July 28, 2015

The Honorable Jim Sensenbrenner
Chairman
House Judiciary Committee
Subcommittee on Crime, Terrorism, Homeland Security, and Investigations
United States House of Representatives
Washington, D.C. 20515

The Honorable Shelia Jackson Lee
Ranking Member
House Judiciary Committee
Subcommittee on Crime, Terrorism, Homeland Security, and Investigations
United States House of Representatives
Washington, D.C. 20515

Dear Chairman Sensenbrenner and Ranking Member Jackson-Lee:

The Drug Policy Alliance appreciates the opportunity to provide this letter for the record of today's hearing, "America's Growing Heroin Epidemic."

Heroin use and overdose have surged in recent years, and its prevalence has ballooned beyond urban centers into suburban and rural areas. However, attention that is being given today by the media and lawmakers to heroin use and overdose has illuminated a decades old crisis. Until recently, opioid analgesics - a class of prescription drugs such as hydrocodone (Vicodin™), oxycodone (OxyContin™) and methadone used to treat both acute and chronic pain - was fueling much of the nation's overdose epidemic.

Prior to the 1990s, opioid analgesics were prescribed primarily in hospital settings to treat acute pain.[1] Beginning in the early 1990s, however, health practitioners increasingly favored treating chronic pain with opioid analgesics. This shift was an important advancement in pain management, but the change in opioid prescribing habits came without careful attention to misuse and overdose risk.

As long-term prescribing of opioid analgesics for pain became more common, a greater proportion of opioid patients became substance dependent and at higher risk of experiencing an opioid overdose. These conditions contributed to a dramatic rise in opioid overdose fatalities.[2]

By 2007, the CDC reported that opioid analgesics had displaced street drugs as the leading cause of overdose death.[3] By 2009, drug overdose deaths outnumbered deaths due to motor vehicle crashes for the first time. More than 35,000 people died from an accidental drug overdose in 2013, the most recent data available from the CDC.[4] Opioids — both in the form of prescription opioid analgesics and heroin — were involved in most of these deaths. The 2013 figure is nearly double the number of accidental drug overdoses in 2003[5] and more than three times the number of accidental drug overdoses in 2000.[6] Today, urban centers continue to struggle as they have for decades with overdose. However, rural and suburban regions have been disproportionately affected by opioid-related overdoses.[7]

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We are the Drug Policy Alliance.

Interdiction

Federal and state lawmakers have responded to mounting unsanctioned opioid use, dependence and overdose by focusing on supply-side policies intended to reduce diversion of opioid analgesics and other prescription drugs from lawful sources. Most states have passed laws implementing the use of prescription drug monitoring programs (PDMPs) as a tool to monitor prescription sales of controlled substances.[8]

As a health promotion tool, PDMPs enable physicians and pharmacists to review a patient's medication history prior to writing a prescription, which can help a physician avoid medication errors or identify a patient with a pattern of unsanctioned use. However, law enforcement are also given varying levels of authority in each state to monitor PDMPs and launch investigations against health practitioners and patients based upon evidence that, in a law enforcement agency's view, a physician is writing too many prescriptions for opioid analgesics, or a patient is engaging in "doctor shopping."

Prescribing practices by physicians who specialize in pain management and treat patients with chronic pain are often scrutinized by law enforcement for running "pill mills." In turn, law enforcement agencies routinely use PDMP sourced data to raid and shut down clinics that treat chronic pain patients and prosecute physicians for "overprescribing" as well as patients for doctor shopping. PDMPs enjoy broad institutional support, and federal funding,[9] despite underwhelming evidence that they have any impact on overdose rates or unsanctioned use of opioid analgesics.[10]

Moreover, federal survey data indicates that the vast majority of people engaged in unsanctioned use of prescription drugs are not obtaining them from a physician or from engaging in doctor shopping. 53 percent of people who engaged in unsanctioned use of prescription drugs in the past year obtained them for free from friends and family; 15 percent bought or took them from a friend or relative.[11]

Supply-side strategies do not address the underlying behavioral and physical health needs of people experiencing opioid dependence. Tragically, heavy emphasis on supply-side strategies can inadvertently worsen drug misuse in a community if demand-side strategies are not given equal emphasis. Case in point, as law enforcement agencies and lawmakers have stepped up restrictions on opioid analgesic prescribing, evidence suggests that opioid-dependent people who can no longer afford or find diverted medication on the illicit market or a health practitioner willing to prescribe it, are switching to heroin.[12]

From a public health and safety standpoint, heroin use is much riskier than unsanctioned opioid medication use.[13] Whereas pharmaceutical opioids generally deliver a reliable and stable dose, people who turn to the illicit market to obtain and use heroin face a greater overdose risk.[14]

Beginning in 2010, heroin overdose fatalities began increasing rapidly across the country while fatal overdoses involving opioid analgesics began to level off and even declined slightly between 2011 and 2013.[15] Fatalities from heroin overdose nearly tripled from 2010 to 2013.[16] Evidence indicates that a growing number of individuals who have been using opioid analgesics are substituting heroin, and that dependence on opioid analgesic medications is a strong risk factor for heroin dependence.[17]

Law enforcement agencies should not be empowered to decide when a physician has prescribed too much or a patient is being prescribed too many. Too often the assumption is made that a physician is prescribing too much pain medication, an assumption that is often fostered by law enforcement officials and echoed by lawmakers. Prosecuting prescribers believed to be overprescribing certain medications can lead to stigma against patients using those medications, as well as reduced access to certain medications that physicians may be reluctant to prescribe out of fear of law enforcement investigation.[18]

Pain remains one of the most severely undertreated conditions in the U.S. today.[19] As the general population in the United States trends older,[20] and more people are surviving illnesses and undergoing surgical operations, demand for prescription opioid analgesics will likely increase.[21]

Federal and state officials have focused resources on diversion and policing physician prescribing practices with poor results. Opioid use and overdose rates have surged across the nation despite supply-side efforts. In fact, the focus on diversion has likely contributed to this recent surge. In addition, individuals with unmet overdose prevention and treatment needs are also not being served or protected by supply-side strategies.

It is this example that underscores the critical need to turn the nation's discussion about prescription diversion into policies that place much greater emphasis on strategies that more effectively target demand for drug use, enhance and facilitate treatment access, and prevent overdose fatalities. The federal government still focuses the vast majority of its drug-related spending on interdiction, enforcement and incarceration. Billions of dollars are wasted each year on supply-side programs that lack real oversight. Shifting resources from interdiction and incarceration to treatment and public health program funding would save more lives and realize substantial savings for taxpayers.

Prevention

In recent years, the opioid prescribing patterns of physicians have faced greater scrutiny from law enforcement. However, little attention has been given to the duty that health practitioners have to educate their patients about opioid overdose risk. Physicians should be informing patients about proper dosing and overdose risk and prescribing naloxone to patients who are taking opioid analgesics.

Naloxone (Narcan) is a low-cost medication available by prescription and is the first line of treatment for paramedics and emergency room physicians who encounter an opioid overdose victim.[22] Naloxone takes as little as two minutes to start working, and provides additional time to obtain necessary medical assistance during an overdose.[23] Evidence suggest that prompt administration of naloxone and provision of emergency care by a bystander can reduce health complications and attendant health care costs to government and private insurers.[24]

However, naloxone's status as a prescription drug is a key barrier to broader naloxone access in the United States.[25] In an effort to improve the utilization of

naloxone, more than 35 states have passed laws to shield healthcare practitioners and laypersons from civil and criminal liability for prescribing or administering this medication.[26] The Committee should advance federal legislation that provides a national floor of civil liability protections for prescribers and laypersons who administer naloxone in the event of an overdose emergency.[27]

Good Samaritan immunity

Witnesses to an overdose often hesitate to call for help or, in some cases, simply don't make the call. The most common reason people cite for not calling 911 is fear of police involvement and legal consequences.[28] A key way to encourage overdose witnesses to seek medical help is to exempt them from arrest and prosecution. Good Samaritan immunity laws typically protect only the caller and overdose victim from arrest and prosecution for simple drug possession, possession of paraphernalia, and being under the influence. Such legislation does not protect people from arrest for other offenses. Twenty five states and the District of Columbia have passed such laws.[29] The Committee should consider whether federal legislation could extend Good Samaritan immunity to federal lands and territories.

Syringe access

People who inject opioids and other drugs are often stigmatized by health care providers and criminalized by law enforcement. Without reliable access to sterile syringes, individuals are prone to share syringes and other drug preparation equipment with other people who inject drugs. The sharing of syringes is associated with elevated risk of contracting HIV and hepatitis C.[30] and syringe sharing has historically been a major contributor to the HIV/AIDS epidemic in the United States and abroad.[31]

Since the early 1990s, advocates and public health officials in urban centers across the United States have offered syringe exchange services. In addition to providing sterile syringes in exchange for used syringes, many syringe exchange programs provide services such as HIV and hepatitis C testing, overdose prevention training, and serve as a linkage to health care, housing, and drug treatment for those not often served by traditional health care providers.[32] Critically, syringe availability has been proven to reduce the spread of HIV/AIDS and hepatitis C without increasing drug use.[33] Syringe exchange programs are supported by leading United States and international government health organizations and medical and public health associations.[34]

Today, there are more than 190 syringe service programs operating in 33 states.[35] Many jurisdictions have made local investments to support syringe exchange.[36] However, as the opioid crisis has transformed in recent years to include a dramatic increase in heroin use that has shifted from urban centers to rural areas, communities affected in rural parts of the United States often do not have – or even legally permit – the provision of syringe exchange.

These changing demographics have recently taken center stage nationally, with a spike in HIV diagnoses among people who inject drugs in Indiana[37] and with the CDC ranking Kentucky number one in the nation for high rates of hepatitis C cases.[38] Yet, a federal ban prohibiting states and the District of Columbia from using their

share of federal HIV/AIDS prevention money on syringe exchange programs has been in place since 2011.

This ban was briefly lifted by the Democratic-controlled Congress in 2009 after being in place for more than 20 years. Republicans restored the ban in 2011 after regaining control of Congress. Earlier this year, House and Senate Republicans agreed to partially repeal the ban for the first time. However, Congress should completely lift the federal ban and allow state and local governments to spend their share of federal prevention dollars without additional cost to taxpayers. There is little doubt that these congressional bans are responsible for hundreds of thousands of Americans contracting HIV/AIDS or hepatitis C.[39]

Treatment

There is broad consensus among experts that an individual struggling with opioid dependence should have access to the full spectrum of behavioral, pharmacological, and psychosocial treatments. However, nearly 80 percent of people experiencing opioid dependence do not receive treatment because of limited treatment capacity, financial obstacles, social stigma, and other barriers to care.[40] Expanding access to drug treatment is a key strategy to reducing demand for opioid analgesics and heroin. Effective treatment modalities should be available to people at all stages of the recovery spectrum.

Barriers to treatment despite healthcare reform

Barriers to drug treatment persist despite federal healthcare reform. Treatment programs still often fail to meet the needs of populations that have historically confronted barriers to accessing treatment, such as women, people of color, lesbian, gay, bisexual and transgendered (LGBT) individuals, and rural populations. Individuals who use heroin and other opioids are also often both uninsured and marginalized by the healthcare system.[41]

It is critical that people experiencing dependence to opioid analgesics or heroin can enroll in medication assisted treatment. Scientific research has established that medication assisted treatment increases patient retention and decreases drug use, infectious disease transmission, and criminal activity.[42] Medication assisted treatments are cost effective[43] and have been proven equally effective in treating heroin or prescription-type opioid dependence.[44] Opioid dependent individuals should have access to affordable, judgment-free, individualized counseling and pharmacological replacement therapies such as methadone and buprenorphine. Under medication assisted treatment, doctors prescribe one or more pharmaceutical drugs to people with drug-related problems to eliminate or reduce their problematic use of drugs and improve their mental and physical well-being.

At present, the FDA has approved only three medications for the treatment of opioid dependence.[45] Methadone is one of the most widely studied medicines and is employed effectively around the world to treat opioid dependence. Methadone therapy is widely regarded as the most effective treatment for heroin addiction.[46] Methadone and other medication assisted therapies lead to better health and social outcomes than any other treatment modality.[47] The Centers for Disease Control and

Prevention,[48] the Institute of Medicine[49] of the National Institutes of Health,[50] the Substance Abuse and Mental Health Services Administration (SAMHSA) of the U.S. Department of Health and Human Services,[51] the National Institute on Drug Abuse (NIDA),[52] the World Health Organization,[53] and over four decades of government-funded, peer-reviewed medical research[54] have unequivocally and repeatedly proven that medication assisted therapies like methadone are the most effective treatments for opioid dependence.[55]

Yet, extensive federal and state regulations and restrictions stand in the way of providing methadone, and to a lesser extent, buprenorphine treatment services to patients.[56] Access to methadone is extremely restricted in the United States and many people who need it cannot obtain it.[57] All told, only about 12 percent of individuals with opioid dependence receive methadone treatment.[58] Ultimately, methadone should be available by prescription and through doctors' visits, as it is in Canada and most of Western Europe.[59]

Access to treatment inside criminal justice settings

People who use opioids are at highest risk of overdose following a period of abstinence or reduced use that leads to lowered tolerance, such as spending time in a rehabilitation facility or serving a court-ordered period of incarceration.[60] For this reason, integration of medication assisted treatment and overdose prevention strategies into criminal justice settings is critical. Many populations, including incarcerated veterans, are acutely vulnerable during the period shortly after their release from jail or prison. People who inject heroin have seven times the risk of death from an overdose during the first two weeks after their release from incarceration.[61]

A growing number of jurisdictions have begun offering medication assisted treatment, overdose prevention and naloxone in criminal justice settings. In New Mexico, the Metropolitan Detention Center for Bernalillo County Methadone Maintenance program, which was launched in 2005, provides a daily dose of methadone to incarcerated people who were previously enrolled in a community-based methadone program. A study by the University of New Mexico indicates that incarcerated people receiving methadone treatment at the Metropolitan Detention Center typically stayed out of jail longer than incarcerated people who did not receive the treatment.[62] In Rhode Island, the state's Department of Corrections has partnered with a community-based overdose prevention program to train incarcerated individuals on how to prevent overdose and use naloxone prior to their release.[63]

People who use opioids illicitly are also vulnerable to arrest. For low-income residents of states that have not expanded Medicaid, the few, if not the only, way(s) for low-income and uninsured people to continue to obtain access to drug treatment or mental health services is to get arrested and hope for participation in a drug, mental health, or other specialty court or diversion program.

In these courts, judges and prosecutors – not healthcare providers – have final say over the defendant's participation in treatment, and usually require costly, abstinence-based episodes of treatment. Non-adherence to the program often results in incarceration. Individuals who are participating in a drug court have often been ordered by a drug court judge to leave methadone or buprenorphine treatment in

order to participate in the diversion program – making it very likely that those going through drug court will relapse and be sent to prison.[64] Moreover, some family court judges require clients to cease methadone treatment before they can receive custody of their children.[65] The Obama administration recently announced it would bar federal funding for drug courts that do not allow participation in medication assisted treatment programs.[66] The Committee should review legislative options for improving the delivery of medication assisted treatment and overdose prevention strategies in federal and state correctional facilities.

Policing

An increasing number of jurisdictions have recognized that the current approach of arresting people for illicit opioid possession and other low-level, nonviolent crimes has proven to be fiscally unsustainable and an ineffective strategy for improving the public safety and health of a community. The existing approach moves a relatively small fraction of offenders off the streets, for brief periods of time, and at a significantly higher cost than non-criminal justice system interventions. Criminalization of possession of small amounts of drugs and paraphernalia for personal use contributes to the marginalization of people who use illicit drugs. The resulting stigma attached to heroin or unsanctioned opioid analgesic use can exacerbate dependence and overdose risk. Further, the system diverts limited law enforcement resources from more serious crimes to policing low level drug offenses, with little to no improvement in neighborhood quality of life or a reduction in drug related deaths.

Law enforcement officers typically have more day-to-day interaction with marginalized populations than traditional service providers. They see firsthand the revolving door of jail to street for these populations. There is now a growing interest both inside and outside the law enforcement community in exploring new approaches to dealing with drug possession and other low-level crimes that that don't rely on arrest and incarceration. .

In 2011, Seattle pioneered a new approach known as Law Enforcement Assisted Diversion, or LEAD, the first pre-booking diversion program in the country. LEAD was established through a unique collaboration between Seattle police, district attorneys, government agencies, mental health and drug treatment providers, housing providers and other service agencies, the business community, public defenders, elected officials and community leaders. LEAD seeks to reduce criminal behavior and improve public safety and order by connecting people who commit low level nonviolent crimes with community-based treatment and supportive services. Following Seattle's direction, Santa Fe, New Mexico implemented its own LEAD program in 2014.

Law Enforcement Assisted Diversion

Under LEAD, police officers exercise discretionary authority at the point of contact to divert individuals for low-level criminal offenses. Instead of arresting and booking people for certain nonviolent crimes, including low-level drug possession and sales, police may immediately connect them to a case manager who links people to housing, treatment and other services.[67] LEAD is designed to work with people

struggling with addiction and/or mental illness whose criminal behavior is motivated by addiction and subsistence needs.

Individuals diverted into LEAD receive intensive case-management and targeted services in a highly-coordinated environment. LEAD devotes a substantial portion of its resources to health and supportive services, and participants are given immediate access to services without displacing voluntary treatment candidates. An Individual Intervention Plan is provided for each participant, which serves as the action blueprint for the participant and his or her case manager. This plan may include assistance with housing, treatment, education, job training, job placement, licensing assistance, small business counseling, child care, or other services. Intensive case management provides increased support and assistance in all aspects of the participant's life.

LEAD is based on a harm reduction and housing first philosophy that requires a focus on individual and community wellness, rather than an exclusive focus on sobriety. LEAD participants, who are usually struggling with drug addiction and are often homeless, sometimes take months or even years to make major behavior changes. LEAD is designed to promote patience and relationship-building that can eventually yield results that shorter-term strategies cannot.

LEAD is a promising alternative to expensive court-based interventions that does not require the presence of judges, court staff, prosecutors, or public defenders. Rather, police officers determine whether or not individuals are appropriate to go into LEAD. Each local jurisdiction that implements LEAD defines its target population.

LEAD recognizes that drug use is a complex problem and people need to be reached where they currently are in their lives. In Seattle, LEAD precipitated a fundamental policy reorientation, from an "enforcement-first" approach, to a health-centered model – reinforced by specialized harm reduction training required of every police officer.

Law enforcement have been supportive of LEAD because it gives them additional tools to handle public safety issues. Diversion of people accused of low-level nonviolent crimes into LEAD allows law enforcement to focus on serious crime while playing a key role in linking people to services instead of funneling them into the justice system.

The Expansion of LEAD to Respond to Unique Local Concerns

New Mexico has the second highest drug-induced death rate in the nation, and the consequences of drug use continue to burden New Mexico communities. Drug induced deaths in Santa Fe County in 2014 was 30.9 per 100,000, up from 24.3 between 2007 and 2011. Santa Fe County had the fourth highest number of drug-induced deaths[68] across the state. In New Mexico, drug overdose deaths have now surpassed car accidents as the leading cause of death.[69]

Santa Fe experienced an increase in property crimes while at the same time experienced an increased use of opiates, both heroin and opiate-based pills. In 2011, the Santa Fe area (the city and the county, including parts of Española) ranked second in the country in residential burglaries per 100,000 residents.[70] Property crimes rose

slightly in 2012 compared to 2011. Residential burglaries increased to 802 from 782 the previous year.[71] Local authorities established that serious drug dependence was fueling the property crime problem.

The city of Santa Fe resolved to address these public safety and public health issues by forming a LEAD Task Force. The Task Force completed a cost-benefit analysis. The task force's analysis determined that the overall cost to the entire system to arrest 100 individuals by the City of Santa Fe Police Department for opiate possession or sales resulting in booking, detention, prosecution and/or adjudication costs was more than $4.2 million or an average of $42,000 per individual across the law enforcement, jail, judicial, 911 emergency and medical systems over just a three year (2010-2012) period alone.[72]

These same 100 individuals cost the City of Santa Fe one million dollars in jail/detention costs over three years for a total of 11,502 jail days. They were arrested 590 times by city police during that three year period and officers spent 9.3 hours per arrest. The majority of these individuals (91 out 100) were repeat offenders. This pattern of persistent recidivism resulted in individuals being re-arrested every six months on average. Fifty-one percent of those individuals had reported property crime histories. Based on these findings, the city acknowledged that it could no longer afford to rely on criminal sanctions to address problematic, drug-related behavior. To break this cycle of addiction and arrest, Santa Fe's City Council approved the implementation of a three-year pilot LEAD project.

LEAD is a Successful Program that Merits Replication

LEAD is credited with reducing drug arrests in Seattle by more than 30 percent from 2010 to 2011.[73] In addition, an independent, case-controlled outcome evaluation of Seattle's LEAD shows that it has resulted in significant reductions in recidivism.[74] Finally, a study released last month found statistically significant reductions in criminal justice and legal system costs for LEAD participants compared to the control group.[75]

LEAD is an evidence-based program that promotes best practices in responding to low level drug crimes. This Committee should advance federal legislation that would authorize funding to support the implementation of pilot LEAD initiatives by jurisdictions desiring a new approach to low-level nonviolent crime.

The Obama Administration's Response to Opioid Crisis

The Obama Administration has taken several important steps to mitigate risks associated with use, dependence and overdose. Earlier this year, the U.S. Department of Health and Human Services (HHS) announced a new initiative focused on reforming opioid analgesic prescribing practices, expanding the use of naloxone and expanding the use of medication assisted treatment. Notably, HHS concluded that expanding the use of naloxone and scaling up access to medication assisted treatment represented strategies grounded in the best research and clinical science available. Yet, funding to carry out this initiative is largely contingent on Congress approving a request for $133 million in President Obama's FY 2016 budget.[76] The Office of National Drug Control Policy (ONDCP) has also taken significant steps to recognize

naloxone's integral role in reversing opioid overdose deaths. ONDCP's most recent *National Drug Control Strategy* articulates policy goals of reducing overdose fatalities by 15 percent, increasing the utilization of naloxone by first responders and working with states to promote Good Samaritan Laws.[77]

Conclusion

The Drug Policy Alliance urges the Committee to confront the opioid crisis as a health issue, rather than a criminal justice issue and develop policies and programs accordingly. The federal government has spent billions of dollars on counterproductive supply-side strategies. The Committee should prioritize the elimination of federal roadblocks to accessible and affordable medication assisted treatment and facilitate the expansion of policy and programmatic solutions that address core issues that drive opioid and other substance use -- including Law Enforcement Assisted Diversion and Good Samaritan immunity laws.

The Committee should advance legislation that will reduce barriers to health services, drug treatment and emergency services -- including sterile syringes and naloxone.

Thank you for considering our views.

Sincerely,

Grant Smith
Deputy Director, National Affairs
Drug Policy Alliance

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[1] Carla K. Johnson, "Rapid rise seen in fatal medication errors." *Associated Press*, July 29, 2008.
[2] Bohnert AS, Valenstein M, Bair MJ, Ganoczy D, McCarthy JF, Ilgen MA et al. *Association between opioid prescribing patterns and opioid overdose-related deaths*. JAMA. 2011;305(13):1315-21.; Gomes T, Mamdani MM, Dhalla IA, Paterson JM, Juurlink DN. *Opioid dose and drug-related mortality in patients with nonmalignant pain*. Arch Intern Med 2011;171(7): 686–91.; Paulozzi LJ, Kilbourne EM, Shah NG, Nolte KB, Desai HA, Landen MG et al. *A history of being prescribed controlled substances and risk of drug overdose death*. Pain Med. 2012;13(1):87-95.
[3] Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services: Hearing before the U.S. Senate Subcommittee on Crime and Drugs Committee on the Judiciary and the Caucus on International Narcotics Control: Trends in Unintentional Drug Overdose Deaths, 110th Congress, (2008) (statement of Leonard J. Paulozzi, MD, MPH, medical epidemiologist in the Division of Unintentional Injury Prevention of the National Center for Injury Prevention and Control (NCIPC)).
[4] Centers for Disease Control and Prevention, National Center for Health Statistics, *Compressed Mortality File 1999-2013*, released October 2014, ICD-10 X40-X44, data are from the Compressed Mortality File 1999-2013 Series 20 No. 2S, 2014, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program, accessed on May 29, 2015, http://wonder.cdc.gov/cmf-icd10.html.
[5] In 2003, 18,294 accidental drug overdoses were recorded by the CDC; in 2013, 35,663 accidental drug overdoses were recorded by the CDC

[6] In 2000, 11,712 accidental drug overdoses were recorded by the CDC; in 2013, 35,663 accidental drug overdoses were recorded by the CDC

[7] White and American Indian men aged 45-54 residing in rural areas (especially in the Appalachian region of the Southeast) who use opioid analgesics on a daily basis, along with other prescription medications, are at greatest risk of experiencing a fatal overdose. Women, however, are increasingly at risk of a fatal opioid analgesic overdose. Between 1999 and 2010, opioid medication overdose fatalities increased by more than 400 percent among women and 265 percent among men. Military veterans are at also at elevated risk of experiencing a drug overdose. The risk of fatal overdose among military veterans is high given the widespread use of opioid analgesics for relief of pain from combat injuries.

[8] Since the mid-1990s, nearly all 50 states and the District of Columbia have passed laws creating PDMPs, which are government administered databases that collect, monitor, and analyze electronically transmitted prescribing and dispensing data submitted by pharmacies and dispensing practitioners. See: PDMP Training and Technical Assistance Center, "PDMP Frequently Asked Questions," http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq.

[9] At the federal level, the Obama Administration has prioritized efforts to restrict access to opioid analgesics. Many states continue to push forward with additional restrictions. The federal government has also provided funding in recent years for states to implement PDMPs. The Office of National Drug Control Policy (ONDCP) has promoted PDMPs and coordinated federal-state crackdowns on pain physicians, patients and illicit sellers. The DEA has aggressively investigated and prosecuted pain physicians for prescribing practices that this law enforcement agency viewed were outside the scope of legitimate medical practice. An FDA panel recently recommended the placement of opioid analgesic hydrocodone (Vicodin™) in the most restrictive federal controlled substance schedule. See: The White House, *National Drug Control Strategy*, (Washington DC: The White House, 2014), pages 74, 76-77, https://www.whitehouse.gov/sites/default/files/ndcs_2014.pdf ; Mark Potter, "Drug Enforcement Administration Raids 'Pill Mills' in Four Southern States," *NBC News*, May 20, 2015, http://www.nbcnews.com/news/us-news/drug-enforcement-administration-raids-pill-mills-four-southern-states-n361956; Drug Enforcement Administration. *DEA Announces Largest-Ever Prescription Drug Operation: Four State Takedown Targets Dirty Doctors, Pharmacies, Pill Mills*, (New Orleans: DEA, 2015), 1, http://www.dea.gov/divisions/no/2015/no052015.shtml ; Sabrina Tavernise, "F.D.A. Likely To Add Limits On Painkillers," *The New York Times*, January 26, 2013, http://www.nytimes.com/2013/01/26/health/fda-vote-on-restricting-hydrocodone-products-vicodin.html?_r=0 ; Fran Lowry, "FDA Panel Calls for Greater Restrictions on Hydrocodone." *Medscape*, Jan 28, 2013, http://www.medscape.com/viewarticle/778275; A growing number of states are requiring physicians and pharmacists to register and enter prescriptions into a state's PDMP. (See: Prescription Drug Monitoring Program Center of Excellence at Brandeis, "COE Briefing Mandating PDMP Participation by Medical Providers: Current Status and Experience in Selected States," last modified February 1st, 2014, http://www.pdmpexcellence.org/sites/all/pdfs/COE%20briefing%20on%20mandates%20revised_a.pdf); Since 2003, Congress has authorized $80,350,000 in funding for the Harold Rogers Prescription Drug Monitoring Programs Grant, which is credited with aiding the creation of PDMPs in 33 states since 2003. The Obama Administration has also prioritized "law enforcement efforts to decrease pill mills, drug trafficking and doctor shopping" since 2011. See: Department of Justice, Office of Justice Programs, Bureau of Justice Assistance, "Harold Rogers Prescription Drug Monitoring Program," Presentation to 19th National Conference on Pharmaceutical and Chemical Diversion (2010), See http://www.deadiversion.usdoj.gov/mtgs/drug_chemical/2010/rrose.pdf ; Erin Bagalman, Kristin Finklea, Lisa N. Sacco, "Prescription Drug Monitoring Programs," (Washington DC: Congressional Research Service, 2014) 15-16, https://www.fas.org/sgp/crs/misc/R42593.pdf. ; Lisa N Sacco, Erin Bagalman and Kristin Finklea, *Prescription Drug Monitoring Programs*, (Washington: Congressional Research Service, 2014), 1-23, http://www.fas.org/sgp/crs/misc/R42593.pdf; The White House. National Drug Control Strategy, (Washington D.C.: White House, 2014), pages 74, 76-77, https://www.whitehouse.gov/sites/default/files/ndcs_2014.pdf

[10] A 2011 CDC study concluded as much, and a more recent literature review of 60 references concluded that evidence merely "suggested" that PDMPs have the intended impact. See: L Paulozzi, E Kilbourne, H Desai, "Prescription drug monitoring programs and death rates from drug overdose," *Pain Med* 12 (2011):747-754.; Prescription Drug Monitoring Program Center of Excellence at Brandeis, "COE Briefing
Mandating PDMP Participation by Medical Providers: Current Status and Experience in Selected States," last modified February 1st, 2014, http://www.pdmpexcellence.org/sites/all/pdfs/COE%20briefing%20on%20mandates%20revised_a.pdf.

[11] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, *2013 National Survey on Drug Use and Health: Summary of National Findings*, (Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014), 31-32,

http://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFWHTML2013/Web/NSDUHresults2013.htm.

[12] Holly Hedegaard, Li-Hui Chen, Margaret Warner, "Trends in Drug-Poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 1999–2012," (Hyattsville, MD: Centers for Disease Control and Prevention, 2014), 1-5; Michelle Peavy et al., "'Hooked on" Prescription-Type Opiates Prior to Using Heroin: Results from a Survey of Syringe Exchange Clients," *Journal of Psychoactive Drugs* 44, no. 3 (2012); R. A. Pollini et al., "Problematic Use of Prescription-Type Opioids Prior to Heroin Use among Young Heroin Injectors," *Substance Abuse Rehabilitation* 2. 1 (2011); A. Goodnough & K Zezima, "Drug is Harder to Abuse, but Users Persevere," *New York Times*, June 15, 2011, http://www.nytimes.com/2011/06/16/health/16oxy.html; George Jay Unick, Daniel Rosenblum, Sarah Mars, Daniel Ciccarone, "Intertwined Epidemics: National Demographic Trends in Hospitalizations for Heroin- and Opioid-related Overdoses, 1993-2009," *Plos One* (2013), doi: 10.1371/journal.pone.0054496; Pradip K. Muhuri, Joseph C. Gfroerer, and M. Christine Davies, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States, Substance Abuse and Mental Health Services Administrati*on, (Rockville, MD, Center for Behavioral Health Statistics and Quality, 2013), 1-17, http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf; Theodore J. Cicero, Matthew S. Ellis, and Hilary L. Surratt, "Effect of Abuse-Deterrent Formulation of Oxycontin," *New England Journal of Medicine* 367. 2 (2012): 187-189; U.S. Department of Justice, National Drug Intelligence Center, *National Drug Threat Assessment 2003*, (Washington DC: DOJ, 2003), 1-3, http://www.justice.gov/archive/ndic/pubs3/3300/pharm.htm; U.S. Department of Justice, National Drug Intelligence Center, *National Drug Threat Assessment 2011*, (Washington DC: DOJ, 2011): 37, http://www.justice.gov/archive/ndic/pubs44/44849/44849p.pdf.

[13] Heroin is more potent, readily available, and a cheaper alternative to prescription opioids. Today, a dose of high-grade heroin is available for about the price of a six-pack of beer. See: Theodore J. Cicero, Matthew S. Ellis, Hilary L. Surratt, SP Kurtz, "The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years," *JAMA Psychiatry* 71 (2014):821-826.; United Nations Office on Drugs and Crime, *World Drug Report 2014*, (New York: UN, 2014), 30, http://www.unodc.org/documents/wdr2014/World_Drug_Report_2014_web.pdf (assuming purchase in the US of an IV dose of 10 mg – would be between $3-5 on average in US).

[14] Factors that contribute to a greater overdose risk include taking new batches of street heroin, buying from a new source selling a stronger drug, or from the presence of adulterants that increase the potency of heroin. The most notable of these additives is fentanyl, a potent synthetic opioid analgesic that is relatively easy to make and to smuggle. Fentanyl, whether in prescription or illegal analog form, is many times more potent than morphine. When added to heroin, fentanyl can cause immediate overdose in unsuspecting users. In 2005-2006, nearly 1,000 people died from a batch of fentanyl-laced heroin in six Midwestern and northeast states. More recently, fentanyl-laced heroin was traced to 17 deaths in Pittsburgh and over 50 in Philadelphia, Pennsylvania in early 2014. Another factor influencing heroin overdose rates is the simultaneous use of multiple drugs, such as alcohol, cocaine and other depressants. See: A Weil, *From Chocolate to Morphine*, (New York: Houghton Mifflin Company, 1998), 161-163.; U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, "Nonpharmaceutical Fentanyl-Related Deaths – Multiple States, April 2005--March 2007" *Morbidity and Mortality Weekly Report 57.29* (July 2008): 793-796, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5729a1.htm.; Substance Abuse and Mental Health Services Administration (SAMHSA), "Advisory to Treatment Community on The Danger of Heroin Contaminated with Fentanyl and What Can be Done to Save Lives," February 07, 2014, http://www.samhsa.gov/newsroom/press-announcements/201402071000; Don Sapatkin, "Deadly drug mix: Fentanyl Makes a Comeback," *Philly.com*, August 24, 2014, http://articles.philly.com/2014-08-24/news/53143422_1_illicit-fentanyl-overdoses-heroin.; Coffin, P.O., S. Galea, J. Ahern, A.C. Leon, D. Vlahov, and K. Tardiff, "Opiates, Cocaine and Alcohol Combinations in Accidental Drug Overdose Deaths in New York City, 1990-98." *Addiction* 98 (2003): 739-47.

[15] Holly Hedegaard, Li-Hui Chen, Margaret Warner, "Drug-poisoning Deaths Involving Heroin: States, 2000-2013," *NCHS Data Brief* 190 (2015), 1-8, http://www.cdc.gov/nchs/data/databriefs/db190.pdf.

[16] Holly Hedegaard, Li-Hui Chen, Margaret Warner, "Drug-poisoning deaths involving heroin: States, 2000-2013," *NCHS Data Brief* 190 (2015), 1-8, http://www.cdc.gov/nchs/data/databriefs/db190.pdf; RA Rudd, LJ Paulozzi, MJ Bauer, RW Burleson, RE Carlson, D Dao, et al., "Increases in Heroin Overdose Deaths - 28 States, 2010 to 2012," *Morbidity and Mortality Weekly Report* 2014; 63(39):849-54; Centers for Disease Control and Prevention, Data for Epidemiologic Research (CDC WONDER), http://wonder.cdc.gov/.

[17] Evidence suggests that the switch from using opioid analgesics to using heroin is particularly prevalent for individuals who are using opioid analgesics without a prescription. However, available evidence does not support the notion that individuals who use opioid analgesics will progress to using

heroin for the purpose of experiencing a more potent drug alone. See: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Vital Signs: Demographic and Substance Use Trends Among Heroin Users — United States, 2002–2013," *Morbidity and Mortality Weekly Report*, 64(26) (2015): 719-725**,** http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6426a3.htm?s_cid=mm6426a3_w; NIDA Report Series, "Heroin," NIH publication number 15-0165, 3 (November 2014, rev.); TJ Cicero, MS Ellis, HL Surratt, "Effect of Abuse-deterrent Formulation of OxyContin," *New England Journal Medicine* 367.2 (2012):187–189; National Institute on Drug Abuse, *Epidemiologic Trends in Drug Abuse, in Proceedings of the Community Epidemiology Work Group*, (Bethesda, MD: NIDA, 2012); Amy Pavuk, "Rx for Danger: Oxycodone Crackdown Drives Addicts to Other Drugs," *Orlando Sentinel*, July 28, 2012, http://articles.orlandosentinel.com/2012-07-28/health/osoxycodonedrug-shift-dilaudid-20120728_1_oxycodone-prescription-drugs-dilaudid-pills.; Theodore J. Cicero, Matthew S. Ellis, Hilary L. Surratt, Steven P. Kurtz, "The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 years," *JAMA Psychiatry* 71 (2014): 821-6.)

[18] Lisa N Sacco, Erin Bagalman and Kristin Finklea, *Prescription Drug Monitoring Programs*, (Washington: Congressional Research Service, 2014), 1-23, http://www.fas.org/sgp/crs/misc/R42593.pdf.

[19] Katherine Addleman, "Undertreated pain festers in our anti-opiate culture," *National Review of Medicine* 1 (30 August 2004); Maia Szalavitz, "Report: Chronic, Undertreated Pain Affects 116 Million Americans," *Time*, June 29, 2011, http://healthland.time.com/2011/06/29/report-chronic-undertreated-pain-affects-116-million-americans/; Human Rights Watch, *Global State of Pain Treatment: Access to Medicines and Palliative Care* (New York, NY: HRW, 2011) 5-10, 16-17, http://www.hrw.org/sites/default/files/reports/hhr0511W.pdf; NB King, V Fraser, "Untreated Pain, Narcotics Regulation, and Global Health Ideologies," *PLoS Medicine* 10.4 (2013), http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001411; Institute of Medicine, Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research, (Washington, DC: National Academies Press, 2011), http://img.medscape.com/pi/features/pain/IOM_RelievingPainAmerica_June2011pdf.pdf

[20] US Census Bureau, *The Next Four Decades: The Older Population in the United States: 2010 to 2050, Population Estimates and Predictions*, (Washington DC: US Census Bureau, 2011), 1-16.

[21] Institute of Medicine of the National Academies, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* (Washington D.C., The National Academies Press, 2011), 8, 62-64, 81.

[22] Naloxone is an opioid antagonist that blocks the brain cell receptors activated by heroin and other opioids, temporarily restoring normal breathing within two to three minutes of administration. First approved by the FDA in 1971, naloxone is effective at reversing opioid overdoses precipitated by the use of heroin, oxycodone (OxyContin™), hydrocodone (Vicodin™), percocet, methadone, fentanyl and other opioids. Naloxone's only effects are to reverse respiratory failure resulting from an opioid overdose and to cause uncomfortable withdrawal symptoms in the dependent user. It has no pharmacological effect if administered to a person who has not taken opioids and has no potential for abuse. It is impossible to overdose on naloxone. See: United Nations Office on Drugs and Crime, *Opioid Overdose: Preventing And Reducing Opioid Overdose Mortality*, (New York: United Nations, 2013), 7, https://www.unodc.org/docs/treatment/overdose.pdf.

[23] If the victim has not been revived after two minutes, another dose of naloxone is administered and so on until the naloxone has the desired effect. Naloxone's effects last for 30 to 75 minutes, allowing time for the arrival of emergency medical assistance. Naloxone is most commonly administered via intramuscular injection, but it can also be administered intranasally using an atomizer device that delivers a mist to the nasal mucus membrane. The intranasal device delivers the intramuscular formation of naloxone. The intramuscular formulation has not yet been formally approved by the FDA for intranasal delivery, but it is in use by EMS responders and law enforcement in a growing number of states and by government health providers and community-based overdose prevention initiatives across the country, and the FDA is expected to soon approve an intranasal formulation of naloxone. Last year, the FDA approved a third method of naloxone delivery by way of an auto-injector delivery system (Evzio™). While the recent arrival of Evzio™ on the market provides health care providers and patients at-risk of an overdose with an important new treatment option, and is covered by some insurance providers, the newly patented auto-injector can be too expensive for the uninsured to access. See: United Nations Office on Drugs and Crime, *Opioid Overdose: Preventing And Reducing Opioid Overdose Mortality*, (New York: United Nations, 2013), 8, https://www.unodc.org/docs/treatment/overdose.pdf. ; Robert 'Skip' Nelson, MD PhD, Senior Pediatric Ethicist & Lead Medical Officer, Office of Pediatric Therapeutics, US Food and Drug Enforcement Administration, "Presentation: Ethical and Regulatory Considerations in Drug Development for IN Naloxone," slide 3, http://www.fda.gov/downloads/Drugs/NewsEvents/UCM300877.pdf; Krystle Vermes, "Pharmacist

Develops Naloxone Nasal Spray to Reverse Drug Overdoses," *Pharmacy Times*, August 27, 2014, http://www.pharmacytimes.com/product-news/Pharmacist-Develops-Naloxone-Nasal-Spray-to-Reverse-Drug-Overdoses; U.S. Food and Drug Administration, "FDA Approves New Hand-held Auto-injector to Reverse Opioid Overdose," *FDA*, April 3, 2014, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm391465.htm; Elisabeth Rosenthal, "For Drugs That Save Lives, a Steep Cost," *New York Times*, April 26, 2014, http://www.nytimes.com/2014/04/27/sunday-review/it-will-save-lives-but-whats-the-cost.html?_r=0; Arielle Pardes, "How the Pharmaceutical Industry Is Making Money on Your Overdose," *VICE Magazine*, July 14, 2014, http://www.vice.com/read/overdoses-are-insanely-profitable-for-pharmaceutical-companies-714

[24] Phillip O. Coffin and Sean D. Sullivan, "Cost-Effectiveness of Distributing Naloxone to Heroin Users for Lay Overdose Reversal," *Annals of Internal Medicine* 158, (2013), 1057.

[25] Depending on state law, prescriptions for naloxone must either be written to individuals who have requested to carry the medication or may be made by overdose prevention programs operating under standing orders from a physician. Access to naloxone and other emergency treatment is also often limited at the state-level by laws and regulations that were implemented before opioid overdose fatalities began climbing in the 2000s. In an attempt to improve utilization of naloxone by health practitioners and laypeople, a number of states have recently amended their laws to increase access to emergency care and treatment for opioid overdose. Naloxone is governed by state and federal prescription drug laws. State practice laws generally discourage or prohibit the prescription of drugs to a person other than the person to whom they will be administered (a process referred to as third-party prescription) or to a person the physician has not personally examined (a process referred to as prescription via standing order). After years of federal prosecutions against physicians accused of professional negligence or corruption for prescribing opioids, health practitioners supportive of naloxone availability are understandably concerned about potential liabilities stemming from prescribing the medication for third-party use. Likewise, even where naloxone is available, bystanders to a drug overdose may be afraid to administer it because of liability concerns. Other states provide a standing order for community-based organizations who distribute naloxone to those who meet certain criteria. See: Network for Public Health Law, Legal Intervention to Reduce Overdose Mortality: Emergency Medical Services Naloxone Access, available at https://www.networkforphl.org/_asset/8b7kmi/EMS-naloxone-overview.pdf.; Sporer, K. A., A. H. Kral. "Prescription Naloxone: A Novel Approach to Heroin Overdose Prevention." *Annals of Emergency Medicine* 49 (2007): 172-77.; Burris, S. Norland, J. Edlin, B.R. "Legal Aspects of Providing Naloxone to Heroin Users in the United States." *International Journal of Drug Policy* 12 (2001): 237-248.; Leo Beletsky, et al., "Physicians' Knowledge of and Willingness to Prescribe Naloxone to Reverse Accidental Opiate Overdose: Challenges and Opportunities," *Journal of Urban Health* 84 (2007), 126.; Scott Burris, et al, "Stopping An Invisible Epidemic: Legal Issues In The Provision Of Naloxone To Prevent Opioid Overdose," *Drexel Law Review* 273 (2009), 273-340.

[26] Network for Public Health Law, Legal Intervention to Reduce Overdose Mortality: Emergency Medical Services Naloxone Access, available at https://www.networkforphl.org/_asset/8b7kmi/EMS-naloxone-overview.pdf.

[27] See Opioid Overdose Reduction Act of 2015, H.R. 1821

[28] Severe penalties for possession and use of illicit drugs, including state laws that impose criminal charges on individuals who provide drugs to someone who subsequently dies of an overdose, only intensify the fear that prevents many witnesses from seeking emergency medical help. See: C. J. Banta-Green et al., "Police Officers' and Paramedics' Experiences with Overdose and Their Knowledge and Opinions of Washington State's Drug Overdose-Naloxone-Good Samaritan Law," *J Urban Health* 90.6 (2013), 1103-1110.; Karin Tobin, et al., "Calling Emergency Medical Services During Drug Overdose: An Examination of Individual, Social and Setting Correlates," *Addiction* 100 (2005), 397-404; Robin A. Pollini, et al., "Response to Overdose Among Injection Drug Users," *American Journal of Preventive Medicine* 31 (2006), 261-263.

[29] Good Samaritan Laws have been passed in: NM, AK, AR, CA, CO, CT, DE, FL, GA, IL, KY, LA, MA, MD, MN, MS, NC, NJ, NV, NY, PA, RI, VT, WA, WI, and WV) and the District of Columbia.

[30] Normand J, Vlahov D, Moses LE, et al., "Preventing HIV Transmission: The Role of Sterile Needles and Bleach," (Washington, DC: National Academies Press, 1995), http://www.nap.edu/books/0309052963/html.

[31] World Health Organization, "People who inject drugs," last updated February 2015, http://www.who.int/hiv/topics/idu/en/

[32] Hagan H, McGough JP, Thiede H, Hopkins S, Duchin J, Alexander ER, "Reduced Injection Frequency and Increased Entry and Retention in Drug Rreatment Associated with Needle-exchange Participation in Seattle Drug Injectors," *Journal of Substance Abuse Treatment* 19 (2000): 247–252; Don C. Des Jarlais, Vivian Guardino, Kamyar Arasteh, Courtney McKnight, Judith Milliken and David Purchase, "Current State of Syringe Exchange in the Known Universe," NASEC, last modified

November 17, 2010, http://www.nasen.org. Also, syringe exchange programs also provide safe disposal of infected syringes, which reduces the risk of accidental needlestick injuries to first responders and public encounters with discarded syringes. Moreover, syringe exchange programs provide crucial support for participants at every point along the continuums of care for HIV and hepatitis C.

[33] US Department of Health and Human Services, *Evidence-based findings on the efficacy of syringe exchange programs: an analysis of the scientific research completed since April 1998,* (Washington DC:US Department of Health and Human Services, 2000), 1-19.; Institute of Medicine (IOM), *Preventing HIV Infection among Injecting Drug Users in High-Risk Countries: An Assessment of the Evidence* (Washington DC: National Academies Press, 2006), 1-2, http://www.iom.edu/~/media/Files/Report%20Files/2006/Preventing-HIV-Infection-among-Injecting-Drug-Users-in-High-Risk-Countries-An-Assessment-of-the-Evidence/11731_brief.pdf; World Health Organization (WHO), *Effectiveness of Sterile Needle and Syringe Programming in Reducing HIV/AIDS Among Injecting Drug Users* (Geneva, Switzerland: WHO, 2004), http://www.who.int/hiv/pub/prev_care/effectivenesssterileneedle.pdf; Center for Disease Control, "Syringe Exchange Programs – United States, 2005," Morbidity and Mortality Weekly 56,44 (2005), 1164-1167, http://www.cdc.gov/IDU/facts/AED_IDU_SYR.pdf; National Institute on Drug Abuse, *Principles of HIV Prevention in Drug-using Populations: A Research Based Guide* (Washington DC: NIH, 2002), 1-32; Melissa Marx et al., "Trends in Crime and the Introduction of a Needle Exchange Program," *American Journal of Public Health*, 90,12 (2000):1933–6. Also, for every dollar invested in syringe access, approximately $3-8 in HIV treatment are saved. This does not take into account further savings from averted hepatitis C infection, avoiding increased healthcare expense due to living with the virus. Examples of the effectiveness of syringe exchange programs in scientific literature are numerous. The CDC estimates that HIV diagnoses among people who inject drugs has declined by 70 percent in the 10-year period, from 2002 to 2011. Many attribute a 70 percent decline in HIV diagnoses among people who inject drugs between 2002 and 2011 to the provision of comprehensive, science-based HIV prevention programs for this population, including syringe services programs. Similarly, the New York State Department of Health credits syringe exchange programs with a major reduction in HIV/AIDS across that state from 1992, when 52 percent of AIDS cases were attributed to injection drug use, to 2004, when only 5.4 percent of HIV cases were so attributed. The District of Columbia Department of Health expanded syringe exchange program access in 2007 and subsequently reported an 81 percent decrease in new HIV infections among people who inject drugs in D.C. from 2008-2012. See: A Wodak, A Cooney, "Do Needle Syringe Programs Reduce HIV Infection Among Injecting Drug Users: A Comprehensive Review of the International Evidence," *Substance Use Misuse* 41 (2006):777–813.; A Johnson, H Hall, X Hu, A Lansky, DR Holtgrave, J Mermin, "Trends in Diagnoses of HIV Infection in the United States, 2002–2011" *JAMA* 312,4 (2014) 432–434. doi:10.1001/jama.2014.853.; New York State Department of Health, "Harm Reduction Initiative," accessed on May 28, 2015, http://www.health.ny.gov/diseases/aids/general/about/prevsup.htm#harmred ; District of Columbia Department of Health, *Annual Epidemiology & Surveillance Report,* (Washington DC: District of Columbia Department of Health, 2012), 17, http://doh.dc.gov/sites/default/files/dc/sites/doh/page_content/attachments/Newly%20Diagnosed%20HIV%20Cases.pdf.

[34] amFAR, "Preventing HIV and Hepatitis C Among People Who Inject Drugs: Public Funding for Syringe Services Programs Makes the Difference," *amFAR Issue Brief* (2015), 1-5, http://www.amfar.org/uploadedFiles/_amfarorg/On_the_Hill/BIMC_SSP_IB-WEB-VERSION_041315.pdf p. 4; Also, the last two directors of the Office of National Drug Control Policy (ONDCP) have cited syringe services as essential to reducing the transmission of blood-borne diseases without increasing drug use when implemented in the context of a comprehensive program that offers referrals to other treatment and prevention services. See: White House Office of National Drug Control Policy, Senate Judiciary Committee confirmation hearing, 111th Congress, (2009), (statement of Gil Kerlikowske, Director of ONDCP); Bruce Schreiner, "McConnell, Drug Czar Talk Heroin in N. KY," *Associated Press,* April 9, 2015, http://www.courier-journal.com/story/news/local/2015/04/09/mcconnell-botticelli/25544135/

[35] amFAR, "Preventing HIV and Hepatitis C Among People Who Inject Drugs: Public Funding for Syringe Services, Programs Makes the Difference," *amFAR Issue Brief* (2015), 1-5 http://www.amfar.org/uploadedFiles/_amfarorg/On_the_Hill/BIMC_SSP_IB-WEB-VERSION_041315.pdf

[36] amFAR, "Syringe Services Program Coverage in the United States –June 2014," last modified in June, 2014, http://www.amfar.org/uploadedFiles/_amfarorg/Articles/On_The_Hill/2013/2013%20SSP%20Map%20Final.pdf

[37] As of April 17th, there were 120 confirmed and 10 preliminary positive cases of HIV from the sharing of drug injection equipment in Scott County, Indiana along the Kentucky border.[37] Public health

officials from the state of Indiana and CDC determined that the localized epidemic of new HIV cases was due to the sharing of syringes used to inject oxymorphone, an opioid analgesic.[37] In response, Republican Indiana Governor Mike Pence declared a public health emergency in the affected county and issued an executive order allowing for the operation of a syringe exchange program.[37] The Indiana legislature subsequently passed legislation authorizing local officials to request approval from the Indiana State Department of Health for a limited syringe exchange program in the event of a public health emergency.[37] See: Debra Goldschmidt, "Indiana governor declares public health emergency due to HIV epidemic," *CNN*, March 27, 2015, http://www.cnn.com/2015/03/27/health/indiana-hiv-outbreak)

[38] In response to a surge in hepatitis C cases in Kentucky, the state legislature passed a comprehensive bill earlier this year to address rising hepatitis C infections that included the legalization of syringe exchange programs in that state. Nationally, there is emerging evidence of a new surge in hepatitis C cases, with CDC reporting a 75 percent increase in new cases from 2010-2012. See: CDC, Division of Viral Hepatitis, "Reported Cases of Acute, Hepattits C, by State—2008–2012," last modified August 28, 2014, http://www.cdc.gov/hepatitis/Statistics/2012Surveillance/Table4.1.htm

[39] Susan F. Hurley, Damien J. Jolley, and John M. Kaldor,"Effectiveness of Needle-Exchange Programmes for Prevention of HIV Infection," *The Lancet* 349, 9068 (1997): 1797-1800, http://www.druglibrary.org/schaffer/misc/effectiveness_of_neps_for_preven.htm (finding that that in 29 cities worldwide where needle exchange programs are in place, HIV infection dropped by an average of 5.8 percent a year among drug users. In 52 cities that did not have needle exchanges, drug-related infection rose an average of 5.9 percent each year).

[40] C.L. Arfken, et al., "Expanding Treatment Capacity for Opioid Dependence with Buprenorphine: National Surveys of Physicians," *Journal of Substance Abuse Treatment* 96, 39 (2010).

[41] William C. Beckera, David A. Fiellinb, Joseph O. Merrilld, Beryl Schulmand, Ruth Finkelsteine, Yngvild Olsenf, Susan H. Busch, "Opioid use disorder in the United States: Insurance Status and Treatment Access," *Drug and Alcohol Dependence*, Volume 94, Issues 1–3 (2008), 207-213, http://www.usatoday.com/story/news/2015/05/24/addiction-treatment-shortage/27181773/ ; The American Society of Addiction Medications, "Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment," (Chevy Chase, MD, ASAM: 2013), 10, 37, http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final; James A. Peterson, Robert P. Schwartz, Shannon Gwin Mitchell, Heather Schacht Reisinger, Sharon M. Kelly, Kevin E. O'Grady, Barry S. Brown, Michael H. Agar, "Why don't out-of-treatment individuals enter methadone treatment programs?" *International Drug Policy 21* (2010):36-41.

[42] National Institute on Drug Abuse, "Medication-Assisted Treatment for Opioid Addiction," *NIDA Topics in Brief* (April 2012), https://www.drugabuse.gov/sites/default/files/tib_mat_opioid.pdf.

[43] The American Society of Addiction Medications, "Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment, Part II: Economic Evaluation of Pharmacotherapies for the Treatment of Opioid Disorders:," (Chevy Chase, MD, ASAM: 2013), 8, 65- 91, http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final; M. Connock, et al., "Methadone and Buprenorphine for the Management of Opioid Dependence: A Systematic Review and Economic Evaluation," *Health Technology Assessment* 11, 9 (2007): 1-192.

[44] C. Banta-Green, et al., "Retention in Methadone Maintenance Drug Treatment for Prescription-Type Opioid Primary Users Compared to Heroin Users," *Addiction* 104 (2009): 775-783.

[45] Methadone, a Schedule II controlled substance used as maintenance treatment for documented opioid dependence for over 40 years, may only be dispensed by clinics, certified by SAMHSA, and subject to both Federal and state regulation. Buprenorphine, a Schedule III controlled substance – which may be offered, under certain circumstances, by methadone treatment clinics – is a more recently introduced synthetic opioid treatment medication approved as an outpatient physician-prescribed treatment for opioid dependence. Naltrexone is a physician-prescribed clinician-administered injectable medication for the prevention of relapse of opioid dependence after detoxification, commonly known by the brand name Vivitrol™. See: American Society of Addiction Medicine, *Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment* (2013), http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioidaddiction-treatment_final

[46] The National Institutes of Health has explicitly recognized methadone is the most successful treatment to date for opioid dependence, and recommended a reduction in the unnecessary regulation of methadone maintenance therapy and other medication assisted treatment programs. National Institutes of Health, "Effective Medical Treatment of Opiate Addiction," *NIH Consensus Statement* 15, 6 (1997), 4, http://consensus.nih.gov/1997/1998TreatOpiateAddiction108PDF.pdf; and National Institute on Drug Abuse (NIDA) "Research Report: Heroin Abuse and Addiction," (Revised 2005), http://www.drugabuse.gov/ResearchReports/heroin/heroin.html; and National Institute on Drug Abuse,

"Principles of Drug Abuse Treatment for Criminal Justice Populations: A Research-Based Guide," (National Institutes of Health, 2006), 5, 22, https://www.drugabuse.gov/sites/default/files/txcriminaljustice_0.pdf; and D.A. Fiellin, et al., "Methadone Maintenance in Primary Care: A Randomized Controlled Trial," *JAMA* 286 (2001):1764-1765; and J.C. Ball and A. Ross, *The Effectiveness of Methadone Maintenance Treatment* (New York: Springer-Verlag, 1991); and Y.I. Hser, et al., "A 33-Year Follow-Up of Narcotics Addicts," *Archives of General Psychiatry* 58 (2001): 503-508; and J. Ward, W. Hal, and R.P. Mattick, "Role of Maintenance Treatment in Opioid Dependence," *The Lancet* 353 (1999): 221-226; and D.M. Novick and H. Joseph. "Medical Maintenance: The Treatment of Chronic Opiate Dependence in General Medical Practice," *Journal of Substance Abuse Treatment* 8 (1991): 233-239; and Centers for Disease Control and Prevention, "Methadone Maintenance Treatment," February 2002, accessed June 4, 2015, http://www.cdc.gov/idu/facts/Methadone.htm; and M. Connock, et al., "Methadone and Buprenorphine for the Management of Opioid Dependence: A Systematic Review and Economic Evaluation," *Health Technology Assessment* 11, 9 (2007); Center for Substance Abuse Treatment, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (Tip) Series 43* (Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005); World Health Organization, *Substitution Maintenance Therapy in the Management of Opioid Dependence and HIV/AIDS Prevention* (United Nations Office on Drugs and Crime, 2004), http://www.unodc.org/docs/treatment/Brochure_E.pdf; and R.P. Mattick, et al., "Methadone Maintenance Therapy Versus No Opioid Replacement Therapy for Opioid Dependence," *Cochrane Database System Review*, 3 (2009).

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