Testimony

Funding Considerations in the Fight Against the Opioid Epidemic

What the Science Tells Us

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Funding Considerations in the Fight Against the Opioid Epidemic: What the Science Tells Us

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The RAND Corporation[2]

Before the Committee on Appropriations
Subcommittee on Labor, Health and Human Services, Education, Related Agencies
United States House of Representatives

April 5, 2017

Chairman Cole, Ranking Member DeLauro, and other distinguished members of the Subcommittee on Labor, Health and Human Services, Education and Related Agencies, thank you very much for the opportunity to testify before you today. I am a senior economist at the RAND Corporation, where I also serve as the co-director of RAND's Drug Policy Research Center and the director of the BING Center for Health Economics. RAND's mission, as a nonprofit, nonpartisan research organization, is to produce and disseminate objective information that can be used to help solve our nation's most pressing challenges. I was asked to speak to you today about the effectiveness of various programs that have been funded by this committee in the country's efforts to end the opioid epidemic. This is something that my RAND colleagues and I have spent considerable time evaluating in recent years, thanks to research support provided by the National Institute on Drug Abuse, the Office of the Assistant Secretary for Planning and Evaluation, and the Centers for Disease Control and Prevention.

Congress has made considerable investments to address the opioid crisis, most recently with the Comprehensive Addiction and Recovery Act and 21st Century Cures Act. While it is too soon to determine the effect of these laws on the opioid epidemic, I will speak to the existing evidence examining policies to stem opioid diversion and misuse and why it might be worth continuing to support some of them until clear evidence emerges related to the effectiveness and relative cost-effectiveness of each intervention.

In this testimony, I will begin by providing some general insights about what we know about drug epidemics more generally, and the relative effectiveness of different types of drug policy

[1] The opinions and conclusions expressed in this testimony are the author's alone and should not be interpreted as representing those of the RAND Corporation or any of the sponsors of its research.

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strategies at different stages in drug epidemics. Such background is important because there are some broad lessons that should be considered when thinking about the effective allocation of society's resources in tackling the opioid problem today. I will then discuss what science tells us about the effectiveness of some of the current strategies supported by funding this subcommittee provides that combats the opioid epidemic. Specifically, this testimony will discuss the value of treatment, particularly medication assisted treatment, expanded availability of naloxone, enhancing prescription drug monitoring programs, and establishing guidelines for safe opioid prescribing. Many more strategies than these exist, including important supply reduction strategies that are undertaken by law enforcement. Given the limited time, I have narrowed my focus in today's remarks to specific strategies funded by the agencies under the jurisdiction of this subcommittee.

Relative Effectiveness of Drug Control Strategies During Phases of a Drug Epidemic

In the mid-1990s, RAND did groundbreaking work modeling the interaction between the supply and demand for cocaine, which enabled us for the first time to be able to consider the relative effectiveness and cost-effectiveness of alternative supply side strategies (e.g. crop eradication, local law enforcement) versus demand-side (e.g. prevention or treatment).[3] Scholars continued to build on this work, developing dynamic models of other drug epidemics.[4] A few scholars have begun modeling the specific dynamics of the opioid epidemic, and the general models provide several important insights for prioritizing opioid epidemic funding.[5]

1. Early in the development of a drug epidemic, when prevalence of use is increasing very rapidly, primary prevention and public awareness campaigns that deter new users are especially effective, as they reduce the pool of "susceptibles"—i.e., those who are at risk of using. Because of a phenomenon we refer to as "social contagion," prevention policies early in an epidemic have the added benefit of deterring more than just the one person they reach. Similarly, traditional law enforcement that aims to shrink the market through

[3] S.S. Everingham and C.P. Rydell, "Modeling the Demand for Cocaine," Santa Monica, Calif.: RAND Corporation, MR-332-ONDCP/A/DPRC, 1994.

[4] J.P. Caulkins, "Models Pertaining to How Drug Policy Should Vary over the Course of an Epidemic Cycle," in B. Lindgren and M. Grossman, eds., *Substance Use: Individual Behavior, Social Interactions, Markets, and Politics, Advances in Health Economics and Health Services*, Bingley, UK: Emerald Publishing, Vol. 16, 2005, pp. 407–439; D. Winkler, J.P. Caulkins, D.A. Behrens, and G. Tragler, "Estimating the Relative Efficiency of Various Forms of Prevention at Different Stages of a Drug Epidemic," *Socio-Economic Planning Sciences*, Vol. 38, No. 1, March 2004, pp. 43–56; G. Tragler, J.P. Caulkins and G Feichtinger, "The Impact of Enforcement and Treatment on Illicit Drug Consumption," Operations Research, Vol. 49, pp. 352–362, 2001.

[5] W. Wakeland, A. Nielsen, and P. Geissert, "Dynamic Model of Nonmedical Opioid Use Trajectories and Potential Policy Interventions," *American Journal of Drug and Alcohol Abuse*, Vol. 41, No. 6, 2015, pp. 508–518; R.L. Pacula, S.B. Hunter, A.J. Ober, K.C. Osilla, R. Vardavas, J.C. Blanchard, E.F. Drabo, K.J. Leuschner, W. Stewart, and J. Walters, *Preventing, Identifying, and Treating Prescription-Drug Misuse Among Active-Duty Service Members*, Santa Monica, Calif: RAND Corporation, RR-1345-OSD, 2016.

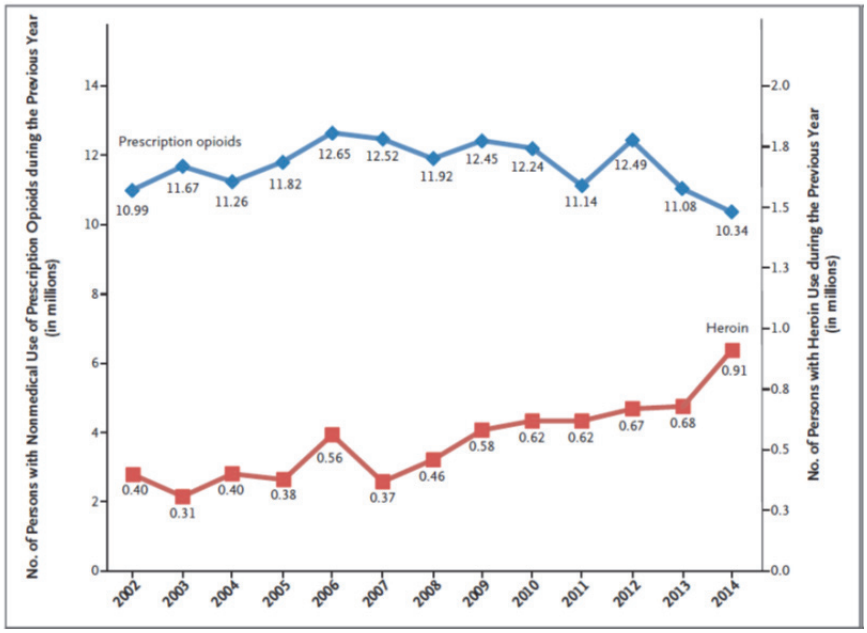
supply disruptions can also be quite effective during this phase, as it can tip the momentum of the upswing in use through "enforcement swamping."

2. After new drug use peaks, secondary prevention (aimed at deterring existing users from transitioning to heavy use) and awareness campaigns focusing on the negative consequences associated with heavy use can be particularly effective. Treatment is also particularly important at this point, to help heavy users quit or reduce the harms experienced by heavy use.
3. The harms from an epidemic usually peak later than the peak in initiation and prevalence of use, as the greatest harms come from the stock of heavy users. Therefore, even if initiation rates or prevalence rates start to fall, sustained investment in treatment is key for reducing the overall harm of the epidemic and transitioning heavy users safely to nonuse. Law enforcement can also support efforts to divert people to treatment at this stage, by keeping prices high in the drug market and/or diverting heavy users to treatment.

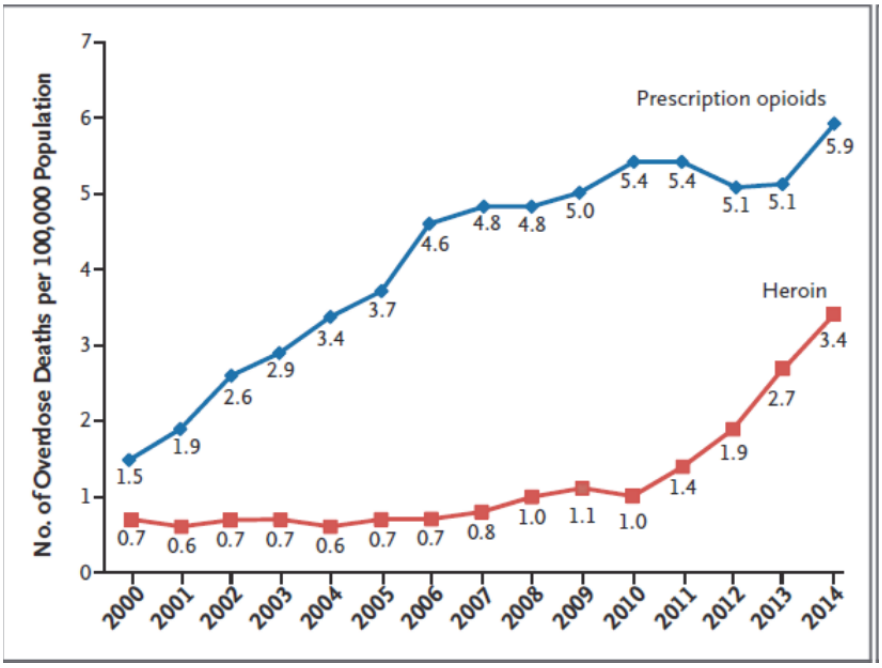
What does this suggest for the current opioid epidemic? One might think that by looking at trends in new initiates, annual prevalence rates and heavy use rates we could see where we are in the opioid epidemic. However, as Figure 1 demonstrates, this epidemic is complicated by the fact that it is fueled by the consumption of two types of opioids, prescription opioids and heroin, whose trends seem to be moving in very different directions.

Figure 1: Trends in Past Year Use and Mortality for Opioids

Part A: Millions of Persons Reporting Nonmedical Use of Prescription Opioids and Heroin in Past Year



Part B: Trends in Age-Adjusted Mortality Related to Prescription Opioids and Heroin



SOURCE: W.M. Compton, C.M. Jones, and G.T. Baldwin, "Relationship Between Nonmedical Prescription-Opioid Use and Heroin Use," *New England Journal of Medicine*, Vol. 374, No. 2, 2016, pp.154–163.

That makes it challenging to say exactly where we are in the opioid epidemic as a whole. As shown in Part A, in the past year, nonmedical use of prescription opioids appears to be declining from what may have been a leveling off between 2006–2012, while heroin use is clearly still on a rise (albeit at a lower absolute level than prescription opioids). Unfortunately, data past 2014 cannot be compared to prior years due to changes in how the data were collected in 2015, making it hard to know at this point of whether trends persisted or changed past 2014. Moreover, we cannot tell from these trends whether the two populations are independent or related. Given recent compelling evidence suggesting that they are not independent, it is hard to say definitively whether annual prevalence rates overall are rising or not.[6] Harms from each group of opioids are clearly on the rise, however, as shown by mortality data in Part B. This means that for the population of users, there is a pretty high rate of transition from regular use to harmful use.

Effective Strategies to Combat the Opioid Epidemic Now

Without the luxury of knowing exactly where we are in this opioid epidemic, particularly if prescription opioid analgesics and heroin are considered together, it is hard to know what mix of

[6] A. Alpert, D. Powell, and R.L. Pacula, "Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids," National Bureau of Economic Research Working Paper #23031, 2017; Compton, Jones, and Baldwin, 2016; T.J. Cicero, M.S. Ellis, and H.L. Surratt, "Effect of Abuse-Deterrent Formulation of OxyContin," *New England Journal of Medicine*, Vol. 367, No. 2, 2012, pp. 187–189.

strategies would be most effective overall. Moreover, law enforcement data, opioid prescribing data, and mortality data all confirm substantial geographic variation in the availability of and harm from both opioid analgesics and heroin, even across counties within the same state, suggesting that local communities are at different epidemic stages.[7] A recent National Association of State Alcohol and Drug Abuse Directors study summarized what states were doing to combat the opioid epidemic as recently as May 2015, largely with support from federal dollars.[8] Here is what we know about the effectiveness of some of the strategies that have been supported by the agencies this subcommittee funds.

Expanding Access to Treatment, Particularly Medication-Assisted Treatment

Opioid addiction is a chronic medical condition that is receptive to effective treatment.[9] Pharmacotherapies, which predominantly include methadone, buprenorphine, and injectable naltrexone, are among the most effective interventions for opioid use disorders.[10] Before 2002, the main opioid pharmacotherapy available was methadone, which can only be dispensed in a licensed opioid treatment program. The approval of buprenorphine, a partial opioid agonist that can be prescribed by waivered physicians in their offices as well as in traditional opioid treatment programs, greatly increased access to medication-assisted treatment (MAT).[11] Options

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[7] D.C. McDonald, K. Carlson, and D. Izrael, "Geographic Variation in Opioid Prescribing in the U.S.," *Journal of Pain: Official Journal of the American Pain Society*, Vol. 13, No. 10, 2012, pp. 988–996; L.M. Rosen, D. Khan, and M. Warner, "Trends and Geographic Patterns in Drug-Poisoning Death Rates in the U.S. 1999-2009," *American Journal of Preventive Medicine*, Vol. 45, No. 6, 2013, pp. e19–e25; National Drug Intelligence Center, *National Drug Threat Assessment 2014,* Jonestown, Penn., 2010.

[8] S. Wickramatilake, J. Zur, N. Mulvaney-Day, M.C.V. Klimo, E. Selmi, and H. Harwood, "How States Are Tackling the Opioid Crisis," *Public Health Reports*, Vol. 132, *No.* 2, 2017, pp. 171–179.

[9] A.T. McLellan, D.C. Lewis, C.P. O'Brien, and H.D. Kleber, "Drug Dependence, a Chronic Medical Illness: Implications for Treatment, Insurance, and Outcomes Evaluation," *Journal of the American Medical Association*, Vol. 284, No. 13, 2000, pp. 1689–1695; National Consensus Development Panel on Effective Medical Treatment of Opiate Addiction, "Effective Medical Treatment of Opiate Addiction," *Journal of the American Medical Association*, Vol. 280, No. 22, 1998, pp. 1936–1943.

[10] N.D. Volkow, T.R. Frieden, P.S. Hyde, and S.S. Cha, "Medication-Assisted Therapies—Tackling the Opioid-Overdose Epidemic," *New England Journal of Medicine*, Vol. 370, No. 22, 2014, pp. 2063–2066; National Institute on Drug Abuse, *Principles of Effective Treatment for Criminal Justice Populations,* Rockville, Md., 2006; R.P. Mattick, J. Kimber, C. Breen, and M. Davoli, "Buprenorphine Maintenance Versus Placebo or Methadone Maintenance for Opioid Dependence," *Cochrane Database Syst Review,* Vol. 6, No. 2, 2014; D.A. Fiellin, M.V. Pantalon, M.C. Chawarski, B.A. Moore, L.E. Sullivan, P.G. O'Connor, and R.S. Schottenfeld, "Counseling Plus Buprenorphine-Naloxone Maintenance Therapy for Opioid Dependence," *New England Journal of Medicine,* Vol. 355, No. 4, 2006, pp. 365–374; J. Kakko, K.D. Svanborg, M.J. Kreek, and M. Heilig, "1-Year Retention and Social Function After Buprenorphine-Assisted Relapse Prevention Treatment for Heroin Dependence in Sweden: A Randomised, Placebo-Controlled Trial," *Lancet*, Vol. 361, No. 9358, 2003; pp. 662–668; P.J. Fudala, T.P. Bridge, S. Herbert, W.O. Williford, C.N. Chiang, K. Jones, J. Collins, D. Raisch, P. Casadonte, R.J. Goldsmith, W. Ling, U. Malkerneker, L. McNicholas, J. Renner, S. Stine, and D. Tusel, "Office-Based Treatment of Opiate Addiction with a Sublingual-Tablet Formulation of Buprenorphine and Naloxone," *New England Journal of Medicine*, Vol. 349, No. 10, 2003, pp. 949–958.

[11] E.M. Oliva, J.A. Trafton, A.H. Harris, and A.J. Gordon, "Trends in Opioid Agonist Therapy in the Veterans Health Administration: Is Supply Keeping up With Demand?" *American Journal of Drug Alcohol Abuse*, Vol. 39, No. 2, 2013, pp. 103–107; A.W. Dick, R.L. Pacula, A.J. Gordon, M. Sorbero, R.M. Burns, D. Leslie, and B.D. Stein,

increased even further with the 2010 Food and Drug Administration approval of extended-release opioid antagonist naltrexone (XR-NTX).[12]

Recent federal legislation and many state policies have been shown to be effective at increasing MAT use.[13] Research by RAND and others has shown that insurance parity, expanding the limits on patients a waivered buprenorphine physician can treat from 30 to 100, and state Medicaid policies providing coverage of buprenorphine and placement on preferred drug lists have over time influenced MAT utilization and the locations in which it is provided.[14] This is not enough, however. Much work still needs to be done to better understand why the majority of waivered physicians do not come close to treating the number of patients allowed by their waiver.[15] Moreover, expanding MAT utilization alone, without paying attention to the quality of the treatment received, might not generate a net public health gain if, for example, substantial numbers of newer providers are not adequately prepared or sufficiently incentivized to provide the quality, comprehensive care essential for safe and effective MAT treatment.[16] Improving MAT quality may be particularly important for improving outcomes for historically underserved or high-risk populations, such as racial/ethnic minorities, individuals with HIV, and individuals in rural counties, who may not receive effective treatments for opioid use disorders at the same rate as nonminority individuals. Policies and programs that improve *delivery* of this

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"Growth in Buprenorphine Waivers for Physicians Increased Potential Access to Opioid Agonist Treatment, 2002-11," *Health Affairs (Millwood)*, Vol. 34, No. 6, 2015, pp. 1028–1034; B.D. Stein, R.L. Pacula, A.J. Gordon, R.M. Burns, D.L. Leslie, M.J. Sorbero, S. Bauhoff, T.W. Mandell, and A.W. Dick, "Where Is Buprenorphine Dispensed? The Role of Private Offices, Opioid Treatment Programs, and Substance Abuse Treatment Facilities in Urban and Rural Areas," *Milbank Quarterly*, Vol. 93, No. 3, 2015, pp. 561–583; B.D. Stein, A.J. Gordon, A.W. Dick, R.M. Burns, R.L. Pacula, C.M. Farmer, D.L. Leslie, and M. Sorbero, "Supply of Buprenorphine Waivered Physicians: the Influence of State Policies," *Journal of Substance Abuse Treatment*, Vol. 48, No. 1, 2015, pp. 104–111.

[12] E. Krupitsky, E.V. Nunes, W. Ling, D.R. Gastfriend, A. Memisoglu, and B.L. Silverman, "Injectable Extended-Release Naltrexone (XR-NTX) of Opioid Dependence: Long-Term Safety and Effectiveness," *Addiction*, Vol. 108, No. 9, 2013, pp. 1628–1637; E. Krupitsky, E.V. Nunes, W. Ling, A. Illeperuma, D.R. Gastfriend, and B.L. Silverman, "Injectable Extended-Release Naltrexone for Opioid Dependence," *Lancet*, Vol. 378, No. 9792, 2011, p. 665; author reply 666.

[13] Stein et al., 2015a; Stein et al., 2015b; R.M. Burns, R.L. Pacula, S. Bauhoff, A.J. Gordon, H. Hendrikson, D.L. Leslie, and B.D. Stein, "Policies Related to Opioid Agonist Therapy for Opioid Use Disorders: The Evolution of State Policies from 2004 to 2013," *Substance Abuse*, Vol. 37, No. 1, 2016; American Society of Addiction Medicine, "State Medicaid Reports," 2015; L. Ducharme, and A. Abraham, "State policy influence on the early diffusion of buprenorphine in community treatment programs," *Substance Abuse Treatment Prevention Policy*, Vol. 3, No. 1, 2008, pp. 17–27; T.L. Mark, R. Lubran, E.F. McCance-Katz, M. Chalk, and J. Richardson, "Medicaid Coverage of Medications to Treat Alcohol and Opioid Dependence," *Journal of Substance Abuse Treatment,* 2015.

[14] Dick et al., 2015; Stein et al, 2015a; Stein et al., 2015b; Ducharme and Abraham, 2008.

[15] B.D. Stein, M. Sorbero, A.W. Dick, R.L. Pacula, R.M. Burns, and AJ Gordon (). "Underutilized Physician Capacity to Treat Opioid Use Disorder with Buprenorphine Opioid Agonist Medication Assisted Treatment," *Journal of the American Medical Association*, Vol. 316, No. 11, 2016, pp. 1211–1212.

[16] J.D. Baxter, R.E. Clark, M. Samnaliev, G. Aweh, E. O'Connell, "Adherence to Buprenorphine Treatment Guidelines in a Medicaid Program," *Substance Abuse,* Vol. 36, No. 2, 2015, pp. 174–182; A.J. Gordon, W. Lo-Ciganic, G. Cochran, W. Gellad, T. Cathers, D. Kelley, and J. Donohue, "Patterns and Quality of Buprenorphine Opioid Agonist Treatment in a Large Medicaid Program," Vol. 9, No. 6, 2015, pp. 470–477; American Society of Addiction Medicine, *The National Practice Guideline For the Use of Medications in the Treatment of Addiction Involving Opioid Use.* Chevy Chase, Md., 2015.

therapy, such as those currently being considered by CMS and AHRQ, could be just as important as expanding treatment.[17]

Expanding Availability of Naloxone

Naloxone is a medication that, when used immediately following an opioid overdose, can counter the life-threatening effects caused by depression of the central nervous system. Despite a push by the prior administration to expand access to naloxone as part of its opioid initiative, there remains considerable debate amongst clinicians, policymakers and researchers about whether providing education and naloxone kits does in fact save lives or instead discourages treatment and causes harm (by reducing interactions with emergency health care providers and/or encouraging increasing risky behavior).[18] There is a growing body of evidence that naloxone can be safely administered by first responders and laypersons who are properly educated and trained in its administration, resulting in a life saved from a specific overdose episode.[19] However, what remains unclear due to limited evidence is whether these programs lead to an increase or reduction in overall rates of opioid overdose, including fatal overdoses, within a community.[20] I

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[17] R. Chou, P.T. Korthuis, M. Weimer, C. Bougatsos, I. Blazina, B. Zakher, S. Grusing, B. Devine, and D. McCarty, *Medication-Assisted Treatment Models of Care for Opioid Use Disorder in Primary Care Settings*, Technical Brief No. 28, Rockville, Md.: Agency for Healthcare Research and Quality, December 2016; P.T. Korthuis, D. McCarty, M. Weimer, C. Bougatsos, B. Zakher, S. Grusing, B. Devine, and R. Chou, "Primary Care-Based Models for the Treatmetn of Opioid Use Disorders: A Scoping Review," *Annals of Internal Medicine*, Vol. 166, 2017, pp. 268–278.

[18] Assistant Secretary of Policy Evaluation, *Issue Brief: Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths,* Washington, D.C., 2015; A.J. Ashworth and A. Kidd, "Take Home Naloxone for Opiate Addicts. Apparent Advantages May Be Balanced by Hidden Harms," *BMJ*, Vol. 323, No. 7318, 2001, p. 935; D. Mountain, "Take Home Naloxone for Opiate Addicts. Big Conclusions Are Drawn from Little Evidence," *BMJ*, Vol. 323, No. 7318, 2001, p. 934, author reply 935; A.R. Bazazi, N.D. Zaller, J.J. Fu, and J.D. Rich, "Preventing Opiate Overdose Deaths: Examining Objections to Take-Home Naloxone," *Journal of Health Care of the Poor and Underserved*, Vol. 21, No. 4, 2010, pp. 1108–1113.

[19] A.K. Clark, C.M. Wilder, and E.L. Winstanley, "A Systematic Review of Community Opioid Overdose Prevention and Naloxone Distribution Programs," *Journal of Addiction Medication*, Vol. 8, No. 3, 2014, pp. 153–163; R. Fisher, D. O'Donnell, B. Ray, and D. Rusyniak, "Police Officers Can Safely and Effectively Administer Intranasal Naloxone," *Prehospital Emergency Care*, Vol. 20, No. 6, 2016, pp. 675–680; D.P. Wermeling, "Review of Naloxone Safety For Opioid Overdose: Practical Considerations For New Technology And Expanded Public Access," *Therapeutic Advances in Drug Safety,*. Vol. 6, No. 1, 2015, pp. 20–31; M. Doe-Simkins, E. Quinn, Z. Xuan, A. Sorenson-Alawad, H. Hackman, A. Ozonoff, and A. Walley, "Overdose Rescues by Trained and Untrained Participants and Change in Opioid Use Among Substance-Using Participants In Overdose," *BMC Public Health*, Vol. 14, No. 297, 2014.

[20] D.P. Wermeling, "Review of Naloxone Safety for Opioid Overdose: Practical Considerations for New Technology and Expanded Public Access," *Therapeutic Advances in Drug Safety*, Vol. 6, No. 1, 2015, pp. 20–31; S.M. Bird, A. Mcauley, S. Perry, and C. Hunter, "Effectiveness of Scotland's National Naloxone Programme for reducing opioid-related deaths: A before (2006–10) versus after (2011–13) comparison," *Addiction*, Vol. 111, No. 5, 2016, pp. 883–891; A.Y. Walley, Z. Xuan, H. H. Hackman, E. Quinn, M. Doe-Simkins, A. Sorensen-Alawad, S. Ruiz, and A. Ozonoff, "Opioid Overdose Rates and Implementation of Overdose Education and Nasal Naloxone Distribution in Massachusetts: Interrupted Time Series Analysis," *BMJ*, Vol. 346, 2013, p. 174; A. McAuley, J. Bouttell, L. Barnsdale, D. Mackay, J. Lewsey, C. Hunter, and M. Robinson, "Evaluating the Impact of a National Naloxone Programme on Ambulance Attendance at Overdose Incidents: A Controlled Time–Series Analysis," *Addiction*, Vol. 112, No. 2, 2017, pp. 301–308.

am aware of only two U.S. studies that have looked at the impact of naloxone distribution on overall opioid mortality as an outcome. One of the studies looked narrowly at a training and distribution program adopted within specific communities in Massachusetts, and found the program did in fact reduce annual community levels of opioid-related mortality with no statistical increase in the rate of acute care hospital utilization, suggesting the program was effective at reducing overall harm.[21] However, the study did not have a within-state control group, making it unclear if the findings were truly attributable to the program and not to broader aggregate trends. A very recent National Bureau of Economic Research working paper used a much more-sophisticated, quasiexperimental design, exploiting variation in state laws providing legal protections for naloxone prescribing and/or administration[22]. The authors of this study found that state adoption of naloxone laws was associated with a 9- to 11-percent reduction in opioid-related deaths overall. Findings from this study are perhaps the most supportive of an overall positive effect, but more research is needed to evaluate if these findings can be replicated in other data.

Enhancing Prescription-Drug Monitoring Programs

Prescription drug monitoring programs (PDMPs) have been promoted by the federal government to improve safety in opioid analgesic prescribing; help identify diversion of these medications; and reduce the harm associated with opioid analgesic abuse, including fatal and nonfatal overdoses.[23] As such, evaluations of their effectiveness have considered a variety of different behaviors and outcomes, including physician prescribing, patient behavior (doctor and pharmacy shopping), and broader population health outcomes, including fatal and nonfatal overdoses and admissions to substance abuse treatment.

While several studies have demonstrated the utility of proactive PDMPs at changing physician prescribing, the effectiveness of PDMPs at reducing the misuse and harm associated with prescription opioids continues to be assessed, as the current literature remains inconclusive about their effects.[24] There are a variety of legitimate reasons why previous studies have failed to

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[21] Walley et al., 2013.

[22] D.I. Rees, J.J. Sabia, L.M. Argys, J. Latshaw, and D. Dave, *With a Little Help from My Friends: The Effects of Naloxone Access and Good Samaritan Laws on Opioid-Related Deaths*, Cambridge, Mass.: National Bureau of Economic Research, 2017.

[23] Centers for Disease Control and Prevention, "Prescription Drug Monitoring Programs (PDMPs)," March 2017; Government Accountability Office, "Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion," May 2002; Executive Office of the President, "Epidemic: Responding to America's Prescription Drug Abuse Crisis," 2011.

[24] Y. Bao, Y. Pan, A. Taylor, S. Radakrishnan, F. Luo, H.A. Pincus, and B.R. Schackman, "Prescription Drug Monitoring Programs Are Associated With Sustained Reductions in Opioid Prescribing by Physicians," *Health Affairs (Millwood)*, Vol. 35, No. 6, 2016, pp. 1045–1051; D.F. Baehren, C.A. Marco, D.E. Droz, S. Sinha, E.M. Callan, and P. Akpunonu, "A Statewide Prescription Monitoring Program Affects Emergency Department Prescribing Behaviors," *Annals of Emergency Medicine,* Vol. 56, No. 1, 2010, pp. 19–23; C. Ringwalt, M. Garrettson, and A. Alexandridis, "The Effects of North Carolina's Prescription Drug Monitoring Program on the Prescribing Behaviors of the State's Providers," *Journal of Primary Prevention*, Vol. 36, No. 2, 2015, pp. 131–137; G.G. Franklin, J. Sabel, C.M. Jones, J. Mai, C. Baumgartner, C.J. Banta-Green, D. Neven, and D.J. Tauben, "A

generate conclusive results, particularly at the population level. First, while there has been wide adoption of state PDMPs, early state adopters were fundamentally different than the programs that exist today. For example, many early states did not require real-time updates or reporting of the system, making the timely dissemination of information or utility for identifying physician and pharmacy shopping limited.[25] Similarly, states tend not to require PDMP participation; as of May 2016, only 29 states require prescribers to register.[26] Moreover, only 34 of the states with PDMPs mandate their use by prescribers or dispensers who are registered in the state.[27] Thus, it is not surprising to see that in a recent nationally representative survey of primary care providers, only 54 percent made use of their state's PDMP program despite a much larger share actually being aware of them.[28]

Research on the differences between state PDMP programs will help us understand the impacts of different PDMP programs and identify how to enhance existing programs. Recent scientific evaluations are starting to do just that, and findings from these studies suggest that PDMPs can be effective at achieving their goals of reducing prescription opioid misuse and harm.[29]

Establishing Guidelines for Safe Opioid Prescribing

Overprescribing of opioids—providing more days' supply or much-higher dosages than what is commonly required to manage pain in most people, or prescribing opioids before trying alternative methods of pain control—has been shown to be a major risk factor for the

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Comprehensive Approach to Address the Prescription Opioid Epidemic in Washington State: Milestones and Lessons Learned," *American Journal of Public Health*, Vol. 105, No. 3, 2015, pp. 463–469; T.M. Haegerich, L.J. Paulozzi, B.J. Manns, and C.M. Jones, "What We Know, and Don't Know, About the Impact of State Policy and Systems-Level Interventions on Prescription Drug Overdose," *Drug and Alcohol Dependence*, Vol. 145, 2014, pp. 34–47; J.E. Brady, H. Wunsch, C. DiMaggio, B.H. Lang, J. Giglio, and G. Li, "Prescription Drug Monitoring and Dispensing of Prescription Opioids," *Public Health Reports*, Vol. 129, No. 2. 2014, 139–147; L.J. Paulozzi, E.M. Kilbourne, and H.A. Desai, "Prescription Drug Monitoring Programs and Death Rates from Drug Overdose," *Pain Medicine*, Vol. 12, No. 5, 2011, pp. 747–754; L.M. Reifler, D. Droz, J.E. Bailey, S.H. Schnoll, R. Fant, R.C. Dart, B. Bucher Bartelson, "Do Prescription Monitoring Programs Impact State Trends in Opioid Abuse/Misuse?" *Pain Medicine*, Vol. 13, No. 3, 2012, pp. 434–442; R. Simeone and L. Holland, "An Evaluation of Prescription Drug Monitoring Programs," 2006.

[25] S.W. Patrick, C.E. Fry, T.F. Jones, and M.B. Buntin, "Implementation of Prescription Drug Monitoring Programs Associated with Reductions in Opioid-Related Death Rates," *Health Affairs*, Vol. 35, No. 7, 2016, pp. 1324–1332.

[26] National Alliance for Model State Drug Laws, "States that Require All Licensed Prescribers and/or Dispensers to Register with the State PDMP," May 2016.

[27] National Alliance for Model State Drug Laws, "Mandated Use of State Prescription Drug Monitoring Programs: Specified Circumstances Requiring Prescribers/Dispensers to Access PMP Data," November 2017.

[28] L. Rutkow, L. Turner, E. Lucas, C. Hwang, and G.C. Alexander, "Most Primary Care Physicians Are Aware of Prescription Drug Monitoring Programs, but Many Find the Data Difficult to Access," Health Affairs (Millwood), Vol. 34, No. 3, 2015, pp. 484–492.

[29] B. Pardo, "Do More Robust Prescription Drug Monitoring Programs Reduce Prescription Opioid Overdoses?" *Addiction*, 2017; Patrick et al., 2016; M.M. Ali, W.N. Dowd, T. Classen, R. Mutter, and S.P. Novak, "Prescription Drug Monitoring Programs, Nonmedical Use of Prescription Drugs, and Heroin Use: Evidence from the National Survey of Drug Use and Health," *Addictive Behaviors*, Vol. 69, 2017, pp. 69–77; Simeone and Holland, 2006.

development of an opioid use disorder.[30] Potentially inappropriate prescribing, which includes prescribing overlapping opioid analgesics and benzodiazepines, has also been verified in studies of both publicly and privately insured populations.[31]

Efforts to reduce these problems have largely emphasized the adoption of clinical guidelines for safe opioid prescribing. I am aware of only a couple of studies that focused on evaluating the impact of just adopting these sorts of guidelines, and both studies focused on effects within a single state. One study shows that implementation of these tools in Washington's workers' compensation system led to a 27-percent reduction in the morphine equivalent doses per day and a 35-percent reduction in the proportion of workers on high doses.[32] Another study evaluated the state's adoption of a PDMP and showed that the guidelines alone helped reduce opioid related fatalities by 27 percent between 2008 and 2012.[33]

However, a recent evaluation of the Veterans Affairs (VA) Health Administration Opioid Safety Initiative demonstrated that system-wide adoption of clinical guidelines, including directives for stepped pain treatment and the adoption of a risk management tool to hold clinicians accountable for their prescribing practices, when coupled with other strategies for managing chronic pain patients and improving access to opioid treatment, led to a 25-percent decline in the number of veterans prescribed an opioid within the VA system, a 36-percent reduction in patients receiving inappropriately high opioid doses, and a 47-percent reduction in simultaneous, inappropriate prescription of opioids and benzodiazepines.[34] Perhaps even more significantly, there was a 50-percent drop in the rate of overdose deaths among veterans prescribed an opioid after program adoption. This strongly suggests that system-wide adoption of clinical guidelines, when coupled with effective education and training, can be very effective at changing physician practice, reducing inappropriate prescribing, in a manner that might actually improve patient health.

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[30] M.J. Edlund, B.C. Martin, J.E. Russo, A. DeVries, J.B. Braden, and M.D. Sullivan, "The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Noncancer Pain: The Role of Opioid Prescription," *Clinical Journal of Pain*, Vol. 30, No. 7, 2014, pp. 557–564.

[31] B.D. Stein, J. Mendelsohn, A.J. Gordon, A.W. Dick, R.M. Burns, M. Sorbero, R.A. Shih, and R.L. Pacula, "Opioid Analgesic And Benzodiazepine Prescribing Among Medicaid-Enrollees with Opioid Use Disorders: The Influence of Provider Communities," *Journal of Addictive Diseases*, Vol. 36, No. 1, pp. 14–22; K.M. Dunn, K.W. Saunders, C.M. Rutter, C.J. Banta-Green, J.O. Merrill, M.D. Sullivan, C.M. Weisner, M.J. Silverberg, C.I. Campbell B.M. Psaty, and M. Von Korff, "Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study," *Annals of Internal Medicine*, Vol. 152, No. 2, 2010; pp. 85–92; J. Logan, Y. Liu, L. Paulozzi, K. Zhang, and C. Jones, "Opioid Prescribing in Emergency Departments: The Prevalence of Potentially Inappropriate Prescribing and Misuse," *Med Care*, Vol. 51, No. 8, 2013, pp. 646–653; L.J. Paulozzi, G.K. Strickler, P.W. Kreiner, C.M. Koris, Centers for Disease Control and Prevention, "Controlled Substance Prescribing Patterns—Prescription Behavior Surveillance System, Eight States, 2013," *MMWR Surveillance Summaries,* Vol. 64, No. 9, 2015, pp. 1–14.

[32] G.M. Franklin, J. Mai, J. Turner, M. Sullivan, T. Wickizer, and D. Fulton□Kehoe, "Bending the Prescription Opioid Dosing and Mortality Curves: Impact of the Washington State Opioid Dosing Guideline," *American Journal of Industrial Medicine*, Vol. 55, No. 4, 2012, pp. 325–331.

[33] Franklin et al., 2015.

[34] W.F. Gellad, C.B. Good, and D.J. Shulkin, "Addressing the Opioid Epidemic in the United States: Lessons From the Department of Veterans Affairs," *JAMA Internal Medicine*, 2017.

Concluding Remarks

Under ideal circumstances, decisions are made based on solid evidence related to effectiveness, including cost-effectiveness calculations. However, at this time it is impossible to apply such strong criteria to funding decisions for the opioid epidemic. So much more information is needed regarding where we actually are in the opioid epidemic and how the use of heroin and opioid analgesics interact. Additionally, we need to better understand the true effectiveness of various programs in light of the changing state and local environments in which they are implemented. What works in some communities may not be particularly effective in others, due to demographic differences, epidemic stage, and/or existing policies that are already in place. Much scientific work is needed to disentangle these things before firm recommendations based on strong science can be offered. Nonetheless, budgetary decisions need to be made today.

My remarks are intended to provide insights regarding the probable effectiveness of key strategies already undertaken by agencies funded by this subcommittee. There are many other strategies to consider as well. In general, we know that demand-side interventions, including treatment and prevention, are cost-beneficial.[35] Moreover, as these strategies generally apply to use of any opioid, they provide the least risk of unintended consequences in terms of pushing individuals into black markets. We also know that many supply-side strategies, at least those targeting diversion of prescription opioids, have reduced the amount of opioids available in the market, although these strategies possibly have unintended consequences when they target only specific opioids (e.g., Schedule II opioids only included in PDMPs, rather than all opioids; abuse-deterrent formulations of OxyContin).[36] A combined approach that considers both demand and supply seems justified. Harm reduction strategies, such as naloxone distribution, should not be ignored. While they may come with some risk (e.g., engaging in more opioid abuse because of less risk of overdose), those hypothesized effects have not yet been scientifically demonstrated, and studies suggest the opposite may in fact be the case.

When making budgetary decisions, bear in mind that some policies, including prevention and treatment, take time before their effects are fully observed in aggregate prevalence numbers. Moreover, natural dynamics influence these epidemics beyond the policies we adopt to try to influence them. Given the availability of both legal and illicit opioid products in many communities, we must be particularly concerned about policies that target just one part of the opioid problem (e.g., prescription opioids) in one particular system (e.g., the VA or Medicaid); singular approaches that only target one of these products or in one health system could generate

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[35] G.A. Zarkin, L.J. Dunlap, K.A. Hicks, and D. Mamo, "Benefits and Costs of Methadone Treatment: Results from a Lifetime Simulation Model," *Health Economics*, Vol. 14, No. 11, 2005, pp.1133–1150; J.P. Caulkins, R.L. Pacula, S. Paddock, and J. Chiesa, "What We Can—and Cannot—Expect from School-Based Drug Prevention," *Drug and Alcohol Review*, Vol. 23, No. 1, 2004, pp.79–87.

[36] D. Powell and R.L. Pacula "Prescription Opiates and Opioid Abuse: Regulatory Efforts to Limit Diversion from Medical Markets to Black Markets in the United States," in E. Savona and M.A.R. Kleiman, eds., *Dual Markets—Comparative Approaches for Regulation*, New York: Springer, forthcoming.

substitution across drugs or across health systems.[37] Moreover, some highly restrictive supply side strategies, such as those that limit opioid prescriptions to five- or seven-day dosages, may make it very difficult for patients with legitimate needs to obtain medication. Supply strategies, whether implemented through the medical system or through law enforcement, must consider all of these things. That is why it is truly difficult to find the right balance of policies for managing the opioid epidemic.

Thank you for inviting me to testify before you today, and I welcome the opportunity to answer any questions you may have.

[37] Alpert, Powell, and Pacula, 2017; Cicero, Ellis, and Surratt. 2012; W.F. Gellad, X. Zhao, C.T. Thorpe, J.M. Thorpe, F.E. Sileanu, J.P. Cashy, M. Mor, J.A. Hale, T. Radomski, L.R. Hausmann, and M.J. Fine, "Overlapping Buprenorphine, Opioid, and Benzodiazepine Prescriptions Among Veterans Dually Enrolled in Department of Veterans Affairs and Medicare Part D," *Substance Abuse*, Vol. 38, No. 1, 2017, pp. 22–25.