MACROSCOPY

The President's Commission on Combating Drug Addiction and the Opioid Crisis: Origins and Recommendations

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The United States has the ignominious distinction of leading the world in opioid prescribing,[1] and in opioid-related overdose deaths. The Centers for Disease Control (CDC) estimates that over 40,000 people died of an opioid-related overdose, with fentanyl-related deaths exceeding those of heroin or prescription opioids.[2] Opioid overdoses are now the leading cause of unintentional deaths in the US and of declining lifespan expectancies.[3] With a worsening crisis, agencies of the US government and others produced an array of reports on the opioid crisis. Yet the death rate escalated further from 2010 to the present.

In 2017, an unprecedented action was taken by President Donald J. Trump. He signed an Executive Order on March 29, 2017 establishing the President's Commission on Combating Drug Addiction and the Opioid Crisis, tasked with producing guidance for the executive branch on how to reverse the crisis. Chaired by Governor Chris Christie (New Jersey), the six-member Commission included Governor Charlie Baker (Massachusetts), Governor Roy Cooper (North Carolina), former Congressman Patrick Kennedy (Rhode Island), Attorney General Pam Bondi (Florida), and the author (Massachusetts). The President complied with an interim report request to declare the opioid crisis a public health emergency under federal law. Charged with coordinating and developing the final report, this author approached the task with several queries, including: 1) What were the root causes of the current crisis and can they be reverse-engineered? 2) What obstacles and obdurate resistance to change can prevent implementation of recommendations? 3) What data analytics and data integration are needed to facilitate action plans? 4) What innovative research and development goals can ease the national crisis? 5) What lessons can be gleaned from the current crisis that can be applied to other drug-related trends?

ROOT CAUSES OF THE CRISIS

The root causes of the modern opioid crisis are complex and traceable to at least 30 or more factors. A prime driver was the health-care system. Pressure on medical practitioners to resort to opioids for managing chronic pain led to a nation awash with prescription opioids.[4] An early catalyst was a 1980 five-sentence Letter to the Editor of the *New England Journal of Medicine*, based on hospitalized patients provided with unknown quantities of prescribed opioids. The irresponsible title of the letter declared that "Addiction Rare in Patients Treated with Narcotics." By 2017, the letter garnered over 600 largely affirmative citations. Other low-quality publications that eroded opiophobia, a historical reaction to a 19th century crisis of iatrogenic addiction to opioids, followed, even in the absence of evidence supporting the use of opioids for chronic pain. The response elicited by these scientifically questionable publications was swift: pain patient groups, vocal physicians, and professional organizations advocated for the use of opioids to manage chronic pain. The Open Society Institute politicized this movement by declaring that pain patients deprived of opioids were victims of the "War on Drugs." Claiming that the risk for developing addiction to extended-release opioid formulations was low, the pharmaceutical industry forged ahead aggressively to promote opioid use for chronic pain. Prescriptions for opioids rose over 300%, with opioid misuse, addiction, and overdose deaths rising in parallel. With the advent of abuse-deterrent opioid formulations and more prudent prescribing, the void was increasingly filled with purer, less expensive heroin and fentanyl/fentanyl analogs. The declining contributions of

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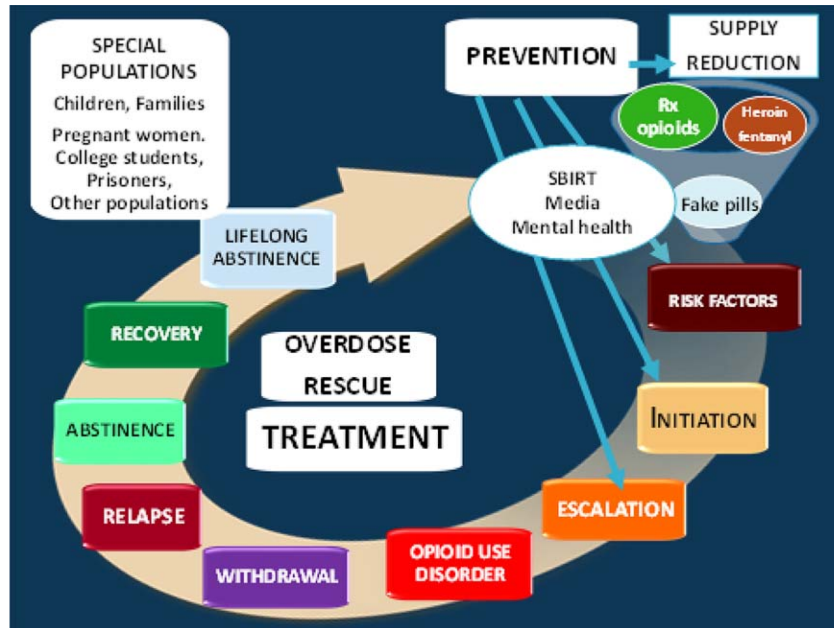

Figure 1 Stages in the progression to addiction and recovery. Recommendations in the final report of President's Commission on Combating Drug Addiction and the Opioid Crisis address the broad categories (shown in white boxes). Prevention strategies include supply reduction, Screening, Brief Intervention and Referral to Treatment (SBIRT) for substance use in healthcare and other settings, a media prevention campaign, and mental health screening as a routine service. Reprinted from The President's Commission on Combating Drug Addiction and the Opioid Crisis (2017). https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf

prescription opioids to overdose deaths was reflected by a contraction in heroin users, 90% of whom were first exposed to opioids via prescription drugs in 2005, to 67% in 2015. A few of the root causes, which served as focal points for "reverse-engineering," include:

1) Inadequate US Food and Drug Administration (FDA) evaluation of opioid abuse liability.
2) Inadequate medical education in quality science, opioid prescribing, pain management, and diagnosis and treatment of substance use disorders.
3) Inadequate guidelines on appropriate prescribing of opioids for chronic pain.
4) Disconnected information flow between physicians, rehabilitation centers, and pharmacies regarding a history of patient opioid and other prescriptions, substance use disorder, and overdoses.
5) Institutional, professional, legal, patient, insurance, and financial pressure on physicians to address pain aggressively with opioids.
6) Healthcare insurers' unconstrained approval of opioid analgesics but impediments for alternatives, for addiction pharmacotherapeutics, and treatment.
7) Noncompliance with mental health and addiction treatment parity laws.
8) Rogue physicians and pharmacies.
9) Low-quality addiction treatment services, with no provisions for pharmacotherapies, or mental health care in traditional rehabilitation centers.
10) Inadequate responses to overdoses.

REVERSE ENGINEERING OF ROOT CAUSES AND OBSTACLES

The final Report outlined a comprehensive set of 56 recommendations and solutions.[5] Based on historical precedent, the author is optimistic that the current crisis can be reversed with regulatory and legal oversight, as evidenced in the early 20th century. The recommendations of the Commission are grounded in this reality, but enhanced with modern epidemiology, data analytics, evidence-based treatments, and medications to reverse overdoses or assist in recovery. The report addresses each stage in the progression to opioid addiction, or death and recovery (**Figure 1**). Its 27 "reverse-engineering" recommendations include prevention, in healthcare and educational settings, and reduction in the supply of heroin and fentanyl supply with aggressive interdiction. It advocates for strategies to prevent initiation of use, screening for substance use and mental health disorders, and referrals to quality treatment services. To limit opioid prescribing, it recommends medical education to fill training gaps in pain management, opioid prescribing, removing institutional incentives for careless overprescribing of opioids, and improvements in the Prescription Drug Monitoring Program (PDMP). For healthcare insurers, it recommends incentivizing alternatives to opioids and reducing treatment barriers. It recommends that the FDA engage in postmarket surveillance related to diversion, addiction, and other adverse consequences of controlled substances. It acknowledges that obvious goals (e.g., "mandated medical education courses," or "expansion of treatment capacity," or "increase naloxone availability") require detailed analyses and strategies to surmount resistance to change and enhance quality of care.

TREATMENT, RECOVERY, RESCUE

Systemic problems in treatment services have plagued the quality of addiction treatment for decades. Proposed recommendations call for expanded access to evidence-

based treatment and recovery services by revising payment policies for federal payers and ensuring private payers are complying with the parity law. The Report addresses the needs of pregnant women, children at risk, college students, and prisoners. To provide persons involved with the criminal justice system an opportunity for rehabilitation, it proposes an expansion of Federal drug courts and other incentives to sustain recovery. To prevent relapse, it recommends training of a cadre of recovery coaches and quality recovery homes. Expanded availability of the overdose antagonist naloxone and training in its use, as well as sharing of overdose data with primary care physicians, are proposed. Advanced data analytics to strengthen data collection, integration, and real-time surveillance of the opioid crisis at the national, state, local, and tribal levels are embedded throughout the report.

RESEARCH AND DEVELOPMENT

Scientific research is a key component in mitigating the opioid crisis. The development of analgesics with limited or no abuse liability, antagonists to reverse newly emerging high-potency opioid agonists, while mitigating withdrawal symptoms, and new pharmacotherapies to treat opioid addiction is warranted. Research ideas in new technologies/devices range from wearable devices that sense respiratory depression to alert the user, or automatically inject naloxone when blood oxygenation levels are dangerously low, or wirelessly report a looming crisis to a first responder. Also included are apps for wireless electronic devices (phones, watches, virtual reality devices) to function as behavioral coaches, to reduce pain, or increase compliance, among others.

LESSONS LEARNED AND SUMMARY

The Commission traced the opioid crisis to a myriad of imprudent policies and decisions, aggressive advocacy, misinformation, and heavily financed marketing. A nation awash with prescription opioids became a fertile ground for misuse, for diversion from medicine cabinets, through rogue pharmacies and physicians, and for opportunistic marketing of illicit heroin and fentanyl. Looking forward, scrutiny of the scientific literature, engagement with all stakeholders (and not only advocates), are essential to assemble a balanced perspective on drugs with abuse potential, including an FDA process that considers the probability of misuse, diversion, and tampering. The current movements to medicalize and legalize other Schedule 1 drugs, e.g. marijuana, parallels the opioid movement. The most compelling lesson of all is that stringent federal regulations on production quotas, transportation, chain-of-custody, DEA licensing, and dispensing of Schedule II and III prescription opioids did not protect the public in the face of an aggressive, financially driven movement to market highly addictive opioids. Solutions reside with sectors in the public and private domain.

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CONFLICT OF INTEREST

The author declares no competing interests for this work.

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