Nos. 22-3750, 22-3751, 22-3753, 22-3841, 22-3843, 22-3844

IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

TRUMBULL COUNTY, OH, *et al.*,
Plaintiffs-Appellees,

v.

PURDUE PHARMA L.P., *et al.*,
Defendants,

and

WALGREENS BOOTS ALLIANCE, INC., *et al.* (22-3750/3841), CVS PHARMACY, INC., *et al.* (22-3751/3843), WALMART, INC. (22-3753/3844),
Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO, CASE NOS. 1:17-CV-MD-2804 (HON. DAN A. POLSTER)

BRIEF OF AMICI CURIAE THE NATIONAL ASSOCIATION OF COUNTIES, THE COUNTY EXECUTIVES OF AMERICA, THE NATIONAL LEAGUE OF CITIES, THE U.S. CONFERENCE OF MAYORS, AND THE INTERNATIONAL MUNICIPAL LAWYERS ASSOCIATION, SUPPORTING APPELLEES URGING AFFIRMANCE

Robert B. Nealon
NEALON & ASSOCIATES, P.C.
119 North Henry Street
Alexandria, Virginia 22314
(703) 684-5755

Counsel for amici curiae and the County Executives of America

Anne K. Davis
BLEICHMAR, FONTI & AULD LLP
555 12th Street, Suite 1600
Oakland, CA 94607
(415) 445-4003

Counsel for amici curiae

J. Carl Cecere
CECERE PC
6035 McCommas Blvd.
Dallas, TX 75206
(469) 600-9455
ccecere@cecerepc.com

Counsel for amici curiae

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STATEMENT OF INTEREST[1]

The National Association of Counties ("NACo") is the only national organization that represents county governments in the United States. Founded in 1935, NACo provides essential services to the nation's 3,069 counties through advocacy, education, and research.

The County Executives of America ("CEA") is a 40-year-old national association dedicated to furthering the interests of county executives from over 700 counties that represent millions of people. CEA allows these county leaders to engage on a collegial basis, sharing best practices and favored policies for managing the operations of county governments.

The National League of Cities ("NLC"), founded in 1924, is the oldest and largest organization representing U.S. municipal governments. NLC works to strengthen local leadership, influence federal policy, and drive innovative solutions. In partnership with 49 state municipal leagues, NLC advocates for over 19,000 cities, towns, and villages, where more than 218 million Americans live.

[1] No counsel for any party authored this brief in whole or in part, and no person or entity other than amici or their counsel made a monetary contribution intended to fund the brief 's preparation or submission. All parties have consented to the filing of this brief.

The U.S. Conference of Mayors ("USCM"), founded in 1932, is the official nonpartisan organization of all United States cities with a population of more than 30,000 people, which now includes over 1,400 cities. Each city is represented in USCM by its chief elected official—the mayor.

The International Municipal Lawyers Association ("IMLA") has been an advocate and resource for local government attorneys since 1935. Owned solely by its more than 2,500 members, IMLA serves as an international clearinghouse for legal information and cooperation on municipal legal matters. IMLA's mission is to advance the responsible development of municipal law through education and advocacy by providing the collective viewpoint of local governments around the country on legal issues before the Supreme Court of the United States, the United States Courts of Appeals, and state supreme and appellate courts.

Collectively, amici include the major national organizations that represent America's counties, cities, villages, and towns—and the people who lead and advise them. As the level of government closest to the people, Amici's members possess intimate, personal connections to those affected by the opioid crisis. And as the officials and governmental bodies with primary responsibility for those communities' public health, emergency response, and

social services, they have for decades been on the front lines combatting the crisis.

Amici write here because the Pharmacy Defendants in this case are threatening Amici's members' capacity to fight that battle. The legal arguments they raise on appeal would, if adopted, improperly prevent pharmacies from being held responsible for the costs of abating the crisis they helped to cause, and improvidently diminish their duty to avert the further spread of the crisis to almost nothing. It is therefore essential that the Court reject these theories and affirm the District Court's judgment, in order to protect Amici's ability to carry out their duties in addressing one of the most staggering public health crises of the age.

INTRODUCTION AND SUMMARY OF ARGUMENT

The opioid crisis represents one of the greatest threats to public health in our lifetime, with profound consequences for the communities Amici serve.[2] From 2010 to 2015, over 63% of the 52,404 drug overdose deaths recorded by

[2] *See* Richard J. Bonnie, Morgan A. Ford, & Johnathan K. Phillips, *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use* 7 (2017).

the Centers for Disease Control and Prevention (CDC) involved an opioid.[3] And the death toll has only risen from there. In 2021, 107,000 people died from drug overdoses—two-thirds involving opioids.[4] Even now, 114 people in the United States lose their lives every day in opioid-related fatalities, making drug overdose driven by opioids the leading cause of death for people younger than 50, killing more Americans than heart disease, cancer, and automobile accidents.[5]

The problem is even worse than this tragic death toll suggests. One Ohio public-health nurse described her Ohio county as "awash in pain pills."[6] And the same could be said of virtually every county, city, and town in the United States. The past two decades have seen dramatic nationwide increases in

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[3] Rose A. Rudd, Puja Seth, Felicita David & Lawrence Scholl, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity & Mortality Wkly. Rep. 1145, 1145 (2016); Ctrs. for Disease Control & Prevention, *Annual Surveillance Report of Drug-Related Risks and outcomes: United States 2019* 41 (2019), https://perma.cc/6YPA-CZSV.

[4] Nick Miroff, *DEA seized enough fentanyl to kill every person in the U.S. in 2022*, Wash. Post, Oct. 20, 2022, https://bit.ly/3YZZvZH.

[5] Nancy La Vigne, *et al.*, Urban Institute, *Interim Report to Congress: Comprehensive Opioid Abuse Program Assessment: Examining the Scope and Impact of America's Opioid Crisis* (Aug. 2019) ("Urban Institute").

[6] Alan Johnson, *OxyContin, Other Narcotic Pain Pills Still Plentiful in Ohio*, CantonRep.com (Jan. 15, 2017), https://tinyurl.com/StillPlentiful.

opioid addiction rates,[7] opioid-related traffic accidents,[8] opioid-related admissions to substance abuse facilities,[9] opioid-related emergency room visits,[10] opioid-related hospital admissions,[11] and the occurrence of entirely new diseases in newborns created by their mothers' opioid addictions.[12]

Amici have witnessed these tragedies first-hand. They have borne witness as the scourge of opioids has killed their residents, torn apart their

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[7] Andrew Kolodny, *et al.*, *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 Ann. Rev. Pub. Health 559, 559 (2015).

[8] Guohua Li & Stanford Chihuri, *Prescription Opioids, Alcohol and Fatal Motor Vehicle Crashes: A Population-Based Case-Control Study*, 6 Inj. Epidemiology 1, 1–3 (2019) ("Li & Chihuri").

[9] Andrew S. Huhn, *et al.*, *A Hidden Aspect of the U.S. Opioid Crisis: Rise in First-Time Treatment Admissions for Older Adults with Opioid Use Disorder*, 193 Drug & Alcohol Dependence 142, 142 (2018).

[10] Christopher M. Jones & Jana K. McAninch, *Emergency Department Visits and Overdose Deaths from Combined Use of Opioids and Benzodiazepines*, 49 Am. J. Preventive Med. 493, 497–500 (2015).

[11] Hilary Mosher, *et al.*, *Trends in Hospitalization for Opioid Overdose Among Rural Compared to Urban Residents of the United States, 2007–2014*, 12 J. Hosp. Med. 925, 925 (2017); Jennifer P. Stevens, *et al.*, *The Critical Care Crisis of Opioid Overdoses in the United States*, 14 Annals Am. Thoracic Soc'y 1803, 1808 (2017).

[12] Stephen W. Patrick, *et al.*, *Neonatal Abstinence Syndrome and Associated Health Care Expenditures: United States, 2000–2009*, 307 JAMA 1934, 1934–1937 (2012).

families, and ravaged their communities. Amici have also been forced to bear much of the epidemic's staggering expense, from the hard costs of administering services to a populace overwhelmed by opioid addiction, to more intangible costs like loss of human capital caused by employees so traumatized from their day-to-day jobs that they suffer depression, risk of suicide, and post-traumatic stress disorder.

Unlike other public health crises of the recent past—including the influenza pandemic of the late 1910s, the spread of the human immunodeficiency virus (HIV) of the 1980s and 1990s, or the ongoing COVID pandemic of the past few years—the opioid crisis is not the result of some new pathogen of indeterminate origin. We know exactly when, where, and how the crisis began: "in doctor's offices and hospitals," with doctors prescribing too many pills in the prescription drug trade.[13] From there, the crisis blossomed to include physician over-access, pill mills, and diversion, and soon came to encompass illegal opioids like heroin and fentanyl. But it all started with the prescription drug trade and spread through the active involvement of the pharmaceutical industry.

[13] White House Comm'n on Combatting Drug Addiction & the Opioid Crisis, *Draft Interim Report* 1 (July 31, 2017), https://bit.ly/3vtk6bf.

The nation's drug pharmacies—represented here by the industry's most prominent pharmacy chains—played a key role in that spread. They failed to comply with their legally imposed duties as handlers of Schedule II prescription drugs to investigate suspicious prescriptions and resolve any red flags in a manner that could have halted the opioid epidemic. Instead, the dispensers chose to overlook troublesome prescriptions, if not facilitate them, in order to sell more pills. Those retail-level failures were central to the opioid epidemic's rise, and any effort to halt the crisis runs through the pharmacies, because their unsurpassed knowledge of physician prescribing practices and patient behavior at the end the prescription opioid supply chain gives them an irreplaceable ability to halt the suspicious transactions that lead to opioid abuse.

Yet in this case, the Pharmacy Defendants would have the Court turn a blind eye to their refusal to block suspicious opioid prescriptions and sales. Adopting their position would absolve the pharmacies of their responsibility for creating an opioid epidemic that costs this country over $78 billion a year, much of which is born by Amici and their members. And it would so constrict pharmacies' duties to identify and halt suspicious drug transactions that they would be required to do virtually nothing to stop diversion of opioids, leaving

them with no appreciable role in preventing the further spread of the crisis, much less helping to reverse it. The pharmacies should not get the last word on their role in fueling the opioid epidemic or their responsibility for stopping it. This Court should therefore reject their arguments and affirm the decision below.

ARGUMENT

I. The scourge of the opioid epidemic has overwhelmed local resources.

The opioid epidemic is a battle "in which nearly every city, county, and state in the country is participating."[14] Lake and Trumbull counties are a microcosm reflecting the problems that every local government faces in that fight. The same loss of life occurring in Lake and Trumbull has also happened in the nation's largest cities like New York City, where for the past two years over 2,000 people have died annually from opioid overdoses.[15] That means in

[14] Dr. Daniel G. Aaron, *Public Health in the Opioid Litigation*, 53 Loyola Chicago L. J. 11, 13 (2021).

[15] New York City Dep't of Health and Mental Hygiene, *Unintentional Drug Poisoning (Overdose) Deaths in Quarter 3, 2021, New York City* 1 (June 2022), https://bit.ly/3VDj1Z2.

the Big Apple itself, more people die of opioid overdoses than from homicides, suicides, and motor vehicle crashes combined.[16]

That same tragic tale has also played out in other locales across the Midwest, like Pittsburgh's home of Allegheny County, Pennsylvania, where there were 564 deaths from opioid overdose in 2019.[17] And the trail of death reaches all the way to the West Coast, in places like Seattle's King County, Washington, where drug overdose deaths as of October of last year had already surpassed 700, having risen every year since 2011.[18]

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[16] *See* New York City Off. of the Mayor, *Healing NYC: Preventing Overdoses, Saving Lives* 9 (2017), https://bit.ly/3vvKBg3; *see also* NYC, *Provisional 2021 NYC Suicide Death Data Remains Consistent with Pre-Pandemic Data* (Dec. 6, 2022) (reporting 542 homicides in 2020 and a similar number for 2021), https://bit.ly/3IkEDq8; Jay S. Kniepel, *New York City Car Accident Statistics – November 2022 Update* (reporting 235 motor-vehicle deaths in 2020, and 245 in 2021), https://bit.ly/3WxDzmV; Dean Meminger, *NYC Murders Up Nearly 45% in 2020*, Spectrum News NY1, Jan. 2, 2021 (reporting 468 homicides in 2020); Thomas Tracy, *NYC Homicide and Shooting Surge Continued in Pandemic-Stricken 2021*, N.Y. Daily News, Jan. 12, 2022 (reporting 408 homicides in 2021).

[17] Lauren Lee, *Allegheny County reports increase in opioid overdose deaths*, Pittsburgh Post-Gazette, July 10, 2020.

[18] Seattle & King County Public Health, *2022 Overdose Death Report* 1 (Nov. 2022).

The opioid scourge has also hit the suburban parts of Cook County, Illinois, which reported 855 opioid-related overdose deaths in 2019.[19] Smaller communities across the country have not been spared either. Multnomah County, Oregon saw an increase of opioid overuse fatalities from 128 in 2019 to 181 in 2020—a big number for a county with only 800,000 people.[20] And Washtenaw County, Michigan, home to only 367,000, has lost more than 450 residents to opioid overdoses since 2011.[21]

America's cities, counties, and towns are completely unable to cope with these preventable deaths of thousands of their residents. In the coldest economic terms, every three drug-overdose deaths translate to a $130,000-$140,000 increase in public expenditures—money that many counties simply do not have.[22] But as hard as it has been to handle these deaths of opioid

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[19] Chicago Dep't of Public Health, *2019 Chicago Opioid Overdose Data Brief* (Dec. 2020).

[20] Brief Amici Curiae of Fourteen Cities and Counties in Support of Petitioner, *Safehouse v. Dep't of Justice*, No. 21-276, 2021 WL 4462986 at *10 (U.S. Sept. 24, 2021) (citing Multnomah County Medical Examiner Database).

[21] Washtenaw County Health Dep't, *Opioid Report* 1 (Apr. 2019), https://bit.ly/3vynm54.

[22] OpenGov Research Team, *Quantifying How Much the Opioid Epidemic Costs Governments*, https://bit.ly/3CfvZFe ("*Quantifying*").

victims, caring for the living opioid victims has proven even more costly and disruptive, overwhelming a variety of community resources and forcing local governments to transform the services they provide to their citizens.

A. Public health resources

Since its outset, the opioid epidemic has placed severe stresses on community health resources, "with opioid sales, addiction, treatment admissions, and death climbing in proportion."[23] These demands sap systems of resources far outside addiction and treatment. Local health agencies' efforts to treat opioid misuse and dependency have also forced them to confront the many health effects that arise from addiction, including liver damage, malnutrition, infectious disease, depression, and risk of suicide.[24]

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[23] *See* Comm. on Pain Mgmt. & Regul. Strategies to Address Prescription Opioid Abuse & Nat'l Acads. of Scis., Eng'g & Med., *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use* 51 (2017) ("*Pain Management*") (explaining that increase in opioid prescriptions that began in the late 1990s was associated with increases in opioid-related deaths and substance use disorders); Nat'l Insts. Of Health: Nat'l Inst. on Drug Abuse, *Overdose Death Rates* (Jan. 29, 2021), https://perma.cc/3RXM-UAFJ.

[24] *Pain Management*, *supra* at 13–14.

B. Child services

Opioid abuse also places stress on the local government systems that serve vulnerable children, like child protective services, foster care, and social work, because one of the opioid epidemic's most tragic tolls falls on children whose addicted parents are unable to properly care for or prioritize them.[25] As a result, the removals of children from their homes because of substance abuse are way up, from 19% in 2000 to 35% today.[26] The numbers are worse in communities that have greater than average incidences of opioid addiction. *Id.*

And the children removed from opioid-addicted families need a great deal of care, usually at public expense. Many have experienced trauma, physical abuse, and neglect. And the epidemic has given rise to entirely new categories of infant-specific diseases, including "neonatal abstinence syndrome" (NAS), a disruption to neonatal development that results from *in utero* opioid exposure, passed from mother to baby through the placenta.[27]

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[25] Urban Institute, *supra* at 15; Substance Abuse and Mental Health Services Administration (SAMHSA), Nat'l Ctr. on Substance Abuse & Child Welfare, *Child Welfare and Treatment Statistics*, https://bit.ly/3Z2opHT.

[26] Urban Institute, *supra* at 15.

[27] Jean Y. Ko, *et al.*, Ctrs. for Disease Control and Prevention, *CDC Grand Rounds: Public Health Strategies to Prevent Neonatal Abstinence Syndrome*, Mar. 10, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6609a2.htm.

32,000 American babies were born with NAS in 2014, a staggering five-fold increase over the number only ten years earlier[28]—a horrifying outgrowth of the epidemic's particularly disproportionate impact on women.[29] While the long-term effects of NAS are not yet fully known, its innocent victims face far-higher risk of childhood development problems that may continue through adulthood.[30] And "infants with NAS require specialized care that typically results in longer and more complicated and costly hospital stays"—costs which usually come out of the public fisc.[31]

Much of the treatment need is also psychological, because many children removed from opioid-abusing households must not only deal with the trauma

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[28] Nat'l Insts. of Health: Nat'l Inst. on Drug Abuse, *Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome*, https://bit.ly/3i8IjAw; *see also* Ko, *et al.*, *supra*.

[29] Mishka Terplan, Am. Soc'y for Reproductive Med., *Women and the Opioid Crisis: Historical Context and Public Health Solutions* (Aug. 2017), https://bit.ly/3Z5RbHF.

[30] Mary-Margaret A. Fill, *et al.*, *Educational Disabilities Among Children Born with Neonatal Abstinence Syndrome*, Pediatrics (2018); *see also* Ctrs. for Disease Control and Prevention, *Key Findings: Children Born with Neonatal Abstinence Syndrome (NAS) May Have Educational Disabilities* (Mar. 10, 2021), https://tinyurl.com/y4q6m4ay.

[31] U.S. GAO, *Newborn Health: Federal Action Needed to Address Neonatal Abstinence Syndrome* 1–2 (Oct. 4, 2017), https://www.gao.gov/assets/690/687580.pdf.

of losing their parents, but also bear the psychological scars of living "amid trauma and chaos"; they "need crisis counseling and speech therapy and tutoring"; and they "wind up with disabilities and delays and problems that teachers can't fix."[32]

C. Law enforcement and first responders

For the nation's local law enforcement officers and other first responders like firefighters and emergency medical services personnel, the opioid crisis has been a transformative experience.[33] First, of course, this change results because of the toll the epidemic places on the health care system, which affects the first responders in that system like firefighters and EMS. It also results from significant strains that the crisis places on law enforcement. People suffering from opioid addiction are more likely to commit crimes than the average person, meaning they have greater contact with law

[32] Doug Caruso, *et al.*, *Billions of Opioids Shipped To Ohio In Just 7 Years*, Columbus Dispatch, July 21, 2019.

[33] *See* TASC Ctr. for Health & Justice, *First-Responder Trauma and the Opioid Crisis* (June 2020) ("First-Responder Trauma"), https://bit.ly/3QdEeHY; *see also* Fed. Healthcare resilience Task Force, EMS/Prehospital Team, *Burnout, self-care and COVID-19 exposure for first responders* (2020); C. Copple, *et al.*, *Law enforcement mental health and wellness programs: Eleven case studies* (Washington, DC: Office of Community Oriented Policing Services 2019).

enforcement and the criminal justice system.[34] The resulting glut of opioid-related arrests has put "severe" pressure on judicial resources. *Id.* And the pressure only increases when it comes to housing this influx of opioid-related arrestees in jails and prisons, because as many as 63% of these prisoners arrive at the jailhouse door dependent on opioids and requiring treatment. *Id.* at 21-22.

These costs have increased police expenses by 15% between 2010 and 2016 and have similarly increased EMS expenditures by about one percent for every opioid-related death.[35] But the increased costs on first responders are more than monetary. On the front lines of the crisis, many first responders are forced to take on new duties that stretch well beyond their traditional ones. The toll is especially high on police, who must frequently shift from enforcing the laws to serving as erstwhile medics, administrating opioid reversal drugs like naloxone sometimes several times a day.[36] And communities must spend millions for first responders to have these drugs on hand.

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[34] Urban Institute, *supra* at 20.

[35] *Quantifying*, *supra*.

[36] *First-Responder Trauma*, *supra*.

The tax on first responders from this shift in priorities is not merely professional and monetary, it is also personal and psychological. Dealing with the victims of the opioid epidemic is often debilitating, soul-crushing work. Having to "revive the same individuals again and again" leads to first-responder frustration. *Id.* at 1. "Stress levels also tend to increase when first-responder efforts to immediately render critical help are met with mistrust and anger instead of appreciation." *Id.* The counterproductive reception that first responders often receive from opioid victims is often a consequence of the drugs themselves: "Several studies have shown that anger and confusion are among the adverse effects that people experience after an overdose reversed by naloxone."[37] Yet receiving that reaction makes responders feel unwanted. As a result, many have left first-responder jobs, and those who stay face risks of post-traumatic stress disorder, depression, suicide, and burnout that are major threats to future retention.[38]

That is only the beginning of the opioid epidemic's effects on the local communities Amici represent. Opioid-related driving incidents tax roadway

[37] Rachael Rzasa Lynn & JL Galinkin, Nat'l Institutes of Health, *Naloxone dosage for opioid reversal: Current evidence and clinical implications* (2017), https://bit.ly/3i8Jikc.

[38] Urban Institute, *supra* at 18.

resources.[39] Opioid addiction produces mortgage default, housing glut, and blight that depresses property values and decreases community cohesion.[40] Literally no cranny of America's local communities has been left untouched, and no resource left untapped—or completely tapped out.

The resulting expenses are spiraling out of control. One study pegged the total cost of the opioid epidemic at $78 billion a year, with one quarter of that amount borne by the public sector, in "healthcare, substance abuse treatment, and criminal justice costs."[41] And the White House Counsel of Economic Advisors believes those numbers are overly conservative, recently estimating that costs may be six times as much.[42] These costs frequently prove too much for many communities to afford, which is why equitable abatement awards like those awarded by the district court in this case are so critical—

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[39] Li & Chihuri, *supra,* at 1–3.

[39] Huhn, *et al.*, *supra*.

[40] *See generally* Walter D'Lima & Mark Thibodeau, *Health Crisis and Housing Market Effects – Evidence from the U.S. Opioid Epidemic*, J. of Real Estate Fin. and Econ. (Jan. 2022), https://bit.ly/3WIZoQw.

[41] Curtis Florence, *et al.*, *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013* 6, 13–14, (PubMed Central May 30, 2018), https://bit.ly/3Z5ORQR.

[42] The White House, Council of Econ. Advisors, *The Underestimated Cost of the Opioid Crisis* 1–3 (Nov. 2017), https://perma.cc/3AWV-EEZD.

even though they only cover some of the most basic costs associated with abating the crisis, not all the costs that arise from it.

II. The Pharmacy Defendants should not be absolved of their undeniable responsibility for causing the opioid crisis, or relieved of their vital duty to help overcome it.

The arguments raised by the Pharmacy Defendants in this case threaten the ability of cities, counties, and towns like Trumbull and Lake counties to properly abate the opioid crisis, because this case is about more than these two communities or a single equitable award. Allowing the Pharmacy Defendants to evade responsibility in this case will also absolve them of the integral role they have played in starting the opioid crisis in communities all over the country.

That is because the origins of the crisis can be traced directly to prescription opioids that the Pharmacy Defendants dispensed to the public. And *that* is because most opioid misuse starts with prescribed pills. In the past year alone, one in 25 people misused prescription opioids.[43] And most opioid

[43] Theodore J. Cicero & Matthew S. Ellis, *Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned from OxyContin*, 72 JAMA Psychiatry 424, 425–427 (2015) (describing users' shift from prescription opioids to heroin); Rebecca L. Haffajee & Michelle M. Mello, *Drug Companies' Liability for the Opioid Epidemic*, 377 New Engl. J. Med. 2301, 2301 (2017) ("[T]he majority of persons with opioid addiction started with prescribed painkillers.").

addiction begins with prescription opioids. *Id.* From these prescription-based purchases, the crisis has expanded to encompass many illicit uses of prescription drugs, including by over-prescription, doctor-shopping, pharmacy-shopping and diversion, as well as from addicts turning to deadly alternatives to prescription opioids like heroin and fentanyl for options that are "less expensive, more accessible, and more potent."[44] But this illicit trade ultimately has its roots in oversupplies from prescription-based purchases.

Under the Controlled Substances Act, pharmacies have unique responsibilities to prevent diversion at the point of sale. Pharmacies have a "responsibility" to "dispense only lawful prescriptions," 21 C.F.R. § 1306.04(a)—a responsibility that requires them to look beyond the prescription itself and to refuse to fill any prescription that they "'know[] or ha[ve] reason to know' … is invalid." *Holiday CVS L.L.C.*, 77 Fed. Reg. 62,316, 62,341 (DEA Oct. 12, 2012) (citation omitted). They also have duties "to provide effective controls and procedures to guard against … diversion of controlled substances" (21 C.F.R. § 1301.71), and to fill prescriptions in the "usual course

[44] *See* Ctrs. for Disease Control, *Combatting the Opioid Overuse Epidemic*, https://bit.ly/3WBhjIO; Michael Fendrich & Jessica Becker, *Prior Prescription Opioid Misuse in a Cohort of Heroin Users in a Treatment Study*, 8 Addictive Behavs. Reps. 8, 8 (2018).

of professional practice," 21 C.F.R. § 1306.06. And the latter duty prevents them from dispensing substances "without addressing or resolving red flags of drug abuse and diversion." *George Pharmacy, Inc.*, 87 Fed. Reg. 21,145, 21,152 (DEA Apr. 11, 2022) (citing 21 C.F.R. § 1306.06). These suspicious circumstances may include indications that a patient is "doctor" or "pharmacy" shopping, or may come from prescriptions that accompany opioid prescriptions—because drug abusers sometimes take "drug cocktail[s]" that multiply the addictive effects of the opioids. Appellees' Br. 9. And if the Pharmacy Defendants had complied with those duties, much of the over-prescription and oversupplies that fueled the opioid epidemic might have been averted. Yet as Appellees have exhaustively demonstrated, the Pharmacy Defendants not only failed to fulfill their duties under the CSA, and failed to help avert the opioid epidemic, they instead exacerbated the crisis for profit. *See* Appellees' Br. 12–28. It is therefore vital that these Defendants be held responsible for violating their duties under the CSA and creating a public nuisance.

Yet the Appellants improperly seek to absolve themselves of those duties and deny Appellees any equitable abatement award. If they succeed, localities nationwide could be deprived of critical resources they need through

other equitable awards—to combat the opioid epidemic or other future crises. Such awards have already proven transformative in combatting the opioid epidemic. For example, the $26 billion settlement with Johnson & Johnson, McKesson, AmerisourceBergen and Cardinal Health reached in February of 2022 contains over $23 billion for public abatement programs.[45] The first dollars from that settlement only began to flow to cities and counties in December, but they will be used in a variety of vitally important ways. These include (1) increasing distribution of naloxone and other overdose-reversing drugs to first responders and providing training on its use; (2) expanding medication-associated treatments (like methadone) for opioid addiction to uninsured and incarcerated populations; (3) providing housing, transportation, childcare, job placement and job training to people who have suffered the economic consequences of opioid addiction; (4) providing screening and treatment for NAS babies; and (5) engaging in evidence-based prevention campaigns for doctors and school-age children.[46]

[45] *See* Nat'l Assoc. of Counties, *Opioid Solutions: Approved Strategies*, https://bit.ly/3QogYal.

[46] *See* Exhibit E to the Final Distributor Settlement Agreement, https://bit.ly/3Iibxrp.

And of course, the counties of Lake and Trumbull have their own plan in place to use the funds they were awarded in this litigation. Their plan, developed by experts, involves expenditures in four key areas: (1) "reducing opioid oversupply and improving safe opioid use; (2) identifying opioid-addicted individuals and removing clinical, economic, and social barriers diminishing their access to comprehensive, coordinated, high-quality care; (3) enhancing measures geared towards "recovery and enhancing public safety and reintegration; and (4) identifying the specific needs of certain critical populations uniquely affected by the opioid epidemic, such as pregnant women, new mothers and infants, adolescents and young adults, and the homeless.[47] But the Pharmacy Defendants would force Trumbull and Lake to absorb these expenses themselves, and if their erroneous arguments are adopted here, the possibility for other equitable awards in other cases could be threatened.

Moreover, affirming the district court's ruling means more than ensuring that the costs to abate that crisis are properly distributed. A refusal

[47] *See* Plaintiffs' Closing Brief for Phase 2 Trial [ECF No. 4513] at 6–12, *In re Nat'l Prescription Opioid Lit.: Track Three Cases*, No. 1:17-md-02804-DAP (N.D. Ohio June 13, 2022).

to force pharmacies to live up to their responsibilities under the CSA will hamstring the communities Amici represent in halting the further spread of the epidemic, because the nation is still awash in prescription opioids, which is now fueling addiction, propelling illicit trades, and further contributing to the opioid epidemic. And pharmacies are ideally situated to halt that flood of pills and prevent opioids from ending up in the wrong hands. "Pharmaceutical companies and pharmacies are closest to their products."[48] And pharmacies have a particularly detailed handle on all the data relating to the drugs they dispense because they depend on that data for operations.

That makes the pharmacies "an important set of eyes ensuring their pills are not harming the public."[49] Indeed, pharmaceutical companies have frequently traded off their superior knowledge of their products in past efforts to advocate for "self-regulation" of prescription drug sales, suggesting that no regulator could know these companies and their practices as well as they know

[48] *See* Wendy E. Parmet & Richard A. Daynard, *The New Public Health Litigation*, 21 Ann. Rev. Pub. Health 437, 447 (2000) ("[P]roduct manufacturers are typically in a better position to anticipate and internalize the costs of accidents than is the consumer who may be harmed.").

[49] Aaron, *supra* at 53.

themselves.[50] That same reasoning now makes the Pharmacy Defendants an irreplaceable "last line of defense" in the distribution chain. *See* Appellees' Br. 7.

The closeness between the Pharmacy Defendants and their products also puts them in a much better position than virtually *anyone else* to halt the illicit prescription drug trades from which the entire crisis emanates. Every other actor in the prescription opioid supply chain possesses only an imperfect understanding of where opioids end up. Only pharmacies have the whole picture. And county regulators have no knowledge of the supply chain at all, because they stand entirely outside the chain, and with limited municipal resources, they cannot create any policy or program that can substitute for the systems that the Pharmacy Defendants already have in place.

For example, Amici have implemented numerous medical interventions recommended by the Centers for Disease Control and Prevention (CDC), including plans for syringe services, medication-assisted treatment, and

[50] *See, e.g.*, Denis G. Arnold & James L. Oakley, *The Politics and Strategy of Industry Self-Regulation: The Pharmaceutical Industry's Principles for Ethical Direct-to-Consumer Advertising as a Deceptive Blocking Strategy*, 38 J. Health Politics, Policy & Law 505, 505–506 (2013) ("Self-regulation is one potential industry strategy for protecting patient well-being while minimizing the inefficiencies that can arise with the introduction of new regulations.").

naloxone distribution, and plan to do more as settlement funds become available.[51] But many of these programs targeting the worst effects of addiction cannot prevent people from becoming addicted in the first place. At that point, most of the harm has occurred. But pharmacies can do much more, stopping these harms before they occur, by stopping addictions, overdoses, and deaths at the source, before any pill is ingested, anyone becomes addicted, or any victim is harmed.

Private pharmacies are also better situated to impact the epidemic than the police, who long ago learned that "we cannot arrest our way out of this devastating [opioid epidemic] problem,"[52] as the "War on Drugs" amply illustrates. Between 1981 and 2006, the number of drug arrests in the United States quadrupled to nearly two million per year, disproportionately affecting people and communities of color.[53] But these massive increases in drug arrests

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[51] *See* Jennifer J. Carroll, PhD, MPH *et al.*, Ctrs. for Disease Control & Prevention, *Evidence-Based Strategies for Preventing Opioid Overdose: What's Working in the United States* 9–13 (2018).

[52] White House Statement, *Biden-Harris Administration Expands Treatment to Underserved Communities with Mobile Methadone Van Ride* (June 29, 2021), https://bit.ly/3Gz0AQL.

[53] Katherine Beckett, *The Uses and Abuses of Police Discretion: Toward Harm Reduction Policing*, 10 Harv. L. & Pol'y Rev. 77, 81 (2016); *see also* Brian Stauffer, Human Rights Watch, *Every 25 Seconds: The Human Toll of*

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and "higher rates of drug imprisonment [did] not translate into lower rates of drug use, arrests, or overdose deaths."[54]

In fact, arrest and imprisonment is usually counterproductive to halting drug abuse. Mass incarceration for drug offenses has devastating consequences for those incarcerated, their families, and their communities.[55] Excessive punishment of drug crimes perpetuates the cycles of generational trauma and socioeconomic marginalization that, in turn, intensify the social determinants of drug use.[56] And fear of the police can actually

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Criminalizing Drug Use in the United States (Oct. 12, 2016), https://bit.ly/3XhkIg3.

[54] The Pew Charitable Trusts, *More Imprisonment Does Not Reduce State Drug Problems* 6 (March 2018), https://bit.ly/3Q8u5fn. Mandatory minimum sentencing regimes, including those for drug offenses, "have few if any deterrent effects." Nat'l Research Council of the Nat'l Academies, *The Growth of Incarceration in the United States: Exploring Causes and Consequences* 83 (Jeremy Travis, Bruce Western, & Steve Redburn eds. 2014).

[55] The Pew Charitable Trusts, *Collateral Costs: Incarceration's Effect on Economic Mobility* 3–5 (2010), https://bit.ly/3X0W1UG; Drug Pol'y Alliance, *The Drug War, Mass Incarceration and Race* 2 (Jan. 2018), https://bit.ly/3G4GkFg.

[56] *See* Leo Beletsky, *America's Favorite Antidote: Drug-Induced Homicide in the Age of the Overdose Crisis,* 4 Utah L. Rev. 833, 862–863 (2019).

prevent people from getting the help they need.[57] Accordingly, police interventions often cause as much harm as good, and are far inferior to investigation of suspicious transactions by pharmacies.

Yet absent enforcement of their legally prescribed duties under the CSA and state law, the pharmacies have no incentive to halt suspicious transactions on their own—all else being equal, they want to sell more pills. The district court's refusal to enforce those duties therefore presents a continuing risk to all communities, everywhere. There is therefore pressing need for the Court to preserve opioid pharmacies' duties and keep them in their rightful place to help local governments end the scourge of opioid abuse.

CONCLUSION

This Court should affirm the judgment of the district court.

[57] *See* Melissa Tracy *et al.*, *Circumstances of Witnessed Drug Overdose in New York City: Implications for Intervention,* 79 Drug & Alcohol Dependence 181, 183–185 (2005).

Respectfully submitted,

/s/ J. Carl Cecere

Robert B. Nealon
NEALON & ASSOCIATES, P.C.
119 North Henry Street
Alexandria, Virginia 22314
Phone: 703-684-5755
rnealon@nealon.com

Counsel for amici curiae and the County Executives of America

J. Carl Cecere
CECERE PC
6035 McCommas Blvd.
Dallas, TX 75206
(469) 600-9455
ccecere@cecerepc.com

Counsel for amici curiae

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Rule 29(d) of the Federal Rules of Appellate Procedure because this brief contains 5,586 words, excluding the parts of the brief exempted by Rule 32(a)(7)(B)(iii) of the Federal Rules of Appellate Procedure and Circuit Rule 32(a)(2).

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/s/ J. Carl Cecere

J. Carl Cecere

CERTIFICATE OF SERVICE

I hereby certify that on February 21, 2023, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit using the CM/ECF system, which will send notice of such filing to all counsel who are registered CM/ECF users.

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