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The Prescription Opioid Epidemic: An Evidence- Based Approach

THE PRESCRIPTION OPIOID EPIDEMIC:
AN EVIDENCE-BASED APPROACH
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PREPARED BY

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Executive Summary

Prescription drugs are essential to improving the quality of life for millions of Americans living with acute or chronic pain. However, misuse, abuse, addiction, and overdose of these products, especially opioids, have become serious public health problems in the United States. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.

At the invitation of the Johns Hopkins Bloomberg School of Public Health and the Clinton Foundation, a diverse group of experts were convened to chart a path forward to address these issues. After a town hall meeting at the School, featuring an inspiring call to action from President Bill Clinton¹, the group — including clinicians, researchers, government officials, injury prevention professionals, law enforcement leaders, pharmaceutical manufacturers and distributors, lawyers, health insurers and patient representatives — spent the next day and a half:

- Reviewing what is known about prescription opioid misuse, abuse, addiction and overdose;
- Identifying strategies for reversing the alarming trends in injuries, addiction, and deaths from these drugs; and
- Making recommendations for action.

Following this meeting, the group released a consensus statement with three guiding principles for translating the meeting discussion into actionable recommendations.²

INFORMING ACTION WITH EVIDENCE.

Some evidence-based interventions exist to inform action to address this public health emergency; these should be scaled up and widely disseminated. Furthermore, many promising ideas are evidence-informed, but have not yet been rigorously evaluated. The urgent need for action requires that we rapidly implement and carefully evaluate these promising policies and programs. The search for new, innovative solutions also needs to be supported.

INTERVENING COMPREHENSIVELY.

We support approaches that intervene all along the supply chain, and in the clinic, community and addiction treatment settings. Interventions aimed at stopping individuals from progressing down a pathway that will lead to misuse, abuse, addiction and overdose are needed. Effective primary, secondary and tertiary prevention strategies are vital. The importance of creating synergies across different interventions to maximize available resources is also critical.

PROMOTING APPROPRIATE AND SAFE USE OF PRESCRIPTION OPIOIDS.

Used appropriately, prescription opioids can provide relief to patients. However, these therapies are often being prescribed in quantities and for conditions that are excessive, and in many cases, beyond the evidence base. Such practices, and the lack of attention to safe use, storage and disposal of these drugs, contribute to the misuse, abuse, addiction and overdose increases that have occurred over the past decade. We support efforts to maximize the favorable risk/benefit balance of prescription opioids by optimizing their use in circumstances supported by best clinical practice guidelines.

Meeting participants formed seven working groups to make recommendations on: 1) prescribing guidelines, 2) prescription drug monitoring programs, 3) pharmacy benefit managers and pharmacies, 4) engineering strategies, 5) overdose education and naloxone distribution programs, 6) addiction treatment, and 7) community-based prevention.

1. www.jhsph.edu/rxtownhall2014

2. www.jhsph.edu/2014consensusstatement

Recommendations for Action

#1 PRESCRIBING GUIDELINES

- 1.1 Repeal existing permissive and lax prescription laws and rules.
- 1.2 Require oversight of pain treatment.
- 1.3 Provide physician training in pain management and opioid prescribing and establish a residency in pain medicine for medical school graduates.

#2: PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs)

- 2.1 Mandate prescriber PDMP use.
- 2.2 Proactively use PDMP data for enforcement and education purposes.
- 2.3 Authorize third-party payers to access PDMP data with proper protections.
- 2.4 Empower licensing boards for health professions and law enforcement to investigate high-risk prescribers and dispensers.

#3: PHARMACY BENEFIT MANAGERS (PBMs) AND PHARMACIES

- 3.1 Inform and support evaluation research.
- 3.2 Engage in consensus process to identify evidence-based criteria for using PBM and pharmacy claims data to identify people at high risk for abuse and in need of treatment.
- 3.3 Expand access to Prescription Drug Monitoring Programs.
- 3.4 Improve management and oversight of individuals who use controlled substances.
- 3.5 Support restricted recipient (lock-in) programs.
- 3.6 Support take-back programs.
- 3.7 Improve monitoring of pharmacies, prescribers and beneficiaries.
- 3.8 Incentivize electronic prescribing.

#4: ENGINEERING STRATEGIES

- 4.1 Convene a stakeholder meeting to assess the current product environment (e.g., products available, evidence to support effectiveness, regulatory issues) and identify high-priority future directions for engineering-related solutions.
- 4.2 Sponsor design competitions to incentivize innovative packaging and dispensing solutions.
- 4.3 Secure funding for research to assess the effectiveness of innovative packaging and designs available and under development.
- 4.4 Use research to assure product uptake.

RECOMMENDATIONS FOR ACTION

#5: OVERDOSE EDUCATION AND NALOXONE DISTRIBUTION PROGRAMS

- 5.1 Engage with the scientific community to assess the research needs related to naloxone distribution evaluations and identify high-priority future directions for naloxone-related research.
- 5.2 Partner with product developers to design naloxone formulations that are easier to use by nonmedical personnel and less costly to deliver.
- 5.3 Work with insurers and other third-party payers to ensure coverage of naloxone products.
- 5.4 Partner with community-based overdose education and naloxone distribution programs to identify stable funding sources to ensure program sustainability.
- 5.5. Engage with the healthcare professional community to advance consensus guidelines on the co-prescription of naloxone with prescription opioids.

#6: ADDICTION TREATMENT

- 6.1 Invest in surveillance of opioid addiction.
- 6.2 Expand access to buprenorphine treatment.
- 6.3 Require federally-funded treatment programs to allow patients access to buprenorphine or methadone.
- 6.4 Provide treatment funding for communities with high rates of opioid addiction and limited access to treatment.
- 6.5 Develop and disseminate a public education campaign about the important role for treatment in addressing opioid addiction.
- 6.6 Educate prescribers and pharmacists about how to prevent, identify and treat opioid addiction.
- 6.7 Support treatment-related research.

#7: COMMUNITY-BASED PREVENTION STRATEGIES

- 7.1 Invest in surveillance to ascertain how patients in treatment for opioid abuse and those who have overdosed obtain their supply.
- 7.2 Convene a stakeholder meeting with broad representation to create guidance that will help communities undertake comprehensive approaches that address the supply of, and demand for, prescription opioids in their locales; implement and evaluate demonstration projects that model these approaches.
- 7.3 Convene an inter-agency task force to ensure that current and future national public education campaigns about prescription opioids are informed by the available evidence and that best practices are shared.
- 7.4 Provide clear and consistent guidance on safe storage of prescription drugs.
- 7.5 Develop clear and consistent guidance on safe disposal of prescription drugs; expand access to take-back programs.
- 7.6 Require that federal support for prescription drug misuse, abuse and overdose interventions include outcome data.

Background

In May 2014, a diverse group of experts — including clinicians, researchers, government officials, injury prevention professionals, law enforcement leaders, pharmaceutical manufacturers and distributors, lawyers, health insurers and patient representatives — gathered at the Johns Hopkins Bloomberg School of Public Health. The group gathered to review what is known about prescription opioid misuse, abuse, addiction and overdose; to identify strategies for reversing the alarming trends in injuries and deaths from these drugs; and to make recommendations for action. The group convened at the invitation of the Clinton Foundation and two of the School's centers: the John Hopkins Center for Drug Safety and Effectiveness and the John Hopkins Center for Injury Research and Policy. Prior to the meeting, the School hosted a public town hall meeting during which President Bill Clinton provided an inspiring call to action.

During the day-and-a-half meeting, participants identified opportunities for intervention along the supply chain (including the development and production process, legal and illegal markets, and insurance coverage); and within the clinical, community and addiction treatment settings. The result was a commitment to develop and implement a plan of action that utilizes the multi-disciplinary skills and expertise of the many stakeholders committed to addressing the issue.

In the months that followed this initial gathering, the group divided into work groups to review the available evidence and make recommendations based on that literature. This process was guided by the following principles:

INFORMING ACTION WITH EVIDENCE.

Some evidence-based interventions exist to inform action to address this public health emergency; these should be scaled up and widely disseminated. Furthermore, many promising ideas are evidence-informed, but have not yet been rigorously evaluated. The urgent need for action requires that we rapidly implement and carefully evaluate these promising policies and programs. The search for new, innovative solutions also needs to be supported.

INTERVENING COMPREHENSIVELY.

We support approaches that intervene all along the supply chain, and in the clinic, community and addiction treatment settings. Interventions aimed at stopping individuals from progressing down a pathway that will lead to misuse, abuse, addiction and overdose are needed. Effective primary, secondary and tertiary prevention strategies are vital. The importance of creating synergies across different interventions to maximize available resources is also critical.

PROMOTING APPROPRIATE AND SAFE USE OF PRESCRIPTION OPIOIDS.

Used appropriately, prescription opioids can provide relief to patients. However, these therapies are often being prescribed in quantities and for conditions that are excessive, and in many cases, beyond the evidence base. Such practices, and the lack of attention to safe use, storage and disposal of these drugs, contribute to the misuse, abuse, addiction and overdose increases that have occurred over the past decade. We support efforts to maximize the favorable risk/benefit balance of prescription opioids by optimizing their use in circumstances supported by best clinical practice guidelines.

This report is the result of the work group process.

Overview

Prescription drugs are essential to improving the functioning and quality of life for patients living with acute or chronic medical conditions. Although all prescription drugs have some misuse risk, of particular concern is the misuse and abuse of the drugs identified by the Drug Enforcement Administration (DEA) as controlled substances. These products, such as prescription opioids, have high abuse potential and can lead to life-threatening adverse events when taken in excess or in combination with other drugs.^{1,2}

Prescription drug abuse and overdose is a serious public health problem in the United States. Drug overdose death rates in the U.S. increased five-fold between 1980 and 2008, making drug overdose the leading cause of injury death.³ In 2013, opioid analgesics were involved in 16,235 deaths — far exceeding deaths from any other drug or drug class, licit or illicit.⁴ According to the National Survey on Drug Use and Health (NSDUH), in 2012 an estimated 2.1 million Americans were addicted to opioid pain relievers and 467,000 were addicted to heroin.⁵ These estimates do not include an additional 2.5 million or more pain patients who may be suffering from an opioid use disorder because the NSDUH excludes individuals receiving legitimate opioid prescriptions.⁶

A public health response to this crisis must focus on preventing new cases of opioid addiction, early identification of opioid-addicted individuals, and ensuring access to effective opioid addiction treatment, while at the same time continuing to safely meet the needs of patients experiencing pain. It is widely recognized that a multi-pronged approach is needed to address the prescription opioid epidemic. A successful response to this problem will target the points along the spectrum of prescription drug production, distribution, prescribing, dispensing, use and treatment that can contribute to abuse; and offer opportunities to intervene for the purpose of preventing and treating misuse, abuse and overdose.

This report provides a comprehensive overview of seven target points of opportunity, summarizes the evidence about intervention strategies for each, and offers recommendations for advancing the field through policy and practice.

- #1: Prescribing Guidelines
- #2: Prescription Drug Monitoring Programs
- #3: Pharmacy Benefit Managers and Pharmacies
- #4: Engineering Strategies
- #5: Overdose Education and Naloxone Distribution Programs
- #6: Addiction Treatment
- #7: Community-Based Prevention

The remainder of this report is organized by these seven topic areas.

The Prescription Opioid Epidemic: An Evidence-Based Approach

STATEMENT OF THE PROBLEM

More than 100,000 people in the United States have died — directly or indirectly — from prescribed opioids since prescribing policies changed in the late 1990's.⁷ At that time, patient advocacy groups and pain specialists successfully lobbied state medical boards and state legislatures to change statutes and regulations to lift any prohibition of opioid use for non-cancer pain. In at least 20 states, these new guidelines, statutes, regulations and laws dramatically liberalized the long-term use of opioids for chronic non-cancer pain, reflecting the prevailing thought at the time that there is no clinically appropriate ceiling on maximum opioid dosing.⁸ An example of such permissive language can be found in Washington State Administrative code (WAC) 246-919-830 from December 1999, which states: “no disciplinary action will be taken against a practitioner based solely on the quantity or frequency of opioids prescribed.”

With the introduction of pain as the “fifth vital sign,”⁹ accompanied by pharmaceutical company efforts to market directly to prescribers,¹⁰ there has been a dramatic increase in prescription opioid sales. Studies have documented a strong and consistent linear relationship between opioid sales volume and morbidity and mortality associated with these products.¹¹

SYNTHESIS OF AVAILABLE EVIDENCE

As opioid-related deaths continued to accelerate, constituting a national epidemic and public health emergency,^{12,13} an increasing number of systematic reviews surfaced assessing the efficacy and effectiveness of opioids for chronic non-cancer pain. These systematic reviews concluded that the overall effectiveness of chronic opioid treatment for chronic non-cancer pain is limited, the effect on improved human function is very small and the safety profile of opioids is poor.^{14,15,16} Briefly stated, the evidence on efficacy and effectiveness of these drugs for chronic non-cancer pain has demonstrated:

1. A variety of adverse events associated with opioid use, including: hypogonadism and infertility; neonatal abstinence syndrome; sleep breathing disorders; cardiac arrhythmias; opioid-induced hyperalgesia; and falls and fractures among the elderly;
2. High rates of healthcare utilization associated with these adverse events, including emergency department visits and hospitalizations from non-fatal overdoses;
3. High rates of deaths from unintentional poisonings, especially at doses at or above 100–120 morphine milligram equivalents (MME) per day, which generally occur at home during sleep;
4. Minimal improvement in pain and function associated with long-term opioid use for chronic non-cancer pain; and
5. An overall unfavorable risk/benefit balance for many current opioid users.

The evidence on state policy strategies and their effect on prescribing patterns demonstrates that state governments are willing to promote safe and effective pain management while taking precautions to curtail the alarming increase of opioid related morbidity and deaths.¹⁷ However, policy language varies: Some states emphasize the need to prevent illicit trafficking and drug abuse,¹⁸ while others encourage appropriate pain management while avoiding undue burdens on practitioners and patients.¹⁹ Some states follow the advice of specialty societies. However, position papers of expert groups differ, as does the soundness of their recommendations, including some recommendations under investigation by the U.S. Senate at the time of this writing.²⁰

The Washington State experience is particularly informative to prescribing guideline policies. In 2007, the State responded to epidemic opioid-related morbidity and mortality by engaging the public state agencies to collaborate with academic and practicing pain clinicians to promulgate opioid dosing guidelines for the local community. The core recommendation developed was to seek specialty consultation if a patient reaches 120 morphine milligram equivalents (MME) per day without improved pain or function. Many states, as well as the Centers for Disease Control and Prevention (CDC) and the Agency for Healthcare Research and Quality (AHRQ), adopted these guidelines as universal precautions.² The Centers for Disease Control and Prevention recently engaged in a comprehensive, evidence-based process to develop guidelines for prescribing opioids for chronic pain. The resulting Guideline will be released early in 2016. (<http://www.cdc.gov/drugoverdose/prescribing/guideline.html>)

#1 PRESCRIBING GUIDELINES

Following the initial success of these guidelines and an initial “bending of the curve” of mortality among beneficiaries of these agencies,²² Washington State passed a landmark bill (ESHB 2876) in 2010. The bill mandated that the boards and commissions representing prescribing providers in the state repeal all prior rules governing opioid prescribing and create new ones by 2011. The bill, which received bi-partisan support, required that the new rules must include:

- Dosing criteria;
- Guidance on when and how to seek consultation (including the use of peer-to-peer video conferencing);
- Guidance on the use of a state prescription drug monitoring program (PDMP); and
- Guidance on tracking clinical progress by using assessment tools focusing on pain, mood, physical function and overall risk for poor outcomes.²³

Lessons learned from the Washington State policy experience:

- Facilitate collaboration among state agencies and medical boards.
- Establish dosing and best practice rules and incentivize those rules.
- Implement an effective prescription drug-monitoring program that includes real-time data.
- Initiate education programs.
- Evaluate the impact of prescribing guideline interventions regularly.

RECOMMENDATIONS FOR ACTION

1.1 REPEAL EXISTING PERMISSIVE AND LAX PRESCRIPTION LAWS AND RULES.

Federal and state agencies, state medical boards and medical societies should work to repeal previous permissive and lax prescription laws and rules.

Rationale: Previous prescription policies, guidelines, statutes and rulings have been too permissive and have contributed to the current opioid epidemic. They require revision.

Current Status: In 2010, Washington State repealed prior rules related to prescribing and ordered new rules promulgated by 2011. State laws on this topic vary. A list of statutes, regulations, and other state policies relevant to opioid prescribing is available from the Pain and Policy Studies Group at University of Wisconsin.²⁴

1.2 REQUIRE OVERSIGHT OF PAIN TREATMENT.

Federal and state agencies, state medical boards and medical societies should require mandatory tracking of pain, mood and function through use of a brief validated survey at every patient medical visit; use of patient treatment agreements, urine drug screening; PDMP use when prescribing long-term opioids for non-chronic pain; and specialty consultation (via peer-to-peer video conferencing when in-person is unavailable) when prescribing over 120 morphine milligram equivalents (MME) per day without pain and function improvement.

Rationale: Given the risks associated with prescription opioids, protocols and tools for monitoring them, and decision-making when prescribing them, are needed to improve the safety of prescribing practices.

Current Status: These guidelines have been adopted by Washington State and appear in whole or in part in many other guidelines endorsed by the Department of Defense (DoD), Veteran’s Administration (VA), and the AHRQ, as well as by professional societies like the American College of Occupational and Environmental Medicine (ACOEM), American Pain Society (APS), American Academy of Pain Medicine (AAPM), and American Society of Interventional Pain Physicians (ASIPP). A comparative table of guideline recommendations published by the CDC has been published.²⁵

1.3 PROVIDE PHYSICIAN TRAINING IN PAIN MANAGEMENT AND OPIOID PRESCRIBING AND ESTABLISH A RESIDENCY IN PAIN MEDICINE FOR MEDICAL SCHOOL GRADUATES.

Federal and state agencies, state medical boards, and medical societies should assure pre-graduate and post-graduate training in pain management and opioid prescription, including: continuing medical education (CME); graduate medical education (GME); post graduate education; and creation of a full three-year residency training program in pain medicine, which currently does not exist.

Rationale: Training in pain management is needed in order to move toward more effective, less risky treatments. An estimated 10,000 pain specialists cannot meet the treatment needs of the millions of chronic pain sufferers in the U.S.

Current Status: The American Association of Medical Colleges (AAMC) has endorsed efforts to increase the instruction of pain medicine in medical schools, however standards have not yet been defined. There is no full three-year residency training program in pain medicine in the U.S., and although legislation to support such a residency has been proposed and endorsed by leadership of the American Medical Association, it has been refused by the American Board of Medical Specialties.²⁶ Accredited post-graduate fellowship training in pain medicine is available only for specialists in select fields, such as anesthesiology, neurology, psychiatry and rehabilitation medicine and not for general practitioners or specialists in family or internal medicine. Also available are continuing medical education (CME) courses, generally sponsored by pharmaceutical manufacturers, through the FDA's Risk Evaluation and Mitigation Strategies (REMS).

#2 PRESCRIPTION DRUG MONITORING PROGRAMS

STATEMENT OF THE PROBLEM

Prescription Drug Monitoring Programs (PDMPs) collect data regarding controlled substances prescriptions from in-state pharmacies and, for most PDMPs, mail order pharmacies that ship prescriptions into the state. There are 51 PDMPs, in all states except Missouri, plus the District of Columbia and Territory of Guam. Through online access to their state's database, physicians and other prescribers can obtain clinical information regarding their patients' controlled substance prescriptions to inform treatment decisions. Typically, information available through the PDMP includes drug name, type, strength and quantity of drugs from previous prescriptions. Physicians and prescribers can also identify patients who may need substance abuse treatment. Similarly, pharmacists can access PDMP data prior to dispensing a controlled substance prescription. These programs are valuable tools to improve patient safety and health outcomes.

PDMPs are under-utilized by prescribers. More than a quarter (28 percent) of primary care physicians in one study reported not being aware of their states' PDMPs.²⁷ While a majority of clinicians (53 percent) reported having obtained data from their PDMP at some point, data are accessed in fewer than a quarter of the instances when these physicians prescribed an opioid. Performance measures reported by 17 states for the first quarter of 2012 indicate that the median percent of prescribers who issued controlled substance prescriptions who registered to use their states' PDMPs was 31 percent,²⁸ and the median number of reports requested by all prescribers who issued one or more controlled substance prescriptions was 3.28. Even the highest rates of PDMP registration did not ensure use. For example, during the first quarter of 2012, Kentucky had the fifth highest proportion of registered prescribers at 49 percent,²⁸ yet prescribers and pharmacists requested information for only 6 percent of 2.9 million controlled substance prescriptions dispensed.²⁹ Physicians identify a number of barriers to PDMP use, including that retrieving the information is too time consuming and difficult.³⁰

This underutilization of PDMPs is particularly troubling because PDMPs can help identify persons who may be engaged in high-risk behavior, such as doctor shopping and prescription forgery, indicating possible abuse of or dependence on controlled substances. PDMP data can be used to alert health care professionals if a patient is at risk for addiction or overdose, since certain indicators are known risk factors for high-risk utilization. For example, persons who doctor shop are seven times more likely to die of opioid overdoses than persons who do not; those who pharmacy shop are more than 13 times more likely to suffer an overdose death.³¹ People who ingest 100 milligrams of morphine milligram equivalents or more per day have an almost nine-fold increase in overdose risk.³²

SYNTHESIS OF AVAILABLE EVIDENCE

In response to the problem of inadequate utilization of PDMPs described above, state lawmakers and PDMP administrators have made several adjustments, including:

- Authorization of delegates (approved clinical professionals) to request PDMP data. As of 2014, 36 states had laws authorizing delegates to request PDMP data.
- Establishment of interoperability with electronic health records and the Affordable Care Act's health information exchanges. The Substance Abuse and Mental Health Services Administration (SAMHSA) is providing grants to support this work in 16 states.^{33, 34}
- Proactive analysis of PDMP data and forwarding of unsolicited reports to prescribers and pharmacists; when these professionals receive unsolicited reports from PDMP administrators, they increase their own data requests.^{35, 36}
- Increased speed of data collection. Twenty-two states require pharmacies to submit data daily, 27 collect data on a weekly basis or less, and one collects data bi-weekly. By June 30, 2015, only one state remains at the old standard of monthly data submission.
- Increased interstate PDMP data sharing so prescribers can observe prescriptions dispensed in other states; 28 states³⁷ are engaged in interstate data sharing and others are working toward these agreements.

States, faced with low prescriber utilization, are increasingly mandating that prescribers use PDMPs. Sixteen states^{38, 39} mandate that prescribers use PDMPs under certain circumstances; an additional 11 states have comprehensive mandates as of December 2014.^{40, 41} Kentucky was the first state to mandate comprehensive PDMP use. Prescribers' PDMP use increased following the mandate, and decreases in opioid prescribing, doctor shopping and prescription overdose hospitalizations were noted in a 2015 evaluation — although heroin treatment admissions rose during the study period.⁴²

#2 PRESCRIPTION DRUG MONITORING PROGRAMS

Additional information about the Kentucky law and the impacts measured to date follow.

- Prescribers must review PDMP data prior to issuing a patient's first opioid prescription, and at least every three months thereafter for continued therapy and new or refill opioid prescriptions, with some exceptions. This requirement went into effect in July 2012. The 2015 evaluation found that the mean number of prescribers' requests increased by 650 percent annually compared to the period prior to the law's effective date.^{43, 44}
- Prior to the mandate, Kentucky clinicians' report requests had increased by about 85,000 reports annually. At that rate it would have taken approximately 38 years to reach the level achieved within three months of the new law.⁴⁵
- Opioid prescriptions decreased by 8.6% in the year following implementation of the law.³
- According to data provided by the Kentucky Office of Drug Control Policy, from 2011 to 2013, overdose hospitalizations due to prescription opioids declined by 26 percent, emergency department visits related to prescription opioids declined by 15 percent,⁴⁶ and prescription opioid deaths declined by 25 percent, the first declines in 10 years.⁴⁷

Like Kentucky, other comprehensive mandate states (Tennessee, New York, Ohio) experienced rapid increases in PDMP registrations, increases in PDMP data use (up to 10,000 percent in New York),⁴⁸ decreases in prescribing commonly abused controlled substances, and decreases in multiple provider, or "doctor-shopping" episodes.

Additional professional groups that could use PDMP data to intervene and interrupt harmful prescription-controlled substance behaviors include:

Third-party healthcare payers and their pharmacy benefit managers (PBMs) that have the ability to intervene with prescribers, dispensers and patients. Medicaid programs and some of the private third-party payers use Patient Review and Restriction (PRR), such as "Lock-in". Typically, these programs restrict high-risk patients to one doctor and one pharmacy for the controlled substance prescriptions. These programs can effectively protect patient health and safety as well as prevent program fraud, especially when augmented by access to PDMP data.^{49, 50}

Professional licensing boards that oversee clinicians and have an interest in identifying who is abusing controlled substances and/or who has high-risk prescribing or dispensing patterns. Recent findings identify a small number of prescribers as responsible for a disproportionate number of opioid prescriptions.⁵¹ Oregon's PDMP found that the top 4 percent of prescribers issued 60 percent of all controlled substance prescriptions.⁵² In New York City, 1 percent of prescribers wrote 31 percent of opioid prescriptions. A large chain pharmacy found 42 outlier prescribers out of more than 1 million. Within that chain alone, the 42 each issued prescriptions for about 5,000 average monthly doses of high-risk drugs over 21 months. On an annual basis that would cumulatively total more than 4 million dosage units.⁵³

Law enforcement agencies that can identify possible criminal activity, such as "doctor shopper" rings and pill mills. Jung, et al found that among 47 physicians arrested by the Drug Enforcement Agency (DEA) in 2003 and 56 whose DEA registrations were revoked in 2003–2004, there was not sufficient information in the majority of cases to confirm the existence of a documented doctor/chronic pain patient relationship.⁵⁴

Public health agencies that provide an early warning system for communities about the risks of opioid overdoses and deaths. PDMP data can also be analyzed at the county and community level within a short time of actual prescription dispensing and provide warnings to states and communities of the risk of increasing opioid overdoses and deaths. The Prescription Behavior Surveillance System (PBSS) was developed by the PDMP Center of Excellence (COE) in conjunction with the National Center for Injury Prevention and Control (NCIPC) and the Food and Drug Administration (FDA) to help identify communities at risk for harmful opioid outcomes. A variety of measures — such as mean daily dosage of opioids per patient, multiple provider episode rates, percentage of days with overlapping prescriptions for opioids and benzodiazepines and median distance in miles from patient to prescriber — can be tracked and followed over space and time.⁵⁵ By using PDMP data for public health surveillance, states and communities can monitor prescribing trends.⁵⁶ In turn, they can take actions to protect against opioid addiction, overdoses and deaths, as demonstrated by Project Lazarus in North Carolina.⁵⁷ Given the limited resources available to states and communities, this type of information is essential for targeting prevention and other resources to areas of greatest need, according to substance abuse prevention specialists and others.⁵⁸

#2 PRESCRIPTION DRUG MONITORING PROGRAMS

RECOMMENDATIONS FOR ACTION

2.1 MANDATE PRESCRIBER PDMP USE.

Through regulation or legislation, states should mandate prescriber use of PDMPs in order to achieve more comprehensive and effective use of PDMP data in treating patients.

Rationale: Mandatory PDMP use policies are associated with increased use.⁵⁹

Current Status: Sixteen states mandate that prescribers use PDMPs under certain circumstances; an additional seven states have comprehensive mandates.

2.2 PROACTIVELY USE PDMP DATA FOR ENFORCEMENT AND EDUCATION PURPOSES.

States should analyze their PDMP data to identify: 1) potential inappropriate or illegal activities and forward the information in unsolicited reports to the relevant professional groups to increase oversight of controlled substance prescribing; and 2) hot spots of inappropriate and/or illegal use so that prevention efforts are data-driven and evidence-informed. Primary recipients of PDMP data reports should include prescribers, dispensers, professional licensing boards, law enforcement agencies, and state and community prevention and treatment programs.

Rationale: Many PDMPs underutilize the data and do not engage in proactive reporting, nor do they participate in PBSS or state-based equivalent reporting. Better use of PDMP data will aid identification of opportunities for intervention, and prevent misuse, abuse and overdose through enforcement and education.

Current Status: Twenty-eight states⁶⁰ engage in proactive data analysis and reporting activities as of 2014. Only four states provide unsolicited reports to all four primary recipient groups (prescribers, dispensers, professional licensing boards and law enforcement agencies).⁶¹

Twelve states⁶² participate in PBSS by sending de-identified PDMP data to and receiving reports from the Brandeis PDMP Center of Excellence (COE). The CDC and FDA fund the project through an agreement with the Bureau of Justice Assistance.⁶³ States not participating in PBSS can initiate their own data analysis and sharing with state and community prevention and treatment programs.

2.3 AUTHORIZE THIRD-PARTY PAYERS TO ACCESS PDMP DATA WITH PROPER PROTECTIONS.

States should authorize Medicaid, Medicare, the Veterans Administration, Department of Defense, Indian Health Service, workers compensation carriers and private third-party healthcare payers to access PDMP data for their enrollees, with proper protections. The authorization should also allow Pharmacy Benefit Managers (PBMs) (See Section 3 of this report for more information on PBMs) to access the data as agents of the third-party payers for whom they manage benefits.

Rationale: Such access can provide third-party payers with valuable information to inform internal policies that address the misuse, abuse and overdose associated with controlled substance prescriptions.

Current Status: Thirty-two states and one territory⁶⁴ authorize some combination of third-party payers to access PDMP data. Only five states provide access to Medicare and three states⁶⁵ to commercial third-party payers. States should consider the Washington State model that authorizes Medicaid and Workers Compensation to access the PDMP data in bulk.⁶⁶

2.4 EMPOWER LICENSING BOARDS FOR HEALTH PROFESSIONS AND LAW ENFORCEMENT TO INVESTIGATE HIGH-RISK PRESCRIBERS AND DISPENSERS.

All states should direct their PDMPs to proactively analyze these data to identify possible misconduct and criminal activities and to provide the information unsolicited to licensing boards and law enforcement in order to develop and inform investigations.

Rationale: Licensing boards need access to PDMP data to investigate possible misconduct involving controlled substances. Authority to enforce controlled substance laws is the responsibility of federal, state and local law enforcement. Law enforcement should have access to PDMP data in order to inform this authority.

#2 PRESCRIPTION DRUG MONITORING PROGRAMS

Current Status: Forty-six states, Guam, and the District of Columbia permit their licensing boards to access PDMP data; three states do not.⁶⁷ Eleven states send unsolicited reports to licensing boards.⁶⁸

Three states⁶⁹ report they permit specially trained investigators to directly access PDMP data on-line. Thirty states⁷⁰ require probable cause, search warrants, subpoenas or other judicial processes in order for law enforcement officers to access data. One state does not authorize law enforcement officers to have access. Seventeen states proactively analyze and send unsolicited reports to law enforcement agencies.⁷¹

#3 PHARMACY BENEFIT MANAGERS (PBMs) AND PHARMACIES

STATEMENT OF THE PROBLEM

PBMs and pharmacies possess different types of data that are relevant to reducing prescription drug abuse and diversion. Since PBMs manage the pharmacy benefits for health plans and large employers, they possess members' claims data for prescription drugs, and at times, other healthcare goods and services. PBMs do not have visibility of prescriptions paid with cash or those paid by another insurer. Pharmacies, on the other hand, only possess information about a patient's prescriptions if the patient filled his or her medicine with that pharmacy or pharmacy chain. The fact that PBMs and pharmacies may lack a comprehensive view of an individual patient's prescription history is one reason that it is essential for state-run prescription drug monitoring programs (PDMPs) to have comprehensive controlled substances information for an individual, and for this information to be shared with payers, as well as with other states. As described in Section 2 of this document, PDMPs can have comprehensive controlled substances prescription records for an individual regardless of whether the individual paid cash or filled prescriptions through multiple insurers and pharmacies. However, not all insurers/PBMs are allowed to access the PDMP information, nor are PDMPs comprehensively interconnected among all states.

SYNTHESIS OF AVAILABLE EVIDENCE

There are many methods that PBMs and pharmacies can use to reduce inappropriate prescribing and to intervene upon individuals likely to be abusing or diverting prescription drugs.^{72, 73, 74} Evidence of the impact of PBMs' procedures and programs has been summarized.^{75, 76} Importantly, as pointed out by Haegerich and colleagues in their report on studies of state policy or systems-level interventions to prevent drug misuse and abuse,

“Overall study quality is low. Knowledge and prescribing practices were measured more often than health outcomes (e.g., overdoses). Limitations include lack of baseline data and comparison groups, inadequate statistical testing, small sample sizes, self-reported outcomes, and short-term follow-up. Evidence of improved health outcomes, particularly from safe storage and disposal strategies and patient education, is weak.”⁷³

Many PBMs perform prescription claims reviews using software algorithms to identify individuals, pharmacies and prescribers that are potentially fraudulently using or dispensing controlled substances. In addition, PBMs' prescription claims surveillance and prescriber intervention programs often use retrospective analysis to identify members meeting excessive controlled substance use criteria, such as some combination of the use of multiple prescribers, multiple dispensing pharmacies, exceeding a threshold of morphine milligram equivalent (MME) dose, and multiple controlled substance claims over a period of three to six months. Most PBMs' internal controlled substance claim surveillance criteria are not disclosed or validated to be associated with controlled substance adverse events, mortality, health care utilization or costs. However, some criteria used by PBMs have been published.^{77, 78} Prescriber letter interventions through PBMs have been shown to decrease members' controlled substance score and controlled substance drug claims.^{79, 80} These programs could be enhanced if the PBM has complete controlled substance claims history, including cash claims, through access to states' PDMPs.

Examples of PBMs' controlled substances utilization management programs include prior authorization, precertification and maximum quantity limits per prescription. The health insurer Aetna reported in 2014 that its PBM “Pharmacy Misuse, Waste and Abuse” program monitors access to opioids through precertification and reviews of pharmacy and medical claims and quantity limits to find patterns of above-normal use. Further, members who have had frequent emergency room visits are identified. Other signs, and suspicion of developing substance abuse problems or a history of controlled substance abuse, also are noted. The program reduced opioid prescriptions among 4.3 million members by 14 percent between January 2010 and January 2012.⁸¹

An Aetna-run Behavioral Health Medication Assistance Program involves nurses and psychologists working with physicians to evaluate members who could be at risk for addiction and those with a history of opioid abuse or who are in treatment. According to Aetna, this program has shown “a 30 percent improvement in opioid abstinence rates; a 35 percent reduction of in-patient hospital admissions and a 40 percent decrease in total paid medical costs.”⁸² Blue Cross Blue Shield of Massachusetts reported in 2014 that its program implemented in July 2012 to require a prior authorization for more than 30 days of opioid therapy reduced prescriptions by 20 percent for common opioids such as Percocet (oxycodone and acetaminophen) and 50 percent for longer-acting drugs such as OxyContin (extended-release oxycodone), and cut total prescriptions of narcotic painkillers by an estimated 6.6 million pills in 18 months.⁸³

For patients who have particularly high-risk controlled substance use and whose utilization cannot be safely addressed using other mechanisms, insurers or PBMs may enroll the member in a pharmacy and/or prescriber restriction program. These

#3 PHARMACY BENEFIT MANAGERS (PBMs) AND PHARMACIES

programs, also known as “lock-in” programs, are applied to fewer than 1 in 1,000 controlled substance-using individuals, and have been used by state Medicaid programs for years. Restricted recipient programs limit an individual to receiving their controlled substance prescriptions from one prescriber and one pharmacy for allowed insurance payment, or else the individual must pay cash. As stated by the Academy of Managed Care Pharmacy:

“Prescriber and pharmacy restricted access programs help to mitigate the issues associated with doctor or pharmacy shopping and may reduce the number of inappropriate controlled substance prescriptions. In 2009, the Oklahoma Medicaid department found that its lock-in program reduced doctor shopping, utilization rates of controlled substances, and emergency room visits with a savings of \$600 per person in costs. As demonstrated in Medicaid and other programs and recommended by the General Accountability Office in 2011, to reduce incidence of doctor or pharmacy shopping, a common way that Medicare beneficiaries obtain inappropriate controlled substances, CMS should consider restricted access to certain prescribers and pharmacies for Medicare beneficiaries.”^{84, 85}

Formulary controls are also used by PBMs to guide patients and prescribers toward the safest, most cost effective medications and then to cover these drugs at a lower member cost share to encourage their use. Exclusion of a controlled substance drug from a formulary results in the drug not being covered by the insurance policy. For example, the product Zohydro ER has been excluded from some formularies due to concerns about its potential for abuse and overdose. Minnesota Medicaid chose to exclude promethazine with codeine syrup and carisoprodol beginning in 2015 due to the potential for concomitant abuse of these three drugs and insufficient evidence to support their clinical benefit when used together.⁸⁶ Research is needed to understand the impact of these types of policies.

Pharmacies can also remove prescriber dispensing privileges to curtail both diversion and inappropriate controlled substance prescribing, and they can require pharmacists to provide patient counseling to help those with controlled substance dependence.^{87, 88, 89} The removal of prescriber dispensing privileges to curtail both diversion and inappropriate controlled substance prescribing is feasible and supported by state and federal law.⁹⁰ With the goal of ensuring that prescriptions for controlled substances are appropriate, one pharmacy chain identified 42 controlled substance outlier prescribers out of more than 1 million prescribers. After allowing for appeal, 36 prescribers had their prescriber dispensing privileges removed,⁹¹ reducing more than 100,000 doses of high-risk drugs prescribed per month.

Electronic prescribing (e-prescribing) is the process by which a prescriber generates and transmits an “accurate, error-free and understandable” prescription directly to a pharmacy through a special secure network. E-prescribing for controlled substance drugs has the potential to reduce forgery and fraudulent controlled substance prescriptions.⁹² Research indicates that few controlled substance prescriptions are e-prescribed.⁹³ It is anticipated that e-prescribing will soon become commonplace, especially with new laws like New York’s iSTOP law. The e-prescribing requirements were a part of the State’s Internet System for Tracking Over Prescribing (I-STOP) laws, enacted in 2012. I-STOP requires all prescribers to: 1) consult the Prescription Monitoring Program (PMP) prior to prescribing Schedule II, III and IV controlled substances and 2) electronically transmit all prescriptions. Evaluations to monitor the impact of such initiatives will be critical to maximizing the use of e-prescribing as a tool for more effectively controlling the supply of controlled substances.

The Drug Enforcement Administration (DEA) and state boards of pharmacy require pharmacists to use sound professional judgment when determining whether or not to fill controlled substance prescriptions. After reviewing the prescription, pharmacists will use their professional judgment on handling any issues that may come up. This professional activity is enhanced through pharmacist access to and use of PDMPs to review a member’s claims history in questionable cases. Interstate PDMP data access with infrastructure supporting high utilization and rapid response times is essential to ensure that PDMP data are optimally used by prescribers and pharmacists.⁹⁴

Although they have not yet been widely enacted, “take-back” programs that foster safer medication disposal by allowing for patients to return unused or unwanted opioids may also help to reduce the potential for diversion of opioids and other controlled prescription drugs from licit to illicit channels. Pharmacies provide a convenient site for individuals to dispose of their unused controlled substance prescriptions. Evidence supporting the effectiveness of allowing pharmacies to take back and destroy prescription drugs is anecdotal. Additional discussion of this strategy is included in Section 7 of this report.

#3 PHARMACY BENEFIT MANAGERS (PBMs) AND PHARMACIES

RECOMMENDATIONS FOR ACTION

3.1 INFORM AND SUPPORT EVALUATION RESEARCH.

Pharmacies and PBMs are engaged in controlled substance interventions. Research funded by the federal government, non-profit and for profit entities is needed to evaluate the clinical and economic impact of these efforts. A stakeholder meeting to review research that is in progress and to identify priorities for new research is needed to inform investment in this area.

Rationale: Without high quality evaluations of interventions, pharmacies and PBMs will lack a reliable evidence base to inform how best to invest prevention dollars.

Current Status: The Patient-Centered Outcomes Research Institute (PCORI) has no funded projects. The Centers for Disease Control and Prevention (CDC) and the National Institute on Drug Abuse (NIDA) have sponsored modest extramural funding in this realm. The private sector is conducting research, much of which goes unpublished. We are unaware of any other funding sources active in this area.

3.2 ENGAGE IN CONSENSUS PROCESS TO IDENTIFY EVIDENCE-BASED CRITERIA FOR USING PBM AND PHARMACY CLAIMS DATA TO IDENTIFY PEOPLE AT HIGH RISK FOR ABUSE AND IN NEED OF TREATMENT.

This can be accomplished through a consensus process that brings together experts in the field to identify criteria to include.

Rationale: Criteria currently in use to identify individuals at high risk for abuse or overdose requires further validation and refinement. It is essential that scientific evidence be applied to reduce false positive or false negative identification.

Current Status: State Medicaid, managed care plans and PBMs are using varying methods with varying degrees of evidence to support them.

3.3 EXPAND ACCESS TO PDMP.

Amend state PDMP laws to allow managed care plans and PBMs access to PDMPs to ensure complete claims history for covered members. These laws must include proper protections for patient privacy.

Rationale: Allowing managed care plans and PBMs access to PDMP data will improve upon their current controlled substances interventions that have been shown to positively influence controlled substances utilization.

Current Status: PDMP legislation generally prohibits managed care plans and PBMs from accessing PDMP data. State legislatures will need to change their state PDMP laws to allow managed care plans and PBMs access to data.

3.4 IMPROVE MANAGEMENT AND OVERSIGHT OF INDIVIDUALS WHO USE CONTROLLED SUBSTANCES.

Encourage the states and Centers for Medicare & Medicaid Services (CMS) to incentivize PBMs, through the Medicaid Innovation Accelerator Program and CMS Innovation Center, to implement and rigorously evaluate innovative medication management strategies for targeted management of individuals who use controlled substances.

Rationale: Managed care plans and PBMs are uniquely positioned to efficiently aggregate data and take action.

Current Status: A systematic assessment of how plans and PBMs are currently implementing and evaluating management and oversight of individuals who use controlled substances does not exist.

3.5 SUPPORT RESTRICTED RECIPIENT (LOCK-IN) PROGRAMS.

The federal government should amend the Medicare Part D to allow prescriber and pharmacy restricted recipient (lock-in) programs.

Rationale: Demonstrated success with the Medicaid restricted recipient programs should be shared with legislators to inform them of the opportunity to prevent opioid abuse in Medicare.

Current Status: Prescriber and pharmacy restricted recipient programs are legislatively prohibited in Medicare. Federal legislators will need to change the Medicare Part D law to allow managed care plans and PBMs to implement prescriber and pharmacy restricted recipient programs.

3.6 SUPPORT TAKE-BACK PROGRAMS.

Pharmacies should encourage their patients to return unused controlled substances.

Rationale: Pharmacies are a convenient site for individuals to dispose of their unused controlled substance prescriptions.

Current Status: Some pharmacies are taking back controlled substances. However, pharmacies are not universally providing this service or advertising this service to their patients. Whether the public is aware of the need to properly dispose of these medications is unknown.

3.7 IMPROVE MONITORING OF PHARMACIES, PRESCRIBERS AND BENEFICIARIES.

All PBMs should provide a list of suspicious pharmacies, prescribers and beneficiaries to the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC). Using the actionable PBM data they are receiving, MEDICs should be reporting potential providers for removal to the CMS.

Rationale: Most PBMs are providing a list of suspicious pharmacies, prescribers and beneficiaries to NBI MEDIC.

Current Status: To our knowledge, CMS is not systematically using the PBM data to exclude providers from being covered and reimbursed by CMS.

3.8 INCENTIVIZE ELECTRONIC PRESCRIBING.

Encourage private insurers and the CMS to incentivize electronic prescribing for controlled substances.

Rationale: E-prescribing for controlled substance drugs has the potential to reduce forgery and fraudulent controlled substance prescriptions.

Current Status: Although controlled substances e-prescribing is infrequent as of this writing, the expectation is that e-prescribing will increase with new state laws and electronic medical record connectivity with pharmacies.

#4 ENGINEERING STRATEGIES: PRESCRIPTION DRUGS AND PACKAGING

STATEMENT OF THE PROBLEM

Although prescription drug abuse is a complex, multi-faceted issue, the data strongly indicate that the vast majority of prescription drugs that are abused come from legitimate prescriptions.⁹⁵ However, once they are dispensed, prescription drugs are frequently diverted to people using them for nonmedical purposes.⁹⁶ Indeed, approximately 70 percent of people who report nonmedical use of prescription opioid pain relievers state they got their most recently used drug from a friend or family member.⁹⁷ One component of a comprehensive approach to the problem is to leverage engineering strategies to inform the development of innovative packaging for prescription drug dispensing that can reduce nonmedical use and diversion.

The concept of engineering solutions to improve product safety is a cornerstone of injury prevention. Research indicates that changing products to make them safer is often more effective at reducing injury and death compared to trying to change personal behaviors.⁹⁸ Successful examples that have resulted in reductions in morbidity and mortality include the introduction of child-resistant caps to reduce pediatric poisonings; and reductions in motor vehicle crash deaths after mandatory implementation of collapsible steering wheels, energy-absorbing vehicle frames and other physical modifications to motor vehicles.^{99, 100, 101, 102} These product-oriented approaches can serve as a model for engineering solutions for prescription drug abuse.

SYNTHESIS OF AVAILABLE EVIDENCE

The U.S. Food and Drug Administration (FDA) highlighted the potential for innovative packaging solutions to be a part of the Agency's response to prescription drug abuse when it published a notice for public comment in the Federal Register in April 2014. The FDA stated that designs for drug packaging have evolved significantly in the past decade and now include many technology-based features — such as electronic systems for monitoring, accessing and improving adherence to medication regimens — that also could help to prevent prescription drug abuse and diversion. Examples of design strategies mentioned by the FDA include: systems that remind patients to take a dose, track when a dose is taken, and limit further access until the next dose is due; radio-frequency identification-based systems; and microchips embedded within tablets. Often these technologies are packaged with data capture systems to provide feedback to providers on adherence, use and potentially tampering.¹⁰³

Although most prescription drug packaging solutions have been designed to improve medication compliance among patients using non-controlled substances for chronic conditions^{104, 105}, these solutions could be adapted to help prevent prescription drug abuse and diversion. For example, these products could reduce serious complications such as overdose by facilitating appropriate dosage and administration, and could help providers monitor for signs of abuse or diversion. In addition, products that limit access to the medication during non-dosing periods could help prevent use of the medication by someone for whom it was not prescribed. The concept of personalization, i.e., use of a personal identification number, radio-frequency device, fingerprint or other biometrics, has been proposed to prevent other types of injuries¹⁰⁶ and could be applied to prescription drug packaging as well. An example is a pill dispenser that requires a specific fingerprint before releasing the appropriate pain medication at the appropriate time.

Data on the effectiveness of packaging designs on prescription drug abuse is limited. One study of 37 individuals assessed the impact of an electronic medicine dispenser on diversion of buprenorphine-naloxone among patients receiving the drug for opioid addiction treatment. The researchers found 68 percent of patients preferred to use the electronic dispenser to store their tablets compared to the traditional prescription container; 16 percent stated that the dispenser had prevented them from diverting their buprenorphine; 23 percent stated the dispenser prevented others from diverting their buprenorphine; and 58 percent believed the dispenser could prevent diversion. Additionally, 19 percent stated that it was difficult to tamper with the dispenser and 58 percent stated it was impossible to tamper with the dispenser.¹⁰⁷ Another product, which couples a flow-controlled, tamper-resistant medication dispenser with a Web and phone accessible treatment portal, has demonstrated sufficient promise to obtain funding from the National Institute on Drug Abuse. A phase II randomized controlled trial will assess use of the device and opioid misuse among patients from two pain management clinics.¹⁰⁸ However, results from this trial were not available as of June 2015.

A review of the currently available and in-development opioid packaging designs by Lehigh University concluded that many of the commercialized technologies such as locking caps, tamperproof packages and pill-dispensing products are most likely to deter unintentional misuse by elderly people or children and have limited abilities to prevent intentional abuse. However, newer technologies, such as radio-frequency identification wireless technologies and simple technologies combined with radio-frequency identification — as well as other types of smart technologies — have the potential to play a role in deterring intentional opioid abuse by increasing communication between healthcare professionals and patients.¹⁰⁹ As part of their senior mechanical

#4 ENGINEERING STRATEGIES: PRESCRIPTION DRUGS AND PACKAGING

engineering design course, students at Johns Hopkins University successfully created a prototype of a new design that is tamper-resistant, personalized with fingerprint technology and programmed to deliver a one-month supply of an opioid in the right time and dosage. Only a pharmacist would be able to open and lock the device.¹¹⁰

Despite the very limited data on effectiveness, there are a number of products currently being marketed to consumers. There is a pressing need for research to understand the impact of these products on prescription drug abuse. In addition to research questions on effectiveness, there are a number of outstanding questions that need to be explored before widespread adoption of these products can occur. These questions include:

- Where will these products enter the medication prescribing and use process? Will they be made available for purchase by patients for use in their homes? Will pharmacists use them instead of traditional pharmacy dispensing vials? Will manufacturers move away from bulk product distribution and incorporate these packaging designs for direct dispensing from the doctor's office or pharmacy?
- How will these products be regulated? As consumer products? As medical devices? As a combination drug-device?
- Who will take on the costs for these products? Pharmacies? Patients? Insurers/PBMs?
- Who will control, monitor and have access to the data available from these devices?

RECOMMENDATIONS FOR ACTION

4.1 CONVENE A STAKEHOLDER MEETING.

Work with the FDA to convene a meeting with product developers and key stakeholders to assess the current product environment (e.g., products available, evidence to support effectiveness, regulatory issues) and identify high priority future directions for engineering-related solutions.

Rationale: Engineering solutions to deter nonmedical use of prescription opioids are promising and under development. There is a need for coordination of and support for the current efforts to ensure this line of innovation is adequately supported, quickly brought to market and rigorously evaluated.

Current Status: There is no national organizing effort underway; the FDA could promulgate rules or guidance to industry that will affect these innovations and the FDA is a logical stakeholder to convene a meeting or to serve as a partner to convene such a meeting.

4.2 SPONSOR DESIGN COMPETITIONS.

Partner with stakeholders to develop design competitions to incentivize innovative packaging and dispensing solutions.

Rationale: Design competitions have been used to encourage and support innovation in many areas. Engineering strategies for prescription packaging are a logical candidate for such a competition.

Current Status: We are unaware of any design competitions on this subject.

4.3 SECURE FUNDING FOR RESEARCH TO ASSESS THE EFFECTIVENESS OF INNOVATIVE PACKAGING AND DESIGNS AVAILABLE AND UNDER DEVELOPMENT.

Rationale: Data on the effectiveness of packaging interventions is limited. Research is needed to evaluate the engineering innovations under development and to inform future development.

Current Status: We are unaware of any funding source dedicated to evaluating engineering designs for prescription packaging.

#4 ENGINEERING STRATEGIES: PRESCRIPTION DRUGS AND PACKAGING

4.4 USE RESEARCH TO ENSURE PRODUCT UPTAKE.

Engage with key stakeholders, such as product developers, drug manufacturers, pharmacies, payers, regulators, chronic opioid therapy patients and the public to explore potential barriers and incentives to product uptake, including a tiered reimbursement structure based on packaging designs with demonstrated effectiveness.

Rationale: Innovations in prescription packaging are promising, but little is known about how to ensure the public will use these products and that the products will be integrated into existing payment policies. Research is needed to ensure that these aspects of translation are understood.

Current Status: We are unaware of any efforts to gather empirical data about how to ensure innovative engineering packaging for prescriptions is effectively integrated into the consumer market.

#5 OVERDOSE EDUCATION AND NALOXONE DISTRIBUTION PROGRAMS

STATEMENT OF THE PROBLEM

Naloxone has been used for many years by healthcare and emergency medical services providers to reverse the potentially fatal respiratory depression associated with opioid overdoses. Community-based overdose education and naloxone distribution (OEND) programs that provide naloxone and train at-risk individuals and their friends, family members or caregivers on overdose prevention and response have been implemented in the U.S. in recent years. As of July 2014, at least 644 sites were in existence in the U.S.¹¹¹ In addition, some healthcare providers co-prescribe naloxone to patients taking high doses of opioids or to patients who are otherwise at risk for opioid overdose. However, there is limited evidence about the effectiveness of these applications of naloxone, and questions with regard to the sustainability of distribution programs remain, since third-party payers do not universally reimburse for naloxone.

SYNTHESIS OF AVAILABLE EVIDENCE

The majority of the available evaluations of OEND programs report on program implementation; training lay persons to recognize and respond to an overdose event, including the administration of naloxone; and provide information on the number of individuals trained, number of naloxone vials distributed and the number of overdose reversals reported by individuals who were trained.

The settings for OEND evaluations have primarily been in large urban center syringe exchange or harm reduction programs, methadone programs or other addiction treatment or detoxification programs, and have focused on heroin users. Evaluations of programs in New York City, Massachusetts, Los Angeles, San Francisco, Chicago, Rhode Island, Pittsburgh and Baltimore have been reported in the published literature.^{112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123} Because the focus of the evaluations has been on the number of trained individuals and overdose reversals reported, it is not possible to describe the population-level impact of these individual programs. Data from a 2014 survey found that OEND programs in the U.S. had trained and provided naloxone to more than 150,000 individuals between 1996 and 2014, and reported more than 26,000 opioid overdose reversals during this time.¹²⁴ Additional evaluations have reported on changes in overdose recognition and response knowledge and/or behaviors as a result of OEND program training.^{125, 126, 127, 128, 129, 130} Taken together, these data demonstrate that people at high risk for opioid-related overdose and their friends or family members can successfully be trained to recognize and respond to an overdose and appropriately administer naloxone in an overdose situation.

The literature examining the broader public health impact of naloxone programs is limited. Two identified studies described the Project Lazarus program in North Carolina, which was created in 2008. One component of this program is the co-prescription of naloxone to people at risk for opioid overdose. An initial evaluation of Project Lazarus in Wilkes County, North Carolina, found significant declines in the unintentional drug overdose death rate from a peak of 46.6 deaths per 100,000 population in 2009 to 29.0 deaths per 100,000 in 2010 and 14.4 deaths per 100,000 in 2011.^{131, 132} However, because Project Lazarus includes overdose prevention components unrelated to naloxone, it is difficult to determine the exact role naloxone played in the reduction of Wilkes County's unintentional drug overdose deaths.

Walley et al., provide the most robust evaluation examining changes in health outcomes as a result of OEND program implementation. They conducted an interrupted time-series analysis to evaluate the impact of Massachusetts' OEND program on opioid-related overdose deaths and non-fatal opioid overdose-related acute care hospital utilization rates from 2002 to 2009. They found that communities that implemented OEND programs during the study time had statistically significant reductions in opioid-related overdose death rates compared to communities that did not implement OEND programs. Acute care hospital utilizations did not differ between OEND program communities and those that did not implement one.¹³⁰

Based on recent systematic analyses, the available evidence suggests that naloxone is a promising strategy with some evidence of effectiveness in reducing opioid overdose mortality rates.¹³³ However, the data almost exclusively pertain to reversals of overdoses from heroin and not among people using prescription opioids. Overall the quality of evidence for the impact of naloxone on opioid overdose is low. Limitations of the available studies include lack of randomization of distribution methods; lack of generalizability because the data are almost exclusively based on people who inject drugs, primarily heroin; self-reported outcomes; short-term follow-up; significant loss to follow-up; and lack of control over other events occurring simultaneously that could be responsible for effects.¹³⁴

#5 OVERDOSE EDUCATION AND NALOXONE DISTRIBUTION PROGRAMS

RECOMMENDATIONS FOR ACTION

5.1 ENGAGE WITH THE SCIENTIFIC COMMUNITY TO ASSESS THE RESEARCH NEEDS RELATED TO NALOXONE DISTRIBUTION EVALUATIONS AND IDENTIFY HIGH PRIORITY FUTURE DIRECTIONS FOR NALOXONE-RELATED RESEARCH.

Rationale: Naloxone is a promising strategy for reversing overdose. Rigorous, high quality research is needed to explore the relative effectiveness of naloxone use in different settings, through different OEND mechanisms (including care and follow-up after overdose reversal events), and on prescription opioid (as opposed to heroin) overdose.

Current Status: There are several evaluations currently underway. However, available funding to evaluate the various types of programs being implemented is insufficient. The scientific community needs to further engage in a discussion on the various research approaches to evaluate naloxone programs being implemented in a variety of settings.

5.2 PARTNER WITH PRODUCT DEVELOPERS TO DESIGN NALOXONE FORMULATIONS THAT ARE EASIER TO USE BY NONMEDICAL PERSONNEL AND LESS COSTLY TO DELIVER.

Rationale: As the legal landscape changes to allow broader access to naloxone, different populations may prefer different delivery mechanisms for naloxone. Having multiple products that are easy for nonmedical personnel to use would likely increase uptake and reduce costs. Price is consistently raised as a concern impacting the sustainability of various naloxone distribution programs, and recent reports indicate that the cost of the drug is increasing dramatically.¹³⁵

Current Status: An auto-injector formulation of naloxone (Evzio) was approved by the FDA in April 2014. Several drug manufacturers have submitted applications to the FDA for approval of intranasal naloxone products as well.

5.3 WORK WITH INSURERS AND OTHER THIRD-PARTY PAYERS TO ENSURE COVERAGE OF NALOXONE PRODUCTS.

Rationale: One approach to sustaining expanded access to naloxone is through pharmacy dispensing and coverage through third parties.

Current Status: Some states and localities have made progress in gaining coverage for certain naloxone products. However, this has not been accomplished in a systematic way.

5.4 PARTNER WITH COMMUNITY-BASED OVERDOSE EDUCATION AND NALOXONE DISTRIBUTION PROGRAMS TO IDENTIFY STABLE FUNDING SOURCES TO ENSURE PROGRAM SUSTAINABILITY.

Rationale: Some community-based programs have little to no dedicated funding for the purchase and provision of naloxone. These programs provide critical access to naloxone among high-risk populations.

Current Status: The federal government has identified some grant program funding that can be used to purchase naloxone. However, it is not clear exactly how these funds will impact community-based programs. Other community-based programs have worked with local and state agencies to develop a sustainable funding model and their experience could be informative to other programs across the country.

5.5. ENGAGE WITH THE HEALTHCARE PROFESSIONAL COMMUNITY TO ADVANCE CONSENSUS GUIDELINES ON THE CO-PRESCRIPTION OF NALOXONE WITH PRESCRIPTION OPIOIDS

Rationale: There is no consensus on the patients who should be co-prescribed or prescribed naloxone in general medical settings. Recent studies show a number of logistical and attitudinal barriers to naloxone co-prescription.

Current Status: Several medical societies have adopted resolutions supporting naloxone co-prescription to patients, and some health systems such as the Veterans Administration have begun implementing campaigns to increase naloxone co-prescription. However, there is no consensus on the most appropriate patients for naloxone co-prescription.

STATEMENT OF THE PROBLEM

Opioid addiction can develop from repeated exposure to opioids. Left untreated, opioid addiction commonly results in serious psychosocial problems, medical problems and death from accidental overdose. Since 1997, the number of Americans seeking treatment for addiction to opioid painkillers increased by 900 percent.^{136, 137} The sharp increase in the prevalence of opioid addiction has been associated with a parallel increase in opioid-related overdose deaths and with increasing use of heroin.¹³⁸ Other health and social problems associated with the epidemic of opioid addiction include rising rates of neonatal abstinence syndrome, HIV and hepatitis C infections;¹³⁹ decreased life expectancy in white women; decreased workforce readiness; and decreased availability of parenting in the affected child-raising demographic.

Treatment of opioid addiction is similar to the management of other chronic conditions¹⁴⁰ and involves a bio-psycho-social approach. Unfortunately, the need for opioid addiction treatment is largely unmet.¹⁴¹ In regions of the country where the epidemic is most severe, there are waiting lists for treatment, especially with buprenorphine. Evidence-based treatment for opioid addiction often involves the use of buprenorphine and methadone, which are currently underutilized. Despite strong evidence supporting the use of buprenorphine and methadone, and evidence that more than 5 million Americans are suffering from opioid addiction, fewer than 1 million are receiving these treatments.¹⁴² A variety of barriers must be removed to allow adequate access to appropriate care.

SYNTHESIS OF AVAILABLE EVIDENCE

Pharmacotherapies for opioid addiction include agonist maintenance with methadone, partial-agonist maintenance with buprenorphine and antagonist treatment with naltrexone. Although some evidence exists supporting use of naltrexone in specific populations,¹⁴³ safety and efficacy has not been well established. However, multiple well-designed randomized controlled trials provide strong evidence that buprenorphine maintenance and methadone maintenance are safe, efficacious and cost-effective treatments for opioid addiction.¹⁴⁴ Both buprenorphine and methadone maintenance treatment are associated with reduced overdose risk, reduced risk of HIV infection and improved maternal and fetal outcomes in pregnancy.^{145, 146} However, when used short term, especially in detoxification regimens, evidence of enduring benefit is lacking.¹⁴⁷

Psychosocial approaches to treating opioid addiction include therapeutic communities, cognitive-behavioral therapies and 12-step facilitation, either provided in professional treatment or by mutual support groups (e.g., Narcotics Anonymous). While 12-step programs are valued by many addiction professionals, it has been difficult to determine which elements of these programs may be of greatest therapeutic value. Psychosocial interventions, like medication treatments, may occur in outpatient or inpatient settings. While some studies support improved effectiveness of combining psychosocial therapies with buprenorphine and methadone maintenance, abstinence-based psychosocial approaches that shun medication-assisted treatment are lacking evidence to support the practice.^{148, 149}

- The ability to expand access to treatment with methadone is limited by a short supply of licensed programs in non-urban communities and requirements such as daily attendance. Unlike methadone maintenance, buprenorphine can be prescribed in an office-based setting. Unfortunately, there are a variety of barriers to treatment with buprenorphine that include:
- Federal limits on the number of opioid-addicted patients a physician may treat with buprenorphine. A physician is limited to treating up to 30 patients in the first year following receipt of a buprenorphine waiver, after which the physician may apply to treat up to 100 patients.
- Prohibition against nurse practitioners' and physician assistants' prescribing. Nurse practitioners and physicians assistants are ineligible to apply for a buprenorphine waiver, even under the supervision of an addiction specialist.
- Inadequate integration of buprenorphine into primary care treatment. Physicians, nurse practitioners, physicians assistants and other allied health care professionals have little training in the recognition and treatment of opioid addiction.
- Stigma against maintenance treatment for opioid addiction. The misperception that maintenance medications are inappropriate because they substitute one drug for another is a commonly held view. These treatments have suffered from misunderstandings and negative attitudes of the public, patients and providers.¹⁵⁰ Less than half of all licensed addiction treatment programs offer these medications, and less than half of the eligible patients in those programs receive them.¹⁵¹

#6 ADDICTION TREATMENT

RECOMMENDATIONS FOR ACTION

6.1 INVEST IN SURVEILLANCE.

Improve epidemiologic surveillance of opioid addiction by revising the National Survey on Drug Use and Health (NSDUH) questions to capture opioid use disorders in patients receiving opioids for the treatment of chronic pain and by identifying other strategies to track the incidence and prevalence of opioid addiction. This effort will involve collaboration with the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Centers for Disease Control and Prevention (CDC).

Rationale: Understanding the size and scope of the opioid addiction problem is essential for developing effective interventions. Revising an existing surveillance tool is a cost effective way to obtain needed information.

Current Status: This effort is not yet underway.

6.2 EXPAND ACCESS TO BUPRENORPHINE TREATMENT.

Addiction specialist physicians are prohibited under federal law from treating more than 100 patients with buprenorphine — a restriction with no counterpart anywhere in medicine and which has led to waiting lists for patients to receive treatment. These federally imposed caps should be lifted. Additional training of prescribers on medication-assisted treatment should be offered and treatment guidelines, such as the American Society of Addiction Medicine (ASAM) Guideline for Medication Assisted Treatment, should be disseminated. Access to buprenorphine treatment across the country should be closely monitored by the federal government. This effort will involve collaboration with SAMHSA and the Drug Enforcement Agency (DEA).

Rationale: Federally imposed caps on the number of patients a physician can treat limit access to buprenorphine.

Current Status: Legislation seeking to lift the buprenorphine patient cap has been introduced in the U.S. Senate. In addition, the Department of Health and Human Services recently announced a plan to lift the cap through the regulatory process.

6.3 REQUIRE FEDERALLY-FUNDED TREATMENT PROGRAMS TO ALLOW PATIENTS ACCESS TO BUPRENORPHINE OR METHADONE

Policies that prevent access to medication-assisted treatment are counter to the evidence and the current standard of care for effective treatment of opioid addiction. This effort will involve collaboration with the SAMHSA, the Centers for Medicare and Medicaid Services and the White House Office of National Drug Control Policy (ONDCP).

Rationale: Buprenorphine is an effective treatment for opioid addiction.

Current Status: In 2015, the ONDCP announced that drug court programs will be ineligible to receive future federal funding if they prohibit receipt of buprenorphine and methadone.

6.4 PROVIDE TREATMENT FUNDING FOR COMMUNITIES WITH HIGH RATES OF OPIOID ADDICTION AND LIMITED ACCESS TO TREATMENT.

Advocate for a Targeted Capacity Expansion (TCE) program that will provide federal funding for increased access to buprenorphine and methadone in communities with high rates of opioid addiction and limited access to treatment. This effort will involve collaboration with SAMHSA.

Rationale: Treatment services are disproportionately distributed across communities and do not always reflect need. Using federal resources to identify communities most in need of treatment services and to expand treatment capacity will help to address this disparity.

Current Status: In 2015, SAMHSA issued a request for applications for prescription opioid and heroin addiction TCE programs. SAMSHA identified a total of \$11 million in funding to support the program. Additionally, bills have been introduced in Congress that increase funding to states for opioid addiction treatment.

6.5 DEVELOP AND DISSEMINATE A PUBLIC EDUCATION CAMPAIGN ABOUT THE ROLE OF TREATMENT IN ADDRESSING OPIOID ADDICTION.

Utilize information from Health and Human Services (HHS) and the National Institute on Drug Abuse (NIDA) through the CDC and ONDCP to educate providers, patients and their families; health plans; state level law enforcement; and policy makers on the nature of opioid addiction as a chronic brain disease, noting that the strongest evidence supports use of maintenance medication with either methadone or buprenorphine. This campaign should also aim to reduce the stigma associated with effective treatment options. A major public education campaign on appropriate treatment that is comprehensive, evidence-based, and follows best practices in health communication is needed and should be evaluated.

Rationale: There is a lack of awareness about the effectiveness of medication treatment options among providers, patients and their families, health plans, law enforcement, and policy makers, and there is stigma against medication treatment. Both the lack of information and the stigma associated with medication treatment are barriers to greater use of effective treatment. Medication treatment is the standard of care for opioid addiction and it should be known as such among providers and the public at large.

Current Status: Federal health officials from the CDC, National Institutes of Health (NIH) and SAMHSA have made public statements supporting medication-assisted treatment. The NIH and SAMHSA have also issued materials for healthcare providers and the public on treatment with buprenorphine. Some health departments, most notably the New York City Department of Health and Mental Hygiene and the Maryland Department of Health and Mental Hygiene, have sponsored efforts to raise awareness and improve access to treatment with buprenorphine and methadone.

6.6 EDUCATE PRESCRIBERS AND PHARMACISTS HOW TO PREVENT, IDENTIFY AND TREAT OPIOID ADDICTION.

Develop, evaluate and disseminate prescriber and pharmacist education to assist in better preventing, identifying and treating opioid addiction. Training should include both information as well as direct skill development in assessment and treatment of opioid addiction. Develop, evaluate and disseminate information about the standard of care for treatment of opioid addiction to substance abuse treatment providers.

Rationale: Prescribers and pharmacists receive little training on substance use disorders. With improved understanding of the etiology of opioid addiction and its treatment, they may be better able to prevent, recognize and care for patients suffering from this condition.

Current Status: The American Society of Addiction Medicine and the American Academy of Addiction Psychiatry are currently involved in efforts to improve medical education about substance use disorders. A coordinated national effort to educate prescribers and pharmacists about opioid addiction is not yet underway.

6.7 SUPPORT TREATMENT-RELATED RESEARCH.

Treatment programs that utilize the most efficacious and cost-effective protocols are needed; research is needed to identify and disseminate such interventions. Specifically, research is needed that answers questions about the relative effectiveness of different types of psychosocial interventions as additions to medication treatment, as well as trials of the enduring effectiveness of psychosocial interventions alone vs. maintenance medication therapies. This effort could include collaboration with the NIH, the Patient-Centered Outcomes Research Institute (PCORI), the Agency for Healthcare Research and Quality (AHRQ), and the CDC.

Rationale: In order to maximize available treatment resources, research about the most effective ways to use medication treatment is needed. In parallel, more effective strategies to implement and disseminate proven efficacious strategies are needed.

Current Status: The NIH is currently funding some research on opioid addiction treatments, including comparisons of treatment interventions.

#7 COMMUNITY-BASED PREVENTION STRATEGIES

STATEMENT OF THE PROBLEM

Prescription drug misuse, abuse and overdose impacts communities across the nation. It is a problem that involves a legal product that is manufactured, marketed and dispensed by professionals through a system that is subject at multiple points to government oversight from different agencies at the federal and state levels. That system has been ineffective in preventing the oversupply of prescription opioids to communities where demand for these products has grown. Whether the supply is in response to demand, a cause of the demand or some combination is unclear. Community engagement in efforts to reduce both the supply of prescription opioids and the demand for them is an under-used, but potentially important part of the solution to the problem. However, there is a dearth of evidence-based community initiatives for addressing prescription drug misuse, abuse and overdose. For the purposes of this report, we consider “communities” to be groups of people defined by a shared experience, such as college students or people living in the same town, or by professional affiliation, such as healthcare providers or pharmacists.

SYNTHESIS OF AVAILABLE EVIDENCE

Defining the problem. Counts of overdose deaths are well publicized and in many ways have defined the concern about prescription opioids as a public health problem. However, additional information about the prevalence of these drugs in communities and homes, and about access to them by nonmedical users through family, friends and underground markets, is needed to better understand opportunities for intervention. Prescription Drug Monitoring Programs (PDMPs) are an important information source. The status of PDMP data, how they are being used, and the potential for greater application of these data are all detailed in Section 3 of this report. However, PDMP data capture information about the initial prescription, and not the dissemination of those drugs beyond the initial recipient. Other studies using cross sectional data provide some insight into the role of family, friends and illegal markets in supplying prescription opioids to people who are abusing, but these data are limited by time and geography. More comprehensive surveillance about prevalence and use is needed.

The supply of prescription opioids is connected to the manufacturing sector that controls production (the amount of product produced), chemistry (e.g., strength, composition, properties) and characteristics (e.g., crush resistance of pills, shelf life) of the drugs produced. Although these supply side issues are being addressed through legislative, regulatory and engineering strategies as discussed in previous sections of this report, an understanding of this supply side context is essential for planning effective community campaigns. The extent to which stakeholders from the supply side are engaged with community prevention advocates and/or involved in community public health campaigns is not known, and needs to be better understood.

Defining solutions. Several professional communities are important stakeholders in the prescription opioid matter. Prescribers, pharmacies and third-party payers are the focus of Sections 1 and 3 included in this document, and we will not duplicate those summaries and recommendations here. We note that those recommendations focus on identifying and intervening with high-risk patient groups who are already using prescription opioids. Here we focus on efforts to engage with patients and the general public about opioid risks and alternatives for pain management prior to the start of misuse or abuse.

Clinical interactions as an opportunity to educate patients about the risks of prescription opioids and alternatives to pain management are not documented in the literature. We are aware of one effort underway at the Johns Hopkins Center for Injury Research and Policy to develop a patient decision aid for emergency room patients who present for pain that would likely lead to an opioid prescription. However, that study is in the field and no results were available at the time of this writing. One community intervention included student nurses as part of a broader community coalition to address prescription drug overdose. The resulting paper focused more on process indicators than on outcome measures, and documents important impacts (e.g., prescription drugs turned in) but did not connect those impacts to overdose or poisoning outcomes. While promising, the intervention lacks the rigorous evaluation required to be considered evidence-based.¹⁵²

Project Lazarus, a community-based initiative in North Carolina, offers perhaps the most insight with regard to population-based impacts on overdose. Included as part of the intervention are a number of strategies to address prescription opioid abuse, misuse and overdose (e.g., naloxone distribution, patient and provider education). Evaluation findings suggest significant declines in overdose deaths and hospital emergency department visits for overdose.¹²⁷

Efforts to raise awareness about the risks associated with prescription opioids and alternatives available for pain management through public education campaigns are underway (e.g., The Medicine Abuse Project aimed at preventing teen misuse/abuse and promoting treatment; Rx for Understanding, a school-based curriculum; the JED Foundation’s college campus initiative; and the National Institute on Drug Abuse (NIDA) PEERx program), however, evaluations of such efforts are lacking. Raising

awareness is generally viewed as an important strategy for addressing prescription opioid misuse and offers an opportunity for prevention when combined with other strategies.

Best practices in health promotion suggest that awareness-raising efforts will have maximum impact when combined with other interventions that address the larger context in which the problem is occurring. For this issue, raising awareness could be enhanced with attention to the policy context (e.g., naloxone availability) as well as the need for other services (e.g., addiction treatment) and the supply side. To our knowledge, no community campaigns have engaged the public in efforts to address the supply side of the issue, nor have they engaged supply-side stakeholders to develop comprehensive prevention initiatives.

Primary prevention strategies targeting those who would use these drugs recreationally could adapt existing effective substance abuse prevention programs to the case of opioids. Primary prevention for patients with pain-related conditions will require effective patient education and access to alternative pain management resources (e.g. physical therapy). Assuring that public education initiatives are appropriately targeted, informed by evidence and rigorously evaluated is critically important to assuring that investments are well placed and effective.

Evidence from another problem: Antibiotic overuse. In 1995, the U.S. Centers for Disease Control and Prevention (CDC) launched the National Campaign for Appropriate Antibiotic Use in the Community, which was renamed Get Smart: Know When Antibiotics Work, in 2003. One important aim of the campaign was to decrease the demand for antibiotics by adults and parents of children with viral upper respiratory infections. Multiple studies have demonstrated the campaign's effectiveness, suggesting that improving patient knowledge of risks, benefits and alternatives may be a promising approach to reducing the number of prescriptions. Further studies have investigated the effectiveness of computerized patient education modules promoting awareness of appropriate antibiotic use and provided initial evidence that these interventions can be effective at reducing demand. For community prevention efforts, there are many parallels to the prescription opioid problem — i.e., the drugs are useful in certain circumstances but over-prescribed in many others and patients are generally unaware of the potential individual and societal impacts associated with over-prescribing. Thus, community prevention interventions would do well to draw from the strategies used to reduce antibiotic overuse.

RECOMMENDATIONS FOR ACTION

7.1 INVEST IN SURVEILLANCE TO INFORM HOW PATIENTS IN TREATMENT FOR OPIOID ABUSE AND THOSE WHO HAVE OVERDOSED OBTAIN THEIR SUPPLY. EXISTING SURVEILLANCE EFFORTS SUCH AS THE NATIONAL ELECTRONIC INJURY SURVEILLANCE SYSTEM (NEISS) CAN PROVIDE AN INFRASTRUCTURE TO ACCOMPLISH THIS TASK.

Rationale: Information about the prevalence of prescription opioids in communities and homes, and access to them by nonmedical users through family, friends and underground markets, is needed to better understand opportunities for intervention. Cross-sectional data provide some insight into these questions, but these data are limited. More comprehensive surveillance about prevalence and use is needed.

Current Status: We are unaware of any ongoing surveillance effort to capture information about the source of prescription opioids for people who seek treatment for opioid abuse or overdose.

7.2 CONVENE A STAKEHOLDER MEETING WITH BROAD REPRESENTATION TO CREATE GUIDANCE THAT WILL HELP COMMUNITIES UNDERTAKE COMPREHENSIVE APPROACHES THAT ADDRESS THE SUPPLY OF, AND DEMAND FOR, PRESCRIPTION OPIOIDS IN THEIR LOCALES; IMPLEMENT AND EVALUATE DEMONSTRATION PROJECTS THAT MODEL THESE APPROACHES.

Rationale: Attention to the complex social and political context in which the problem of prescription misuse, abuse and overdose occurs has not been reflected in existing community campaign efforts. Broader stakeholder engagement may yield impactful new approaches.

Current Status: We are unaware of any systematic efforts to utilize community engagement to build comprehensive model programs that address both supply and demand.

#7 COMMUNITY-BASED PREVENTION STRATEGIES

7.3 CONVENE AN INTER-AGENCY TASK FORCE TO ASSURE THAT CURRENT AND FUTURE NATIONAL PUBLIC EDUCATION CAMPAIGNS ABOUT PRESCRIPTION OPIOIDS ARE INFORMED BY THE AVAILABLE EVIDENCE AND THAT BEST PRACTICES ARE SHARED.

Rationale: Past success with reducing antibiotic use is generally attributed to a national campaign. Applying lessons learned from that success to the current prescription opioid challenge will increase the likelihood that public education strategies benefit from the available evidence.

Current Status: Public education about the risks of prescription opioids and alternatives for pain management is needed, and many efforts are underway and will likely be developed. The extent to which these efforts are informed by the available evidence is unknown, and there is no central repository for collecting this evidence and sharing best practices.

7.4 PROVIDE CLEAR AND CONSISTENT GUIDANCE ON SAFE STORAGE OF PRESCRIPTION DRUGS.

Rationale: One source of prescription medications for nonmedical users is family and friends. Ensuring prescription medications are not easily accessible may reduce intentional misuse by teens and adults and unintentional misuse by young children.

Current Status: While engineering solutions to packaging hold great promise, as detailed earlier in this report, clear guidance about safe storage options for patients who bring prescription drugs home is needed. Messages should be appropriate for all populations, including those with low literacy and non-English speakers, and should be consistent across all sources — the prescriber, the pharmacist, in the drug packaging materials for patients, and in community campaigns.

7.5 DEVELOP CLEAR AND CONSISTENT GUIDANCE ON SAFE DISPOSAL OF PRESCRIPTION DRUGS; EXPAND ACCESS TO TAKE-BACK PROGRAMS.

Rationale: There is a need for safe disposal options for prescription medications. Guidance from the federal government about how to accomplish safe disposal is needed and can serve to launch community-based take-back initiatives that are responsive to local needs and culture.

Current Status: Clear guidance on how to safely dispose of prescription drugs is lacking; access to take-back programs is also limited and highly variable across jurisdictions. Messages should be appropriate for all populations, including those with low literacy and non-English speakers, and should be consistent across all sources — the prescriber, the pharmacist, in the drug packaging materials for patients, and in community campaigns.

7.6 REQUIRE THAT FEDERAL SUPPORT FOR PRESCRIPTION DRUG MISUSE, ABUSE AND OVERDOSE INTERVENTIONS INCLUDE OUTCOME DATA.

Rationale: Promising interventions are in the field, and have been demonstrated to be feasible and impactful. Population-based outcome data are lacking and needed to inform decisions about replication and scale-up of promising interventions.

Current Status: The federal government is funding a number of interventions to address prescription drug misuse, abuse and overdose. We are unaware of any requirement that outcome data be included with such initiatives.

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