Congressional Testimony by the Prescription Drug Monitoring Program Center of Excellence at Brandeis University

Caucus on International Narcotics Control, United States Senate

Enhancing Prescription Drug Monitoring Programs' Ability to Impede the Prescription Drug Abuse Epidemic

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Good afternoon Chairman Feinstein and distinguished members of the Caucus. My name is John Eadie. I am the Director of the Prescription Drug Monitoring Program Center of Excellence at Brandeis University (Center). Thank you for the opportunity to appear before you on behalf of the Center to discuss our work on enhancing Prescription Drug Monitoring Programs' ability to impede the prescription drug abuse epidemic. We thank you for the honor of testifying on this critical matter.

I) The Center

The Center seeks to help end the prescription drug abuse epidemic in the United States without compromising accepted standards of pain management or the legitimate prescribing of controlled substances. In collaboration with the PDMP Training and Technical Center at Brandeis University, the Center of Excellence provides academically sound and practice-relevant information, evaluation, and expertise to PDMPs and other stakeholders.
The Center of Excellence's base funding is provided by a grant from the Bureau of Justice Assistance (BJA) in the Department of Justice, with funds from the Harold Rogers PDMP Grant Program. In addition, BJA, the Food and Drug Administration (FDA) and the Centers for Disease Control and Injury Prevention (CDC) provide a combined grant for the new Prescription Behavior Surveillance System (PBSS) and the Pew Charitable Trusts have provided a grant to produce a White Paper on PDMP Best Practices.

To independently and objectively carry out our mission, the Center does not accept funding, directly or indirectly, from drug manufacturers or others with a financial stake in sales of

controlled substances. This is stated at our website at: http://pmpexcellence.org/content/coe-funding-acceptance-policy

Our work is focused on helping PDMPs and other stakeholders to identify and implement the most effective means possible to intervene in the prescription drug abuse epidemic. Our work includes:

- Identifying PDMP Best Practices, including innovative, cutting edge developments that will increase PDMP effectiveness.
- Encouraging innovative uses of PDMP data.
- Assisting in the deployment and evaluation of interstate PDMP data sharing.
- Advancing the methodology for assessing PDMP effectiveness to identify, improve and extend the applications of PDMPs.
- Analyzing PDMP performance measures and identifying improvements in measurement.
- Analyzing and disseminating relevant information through a clearinghouse.
- Providing support to states and federal agencies.

At the Center, we believe we must improve the methods for identifying and interdicting prescription opioid abuse in order to slow down and reverse this epidemic's ever rising toll.

II) Prescription Drug Monitoring Programs – a brief overview

Prescription Drug Monitoring Programs collect from pharmacies information regarding prescriber, pharmacy, patient, and drug information regarding each controlled substance prescription dispensed within their states and, in some cases, prescriptions sent by mail order into their states. The data is compiled in each PDMP's database and then made available to prescribers, pharmacies, law enforcement, health professional licensing agencies, and, depending on the state, to Medicaid Programs, medical examiners, drug courts, drug treatment programs and others. De-identified data is generally made available to researchers and evaluators and patients may see their own data in some states.

The rapid growth in states with Prescription Drug Monitoring Programs, with 49 states now having statutorily authorized PDMPs, is a very significant accomplishment. The majority of these programs have been authorized since 2003, when the Harold Rogers Prescription Drug Monitoring Programs Grant program began. Administered by the Department of Justice's

Bureau of Justice Assistance, the Harold Rogers' competitive grant program has stimulated growth and enhancements among the PDMPs.

Funding provided by the NASPER program, as administered by the Substance Abuse and Mental Health Administration, is a formula grant program that has been important in assisting states' PDMPs by supporting their operations.

The continued operation of PDMPs and the significant enhancements called for to address the prescription drug abuse epidemic appear to call for continuation and expansion of these funding programs.

III) PDMPs are for both Public Health and Public Safety

At state and national levels, questions have been raised, i.e. should PDMPs follow a public health model rather than a law enforcement model?

As public health professional with forty-two years of experience, I can say this is a specious question; it creates a false dichotomy. The only way for PDMPs to help effectively interdict the opioid epidemic in the United States is to fully engage both the public health and public safety communities in every state and the nation.

For analogy, can you imagine the major public health initiatives to reduce traffic accident injuries and fatalities without fully engaging law enforcement? How would public health agencies enforce speed limits and seat belt laws without law enforcement?

In the same vein, the opioid epidemic, cannot be resolved without the engagement of the entire public health and public safety communities.

For example, the drug overdose death rates for 2008 varied significantly between states (National Vital Statistics System for 2008). What is important to note is three of the largest states, California, New York and Texas, have some of the lowest death rates; lower than many other PDMP states. Common characteristics of these states' PDMPs include:

- The PDMPs provide solicited and unsolicited reports to Law Enforcement personnel: within the CA State Attorney General's Office, the NY State Department of Health's Bureau of Narcotics Enforcement (26 narcotic investigator positions currently) and the

TX Department of Public Safety and to Professional Licensing Agencies directly or indirectly.

- They provide PDMP data to the DEA upon request.
- Reports and investigations have focused on criminal activity, e.g. prescribers selling prescriptions, pharmacies selling controlled substances, organized rings of doctor shoppers, pill mills like Sleep Clinics in the late '70s and early '80s (Quaaludes and barbiturates) and Weight Clinics (stimulants – NY) and Stress Clinics in the '80 and '90s (benzodiazepines)
- The three states have used state issued serialized prescription forms – originally for Schedule II drugs. (TX currently issues a single copy serialized prescription form for schedule II prescriptions, NY currently issues a single copy serialized prescription form for all prescription drugs, CA issued serialized forms until 1/1/2005)
- Reports to prescribers or pharmacists are a recent development in these three states.
- All have been in operation for 3 decades or more

Without law enforcement use of PDMP data, these states could not have kept their death rates at these low levels.

Another specious argument has held that doctors and pharmacists will be unwilling to request data from a PDMP is administered by a law enforcement agency. We have examined that question by looking at the proportions of reports issued by six PDMPS (2007) and found there is no difference, i.e. prescribers and pharmacists request 90% to 96% of reports from law enforcement administered PDMPs and board of pharmacy administered PDMPs.

IV) A new generation of PDMPs: adopting Best Practices

To deal with the prescription drug abuse epidemic, the nation needs a new generation of PDMPs: *In addition to responding to others' requests, PDMPs need to proactively confront the epidemic.*

Under the grant from BJA, The Center is responsible for identifying and advancing the use of PDMP Best Practices. The Pew Charitable Trusts have provided a grant to develop a White Paper on this subject, which identifies promising practices and the scientific evidence, both current and needed to support these into Best Practices. High priority practices include:

IV – A) Proactive, unsolicited reports -- Some PDMPs proactively analyze their databases and, when they identify probable doctor shoppers, they send an unsolicited report to the prescribers and pharmacies. Such reports result not only in reducing the subsequent prescriptions obtained by the doctor shoppers listed in the reports but also in significantly increasing prescriber requests for solicited PDMP data. In addition, there has been a general reduction in prescriptions to doctor shoppers, even for those for whom no report is issued. As of a November 2011 survey of 38 states, only 30 PDMPs were authorized to provide unsolicited reports to providers, and only 16 of them were actually doing so. (COE survey of PDMPs, 2011).

A few PDMPs, analyze their data to identify possible criminal activity or professional misconduct and then provide unsolicited reports to the appropriate agencies. In the 2011 survey, only 8 states were providing such reports to law enforcement and only 7 states to professional licensing agencies.

To stem the epidemic, PDMPs must increase the analysis of data and use of unsolicited reports to law enforcement and professional licensing agencies as well as prescribers and pharmacies.

IV – B) Prescribers and pharmacists: requested (solicited) reports - Upon request, PDMPs provide prescription histories to prescribers and pharmacists so they can make clinically sound decisions prior to issuing or dispensing prescriptions for controlled substances and can avoid being duped by doctor shoppers. This is generally done by PDMPs providing web-portals through which practitioners may request data.

We need to increase prescriber and pharmacists use of PDMPs. Enrollment of prescribers in PDMPs' online data web portals varies by state, between 20% and 50%. The proportion of prescribers who actually request data reports is somewhat less. Thus it is not surprising that Kentucky, New York and Tennessee passed legislation in 2012 basically mandating prescribers to access PDMP data prior to issuing the first controlled substance prescription and periodically thereafter, with some exceptions. These mandates are more significant than some prior states' mandates for accessing PDMP data under special circumstances.

Given the severity of the epidemic and the reality that prescribers are unable to tell when an individual may be a doctor shopper, such mandates may be increasingly considered by states.

IV – C) Law Enforcement Agencies: requested (solicited) reports – Local, state and federal Law Enforcement agencies are essential users of PDMP data. The relatively lower overdose death rates in California, New York and Texas, demonstrate this.

While many states permit law enforcement to request and obtain data for an open investigation, other states have added unnecessary hurdles, such as requiring court orders, grand jury subpoenas, and personal review by a state health commissioner.

To stem the epidemic, unreasonable hurdles need to be replaced by a more rational process of providing adequate training for law enforcement investigators, a process in which the agency directors retain supervision and accountability.

IV – D) Health Professional Licensing Agencies – Agencies such as State Medical Boards and State Pharmacy Boards need ready access to PDMP data to investigate potential misconduct and inappropriate use of controlled substances, e.g. self-abuse, over prescribing, and offering drugs to solicit sexual favors. Likewise, PDMPs need to analyze their data and forward unsolicited reports to licensing boards when patterns of possible misconduct are found. This process needs to be automated to the extent feasible.

IV – E) Pharmacies: verifications prior to dispensing – Pharmacies should only dispense controlled substances prescriptions after appropriate verification that requirements have been met. For example, controlled substances should not be dispensed unless a pharmacy positively identifies who is picking up the drug and forwards that person's identifying information to the state PDMP. The importance of this was demonstrated when Massachusetts found that 38% of persons dropping off written Schedule II prescriptions or picking up the drugs were someone other than the patient.

Should mandatory prescriber education be established (which the Center strongly supports), the list of trained prescribers should be automatically checked before a prescription is dispensed. The factors identified in the 2009 GAO report should be reviewed prior to dispensing, including verification that the prescriber is currently licensed and registered with DEA, has no licensure or registration restrictions that would affect controlled substances prescribing, and is not deceased.

Likewise, patients known to be deceased should not be allowed to have prescriptions dispensed in their names. PDMPs may help facilitate these verifications. Pharmacies will need to be properly compensated for this new work.

IV – F) Expanding PDMP data use to other users – If the expansion of the prescription drug abuse epidemic is to be slowed and reduced, then other parties need to have access to PDMP data. Some states permit some of the parties below to have access, but this needs to be regularized and expanded:

a. State's Medicaid agency's unit(s) with legal authority to conduct investigations and utilization review of program services regarding Medicaid program recipients or Medicaid program providers.
b. Appropriate Medicare personnel (only one PDMP currently has legislation authorizing such use).
c. Medical examiners, coroners or others authorized under law to investigate causes of deaths for cases under investigation pursuant to their official duties and responsibilities.
d. Substance abuse treatment providers – to track for drugs obtained without knowledge of the treatment programs.
e. Substance abuse treatment state agencies (e.g. analyzed generic information can assist planning for location of treatment programs).
f. Worker's compensation board reviewers.
g. Drug court judges.
h. Department of corrections' health care professional staff, and probation departments, (if they cannot receive information under law enforcement provisions).
i. The Indian Health Services, Veterans Administration, and Department of Defense health care system (not just their prescribers but also the health care clinical supervisors who oversee prescribing and dispensing within those systems).
j. Health care systems' peer review organizations in order to identify and intervene in prescriber and pharmacist over-prescribing and miss-prescribing as early as possible, i.e. before the practices rise to the level that licensure or law enforcement action are required.

k. Other third party payers' health professional care reviewers - this is not currently being done and will require careful design to protect all data, but given the nature and extent of the epidemic, it appears unwise not to develop means by which PDMPs and other third party payers can meaningfully exchange information.

IV – G) Interstate PDMP Data Sharing --The efforts to establish interoperability between all PDMPs needs to be completed. The Prescription Monitoring Information Exchange (PMIX) Architecture which BJA, the IJSI Institute, and the Alliance of States with Prescription Drug Monitoring Programs have developed provides the basis upon which all PDMPs and the various hubs for data sharing are able to share PDMP data.

V) Prescription Behavior Surveillance System

With funding under a grant from BJA, the FDA and CDC, the Center is establishing a Prescription Behavior Surveillance System (PBSS) with de-identified PDMP data from a diverse group of states. With five states expected to participate in 2012 and ten in 2013, the data will be extremely important for tracking the progression of the prescription drug abuse epidemic and its characteristics, for monitoring and evaluating the outcomes from interventions such as new medical education programs, expansion of PDMP unsolicited reports' use and adoption of other PDMP promising and Best Practices.

V – A) Early Warning System – Pioneering work by the Massachusetts Department of Public Health's PDMP and the principal investigator at the Center has identified an important new function for PDMP data. Using spatial analysis methodology to examine probable doctor shopping when the drug OxyContin was introduced and subsequent years, a rapid expansion of doctor shopping can be seen, beginning in the first year, 1996. Review of data for 2005, shows that doctor shopping for all opioids had become widespread across the state and was concentrated most heavily in five geographic areas. A geospatial comparison to hospital data on opioid overdoses and opioid related deaths shows high rates of overdoses and deaths in these same areas. Had this analysis been possible in prior years, the MA PDMP could have issued warnings before the overdoses and deaths became epidemic. Warnings could be sent to all community, state and national stakeholders including health care practitioners, law enforcement, education, substance abuse prevention and treatment organizations, schools, parent teacher organizations, religious organizations and other groups.

The PBSS will be able to use this methodology for the included states and for other states that send de-identified data to the Center. Alternatively, the methodologies can be shared with states wishing to do their own geospatial analyses.

VI) Third Party Health Care Payers and PDMPs

The ONDCP, in its 2011 Action Plan for addressing America's Prescription Drug Abuse Crisis, called upon the Center to host a meeting with third party health care payers and PDMPs to explore appropriate collaborations. The meeting, planned for December 2012, will include participants from public and private health insurers with representatives from units that develop program policies, administer drug utilization review type programs and investigate fraud and abuse.

The private insurance industry's Coalition against Insurance Fraud has identified that annually all public and private health insurance payers pay an excess of $70 billion for enrollees who abuse opioid prescriptions; more than $24 billion is the private insurers' share. (Coalition against Insurance Fraud, 2007). Workers compensation programs which pay claimants' costs for treatment and rehabilitation following work-related accidents have found opioid misuse to be a major problem. The National Council on Compensation Insurance found that a single opioid product became the highest cost pharmaceutical for Workers Compensation Programs (Lipton, 2011).

The Center is following the Office of National Drug Control Policy's call to convene a meeting with PDMPs and third party payers (ONDCP's 2011 Action Plan to address the prescription drug abuse epidemic). The meeting is intended to open dialogue regarding how PDMPs and third party payers may coordinate activities and work together to interdict the epidemic. The meeting will explore, issues such as how the PDMP data, which includes all prescriptions obtained by a person might be utilized to help third party payers assure that enrollees don't bypass lock-ins or other restrictions by paying cash for prescriptions, thus avoiding third party payers from becoming aware of the prescriptions.

Another topic will be considering with public and private third party payers the value of mandating prescribers to access PDMP data prior to issuing the first controlled substance prescription and periodically thereafter, as a condition of payment.

VII) Mandatory Prescriber Education

A majority of prescribers have insufficient training in the use of opioids and other prescription controlled substances to safely prescribe these drugs. Such education needs to include training in not only the proper use of the drugs but also the misuse of, abuse of, and addiction to these drugs by bona fide patients; the nature and extent of doctor shopping; the extent of theft, counterfeiting and forgery of a prescribers' prescription pads; and how to access and use PDMP data. As noted above, such training should not only be required but technologically monitored by pharmacies prior to dispensing. In addition, PDMPs should periodically review their databases to assure that prescribers were trained at the time their prescriptions were dispensed; non-compliance should be proactively reported by the PDMP to DEA and the state professional licensing agency.

VIII) Issues the Senate Caucus on International Narcotic Control Might Consider

The Federal Government provides funding for the Medicaid, Medicare, Department of Defense, Indian Health Systems and Veterans Administration health care systems. Involved in the prescription drug abuse epidemic are some of the prescriptions issued by prescribers and dispensed by pharmacies who practice within such systems or who are reimbursed by the systems. Persons enrolled in these systems are experiencing opioid and other controlled substances misuse and abuse, overdoses, and deaths.

Given these factors, does it make sense for the federal government not to require, as a condition of payment, that prescribers and pharmacies request PDMP data prior to issuance of the first controlled substance prescription and periodically thereafter (e.g. every six months) when therapy is continued?

Also given these factors, would it make sense for PDMPs receiving federal funds to provide PDMP data to the authorities that administer these health care systems and that investigate fraud within these systems? For example, such data could identify enrollees who may be at serious risk of overdose or death or be involved in criminal doctor shopping rings, i.e. the PDMPs can identify enrollees who are avoiding Drug Utilization Review, Lock-in or other enrollee restriction programs by paying cash for prescriptions or using alternative third party payers to cover some of their prescription costs. Such data might also allow identification of inappropriate activity by health care professionals that extends from within the federal health care systems and then beyond.