


How penalizing substance use in pregnancy affects treatment and research: a qualitative examination of researchers' perspectives

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ABSTRACT

Introduction: Laws regulating substance use in pregnancy are changing and may have unintended consequences on scientific efforts to address the opioid epidemic. Yet, how these laws affect care and research is poorly understood.

Methods: We conducted semi-structured qualitative interviews using purposive and snowball sampling of researchers who have engaged pregnant people experiencing substance use. We explored views on laws governing substance use in pregnancy and legal reform possibilities. Interviews were double coded. Data were examined using thematic analysis.

Results: We interviewed 22 researchers (response rate: 71 per cent) and identified four themes: (i) harms of punitive laws, (ii) negative legal impacts on research, (iii) proposals for legal reform, and (iv) activism over time.

Discussion: Researchers view laws penalizing substance use during pregnancy as failing to treat addiction as a disease and harming pregnant people and families. Respondents routinely made scientific compromises to protect participants. While some have successfully advocated for legal reform, ongoing advocacy is needed.

Conclusion: Adverse impacts from criminalizing substance use during pregnancy extend to research on this common and stigmatized problem. Rather than penalizing substance use in pregnancy, laws should approach addiction as a medical issue and support scientific efforts to improve outcomes for affected families.

KEYWORDS: biomedical research, human subjects research, research ethics, regulation of research, health law

I. INTRODUCTION

Substance use and misuse have contributed to falling life expectancy in the US,¹ an increasing risk of mortality for pregnant and postpartum persons,² and the exposure of fetuses to substances that can negatively affect their neurological development.³ The opioid epidemic has led to national increases in maternal opioid use disorder (OUD) at delivery and neonatal opioid withdrawal syndrome (or ‘NOWS’, ie infants with symptoms of withdrawal related to opioid exposure *in utero*) in the 21st century. While the negative consequences of the opioid epidemic vary by state, 24 states reported 100 per cent or greater increases in rates of maternal opioid use disorder and neonatal abstinence syndrome from 2010 to 2017.⁴ Furthermore, in 2018, ~5 per cent of all pregnant people experienced opioid misuse during pregnancy.⁵

1 Stephen H. Woolf & Heidi Schoomaker, *Life Expectancy and Mortality Rates in the United States, 1959–2017*, 322 JAMA 1996 (2019).

2 Emilie Bruzelius & Silvia S. Martins, *US Trends in Drug Overdose Mortality Among Pregnant and Postpartum Persons, 2017–2020*, 328 JAMA 2159 (2022).

3 Elisabeth Conrardt, et al., *Prenatal Opioid Exposure: Neurodevelopmental Consequences and Future Research Priorities*, 144 Peds e20190128 (2019).

4 Ashley H. Hirai, et al., *Neonatal Abstinence Syndrome and Maternal Opioid-Related Diagnoses in the US, 2010–2017* 325 JAMA 146 (2021).

5 Elisha M. Wachman, et al., *Neonatal Abstinence Syndrome: Advances in Diagnosis and Treatment*. 319 JAMA 1362 (2018).

Yet the effects of substance use and misuse during pregnancy on children and families have not been well-characterized in research.⁶ More robust data are needed to demonstrate long-term harms to children who were exposed to substances *in utero*, particularly for children exposed to multiple substances (with alcohol as the main exception to this general rule).⁷ Because substance use often accompanies other potential harmful influences on development, including family stress, disruption, co-occurring mental health problems and poverty, isolating the effects of substance use, establishing causation, and understanding factors that protect families from harm can be challenging. To better understand how substance use and other exposures affect early brain development, the National Institutes of Health (NIH) has funded the HEALTHY Brain and Child Development (HBCD) study to develop a nationally representative cohort of pregnant people and their children who will be followed over time.⁸

As with other studies that enroll pregnant people, the HBCD study has had to address substantial and increasingly challenging barriers to enrolling and retaining participants.⁹ Existing federal and state laws have established a complex legal framework to address substance use in pregnancy. At the federal level, the Child Abuse Prevention and Treatment Act (CAPTA) provides guidance and funding to address state action related to child abuse, provided states meet certain requirements. More specifically, CAPTA requires states to develop policies and procedures that require health professionals to report infants born with ‘substance use and withdrawal symptoms resulting from prenatal drug exposure’, including exposure to alcohol, and ‘develop a plan of safe care’ after exposure.¹⁰ In 2016, the Comprehensive Addiction and Recovery Act amended CAPTA to do three things: (i) include a broader range of substances that are not illegal but may yet affect child development, (ii) define the ‘plan of safe care’ to include treatment for infants and family members, and (iii) mandate that states collect data on infants identified with substance exposure, including what happens to them.¹¹

Accordingly, all states have laws that apply when a pregnant person is identified as using substances. Importantly, CAPTA distinguishes between notification—which does not require prosecution but helps identify treatment needs for individuals and collect data about the scope of the problem—and reporting, which treats substance exposure as a form of child abuse or neglect that can include punitive consequences. CAPTA makes clear that states should not consider notification of state agencies about prenatal exposure as *requiring* prosecution, but also does not prohibit civil

6 Marylou Behnke & Vincent C. Smith, *Prenatal Substance Abuse: Short- and Long-term Effects on the Exposed Fetus*, 131 PEDIATRICS e1009 (2013).

7 Tina B. Irner, *Substance exposure in utero and developmental consequences in adolescence: A systematic review*, 18 CHILD NEUROPSYCH 521 (2012).

8 Nora D. Volkow, et al., *The Healthy Brain and Child Development Study—Shedding Light on Opioid Exposure, COVID-19, and Health Disparities*, 78 JAMA PSYCH 471 (2021).

9 Seema K. Shah SK, Marielle Gross, Camille Nebeker, *Optimizing Ethics Engagement in Research: Learning from the Ethical Complexities of Studying Opioid Use in Pregnancy*, 50 J LAW MED ETHICS 339 (2022).

10 The Child Abuse Prevention and Treatment Act (CAPTA). 42 U.S.C. chapter 67, sections 5101–5116i. (October 24, 2018). Available at: <https://www.acf.hhs.gov/sites/default/files/documents/cb/capta.pdf>.

11 Comprehensive Addiction and Recovery Act of 2016 (P.L. 114-198, 7/22/2016); see also Children’s Bureau. US Department of Health and Human Services. About CAPTA: A legislative history. Published 2019. <https://www.childwelfare.gov/pubPDFs/about.pdf>. Accessed May 10, 2022.

penalties.¹² Because CAPTA is a complex, inadequately enforced law that allows states discretion in what counts as an infant ‘affected by’ substance use and in enacting civil penalties for prenatal substance use,¹³ state laws vary in the extent to which they focus on treatment or punishment.¹⁴ Many states broaden the scope of CAPTA by not requiring evidence that the infant was ‘affected by’ prenatal substance use, and 40 states require reporting instead of notification, disregarding CAPTA’s emphasis on treatment and data collection as opposed to criminal penalties.¹⁵ While some state laws focus on prioritizing pregnant people to receive treatment for addiction, others define substance use in pregnancy as a form of child abuse or impose civil or criminal sanctions.¹⁶

These laws can affect the conduct of clinical research. States typically impose reporting requirements on clinicians, although whether such duties apply to clinicians engaged in research is not always clear. A few states even extend these reporting requirements to the extent that they are likely to include non-clinical members of research teams working with pregnant people. For example, Alabama requires ‘employees of public and private institutions of postsecondary and higher education . . . or any other person called upon to render aid or medical assistance to any child’ who learn of substance use during pregnancy to report this information.¹⁷ One tool to protect research participants is a Certificate of Confidentiality (CoC). A CoC prohibits researchers from sharing participants’ information unless it is required by law, the participant consents to it, or it is necessary for the participants’ medical care or other scientific research.¹⁸ While NIH-sponsored research now automatically issues Certificates of Confidentiality for all research collecting identifiable information, researchers without NIH-funding would have to apply for CoCs to obtain this protection. Additionally, CoCs protect against disclosure of information compelled for legal proceedings but would not apply if researchers are legally mandated to report information about substance use in pregnancy.¹⁹

What happens after a report is made, however, depends on whether the state takes a more or less punitive approach. In more punitive states, a mandatory report could lead to consequences in the criminal justice (eg incarceration) and/or child welfare systems (eg loss of child custody). Moreover, some courts have held that child endangerment acts that consider substance exposure a form of child abuse do apply to fetuses.²⁰ This

12 McCourt AD, White SA, Bandara S, Schall T, Goodman DJ, Patel E, McGinty EE. Development and Implementation of State and Federal Child Welfare Laws Related to Drug Use in Pregnancy. *Milbank Quarterly* 2022;100(4):1076–1120.

13 Sieger MHL, Rebbe R. Variation in States’ Implementation of CAPTA’s Substance-Exposed Infants Mandates: A Policy Diffusion Analysis. *Child Maltreatment* 2020;25(4):457–467.

14 Pilar N. Ossorio, *Infants with Prenatal Substance Exposure*, <https://morgridge.org/research/bioethics/prenatal-substance-exposure/> (Last accessed: 3 January 2022).

15 Lloyd MH, Luczak S, Lew S. 2019. Planning for safe care or widening the net? A review and analysis of 51 states’ CAPTA policies addressing substance-exposed infants. *Children and Youth Services Review* 99;343–354.

16 *Id.*

17 Ala. Code § 26–14–3 (3) (a) 12 [Code Of Alabama (2021 Edition)].

18 42 U.S.C § 241(d)(1)(C) (2016).

19 Wolf LE, Beskow LM. New and Improved? 21st Century Cures Act Revisions to Certificates of Confidentiality. *Am J Law Med.* 2018 May;44(2–3):343–358. doi: 10.1177/0098858818789431. PMID: 30106660; PMCID: PMC6173954.

20 In Re: Hope Elisabeth Ankrom v. State of Alabama (2013).

has encouraged some prosecutors to bring criminal charges against pregnant individuals suspected of using substances.²¹ These laws are disproportionately enforced against people of color and/or with lower socioeconomic status.²² With the recent Supreme Court decision, *Dobbs v. Jackson Women's Health Organization*,²³ which overturned established precedent protecting the constitutional right to abortion, state officials may be emboldened to change how they interpret, apply, or develop laws. For example, prosecutors may be more likely to charge pregnant people under existing statutes, and more states may pass laws punishing substance use during pregnancy through the criminal justice system or by defining prenatal substance use as a form of child abuse in the child welfare system.

Punitive legal approaches to substance use in pregnancy can have negative consequences for treatment and research. For instance, laws punishing substance use in pregnancy are associated with delays in pregnant people seeking prenatal care, lower rates of adequate prenatal care, and a lower chance of engagement in care postpartum.²⁴ Researchers seeking to study substance use during pregnancy may find that many individuals are unwilling to participate because of concerns about the legal risks involved.²⁵ Researchers therefore may face tough decisions about whether to make scientific compromises or refrain from asking about participants' behaviors to minimize legal risks, even if those steps diminish the quality of the data they can collect.

Notwithstanding these challenges, important research on substance use in pregnancy has been conducted since the 1970s²⁶ and is now underway in the HBCD study.²⁷ In the pilot phase of HBCD, we studied barriers and facilitators to research on substance use in pregnancy across the United States. In this study in particular, we interviewed researchers who have experience conducting research on substance use in pregnancy to understand their views of existing laws, approaches to overcoming legal barriers, and recommendations for legal reform.

II. METHODS

This prospective qualitative study was conducted as part of the pilot phase of the HBCD project. The purpose of HBCD is to investigate the impact of early life adverse

21 Li Cohen. *Manslaughter conviction of 21-year-old Oklahoma woman who suffered miscarriage sparks outcry*. CBS NEWS (Oct. 20, 2021), <https://www.cbsnews.com/news/brittany-poolaw-manslaughter-miscarriage-pregnancy/>.

22 Khiara M. Bridges, *Race, Pregnancy, and the Opioid Epidemic: White Privilege and the Criminalization of Opioid Use during Pregnancy*, 3 HARVARD L REV 772 (2020); Ira J. Jasnoff, et al. *The Prevalence of Illicit-Drug or Alcohol Use during Pregnancy and Discrepancies in Mandatory Reporting in Pinellas County, Florida*, 322 N ENGL J MED 1202 (1990).

23 597 US __ (2022).

24 Anna E. Austin et al., *Association of State Child Abuse Policies and Mandated Reporting Policies With Prenatal and Postpartum Care Among Women Who Engaged in Substance Use During Pregnancy*, 176 JAMA PEDIATR 1123 (2022); Katrina Hui et al., *Criminalizing substance use in pregnancy: misplaced priorities*. 112 ADDICTION 1123 (2017).

25 Jonathan M. Davis, et al., *Protecting Pregnant Women With Substance Use Disorders and Their Neonates Participating in Research*, 322 JAMA 609 (2019).

26 Kenneth L. Jones & David W. Smith, *Recognition of the Fetal Alcohol Syndrome in Early Infancy*, 302 LANCET 999 (1973).

27 HEALTHy Brain and Child Development (HBCD) Study, <https://hbcdstudy.org/> (Last accessed: Jan. 3, 2022).

exposures to different substances, including opioids, and stressors on brain and behavioral development across childhood. In this study, we sought to identify and understand the legal and ethical barriers for research involving substance use by pregnant participants from the perspective of researchers. This report conforms to the Standards for Reporting Qualitative Research ([Appendix A](#)).²⁸

Semi-structured interview guides were developed based on study goals, a literature review, and input from members of the interdisciplinary investigative team for the larger study. The guides were pilot-tested with a member of the study team with experience in conducting research with pregnant individuals who have used substances and covered the following domains: experience conducting research with pregnant individuals on substance use, knowledge about laws governing substance use in pregnancy, and experience with the criminal justice system and/or child protective services ([Appendix B](#)).

The study team recruited a purposive sample of researchers with experience conducting research with pregnant or postpartum people with substance use, drawing primarily from an established network of researchers who have conducted research to measure environmental influences on child development, including substance use. We also contacted eligible researchers who study substance use during pregnancy and were known to members of the larger study team. We then conducted snowball sampling by asking those who agreed to participate to recommend other potential participants with relevant experience. Participants were eligible if they spoke English, had capacity to give informed consent, and had experience conducting research involving pregnant or postpartum people where substance use was identified.

The study principal investigator (PI) and two female research coordinators with master's level training (LPC and KH) emailed researchers with whom they had no prior connection. Participants were informed about the study goals. Two interviewers (LPC and KH) conducted audio-recorded interviews over Zoom between October 6, 2020, and February 10, 2021. Interviews lasted 30–60 min. Transcripts were not returned to participants for comment. The interviewers also took field notes after interviews. The sample size was regularly revisited to determine when there was sufficient information power,²⁹ which was reached after 22 interviews were conducted, consistent with widely cited guidance for qualitative research sampling.³⁰

To protect participant confidentiality, Zoom calls had passwords and waiting rooms and interviews were conducted in private rooms in the workplace. Participants were sent a copy of the consent form in advance. Participants were requested to change their names to a preidentified pseudonym—eg Researcher1—for their recording. Audio and visual recordings and transcripts were saved immediately after the interview to password-protected folders on a secure drive and any files generated by the interview were deleted from the Zoom cloud. Qualitative data were then de-identified and uploaded to an online software program [Dedoose, version 9.0.17 (2021), Socio-

28 Allison Tong, et al., *Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups*, 19 *INT J QUAL HEALTH CARE* 349 (2007).

29 Kirsti Malterud et al., *Sample Size in Qualitative Interview Studies: Guided by Information Power*, 26 *QUAL HEALTH RES* 1753 (2016).

30 Frank J. van Rijnsoever, *(I Cannot Get No) Saturation: A simulation and guidelines for sample sizes in qualitative research*, 12 *PLOS ONE* e0181689 (2017).

Cultural Research Consultants, LLC, Los Angeles, CA] for analysis. A hierarchically organized codebook was developed prior to analysis based on the interview guide; codes were revised through a consensus process after testing the codebook on three transcripts with the two research coordinators and the PI until identification of a comprehensive but manageable set of codes. Data were then independently coded by two research coordinators; the research coordinators and the PI met to discuss all disagreements until consensus was reached. After coding was completed, thematic analysis was used to identify common themes, following the approach outlined by Braun and Clark.³¹ In particular, data were synthesized by reviewing code reports as a team, discussing patterns and themes across the data, and summarizing coding excerpts into themes with associated quotes.

The study was approved by Institutional Review Boards (IRBs) at Lurie Children's Hospital and Washington University of St. Louis. Participants were offered a \$50 gift card for their participation.

III. RESULTS

We contacted 43 researchers in total. Twelve were ineligible because they indicated they did not have experience conducting research with pregnant people where substance use was identified, and 22 were eligible and agreed to participate (response rate: 71 per cent). Of those who declined, nine refused either due to lack of time or because another colleague who had collaborated with them on a study enrolling pregnant people had already been interviewed; seven did not respond to multiple attempts to contact them and were considered passive refusals. Some participants declined the incentive. Most participants identified as female ($n = 17$) and the rest identified as male. Most identified as non-Hispanic White ($n = 19$), with one identifying as Hispanic White, and two identifying as Asian. Most participants (59 per cent) had >20 years of experience conducting research. While most participants lived in urban environments (55 per cent), they frequently conducted their research in urban, suburban, and rural settings (Table 1).

Through thematic analysis, we identified four dominant themes: (i) harms of punitive laws, (ii) negative legal impacts on research, (iii) proposals for legal reform, and (iv) activism over time.

III.A. Harms of Punitive Laws

When asked about laws governing substance use in pregnancy, nearly all researchers responded with sharp criticisms of punitive approaches to regulating substance use in pregnancy. In particular, researchers were critical of laws that classified substance use in pregnancy as a form of child abuse in the child welfare system. Many believed that substance use is neither intentional nor a form of child abuse. One researcher captured the general sentiment that, given the involuntary nature of addiction, treatment is a more appropriate response to substance use in pregnancy than punishment:

31 VIRGINIA BRAUN & VICTORIA CLARKE, *SUCCESSFUL QUALITATIVE RESEARCH: A PRACTICAL GUIDE FOR BEGINNERS* (2013).

Table 1. Researcher participant characteristics

Characteristic	N (%) or mean
Researchers (N = 22)	
Age, years	Average = 52.3
Race and ethnicity (self-identified)	
Non-Hispanic White	19 (86%)
Hispanic White	1 (4.5%)
Asian	2 (9%)
Years of experience conducting research	
0–9	3 (13%)
Oct-19	6 (27%)
20–29	7 (32%)
≥30	6 (27%)
Female	17 (78%)
Training (primary discipline)	
Medicine	9 (41%)
Clinical psychology	9 (41%)
Epidemiology/public health	4 (18%)
Setting of residence	
Urban	11 (50%)
Suburban	9 (41%)
Rural	0 (0%)
Didn't answer	2 (9%)
Setting where research is conducted	
Urban only	8 (36%)
Suburban only	0
Rural only	0
Urban & Suburban	4 (18%)
Rural & Suburban	1 (5%)
Urban, Suburban, & Rural	7 (32%)
Didn't answer	2 (9%)
Laws on substance use in pregnancy in respondent's state of residence	
Punishment focused*	11 (50%)
Treatment focused**	11 (50%)

*Substance abuse in pregnancy is considered form of child abuse, researchers do or may have reporting requirements, no special treatment program or priority for pregnant people, and/or researcher indicated they were working in a punitive environment. **Focused treatment program for substance use exists, and in some cases, pregnant people are prioritized.

'I don't think substance use during pregnancy [] should be considered a form of child abuse. I think that women aren't, like, getting pregnant and saying, I want to hurt my baby and use drugs . . . [A] lot of times, you know, they are addicted to substances and they don't even know they're pregnant until later. And then they feel extremely guilty and bad about themselves. Sometimes they've had a past experience where their baby was taken away from them and they don't want that for the future, so they don't . . . go to a specialty substance use clinic . . . [T]hat

it's framed in terms of as a form of child abuse, I think, is overly harsh and ultimately hurts the mom and the baby in the long run.' (R2).

Many researchers assumed good intentions among most of their participants that they felt were not served by punitive legal approaches. As one researcher explained:

'[I]t's a really difficult-to-treat disorder in general. Pregnancy is a huge motivator and our patients are trying so hard during their pregnancies to be in recovery . . . [A]ll of these other legal ramifications . . . are sometimes barriers to better research and better treatment for the patients.' (R11).

Further, some researchers emphasized that substance use/misuse is a disease like any other, and should be treated as such from a legal perspective:

'I really disagree with those laws and I really do not think those laws should exist. We have lots of medical conditions that are not well controlled in pregnancy that have detrimental side effects—diabetes, high blood pressure. All of those conditions are in better control for some patients and in terrible control for other patients . . . [T]hose conditions can cause stillbirths, growth restriction, preterm birth—the same things that substance use disorders can cause. There should be no difference between...all of those medical conditions.' (R11).

One researcher felt that punishment raised equity concerns because, in their experience, pregnant persons were often particularly motivated to get into treatment but some faced barriers to access due to lack of resources:

'I know of older adults who are middle class, who are addicted, but they can get by because they have supports around them, and they don't really cross over the line to a certain extent. A lot of [exposure during pregnancy] has to do with poverty and not having anything else, and not getting the supports . . .' (R22).

Some found punitive approaches problematic because of the biased treatment of pregnant people by such laws: *'[The law punishing substance use in pregnancy] should be removed. I mean it's, it's, um, it's inhumane, it's...sexist and viewing the woman as a vessel for her child, rather than a person herself, and disregarding her pain.'* (R15).

Finally, some researchers pointed out that these laws can be counterproductive for families:

'Part of the reason is if moms get charged with that as well, that's a felony charge. They have trouble even securing basic housing after that point or a job. And so we're not only knocking down a pregnant woman for using substances during pregnancy but setting them up for future great troubles going forward, which is then going to just perpetuate the issues and kind of the vicious cycle these women get into . . .' (R4).

The only exception to the view that punishment was the wrong response to substance use during pregnancy was one researcher who did not believe cannabis use should be reported but thought there might be reasons to report substances they felt were higher risk:

'I don't think it's very helpful to report every woman who tests positive for marijuana, and this is coming from somebody who thinks that prenatal marijuana use [is] not a good thing, but I don't know that it's helpful to get legal people involved . . . I do think that the law should differentiate between . . . occasional use and use that is clearly detrimental to the mother and child that lead to

abusive, neglectful situations for babies . . . I just think it's so much more clear cut with something like opioids...than it is with other drugs.' (R16).

III.B. Negative Legal Impacts on Research

When asked whether they made modifications to their study design in order to enroll pregnant people who use substances in their research, most researchers reported that they needed to make changes to their studies. While some said their research was focused on other questions and only incidentally enrolled pregnant people using substances, others had addressed this potential risk by designing their studies to avoid obligations to report pregnant people to authorities within the child welfare or criminal justice systems. Indeed, one researcher had a defiant attitude toward potential restrictions of their research, saying: *'I have never been stopped and I don't intend to be.'* (R5).

More specifically, many researchers described having to make modifications throughout the lifecycle of research in terms of their choice of methods, the types of data they collected, and how they engaged participants. In fact, one researcher summarized the pervasive impact of these laws on their thinking by saying, *'I can't think of a study we've done in maternal child health where that [i.e., the law on substance use in pregnancy] wasn't at least a factor taken into consideration.'* (R4) For example, one research team modified the methods they used to collect data:

'[W]e initially were going to offer focus groups . . . what, in our clinic, works . . . but all of us are trying to move to more virtual platforms because of COVID-19 . . . And there's a lot of concern that someone could be . . . recording a virtual session without people's consent and without their knowledge and so a lot of the research now instead [is] moving more towards individual surveys . . .' (R11).

Several only collected de-identified data:

'I have definitely opted to do things like submit grants with de-identified data . . . it's just much easier in terms of being able to do the work without jumping through as many of these legal hoops . . . or really putting patients at risk of needing to jump through the legal hoops . . . [T]he only studies that we did there were completely de-identified . . . We usually . . . did not run biologic specimen data until (in batches) . . . down the road so it wouldn't be any longer impacting their clinical care in any way.' (R13).

'[W]e are doing a research study right now basically using deidentified urines just discarded from the OB clinics . . . I did not want any way that the results of these urines to be traced back to the patient themselves . . . if it could be linked and it certainly snowballs into huge, you know, policy and legal complexities during and after delivery.' (R11).

Furthermore, some researchers who would ideally have collected information from biological samples and by asking participants about their substance use had to collect only one type of information, even though it was not ideal for answering their scientific questions about which substances were able to cross the placenta and affect the fetus:

'We wanted to be able to collect meconium specimens from neonates and see if they had marijuana metabolite, and we weren't able to do that because . . . it would have been a positive neonatal specimen, which would have required mandatory reporting . . . [I]t led to a significant limitation in the project . . . it would [have been] a valuable specimen in terms of being able to see what is crossing the placenta and being detected in neonatal meconium, but we weren't able to do that at all.' (R13).

By contrast, a researcher in a different state relied on samples rather than asking pregnant people about their substance use:

'[T]he challenge with our study is that we didn't actually ask the women if they were using cannabis during pregnancy, that was not part of the questionnaire. So we're relying on these biomarkers . . . [but] you can't actually know if they were using.' (R17).

Some researchers mentioned that they were unable to answer specific scientific questions of great interest. For example, one researcher who wanted to study racial disparities regarding who is screened and tested after delivery. This researcher felt that they could not collect the data without raising legal risks for patients, and decided there was not a safe enough way to study this issue, stating the following:

'One of the things that we really wanted to look at was just racial disparities and who get screened and tested on delivery . . . we essentially scrapped [collecting data on race and ethnicity] and had to kind of estimate it . . . So it definitely changes our ability to be more specific in our research, but we felt that that was important in order to protect the research participants.' (R11).

These researchers felt that collecting data in ways that minimized legal risks decreased the reliability of the research, along with their ability to answer important questions.

Other researchers made modifications further downstream by changing how they engaged with and recruited participants. For example, one researcher described modifying their recruitment approach:

'We recruit [participants] through a substance use during pregnancy clinic and so I know that the head of that clinic is an Ob/gyn. She's incredibly supportive and collaborative and it's a sort of a shared process that they go through for reporting, and so we've never had to do it.' (R2).

Others described waiting to engage with participants after delivery to address laws or concerns from oversight committees about reporting of substance use: *'It's possible that we have in a study waited until after the baby was delivered to avoid, even if there's not a state requirement, some concern on the part of the IRB about reporting.'* (R7) Similarly, another stated:

'[W]e have had studies where we've collected prenatal exposure information after the baby was born, retrospectively . . . it doesn't have the same reporting requirements because there's no imminent danger, because it's already happened . . . I mean, we try to ask things as close to the time period as we can, but we have done that.' (R4).

Again, modifications to recruitment varied based on the types of legal restrictions in place. Based on the laws in a different state, another researcher would engage with participants either before or well after delivery:

'[W]e make modifications and design studies as such a way to get around the laws . . . we see women in the first, second, third trimester of pregnancy and then we don't see them again until six months after the pregnancy and ideally I would have liked to see them . . . around delivery. And we do not do that because we are concerned with reporting. So we . . . kind of modified the design of the study before we even did it.' (R16).

This researcher further explained that the law in their state required reporting if a pregnant person tested positive for substance use, including marijuana use, at the time of delivery, but not prior to delivery or postpartum.

More generally, some researchers described chilling effects of these laws on certain types of research, particularly regarding research done across the United States. One researcher said:

' . . . [We might do] broad research in this area, if we didn't think that it might be a heavier lift to sort of ask the right questions [to] get the data we're interested in . . . and then when you start doing multi site studies this becomes even more of an issue because there'll be another inevitably there's some site that has a different law and they say, well, we can't ask that.' (R6).

Despite, or perhaps because of, the many modifications they made in anticipation of laws governing substance use in pregnancy, most researchers had limited interactions with either the criminal justice or child welfare systems while conducting their studies. As noted above, some researchers recruited participants whose substance use had already been reported by their clinicians. As will be discussed further below, some researchers were able to use legal protections like CoCs to protect their participants' data. Indeed, a few researchers found that the child welfare system was not sufficiently responsive when they were concerned about abuse or neglect. For example, one researcher mentioned an experience where they tried to obtain help for a child and were unable to do so:

'[W]e saw very strongly that the mother was highly abusive and we did make a referral to the county, to protective services, and they would just come back and say everything's fine. So, we really worried about that child . . . We . . . were able to get more services for families, through our social worker . . . but in many cases . . . it was very frustrating . . . [M]ost families are trying to do the best they can . . . [T]hese are only a small percentage of the cases, but they do raise high ethical issues.' (R22).

Yet it is also worth noting that one researcher highlighted experiences with child welfare agencies in their setting that were more positive and focused on keeping families together: *'[T]he general impression you know of child protection services is that that they have to take babies away . . . but I think they really don't come from that standpoint. They're probably doing their best to see how they could keep families together rather than split them apart.'* (R3).

With respect to the criminal justice system, another researcher mentioned learning about research participants' experiences by watching court proceedings. In this example, the researcher made a report of domestic violence related to one of their research participants, and followed through to see what happened next:

'[Y]ou make this report and now they go to go to court and you see you know there's a countersuit from the person that [your participant] initially was . . . seeking a restraining order against . . . I actually thought that was an eye opening experience . . . We can't sort of sit in the white castle in the sky and do our research disconnected from a lot of the other processes that people are going to face . . . some of that is actually gotten woven into our thinking with the things that we are studying as well.' (R6).

This researcher suggested that, in addition to studying substance abuse, participants' interactions with the child welfare and criminal justice systems should also be studied.

III.C. Proposals for Legal Reform

We asked researchers to draw from their experiences to describe their views on existing laws and possibilities for legal reform. While some considered it a gray area, none thought that punishment for substance use during pregnancy was the ideal approach for the pregnant person or infant. This theme was comprised of two sub-themes: (i) how well existing protections like CoCs functioned to protect participants, and (ii) what the ideal law would say.

First, researchers disagreed on how current protections—specifically, CoCs that are now issued automatically for sensitive research by the National Institutes of Health—functioned to protect participants. Some researchers felt these CoCs provided little protection, with one explaining as follows:

‘[T]he Certificate of Confidentiality, . . . I’m not a lawyer, I don’t really [know], but it doesn’t seem very protective at all . . . because you still are required to report . . . if someone actually did you know subpoena, you know us and and really push for these documents. I’m not . . . certain how the Certificate of Confidentiality would protect us.’ (R2).

Three other researchers, however, explained how they had used the Certificate effectively to stave off inquiries from legal authorities. Simply stating that they had a CoC was enough for one researcher to avoid having to share any information with law enforcement:

‘So we had, I believe, two instances that I can remember where we were approached by law enforcement asking for research specimens, because they were notified somehow that you know that this individual may have been a research subject and now she was being charged with child abuse. And so they wanted to see if they could get access to some of the specimens we collected in the prenatal period to use it against her potentially. And so we, when we got a call, you know, we just said, because that’s what the CoC allows you to say is that, that you cannot really confirm or deny if somebody [is] in the research study and that we are not allowed to reveal any other information about their participation, and when we kind of gave them information [about] what the CoC does, they really did not pursue it further. So we didn’t have to go to court.’ (R3).

Another researcher was approached by the Attorney General, who questioned whether the CoC would hold up in court but did ultimately back down:

‘[W]e got the certificate and we went ahead and used it and . . . the Attorney General quote unquote threatened us with, “You know, it hasn’t been tested yet.” And we said, “Okay,” but we never really heard from, you know, him again. [B]ut it only works when that information is not available . . . We couldn’t do anything about [information in the medical record] or if the mom happens to say something to a nurse or a doctor . . . they’re automatically going to get reported. But if they told it to us and nobody else, and it did not appear in the record, yes, absolutely, it works . . . It was very effective also . . . because it was a way of developing a relationship with these moms . . . the certificate helped a lot. It formed that initial relationship, and then, you know, we sustain that.’ (R5).

This researcher also found that the CoC was useful to reassure potential participants. Finally, a third respondent used the CoC as a tool to enter into a memorandum of understanding with state authorities and felt that these documents together offered even stronger protection to participants:

'[The Certificate of Confidentiality] serves as the basis of that memorandum of agreement that I was mentioning [with state authorities], and we have had local law enforcement, try to get information about a participant or . . . trying to see if somebody was in the study and were able to kind of hold up those two documents to show that we would not be able to provide them with any information.' (R4).

While some researchers did not see the value in CoCs, it is worth noting that even those who were able to use them effectively were not certain that CoCs would prevent them from having to share information if it were legally compelled.

In addition to asking about existing protections, we further questioned researchers about how they thought laws should address substance use in pregnancy. A few researchers stated the law should not be involved at all, and that clinicians should be able to work with their patients to get them into treatment. Some respondents were hard-pressed to think of what the ideal law would say, noting that they did not have legal training. Some focused on the researcher–participant relationship and the need to respect confidentiality of information that individuals share with researchers:

'[A] law should have provisions for research to be conducted, and the provisions should make sure/guarantee the confidentiality of the information that the participants share with researchers . . . [R]eporting can be done at an aggregate level, not an individual level, because that's useful information for, you know, surveillance purposes.' (R12).

Similarly, many respondents felt that researchers should not be asked to disclose information to others, and that the criminal justice system in particular should not be involved, but that laws could help ensure women had access to treatment:

'[My proposal would be to] design all our laws around substance use, but it would be all towards treatment and help and so more of a harm reduction approach, . . . particularly when it comes to pregnant women, less about viewing them as a vessel for the baby . . . So it would be all about clinical health and intervention and not separating her from her baby . . . assuming she is not currently abusing the child.' (R15).

One researcher suggested that states should allocate funding for treatment for substance use and misuse and participants should be allowed time to seek treatment before they are reported: *'I would say that part of the law would be that there needs to be funding set aside for that so these women can get treatment . . . I think the woman should be given the opportunity to seek treatment and to be counseled on it, to get some education before it's reported . . .'* (R17).

Another researcher went farther and stated they would mandate treatment for pregnant people who use substances. This researcher also connected the need to protect participants to the history of exploitation of vulnerable participants in research:

'I mean, if you think about, you know, the most egregious things in terms of some of the terrible clinical trials that have happened in the past is when it's been, you know, folks were not fully aware of the implications of their doing research either for their own bodies or what's running through their own bodies, whether you think about prisoners or whether you think about some of the terrible things that have been done in the past . . . I don't think there should be a mandatory aspect for this.' (R9).

The legacy of mistrust based on ethically questionable research in the past led this researcher to feel that mandatory reporting would undercut their efforts to build trust with participants and be trustworthy.

Finally, one researcher demonstrated how legal reform can enhance the conduct of research by explaining that they began asking new questions once a substance (cannabis) became legal: *'We had a few participants who reported marijuana consumption even before it was legal . . . but a handful. And of course after it became legal, we added a question and we now are collecting more.'* (R12).

III.D. Activism Over Time

Notably, some researchers engaged in outreach and activism to change the law, working with relevant stakeholders. As one researcher explained: *'[T]here are dangerous home environments where if you're involved, you have to do something . . . But [the response] can be . . . constructive and supportive. But I think as a researcher, you might have to build it.'* (R19) This researcher felt an obligation to work with child welfare services to tailor their response to the needs of the family.

One researcher discussed the evolving understanding of substance use over time, as well as the fact that the race and ethnicity of groups affected by substance use can increase or decrease political willingness to pass rehabilitative laws. This respondent took it upon themselves to educate judges, nurses, and other stakeholders and was able to enact specific legal reform as a result:

'[W]e did presentations for the judges and I tell you the judges were furious when we told them what was going on . . . they were saying...I'm taking these babies away from their mothers and you're telling me that they're not necessarily bad mothers and the kids aren't going to be damaged. Why don't I know this? They were they were really, really angry....'[S]o we got federal funding to create a family treatment court as an alternative to the . . . punishment-oriented family court . . . It was called "treatment with teeth" because there were sanctions, so that if you did not do what you were supposed to do . . . it will delay the reunification process . . . And then we did research to show that, yes, guess what, you know, treatment works.' (R5).

This respondent further described a trajectory of progress that included efforts at the federal level. They felt that bipartisan support of legislation to address the opioid crisis was because so many politicians personally knew someone who had been affected, explaining as follows:

'I mean, the population that we're working with today is different from the population that we were working with in . . . the early 1990s . . . Back then, we know what we know now that we didn't know then, right, [is] the whole idea of drug addiction, drug use being a disease of the brain and not about that people wanting to hurt their kids and doing bad things . . . that was a real eye opener . . . for a lot of people. And when we were able to go out and talk in public speaking...and show the research and try and make that distinction. You know what it means for drug use to be a disease of the brain that helped change . . . public perception and to some extent public policy. [A] lot of the attention that you're seeing now with the opioids . . . is . . . because they're the wives and the kids of middle class people...so that the problem has...become gentrified....[W]hen we were finishing up the research and right after I was convinced that we have made a difference, that public policy . . . and attitudes changed....I saw that the attitudes in the hospitals and nurses weren't being as hostile anymore. And now with the opioid stuff, we're seeing a resurgence of all

that negativity . . . I don't think it's as bad as it was then. But we have [seen] . . . it swing back toward that. And that really bothers me.' (R5).

Yet this researcher also believed that prior progress is currently being eroded.

IV. DISCUSSION

To our knowledge, this was the first study to explore how researchers who study prenatal substance use view laws and policies on substance use in pregnancy, legal barriers to research participation and treatment, and their recommendations for legal reform. This work adds to a growing body of research on how stakeholders, focusing on pregnant people and obstetric providers, view and interact with laws governing substance use. These data fill an important gap, which is particularly relevant now as reproductive rights are being restricted in many parts of the United States. The results of this study have implications for future research, clinical care, advocacy, and policy.

Our respondents identified the potential for legal system involvement as a key factor that negatively affected clinical care and research and led them to make scientific compromises. Researchers who were very knowledgeable about the potential effects of prenatal substance use on families saw punishment and incarceration as detrimental. They explained that punitive policies prevent people from seeking healthcare and fail to account for the motivations of many pregnant people to seek treatment for addiction. Additionally, while their interactions with the legal systems were limited, our respondents anticipated (and occasionally witnessed) harms of punitive laws affecting pregnant persons, children, and families.

Some respondents also thought that taking a punitive approach to substance use was unfair, highlighting the fact that many health conditions in pregnancy have similar potential to harm fetuses, but punishment rather than treatment is only seen as an appropriate response to the disease of addiction. They pointed out that for a pregnant person with diabetes or high blood pressure, few would argue that removal of child custody or incarceration is the best approach, and argued that facilitating treatment for any health condition during pregnancy is the best way to help the pregnant person and the infant. One exception to this general view was a researcher who differentiated between casual use of marijuana and the use of harder drugs (eg opioids); this researcher thought that opioid use might be linked more closely to child abuse or neglect and therefore may need to be treated punitively through child protection services. It is worth noting, however, that this researcher did not study opioid use and this view was not held by other respondents who conducted research on opioids.

The minority view we identified is consistent with a belief about the need for a more punitive response to addiction during pregnancy as compared with other diseases, based on a perceived association between prenatal substance use and child maltreatment of substance-exposed children. While infants with substance exposure during pregnancy are at higher risk of injury from subsequent child abuse and neglect, this risk is based on many different factors, including poverty and access to healthcare. Focusing on maternal substance use as the only problem to resolve is unlikely to provide effective protection for these children.³²

32 Stephanie A. Deutch et al., *Factors Associated with Child-Welfare Involvement among Prenatally Substance-Exposed Infants*, 222 *JOURNAL OF PEDIATRICS* 35 (2020).

The concerns our participants raised about the effects of punitive laws on the behavior of pregnant persons align with the views of people with lived experience using substances during pregnancy, their clinicians, and other experts. Studies of women using substances during pregnancy show that they fear detection and employ multiple strategies, including skipped medical appointments and avoidance of care altogether, based on concerns that clinicians might recognize their substance use and report them to state authorities.³³ Pregnant people have described the ways that stigma, the threat of prosecution, or the potential loss of custody of their children can prevent from participating in care and research that could be beneficial for them, their infants, and for society.³⁴ Persons with lived experience have variable understanding of the potential legal consequences, but are well aware of the possibility of losing custody of their children, and some worry that data collected during research could be included in court proceedings against them.³⁵ In one study, a few patients shared information about their substance use with providers and described having this strategy backfire by leading to poorer treatment.³⁶ These strategies are detrimental to the health of pregnant people and fetuses.³⁷ Though professional societies have recommended that obstetricians and maternal-fetal medicine physicians should only test patients for substance use with their consent and if the benefits outweigh the risks of legal consequences, some providers and pregnant people may not be aware of this guidance.³⁸ Punitive laws can therefore diminish the willingness of pregnant persons to seek the help and care they need.

Our respondents' views were aligned with those of other experts who also hold negative perceptions of punitive approaches to governing substance use in pregnancy.³⁹

Some have noted that 'professional health care and child advocacy communities are uniform in their critique of coercive interventions such as criminalization (arrest and incarceration) or automatic removal of child custody as counter to the best interests of unborn children, chemically dependent women, and their families.'⁴⁰ Similarly, a study of obstetric and pediatric providers found that clinicians felt that more resources

33 Rebecca Stone. *Pregnant women and substance use: Fear, stigma, and barriers to care*. 3 HEALTH & JUSTICE 2 (2015); Sarah C. M. Roberts & Amani Nuru-Jeter. *Women's perspectives on screening for alcohol and drug use in prenatal care*; 20 WOMENS HEALTH ISSUES 193 (2010); Sarah C. M. Roberts & Cheri Pies. *Complex calculations: How drug use during pregnancy becomes a barrier to prenatal care*. 15 MATERN CHILD HEALTH J. 333 (2011).

34 Roberts & Nuru-Jeter, *supra* note 25, at 193; Mishka Terplan et al., 'Compassionate coercion': factors associated with court-mandated drug and alcohol treatment in pregnancy 1994–2005, 4 J ADDICT MED 147 (2010); Roberts & Pies, *supra* note 25, at 334.

35 Florence Hilliard, et al., *Voices of Women with Lived Experience of Substance Use During Pregnancy: A Qualitative Study of Motivators and Barriers to Recruitment and Retention in Research*, 46 FAMILY & COMMUNITY HEALTH 1 (2023).

36 Rebecca Stone, *supra* note 25, at 2.

37 Gale A. Richardson, et al. *Growth of infants prenatally exposed to cocaine/crack: comparison of a prenatal care and a no prenatal care sample*. 104 PEDIATRICS 118 (1999).

38 Jeffrey Ecker, et al. *Substance use disorders in pregnancy: clinical, ethical, and research imperatives of the opioid epidemic: A report of a joint workshop of the Society for Maternal-Fetal Medicine, American College of Obstetricians and Gynecologists, and American Society of Addiction Medicine: Practice Guideline*. 221 AM J OBSTET GYNECOL B5 (2019).

39 Nora D. Volkow. *Addiction should be treated, not penalized*. 46 NEUROPSYCHOPHARMACOLOGY 2048 (2021).

40 Mary F. Marshall, et al. *Perinatal substance abuse and human subjects research: Are privacy protections adequate?* 9 MENT RETARD DEV DISABIL RES REV 54 (2003).

should be provided for pregnant people who use substances.⁴¹ Moreover, respondents in this study felt, as many of our participants did, that clinicians should not have to report substance use in pregnancy because the degree of harm is often unclear. They argued that a more appropriate response would be to focus on treating a chronic illness. Significantly, some of these respondents highlighted the need for more research of the kind that participants in this study have conducted.

One of our most striking findings was the many examples of scientific compromises made by our participants, including adopting ‘don’t ask, don’t tell’ approaches to studying substance use. Laws penalizing substance use in pregnancy may not be designed to restrict the conduct of research but do have this unintended consequence. These laws might raise dilemmas for researchers and oversight bodies deciding when to allow research to go forward, given the potential for legal risks, especially if laws are ambiguous or in flux. Research is sorely needed to understand the potentially causal effects of substance use during pregnancy on neurological development in a nuanced way, using high quality methods to disentangle the direct effects from other influences on the mother and the fetus.⁴² The absence of robust evidence may contribute to misinformation among the public about harmful effects which have not been demonstrated, which is likely to exacerbate bias and inequities. A solid scientific foundation could inform the development of interventions that can benefit pregnant people, children exposed to substances in utero, and families. Laws that purport to protect children exposed to substances prenatally but impede rigorous research therefore make it harder to protect the very children they were intended to help.⁴³

While it is increasingly recognized that the effects of a hostile legal climate are felt disproportionately by pregnant people of color, the issue of bias only arose in our study tangentially, perhaps because our interview guide focused chiefly on research and not as much on the laws themselves. In prior studies, pregnant individuals who identified as Black or Indigenous faced higher rates of screening for drug use and reporting than pregnant people who identified as White⁴⁴ and are less likely to receive treatment for addiction.⁴⁵ Clinicians have expressed concern about the risk of bias in implementing punitive policies.⁴⁶ Nevertheless, some of our respondents did note that pregnant people of lower socioeconomic status were more likely to struggle under punitive legal regimes. One researcher highlighted that differences between the population affected by the drug epidemic in the 1990s and those affected by the opioid epidemic, implicitly connecting the differential treatment to race. This researcher explained that the opioid

41 Marian Jarlenski et al., *Obstetric and Pediatric Provider Perspectives on Mandatory Reporting of Prenatal Substance Use*, 13 J ADDICT MED. 258, 259 (2019).

42 Ryne Estabrook, et al. *Separating Family-Level and Direct Exposure Effects of Smoking During Pregnancy on Offspring Externalizing Symptoms: Bridging the Behavior Genetic and Behavior Teratologic Divide*. 46 BEHAV GENET 389 (2016).

43 Marshall et al., *supra* note, at 29.

44 Simon R, Giroux J, Chor J. Effects of substance use disorder criminalization on American Indian pregnant individuals. *AMA J ETHICS*. 2020;22(10):E862-E867;

45 Schiff D, Work EC, Foley B, et al. Perinatal Opioid Use Disorder Research, Race, and Racism: A Scoping Review. *PEDIATRICS*. 2022 Mar 1;149(3):e2021052368. doi: 10.1542/peds.2021-052368.

46 Roberts S, Zaugg C, Martinez N. Health care provider decision-making around prenatal substance use reporting. *DRUG ALCOHOL DEPEND*. 2022 Aug 1;237:109514.

epidemic ‘gentrified’ drug policy to be more humane and compassionate as more White people were affected by it.⁴⁷

Notably, scholars have recommended that researchers also conduct advocacy for legal reform that promotes treatment over punishment for individuals who use substances during pregnancy. These scholars have argued that investigators have moral responsibilities to know the relevant laws and policies that might cause harm to participants at their institutions, and to carefully consider whether adequate protections are possible to justify conducting the research.⁴⁸ Our study builds on these calls to provide concrete examples of researchers conducting advocacy that was effective over time. These researchers helped enact criminal justice reforms that directed pregnant people into care—what one researcher called ‘treatment with teeth.’ This translation of research into advocacy was possible once researchers were able to show that addiction is a disease that can benefit from treatment and support and educate stakeholders with their findings. These researchers found that judges were open to adopting these approaches once they understood the data did not support removal or even concern for harm to children in some cases.

Our study also has several implications for policymakers. First, greater clarification may be needed about CoCs. Wolf and Beskow have noted that CoCs do not currently protect against mandatory reporting in research on substance use in pregnancy, even though they were presumably created with the goal of facilitating research of this nature. Wolf and Beskow have called for further research to understand the full scope of protections provided and how these gaps in protection should be explained to participants.⁴⁹ In our study, while some researchers correctly noted the limits of CoCs, others received formal inquiries or data requests from legal authorities and were successful in using these CoCs to protect their participants. These researchers also felt that the CoC helped them ease the concerns of potential participants. Yet, even those who were successful in protecting participants faced pushback from legal actors who stated that CoCs may not hold up if they were challenged in a court of law. Our data suggest that researchers should be educated about how to use CoCs effectively to protect their participants, but should also take care not to oversell the level of protection they offer. Additionally, as other scholars have noted, the federal structure for state child welfare laws provided by CAPTA could be clarified and better enforced to ensure states focus on notification of state agencies about prenatal substance use rather than reporting it as a form of child abuse; reducing or eliminating the discretion given to states is warranted as it fails to align with Congressional intent and scientific evidence about the approaches that are best for families.⁵⁰

More fundamentally, researchers studying substance use in pregnancy are likely to be among the most informed and sophisticated about how substance use should be understood and approached by the law, and it is striking that they largely do not support

47 *Id.*

48 Marshall et al., *supra* note 32, at 55.

49 Leslie E. Wolf & Laura Beskow. *Certificates of Confidentiality: Mind the Gap*. 4 UTAH LAW REV. 937, 938 (2021).

50 McCourt AD, White SA, Bandara S, Schall T, Goodman DJ, Patel E, McGinty EE. Development and Implementation of State and Federal Child Welfare Laws Related to Drug Use in Pregnancy. *Milbank Quarterly* 2022;100(4):1076–1120.

punitive approaches to addressing addiction during pregnancy. These experts favored non-punitive laws that would permit clinicians or researchers to refer participants to substance use disorder treatment services that provide care for pregnant and postpartum persons. To the extent that insurance coverage poses a barrier to treatment,⁵¹ states could cover substance use disorder treatment services as part of pregnancy-related Medicaid coverage. Policymakers should take note that there is a clear disconnect between state laws that view substance use as a moral failing deserving punishment through the criminal justice system or family separation through the child welfare system, and experts' understanding of addiction during pregnancy as a disease that requires treatment.

This study has several limitations. While a majority of respondents had >9 years of experience conducting research, some had not conducted research studying substance use in pregnancy directly, but only incidentally enrolled participants who became pregnant while using substances. Additionally, most of our participants were White people. Although our demographic data are consistent with the Science, Technology, Engineering, and Mathematics (STEM) workforce,⁵² it is possible that the lack of ethnic/racial diversity in our sample affected respondents' perceptions of laws related to substance use during pregnancy and how they responded to these laws. Our respondents did, however, reflect a broader group of researchers with considerable experience doing work that may be impacted by laws restricting reproductive autonomy. The sampling strategy selected for certain types of researchers who may have had strong views against punitive approaches, were less busy, or are more interested in qualitative research. Some respondents were pressed for time, and some interviews were shorter than others, but many extended to an hour or more. Finally, our respondents did not have a great deal of direct experience with the criminal justice system, though some were able to use existing protections to prevent law enforcement or other legal authorities from accessing information about their participants.

V. CONCLUSION

In this study, we found that researchers who have engaged with pregnant persons using substances during pregnancy sharply criticized punitive legal approaches and made many scientific compromises to protect their participants. A few researchers attained hard-earned gains through research dissemination and advocacy, but this progress is now threatened as legal approaches could trend back toward punitive approaches to substance use in pregnancy. Now more than ever, it is critical to learn from those who have done the important and difficult work to engage with pregnant people to support research into the long-reaching effects of the opioid epidemic and the use of other substances in an empirically rigorous way. Ultimately, researchers and policymakers are likely to have shared interests in identifying ways to improve health and well-being for all children and families.

51 Cara Angelotta, et al. *A Moral or Medical Problem? The Relationship between Legal Penalties and Treatment Practices for Opioid Use Disorders in Pregnant Women*. 26 *WOMEN'S HEALTH ISSUES* 595 (2015).

52 Cary Funk & Kim Parker. *Diversity in the STEM Workforce Varies Widely Across Jobs*. Pew Research Center 2020; <https://www.pewresearch.org/social-trends/2018/01/09/diversity-in-the-stem-workforce-varies-widely-across-jobs/> (Last accessed: 3 January 2022).

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SUPPLEMENTARY DATA

[Supplementary data](#) are available at *Journal of Law and the Biosciences* online.

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