled substance prescribing practices.

This last component raises another important issue. There are a number of reasons why clinicians prescribe opioid pain relievers as frequently as they do, especially to older adults. First, for many years, experts at the American Geriatric Society have evaluated the research on the benefits and harms of a variety of pain medications, and have concluded repeatedly that opioid pain relievers may be safer and more effective for older adults than many non-controlled medications (e.g., NSAIDs, acetaminophen, anticonvulsants, muscle relaxants, etc.). Second, many clinicians are uneducated and inexperienced with respect to the use of non-pharmacological treatments for pain, such as chiropractic and osteopathic manipulation, acupuncture, massage therapy, biofeedback, yoga, etc. Third, even if clinicians know about the effectiveness of these non-pharmacological interventions, many patients effectively have no access to them. Chiropractic and osteopathic manipulation are covered to a limited extent by Medicare, while none of the others is covered at all. Consequently, if patients are to receive these treatments, they have to pay out of pocket, and many can't afford to do so. Legislative direction to, at the very least, study the economic impact of providing coverage for these non-pharmacological therapies, would be welcomed by many in the pain management community, including the Academy.

Clearly, any efforts the federal government can undertake to foster clinician education would be welcomed. Even the Risk Evaluation and Mitigation Strategy (REMS) currently in place for extended release/long-acting (ER/LA) opioids is tremendously under-subscribed, primarily because it is not required for clinicians to participate. There has been discussion about tying completion of this REMS program to renewal of the clinician's Drug Enforcement Administration (DEA) registration. Doing so would require passage of legislation, but this idea has not gained traction on Capitol Hill. Perhaps another mechanism that should be considered is making completion of the ER/LA REMS a condition of participation in Medicare. Doing so would not catch all of the prescribers who would be caught by making completion a requirement for DEA registration renewal, but it would capture most of the prescribers who treat older adults, and a substantial majority of prescribers treating patients of all ages.

Additionally, any action the federal government can take to promote the following would, we believe, be important in improving pain care for all Americans, especially older Americans:

- Improved amount and quality of education about all forms of pain management, and about substance abuse, in:
 - primary training settings
 - o practicum/internship/residency/fellowship programs
 - continuing education settings
- Policies that ensure an adequate workforce in other licensed and certified professions that deliver non-pharmacological pain care, including chiropractic, acupuncture, massage therapy, naturopathic medicine, mental health professions, and others
- Policies that ensure adequate reimbursement for non-pharmacological pain care, including, at a minimum, Medicare and Medicaid coverage of a wide range of chiropractic care, acupuncture, biofeedback, and massage therapy
- Increased research funding for clinical and translational research into all types of pain care, both pharmacological and non-pharmacological

We view comprehensive, multimodal, multidisciplinary, integrated pain care to be one of those solutions that can solve both of the major public health crises identified at the beginning of this document, preventing a "zero-sum game". By providing this type of pain care, we will produce improved pain control and improved functioning in multiple arenas, saving money and producing better outcomes when compared to the current "usual care". We also will achieve this positive outcome while decreasing the use of opioid pain relievers, thus decreasing patients' exposure to the potential harmful side effects associated with these important, but dangerous, medications.

The American Academy of Pain Management stands ready to assist the committee in any efforts it may pursue with respect to improving pain care and addressing prescription drug abuse. Our unique focus on integrated, team-based, comprehensive pain care makes us best suited to providing the kind of advice and support that will best enable policymakers to find solutions for the two major public health crises we face today.





