UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WISCONSIN

TAMARA M. LOERTSCHER

Plaintiff,

v.

J.B. VAN HOLLEN, in his official capacity as ATTORNEY GENERAL OF THE STATE OF WISCONSIN, and

ELOISE ANDERSON, in her official capacity as SECRETARY OF THE DEPARTMENT OF CHILDREN AND FAMILIES

Defendants.

CIVIL ACTION

Case No. 14-cv-870

DECLARATION OF MISHKA TERPLAN, M.D., MPH

I, Dr. Mishka Terplan, do hereby swear and affirm that I make the following declaration, under penalty of perjury, from my expertise and personal knowledge.

Expertise and Qualifications

1. I am a physician with board certification in both obstetrics and gynecology and addiction medicine. I currently serve as Medical Director of Behavioral Health System Baltimore, in Baltimore, Maryland. Additionally I am a staff physician at both Mercy Medical Center and Planned Parenthood Maryland. A copy of my current curriculum vitae is attached as **Exhibit A**. If called as a witness in the matter, I could and would testify competently to the following:

2. I received my M.D. from the University of California, San Francisco, completed my residency in obstetrics and gynecology at the University of Southern California and my Masters in Public Health from the University of North Carolina School of Public Health, with a

concentration in Epidemiology. I am certified as a Fellow of the American Congress of Obstetricians and Gynecologists and as a Diplomate of the American Board of Addiction Medicine. My clinical and research work focuses on the intersection of reproductive health and substance use disorders.

3. I have written more than 40 published, peer-reviewed journal articles. For example, I am the lead author on "Methamphetamine Use Among Pregnant Women," published in Obstetrics & Gynecology in 2009, an article that describes the prevalence of methamphetamine use and associated characteristics among pregnant drug treatment admissions, attached as **Exhibit B**. I am also the lead author of "The Effects of Cocaine and Amphetamine Use during Pregnancy on the Newborn: Myth versus Reality" published in the Journal of Addictive Diseases in 2011, an article that reviews the scientific evidence and limitations of the evidence regarding the outcomes of cocaine and amphetamine use in pregnancy, attached as **Exhibit C**.

4. I am the co-author of a textbook chapter, "Prenatal Substance Abuse", in the Textbook of Substance Abuse Treatment, 5th Edition, published in December, 2014.

5. I am a member of the graduate faculty at the University of Maryland School of Medicine, and prior to my current position was an Assistant Professor of Obstetrics, Gynecology, and Reproductive Services at that institution. I also serve as an Adjunct Assistant Professor at the University of Maryland School of Medicine, Department of Epidemiology & Public Health. Previously, I was an Assistant Professor at the University of Chicago School of Medicine's Department of Obstetrics and Gynecology.

6. Since 2010 I have served on the "Women and Substance Use Disorders Action Group" for the American Society of Addiction Medicine ("ASAM") which in collaboration with

the American Congress of Obstetricians & Gynecologists ("ACOG"), co-authored two Committee Opinions: "Public Policy Statement on Women, Alcohol and Other Drugs, and Pregnancy," published July, 2011 and "Opioid Abuse, Dependence, and Addiction in Pregnancy," published May, 2012.

7. I have served on numerous professional committees, both national and local. Currently, I represent ACOG as a member of the American Medical Association's "Task Force to Reduce Opioid Abuse", and am the Medical Advisor at the National Research Center for Women and Families in Washington DC. Since 2010 I have been a member of the Pregnancy Risk Assessment Monitoring System steering committee for Maryland and the National Institutes on Drug Abuse's International Women's and Children's Health and Gender Group. I was an Invited Participant to the "Expert Meeting on Perinatal Illicit Drug Abuse" by the Center for Disease Control and Prevention (CDC) in 2012 and an author on the resulting manuscript: "Clinical care for opioid-using pregnant and postpartum women: The role of obstetric providers" published in the American Journal of Obstetrics and Gynecology in 2013.

8. I am also currently co-lead of the Baltimore City Health Department's "Prevention of Substance Exposed Pregnancy" Coalition, as well as a current member of numerous other state and city committees and workgroups that focus on preventing overdose deaths and improving substance use disorder treatment in Maryland and in Baltimore.

9. I was retained to give my expert opinion on two matters: first, the state of Ms. Loertscher's health and the medically appropriate, ethical response to her care during her stay at the Eau Claire Mayo Clinic Hospital ("the Mayo Clinic") from August 1-7, 2014; second, the ethical and medically responsible care for pregnant women who suffer from substance use disorders or who use non-prescribed, illegal drugs during pregnancy.

Tamara Loertscher's health status August 1-7, 2014

10. I reviewed medical records prepared by health care providers and other hospital staff during Ms. Loertscher's stay at the Mayo Clinic from August 1st through 7th, 2014. I do not know whether this is a complete set of the records, although there are charts and notes from each of those days within the notes provided to me. I have never met Ms. Loertscher, other than to hear her speak at a press teleconference in which I participated as a general expert on obstetrics, gynecology, and addiction medicine, before I was retained as an expert witness in this matter. I have not evaluated Ms. Loertscher's health through any examination of my own. My opinion is based on the medical records provided to me.

11. From review of those records, Ms. Loertscher is a pregnant woman who was acting in the best interests of her pregnancy.

12. According to these records, there's little question that she used methamphetamine and marijuana in the months prior to seeking medical care. While an unconfirmed positive drug test does not provide concrete evidence of such use, Ms. Loertscher stated in the records that she had used methamphetamine at least twice weekly, up until the point that she understood she might be pregnant, and similarly informed the treating physician that she had used marijuana occasionally.

13. But the medical records do not reveal that Ms. Loertscher suffered from an actual substance use disorder. From my review of the records, she does not.

14. First, it's important to understand that use of a substance is not the same thing as a substance use disorder, also called addiction. The American Society of Addiction Medicine (ASAM) defines addiction, in part, as "a primary, chronic disease of brain reward, motivation,

memory and related circuitry." Addiction is commonly understood to include compulsion or cravings that are often difficult for the individual with an addiction to address without supportive treatment. As ASAM explains, "like other chronic diseases, addiction often involves cycles of relapse and remission." (This information is available at the ASAM website, at, http://www.asam.org/for-the-public/definition-of-addiction). Treatment or other recovery activities may be necessary to prevent the disease's progression. In short, use of a drug is not necessarily addiction to that drug.

15. Pregnancy can be seen as a window of opportunity for behavioral change as all pregnant women are motivated to improve their health and that of their baby-to-be. This is also true for women with substance use disorders. In my years of experience treating pregnant women who have substance use, they universally seek to actively change the conditions that could be harmful to their pregnancies. But for pregnant women who actually suffer from a substance use disorder, characteristic of that disorder is continued use of the drug, despite both the knowledge and the desire to stop. It's women who cannot change their behavior despite this awareness who meet the criterion for the diagnosis of a substance use disorder.

16. Ms. Loertscher's medical records do not reveal this kind of problematic use of drugs or alcohol. Her unconfirmed positive urine toxicology – even if it had been confirmed, which it does not appear from the records that it was – is not a test of whether someone has a substance use disorder. No one with expertise in this field would endorse a simple urine test result as a test of whether someone has substance use disorder as a medical condition. It does not tell you the magnitude of the consumption, and captures nothing about the behavioral component, a necessary element of a substance use disorder diagnosis.

17. Further, the medical records indicate that no health care provider or hospital personnel at the Mayo Clinic used a validated instrument to screen Ms. Loertscher for substance use and whether her use constituted a substance use disorder. There are several validated instruments that could have been used, all of which are brief and easily incorporated into clinical practice.

18. Nor did anyone at the Mayo Clinic, despite their apparent emphasis on her past substance use, treat Ms. Loertscher for a substance use disorder. There is nothing in the medical record to indicate that she received anything that could be understood as substance use disorder treatment. Furthermore, no specialist in addiction medicine was called in to treat her and there are no notes indicating that any of her treating physicians consulted with anyone with such expertise. Not one of the nursing assessments in this record – and there are many – mention anything related to addiction. There is nothing in the content of these notes to indicate that Ms. Loertscher was receiving any treatment for a substance use disorder or that the providers were attuned to any of the needs that a patient with a substance use disorder might have while undergoing a hospitalization. According to these records, Ms. Loertscher never expressed the things that you would expect to see from someone with an actual substance use disorder. For example, there is no mention of cravings or withdrawal symptoms.

19. It is also important that, nowhere in these records, is it reported that Ms. Loertscher actually said she had a problem with substance use. In fact there are multiple instances where she states that she does not think she has a problem, that stopping use will not be an issue, and that she does not think she needs treatment. Popular culture and beliefs may teach us that people suffering from addiction deny their addiction, but in my experience with women

like Ms. Loertscher, who are actively seeking medical help, it is far more typical for a pregnant patient with a problem to state that they have a problem with drug addiction.

20. In short, there is no evidence from the medical records I reviewed that Ms. Loertscher actually had a substance use disorder. Her prior use of drugs does not, alone, provide the necessary information to make such a diagnosis. Nor does the urine toxicology test. Inpatient drug treatment, then, is a medically unnecessary and inappropriate recommendation for a patient with no such diagnosis.

21. What is far more concerning, from the perspective of an obstetrician gynecologist, was Ms. Loertscher's severe untreated hypothyroidism and related symptoms. From these records, it appears that when she presented herself to the hospital that she was medically ill and in need of immediate medical treatment.

22. As an obstetrician gynecologist, I have treated pregnant women with hypothyroidism. Untreated or inadequately treated hypothyroidism in pregnancy is associated with risks to both the mother and to her pregnancy. The most severe complication of hypothyroidism is myxedema coma or crisis, a life-threatening form of untreated hypothyroidism, something she does not appear to have been evaluated for. It presents with mental status changes and leads to stupor and, in the worst scenario, coma and death. It is a rare condition and usually precipitated by some additional insult such as infection.

23. More commonly maternal hypothyroidism has been associated with a wide range of adverse outcomes including miscarriage, preterm birth, and fetal loss. (I have attached as **Exhibits D and E** the clinical guidelines for management of hypothyroidism in pregnancy, one from the American Thyroid Association and the other from the Endocrine Society.) The thyroid hormone contributes to normal fetal brain development. Hence one concern regarding untreated

hypothyroidism is in the cognitive function in the newborn. Indeed untreated hypothyroidism in the mother has been associated with lower IQ scores in the child.

24. Ms. Loertscher had extremely elevated levels of thyroid stimulating hormone (TSH) (her level was literally out of the range of the assay as it was higher than the cut point) and extremely low levels of free thyroxine (free T4) one of the thyroid hormones. I have never seen a TSH as abnormal as Ms. Loertscher's in pregnancy. All of her symptoms, including her depression and mental confusion, were likely secondary to the hypothyroidism, and certainly would have been exacerbated by it. Similarly her anemia (which was attributed to "diet" in the medical record, although her mean cell volume (MCV) was normal, which indicates that her anemia was unlikely to have been due to iron deficiency) was likely caused by and/or exacerbated by her hypothyroidism.

25. Hypothyroidism can disrupt ovulation leading to irregular periods and is a cause of infertility. It is not surprising then, that Ms. Loertscher would not have believed she could be pregnant prior to having it confirmed through medical testing. Given her history of irregular periods, it is also not surprising that she did not know she was pregnant until the second trimester.

26. To reiterate, Ms. Loertscher's primary medical concern for her health and the health of her pregnancy was (and probably remains) her extreme hypothyroidism. The right treatment for hypothyroidism is thyroid hormone replacement, and she received that at the Mayo Clinic. She never refused the hypothyroid medicine, as indicated in her records. Although as the hospital social workers and other staff began to emphasize her past drug use as their primary concern, she became less and less willing to participate in group activities (that are of negligible

therapeutic value) or accept other medicines, she never rejected care for her primary and most serious medical concern: her hypothyroidism.

27. Had I been asked to care for this patient, my foremost concern would have been treating her overt hypothyroidism and working to determine what was causing such a severe condition. I would have at least informally consulted with an endocrinologist, if not called in a formal consult. Perhaps someone did that, and did not record it in these records, but I would have done so; not knowing the etiology of her hypothyroidism I would have considered the possibility of pituitary or thyroid tumors, especially because she presented with headaches. Again, the only information I have is from these records, but there are no notes indicating that these conditions were considered or explored.

28. It also appears from the records that Ms. Loertscher agreed to a voluntary admission to the Behavioral Health Unit at the Mayo Clinic for treatment for depression and other mental health symptoms she was having. It would not, in my experience, be typical to admit a patient to the hospital for treatment of hypothyroidism alone (aside from previously mentioned rare conditions that Ms. Loertscher did not apparently have). Although it takes time for the medicine to begin to work, her medications should be titrated to rapidly reach and thereafter maintain a normal TSH level. It would therefore have been reasonable to send her home with the medicine with a short interval follow up for symptom management and a repeat blood test in 30-40 days for TSH levels and then every 4-6 weeks. My understanding of my review of these records is that Ms. Loertscher not only voluntarily sought and complied with treatment for hypothyroidism, but was willing and wanted to stay in the hospital for treatment of the secondary condition she was suffering – depression.

29. As an addiction specialist, with both clinical and research experience in treating pregnancy and substance abuse disorders, I would never have considered reporting this patient to child protective services. Even if she had been actively using methamphetamine, I would have tried to engage her in services. Reporting her to child welfare authorities is antithetical to the physician/patient trust relationship and can drive a patient from engaging in further care and this patient had a significant medical condition (hypothyroidism) requiring medical treatment. In this case, from what I can discern from these records, Ms. Loertscher was in fact engaging in positive behavioral change regarding substance use in pregnancy: she reports ceasing all illicit substance use after discovering she was pregnant.

30. In the press teleconference that I participated in on December 11, 2014, I heard Ms. Loertscher explain that her hypothyroidism worsened after she lost her health insurance and was no longer able to obtain her prescription thyroid medication. Although I am not aware of any "over-the-counter thyroid medication," she reported in her medical records that she had purchased and was taking such medication – again demonstrating to me that she was acting in the interests of her health.

31. I also would have been concerned about Ms. Loertscher's uninsured status prior to pregnancy, and the fact that she may likely lose health insurance after she gives birth. I would respond to this concern by working with hospital social work staff and community partners, with the patient's consent, to help address the underlying conditions, whether joblessness or poverty, that caused this status.

Effects of methamphetamine and marijuana use in pregnancy

32. I also reviewed the notes in Ms. Loertscher's medical records of what she was told at the Mayo Clinic about the impact of her past drug use on her pregnancy and the child

once born. In the notes, Dr. Jennifer Bantz indicates that she advised Ms. Loertscher that with her past drug use there was "a good likelihood for cognitive defects" or cognitive delay in the child once born. This statement greatly exaggerates current evidence regarding either methamphetamine or marijuana use during pregnancy. Scientific studies simply do not support such a statement.

33. There is less literature on the effects of methamphetamine on pregnancy and newborn/child outcomes than there is on other substances such as alcohol, tobacco or opioids. The one consistent finding across many studies is that the infants exposed to methamphetamines are "small for gestational age" – that is they are born at a lower than average weight for their gestational age. This is also an effect of maternal tobacco smoking. As women who use methamphetamine during pregnancy also commonly smoke cigarettes, it is not known whether "small for gestational age" results from methamphetamine alone, methamphetamine with tobacco or is a result of the tobacco use alone.

34. The best source of data on newborn and child outcomes for methamphetamine is from the Infant Development, Environment, and Lifestyle Study (IDEAL) – a prospective cohort of methamphetamine-exposed newborns matched to non-methamphetamine-exposed newborns. Many publications evaluating a multiplicity of outcomes have emerged from this study. Overall there appear to be subtle effects of methamphetamine exposure. This study, however, cannot account for the caregiving environment and the role that it plays in child development. Additionally it is notable that the women in the methamphetamine group smoked more cigarettes and consumed more alcohol during pregnancy than in the non-methamphetamine group. Finally it is important to note that methamphetamine-exposure in the study is defined as a positive toxicology test (from either mother or baby) at the time of delivery. Therefore it is difficult to

generalize these findings to exposure that only occurred earlier in pregnancy as Ms Loertscher's did. Certainly we do not look at these studies and suggest that methamphetamine use in pregnancy is healthy, but these data are in fact reassuring for patients who, like Ms. Loertscher, have used methamphetamine, find out they are pregnant, and then stop using.

35. Prenatal marijuana exposure is not linked to birth defects, although the data available is not as complete as that of cigarettes, which we know is associated with stillbirth and other negative outcomes – indeed, cigarette smoking is well established as being associated with low birth weight, stillbirth, miscarriage, and pre-term delivery. There are some studies involving marijuana that indicate lower birth weight, but others that counter that conclusion. In short, there is no conclusive science to support a claim that marijuana use is likely to cause substantial or even minor harm to a developing fetus. Compared to marijuana, the ill effects of cigarette smoking are far greater and are well established.

37. As for alcohol use, Ms. Loertscher indicated in her medical records that she had one half of a glass of wine in her first trimester. Research on fetal alcohol syndrome or fetal alcohol effect indicate that prenatal exposure to large quantities of alcohol can harm the developing fetus. These effects can be very serious and include harm to cognitive functioning. What is not well established in the scientific literature is whether moderate or limited alcohol consumption during pregnancy causes any harm to the developing fetus. Thus the maternal health guidelines in the United States recommend abstinence from alcohol during pregnancy. With that said, Ms. Loertscher's alcohol consumption was within normal patterns, and her having a drink before she knew she was pregnant is exceedingly common in early pregnancy. Most people, as Ms. Loertscher's medical records indicate she did, stop when they find out they are pregnant. Generally speaking, the data are reassuring that normal alcohol consumption early

in pregnancy, stopped upon discovery the pregnancy, will have no ill effect on the developing fetus or the child once born.

38. Unlike methamphetamine and marijuana use, untreated hypothyroidism in pregnant women is scientifically linked to cognitive delay in children once born. Seeking treatment for that condition within two days of taking a positive pregnancy test is, then, what we would want to see from a perspective of maternal/fetal health. It appears from the record that she was always adherent with the treatment for thyroid medication throughout her hospitalization. I find no evidence in the medical records that she did anything but act in the best interest of her pregnancy from the moment she presented for care.

39. As to substance use disorder, Ms. Loertscher was not properly evaluated, tested, or treated for one. It is hard to understand, from a medical perspective, why the state would want to enforce treatment for a condition that she does not have. Ironically, it appears from the record that it was, in fact, her pregnancy that was motivating her to get help for her health conditions.

40. In conclusion a few facts regarding the biology of conception and pregnancy are important to consider. Overall human beings are surprisingly poor reproducers. Without the assistance of reproductive technologies (such as in vitro fertilization/IVF) pregnancy rates are at best 20% per month. Depending how one defines pregnancy, between 20 and 50% of those pregnancies will end in a loss, usually an early miscarriage. Medical conditions such as hypothyroidism can interfere with the hormonal regulation of ovulation making becoming pregnant more difficult and, once pregnant, can also increase the likelihood of a miscarriage. Therefore without a medical evaluation (including pregnancy testing and/or ultrasound examination) it can be difficult for many women to know if they are pregnant and whether the pregnancy is viable.

41. Pregnancy occurs when the fertilized ovum (zygote) successfully implants in the uterus. This is preceded by fertilization – when the sperm and the ovum meet. Although fertilization is the first and essential antecedent of the biologic process that becomes a pregnancy, unless fertilization takes place in a laboratory (as it does for IVF), there is no medical test to determine whether it has occurred. Nor is there any way to predict that the fertilized ovum will implant. Only after implantation does the maternal physiological support for pregnancy begin as can be measured through laboratory testing. Human chorionic gonadotropin (hCG) is the hormone produced by the syncytiotrophoblast, a portion of the placenta following implantation. The presence of hCG is what we measure in pregnancy tests. There is no clinical test for fertilization.

42. In order for the pregnancy to grow normally, it must implant in the uterus (and not in the fallopian tube or other extra-uterine site – a so-called ectopic pregnancy). If the pregnancy proceeds normally after implantation, the zygote will develop into both the placenta and the embryo. As pregnancy progresses, the embryo will develop into a fetus.

43. As a researcher I use the term "fetus" because it is the scientifically accurate term. As a clinician I also sometimes use the term "baby-to-be" because it captures the possibility of a growing and healthy pregnancy becoming, after birth, a baby. However I would never use the term "unborn child." Not only is "unborn child" not scientific, it is also misleading as it neglects the essential biological inter-relationship between the fetus, the placenta and the pregnant woman. In obstetrics and gynecology we refer to this inter-relationship also as the "maternal-fetal unit" – a term that captures the unique biology of pregnancy.

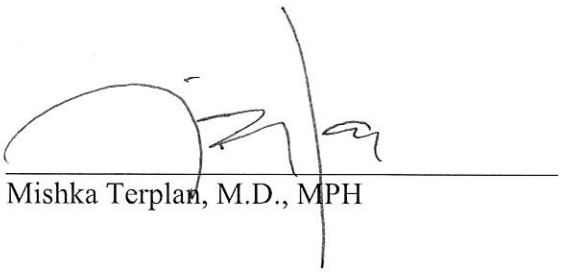
44. This biological inter-dependency is critical to understand when considering who is the appropriate authority for health care decisions related to the pregnancy. I believe that the

default authority should always be the mother. There are rare situations where the mother is incapable of making sound decisions such as during an acute psychotic episode (where she might pose a danger to herself and others) or if incapacitated from illness or trauma in an intensive care unit. In such rare circumstances it makes sense for others (family, physicians or the state) to intervene on both her and her pregnancy's behalf.

45. My concern with mandatory or permissive reporting "substance-exposed" laws extends beyond the fact that such practices can result in pregnant women not seeking care for fear of legal consequences. From a public health perspective, such legislation can be considered harmful as ultimately it leads to fewer women receiving beneficial services (both prenatal care and substance use disorder treatment). More concerning to me are the assumptions behind such legislation – that maternal interests vis-à-vis her own pregnancy are in conflict with the interests of others whose authority is then inserted between the woman and her pregnancy – in essence cleaving the maternal-fetal unit. Historically the pregnant woman has been understood as the best advocate for her pregnancy - a perspective that is consistent with the biology of pregnancy, the maternal-fetal unit. As an obstetrician gynecologist I believe laws that assume otherwise to be not just unwise but unnatural.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury, under the laws of the United States, that the foregoing is true and correct to the best of my knowledge.

Dated this 5th day of January, 2015.



Mishka Terplan, M.D., MPH