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Missouri Opioid Trial Shows County Awash in Misery: A Q&A With Joanne Cicala of Cicala Law Firm

Jefferson County's efforts are a model for engaged, responsible local government to hold those responsible for creating and cultivating the country's opioid epidemic.

By **Kenneth Artz** | August 13, 2020



Joanne Cicala, managing partner of Cicala Law Firm. Courtesy photo

Texas Lawyer spoke recently with Texas attorney Joanne Cicala about a recent circuit court decision that denied motions by pharmacy benefit managers Caremark, Express Scripts and Optum Rx to dismiss public nuisance and other state law claims alleged by Jefferson County, Missouri, in its effort to hold those

responsible for creating and cultivating the country's opioid epidemic.

Can you tell us about the Jefferson County, Missouri, case?

Joanne Cicala: The Jefferson County case was filed in August 2018, charging pharmacy benefit managers Caremark, Express Scripts and Optum RX, along with opioid manufacturers, distributors, and pharmacies, including mail-order pharmacies run by PBMs, as responsible parties for creating and cultivating an opioid epidemic that has strained the financial and human resources of the county. Jefferson County filed together with 23 other Missouri counties represented by the Carey Danis & Lowe law firm out of St. Louis. Retired Judge Jack Garvey and Jeff Lowe are lead counsel for Jefferson County. Mark Lanier of the Lanier Firm is trial counsel. My firm, the Cicala Law Firm, was brought onto the team, given our unique position as the first firm in the United States to identify PBMs as among the defendant groups responsible for fueling the opioid crisis.

Jefferson County filed its case in Missouri state court and had to fight hard — over a year and a half — to keep it there. Defendants wanted to litigate in federal court. Jefferson prevailed, and the case was assigned to Judge Joe Rathert in the 23rd Judicial Circuit Court, Jefferson County, Hillsboro, Missouri.

On Feb. 12, all defendants moved to dismiss Jefferson's claims. Over a dozen motions to dismiss were filed leveling every imaginable assault. Jefferson vigorously defended its claims, and after four days of oral argument in May (all conducted by Zoom because of COVID-19), Judge Rathert ultimately denied the defendants' motions in their entirety.

Why is this an important case?

The case is important because it demonstrates the lengths political subdivisions will go to address the extraordinary harms this national opioid epidemic — a man-made crisis — has placed at their doorsteps. It's also important because the court's decision is one more tug back on the curtain that reveals PBMs as potentially liable key players in creating the crisis.

In my experience, no municipality wants to litigate. They have more than enough to do in their day-to-day challenge keeping their communities operating safely. I don't say this from a distance. I put myself through Fordham Law School at night by working full time during the day for the city of New York. While working on the implementation of demanding welfare reform policies, I saw firsthand the tremendous challenges our municipal civil servants must confront to deliver critical supports to their constituents with limited resources and navigating real-world, real-time demands that routinely present themselves. For a county such as Jefferson to step up and address the serious consequences of the opioid epidemic, a crisis Jefferson recognizes to be not of nature's making but hatched in corporate boardrooms, is impressive and reflects a model of proactive democracy at work.

I like to say at our firm, and when speaking with clients, "democracy is hard enough without fraud." And I feel that to my core. Our incredible American political system has more than enough challenges already without layering atop that a deliberate and pernicious scheme to intentionally release and make widely available absurd quantities of highly dangerous drugs that inevitably would lead to the devastation we now see across America in the form of the opioid crisis. Jefferson County and all political subdivisions who

have stepped up in response are to be genuinely commended. There is no alternative but to shed light on the sort of evidence we see here of purposeful activity designed to maximize corporate profits at the expense of taxpayers and communities nationwide.

Is it accurate to say PBMs are the villains of this story?

PBMs are absolutely among the villains in this story. The “Big 3” who are named in Jefferson County and now in over 85 cases throughout the country, including in the federal opioid MDL proceeding in Ohio, have managed pharmacy benefits during the relevant period for as much as 90% or more of Americans. Their fingerprints are on nearly every opioid prescription that was filled at a pharmacy and paid for by insurance. At all times, these PBMs could have constructed their national formulary offerings in a manner that would have resulted in fewer opioids entering the marketplace.

It is undeniable that the national formularies of these three PBMs determine which drugs get paid for by insurance and which don't. It is for that reason — precisely because these three PBMs have such a huge market share and influence — that drug companies pay them multimillions of dollars annually to ensure that their addictive drugs receive the most preferential treatment possible on these national offerings. The drug companies know that if their drugs don't have preferred formulary placement, they will make less money. That is why they have departments focused solely on these PBM relationships. It's just that simple. And so, what we talk about in the Jefferson County case and the others my firm is handling is that the PBMs could have constructed national formularies that made less-addictive pain alternatives more readily available than oxycontin. And our research has confirmed that these PBMs made it easier to access oxycontin (to pick one example) than, for example, to obtain prescription-level Tylenol.

What I am saying about the PBMs' ability to influence opioid utilization is not conjecture. These three PBMs themselves have belatedly, in very recent years, now introduced what they call “Opioid Management Programs” and in the context of those programs, they now tout to the world that they are “uniquely situated to abate the opioid crisis.” Their public documents show us that their new Opioid Management Programs result in 80% drops in opioid utilization and that their programs are resulting in lower quantity limits and daily doses.

Also, in part as a result of an injunction my firm sought against them in another opioid proceeding, these three particular PBMs are now making MAT (medication-assisted treatment) for opioid use disorder more readily available. Under increased scrutiny, they are now imposing routine controls such as prior authorization requirements and step therapies before permitting the reimbursement of opioids.

All of these are tools the PBMs have always had at their disposal to assist in the control of opioid use and routinely use in the context of other drugs. And yet they did not use them here until they were forced. They chose not to use their market power and knowledge for good, but they used it to fuel an epidemic. Jefferson County seeks to hold them responsible for that, and now, with the denial of their motion to dismiss the county's claims, Jefferson may proceed to work up its case for trial.

Can you tell us about the county's opioid epidemic; for instance, how bad is it and what are the costs?

It's bad and costing a fortune in Jefferson County, and throughout the United States. According to the Missouri Department of Health and Senior Services statistics, between 2013 and 2017, Jefferson County saw 324 deaths due to opioid overdoses. In 2017 alone, there were 73 fatal opioid overdoses in the county, reflecting a 40% increase from 2015. The county also handled over 2,200 emergency room visits due to opioid misuse in the same time period. This is on top of the significant costs to combat other harms of the opioid epidemic, including costs for law enforcement, emergency medical services, prisons and/or jails, probation, public works, family protective services, addiction treatment, detox and rehabilitation facilities and services, social services, housing, and prevention and education programs, treating opioid-addicted newborns in neonatal intensive care units, burying the dead and significant increases in foster care placements.

The Centers for Disease Control and Prevention reports that for each of the years 2006-2018 Jefferson County has significantly outpaced national averages for opioid prescribing rates. And Jefferson County's experience is consistent with Missouri and the nation. For example, in 2018, 1,132 Missourians lost their lives due to an opioid overdose. That means one out of every 56 deaths statewide was attributable to opioids. Put otherwise, in 2018, Missouri experienced a loss of 40,376 total years of life due to opioid-involved overdoses. Years of potential life lost involves estimating the average time a person would have lived had they not died prematurely, in this case from opioids. Between 2014-2018, an estimated \$116 million was spent in Missouri on charges related to ER visits due to opioid misuse, and \$94 million was spent on costs related to babies born addicted to opioids, or neonatal abstinence syndrome.

Other statistics:

Missouri Hospital Association

- Between 2006 and 2015, the rate of hospital inpatient and emergency department visits for analgesic opioid overuse in Missouri increased 138% from a rate of 204.3 per 100,000 in 2006 to 486.9 per 100,000 in 2015.
- Missouri's Senate District 3, which Jefferson County is a part of, had a rate of 553.1 to 1,525 per 100,00 for hospital inpatient and emergency department visits for analgesic opioid overuse in 2015.
- Between 2006 and 2016, the number of infants born with NAS increased by 538% [a 495+ case increase] in Missouri.
- Jefferson County's NAS case rates per 1,000 births between 2012-2016 was 8.68 compared to the Missouri rate of 6.16 or the national rate of 7.7.

Local News – KSDK

- A prescription drug monitoring program launched in 2017 across 32 Missouri cities and counties found Jefferson County has the third-highest rate of controlled substance prescriptions.
- Numbers from the Jefferson County PDMP show an average of 2.1 prescriptions per resident. That's higher than the 1.6 average across all other locations in the program—opioids comprised approximately 40% of all controlled substances dispensed.
- Opioid overdose deaths caused more than two times as many deaths as car crashes in Jefferson County in 2016.

Is Jefferson County the only place where this is happening?

No. The opioid epidemic has negatively impacted nearly every local government in the United States. It is a crisis that knows no geographic, demographic, or economic boundaries. This ubiquitous harm reflects the wildly successful collective efforts of the defendants to deliver billions of opioids into our communities.

The defendants' efforts to deceive and make opioids widely accessible have also resulted in a windfall of profits. Opioids are now America's most prescribed class of drugs, generating \$11 billion in revenue for drug companies in 2014 alone. While Americans represent only 5% of the world's population, they consume 80% of the world's production of prescription opioids.

In 2012, 259 million prescriptions for opioid painkillers were filled; enough to medicate every adult in America around the clock for a month. Twenty percent of all doctor visits in 2010 resulted in the prescription of an opioid, nearly double the rate in 2000. Once a niche drug, opioids are now the most prescribed class of drugs, more than blood pressure, cholesterol, or anxiety drugs. While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply. Together, opioids generated \$8 billion in revenue for drug companies in 2012 and, until recently, have been increasing at a record pace.

According to the CDC, the nation has been swept up in an opioid-induced public health epidemic in which prescription opioid use contributed to 16,651 overdose deaths nationally in 2010; 16,917 in 2011; and 16,007 in 2012. One defendant's own 2010 internal data shows it knew that prescription opioids gave rise to 40% of drug-related emergency department visits in 2010 and 40% of drug poisoning deaths in 2008 and that the trend of opioid poisonings was increasing from 1999-2008. For every death, more than 30 individuals are treated in emergency rooms. By 2017, it has been reported that there are over 60,000 opioid-related deaths in the U.S.

Further CDC Findings:

- The defendants' opioid-related misconduct causes heroin abuse. A 2015 study found four out of five heroin users reported that their addiction started with opioid pain relievers. Defendants created a rebirth in the heroin industry by starting patients or any end user on the gateway drug of opioids and transforming opioid users into illegal heroin users and abusers.
- More than 12 million Americans ages 12 or older have used prescription painkillers without a prescription in 2010, and adolescents abuse opioids in alarming numbers.
- Opioid abuse has not displaced heroin, but instead triggered a resurgence in heroin use, imposing additional burdens on the plaintiffs and local agencies that address heroin use and addiction. According to the CDC, the percentage of heroin users who also use opioid pain relievers rose from 20.7% in 2002-2004 to 45.2% in 2011-2013 and continues to grow.
- The opioid epidemic continues to kill more than 130 Americans every day. Prescription and illegal opioids account for more than 60% of overdose deaths in the United States, a toll that has quadrupled over the past two decades. More people died from opioid-related causes in 2016 than from car accidents or guns.
- The costs of health care, lost productivity, addiction treatment, and criminal justice involvement

due to opioid misuse alone is \$78.5 billion a year.

- The devastating impact of opioid abuse cannot be overstated. After years of decreasing death rates in the United States, they are now on the rise fueled by an increase in opioid-related drug overdose deaths. Drug overdoses are now the leading cause of death for Americans under the age of 50. The number of Americans who died of drug overdose deaths in 2017 was roughly equal the number of Americans who died in the Vietnam, Iraq, and Afghanistan wars combined.

When did crisis start and how did it get this way?

As Jefferson County describes in its pleading, the epidemic started when Purdue Pharma and other manufacturers deliberately hatched a plan to flood the market with false and misleading information regarding the efficacy of opioids for the treatment of long-term chronic pain outside of an end-of-life/palliative care environment. Distributors, pharmacies, and PBMs all jumped on the bandwagon the manufacturers constructed to ensure their unlawful plan's success. Without the willing and knowing participation of all defendants, the opioid epidemic would not have occurred.

Distributors and pharmacies turned a blind eye to their federal and state obligations concerning controlled substances. PBMs purposefully constructed national formularies that ensured easy access to opioids, making them often more readily available than less addictive alternatives or addiction treatments.

All of this combined for a perfect dangerous storm leading predictably to the extraordinary costs Jefferson County and municipalities nationwide now confront.

If the plaintiffs are successful in trying their case, what could a favorable verdict lead to?

Two potential favorable outcomes include: 1) Critical injunctive relief, meaning a change in practices by the defendant groups such that Jefferson County would no longer be flooded with these dangerous and highly addictive opioids that foreseeably lead to the harm the county has experienced; 2) Monetary relief to recoup some if not all of the costs the county has unnecessarily had to incur these many years to clean up from the epidemic defendants purposefully unleashed and fueled; and 3) Critically essential monetary relief to permit the county to fund necessary abatement activities focused on prevention, treatment and recovery; and to fund necessary law enforcement and judicial responses to the crisis.

Is there anything else you would like to mention about the case?

Jefferson County's efforts here are a model for engaged, responsible local government—an unfortunately necessary response to a crisis that was entirely avoidable but deliberately sewn by the defendants named in its suit, each of whom has profited mightily from it. My firm is honored to represent Jefferson County in this effort and honored to do all it can to achieve a favorable and timely resolution. The county has more than enough good work to do, especially now as we all confront a pandemic overlay to this epidemic. We are committed to helping Jefferson County turn the page on this opioid crisis for the benefit of all it ably serves and represents.

Joanne Cicala is the managing partner for **Cicala Law Firm**. She is an experienced civil litigator who specializes in complex commercial matters in both state and federal court, primarily representing plaintiffs. Cicala's practice focuses on public client litigation, fraud in the health care space, class actions, commercial disputes, community advocacy, consumer protection, breach of contract and false claims. She can be reached at joanne@cicalapllc.com (<mailto:joanne@cicalapllc.com>).

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