

NAPW FACT SHEET:

The Dangerous Litigation That Sells Out Science and Hurts Women and Babies

In the context of the nationwide litigation seeking to hold pharmaceutical companies liable for the over-prescription of opioids in the U.S., a team of private lawyers is seeking court approval to separately represent the interests of children born to women who used opioids during pregnancy. In some of their court papers, this group of private attorneys have identified their separate interest as one in representing “all women capable of becoming pregnant.” By attempting to distinguish themselves from hundreds of other lawsuits and claims that have been combined into a single nationwide prescription opioid lawsuit, these lawyers are trying to position themselves to recover enormous money damages for their clients and attorneys’ fees for themselves. As evidenced by their court papers, a widely distributed press statement,¹ and a recent *Washington Post* story,² these lawyers are pushing legal claims rooted in dangerous myths about women, pregnancy, drug use and the children born to women who have used opioids in any form and for any reason. These attorneys are also proposing “solutions” to nonexistent problems that will undermine the health and rights of women, mothers, and babies.

In their court filings and public statements, some of these private lawyers have called themselves the “Opioid Justice Team.” The private lawyers purporting to represent the interests of women and babies, however, are better described as “Pregnancy Profiteers.” They have made false, medically unsubstantiated, and dangerous claims about the impact of opioid use by pregnant women. Similar claims about pregnant women’s drug use in the past have led to the wrongful arrest, prosecution, detention, and forced treatment of pregnant women and to government action stigmatizing and traumatizing children born to those women. These lawyers go even further. Not only do they promote wholly unsubstantiated claims about the impact of opioid use, they also advocate for “remedies” that would delay or deny needed medical care to all women capable of becoming pregnant.

History of this litigation

After it emerged that several of the leading pharmaceutical companies misled the public about the addictive potential of their opioid drugs, various states, county and municipal governments, Native American tribes, hospitals and other entities filed more than fifteen hundred lawsuits against these companies. The original plaintiffs sued these companies to force a change in the composition, labeling and marketing of these drugs to reduce their dangers, and to obtain billions of dollars in damages. The lawsuits would also (1) partly compensate the costs incurred from the resulting widespread opioid addiction, illness, overdose and death, and (2) recoup ill-gained profits.

The many federal court lawsuits have been bundled together into a single multi-district litigation, or “MDL.” The MDL was created by the courts so that the plaintiffs’ claims and defendants’ defenses can be more efficiently addressed together, by a single court. Through the MDL process, that court will gain a comprehensive understanding of and perspective about the many

issues raised by the litigants and will be best positioned to fashion practical remedies that are equitable to everyone.

Why are These Pregnancy Profiteers Eager to Have Their Claims Stand Apart from the other MDL Cases?

Because large pharmaceutical companies, distributors and drug store chains profited so greatly from the sale of opioids, and because hundreds of thousands of people have been adversely affected by problematic opioid use, addiction and overdose, the potential money damage awards for these cases could reach tens of billions of dollars. Private plaintiffs' class action attorneys stand to earn substantial fees. By trying to create a separate case on behalf of purportedly "unique" clients, who allegedly suffered harms and damages different from all of the other people on whose behalf lawsuits had already been filed, the Pregnancy Profiteers seem intent on securing for themselves a cut of the potentially massive attorneys' fees.

What is the Separate Litigation Claiming to Represent Women and Babies?

The Pregnancy Profiteers have filed numerous court documents asking the court to establish a separate litigation track for their cases on behalf of all women capable of become pregnant and/or all babies prenatally exposed to opioids. Having failed in that attempt, they then tried to leapfrog their cases ahead of the many other cases by *asking for an urgent order (preliminary injunction) requiring pregnancy tests for all women in the country "capable of becoming pregnant" before doctors can prescribe them opioid pain medication*, and limiting the number of days women may receive legitimate medical treatment for pain. The Pregnancy Profiteers pursued their litigation even though the injuries experienced by pregnant women who have suffered opioid-related dependence addiction or overdose are already included in the original set of lawsuits in the MDL. As reported in the Washington Post, lawyers for the cities, counties, states and tribes in the MDL have informed the MDL court that pregnant women and their children will already be included in overall health strategies that can be put into place as a result of any financial settlements in the case.

Nevertheless, the Pregnancy Profiteers seek special, separate consideration by alleging that babies who are born with transitory and treatable opioid withdrawal symptoms (termed neonatal abstinence syndrome or "NAS") suffer opioid-related harms that are very different from the harms experienced by the other MDL plaintiffs. To this end, these attorneys claim – *without scientific/medical support* – that opioid pharmaceuticals "increase the risks of abnormal brain development" of fetuses and they allege an array of physiological, cognitive and behavioral problems that afflict and "permanently impair" the fetus and newborn when women are pregnant and ingest opioids. The attorneys go so far as to recklessly equate the effects of opioids with the medication Accutane – an acne treatment drug that is chemically nothing like opioids and that actually can and often does cause newborns to be born with severe brain, heart, and face malformations.³

The permanent NAS-related harms alleged by these attorneys have never been shown to exist. Moreover, the remedy the attorneys seek from the courts would undermine the rights of women and endanger the lives of mothers and babies.

Who are the Plaintiffs Bringing the Women and Babies Lawsuits?

The named plaintiffs in the proposed class action are specific women who fear that they and/or their daughters might become pregnant, or women who are caring for children whose birth mothers used opioids while pregnant and whose children had been removed by state authorities. These women purport to represent a class of persons breathtaking in scope, including all of the millions of women in the U.S. “capable of pregnancy.”

Importantly, none of these named plaintiffs have alleged that the children to whom they gave birth, will give birth, or for whom they care, are or will be permanently damaged as a result of prenatal exposure to opioids. This stands in stark contrast to the original MDL plaintiffs who are able to show actual and widespread harms connected to the misleading practices of the MDL defendants.

What Does the Requested Preliminary Injunction Ask the Court to Do?

The Pregnancy Profiteers claim that the MDL defendants are liable to a class of women “capable of becoming pregnant.” These lawyers ask the court to:

1. Require all women “of childbearing age” to test negative for pregnancy before they can lawfully be dispensed an opioid medication;
2. Limit women from receiving more than a seven-day supply of opioid medications unless they take additional pregnancy tests and test negative each time;
3. Declare that “opioids have a teratogenic effect;” and
4. Award attorneys’ fees and costs.

The substance and breadth of this suggested court order are shocking and should concern all women and anyone who cares about public health. Were a court to issue such an order, no woman who is or becomes pregnant could receive any opioid pain medication regardless of how much pain she suffers and regardless of the source of that pain, be it from kidney stones, broken bones, cancer or any other medical condition. Such an order also would also be likely to prevent a pregnant woman from receiving the American Medical Association and the World Health Organization recommended gold standard of treatment for pregnant women if she does have a substance use disorder (the treatment, with prescribed buprenorphine or methadone, uses opioid-based medications). The Pregnancy Profiteers’ proposed requirement of weekly pregnancy tests for *all* women who might be prescribed opioid medications is discriminatory. It creates a gender specific barrier to appropriate medical care by delaying needed care and forcing women to prove that they are not pregnant as a condition of receiving that care. Many women would not be able to afford to go to a medical office or pay for weekly pregnancy tests (physicians would insist that the pregnancy testing be supervised) and would thus forfeit their right to adequate pain care and substance dependency care. Many physicians, in turn, would be deterred from prescribing needed medications to women for fear of liability.

In What Ways is this Pregnancy Profiteering Litigation Medically and Scientifically Unfounded?

The separate litigation being pushed by the Pregnancy Profiteers rests upon a series of assertions for which there is no scientifically accepted supporting evidence. Some key facts:

- Opioids are not teratogens (drugs that cause “birth defects”) and have not been shown to cause lasting harm to children exposed prenatally. But the Pregnancy Profiteers claim otherwise, and allege that opioids cause lasting harm to a developing fetus or newborn child.
- Pregnant or parenting women should not be prohibited from ingesting opioids, especially since opioid assisted treatment is medically the best practice for people with substance use disorders who are pregnant.⁴ But the Pregnancy Profiteers ignore the findings of all of the world’s leading medical bodies and instead assert that pregnant women should never be prescribed opioid medication.
- Many children are born with transitory or treatable health conditions – from colic to heart defects. We do not typically consider these children to have been “harmed” as a result of being born and needing some kind of health care. Similarly, a child born with NAS should not be considered “harmed”. Thankfully, the symptoms of withdrawal are temporary and treatable, often merely by ensuring that newborns can stay with their mothers, experience skin to skin contact, and benefit from being breastfed.⁵ But the Pregnancy Profiteers claim, without evidence, that babies and children who are exposed to opioids prenatally are likely to suffer widespread and long lasting harms.⁶

Medical research presented in multiple studies contradicts the lawyers’ assertions. Importantly, even the authors of the one study chiefly relied upon by the Pregnancy Profiteers in their court filings warn that their research cannot be used to establish that opioids cause the harms that these attorneys allege.⁷

Why is the Litigation Trying to Separate Women from Other Litigants Dangerous to Public Health?

Children’s health and well-being is advanced when maternal health is promoted through evidence-based policies and practices. By contrast, the attorneys pursuing this separate litigation are peddling dangerous propaganda that disregards the scientific research concerning the effects of opioids on pregnancy and ignores the abundant experience that shows that NAS is a treatable condition that does not have long-term health consequences to children. Their claims are irresponsible and threaten to undermine public health by encouraging prejudice against women who ingest opioids, deterring women from seeking health care due to higher costs and burdens, and justifying punitive or non-therapeutic responses to women who ingest opioids.

The Pregnancy Profiteers fail to offer a single piece of research suggesting that the specific relief they seek from the court – denying women opioid medications unless they can prove they are not pregnant – will benefit maternal and child health. At the same time, these attorneys ignore the vast body of research that shows that undermining women’s rights and erecting barriers to

treatment singling out pregnant women poses serious threats to the well-being of women and children.

Finally, the Pregnancy Profiteers erroneously posit that their separate legal action is necessary to provide needed services for children born who experience withdrawal. While this litigation is likely to saddle such children with a life-long, stigmatizing label (much like the now discredited label “crack babies”) the audacity of the attorneys’ demands is exacerbated by their refusal to identify any specific course of treatment, therapy or education for children who they allege are or will be damaged from prenatal exposure to opioids.

How Does the NAS Baby Litigation Threaten Women’s Legal and Constitutional Rights?

Hawking myths and overstatements about long-term and permanent effects on children of prenatal drug exposure is harmful to those children and their parents. The stigma for the children, combined with punitive government interventions against women who are pregnant and use drugs or alcohol (justified by this type of fear-mongering), undermines public health and helps no one. Combining claims of “fetal personhood” rights with the war on drugs has resulted in an increasing number of punitive laws and policies that deter people from obtaining health care for drug dependency problems when they need it and deny pregnant and parenting women their rights to liberty, bodily autonomy, and privacy.

Conclusion

The claims of the Pregnancy Profiteers are rooted in myth - not science. They should be held accountable for promoting discriminatory, health care-denying policies that target women capable of pregnancy; for dangerously and unfairly stigmatizing a generation of children; and for attempting to distract the courts and the public from the real need – for increased public health and human rights-based investments in people and families affected by the opioid crisis.

NAPW calls on the plaintiffs and parties in the nationwide opioid litigation, courts, journalists, and members of the public who care about the health and well-being of women and children to reject the stigmatizing medical misinformation and dangerous recommendations of the Pregnancy Profiteers.

¹ Lawyers’ press release, PRNewswire, “Landmark Legal Injunction Filed to Stop Prescription-Related Opioid-Dependent Births to Opioid-Using Women,” Mar. 29, 2019

² L. Bernstein, “Babies Born After Opioid Exposure Deserve Legal Recognition, Lawyers Argue,” Washington Post, Aug. 22, 2019, available at <http://bit.ly/WPAug22-2019>

³ Accutane has been called “the most widely prescribed birth-defect causing medicine in the United States.” E. Rafshoon, What Price Beauty? Boston Globe Magazine, Apr. 27, 2003, p. 15 (describing confirmed reports of 160 drug-affected births).

⁴ Am. College of Obstetricians & Gynecologists, Opioid Use and Opioid Use Disorder in Pregnancy, Committee Opinion 711 (August 2017); Substance Abuse & Mental Health Services Administration, U.S. Department of Health & Human Services, Pub. No. [SMA] 06-4124, Methadone Treatment for Pregnant Women (2006).

⁵ Kathryn Dee L. MacMillan, et al., Association of Rooming-in With Outcomes for Neonatal Abstinence Syndrome: A Systematic Review and Meta-analysis JAMA Pediatrics, 172(4): 345–351, Apr. 2018, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5875350>; Ronald R. Abrahams, et al., Rooming-in Compared with Standard Care for Newborns of Mothers Using Methadone or Heroin, Canadian Family

Physician, Oct. 2007; Alison Volpe Holmes et al., Rooming-in To Treat Neonatal Abstinence Syndrome: Improved Family Centered Care at Lower Cost, *Pediatrics* 137(6), 2016; Nikoo, Nooshin et al., Health of Pregnant Women with Substance-Related Disorders, A Neglected Global Health Issue Requiring Combined Maternity Care Units, *Mental Health in Family Medicine* 11, 2015, 26-35, <https://pdfs.semanticscholar.org/a01f/8e15940c7e5f73a4de57b8123b2db8807650.pdf> ;Zoe G. Hodgson & Ronald R. Abrahams, A Rooming-in Program to Mitigate the Need to Treat for Opiate Withdrawal in the Newborn, *Journal of Obstetrics and Gynaecology Canada* 34(5), May 2012, 475-481, <https://www.sciencedirect.com/science/article/abs/pii/S1701216316352458>.

⁶ Hendrée E. Jones, et al., Prenatal Opioid Exposure, Neonatal Abstinence Syndrome/Neonatal Opioid Withdrawal Syndrome, and Later Child Development Research: Shortcomings and Solutions, *Commentary*, 13 *Addict Med.*, No. 2, Mar./Apr. 2019; Harold Pollack, Opioid Use by Pregnant and Parenting Women: Let's Not Repeat the Mistakes of 25 Years Ago, *The Milbank Quarterly*, July 23, 2019.

⁷ In their court filings, the Profiteers cite Jennifer N Lind, et al., Maternal Use of Opioids During Pregnancy and Congenital Malformations: A Systemic Review, 139 *Pediatrics* Vol 6, June 2017 (Plaintiffs' Supporting Motion for Preliminary Injunction, Mar. 28, 2019). The authors of that study themselves, however, expressly caution that "*uncertainty . . . remains* regarding the teratogenicity of opioids," call for "a careful evaluation of the potential risks *and benefits*" when using opioid therapies with reproductive-aged and pregnant women, and underscore that the Centers for Disease Control and Prevention Guidelines call for health care providers to "offer medication-assisted therapy with buprenorphine or methadone" – two long-acting opioids – to pregnant women with opioid use disorders. Lind, et al. at p. 21 (emphases added).