Health Research and Development to Stem the Opioid Crisis: A National Roadmap (Report)

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The Policy

Synopsis

Health Research and Development to Stem the Opioid Crisis: A National Roadmap is a report that summarizes the scientific, medical, and societal landscapes related to the opioid crisis. The report, created by the Opioid Fast Track Action Committee (FTAC) within the Office of Science and Technology Policy (OSTP)'s National Science and Technology Council (NSTC), specifically outlines and provides recommendations for seven areas of research and development on which the United States federal government could focus to respond to the opioid crisis:

1. Biology and Chemistry of Pain and Opioid Addiction: Studying the biological mechanisms that cause pain and opioid addiction using innovative scientific approaches, research studies, and tools;
2. Non-Biological Contributors to Opioid Addiction: Identifying the social, cultural, economic, political, and geographic factors that may influence opioid addiction, as well as developing strategies to reduce the risk of such addiction and address the stigma associated with it;
3. Pain Management: Developing alternative treatment strategies for both acute and chronic pain;
4. Prevention of Opioid Addiction: Improving methods to track opioid use and intervention efficacy;
5. Treatment of Opioid Addiction and Sustaining Recovery: Evaluating the efficacy of drug treatments for opioid addiction, expanding options for new non-drug treatment approaches such as vaccines and medical devices, improving access to such treatment options, and identifying factors associated with successful and unsuccessful long-term outcomes for people who have overdosed;
6. Overdose Prevention and Reversal: Enhancing methods to prevent deaths caused by opioid overdoses, detecting and intercepting synthetic opioids, increasing knowledge of opioid reversal medication, and improving access to such medication; and
7. Community Consequences of Opioid Addiction: Assessing the effects of opioid addiction and opioid overdose deaths on communities, and determining strategies to allocate public health resources to communities that are greatly affected.

In addition to recognizing these areas for future research focus, the report also recommends actions that would improve coordination...
between federal agencies and other sectors in each of these research areas. These recommendations include establishing a research community to focus on the opioid crisis, enhancing coordination between public health experts and law enforcement in response to the crisis, and identifying common language and datasets to accelerate research.

**Context**

The National Institute on Drug Abuse estimates [13] that over 45,000 Americans die every year from opioid overdoses, with this figure increasing more than five-fold [14] between 1999 and 2016. Further, the direct effects of opioid misuse in the United States cost [11] up to $78.5 billion per year. To help combat this health crisis, the United States federal government has taken several actions.

In March 2017, the President’s Commission on Combating Drug Addiction and the Opioid Crisis [15] was formed to study how drug abuse and addiction could be mitigated, with a particular focus on the opioid crisis. In October 2017, President Trump classified [16] the opioid crisis as a national public health emergency requiring federal action.

The White House National Science and Technology Council [12] created the Opioid Fast Track Action Committee (FTAC) on Health Science and Technology Response to the Opioid Crisis in December 2017. The FTAC aims to identify solutions to the opioid crisis by recognizing research and development needs and supporting government coordination to respond to this crisis. In addition, the President's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand [17] was established in March 2018 to focus on research and development related to opioid use.

In November 2018, the FTAC released the draft National Roadmap report [14] that identified research areas and coordination opportunities that could enhance the United States federal government’s response to the opioid crisis. The draft and now final reports follow several prior reports and recommendations, including:

- A report [18] from The President's Commission on Combating Drug Addiction and the Opioid Crisis [15];
- A report on Pain Management and the Opioid Epidemic [19] by the National Academy of Sciences;
- A report on the Governor’s Recommendations for Federal Action to End the Nation’s Opioid Crisis [22] by the National Governors Association [23]; and

The NSTC accepted public comments [26] about the draft National Roadmap report until December 5, 2018. Since that time, the Food and Drug Administration announced [27] support for the development of an over-the-counter version of naloxone [28], a life-saving medication that reverses opioid overdose. Similarly, the National Institutes of Health announced [29] $945 million in grants as part of its Helping to End Addiction Long-Term (HEAL) Initiative [30] for research on reversing the opioid crisis.

**The Science**

**Science Synopsis**

The opioid crisis [11] is a public health issue in which overprescription and misuse of pain relievers [31] called opioids [32] leads to addiction [33] and drug abuse [34].

Opioids are a class of painkilling drugs commonly prescribed to treat acute (short-term) or chronic [35] (long-term) pain. Common opioids include prescription drugs such as codeine [36] and morphine [37], as well as illicit drugs [38] such as the morphine-derived drug heroin [39].

Opioids interact with receptors [40] called opioid receptors [41], which are proteins [42] that reside on the outer membrane [43] of cells in the brain and throughout the body. Interaction with an opioid drug causes the receptor to activate, leading to a reduction in pain.

Opioids are highly effective painkillers [31] for acute pain and are generally safe [44] when used as prescribed for a short time. However, due to their euphoric [45] effects, opioids are also highly addictive [33], especially when used over time as a treatment for chronic pain. Thus, patients who are prescribed these drugs to treat pain may become dependent and continue to use opioids beyond the original prescription. In addition, people may use opioids as an illicit drug (e.g., heroin) without prior therapeutic use, or they may seek out synthetic opioids [46] such as fentanyl [47] or carfentanil [48] as alternatives.

If a person takes a greater dose of an opioid than is recommended, they may overdose [49], a condition in which breathing slows or stops, potentially leading to death. Opioid overdose can be counteracted with a drug called naloxone [28], which prevents opioids from interacting with opioid receptors. Synthetic opioid overdoses may require extra doses of naloxone to treat because synthetic opioids are more potent...
Long-term use of opioids can lead to addiction [33], a chronic mental illness [51] characterized by compulsive drug-seeking behavior. In the case of long-term opioid addiction [52], common treatments include drugs such as methadone [53], buprenorphine [54], and naltrexone [55]. These drugs work by blocking the effect of other opioids and reducing withdrawal [56] symptoms. Long-term opioid use during pregnancy can also lead [57] to neonatal abstinence syndrome [58], a condition in which an infant is born with symptoms of substance withdrawal due to prenatal exposure to the substance.

To help combat the effects of opioid use, the FTAC’s National Roadmap report recognizes opportunities for federal coordination in research and development efforts related to pain management and opioid addiction treatment.

Scientific Assumptions

- **Opioid overdose can lead to death (Introduction)**: Researchers widely agree [59] that opioid overdose can lead to death.
- **Synthetic opioids have similar pharmacological and behavioral effects to naturally occurring opioids (Introduction)**: Scientists widely consider [47] synthetic opioids to be accurate imitators of naturally occurring opioids. In addition, it is well-established [60] that synthetic opioids can lead to overdose deaths similar to those caused by naturally occurring opioids.
- **Infectious disease transmission is associated with opioid use (Introduction)**: Many researchers have found links between injection of opioids and transmission of infectious diseases such as the Human Immunodeficiency Virus (HIV) [61] and Hepatitis C virus [62].
- **Prenatal opioid exposure can cause an infant to exhibit symptoms of opioid withdrawal upon birth (Introduction)**: The link between prenatal opioid exposure and neonatal abstinence syndrome [58] is strong and well-researched [63].
- **Non-opioid approaches could replace opioids as effective pain treatments, and these approaches could be non-addictive (Biology and Chemistry of Pain and Opioid Addiction; Pain Management; Prevention of Opioid Addiction)**: It is well-established that non-opioid drug treatments [64] and non-drug treatments [65] can be effective pain treatments, but further research is needed to determine whether certain non-opioid drug treatments could be addictive.
- **New technologies could be developed to detect the use of new synthetic opioids (Biology and Chemistry of Pain and Opioid Addiction; Pain Management; Prevention of Opioid Addiction)**: Researchers are developing [66] new methods that detect synthetic opioids. Further research could clarify whether these methods are effective and whether new methods will be needed as new synthetic opioids arise.
- **Objective pain assessment methods could be developed (Pain Management)**: Scientists have already developed metrics such as measurements of brain activity [67] and blood tests [68] to measure pain more objectively than self-reports.
- **Current drug treatments for opioid addiction are effective (Treatment of Opioid Addiction and Sustaining Recovery)**: Scientists generally agree [69] that pharmaceutical treatments for opioid addiction are effective in reducing opioid use.
- **Non-drug treatment options could effectively replace prescriptions drugs to treat opioid addiction (Treatment of Opioid Addiction and Sustaining Recovery)**: Non-drug treatment options such as cognitive behavioral therapy [70] are well-researched [71] and are often paired with prescription medications. However, whether these strategies could completely replace prescription drugs and have the same efficacy remains uncertain [72].
- **Naloxone reverses opioid overdoses when used appropriately (Overdose Prevention and Reversal)**: Scientists widely consider [28] opioid reversal medication to be an effective way to reverse the effects of opioid overdose.

The Debate

Scientific Controversies / Uncertainties

While opioids are commonly prescribed to treat acute pain, some scientists debate [73] their effectiveness for chronic pain [35] management. Experts have also developed effective non-opioid drug treatments [64], but further research is needed to clarify whether these drugs still pose a risk of addiction. In addition, the highly addictive nature of opioids raises questions about whether non-drug treatment options [65] could be safer alternatives.

Cognitive behavioral therapy [71] and other non-drug treatment methods can be paired with prescription medications. However, it is unclear [72] whether these methods are effective enough to replace drug treatments completely. Further research could establish how non-drug treatment options might be incorporated into standard medical practice to treat opioid use disorder.

Endorsements & Opposition

- Infectious Diseases Society of America and HIV Medicine Association: public comment [74], December 4, 2018: “The Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA) appreciate that the White House National Science and Technology Council (NSTC) is supporting a wide range of research projects to provide scientific solutions to help end the opioid crisis. However, more needs to be done to combat the epidemic of morbid and life-threatening infectious diseases occurring concurrently with opioid use disorder and to address outstanding research gaps in this area.”
“Morbid and life-threatening infectious diseases” could refer to any of the infectious diseases [75] associated with opioid use, including the human immunodeficiency virus (HIV) [61] and hepatitis C virus [62]. These infections can lead to death if untreated.

- National Advocates for Pregnant Women, public comment [76], December 5, 2018: “We support the objectives of the Fast Track Action Committee to facilitate coordination, interagency sharing of findings and tools, assessment of gaps in response to the crisis, and identification of opportunities. However, the current draft Roadmap lacks key data to achieve those goals effectively, especially when it comes to pregnant women and their families.”

- American Psychiatric Association, public comment [77], December 5, 2019: “We are pleased to see the roadmap’s additional focus on the biology and chemistry of pain and opioid addiction, the non-biological contributors to opioid addiction, community impact, and opportunities for enhanced coordination. We know that addiction is a complex brain disease and seeking treatment can take several attempts. We applaud the Administration’s efforts to contextualize both the science and the social determinants of health that impact a patient’s recovery outlook.”

- Office of Science and Technology Policy, press release [78], October 24, 2019: “Under President Trump’s leadership, our Nation has made demonstrable achievements to combat the opioid crisis. Still, much work remains to end the suffering of families and communities from opioid addiction. The National Roadmap establishes a framework for the path forward to continue the fight and successfully end the opioid crisis for all Americans.”

**Potential Impacts**

Every year, over 45,000 Americans die [13] from opioid overdoses. These deaths have risen [14] more than five-fold in the past twenty years, and experts estimate [79] that the total number of opioid overdose deaths over the next decade could reach 500,000. These rising numbers reflect a need to coordinate action between researchers, the medical community, law enforcement, and others to prevent further exacerbation of the opioid crisis. In a November 2018 letter [80], Mary Woolley, the President of Research!America [81], said: “Facing down the opioid epidemic requires smart work across the continuum of research and clinical professionals, including those conducting health services research (HSR). HSR can make all the difference, since in the absence of evidence for which interventions work, we are wasting time and money and jeopardizing too many lives in what can amount to a scatter-shot approach to ending this scourge.”

In addition to the deaths caused by drug overdoses, the opioid crisis also contributes to the transmission of diseases such as human immunodeficiency virus (HIV) [61] and hepatitis C [62], which can be transmitted through shared needles. If implemented, the FTAC’s recommendations could reduce the incidence of these infectious diseases [75] and prevent associated deaths. The recommendations could also reduce the risk of infants being born with opioid withdrawal due to prenatal opioid exposure.

Besides the potential health benefits, the FTAC’s recommendations could also have economic effects. The White House Council of Economic Advisors estimates [82] that opioids and their indirect effects incur costs of $504 billion per year, including an estimated $78.5 billion per year [11] due to opioid misuse alone. Implementing the FTAC’s recommendations could reduce these costs through medical advances and cost-saving social initiatives.

Finally, the report’s identification of different drug overdose rates across geographic and other demographic categories could have social implications in education and allocation of other resources in an attempt to prevent opioid misuse before it occurs.

**Status**

The FTAC released the draft report [14] on November 5, 2018 and accepted public comments [26] until December 5, 2018. On October 29, 2019, the FTAC released the final version of the report; in comparison to the draft report, the final version contains minor wording changes and further explanations of certain research and development recommendations, but has no significantly new or revised provisions. As of December 2019, no legislative action has been taken in direct response to the report.

**Related Policies**

**H.R. 1614 - John S. McCain Opioid Addiction Prevention Act** [83]

This policy requires practitioners to limit prescription of opioids to treat acute pain in order for their physician licenses to be renewed. This requirement fulfills similar goals to those outlined in the National Roadmap report, but with a focus on controlling opioid prescriptions instead of investigating other pain management options.

**S. 724 - John S. McCain Opioid Addiction Prevention Act** [84]

This policy requires practitioners to limit prescription of opioids to treat acute pain in order for their physician licenses to be renewed. This requirement fulfills similar goals to those outlined in the National Roadmap report, but with a focus on controlling opioid prescriptions instead of investigating other pain management options.

**H.R. 2732 - Lessening Addiction By Enhancing Labeling Opioids Act of 2019** [85]

This policy requires opioids to be labeled with a warning about their potential to lead to addiction and overdose, aiming to prevent opioid dependence in a similar manner to the National Roadmap report.

**S. 1449 - Lessening Addiction By Enhancing Labeling Opioids Act of 2019** [86]

This policy requires opioids to be labeled with a warning about their potential to lead to addiction and overdose, aiming to prevent opioid dependence...
in a similar manner to the National Roadmap report.  

**H.R. 2281 - Easy Medication Access and Treatment for Opioid Addiction Act**

This policy establishes new regulations stating that physicians may not treat acute withdrawal symptoms with more than three days’ worth of a narcotic drug at any one time. While this policy helps to control treatment of opioid withdrawal, it does not aim to use alternative treatment approaches or prevent opioid addiction before it occurs, as is a focus of the National Roadmap report.

**H.R. 3153 - Expanding Findings for Federal Opioid Research and Treatment Act**

This policy requires the National Science Foundation to promote further research on opioid addiction, directly supporting the recommendations made by the National Roadmap report.

**S. 2354 - Expanding Findings for Federal Opioid Research and Treatment Act**

This policy requires the National Science Foundation to promote further research on opioid addiction, directly supporting the recommendations made by the National Roadmap report.

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**Recommended Citation**


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**Related Tags**

opioid crisis, opioids

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