

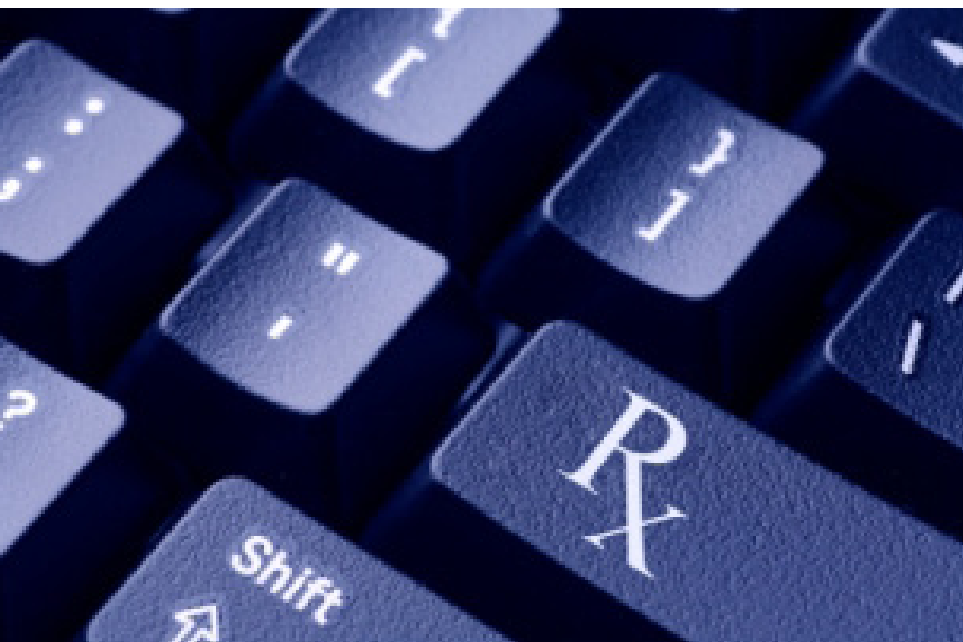


Should Missouri Have a Statewide Prescription Drug Monitoring Program?

On July 17, 2017, Governor Greitens issued Executive Order 17-18 in response to the opioid epidemic. Although many press reports have concluded that this order establishes a PDMP, it actually only allows the state to more closely observe prescribing practices. Inappropriate opioid prescribers identified by this new system will be turned over to law enforcement and licensing boards.

What the new program does not do is allow physicians to access the prescribing and dispensing data of their patients - a necessary component of all PDMPs. This information assists prescribers in identifying, treating, and preventing addiction. In the absence of a statewide prescription drug monitoring program (PDMP) in Missouri, St. Louis County launched its own in May of this year. A growing number of other counties and municipalities have joined that effort as subscribers, and many more are considering it.

Missouri is the only state without a PDMP. MSMA will continue to advocate for a statewide PDMP that offers physicians the clinical tools they need to fight the opioid epidemic.



What follows is a discussion for and against a statewide Prescription Drug Monitoring Program by MSMA members Sam Page, MD, St. Louis, and John Lilly, DO, Springfield.



The Case for a PDMP in Missouri

by Sam L. Page, Jr., MD

The most widely attributed writing declaring opioid analgesics as risk free of addiction is a 1980 letter to the editor in the *New England Journal of Medicine*. Dr. Hershel Jick and his graduate assistant, Jane Porter, wrote that in 39,946 hospitalized patients, 11,882 received at least one narcotic. They reported only one instance of major addiction and four cases total of addiction in patients who did not previously have documented addiction. They concluded that the widespread use of narcotic drugs in hospitals was unlikely to lead to addiction in medical patients, and the risk of addiction was indeed rare.¹

The letter was frequently cited to advocate for the widespread use of opioids in outpatient settings, and was widely used to create momentum for the establishment of pain as the 5th vital sign. Until almost ten years ago, physicians were frequently taught to treat inpatients without fear of opioid addiction. Now, however, physicians and the medical community have spent the last decade fighting the tsunami of the opioid epidemic and its concomitant addiction, overdose, and death.

All MSMA members know that Missouri remains the last state in the United States without a state-run prescription drug monitoring program (PDMP). This article will outline how a PDMP is an important part of the physician and medical community's response to the opioid epidemic sweeping our state.

Why does this matter to Missourians?

According to the Missouri Department of Mental Health, from 1999 to 2014, opioid-related death rates in Missouri increased:

- 7.6 times for females
- 3.8 times for males

- 5.9 times for Caucasians
- 2.6 times for African Americans
- 7.2 times for young adults age 25 to 34
- 3 times for adults age 35 to 44
- 6 times for adults age 45 to 64

As if to underscore the point, the *St. Louis Post-Dispatch* recently described how St. Louis County has had to resort to creating temporary morgues with mass-casualty refrigerated trucks to manage overdose victims.² Narcan is now available to first responders and is often prescribed by physicians for patients or their families to have on hand in the event an overdose requires resuscitation. But even with Narcan readily available – and many successful interventions – opioid-related deaths in Missouri are skyrocketing.

This is everyone's problem. It is especially our problem because we are a critical piece of the prescribing pathway. Public health data has shown several critical areas that need our attention. Among them are young people, who often get their first exposure to opioids from sports injuries and dental procedures – both of which have good data demonstrating successful treatment with NSAIDs and acetaminophen. The picture is even more challenging for those with chronic pain.

Opioid abuse is a major public health epidemic that demands a paradigm shift in the medical community's approach to chronic pain, and the creation of several tools to help physicians make good patient care decisions. A PDMP is the simplest and most widely accepted tool to fight narcotic addiction and diversion. There are many other resources, such as an Opioid Risk Tool (<https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf>)³, disease-specific functional assessment tools, urine drug testing, medication management agreements, and opioid treatment guidelines. But without a well-run and functioning PDMP, these other tools become part of a treatment chain with a critical missing link.

A PDMP is simple. It's an electronic medical record, accessed by confidential user ID and password. It pools information from all area pharmacies to determine if narcotic prescriptions have been dispensed. It's well known that a prescription is not always filled, perhaps due to such issues as insurance co-pays and deductibles or the availability of that prescription at pharmacies. Patients



Sam L. Page, Jr., MD, MSMA member since 1989, is an anesthesiologist and Chair of the St. Louis County Council.
Contact: sampage@aol.com

may read something on the Internet or hear something from a friend or family member and decide a medicine is not right for them. Many of our older patients are unclear about their medications and don't realize they already have a prescription for an opioid or other substances that may interfere with opioids. There is also a subset of patients who have true addiction issues, or even a smaller subset who are diverting medications for sale.

It is essential that physicians address the correct diagnoses and use other interventions prior to starting a trial of opioid analgesics. It is critically important to ensure that the patients are not receiving opioids or other narcotics from other physicians. Other prescriptions do not necessarily mean the patient is not a candidate for opioids, but it does mean that a conversation is required to determine why they received those other medications. That may affect the treatment plan, and if addiction or other mental health disorders are also present, it would require appropriate intervention.

State-run PDMPs are well-established systems that function as a shared-pharmacy electronic medical record. No longer is a concerned physician relegated to calling pharmacies around town to check on the medication history of a patient who raises concerns. Prescribing data is merged into the database from all pharmacies, and often will include data from PDMPs in surrounding states. Physicians and other prescribers simply log on to this database for patients under their care, or have a designated and trained member of their team access the database to check the opioid prescriptions filled for a particular patient. Ideally, as with the St. Louis County PDMP, all narcotics (Schedule II-IV) for the past two years are contained in the database.

PDMPs are a demonstrably effective tool to reduce opioid diversion and identify and refer for treatment patients with opioid misuse syndrome. The PDMPs work for patient populations currently under the care of a physician, and for decisions regarding a trial of opioid analgesics for chronic pain.⁴ In border state medical communities, PDMP interconnectivity is proven to reduce abuse and diversion of controlled substances.⁵ Missouri is a health care export state, providing medical care to many residents of neighboring states. One of the most prevalent complaints in our neighbor state medical communities is the absence of a PDMP in Missouri and the doctor shopping tourism that allows patients to come to Missouri for narcotics and return home undetected. The St. Louis County PDMP can be accessed in large metropolitan regions in border states, but it is not yet universally available.

Emergency room physicians are especially plagued by a subset of patients seeking opioids for various ailments; some legitimate and some questionable. A PDMP helps these physicians make more informed decisions. One study in Ohio emergency departments showed a 41% decrease in opioid prescriptions with PDMP use.⁶

Opioid misuse falls into three primary groups: (1) Those with under-treated symptoms, including those who use pain medication for sleep or anxiety; (2) those who demonstrate addictive behavior; and (3) those who divert their prescriptions. Some patients take medication faster than prescribed, from multiple sources, or without a benefit that exceeds the risk of opioid-related side effects.

Physicians are trained to be compassionate and to seek to relieve pain whenever possible. Reflexively, we often err on the side of accepting patient's presentations and complaints and giving them the benefit of the doubt. We also understand that addiction, especially involving opioid medications, is powerful.

What are the concerns about PDMPs? Electronic information is certainly at risk to be breached. Based on the experience of the other 49 states with a database, the incidence of unauthorized access is very rare. This information is protected by the same HIPAA rules that govern all other protected health information.

Also, prescribers are at risk for prosecution. The rules for governing PDMPs can be designed such that law enforcement cannot access the prescriber information without a warrant. Lawsuits are arising against prescribers who are not aware of overlapping prescriptions. Recently a case in St. Louis resulted in a very large settlement to a plaintiff who claimed to have been negligently prescribed pain medications for chronic pain that resulted in addiction.

There are concerns that prescribers will find a PDMP too difficult to use and quit prescribing pain medications to patients in need. Systems are now able to integrate with existing EMR's, and PDMP rules can allow a designee to access the database on your behalf. Finally, we are still governed by our goals of good clinical care for patients, and that will guide us in the best method for prescribing by treating physicians.

As a temporizing measure in the absence of a state-run database, Missouri counties are finding their own way to a regional PDMP. As of this writing, fully 27 counties and municipalities are participating in the St. Louis County PDMP, covering well over half of the population in Missouri. St. Louis took the lead to establish this system but has structured it in a way that adding counties can be done through local ordinances. This is a first class program initiated by a law that I sponsored and passed as a member



of the St. Louis County Council in March 2016. It is been live and functioning since May 2017. The program is run by Appriss, a company that operates prescription drug monitoring programs in 25 other states. And any licensed physician in Missouri or a neighboring state may visit <https://missouri.pmpaware.net> and register for access.

Unfortunately, many rural counties have not yet joined the Missouri effort, and remain at risk for continued issues. Ideally, the state legislature would enact a strong statewide PDMP that allows physicians to take good care of their patients regardless of the county in which they practice. Many physicians and other advocates worked very hard to get a statewide effort passed this year. As listed on the SafeandStrongMO.com website, a coalition of 33 health care providers and associations (including MSMA), 11 law enforcement agencies, 38 drug abuse prevention advocates, and 26 major Missouri employers has endorsed a statewide PDMP, and worked to pass enabling legislation. Unfortunately, PDMP opponents in the 2017 General Assembly managed to alter the original legislative language in a manner that made the proposed system ineffective for both providers and patients. And the amended version ultimately was opposed by MSMA and others for that reason. The objectionable changes included mandatory use of the system for all prescriptions, regardless of clinical indications and including patients in the hospital (with licensure penalties for failure to comply); mandating that only the physician could check the PDMP (no nurse or office staff delegation); limitation of the data to only 90 days of prescription history; and preemption of the higher functioning and much more effective and user-friendly regional PDMP database.

As the last state to have a functioning PDMP, the thirst for this information is extraordinary and no one expects the PDMP to be underused when appropriate. A poorly conceived mandate that paralyzes physician offices is punitive and runs counter to providing good medical care based on clinical decisions by the treating physician. To date, no PDMP has mandated physician usage prior to testing and validation.

A PDMP with streamlined data into individual patient electronic medical records would improve care for patients receiving opioid analgesics. Allowing delegated users to access the database on behalf of physicians and provide that information as part of the normal workflow in the office setting is good public health policy.

Addiction affects patients from all walks of life and demographic groups – from those in poverty to the most affluent members of society. Physicians have a responsibility to properly diagnose and treat these patients, either in our

own practices or referral to the proper specialists. One important tool to aid the decision-making is easy access to a PDMP and the information it contains.

Throughout history, physicians have struggled with various epidemics and faced community opposition to health policy and interventions. Quarantines have been argued as a violation of individual rights and liberties. The December 30, 2016 issue of *The Atlantic* described concerns that civil liberties could be violated with new CDC rules issued to manage the Ebola virus outbreak.⁷

Requirement of immunizations to attend public schools has been argued as a violation of individual rights and liberties and has been a public health vs. individual liberties argument as well. But a century old United States Supreme Court decision recognizing the public health benefit of immunizations was upheld in 2015, by the U.S. Court of Appeals for the Second Circuit.⁸

Not only is adoption and widespread use of a PDMP the right decision from the standpoint of organized medicine, a wide and deep collection of nearly every health policy interest group in America has joined in advocacy. The AMA and MSMA have been advocates for this legislation for more than a decade.

A well-functioning PDMP provides the tool for physicians to make more informed clinical decisions. I join the coalition of physicians and community leaders calling for a well-designed state-run PDMP, like the one sponsored by State Representative Holly Rehder. In the meantime, I ask you to lend your voice to this effort for the 2018 session of the Missouri General Assembly. I also encourage you to lead your county to join in the efforts spearheaded by St. Louis County. We are both entrusted with and empowered to work for the safety and wellbeing of the good people of Missouri.

References

- Porter J, Jick H. "Addiction Are in Patients Treated With Narcotics." *NEJM*; (302) 2:123
- St. Louis Post-Dispatch*. June 25, 2017: A1
- Webster L, Webster R. "Predicting aberrant behaviors in Opioid-treated patients: preliminary validation of the Opioid risk, too." *Pain Med* 2005; (6) 6:432
- Wang J, Christo P. "The influence of prescription monitoring programs on chronic pain management." *Pain Physician*, 2009
- Morgan L, Weaver M, Sayeed Z, Orr R. "The use of prescription monitoring programs to reduce opioid diversion and improve patient safety." *Journal of Pain & Palliative Care Pharmacology* 2012
- Baehren D, Marco C, Droz D, Sinha S, Callan E, Akpunonu P. "A statewide prescription monitoring program affects emergency department prescribing behaviors." *Ann Emerg Med* 2010; 56:19–23
- Yong E. "The CDC's New Quarantine Rules Could Violate Civil Liberties." *The Atlantic*. 30 December 2016
- Farias C. "Yes, The Government Can Make You Vaccinate Your Child." *New Republic*. 3 February 2015



Prescription Drug Monitoring Program: Useful Tool or Government Control?

by John D. Lilly, DO

To quote one of my business school professors, “The plural of anecdote is anecdotes, not data.” Public policy must be based on data, not anecdotal evidence. The proponents of the Prescription Drug Monitoring Programs (PDMP) use personal stories at legislative hearings and no valid evidence that the PDMPs work to decrease prescription drug deaths.

A National Institute on Drug Abuse report shows the number of deaths caused by all prescription drugs for the entire country has increased from 7,885 in 2000 to 29,728 in 2015, and the number of deaths per 100,000 population, age adjusted, has increased from 2.81 in 2000 to 9.23 in 2015.¹ About 75% of the deaths are due to opioids and 25% of the deaths are due to benzodiazepines.

Almost all to the research on PDMPs have been limited studies in order to show some minimal success. Using the same ICD-10 codes used by the National Institute on Drug Abuse in the CDC Wonder database website for every state from 2000 to 2015, will show an increasing overall death rate.² In 2000, 16 states had an operational PDMP. That number increased to 21 by 2005 and to 34 by 2010. In 2014, 49 states had an operational PDMP. The exception was Missouri (See Figure 1). Does this look like the PDMPs are working?

If the PDMPs worked to reduce the number of deaths, then Missouri should be at the top of the list. The number of deaths per capita in Missouri for 2015 was 9.76. Missouri was 22nd in descending order for all of the states and the District of Columbia (DC). West Virginia had the highest death rate in 2015 at 35.20 (See Figure 2). In 2015, eight states that had an operational PDMP before 2000 had a death rate higher than Missouri. That is

evidence that the PDMPs are ineffective. So why don't they work? The proponents claim the purpose of the PDMP is to eliminate “doctor shopping” which is the practice of one patient going to two or more physicians to obtain prescription drugs and having the prescriptions filled at two or more pharmacies in order to sell or abuse the medication.

The U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services, Administration Center for Behavioral Health Statistics and Quality performs an annual National Survey on Drug Use and Health.³ This survey is the primary source of information on the use of illicit drugs, alcohol, and tobacco in the civilian, non-institutionalized population of the United States aged 12 years old or older. In the 2015 survey, table 6.56B on page 1873, shows the source where pain relievers were obtained for the most recent misuse among past year users aged 12 and older. The percentage of prescriptions from more than one doctor was 1.7%. This table also showed the percentage (40.5%) if the primary source was from a friend or relative for free. The survey then asked where the friend or relative obtained the pain medication using the same questions. Table 6.57B on page 1875, shows the source where pain relievers were obtained among past year misusers aged 12 or older who obtained the most recently misused pain relievers from a friend or relative for free in past year. The percentage of prescriptions from more than one doctor in table 6.57B was 1.4%. The total percentage of prescriptions from more than one doctor was 2.3% ($1.4\% \times 40.5\% = 0.6\% + 1.7\% = 2.3\%$). The survey started asking the “from more than one doctor” question in 2011. The percentage from more than one doctor increased incrementally each year from 3.6% in 2011 to 3.7% in 2012 to 4.3% in 2014 to 4.8% in 2014. The decrease in 2015 was due to a change in the question asked in the survey from lifetime misuse to misuse in the past 12 months.⁴ Even when almost every state had a PDMP, the programs still could not stop doctor shopping.

Clearly, doctor shopping is not the problem. In the 2015 survey, 85.8% obtained the pain medicine from one



John D. Lilly, DO, MBA, MSMA member since 1998, is a family practice physician in Springfield, Mo.
Contact: johnlilly97@gmail.com

doctor either directly or from a friend or relative. 11.9% stole it from a clinic or hospital, bought it from a stranger or off the internet, or some other way (See Figure 3). The real problem is the 97.7% that got the pain medicine from a source other than doctor shopping. The PDMPs will never catch the 97.7%. Is it any wonder that the programs don't work. I have yet to see this survey referenced in any published research on PDMPs.

Let's evaluate the death rate of the states that have a PDMP. By calculating the slope of the line of the number of age adjusted deaths per 100,000 population each year for each state starting with the year the PDMP became operational or the year 2000, whichever comes later, one will find that forty-three states had a positive slope indicating the death rate was increasing, and six states had a negative slope indicating the death rate was decreasing. Of those six, five had some annual increases and some annual decreases over the last three to four years. Only one state, Washington, had a consistent annual decreases over the last four years. How can anyone claim the PDMPs are succeeding when the per capita death rate is increasing in forty-three states. When only six states show a decreasing death rate and only one of those states showed a consistent decrease in the death rate over the last four years after the PDMP became operational, that is not an example of success. That's called normal variation or random chance. In fact, if one tabulates the slope of the lines in 0.5 increments and throws out the top outliers the resulting curve looks like a normal distribution curve.

Proponents of PDMPs are now pushing for real time programs claiming that is what will make the difference. Currently, only Oklahoma has a real time

system. Twenty-nine states and DC have a reporting system of 24 hours or one business day. Fifty states and DC have a maximum of 7 days. Only Alaska has a monthly reporting period. A real time system is only beneficial the very first time a person is entered into the database. From then on, a real time system is meaningless. If I fill a prescription at one pharmacy and another prescription at another pharmacy the same day, the PDMPs that are not real time will not catch that. But that only applies to the very first time I try to fill a prescription. After one day, twenty-nine states will know what I am trying to do, and after one week, all of the states except Alaska will know. The real time systems are an improvement only on the very first day in ones life that one ever tries to fill multiple prescriptions. After that one, single day, it's unnecessary.

Private insurance companies and government programs like Medicare, Medicaid and the Veterans Administration have prescription databases. When you sign up for the insurance policy or the government program, you agree to become part of their database. The PDMP is completely different. It is a mandatory, involuntary database which makes it unconstitutional. It violates Article I, Section 15 of the Missouri Constitution which states, "That the people shall be secure in their persons, papers, homes, effects, and electronic communications and data, from unreasonable searches and seizures; and no warrant to search any place, or seize any person or thing, or access electronic data or communication, shall issue without describing the place to be searched, or the person or thing to be seized, or the data or communication to be accessed, as nearly as may be; nor without probable cause, supported by written oath

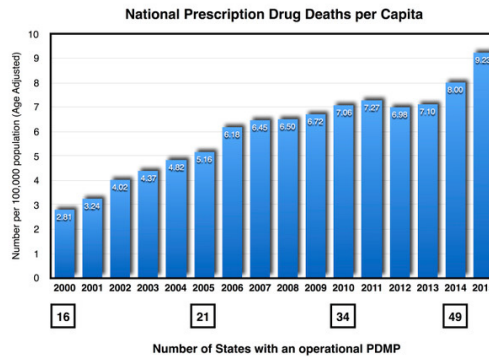


Figure 1

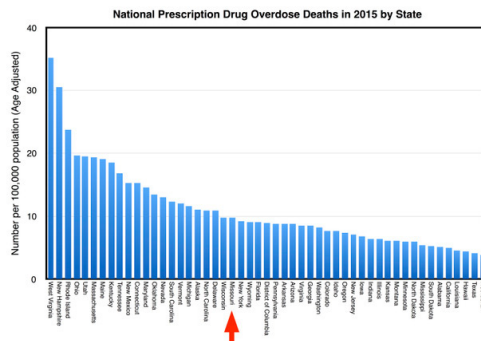


Figure 2

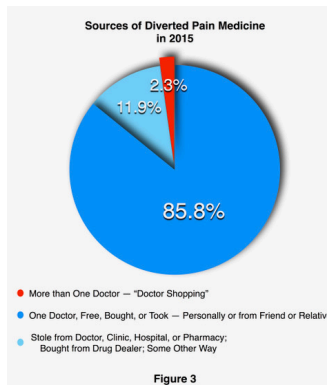


Figure 3

or affirmation.” The electronic data and communications language was added in 2014.

Do I blame physicians for wanting this? Absolutely not. It would benefit my practice. I blame the politicians for passing the legislation. Their job is not to make my job easier. Our legislators primary job is protecting our liberty, not trying to correct the problems of individual citizens. The Missouri Constitution is very clear. Article I, Section 2 states, “That all constitutional government is intended to promote the general welfare of the people; that all persons have a natural right to life, liberty, the pursuit of happiness and the enjoyment of the gains of their own industry; that all persons are created equal and are entitled to equal rights and opportunity under the law; that to give security to these things is the principal office of government, and that when government does not confer this security, it fails in its chief design.” The legislators in all of the states that have passed a PDMP are failing in their primary mission, which is maintaining the liberty of the citizens.

Clearly, doctor shopping is not the massive problem the proponents of PDMPs would have us believe. It was only 2.3% of misused pain medicine in 2015. Furthermore, the PDMP could not even stop the tiny amount of doctor shopping that does occur despite almost all of the states spending hundreds of millions of dollars to try to stop it. The real problem is the 97.7% which will never be caught by a PDMP. All of the talk about doctor shopping and saving lives is not the real goal. The real goal of those pushing the PDMP is a de facto national prescription database. The real goal is not fixing problems. The real goal is controlling people. Unfortunately, we are almost to a national prescription database. Forty-six states plus DC share the information on their databases.⁵ If Missouri passes a PDMP bill, it will be number 47. The citizens are slowly losing their republic.

What is the American Medical Association’s (AMA) policy concerning PDMPs?⁶ The AMA House of Delegates has passed several resolutions since 1981. The following statements are part of these resolutions:

- The AMA supports permanent authorization of and adequate funding for the National All Schedules Prescription Electronic Reporting (NASPER) program so that every state, district and territory of the US can have an operational Prescription Drug Monitoring Program (PDMP) for use of clinicians in all jurisdictions;
- The AMA supports the voluntary use of state-based prescription drug monitoring programs

(PDMP) when clinically appropriate;

- The AMA supports the ability of physicians to designate a delegate to perform a check of the PDMP, where allowed by state law; and
- The AMA opposes any federal legislation that would require physicians to check a prescription drug monitoring program (PDMP) prior to prescribing controlled substances.

All of that sounds fine to physicians, but let’s look at what we are really saying when we translate these policies into the language of liberty.

- “I want to use the police power of government to force other people, including my patients, to do something that will make my job easier.”
- “I want someone else to pay for a program that will make my job easier.”
- “I don’t want to be held accountable for my actions.”
- “I want to be able to appoint someone else to do my job.”
- “I don’t care if my actions trample on the liberties of my patients.”

What if we were forced to disclose this to our patients prior to an office visit? How many of us would be proud to make these statements? When we look at these policies through the patient’s eyes using the language of liberty, it is not flattering and does not conform to the oaths we took upon graduation. Is this really what we want for a national policy?

References

1. National Institute on Drug Abuse. <https://www.drugabuse.gov>. Graphs on deaths due to prescription medication and illicit drugs. <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>
2. CDC Wonder website. <http://wonder.cdc.gov>
3. Substance Abuse and Mental Health Services Administration. 2015 National Survey on Drug Use and Health: Detailed Tables (tables 6.56A, 6.56B, 6.57A, and 6.57B) <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015.pdf>
4. 2015 National Survey on Drug Use and Health Methodological Summary and Definitions, page 17. <https://www.samhsa.gov/data/sites/default/files/NSDUH-MethodSummDefsHTML-2015/NSDUH-MethodSummDefsHTML-2015/NSDUH-MethodSummDefs-2015.htm>
5. 2016 Compilation of Prescription Monitoring Program Maps. The National Alliance for Model State Drug Laws. 2016, page 16. <http://www.namsdl.org/library/CAE654BF-BBEA-211E-694C755E16C2DD21/>
6. AMA Policy on PDMP <https://policysearch.ama-assn.org/policyfinder/search/pdmp/relevant/1/>