December 5, 2018

Opioid Fast Track Action Committee  
The National Science and Technology Council  
Office of Science and Technology Policy  
OpioidsRoadmap@OSTP.eop.gov

Re: Comments on the FTAC report “Health Research and Development to Stem the Opioid Crisis: A National Roadmap”

Members of the Opioid Fast Track Action Committee:

We are submitting these comments on the Fast Track Action Committee's report “Health Research and Development to Stem the Opioid Crisis: A National Roadmap” (Roadmap) to ensure that critical data and evidence related to pregnant women and opioid use is included in the final report.

At National Advocates for Pregnant Women we advocate for the human and civil rights, health and welfare of all people, with particular attention to pregnant and parenting women. We protect the rights, health, and dignity of pregnant and parenting people by working closely with medical, legal, public health, and mental health experts from across the country.

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.

Below, we make recommendations for each section of the draft Roadmap, but first we address overall concepts that should be incorporated throughout:

- Neonatal abstinence syndrome (NAS) is often the result of appropriate use based on best-practices, and the presence of NAS should not be conflated with substance misuse.  
  - This is because the current standard of care for treating pregnant women with opioid dependence is opioid-assisted therapy with methadone or buprenorphine, which results in better pregnancy outcomes and shorter hospital stays for newborns, but may still result in a baby experiencing the transitory and treatable symptoms named in the Roadmap “neonatal opioid abstinence syndrome,” “neonatal abstinence syndrome,” “neonatal opioid withdrawal syndrome,” and “neonatal abstinence.” Symptoms are collectively referred to as neonatal abstinence syndrome (NAS) which is not life threatening or permanent, and does
not preclude normal development. The effects on newborns of prenatal opioid exposure are transitory and treatable. Prenatal exposure to opioids does not always result in NAS. Medical science has not yet determined why some babies develop NAS and others do not.

- Research shows that skin-to-skin contact, breastfeeding, and caring for mother/baby in the same room (“rooming in”) can significantly reduce a newborn’s hospital stay and need for medication. Some NAS-diagnosed newborns may also need medication.

- Alarm about opioid misuse can lead to misdirected research and overstatement of risks to both the users themselves and infants exposed prenatally. Experience with alarm over other drugs has demonstrated the importance of measured public messaging and accurate reporting of data, even when data does not reinforce expectations of harm. This also serves to reduce stigma which can be more harmful than the effects of the drug.

- Individuals are best served by programs in their communities, offered by providers they trust who can ensure provider-patient confidentiality. It is well established that the best health outcomes for pregnant women and their babies occurs when are able to obtain such care.. Pregnant women avoid care when they fear loss of confidentiality and state interventions that can result in arrest, loss of children and loss of privacy due to state surveillance. It has long been recognized by every leading medical group to address the issue of pregnant women and drug use that maternal, child, and fetal health is undermined when women fear that health care and honest communications will result in loss of privacy, confidentiality, that can lead to state intervention.

Section 1: Biology and Chemistry of Opioid Addiction and Pain

We note that this is a place where assumptions and alarm may lead to misdirected research. While there may be biological mechanisms or pathways that underlie both opioid addiction and pain for some, existing research suggests that many pain patients do not develop opioid use disorders and that those who do had other pre-existing risk factors. Research in this area should not start from the assumptions that most patients receiving pain medications end up with substance misuse problems or addictions.

Section 2: Non-biological Contributors to Opioid Addiction

It is essential to meaningful health research and action to acknowledge the role that drug-related policies play in creating the stigma and trauma that contribute to opioid use and addiction. **Criminalization** of drug use and child apprehension through state civil child welfare systems for drug use stigmatize and traumatize not only the people using drugs, but their families. Indeed, the Roadmap acknowledges that parental separation for women is “particularly highly correlated with opioid abuse”. In addition, apprehension of children by child welfare authorities is recognized to be traumatizing for children, and “individuals with high childhood trauma score were more likely to . . . have complicated addiction histories.”

We appreciate that the research agenda includes the recommendation to study the efficacy of existing policies designed to address the opioid crisis. We know that child abuse and neglect laws have been used to address the opioid crisis, with reports and foster care placements increasing, especially in places with high incidents of opioid related overdose hospitalizations and deaths. In order to be meaningful, this research must include a study of the efficacy and impact of these laws and policies, for both the parent and child.

In addition, both **criminalization** and **child welfare** systems target certain communities, particularly low-income communities and people of color and contribute to the experience “of discrimination [that] influence[s] susceptibility to opioid addiction.” While research shows that communities of color do not have higher rates of drug use, they are more often punished for drug use (through criminal charges or child welfare cases). They also experience more surveillance⁵, whether it be through reporting attached to public benefits or disproportionate policing. Whether and to what extent these disparities contribute to addiction should be studied, along with the traumatic effects of surveillance itself.

Finally, research should explore the extent to which lack of access to health care contributes to addiction, and whether there is a correlation between addiction and States that failed to expand Medicaid or limited implementation of the Affordable Care Act.

**Section 3: Pain Management**

Research indicates that pregnant women with a history of drug misuse are **often denied adequate pain management during pregnancy and labor**. Breastfeeding women are often forced to choose between pain management and continuation of breastfeeding. The efficacy and relative risks of cannabis for pain management in pregnancy and breastfeeding should be studied, as **research indicates that pregnant women experience benefits**.

For babies and their mothers alike, **non-pharmaceutical techniques** should always be offered. Access to continuous labor support in the form of doulas, can help pregnant women manage pain during labor, along with access to food and water, and the ability to change positions and move during labor. Postpartum doula support can help establish and maintain breastfeeding, and can be especially helpful for women with a substance use disorder.

Considering the significant evidence of the value and cost effectiveness of rooming in and skin to skin contact between new mothers and newborns⁶, all newborns should be guaranteed that

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⁶ Supra note i.
they will not be separated as a result of non-evidence based hospital policies or for the convenience of hospital staff and room availability. Access to medication should be provided, when needed, alongside proven non-pharmaceutical techniques.

Section 4: Prevention of Opioid Addiction

The use of “additional surveillance systems that collect data on pregnant women and their infants” is not supported by evidence as an effective means of prevention. The primary result of such surveillance is not reduced incidents of addiction, increased knowledge useful to treatment, or provision of services, but implementation of punitive policies and the resulting avoidance of healthcare and treatment altogether. Creation of such surveillance systems have made pregnant women more vulnerable to punitive state action through the criminal law and civil child welfare systems.⁷

Experience from Tennessee demonstrates that data collected about pregnant women and newborns has been used to justify creation of gender-specific criminal laws targeting women who use opioids. In Wisconsin, government agents are empowered to force medical treatments on pregnant women who disclose current or even past drug use and have forced women to submit to inappropriate treatment. These are just two examples of State responses, but we see punitive responses like these across the country. The value of screening obstetric patients needs to be weighed against the possibility and in some states the likelihood (especially for low income women and women of color), that screening for opioid misuse will lead to criminal or civil action against the woman and deter women generally from seeking valuable healthcare or from speaking openly with their doctors about their drug use and other sensitive and highly stigmatized health issues.

Both individuals and public health generally benefit when patients can speak openly with their doctors and trust that information and test results will be kept confidential. The draft Roadmap states, “Screening for opioid misuse during routine medical and obstetric visits could also be considered.” But in many states screening for opioid misuse can result in a pregnant woman’s loss of physical liberty, medical decision making, bodily integrity and other well established constitutional and human rights. In those contexts, screening is counter to individual and public health.

Furthermore, the current draft of the Roadmap claims on the one hand that research needs to be done to determine the impact of prenatal exposure to opioids, while on the other hand the harm of prenatal exposure is presumed and provides the justification for “additional surveillance systems.” In fact, neonatal abstinence syndrome is a treatable and transitory condition that has long been known by medical professionals and has never been shown to cause “birth defects.” Alarm over other drugs has demonstrated the importance of measured public messaging and accurate reporting of data related to prenatal exposure to opioids, even when data does not reinforce expectations of harm, as is the case here.

Moreover, the assumption that there is a particular kind of service that children prenatally exposed to opioids need is not supported by research data, nor is there research supporting the assumption that surveillance and reports result in provision of services. Experience with reporting under CAPTA and state child welfare laws demonstrates that the primary intervention, or “service,” provided to children is separation from their mothers and ongoing surveillance of mothers by state agents. This is the opposite of what newborns and families need. Research finds that practices including skin-to-skin contact, breastfeeding, and being cared for in the same room as their mother (“rooming in”) not only reduce and in some cases prevent altogether symptoms of withdrawal but they can prevent trauma associated with substance misuse later in life⁸. Loss of contact with or custody of a newborn is devastating to mothers and is likely an adverse experience that undermines their harm reduction and recovery efforts. The importance of skin-to-skin contact, breastfeeding, and “rooming in” should be emphasized as evidence based prevention strategies.

Section 5: Treatment of Opioid Addiction and Withdrawal

When it comes to considerations of treatment and withdrawal the interconnectedness of treatment for moms and babies must be understood. The treatment of pregnant women with opioid addiction and the treatment of infants with symptoms of withdrawal go hand in hand. For pregnant women who have opioid dependence the current standard of care, supported by the U.S. government, is opioid-agonist treatment with methadone or buprenorphine. Taken in daily doses, methadone and buprenorphine work by blocking the euphoric and sedating effects of opioids, preventing withdrawal symptoms, and reducing the craving for opioids. This treatment results in better pregnancy outcomes and shorter hospital stays for newborns, even when it results in predictable and treatable withdrawal symptoms for the infant.

Pregnant women and infants are “especially vulnerable” not so much from opioid misuse as overstated in the draft Roadmap, but from stigma and lack of access to treatment. In fact, it is the abrupt discontinuation of opioid use, often stemming from misdirected policies, that puts the pregnant woman and her fetus in danger. Alarm about neonatal abstinence syndrome has led some to deny pregnant women methadone and buprenorphine treatment and has often resulted in under-medicating pregnant women.

This draft Roadmap conflates neonatal opioid abstinence syndrome with “the serious health and social harms associated with opioid misuse,” despite the fact that neonatal opioid abstinence syndrome is often the result of appropriate use as part of evidence-based treatment. Data from some states, including Tennessee, show that the majority of newborns diagnosed or labeled as having NAS are born to women receiving medication treatment as recommended by the World Health Organization and the U.S. Federal government.

Opioid use and dependency among pregnant women in the United States has increasingly been the subject of new laws and policies. These new laws and practices, however, have not led to increased funding for treatment, or improved maternal health care. This is so despite the fact most pregnant women reduce or discontinue use during pregnancy, and that pregnancy presents a unique opportunity to initiate treatment and increase healthy activities.

⁸ Supra note i.
Instead, misinformation and myths about the harms of drug use have resulted in policy decisions that are counter to evidence and treatment best-practices: such as the decision to arrest pregnant women who use drugs or force or coerce them into “treatment” that is not consistent with their needs, their pregnancy, or their beliefs. In some states pregnant women are forced to undergo faith-based treatment even when they do not share that faith and such programs are not proven to be effective.

All pregnant people need guarantees of confidentiality, support, and access to care. None should be criminalized, detained, subjected to coerced or forced medical interventions or treated as if they are engaging in civil child abuse or neglect because they are pregnant and use opioids, are receiving methadone or buprenorphine treatment, or using any substances including cigarettes and SSRI's that are also associated with symptoms of neonatal withdrawal symptoms.

As the ACOG committee on Healthcare for Underserved Women concludes:

Seeking obstetric–gynecologic care should not expose a woman to criminal or civil penalties, such as incarceration, involuntary commitment, loss of custody of her children, or loss of housing. These approaches treat addiction as a moral failing. Addiction is a chronic, relapsing biological and behavioral disorder with genetic components. The disease of substance addiction is subject to medical and behavioral management in the same fashion as hypertension and diabetes. Substance abuse reporting during pregnancy may dissuade women from seeking prenatal care and may unjustly single out the most vulnerable, particularly women with low incomes and women of color. Although the type of drug may differ, individuals from all races and socioeconomic strata have similar rates of substance abuse and addiction.

In addition, the committee states, “policy makers, legislators, and physicians should work together to retract punitive legislation and identify and implement evidence-based strategies outside the legal system to address the needs of women with addictions.” Warnings that criminalization and other forms of punitive state interventions are bad for public health and the welfare of mothers and babies are widespread, and yet punitive laws and practices persist.

To counter this when making policies related to pregnancy and substance use, it is important that care be taken not to stigmatize or sensationalize the mother’s substance use nor the infant’s experience. “Significant risk” as a descriptor for neonatal opioid abstinence syndrome used in the draft Roadmap, is misleading. Neonatal abstinence syndrome is an expected and treatable outcome with short-lived effects that dissipate over time. “Significant risk” and other claims made about the impact of opioid misuse are not supported by the cited material.

Regardless of the substance used, whether it be cigarettes (carrying greater risk of harm than any of the criminalized drugs) or opioids, access to individualized, non-judgmental care, in a

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9 Supra note vi.
11 Id.
safe environment, that supports the mother-baby dyad provides long term benefits and optimizes care.  

Section 6: Overdose Prevention and Recovery

Improvements that can be made to the maternal health system should be explored as a part of an overdose prevention strategy overall. Maternal mortality rates in the United States have been increasing for years, and now, an increase in overdose deaths among postpartum women are contributing to those rates. Increases in maternal mortality have been attributed to failures in the maternal health care system, including a focus on newborn health to the exclusion of the postpartum woman, a lack of adequate postpartum care, and the failure of healthcare providers and systems to listen and be responsive to the needs of postpartum women. Improving the maternal healthcare system overall, by increasing attention to postpartum care and responsiveness to the needs of postpartum women, will also help reduce overdose death.

Along these lines, evidence supporting existing strategies for reducing overdose deaths, including naloxone distribution, regulated supplies, safer consumption spaces, use of fentanyl test strips, and harm reduction overall must be included in overdose prevention strategies. As is true in maternity care as well, often, less costly and more effective interventions are overlooked in the pursuit of costly technological interventions. Therefore, the relative cost of various interventions should be balanced with their effectiveness. Highly effective and low cost interventions, like the use of fentanyl test strips, should be prioritized over high cost interventions that are even comparably effective.

Section 7: Community Consequences of Opioid Addiction

We appreciate that the draft Roadmap acknowledges the context of opioid addiction and that its impact on communities is exacerbated by underlying issues. Among those issues it is essential to address how criminalization of drugs has impacted people, especially, poor people and people of color, and the specific ways that criminalization of drugs has impacted pregnant women and been used to justify clear violations of fundamental rights. Policies that criminalize drugs are closely connected to punitive child welfare policies that are too quick to remove children from parents who use drugs.

While it's true, as the draft Roadmap states, that communities “impacted by the opioid crisis report increases in child abuse and neglect; displaced and at-risk children, including those entering foster care systems and children prenatally exposed to opioids,” understanding of the causes and effects at play remain limited and obscured. The existing child welfare system strives to receive increased reports and the vast majority of reports they receive are unfounded for abuse or neglect.  

The existing system is tied to mandatory reporting laws that require healthcare providers to disclose private health information to government agencies, even when they do not think such disclosure will be in the best interest of their patients, and even when such disclosure contributes to pushing pregnant women away from treatment and healthcare. In

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12 Supra note i.
some cases, methadone and buprenorphine treatments, were reported to child welfare, and some states have tried to interpret such treatment as child neglect.

There are a disproportionate number of reports made about poor people and people of color, despite the fact that neither drug use nor child abuse and neglect are overrepresented in those communities, just as more children from communities of color enter the foster care system, indicating that racial bias is further inflating numbers. Similarly, as described above, the increase in prenatal exposure to opioids is not necessarily indicative of opioid misuse since it is often the result of appropriate treatment. It’s also not clear that research on prenatal exposure to opioids controls for other exposures like lead, arsenic, mercury, and air pollution and further research is needed to distinguish causes and effects.

When looking for “data that identifies factors contributing to quantifiable economic impacts” the Roadmap must include the economic consequences of criminal and child welfare policies on families. And such policies should be examined for their effectiveness in increasing treatment, decreasing trauma, and increasing family unification. Research has consistently established the value of maintaining family bonds, even when risk factors including parental substance use are present.

Section 8: Opportunities for Enhanced Coordination

We agree that collaboration is particularly critical with regard to pregnant and breastfeeding women and that including pregnant and breastfeeding women is fundamental to a successful response to the opioid crisis. We recommend that collaboration include education about and incorporation of the opinions of leading medical groups addressing the harm of punitive approaches to issues concerning women who are pregnant and use opioids including the American Medical Association, the American College of Obstetricians and Gynecologists, the National Perinatal Association, the American Academy of Family Physicians, the American Society of Addiction Medicine, the American Public Health Association, the American Nurses Association, the Association of Women's Health, Obstetric and Neonatal Nurses, American College of Nurse Midwives, the American Academy of Pediatrics, March of Dimes, American Psychological Association, National Organization on Fetal Alcohol Syndrome, American Psychiatric Association, National Association of Public Child Welfare Administrators, National Council on Alcoholism and Drug Dependence, and the Association of Maternal and Child Health Programs.

Thank you for the opportunity to provide feedback on the draft Roadmap. Please do not hesitate to reach out for additional information.

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