THE PEW CHARITABLE TRUSTS

2005 Market Street, Suite 1700 215.575.9050 Phone
Philadelphia, PA 19103-7077 215.575.4939 Fax

901 E Street NW, 10th Floor 202.552.2000 Phone
Washington, DC 20004 202.552.2299 Fax
www.pewtrusts.org

February 1, 2016

Michael P. Botticelli
Director
National Drug Control Policy
750 17th St. NW
Washington, D.C. 20006

RE: Request for Feedback for Development of the "2016 National Drug Control Strategy"

Dear Director Botticelli:

The Pew Charitable Trusts appreciates the opportunity to offer comments to the Office of National Drug Control Policy (ONDCP) on the National Drug Control Strategy. Pew is an independent, nonpartisan, nonprofit research and policy organization dedicated to serving the public. Pew's prescription drug abuse project works to develop and support policies that will help reduce the inappropriate use of prescription drugs while ensuring that patients have access to effective pain management.

For the 2016 Strategy, Pew encourages ONDCP to continue placing emphasis on tactics to prevent and address prescription drug abuse. Almost 19,000 Americans died in 2014 from prescription opioid overdoses, an increase of 16 percent when compared with 2013.[i] With opioid overdoses at the highest level ever recorded, there is a need to augment efforts to reduce prescription drug abuse. Pew recommends the expansion or inclusion of three key areas of focus in the 2016 Strategy: (1) continue to support the use of drug utilization review and restriction (DURR) programs in Medicaid by highlighting the utility of these programs and encouraging congressional action that would authorize the use of these programs in Medicare; (2) increase efforts to enhance prescription drug monitoring program (PDMP) functionality and integrate these databases into prescriber workflows; and (3) emphasize the safety concerns associated with the use of methadone for pain and its inclusion on Medicaid preferred drug lists.

1. **Continue to support the use of drug utilization review and restriction (DURR) programs in Medicaid by highlighting existing evidence for these programs and encouraging congressional action that would authorize the use of these programs in Medicare**

In the 2015 strategy, ONDCP emphasized the use of DURR programs as an evidence-based and systematic approach to identify patients at-risk for prescription drug abuse and intervene to prevent harm. DURRs, also known as patient review and restriction (PRR) programs, are designed to identify instances when patients over-utilize narcotics and other prescription drugs that are subject to abuse. These programs can increase care coordination by requiring at-risk individuals to obtain controlled substance prescriptions from a single pharmacy or physician.

A recent survey of state Medicaid programs conducted by Pew's prescription drug abuse project found that 49 states, including the District of Columbia, operate a PRR for their fee-for-service and/or managed care populations.[ii] Further, the majority of states (59 percent) indicated that PRRs in

combination with other mechanisms are likely the best approach to reduce and prevent prescription drug abuse. An evaluation performed by a Centers for Disease Control and Prevention (CDC) expert panel found that PRRs used in state Medicaid programs have generated savings and reduced narcotic prescriptions, drug abuse, and visits to multiple doctors and emergency rooms.[iii]

Current law does not permit use of PRR programs in Medicare; however bipartisan, bicameral support is increasing. In July of 2015, the House of Representatives passed legislation authorizing the use of PRRs in Medicare and similar legislation was introduced in the Senate. Speaking about this legislation at a Senate Finance Committee hearing just last month, Centers for Medicare and Medicaid Services Acting Administrator Andy Slavitt indicated that authority to operate PRRs in Medicare would be "very helpful in really taking a practical measure to stem abuse."[iv] In February of last year, President Barack Obama signaled his support for these programs in his FY 2016 budget request for the Department of Health and Human Services.[v] The Office of the Inspector General has also included PRR programs in its list of top 25 unimplemented recommendations that would improve quality and generate cost savings for the department.[vi] Pew and other stakeholders have encouraged Congress to grant Medicare the authority to implement these programs. Inclusion of PRRs within the 2016 Strategy would highlight the effectiveness of existing PRRs and support efforts to authorize these programs in Medicare.

2. **Increase efforts to enhance prescription drug monitoring program (PDMP) functionality and integrate these databases into prescriber workflows**

PDMPs have been shown to be effective in changing prescriber behavior and reducing the number of patients who visit multiple prescribers for the same or similar drugs. While 49 states operate PDMPs, prescribers have reported that accessing PDMP data is a time-consuming process and utilization remains suboptimal. Pew recommends that ONDCP continue to highlight efforts to enhance PDMP utilization by supporting strategies that have been demonstrated to enhance PDMP effectiveness. For example, evidence suggests that providing prescribers with unsolicited reports on patients who meet thresholds associated with risk are effective in prompting those prescribers to access and use PDMP data in clinical decision-making.[vii] Implementation of policies permitting prescribers' delegates to access PDMPs has also been shown to increase PDMP utilization by addressing workflow barriers and time limitations. In addition, more up-to-date data, which can be achieved with daily uploads from pharmacies, increases the PDMP's value for prescribers, thus incentivizing use. Further, as the 2015 Strategy notes, the federal government's investment in pilot programs has demonstrated successful strategies to integrate PDMP data with other health information technologies, such as electronic health records. Pew supports these efforts to enhance and integrate PDMPs into prescriber workflows as a mechanism to help reduce prescription drug abuse.

3. **Emphasize the safety concerns associated with the use of methadone for pain and its inclusion on Medicaid preferred drug lists**

Methadone, which accounts for just two percent of opioid pain reliever prescriptions, is responsible for nearly 30 percent of all opioid overdose deaths.[viii] Pew recommends that ONDCP include in its 2016 Strategy an overview of safety concerns associated with using methadone for pain and a call to action for Medicaid directors to examine its inclusion on Medicaid preferred drug lists.

Methadone's unique pharmacologic properties distinguish it from other opioid drugs. Pain relief from methadone lasts four to eight hours, but its effects on other organs, such as the lungs and heart, can continue for eight to 59 hours.[ix] As a result, patients may put themselves at risk by taking more of the drug before the original dose has been fully metabolized. When taken too often or at too high a dose, methadone can cause life threatening respiratory depression and heart rhythm or heart rate abnormalities.[x] The Food and Drug Administration,[xi] the CDC,[xii] the American Academy of Pain Medicine,[xiii] and the American Society of Interventional Pain Physicians,[xiv] have recommended against using methadone as a first-line therapy for chronic pain. However, the drug is prescribed due to factors that include its long duration of action, effectiveness for refractive pain, and low cost.[xv]

Specifically, methadone is responsible for a disproportionate share of overdose deaths among Medicaid beneficiaries.[xvi] A study published in the *Journal of the American Medical Association* that evaluated outcomes for a cohort of Tennessee Medicaid patients receiving sustained-release morphine or methadone for non-cancer pain found that patients receiving methadone were 46 percent more likely to die than patients receiving sustained-release morphine. [xvii] Further, risk was increased for doses of methadone as low as 20 mg per day. A 2007 study found that approximately one third of unintentional overdose deaths in North Carolina occurred in the Medicaid population.[xviii] Methadone was a contributing cause of death for almost 33 percent of these deaths. Despite growing evidence of harm, the inclusion of methadone as a preferred treatment for chronic pain on some state Medicaid preferred drug lists, which are intended to indicate drugs that are safe and effective for a specific disease or condition, may be driving use. Several alternatives to methadone are available, including therapies that have been associated with less patient harm.[xix] These therapies include extended- or sustained-release formulations of morphine, fentanyl and hydromorphone.[xx]

* * *

Thank you for the opportunity to provide feedback to inform the development of the 2016 National Drug Control Strategy. Should you have any questions or if we can be of assistance with your work, please contact me by phone at 202-540-6916 or via email at creilly@pewtrusts.org.

Sincerely,

Cynthia Reilly, B.S. Pharm.
Director, Prescription Drug Abuse
The Pew Charitable Trusts

[i] Centers for Disease Control and Prevention (CDC), National Center for Health Statistics. Compressed Mortality File 1999-2014. http://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf

[ii] The Pew Charitable Trusts. Curbing Prescription Drug Abuse with Patient Review and Restriction Programs: Learning from State Medicaid Agencies (2016) (forthcoming)

[iii] CDC; National Center for Injury Prevention and Control. "Patient Review & Restriction Programs. Lessons Learned from State Medicaid Programs" (2012), http://www.cdc.gov/drugoverdose/pdf/pdo_patient_review_meeting-a.pdf

[iv] Healthcare Co-ops: A Review of the Financial and Oversight Controls. Senate Finance Committee Hearing, (2016) (statement of Andy Slavitt, acting administrator of the Centers for Medicare and Medicaid Services), http://www.finance.senate.gov/hearings/healthcare-co-ops-a-review-of-the-financial-and-oversight-controls

[v] 21st Century Cures Act, H.R.6, 114th Cong. (2015), Prescription Drug Abuse Prevention and Treatment Act of 2015, S.1431, 114th Cong. (2015); Department of Health and Human Services, "HHS FY2016 Budget in Brief" (2015), http://www.hhs.gov/about/budget/budget-in-brief

[vi] Office of the Inspector General, "Compendium of Unimplemented Recommendations" (2015), http://oig.hhs.gov/reports-and-publications/compendium/files/compendium2015.pdf

[vii] Brandeis University Prescription Drug Monitoring Program Center for Excellence and The Pew Charitable Trusts. Optimizing Prescriber Utilization of Prescription Drug Monitoring Programs: Evidence-based Practices and Strategies for Implementation (2016) (forthcoming)

[viii] CDC, "Vital Signs: Risk for Overdose From Methadone Used for Pain Relief—United States, 1999-2010," *Morbidity and Mortality Weekly Report* 61 no. 26 (2012): 493–97, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6126a5.htm?s_cid=mm6126a5_w; CDC, "Prescription Painkiller Overdoses: Use and Abuse of Methadone as a Painkiller" (2012), http://www.cdc.gov/vitalsigns/MethadoneOverdoses/?s_cid=bb-vitalsigns-128&utm_campaign=vital%20signs&utm_medium=banner&utm_source=external&utm_content=0712-pdo-128

[ix] Food and Drug Administration (FDA), "Public Health Advisory: Methadone Use for Pain Control May Result in Death and Life-Threatening Changes in Breathing and Heart Beat" (2006), http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm124346.htm

[x] K.W. Chen et al., "Benzodiazepine Use and Misuse Among Patients in a Methadone Program," *BMC Psychiatry* 11 no. 90 (2011), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3117775/; CDC, "Methadone for Pain Management: The Clinician's Role in Reducing the Risk for Overdose" (2012), http://www.bt.cdc.gov/coca/ppt/2012/08_01_12_Methadone_FIN.pdf

[xi] FDA, "Methadone Hydrochloride Approved Label" (Revised 2014), http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/090707Orig1s003lbl.pdf

[xii] CDC, "Vital Signs: Risk for Overdose from Methadone Used for Pain Relief—United States, 1999-2010," *Morbidity and Mortality Weekly Report* 61 no. 26 (2012): 493–97, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6126a5.htm?s_cid=mm6126a5_w

[xiii] The American Academy of Pain Medicine, "The Evidence Against Methadone as a 'Preferred' Analgesic: A Position Statement From the American Academy of Pain Medicine" (2014), , http://www.painmed.org/files/the-evidence-against-methadone-as-a-preferred-analgesic.pdf

[xiv] American Society of Interventional Pain Physicians, "Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2—Guidance" *Pain Physician Journal* 15 (2012): S67–S116, http://www.painphysicianjournal.com/2012/july/2012;%2015;S67-S116.pdf

[xv] CDC, "Overdose Deaths Involving Prescription Opioids Among Medicaid Enrollees—Washington, 2004-2007," *Morbidity and Mortality Weekly Report* 58, no 42 (2009):1171-5, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5842a1.htm

[xvi] CDC, "Overdose Deaths Involving Prescription Opioids Among Medicaid Enrollees—Washington, 2004-2007," *Morbidity and Mortality Weekly Report* 58 no. 42 (2009): 1171–75, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5842a1.htm

[xvii] W.A. Ray, C.P. Chung, K.T. Murray, W.O. Cooper, K. Hall, and C.M. Stein, "Out-of-Hospital Mortality Among Patients Receiving Methadone for Noncancer Pain," *Journal of the American Medical Association Internal Medicine,* 175 (3) (2015): 420-427, http://archinte.jamanetwork.com/article.aspx?articleid=2091400&resultClick=3

[xviii] J.T. Whitmire and G.W. Adams, "Unintentional Overdose Deaths in the North Carolina Medicaid Population: Prevalence, Prescription Drug Use, and Medical Care Services," State Center for Health Statistics Studies (2010), http://www.schs.state.nc.us/SCHS/pdf/SCHS_162_WEB_081310.pdf

[xix] CDC, "Vital Signs: Risk for Overdose From Methadone Used for Pain Relief—United States, 1999-2010," *Morbidity and Mortality Weekly Report* 61 no. 26 (2012): 493–97,

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6126a5.htm?s_cid=mm6126a5_w; CDC, "Prescription Painkiller Overdoses: Use and Abuse of Methadone as a Painkiller" (2012), http://www.cdc.gov/vitalsigns/MethadoneOverdoses/?s_cid=bb-vitalsigns-128&utm_campaign=vital%20signs&utm_medium=banner&utm_source=external&utm_content=0712-pdo-128

[xx] American Society of Interventional Pain Physicians, "Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2—Guidance," *Pain Physician Journal* 15 (2012): S67–S116, http://www.painphysicianjournal.com/2012/july/2012;%2015;S67-S116.pdf