

## **DECLARATION OF DR. KANWALJETT S. ANAND**

I am Dr. Kanwaljeet S. Anand, M.B.B.S., D. Phil, FAAP, FCCM, FRCPCH, who files this Declaration under penalty of perjury. I know from my education, training, and experience that the foregoing facts are true and correct and to the extent I have stated opinions, the basis thereof is also stated:

1. I am a pediatrician specialized in the care of critically ill newborns and children. I serve as a tenured Professor of Pediatrics, Anesthesiology, Perioperative & Pain Medicine at Stanford University School of Medicine, and as Director of the Pain/Stress Neurobiology Laboratory at the Maternal & Child Health Research Institute. For more than 30 years, I have conducted intensive research and study of the development of pain/stress in human newborns, their development during early childhood, and long-term outcomes. I have authored 316 scientific publications (125 in the last 10 years), edited 9 books and received numerous professional awards. My true and correct Curriculum Vitae is attached.
2. I am personally familiar with Opioid Use Disorder in pregnancy and Neonatal Abstinence Syndrome and have reviewed all materials referenced below along with the Statement of Facts Supporting the Motion for Preliminary Injunction and the Exhibits referenced therein.
3. The medical journal articles attached as exhibits # are peer-reviewed or are issued by governmental agencies and reliable treatises/reports on which I and others in healthcare routinely rely.
4. Neonatal abstinence syndrome (NAS) is a clinical diagnosis, and a consequence of the abrupt discontinuation of chronic fetal exposure to opioids that were used or abused by the mother during pregnancy. NAS is a generalized multisystem disorder, which predominantly involves the central and autonomic nervous systems, as well as the gastrointestinal tract. Neonatal

withdrawal due to prolonged maternal opioid use may be severe and intense. Although NAS is rarely fatal, it can cause significant illness and often results in prolonged hospital stays with the potential for abnormal brain development and future disability. Opioid exposures in early pregnancy can be associated with brain damage and/or congenital defects or deformities, some of which can be improved by surgical or other interventions.

5. Opioid Use Disorder (OUD) is defined in the DSM-5 as a problematic pattern of opioid use leading to clinically significant impairment or distress. OUD has also been referred to as “opioid dependence” or “opioid addiction.”
6. In my opinion, the proposal sought by the Motion for Preliminary Injunction is medically and scientifically reasonable because prevention and education are the only feasible means of preventing in-utero opioid exposure. This is because since the introduction of Oxycontin and other similar synthetic and time-released-synthetic opioids the use of prescription opioid medications tremendously increased in the US population as a whole and particularly among women, including those with the ability to become pregnant. Epidemiological studies show that increasing numbers of women are taking opioids during pregnancy, associated with an increasing potential for NAS and OUD-related effects in babies. Since 1995, as is well-documented in the literature, increasing numbers of women within the reproductive age group are using licit and illicit opioids. This too increases the potential for NAS and OUD injuries to babies since pregnancy can occur at any time during the opioid treatment. Patients taking licit or illicit opioids can become addicted and there is a recognized correlation between licit and illicit drug abuse and addiction. At all ages, but particularly among adolescents or young adults, many patients report first taking prescription opioids before using illicit opioids. Medical standards of care involving opioid use in pregnant women are evolving. The date on which every healthcare provider and patient will understand and appreciate the danger of

opioids to fetal development is unknown. It is likely that the prevalence of opioid use changed after the admission of Oxycontin and similar drugs on the market. Since medical information concerning these medications has grown and addiction and abuse from them is now recognized, the standard of care is still evolving. As a fundamental matter, opioid addiction and in-utero opioid-related injuries are difficult to treat. The efforts and costs associated with the proposed Preliminary Injunction, requiring negative urine pregnancy tests and coupled with the seven-day limitation, is consistent with other drugs known to cause fetal injury, such as Accutane. My office, like doctors' offices around the country, routinely deals with the administrative tasks associated with filling a prescription, which are already part of the prescription process. Urine pregnancy tests are inexpensive, readily available, and reliable; they are routinely administered in hospitals, clinics, or other testing facilities before a woman undergoes certain procedures and tests.

7. Prescription opioid use in pregnancy is strongly associated with neonatal complications.
8. Opioid use can disrupt fetal development at any stage during pregnancy, except the first ten days.
9. Opioid use can disrupt fetal development at any stage during pregnancy, except the first ten days.
10. Risks of sudden death sudden infant death syndrome in sudden and unexpected death and infancy in preterm infants with prenatal opioid exposure are increased because of the changes in normal infant sleeping patterns, depressed respiration or responses to hypoxia (low oxygen levels).
11. Preschool aged children, exposed to opiates, are known to the experience one or more of the following symptoms: mental and motor deficits, cognitive delays, hyperactivity, impulsivity,

attention deficit disorder, behavior disorder, aggressiveness, poor social engagement, failure to thrive (socially), and short stature.

12. School-age children exposed to opiates may experience one or more of the following cognitive/behavioral deficits: verbal impaired performance, impaired reading and arithmetic skills, for mental and motor development, memory and perception problems, attention deficit hyperactivity disorder, developmental delays, speech problems, language disorders, impaired self – regulation, school absence, reduced executive functions and behavioral regulation, for responses to stressful stimulations situations, poorly developed confidence or efficacy, impaired task performance, depressive disorder, and substance abuse disorder.
13. A recent study concluded that the opioid exposure to a developing animal brain may cause epigenetic modifications that makes addiction in that individual more likely. This modification, no matter the sex of the exposed fetus, is thought to pass on in their genetic material to their offspring.
14. The number of NAS/ODU children in the U.S. is estimated by the CDC to be hundreds of thousands. But when mothers stop taking opioids during pregnancy the fetus may go through in utero withdrawal, so those babies cannot be counted. Only 28 states report NAS/ODU births.

I declare under penalty of perjury that the statements in this declaration are true and correct to the best of my knowledge, information, and belief.

Executed the 27<sup>th</sup> day of March 2019

**Dr. Kanwaljeet S. Anand, M.B.B.S., D. Phil, FAAP, FRCPCH**

