THE LEGAL BACKGROUND FACTS…

34.46. Opioid means “opium – like” and the term includes all drugs derived in whole or in part from the opium poppy.
35.47. Opioids or opiates include any of various sedative narcotics containing opium or one or more of its natural or synthetic derivatives.
36.48. The United States Food and Drug Administration’s website describes this class of drugs as follows: “Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose, and death.”
37.49. The Controlled Substances Act (“CSA”) defines “opiate” or “opioid” as “any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining ability.”
38.50. Prescription opioids with the highest potential for addiction are categorized under Schedule II of the CSA. They include non-synthetic derivatives of the opium poppy (such as codeine and morphine, which are also called “opiates”), partially synthetic derivatives (such as hydrocodone and oxycodone), or fully synthetic derivatives (such as fentanyl and methadone).
39.51. Before the epidemic of Defendants’ prescription opioids, the generally accepted standard of medical practice was that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients’ ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.
40.52. However, the past two decades have been characterized by increased abuse and diversion of prescription drugs, including opioid medications, in the United States.
The Opioid Epidemic
41.53. Prescription opioids have now become widespread. Opioids are the most-prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.
42.54. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.
43.55. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older – a total of 12 million people – reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health.
44.56. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, (“CDC”) declared prescription painkiller overdoses at epidemic levels. Specifically, the CDC reported that the death toll from overdoses of prescription painkillers has more than tripled in the past decade and more than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
45.57. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.
46.58. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year.
47.59. The President of the United States declared an opioid and heroin epidemic the same year.
48.60. The CDC released a report analyzing opioid-related hospital emergency department data between July 2016 and September 2017 and finding that nearly two thirds (66.4%) of drug overdose deaths in 2016 involved prescription opioids, illicit opioids, or both, an increase of 27.7% from 2015.

49.61. Moreover, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.
62. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.
50.63. The National Institute on Drug Abuse identifies misuse and addiction to opioids as "a serious national crisis that affects public health as well as social and economic welfare." The economic burden of prescription opioid misuse alone is $78.5 billion a year, including costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.
51.64. The epidemic of prescription pain medicineal and heroin deaths is devastating families and communities across the country. Meanwhile, the manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted American public while billions of dollars of injury are caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.
52.65. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or contributing to the national, state, and local opioid epidemic.
Neonatal Abstinence Syndrome
53.66. Many of the victims of the opioid epidemic, and certainly some of the most harmed, are babies born with Neonatal Abstinence Syndrome. NAS babies likely experience DNA changes at the cellular level, particularly in the tissues of the brain and nervous system and suffer lifelong afflictions as a result of maternal use of prescription opioid medications during gestation. These patients often require extensive care because they are likely to experience lifelong mental health problems and disorders, developmental impairment and cognitive defects, and physical health limitations and disorders.
54.67. Recently, there has been a dramatic increase in the number of fetuses that have been exposed to opioids. Women are also victims of the opioid epidemic, and health care for opioid exposed mothers and their babies is a major factor in the nation's rising unreimbursed healthcare costs.
55.68. The number of infants born suffering from this insidious condition is staggering. The incidence of NAS in the United States grew five-fold between 2000 and 2012. Specifically, cases of NAS increased nationally from a rate of 1.2 per 1000 hospital births per year in 2000 to 5.8 per 1000, with a total of 21,732 infants diagnosed with NAS by 2012. Currently, the best estimates are that a child with NAS is born as frequently as every 15-25 minutes, depending on the time period referenced. perhaps every 15 minutes.
56.69. In 2011, tThe Substance Abuse Mental Health Services Administration reported that 1.1% of pregnant women abused opioids (0.9% used opioid pain relievers and 0.2% used heroin).
57.70. In 2014, the number of babies born drug-dependent had increased by 500 percent since 2000, and children being placed in foster care due in part to parental drug abuse are going up — now it is almost onea third of all child removals.
58.71. Opioid-related cases of NAS are rising at such a rapid pace that cities, counties, and health care systems are unable to keep up logistically.
59.72. Heroin and other opioid misuse during pregnancy are also associated with increased risks and incidence of placental abruption, preterm labor, maternal obstetric complications, maternal mortality, and fetal death. The oOpioid cCrisis caused by the Defendants served to fuel an epidemic of heroin use.
60.73. NAS-diagnosed children are at increased risk for neuropsychological function. The challenges presented to them and their caregivers at birth can be summarized as: "Do they catch up, remain at a disadvantage, or do they proceed to function even more poorly than their peers over time?" Unfortunately, research arising from the Opioid Epidemic reveals that all children exposed to opioids and other drugs in utero are at a substantially higher risk for lower mental abilities and more signs of attention deficits, and that these effects will persist or worsen through adolescence.
61.74. Specifically, children diagnosed with NAS exhibit:
•by age 1: diminished performance on the Psychomotor Development Index, growth retardation, poor fine motor skills, short attention span, diminished intellectual performance;

•between ages 2-3: significantly lower cognitive abilities, including lower motor development, lower IQ, and poor language development;
•between ages 3-6: significant detrimental impact on self-regulation, including aggressiveness, hyperactivity, lack of concentration, lack of social inhibition, lower IQs (8-15 point difference), poor language development, and behavioral and school problems; and
•after 8.5 years: significantly greater difference in cognitive scores than at previous ages, especially in girls.

62.75. While the specific pathophysiological mechanism of opioid withdrawal in neonates is currently not known, several factors can affect the accumulation of opioids in the fetus. Opiate drugs have low molecular weights, are water soluble, and are lipophilic substances; hence, they are easily transferable across the placenta to the fetus. It is known that tThe transmission of opioids across the placenta increases as gestation increases. It is also known that and synthetic opiates cross the placenta more easily compared withthan semisynthetic opiates. Neonatal abstinence syndromeNAS is the end result of the sudden discontinuation of prolonged fetal exposure to opioids.

63.76. NAS babies' mothers either directly purchase and consume prescription opioids from one or more Defendants in the primary market, or indirectly (but foreseeably) obtain them from other sources in the diversionary or secondary market. Each minor child suffers, and faces an increased risk of lifelong mental illness, mental impairment, and loss of mental capacity. The minor child's entire health, use of the child's body and mind, and life, including the minor child's ability to live normally, learn and work normally, enjoy relationships with others, and function as a valuable citizen, child, parent, income-earner, and person enjoying life, are at risk of being compromised and permanently impaired.

64.77. Plaintiffs seek equitable relief in the form of medical monitoring, in order to provide this class of infants with monitoring of developmental issues confronting them as they mature. The ongoing and robust medical monitoring and medical surveillance of opioid-related NAS-diagnosed children is medically necessary. Further, this is a rapidly transforming field, as multiple members of multiple disciplines and support systems, ranging from medical providers to psychologists to behavioral therapists to childcare providers, come together to research the latent negative health impacts of NAS and the need for medical surveillance, and the release of all Defendants' health studies becomes evident.

65. The ongoing and robust medical monitoring and medical surveillance of opioid-related NAS-diagnosed children is medically necessary.

66.78. Neonatal exposure to opioids necessarily results in medical needs that exist throughout the entire period of the adolescent development of the putative Class Members. These needs absolutely exist for any child who had to be weaned from these substances. These needs relate primarily to the well-known adverse effect of opioids on behavioral and regulatory development in exposed children. Every single child diagnosed with opioid-related NAS and weaned from opioids must have robust medical monitoring, medical surveillance and medical referral in order to maximize his or her future as an adult. This relief will also largely abate the public nuisance created by Defendants' conduct. For this reason, Plaintiffs and the Class seek, inter alia, injunctive relief.

67.79. In a study from Florida, the number of newborns who had NAS and were admitted to the NICU increased by 10-fold from 2005 to 2011. Increases in the incidence of NAS have been reported uniformly across community hospitals, teaching hospitals, and children's hospitals.

68.80. The NAS epidemic and its consequences could have been, and should have been, prevented by the Defendants who control the U.S. drug distribution industry and the Defendants who manufacture the prescription opioids. These Defendants have profited greatly by allowing West Virginia to become flooded with prescription opioids.

69.81. The drug distribution industry is supposed to serve as a "check" in the drug delivery system, by securing and monitoring opioids at every step of the stream of commerce, protecting them from theft and misuse, and refusing to fulfill suspicious or unusual orders by downstream pharmacies, doctors, clinics, or patients. Defendants woefully failed in this duty, instead consciously ignoring known or knowable problems and data in their supply chains.

70.82. Defendants thus intentionally and negligently created conditions in which vast amounts of opioids have flowed freely from drug manufacturers to innocent patients who became addicted, to opioid abusers, and even to illicit drug dealers - with distributors regularly fulfilling suspicious orders from pharmacies and

clinics, who were economically incentivized to ignore “red flags” at the point of sale and before dispensing the pills.
71.83. Defendants’ wrongful conduct has allowed billions of opioid pills to be diverted from legitimate channels of distribution into the illicit black market in quantities that have fueled the opioid epidemic in West Virginia. This is characterized as “opioid diversion” and created a secondary market. Acting against their common law and statutory duties, Defendants have created an environment in which opioid diversion is rampant. As a result, unknowing patients and unauthorized opioid users have ready access to illicit sources of diverted opioids.
72.84. For years, Defendants and their agents have had the ability to substantially reduce the consequences of opioid diversion, including the dramatic increase in the number of infants born with NAS. All the Defendants in this action share responsibility for perpetuating the epidemic and the exponential increase in the number of infants afflicted with NAS.
73.85. Defendants have foreseeably caused damages to Plaintiffs and putative Class Members including the costs of neo-natal medical care, additional therapeutic, prescription drug purchases and other treatments for NAS afflicted newborns, and counseling and rehabilitation services after birth and into the future. Plaintiffs bring this civil action seeking class-widefor injunctive relief compensatory damages, statutory damages, and any other relief allowed by law against the Defendant opioid drug distributors and manufacturers that, by their actions and omissions, knowingly or negligently have distributed and dispensed prescription opioid drugs in a manner that foreseeably damagedinjured, and continues to damageinjure, Plaintiffs and the Class.
DEFENDANTS’ MISREPRESENTATION OF THE RISK OF SERIOUS LATENT DISEASE TO THOSE EXPOSED TO OPIOIDS IN UTERO
86. By definition the putative Class Members have sustained an exposure to opioids greater than that expected by members of the general population. As part of the anticipated claims process, each Class Member will be required to show medical records evidencing exposure to opioids.
87. The neonatal abstinence syndrome (NAS) is a generalized multi-system disorder that produces a constellation of symptoms in neonates, and results from abrupt discontinuation of opioids consumed by the mother during pregnancy at the infant’s birth.
88. All infants born to mothers with opioid use disorders are at high risk for developing NAS and there are no well-defined strategies to prevent NAS from occurring in at-risk infants.
89. Opioids represent a single class of exposures since they all cause their effects at the same receptors which are those that mediate the effects of endogenous opiates.
90. Opioids represent a single class of chemical substances since their molecular structures are very similar.
91. Opioids have typical pharmacological effects which are common to the group: effects on the brain, the nervous system and the gastrointestinal system.
92. The opioid compounds all act at the same biological receptors and mimic natural peptides which have powerful and wide-ranging activity in living systems. Thus, they can be considered a class of chemical drugs both in terms of their pharmacological dosage activity relationships and also their overall chemical structure. They produce common effects, bind to common receptors, the opioid and also have similar chemical structures. They all produce addiction and dependence and cause withdrawal symptoms on removal. Their activity as modulators of neurological signalling make them especially dangerous in adults due to rebound effects but also they are now known to have significant effects on fetal development since they alter the cellular signalling environment.
93. The effect of all opioids is produced through a single common pathway – the opioid receptor. The opioid receptor system is ancient and highly conserved, being present by the time that jawed vertebrates first appeared at least 450 million years ago. Clearly, differences between opioid products and potency exist but their mode of action via the opioid receptor system remains identical.
94. Fetal development relies on the balanced control of cell proliferation and cell death through apoptosis (otherwise termed ‘programmed cell death’).
95. It has been demonstrated scientifically that exposure to opiates will increase the rate of apoptotic cell death in developing biological systems. This represents a common mode of action which leads to the

large plethora of adverse conditions associated with fetal opioid exposure, including – sub-optimal brain maturation, a form of functional teratogenesis associated with reduced cognitive function
96. Perturbed apoptosis is also a contributory factor in gross fetal malformations. These include mid-line fusion defects such as cleft palate, spina bifida and gastroschesis postnatally.
97. Apoptosis is also essential for normal heart development. The heart develops from a single tube into a four-chamber heart through a series of complex foldings. Such foldings are produced by cellular proliferation on one side of a tube accompanied by apoptosis on the other side, the assymetric growth rates thus producing folding. It is clear to see that the mechanism of altered apoptosis rates leads to malformations.
98. Supportive measures are the standard of care, and pharmacotherapy is often initiated to treat their inability to sleep, lack of weight gain, inadequate caloric intake, extreme irritability, seizures and hypertonicity. If a neonate is treated with an opioid, the drug withdrawal has to be gradually tapered as the infant regains the capacity for self-regulation.
99. Buprenorphine and methadone are the most commonly used agents for opioid replacement therapy.
100. Upon information and belief, the agents used in Opioid Replacement Therapy are manufactured and distributed by the Defendants thereby creating a revenue stream not only from addicting adults who obtained opioids from the street or through a prescription but also creating a revenue stream for Defendants by treating the babies born addicted to opioids.
101. Although a widely-accepted treatment, Opioid Replacement Therapy in neonates is associated with a plethora of negative health impacts including but not limited to reduced brain and somatic growth, intractable nystagmus, altered visual evoked potentials, delayed encephalopathy, respiratory depression, bradycardia, hypotension, urinary retention, reduced gut motility and emesis.
102. Specifically, the widely-used Opioid Replacement Therapy agent, Buprenorphine, has been associated with extremely poor outcome in children up to the age of 3 to whom the drug was prescribed including congenital heart disease, urinary collecting system defects, ophthalmic defects and maxillofacial defects.
103. Major risks from prenatal opioid exposure include birth defects, altered brain development and NAS. NAS can cause latent defects to the muscular-skeletal system, the digestive system, the cardio-vascular system and the nervous system.
104. Evidence that opioids behaved as they were predicted to and caused major birth defects appeared in the results of the National Birth Defect Prevention Study published in 2010. The study looked at 17,449 cases and 6701 controls. Statistically Significant effects were found for associations between early pregnancy maternal opioid analgesic treatment and certain birth defects, notably heart defects, anencephaly, cleft palate and spina bifida.
105. Long-term cognitive development is impaired in children born with NAS. Further, those children face a significantly increased risk of mental, speech/language and emotional disorders.
106. Children born with NAS face increased risk of falling prey to the disease of addiction.
107. These known risks create a need in the NAS population for medical monitoring.
108. While much is known about the risks of serious latent disease faced by children born with NAS who underwent opioid replacement therapy, recent animal studies have revealed evidence indicating association with additional negative health outcomes:
a. increased incidence of neural tube defects
b. severe heart defects
c. spina bifida
d. impaired nerve mylenation
e. reduced regional brain volumes in the basal ganglia
109. The aforementioned risks of serious latent negative health impacts were published, widely-available, but not disclosed, or even mentioned, in the Pharmaceutical Defendants' marketing materials, package inserts, label warnings, unbranded research, captive advocacy group communications, FDA applications, FDA filings or any other means of communication. This information was also available to the Distributor Defendants.
110. The Defendants purposely misrepresented that there were no teratogenic or mutagenic effect associated with the use of opioids to increase their profits.

111. The Defendants purposely misrepresented the potential of opioids to result in the negative health impacts described above.

CLASS ACTION ALLEGATIONS

406. Plaintiffs seek to represent the following class of individuals:

Children born after 1998 were diagnosed as being exposed to opioids in utero Children who are West Virginia residents, born after May 9March 2, 2000, who were medically diagnosed as being exposed in utero to opioids, who were pharmacologically weaned from opioids and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant and/or unnamed, co-conspirator affiliated with Purdue Pharma.