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Opioids' most innocent victims: Lawsuit takes aim at drug companies over effects on children

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CHILLICOTHE, Ohio -- Liam's adoptive mother picked up her son and asked him to display his feet. With his right foot on the glass table, the 5-year-old showed that one of his toes was inches removed from the rest.

Liam was born with opioids in his system as a result of his birth mother's drug use. Today he has a myriad of health issues that include physical deformities, his family says. His adoptive mother Tabitha Smalley said Liam will eventually undergo surgery to remove the separated toe.

Smalley calls him her "miracle baby."

The Smalleys are just one family out of thousands in Ohio and nationwide who say they live with the long-term effects of raising children diagnosed at birth with neonatal abstinence syndrome. The phrase is a sort-of catch-all for the symptoms a baby exposed to addictive drugs in the womb, often opioids, experiences when they go through post-birth withdrawal.

The withdrawal can sometimes last for months.

Liam is part of a group of children that are now the subject of lawsuits filed in several states against major pharmaceutical manufacturers and distributors. A proposed class-action lawsuit was filed in May in Ohio.

The symptoms the children in the lawsuit exhibit include learning disabilities, behavioral problems and birth defects. The attorneys behind the lawsuit also say a mother's drug use during pregnancy can lead to long-term physical, mental and emotional developmental issues for her child.

Two families who are party to the suit agreed to interviews with cleveland.com in late June at Chillicothe attorney Anna Villarreal's office.

In addition to the Smalleys, the Rout family includes a brother and sister whose mother used opioids while pregnant, they say.

The children, Gabriel Detty and his sister Frankie, played as their grandparents Michele and James Rout explained being thrown back into parenthood after raising five children of their own. James Rout tried to calm the children as he explained how their mother's drug use may have contributed to the children's wild behavior.



"It's chaos that you're just not used to," the 56-year-old Chillicothe resident said.

Comprehensive national statistics on how many infants are born with opioids in their system are scarce because reporting requirements vary from state to state. There were 8,270 cases identified among children born in 21 states in 2013, **according to the Centers for Disease Control and Prevention**. That number was more than three times as many as reported in 1999 in 14 states and likely grew even higher as the opioid epidemic took hold nationwide.

Ohio has seen a high number of infants treated for neonatal abstinence syndrome. In 2015, 2,174 infants were admitted to hospitals to be treated for symptoms, which is equal to nearly six admissions per day, **according to the Ohio Department of Health**.

"I don't know that any litigation is going to stop it, but it's all part of a process to get it stopped," New Orleans attorney Jack Harang said of the lawsuits.

Doing so would bring no solace to the parents, grandparents and foster parents of children born addicted to opioids. The lawsuit represents the possibility of some money in their pockets, and maybe a better future still fraught with struggle.

Legal battles

The attorneys who filed the suit say the children born to opioid-addicted mothers are hurt through no fault of their own. They lay the blame at the feet of drug companies like Purdue Pharma and Ohio-based Cardinal Health.

Those companies, and others, are the subject hundreds of lawsuits accusing them of using dishonest marketing strategies that downplayed the addictive nature of their highly-addictive drugs. Doing so led to a deadly nationwide wave of opioid addiction and prescription pill dependency.

In addition to Ohio, lawsuits related to babies born addicted to opioids were filed in other states, including West Virginia, Missouri, Illinois, California, Louisiana, Tennessee and Mississippi, among others. Others are expected to follow, Harang said.

Purdue Pharma and the Healthcare Distribution Alliance, a consortium of pharmaceutical distributors, did not respond to requests for comments. But drug companies have argued against multiple lawsuits by saying prescription painkillers such as Oxycontin have legitimate medical uses approved by the U.S. Food and Drug Administration. They have also said they are committed to ensuring prescription painkillers are used properly.





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Claim system

Harang's goal is to set up a program for infants born with neonatal abstinence syndrome, and for future cases.

He envisions a system akin to [the National Vaccine Injury Compensation Program](#), a wing of the U.S. Court of Federal Claims established in 1988 for people to get money if they or a loved one were hurt or died as a result of receiving certain childhood vaccines.

A 75-cent excise tax on vaccines recommended for children by the Centers for Disease Control and Prevention pays for the program. A similar fee could be imposed on prescription painkillers to pay for a similar program for opioid babies, Harang said.

Ohio's lawsuit was first filed in Ross County in southeastern Ohio, the same county [where state Attorney General Mike DeWine filed suit](#) against several pharmaceutical companies. It was removed to federal court in July and will likely end up before U.S. District Judge Dan Polster. The judge [was appointed by a federal panel in December](#) to preside over hundreds of lawsuits filed by governments and unions from across the country against many of the same drug companies.

Villarreal learned about this sort of litigation when she attended her college reunion at Marshall University in Huntington, West Virginia. The husband of a sorority sister told her about a similar lawsuit he planned to file in another state, Villarreal said. She started working on Ohio's case soon thereafter.

Villarreal is traveling to counties across the state to recruit as many affected children as possible to participate in the case.

"I'll do whatever we have to do to tag as many of these kids as necessary," Villarreal said.





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Liam

Villarreal's proposed class of clients includes children with a variety of medical issues, including anger management to problems with vision and hearing to outright birth defects.

This includes Liam Smalley. He has suffered a long list of medical problems since his birth in May 2013. Born at 25 weeks to an opioid-addicted mother, Liam spent 215 days in the neonatal intensive care unit, Tabitha Smalley said.

Liam was born without an anus and his fingers and toes were fused together. Smalley, who serves as a foster mother for five to six children at a time in Scioto County in southern Ohio, said she and her husband initially declined to take in Liam because of his myriad medical issues. They later adopted him.

Liam has undergone many surgeries to separate his fingers and toes and for doctors to build him an anus.

"He had wheelchair, but God had other plans," Smalley said. "He's walking now. He wasn't supposed to walk at all."

His development is several years behind other 5-year-olds. He played with a small Lego car as his mom spoke, occasionally making a siren sound as he rolled it across the glass conference table. His voice is muffled, and sounds like his tongue is resting on the roof of his mouth.

His mother understands him, and he even sings a bit of a song about Humpty Dumpty when his mother prompts him.





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The Routs

James and Michele Rout are now raising their daughter's kids, after raising five children of their own. Gabriel is 7, Frankie is 2.

They learned in 2009 that their daughter Amanda was addicted to opioids. Their daughter was a good student in high school who got into drugs that changed her life in a dramatic way. Her father, a retired Chillicothe police officer, said his daughter is serving four years in prison after she and a few others beat a drug dealer and stole his dope.

James Rout choked up as he described his last day with the Chillicothe Police Department in 2009. At the time, his daughter had been picked up in relation to an assault case to which she later pleaded.

"They had cake and ice cream and a little celebration in the law complex," he said. "We were on the ground floor. My daughter was in the felony pod upstairs, waiting for sentencing."

Amanda Rout got pregnant with Gabriel in 2010. She tested positive for Percocet, Oxycontin and other drugs during her pregnancy, her mother said.

She was placed in a detox program at Ohio State Wexner Medical Center when she was six months pregnant and was given Subutex, an opioid and variation of Suboxone used to wean drug users off of heroin and other opioids.

She remained on Subutex until she gave birth to Gabriel, who had drugs in his system when he was born, Michele Rout said. The grandparents took custody of him.

Amanda Rout went through a similar pattern in 2015 when Frankie was born, her family said. She was given Subutex to curb addiction, though she also used cocaine.





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Gabriel's problems

Gabriel lives with vision and hearing problems, his grandparents said. They are waiting to see whether their granddaughter Frankie will manifest similar symptoms. They also fear Frankie is learning behaviors from her brother and thinking they are normal.

The stress of raising two young grandchildren, who frequently need to be separated for fear they will hurt each other, led James Rout to take a part-time job as a valet at a local hospital. He said being home with the children 24-7 can make him angry and a person he does not want to be.

The problem is the family paid for childcare while he worked, which costs about \$100 more a month than what he took in. Their live-in nanny will soon move away, and he said he will soon quit his job to go back to caring for his grandchildren.

Villarreal and the Rout family attributes many of the problems with the children to the mother's use of Subutex while pregnant.

"Subutex is created for pregnant women. It's still an opiate. It's still addictive. It causes birth defects and they push it, even though they've known for decades the harms it causes," Villarreal said.

Studies have shown that medication such as Subutex or methadone administered by a doctor during pregnancy can lead to infants experiencing symptoms associated with neonatal abstinence syndrome. However, the studies showed that the symptoms did not last as long.





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Cost

Harang said caring for an opioid addicted infant can cost up to \$260,000 for the first year alone. Once the baby gets older, should social and physical problems arise, the cost of hospital visits, supplies, counseling and general special care are expected to increase.

That's why the trust fund is necessary, the attorney explained. Right now, the money falls on either private insurers or state programs, if the parents or guardians qualify, and even that doesn't always cover expenses such as gas mileage to a hospital or babysitters.

"This has got to be something overriding that allows ... these kids to be able to receive access to care without going over hurdles or months and months and months of litigation," Harang said. "If we don't do that, we're going to lose these kids."

Michele Rout, who works as an assistant law director for the city of Chillicothe, acknowledges that her family has it better than many others. Her insurance through the city covers a lot of the medical costs for her grandson. That doesn't mean there aren't incidental expenses.

As for Liam, his future includes a life of physical and occupational therapy, Smalley said. She, unlike many, will likely have the cost of those services covered by the government.

It's the only way to give him the hope of a good future, though.

"I think with a lot of work from my part, teachers, (and therapies), I think he will be able to succeed," Smalley said. "It's just he might be behind and he might have to have extra help to take care of him, but our goal is to help him succeed."

More information was added to this story about Subutex and methadone use during pregnancy.



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