Emily Walden was looking for answers even before the death of her son. Walden, from Louisville, Kentucky, first wanted to know what led TJ into the grasp of prescription opioid painkillers when he was still a teenager. But she soon latched on to another question.

How was it that a powerful narcotic pulled from sale in the 1970s as too dangerous - oxymorphone - was back in pharmacies and TJ’s pocket until it killed him at the age of 22?

Walden waded through documents fat with technical language. She talked to doctors, regulators and politicians. The more she learned, the more outraged she became, and the more determined to call those responsible to account. “I’m very persistent,” she said. “Our federal government has been controlled by these pharmaceutical companies for years. They spend $80m a year on lobbying. So when parents like me go to Washington, they just nod their heads and move on.”

Walden was relentless. She banged on politicians’ doors. She wrote letters. In meetings, she told members of the Food and Drug Administration, responsible for licensing opioids, that it put pharmaceutical company profits before American lives.

Through it all, Walden was patronized by doctors and dismissed by opioid manufacturers as a hysterical mother too traumatized by the death of her son to see reason.

As it turned out, Walden was right. And she was not alone. She is part of a large band of parents bereaved by the opioid epidemic, which now claims close to 60,000 American lives a year. Some retreat into grief; others hide their tragedy behind a veil of shame over addiction.

Walden is among those who came out fighting.

In the early years it was a struggle just to bring attention to what was evolving into the biggest health emergency since HIV/Aids as the medical profession’s caution about the prescribing of opioids fell away. Drug companies and some specialists pushed the notion that opioids were not addictive when used to treat pain based on the flimsiest of evidence, including a letter to the New England Journal of Medicine citing a small study that its authors say was misused. Out of that flowed a policy of treating pain as a “fifth vital sign” that corralled hospitals and doctors into mass prescribing opioids. Deaths from opioid overdoses quadrupled between 1999 and 2015; ninety-one Americans die from opioid overdoses every day.
“For me, that was a horrendous crime that nobody wanted to listen,” said Sherrie Rubin, whose son Aaron overdosed in 2005 on OxyContin, a high dose opioid which kickstarted the addiction crisis in the mid-1990s. “I could see this epidemic coming, and I could see a train that was not going to stop. Nobody would listen in the first five years.”

Heribred parents across the US couldn’t understand the deaths of children at the hands of routinely prescribed drugs. Some were following those prescriptions when they died. Others were sucked into a nether world of buying the same pills on the black market or switching to heroin to meet the craving for ever higher doses.

April Rovero was blindsided by an epidemic she didn’t even know existed until it smashed into her family. Her son, Joey, died from drugs prescribed by the only doctor so far convicted of murder for illegally supplying opioids, Lisa Tseng.

Rovero sat through every day of Tseng’s two-month trial. “Probably the most difficult day for me was when they showed a particular photo of Joey found in his bedroom and he was deceased. I had never seen that photo,” she said. “To listen to the devastation, all these beautiful lives lost, that was for me the biggest takeaway.”

Rovero came out of it determined to educate others and set up the National Coalition Against Prescription Drug Abuse. “If you wait until the end when people have an addiction problem it is so hard to turn that around,” she said.

She quickly discovered that not many in her upmarket community of San Ramon, California wanted to hear her message. She counted nearly 40 opioid deaths in the surrounding valley over five years but little public acknowledgement of it. “People don’t want to talk about it. More and more brave people are actually putting stuff in their obituaries but it used to be zero. You just weren’t hearing about it,” she said.

Rubin saw the same thing near San Diego. “I started hearing about these kids dying supposedly because their heart had just given out. I know these kids in our community, they were healthy and athletic,” she said.

With stigma and ignorance came fear. Rubin’s son, Aaron, survived an OxyContin overdose but
his brain was starved of oxygen. He was left paralyzed and only able to communicate using two
fingers. Aaron collapsed after taking the pill for fun at a friend’s house but the family delayed
calling the emergency services because her son bought the drugs illegally in Mexico. The
parents of Aaron’s friend finally drove him to the hospital but pretended not to know what was
wrong with him.

“Information that would help save my son’s life because of fear,” said Rubin, . “My son isn’t buried in the ground, he’s buried above ground. He’s buried
fighting every day to break out. It’s hard for me every morning to wake up
to carry me around, dance with me, joke with me and I have to turn him, I
n, I have to feed him. And he can’t even say ‘good morning mom’ verbally.”

Rubin, now the executive director of Hope2gether, channelled her pain into pushing through a
Good Samaritan law in California to protect a person from being arrested for possession of
illegal drugs when summoning help for someone who is overdosing.

Local victories have had a significant impact in pushing back against the epidemic
and saving lives. They have led to pharmacies being forced to monitor opioid
prescriptions and wider access to life-saving antidotes. But for all the success, quite
a few of the parents felt that while they were winning local battles they were losing
the war to change national policy in the face of the considerable power of the
pharmaceutical companies. So they drew their disparate organizations together
under an umbrella group, Fed Up!, to press for change in Washington.

Fed Up! quickly made its mark with rallies, speaking up at public meetings and letter writing to
demand national political leadership.

Parents were dismayed that President Obama had so little to say, only addressing the epidemic
in 2015. But the focus of Fed Up!’s anger was directed at two institutions: Congress and the
FDA (the US Food and Drug Administration), which stood accused not only of failing to take the
crisis seriously but of facilitating the spread of addiction.

Several years after TJ’s death, Walden learned his addiction was rooted in surgery for a broken
at arm at 11, for which he received a string of opioid painkiller prescriptions. “Your child is in
pain and you want them to feel better. You don’t know there are dangers,” said Walden.
In high school, TJ experimented with OxyContin, which was so widely prescribed pretty much anyone who wanted it could get it from a doctor or the black market. The drug was pushing against a door opened by the earlier prescriptions and it quickly got a grip on TJ.

Before long, he was using an even more powerful narcotic pill, Opana. In 2003, the manufacturer, Endo, sought approval from the FDA for a new high strength version of the drug, Opana ER. The FDA rejected the application because of safety issues exposed in clinical trials; the agency then changed the rules for the trials and three years later Opana was approved.

How the rules came to be rewritten remains a subject of controversy. Suspicion has focused on the FDA, doctors with close ties to drug companies and opioid pharmaceutical companies funded the meetings and paid up to $35,000 to attend as the procedures were drawn up.

Critics accused the FDA of rigging drug trials in favor of pharmaceutical companies. The FDA denied improper influence but Senator Joe Manchin of West Virginia called the meetings a “pay-to-play scheme”. Walden does too.

“Opana did not change between 2003 and 2006. The only thing that changed was the clinical trial,” she said.
Walden began banging on doors on Capitol Hill demanding an investigation. Her first stop was her own senator, Mitch McConnell, at the time the Republican minority leader in the Senate. “He said that he had met with many parents who had lost their children to an overdose,” she said. Walden heard all the right things but walked away wondering. “I believed that he was going to help when I left that meeting. I believed it for a year or two after that. Now I can’t really say that Mitch McConnell’s come through for me,” she said.

At least Walden got the meeting. The other senator from Kentucky, Rand Paul, has declined to see her even though she is a constituent.

“Rand Paul never spoke about opioids until he was up for reelection. Kentucky was number two in the country for overdose deaths and he never said a word until the election. Then he said that if people had jobs they wouldn’t be doing heroin. He’s a doctor and he sits on the (Senate) health committee. It’s unbelievable he said that,” she said.

Walden did not give up. She typed up everything she had learned about Opana and the role of the FDA, and dropped it off at senators’ offices. She rang politicians offices every week but was mostly rebuffed.

Other parents were equally persistent.

Sandra Kresser’s son Josh was given a painkiller prescription for a back injury at work and was drawn into addiction. He died in 2006 at the age of 25, killed by a prescription cocktail of painkillers, an anti-anxiety drug and a muscle relaxant. One of the doctors treating Josh lost his licence to practice medicine because he was held responsible for a total of five deaths.

“After Josh died, I did not want to see another mother bury their child from this epidemic,” said Kresser. “I am absolutely dumbfounded at what’s going on. The outcry is getting louder and louder but how did we ever allow it to get to the point that it’s at now?”

A few months after Josh’s death, Kresser contacted one of her senators, Orrin Hatch of Utah. “Orrin Hatch told me he had heard nothing of an epidemic that was sweeping through the country but if in the future he heard anything about it he would be sure to get back to me. I never heard anything back,” she said. “By 2006 the epidemic had already been going for at least seven years in West Virginia and Kentucky.”

By 2012, Hatch had heard about the epidemic and was co-chairing a Senate finance committee investigation of the role of the pharmaceutical companies in the spread of opioid addiction. Kresser and other parents thought that finally the truth would be laid bare.

“They spent months doing research but the report has never been released,” she said.

Hatch said information gathered from drug companies was confidential. The parents see a cover-up.

Walden took Dr Andrew Kolodny, the leader of a group of physicians opposed to mass
prescribing of opioids, along to her first meeting with McConnell. Kolodny concluded that McConnell was unwilling to go against the financial power of the drug companies.

“Democrats and Republicans are very cautious about upsetting big pharma because they’re dependent on pharma for campaign contributions,” he said.

Some members of Congress did work hard to change policies but most politicians adhered to the opioid makers’ claims that mass prescribing was necessary to combat an epidemic of untreated pain in America, and that only those who abused the drugs became addicted. The FDA also accepted those claims, even though they were increasingly challenged by doctors, and kept approving new opioid drugs.

“I would argue that we wouldn’t have an opioid addiction epidemic today if the Food and Drug Administration had been doing its job from the beginning,” said Kolodny.

To the bereaved parents, the relationship between the FDA and the industry it was supposed to be regulating looked far too cozy. The opioid manufacturers were paying for one on one meetings and FDA officials sat on panels alongside the drug manufacturers. Meanwhile, the people whose children were claimed by the epidemic struggled to be heard. And when they were, all too often they were dismissed as unreasoned by grief.

“A lot of it was really patronizing,” said Walden.

In 2012, the familiar pattern began to play itself out at an FDA hearing in 2012 to consider approval of the most powerful hydrocodone pill to date, Zohydro ER.

The agency convened an advisory committee, made up mostly of doctors, to make a recommendation on whether the drug should be approved.

FDA officials indicated that they regarded approval as a formality, but times were changing. A year earlier, the Centers for Disease Control and Prevention (CDC) declared an opioid epidemic.

The parents stood up to speak. Avi Israel told the hearing about his son, Michael, who shot himself while addicted to hydrocodone prescribed for Crohn’s disease.
“My son took his last breath while in my arms. Half his face was plastered all over the wall, and he was struggling to breathe,” Israel told the committee. “My son Michael had a medically sanctioned addiction. He wasn’t out on the street looking for drugs. He got his prescriptions from a doctor and then he filled them at our local pharmacy.”

Israel, who found an organisation named after his son, Save the Michaels of the World, said that an earlier FDA committee had approved the drug Michael was addicted to “without knowing or thinking of the consequences”.

“So here you are today, and you could be making the same mistake. But you need to ask yourself a question: is this medication really going to help somebody? Do we really need another pill in this country?” he said.

The panel also heard from people grappling with almost unbearable pain and how they believe prescription opioids help them control it. Members of the review committee repeatedly raised questions about safety and the need for another opioid pill.

But the FDA had a different focus.

The meeting was overseen by the head of its anesthesia, analgesia, and addiction products section, Dr Bob Rappaport. He spoke about the manufacturer’s right to make money and said the law required the FDA to approve Zohydro if similar drugs were already on the market – even if it was “in best interest of patients and the public health” not to do so.

In other words, the committee was not expected to consider whether Zohydro was necessary or safe, only whether it was any worse than Opana and OxyContin.

Israel grew so agitated at this he held a $20 bill over a picture of his dead son and shouted at Rappaport. “I said: ‘The FDA, they don’t see people, they see money’. I just wanted to let them know that a lot of the decisions the FDA is making are not based on the good of the people. It’s based on the commercial interest of pharmaceutical companies,” he said.

The committee voted 11 to two against approving Zohydro. Israel was delighted. “It was really a good feeling to know we were able to do that,” he said.
“I never ever thought that the FDA would go back and approve it. That was the work of people in the FDA with very strong ties to pharmaceutical companies,” said Israel.

Manchin called the FDA’s decision “shameful” and accused it of compromising patient safety for the financial benefit of pharmaceutical companies. He proposed legislation to ban Zohydro and to force the FDA to explain to Congress any future decisions to override its own review committees’ recommendations.

Attorney generals of 28 states wrote to the FDA commissioner, Margaret Hamburg, pleading for the withdrawal of Zohydro. “Those on the front lines of the battle against the worsening opioid drug addiction epidemic recognize that the reckless decision to approve Zohydro represents a remarkable failure to act in the best interests of protecting public health,” they said.

But the ground was shifting. Last year, the CDC issued guidelines urging doctors not to prescribe opioids as a first stop for chronic pain. Through it all, Walden kept up her campaign against Opana. Earlier this year, the FDA finally held a hearing about the drug. Walden addressed it.

“I was able to look Endo executives in the eye and I felt I had to do that for my son,” she said. “I think that the FDA put profits over American lives. They need to make some serious changes or we will never get past this epidemic. Never. It started with the FDA. It needs to stop with the FDA.”

In June, the FDA asked Endo to remove Opana from pharmacy shelves. The FDA’s reversal was tantamount to an admission that Walden had been right all along. Opana should never had been on the market.

The new FDA commissioner, Scott Gottlieb, went a step further in July when he endorsed a report which recommended that approval of new opioids take into account “the public health effects of the inappropriate use of these drugs”. Zohydro would never have been approved if that policy had been in place. It remains to be seen if it will meet a similar fate to Opana.

Earlier this month, Gottlieb phoned Walden. It was the first time an FDA commissioner heard her out. “He laughed and said you must be a pretty persistent person to get this phone call with me,” she said.

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