Written Testimony

Of

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Before the

House Energy and Commerce Subcommittee on Health

Regarding

Examining Public Health Legislation: H.R. 2820, H.R. 1344, and H.R. 1462

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Summary of Testimony

The testimony of Dr. Mishka Terplan will seek to summarize how passage and implementation of H.R. 1462, the Protecting Our Infants Act, will improve access to quality treatment and care for pregnant women with opioid addiction and their infants.

1. Prevention and treatment of prenatal opioid use disorders
    - Among women with opioid addiction, 86% of pregnancies are unplanned
    - Safe prescribing during pregnancy includes opioid-based medications, such as methadone or buprenorphine. In most instances, withdrawal or detoxification is not clinically appropriate.
    - Screening, brief intervention, and referral to treatment can facilitate early detection and referral.
    - Provider education and public awareness efforts can enrich the patient-provider discussion on the risks and benefits of various medications, including opioids, and potential risks to the fetus.

2. Gaps in research and programming
    - Medically-appropriate opioid use in pregnancy is not uncommon and opioids are often the safest and most appropriate treatment for a variety of medical conditions and severe pain during pregnancy. Additional research is needed on effective and non-addictive pain treatment.
    - Punishing pregnant women with substance use disorders by targeting them for criminal prosecution or forced treatment is inappropriate and will drive women away from seeking prenatal care and other drug treatment.
    - Innovative treatment models are needed and should be tailored to pregnant or parenting women.

3. Improved data collection and surveillance
    - Opioid addiction has become more widespread geographically and demographically. In communities with high opioid prescription and addiction rates, there will be higher rates of pregnant women with opioid addiction and subsequent NAS.
    - Access to national and state-specific NAS data would enable trend analyses and foster greater sharing of best practices and treatment strategies.
    - Improved data will help us better track and understand long-term outcomes of infants with NAS. Data end points need to be long term.

Good morning Chairman Pitts, Ranking Member Green, and distinguished members of the Subcommittee on Health of the Energy & Commerce Committee and thank you for having me here today. My name is Dr. Mishka Terplan and I am double boarded in obstetrics and gynecology and addiction medicine and currently serve as the Medical Director of Behavioral Health System Baltimore.

As a specialist in both women's health and addiction, I have devoted my career to treating women with psychosocial risk including substance use disorders and improving prescribing practices. As a Fellow of the American College of Obstetricians and Gynecologists (ACOG) and member of the American Society of Addiction Medicine (ASAM), I was an author of the joint Committee Opinion "Opioid Abuse, Dependence, and Addiction in Pregnancy." In addition I represent ACOG on the American Medical Association's (AMA) Federation Task Force to Reduce Opioid Abuse and am a member of ASAM's Women and Substance Use Disorders Action Group. I have also participated in expert panels for the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Office of National Drug Control Policy (ONDCP) on screening tools for substance use among pregnant women, maternal addiction and neonatal abstinence syndrome (NAS).

I am pleased to testify on behalf of the American Congress of Obstetricians and Gynecologists (ACOG) in support of H.R. 1462, the Protecting Our Infants Act. I would like to thank Representatives Katherine Clark (D-MA) and Steve Stivers (R-OH) for their leadership in introducing this legislation, and the 8 cosponsors on the Health Subcommittee: Representatives

Susan Brooks (R-IN), Kathy Castor (D-FL), Chris Collins (R-NY), Brett Guthrie (R-KY), Joseph Kennedy (D-MA), Leonard Lance (R-NJ), Jan Schakowsky (D-IL) and Ed Whitfield (R-KY). I urge the Committee to act swiftly in reporting out this legislation.

H.R. 1462 represents a bipartisan effort to address the critical problem of opioid addiction and (NAS) facing pregnant women from all socioeconomic backgrounds. NAS refers to medical issues associated with drug withdrawal in newborns following prenatal exposure to opioids and is expected and treatable with no long term negative outcomes documented in the literature. Specifically, H.R. 1462 would commence three important initiatives:

1. Direct HHS to conduct a study and develop recommendations for the **prevention and treatment of prenatal opioid use disorders** and neonatal abstinence syndrome, soliciting input from stakeholders like ACOG.
2. Task the Secretary of HHS with leading a review of planning and coordination within HHS to **close the gaps in research and programming** identified by GAO in their February 2015 report.
3. Encourage **improved data collection and surveillance** by the states and promote an increased public health response to reducing NAS.

This bipartisan, bicameral legislation provides a badly needed public health approach to addressing maternal addiction and NAS and moves us away from punitive proposals that we have seen in many states. In fact, so far in 2015 at least 8 states have considered criminal penalties or immediate revocation of child custody for women who use opioids or other

substances during pregnancy. These efforts are harmful to families and drive women away from accessing prenatal care and addiction services.

I have seen firsthand the recent increase in opioid use and its impact on women and their babies. And I can say with confidence that passing the Protecting Our Infants Act would be a good thing for families. While I want to stress the importance of the mother-infant dyad, my testimony will focus primarily on the woman and how passage and implementation of H.R. 1462 would improve access to quality treatment and care for this population.

1. Prevention and treatment of prenatal opioid use disorders

Preventing inappropriate opioid use among pregnant women and women of childbearing age is crucial. Addressing this issue requires a focus on women of childbearing age, pregnant women, and infants from preconception through early childhood. **For pregnant women, it is most appropriate to treat and manage maternal substance use in a non-punitive manner through family-centered medical treatment.**

For women of childbearing age, quality preconception care and family planning optimize a woman's health and knowledge before planning and conceiving a pregnancy, improving the likelihood of having a healthy pregnancy and a healthy baby.[i] Unplanned pregnancies are at greater risk for a range of negative birth outcomes, such as low birthweight and preterm birth. Among women with opioid addiction, about 86% of pregnancies are unplanned, compared with 46% of pregnancies in the overall population.[ii]

All pregnant women are concerned for the health of their baby-to-be and all are motivated to change unhealthy behaviors. From population level data, we know the natural history of substance use during pregnancy – most women who use substances including opioids quit or cut back. Those who cannot stop using, by definition, meet criteria for having a substance use disorder. In other words, continued substance use in pregnancy is pathognomonic for addiction, a chronic, relapsing brain disease.

When treating pregnant women with opioid addiction, in most instances withdrawal or detoxification it is not clinically appropriate. Medically supervised tapered doses of opioids during pregnancy often result in relapse to former use within a short period of time, adding increased risk to the fetus and increasing the mother's risk for overdose postpartum. Abrupt discontinuation of opioids in an opioid-addicted pregnant woman can result in preterm labor, fetal distress, or fetal demise.[iii]

Safe prescribing during pregnancy includes opioid-based medications, known as opioid agonist therapy (OAT). OAT, such as methadone or buprenorphine, is the medical standard of care for pregnant women with opioid addiction. Physician prescribed and supervised use of OAT improves outcomes for both mom and baby when compared to no treatment or to medication-assisted withdrawal. However, pregnant women continue to face access issues. In fact most pregnant women with opioid addiction in the U.S. do not receive OAT.[iv] It is important to note that denying pregnant women evidence-based treatment, such as OAT, out of concern for NAS, is not only discriminatory, but is counter to the standard of care and will result in worse outcomes for mom and baby.

Screening, brief intervention, and referral to treatment (SBIRT) can facilitate early detection and referral and should be expanded to diverse settings where at-risk women can be reached. If biological testing for drugs is utilized, the woman should be informed of the test and how the results of the test will be managed.

Additionally, provider education and public awareness efforts can enrich the patient-provider discussion on the risks and benefits of various medications, including opioids, and potential risks to the fetus. Providers should be educated on the most current substance use screening tools and universal screening should be the standard of care for all obstetrics patients. Opioid medication should be accurately and precisely labeled to ensure appropriate access to medication and therapy for women who are addicted and for whom the alternatives – such as heroin or withdrawal during pregnancy – are much more dangerous. Specifically, the FDA boxed warning related to pregnancy should be removed or updated to remove the inaccurate and imprecise information linking opioid use during pregnancy with "life-threatening neonatal opioid withdrawal syndrome," a claim with no scientific evidence.

There are a number of provider education efforts currently underway. For example, as a member of AMA's Task Force to Reduce Opioid Abuse, I am assisting in the development of a CME course on safe prescribing, I will be representing ACOG at AMA's Pain Management Expert Panel in Chicago next month, and am on an expert panel to develop a "guide to the management of opioid-dependent pregnant and parenting women and their children" through SAMHSA.

2. Gaps in research and programming

Additional research is needed on effective and non-addictive pain treatment, and any such research should include women of childbearing age and pregnant women. However it is important to note that medically-appropriate opioid use in pregnancy is not uncommon and opioids are often the safest and most appropriate treatment for a variety of medical conditions and severe pain during pregnancy.

Pregnant women with substance use disorders need access to comprehensive services, including prenatal care, drug treatment, and social support services. Women with substance use disorders often have other psychosocial risk factors that need to be addressed in order to ensure they successfully discontinue using drugs. **Punishing pregnant women with substance use disorders by targeting them for criminal prosecution or forced treatment is inappropriate and will drive women away from seeking prenatal care and other drug treatment**.

Innovative treatment models are needed and should be tailored to pregnant or parenting women, taking into account the woman's family and professional obligations, and should provide priority access for pregnant women.

3. Improved data collection and surveillance

Opioid addiction has become more widespread geographically and demographically, crossing into unexpected affluent suburban and rural communities. In fact, according to the CDC, in some states there are as many as 96-143 prescriptions for opioids per 100 adults per year.[v] In

communities with high opioid prescription and addiction rates, there will be higher rates of pregnant women with opioid addiction and subsequent NAS.

While we have general state-by-state data for prescribing rates, similar information is absent for rates of NAS. Access to national and state-specific NAS data would enable trend analyses and foster greater sharing of best practices and treatment strategies. For instance, select states with active maternity and perinatal quality collaboratives have enacted programs to address NAS, and many of these programs have partnerships with hospitals and a data collection component.

Improved data collection will also help us to better track and understand the long-term outcomes of infants with NAS. For those purposes, data end points need to be long term, not just short term, and be of both clinical and sociological significance.

Thank you for the opportunity to testify at today's hearing. The Committee's attention to and interest in reducing maternal opioid addiction and NAS is crucial and the Protecting Our Infants Act represents a positive step forward in addressing this growing issue. I welcome your questions.

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[i] American College of Obstetricians and Gynecologists Committee on Gynecologic Practice, *Committee Opinion No. 313 The Importance of Preconception Care in the Continuum of Women's Health Care*, September 2005 (Reaffirmed 2012).
[ii] Heil S, Jones H, Arria A, et al. "Unintended pregnancy in opioid-abusing women." J Subst Abuse Treat. 2011 Mar, 40(2): 199-202.
[iii] ACOG. *Committee Opinion No. 524. Opioid Abuse, Dependence, and Addiction in Pregnancy (Reaffirmed 2014).*
[iv] Martin C, Longinaker N, Terplan, M. "Recent trends in treatment admissions for prescription opioid abuse during pregnancy." J Subst Abuse Treat. 2015 Jan, 48 (1): 37-42
[v] Paulozzi L, Mack K, Hockenberry, J. "Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines – United States, 2012." CDC MMWR. 2014. 63(26); 563-568.