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A Strategy to Counter the Opioid Epidemic: Contain, Reduce, Extinguish

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Table of Contents

Introduction	3
Synopsis of the National Problem	5
Heroin	5
Diverted/Misused Medications	6
Black-Market Synthetic Opioids	7
Effective Response to an Immediate Crisis: Southern	9
Indiana	
Overdose Intervention and Treatment	10
Naloxone	10
Medication Assisted Therapies	10
Supervised Injection Facilities	11
Prevention Initiatives: Messaging and the Marijuana Market	13
Conclusion	14

Introduction

he opioid crisis has worsened rapidly since 2010 and continues unchecked. It has been driven by an increase in the supply of opioid substances and expanded use, as well as the known consequences of that use—most troubling, addiction and overdose deaths.

Persistent, long-term use of opioids frequently leads to an opioid disorder—in everyday language, opioid or heroin addiction. Unfortunately, there are no current, national estimates of the extent and intensity of the opioid epidemic. According to the December 31, 2015 White House National Heroin Task Force Final Report, in 2014 there were an estimated 1.9 million people who met diagnostic criteria for prescription opioid use disorder and an estimated 586,000 who met criteria for a heroin use disorder.

An estimate of the extent (or prevalence) of opioid use for the year 2015 can be found in the 2016 National Survey on Drug Use and Health NSDUH. This survey may greatly understate the true extent of opioid use, however, because it is limited to individuals residing in households and willing to participate in the survey. Many troubled drug users cannot or will not be captured by such methodology.

The most dangerous result of greater opioid use is the <u>increase</u> in overdose episodes, a substantial proportion of which result in death. Deaths from all drug-induced causes, and particularly the opioid overdose death totals, are now at unprecedented levels (of 52,404 Americans who died in 2015 from drug-induced causes, more than 33,091 deaths were attributable to opioids).

According to the Centers for Disease Control and Prevention (CDC) <u>WONDER</u> data base (accessed online), opioid overdose deaths have increased since 2008 by 69 percent (19,582 to 33,091). This rapid rise suggests three conclusions:

- 1. The threat has changed and worsened with the appearance and wider use of new opioid drugs.
- 2. Earlier policies of proven drug control effectiveness have either been neglected in recent years or abandoned.
- 3. New policies and mechanisms are required to overcome the unprecedented threat.

The most urgent need is to stop overdose deaths and reduce the supply of illicit opioid drugs that are now lethal poisons. Current strategies have primarily sought to mitigate the impact of use disorders.

Strategic efforts against the opioid threat require much better information. Current data are inadequate to measure the impact of policies. Consider that at this writing in early 2017, national reporting from the CDC on drug overdose data is no more recent than the end of 2015. Evidence for increased deaths for 2016 has already been observed at the state level, but it is not yet compiled on a national basis.

Under these conditions, the impact of policy changes effected this year will not be reported until 2018-19, at the earliest. This is utterly inadequate to combat a rapidly moving epidemic.

To contain and counter the epidemic, individuals working at the federal, state, and local level need a national surveillance and monitoring system, approaching real-time reporting, with local geographic coding and mapping. One way to build such a system would be to develop standardized collection and reporting criteria for the growing number of state health departments now compiling and analyzing overdose incidents on a quarterly basis. Critical "sentinel states" with the highest rates of overdose deaths could be collocated into interim reports that, while still retrospective, could constitute an improved "early warning" response, perhaps tied to the CDC "HAN," or Health Alert Network. Recent work by the High Intensity Drug Trafficking Areas (HIDTA) fusion cells that combine law enforcement agencies with public health resources have also been promising, developing measures for time-stamping and geo-locating regional overdose incident reporting.

In addition, since existing federal data sets are retrospective and lacking in geographic and temporal texture, authorities need to develop additional and novel monitoring and data-set capacities able to detect (and even predict) emerging trends. Such reporting should then be used to target drug control resources, from law enforcement to medical interventions and treatment provisions, allowing a response to specific outbreaks that is proportional to and directed at the location of the threat. Information sources should include public health resources comparable to those of the CDC and the National Institute on Drug Abuse (NIDA); these data should be integrated with law enforcement and judicial resources, through entities such as the Drug Enforcement Administration (DEA), the nationwide HIDTA networks, Drug Courts, and prison release/probation/parole programs providing drug treatment.

Establishing a common, detailed understanding of the epidemic in real time is critical to deploying effective responses to contain and reverse the current rates of addiction and death.

Synopsis of the National Problem

The current opioid crisis has three distinct substance profiles:

- 1. Illicit opioid markets and use, traditionally heroin;
- 2. Misused (or diverted) prescription pharmaceutical opioids, often related to medical practice; and
- 3. Novel illicit synthetic opioids, remarkably lethal, such as fentanyl and its multiple analogs, which initially appeared as adulterants to heroin, but now are found increasingly in the form of a <u>counterfeit</u> pharmaceutical products.

Each of these three parts of the epidemic presents a unique threat and follows its own trajectory.

Heroin

The profile of heroin use shows that the market is of long-standing, experiencing a dramatic recent upsurge, clearly correlated with sharply rising heroin production, particularly from Mexico. Between 2013 and 2015, Mexican potential pure heroin production rose 160 percent (from 26 to 70 metric tons—an estimate far in excess of standard assumptions for total US heroin consumption).

Between 2008 and 2015, moreover, while total drug-induced deaths have risen 44 percent (currently at 52,404), the majority of which implicate all three opioid dimensions, the strictly heroin deaths have increased 327 percent (standing at 12,990 as of 2015, out of 33,091 total opioid deaths).

As the CDC <u>reported</u> in February, 2017, the opioid <u>contribution</u> to the overall drug-induced deaths in 2010 stood at 56 percent of the total. By 2015, they accounted for fully 74 percent (a growth in the opioid share of all deaths of almost one-third).

During that time period the deaths for strictly prescription opioids such as Oxycodone and hydrocodone have fallen as a percentage of the total, from 29 percent in 2010 to 24 percent in 2015. Hence, their proportioned share of the total is subsiding as a rate; at the same time, the raw number of total deaths attributed to strictly prescription opioids has flattened. CDC WONDER shows 12,159 deaths for 2014, and 12,727 for 2015.

The rate of strictly heroin overdose deaths, meanwhile, has tripled during that same time period, from 8 percent in 2010 to 25 percent of all drug-induced <u>deaths</u> in 2015 (from 3,036 deaths to 12,989).

Notwithstanding the impact of heroin production and trafficking, recent drug control strategies have neglected the international sources of this problem. The Obama Administration's National Heroin Task Force Final Report and Recommendations, while stressing doctor prescribing practices, notes that their entire report, by design, does not address international heroin sources or trafficking. Instead, the document is

"focused exclusively on addressing the domestic dimensions of the opioid epidemic and proposing domestic solutions to the crisis."

This approach cannot be adequate. <u>Heroin</u>, as seen in intelligence-driven production <u>estimates</u> and in interdiction/seizure statistics, has become not only abundant nationally, but significantly more pure and potent. At the same time heroin has been dropping in price, especially as new forms of the drug (white and purer) have supplanted, in some demographics, traditional Mexican black-tar heroin, of lower quality.

Moreover, the demographics of traditional heroin use (and consequent overdose impact) have shifted, moving from a largely minority-focused inner-city crisis, concentrated in the urban northeast, to a <u>pattern</u> now breaking out into wider social, racial/ethnic, and geographic dispersal.

This "breakout" can be correlated not only with increased Mexican heroin production but further with the presence of Mexican/Central-American-based trafficking networks, intensified by immigration patterns, many of which are clearly linked to Mexican cartelaffiliated criminal gangs now found nationwide.

Recommendations:

- Efforts to stem the strictly heroin dimension of the opioid epidemic should include greater/renewed efforts to control cultivation and initial production through partnerships with Mexico—and to forestall an even larger future problem, Afghanistan.
- These efforts should include stronger interdiction and border controls, and increased efforts at striking at Mexican trans-national cartels.
- Further, effective supply control should include strengthened enforcement against Mexican-controlled and allied domestic trafficking gangs.
- Reducing the supply and availability of opioids, and the networks of trafficking, are imperative as a primary component of any opioid drug control strategy.

Diverted/Misused Medications

Prescription opioid misuse associated with medical practice was an emerging threat that had increased steadily from 1995, reaching a peak in misuse around 2006, with a peak in overdose deaths for the year 2011.

Now that strictly synthetic fentanyl overdose deaths are correctly categorized in the death toll data as derived from illicit manufacture, we can <u>observe</u> that deaths associated with medical practice have <u>stabilized</u>.

This positive trend is substantially a result of efforts to limit prescribing practices; expanded Prescription Drug Monitoring Programs (PDMPs) that have reduced "doctor shopping;" DEA take-downs of illicit (and often on-line) "pill mills;" and the

introduction of abuse-resistant formularies of some medications — that is, the supply and availability of prescription opioids were sharply curtailed.

Yet because these are often legitimate medicines, a balance must be maintained. Tighter drug scheduling and prescribing restrictions should not unduly impede legitimate access to opioid medications in acute and chronic conditions. A key criterion for sound policy should be the presence of supervised medical care.

Recent restrictions have led some to charge an unintended consequence of stimulating greater heroin use. There is evidence that some initial users of prescription opioids transitioned to the use of illicit opioids when faced with <u>constraints</u>. A percentage of new <u>initiates</u> of heroin, for instance, report beginning opioid misuse with prescription pills.

But the extent of this "cross-over" is not well-known, as many opioid users are poly-drug users who avail themselves of whatever opioids the market provides. A recent National Epidemiological Survey on Alcohol and Related Conditions (NESARC) <u>report</u> shows that between 2001-2002 and 2012-2013, the proportion of those reporting initiation of nonmedical use of prescription opioids before initiating heroin use increased across time (among white individuals) from 36 percent to 53 percent.

Recommendations:

- It is reasonable to conclude that, at the least, the sheer magnitude of opioid prescriptions facilitated the "breakout" of illicit opioid use into new populations. Prescribing practices and patterns need review to reduce the excessive use and misuse of opioid medications while maintaining responsible medical care.
- Curtailing new entrants into opioid medication abuse should be the priority response with tighter prescribing practices, while longer-term existing patients should be carefully supervised and such prescribing subject to PDMPs at the state level.
- Even with PDMPs in place, more must be done. An integrated national system
 must be established to quickly identify and arrest unscrupulous physicians and
 shut down illicit pharmacies.
- As even the recent best-selling book Dreamland by Sam Quinones notes, there is abundant evidence that public Medicaid funds are being used to support addiction and criminal diversion, the federal government should fully investigate the role and scope of public funds in pharmaceutical abuse.

Black-Market Synthetic Opioids

Use of novel synthetic opioids, such as fentanyl and its analogs, has risen rapidly, with shocking lethality. They may soon eclipse heroin as a cause of overdose deaths, given that associated deaths have <u>surged</u> 79 percent between 2013 and 2014, alone, and that rise continues through 2017.

Synthetics present unique drug control problems. A recent <u>alert</u> from the DEA characterized the drug as "an unprecedented threat."

Since they are of chemical manufacture, their production is difficult to detect, as no fields of poppy can be observed in source countries, as with heroin. And owing to their extreme potency, they can be <u>smuggled</u> in small packages that also present acute dangers to enforcement personnel.

Most are manufactured in illicit or "rogue" labs in a manner comparable to methamphetamine, and likewise rely on international chemical precursors often with licit industrial uses—hence, some of these chemicals are difficult to restrict legally.

The DEA is seeking greater legislative measures allowing them to <u>control</u> broader classes of precursor chemicals, as they now find themselves in a near-futile "chase" with illicit manufacturers who constantly seek novel chemical formulations that skirt the law.

Currently both the US and Canada face a smuggling threat (including mail packages) traceable to China, with additional production in Mexico. The Customs and Border Commission revealed in Congressional <u>testimony</u> that southwest border seizures of the drug rose from 2.4 pounds in 2013 to 198 pounds in 2015, while <u>prosecution</u> "exhibits" of fentanyl rose from a handful to over 13,000 cases, rising 65 percent between 2014 and 2015 alone.

Recommendations:

- State coroners/medical examiners and national labs should develop forensic drug testing to more rapidly and systematically identify novel opioid and related substances.
- Overdose death surveillance data (and Naloxone utilization) should be collected into national real-time reporting, which should be integrated with CDC and NIDA capacities.
- In addition to legislative pressures on chemical bans, efforts to restrict these smuggling operations depend on broader enforcement capacity, and should include stronger international pressure and coordination with producer nations.
- In addition to stronger border controls, international postal packages should present electronic information prior to arrival in the US, permitting more systematic package inspection protocols and more effective shipment interception.
- Partnerships with chemical producer nations such as China, and greater cooperation against drug production in Mexico, requiring both eradication of marijuana and opium crops and stronger chemical controls, are each imperative. The recent international United Nations meeting of the Commission on Narcotic Drugs (CND), the US, in coordination with partner nations, developed resolutions to control fentanyl and its analogs internationally.
- Model efforts against a similar chemical-based drug threat in Florida, involving the synthetic cathinone "Flakka," led to a joint Chinese/DEA/State of Florida initiative that drastically reduced the supply and the deadly impact. These

effective practices should be adapted and deployed on the widest scale against black-market, synthetic opioids.

Effective Response to an Immediate Crisis—Lessons of Southern Indiana

In mid-2015, public health and law enforcement authorities in southern Indiana encountered a <u>crisis</u> of spreading injection drug use (Oxymorphone in the form of Opana) that precipitated an HIV outbreak through contaminated syringes. The outbreaks were linked to a methamphetamine-trafficking ring from nearby urban areas that had targeted vulnerable rural communities.

The outbreak was devastating and tragic, but the subsequent mobilization of both public health and law enforcement resources offers a compelling lesson in how to contain and then push back against the threat. Multiple agencies combined their resources to form a comprehensive rapid response. Subsequent to the outbreak, community analyses were performed to diagnose social and economic dimensions of the risk factors. Because HIV is an infectious and notifiable disease, the CDC was quick to signal <u>alerts</u> through their Mortality and Morbidity Weekly Reports (MMWR). <u>Epidemiological</u> tools such as tracing of contacts were brought to bear, along with the realization that the crisis was "preventable."

NIDA <u>responded</u> through their National Drug Early Warning System (NDEWS) built on the work of their Community Epidemiology Working Groups (CEWG) that monitor and report on emerging drug trends with an account of the outbreak, tying it to the drug Opana. Equally important, local, state, and national law enforcement entities, ranging from <u>sheriffs</u>' offices to the <u>DEA</u> and the resources of the Department of <u>Justice</u> and nationwide HIDTA fusion centers were mobilized into a strike force that collapsed the underlying trafficking networks.

Through this comprehensive response, the trafficking supply chains were broken, and focused treatment and recovery services were mobilized to stem and stabilize the dual public health threats of the drugs and the consequent blood-borne pathogen infections.

Overdose Intervention and Treatment

o date, the federal response to the opioid crisis has been inadequate, relying on efforts to mitigate the impact on individuals without addressing the underlying causes of the epidemic.

Naloxone

The widespread dispersal and administration of overdose antidote Naloxone, substantially expanded during the Obama Administration, is credited with successful overdose reversals; clearly, timely Naloxone administration saves lives. This fact must be provided with several *caveats*, however, which indicate that a Naloxone-based strategy is insufficient to meet the current crisis.

First, Naloxone administration does not reduce the number of opioid overdose events; rather, it may prevent a death in a particular episode. In the aggregate, opioid users may return to their use patterns after revival, with the result of deferring the timing of an overdose death, not saving the individual in the longer term. Moreover, there may be risk of eroding "deterrence" effects for either initial or subsequent drug use if the presence of Naloxone encourages higher-risk opioid practices, a constant threat because of drug tolerance connected to opioid use and abuse.

There is also no strong evidence that a Naloxone episode leads individuals to enter drug treatment. This failure to tie emergency care to treatment is worsened by policies promoting Naloxone distribution and use by people other than first-responders with medical training.

Further, research indicates that a substantial percentage of those who overdose on prescription opioids <u>continue</u> to receive subsequent opioid prescriptions, often from the original prescriber, just as there is ample indication that a single opioid user may return again and again to the overdose condition after the initial episode.

Finally, with the advent of the novel synthetic opioids of greatly enhanced potency relative to heroin, Naloxone administration is increasingly inadequate for revival. The CDC <u>notes</u>, regarding a recent multiple-patient fentanyl episode in New Haven, that the drug was "refractory" for Naloxone, requiring doses exceeding 4 mg, compared to a usual dose of 0.1-0.2 mg intravenously. One patient even required a continuous Naloxone infusion. Several patients nonetheless died, while others suffered major organ damage.

Simply put, Naloxone deployment is not alone a sufficient strategy, but must be supplemented with a comprehensive treatment and prevention strategy.

Medication Assisted Therapies

With respect to opioid treatment, a principal response to date has been amplifying Medication Assisted Therapy (MAT). The objective is to provide substitute opioid

substances such as buprenorphine or methadone as a treatment provision, seeking to dampen illicit drug use (or pharmaceutical misuse), using the substitute as a means of "retention in treatment."

It is essential to note that this "medication-assist" is not currently available for any drug threat other than opioids. This means we must rely on strengthened treatment modalities beyond methadone or buprenorphine to treat those addicted to multiple drugs (so called, poly-drug users) and for a comprehensive drug threat response.

Perspectives differ as to whether the MAT substitution for opioids should be used temporarily to stabilize the drug user and transition them to abstention, or is to be regarded as a goal-state for treatment outcomes. The movement to regard opioid misuse/drug addiction as a "chronic, relapsing condition" in near perpetuity has influenced this debate. But the debate continues and there is insufficient, extended longitudinal research to settle the question.

It is dismaying to note recent <u>evidence</u> that more than 40 percent of those receiving buprenorphine for opioid disorder treatment were simultaneously being prescribed other opioids. For those completing treatment, that figure rose to two-thirds. Such evidence presents a challenge to the presumed goals of an MAT-based treatment policy.

Supervised Injection Facilities

A recent development in this regard is the argument by some in the treatment community that since MAT has a mixed record preventing relapse to illicit opioid use (and the realization that methadone presents an exacerbated lethality profile, itself implicated in a large percentage of overdose deaths), therefore the treatment response should be to provide government-authorized heroin itself as the form of "MAT."

Such developments are often accompanied by "harm reduction" calls for Supervised (or Safe) Injection Facilities where heroin or other injection drugs can be either provided or consumed under government auspices. Proposals to support officially-sponsored "injection facilities" will not alter the course of the epidemic, however.

<u>Evidence</u> shows that such facilities, where established in other countries, attract only a small proportion of intravenous drug users, who use them inconsistently, at best. This means that even were such programs established in the US, overdose deaths would likely still increase sharply, as participants develop tolerance and often continue to use illicit sources of opioids and other drugs, continuing the exposure to overdose risk.

There is some <u>evidence</u> that facilities providing illicit opioid substitutes in the form of approved pharmaceutical opioids under strict physician supervision can stabilize those at high risk of mortality, and can serve to induct such patients into treatment. Unlike the provision of government heroin for injection, this experiment more closely approximates a model of physician-controlled opioid prescribing.

Nevertheless, these responses, which further risk eroding prevention measures and

incentives to achieve treatment and recovery, also perpetuate a fundamental flaw—they do not address the causes of the epidemic, which are found in the increasing supply, availability, and acceptability of these poisons in our communities, where quantities the size of several grains of salt (in the case of fentanyl, for example) can take a life.

Finally, whatever treatment efforts are utilized, the continued presence of legal sanctions against drug use are critical adjunctive tools. In fact, there is evidence that not only does law enforcement control the expansion of illicit drug markets and help diversion into treatment from drug courts, effective <u>intervention</u> can increase treatment utilization. Decriminalizing drug use diminishes this effect.

Prevention Initiatives: Messaging and the Marijuana Market

he rise and spread at the state level of both "medical marijuana," and now commercial, recreational marijuana markets, have been counterproductive for drug control efforts, and not just affecting marijuana use itself. The effects of increased, widespread, and normalized marijuana sales and use, especially given the extraordinary rise in potency of the drug, its near-daily use, and access by youth who are developmentally at risk, have all generated a clear "gateway" risk for habitual marijuana users over and above their development of marijuana disorders.

At the community level, we know that the first state to legalize commercial marijuana, Colorado, quickly became a national leader in not only youth marijuana use, but further, use of <u>other</u> drugs. A <u>surge</u> in opioid overdose deaths quickly accompanied legalization developments, indicating a rising heroin and synthetic opioid market.

For the individual marijuana user, scientific studies in both <u>animal</u> and <u>human</u> subjects indicates an increased risk for opioid use and misuse. The effect of early and prolonged marijuana exposure appears to negatively <u>affect</u> neurophysiology, increase <u>heroinseeking</u> and to <u>"cross-sensitize"</u> the brain with between marijuana and morphine. Overall, marijuana use has consistently been shown to have an <u>effect</u> on the likelihood of developing dependency on other drugs.

Moreover, heroin users themselves are also consumers of <u>other</u> illicit drugs, including marijuana. While not all marijuana users become opioid users, the <u>majority</u> of current heroin users are current users of marijuana. Importantly, this relationship also holds for <u>youth</u>, who consume multiple drugs in addition to marijuana, and whose opioid abuse is linked to their marijuana consumption. The relationship of marijuana use to opioid use pertains for both heroin and for <u>prescription</u> opioids for youth.

These risk factors and associations demonstrate that drug use prevention efforts, including those targeting the use of opioids, will not be effective in the presence of large or expanding marijuana markets. Nor should marijuana use become normalized, allowing a decline in perceptions of risk in using drugs, and a loss of social norms discouraging drug use and even discouraging treatment entry.

Finally, <u>experience</u> to date in states that have legalized marijuana, particularly Colorado, demonstrates that criminal cartels that market all drugs, both domestically and internationally, establish themselves in such states, and derive enhanced black-market funding for their criminal enterprises, which include trafficking in lethal opioids.

Conclusion

The urgent need for a response to the current opioid crisis should not obscure the well-established realization that an effective drug control strategy should be comprehensive across drug threats, persistent across political administrations, and a policy priority for public health as well as criminal justice and national security concerns.

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