

No. 22-125151-A

IN THE COURT OF APPEALS OF THE STATE OF KANSAS

**M.T. and M.T., as next friend of her
minor daughter, M.K.,**

Plaintiff/Appellee,

v.

WALMART STORES, INC., et al.,

Defendants/Appellants

**BRIEF OF *AMICUS CURIAE*
THE CHAMBER OF COMMERCE OF
THE UNITED STATES OF AMERICA**

Appeal from the District Court of Johnson County, Kansas,
Honorable Judge James F. Vano,
District Court Case Nos. 21-cv-5493 and 22-cv-264

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U.S. Food & Drug Admin., Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Pfizer-BioTech COVID-19 Vaccine), Dec. 10, 2020 https://www.fda.gov/media/144416/download	6
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Centers for Disease Control & Prevention, COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker/ (last visited Oct. 10, 2022)	5

Centers for Disease Control & Prevention, The Federal Retail Pharmacy Program for COVID-19 Vaccination, https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/participating-pharmacies.html (last reviewed June 30, 2022).....	6
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Erin Schumaker, <i>Long Lines for COVID-19 Vaccines Build in Florida, Tennessee, Puerto Rico</i> , ABC News, Dec. 31, 2020, https://abcnews.go.com/US/long-lines-covid-19-vaccines-build-florida-tennessee/story?id=74988405	14

Ruth Simon, *COVID-19 Shuttered More than 1 Million Small Businesses*,
 Wall St. J., Aug. 1, 2020, <https://www.wsj.com/articles/covid-19-shuttered-more-than-1-million-small-businesses-here-is-how-five-survived-11596254424> 4

Rachel Weiner, *As Cases Surge, Lines for Coronavirus Tests Sometimes Stretch Miles in the Summer Heat*, Wash. Post, July 1, 2020,
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STATEMENT OF INTEREST

The Chamber of Commerce of the United States of America (Chamber) is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus* briefs in cases, like this one, that raise issues of concern to the nation's business community. The scope of immunity provided under the Public Readiness and Emergency Preparedness ("PREP") Act affects Chamber members that have mobilized during a global pandemic to develop, manufacture, distribute, and administer vaccines, treatments, and protective equipment that reduce the likelihood of contracting COVID-19 and the chance of severe illness or death from the virus.

SUMMARY OF ARGUMENT

The COVID-19 pandemic called for an all-hands-on-deck approach to save lives, allow Americans to return to work and school, and bring life back to normal. To do so, the nation took on the monumental but achievable task of quickly developing, producing, distributing, and administering hundreds of millions of doses of vaccines for this virus. This effort required the federal government to partner with pharmaceutical companies to research and manufacture such vaccines on an unprecedented scale; with pharmacies, retailers, and other businesses to offer the vaccines across the country; and with doctors, pharmacists, and others to maximize participation by the American people.

Congress enacted the Public Readiness and Emergency Preparedness (“PREP”) Act, 42 U.S.C. §§ 247d-6d, 247d-6e, in 2005 to facilitate such a massive mobilization. It understood that in the midst of a public health emergency, such a response could not be flawless. It provided the Secretary of the Department of Health and Human Services (HHS) the ability to designate “covered countermeasures” and to provide those who administer them with protection from liability unless they engage in willful misconduct that causes death or serious injury. 42 U.S.C. § 247d-6d(c)(3). Congress did not want liability for simple mistakes to interfere with the national response to a public health crisis.

The Secretary’s PREP Act Declaration, which has been amended but not significantly altered across two Administrations, defines the scope of federal preemption and liability protection for the COVID-19 emergency response. This Declaration clearly covers the situation at bar, where a pharmacist is accused of misunderstanding and miscommunicating Kansas’s parental consent rules. There is no question that the vaccine Plaintiff’s daughter received is a “covered countermeasure.” Memorandum Decision, *Tonkinson v. Walmart, Inc.*, No. 21 CV 5483, at 17 (Dist. Ct., Johnson Cnty, Apr. 27, 2022). Nor is it disputed that the pharmacist who gave her the vaccine and the retailer, Walmart, that employed this pharmacist, were “covered persons” under the Declaration. *Id.* It should be similarly clear that an inadvertent violation of Kansas’s parental consent law in the distribution of this covered countermeasure by a covered person is the exact type of claim that Congress preempted. Congress plainly acted to assure those participating in the public health response that they would not face liability for such an accident or mistake.

Here, the trial court properly dismissed claims related to the physical aspects of administering the vaccine, namely battery, negligence, and deceptive marketing related to the efficacy of the vaccine. *See id.* at 21. But the trial court erred in limiting the PREP Act’s liability protection to losses stemming from the actual introduction of the vaccine into one’s body. *See id.* at 18, 21. This narrow reading has no textual basis in the PREP Act or the Secretary’s application of the Act. These measures clearly extend liability protections to all claims related to the administration of a vaccine, including all activities and decisions related to dispensing the vaccine, the management of the vaccination program, and the vaccination location. *See* 42 U.S.C. 247d-6d(a)(1); 85 Fed. Reg. 15,198, 15,202 (Mar. 17, 2020) (PREP Act Declaration). The administration of a vaccine includes more than a needle in an arm. It encompasses the entire process leading up to and following the injection, including the application of parental consent laws.

Amicus respectfully requests that the Court overturn the ruling below. The trial court’s unduly narrow interpretation of the PREP Act’s liability protections improperly penalizes businesses that joined the federal government’s response to the COVID-19 public health crisis and jeopardizes the nation’s ability to respond to future pandemics and public health emergencies—a scenario Congress specifically enacted the PREP Act to avoid.

ARGUMENT AND AUTHORITY

I. THE FEDERAL GOVERNMENT’S RESPONSE TO THE COVID-19 PANDEMIC REQUIRED A FULL MOBILIZATION IN WHICH PHARMACIES PLAYED A KEY ROLE

Developing vaccines and making them readily accessible to Americans was at the heart of the federal government’s response to the COVID-19 pandemic. The pandemic had

led schools to close, millions of businesses to shutter, and people to shelter at home. *See, e.g.,* Kan. Exec. Order No. 20-16 (Mar. 28, 2020) (establishing a statewide “stay-home” order in conjunction with the Kansas Essential Function Framework for COVID-19 response efforts); Ruth Simon, *COVID-19 Shuttered More than 1 Million Small Businesses*, Wall St. J., Aug. 1, 2020; Robert Fairlie, *The Impact of COVID-19 on Small Business Owners: Evidence from the First Three Months After Widespread Social-distancing Restrictions*, 29 J. Econ. Mgm’t Strategy 727, 728 (2020).

Mere exposure to someone with COVID-19 could require everyone present to quarantine for as long as two weeks. *See, e.g.,* Kan. Dep’t of Health & Env’t., *KDHE Issues New Recommendations for Quarantine and Isolation of Travelers, Close Contacts and Those Being Tested*, Mar. 15, 2020 (recommending 14-day home quarantine for anyone notified that a person is a close contact of a confirmed case of COVID-19). The rise of new variants of the virus dealt repeated setbacks to the fragile recovery. *See* Theo Francis, et al., *The Delta Variant Is Already Leaving Its Mark on Business*, Wall. St. J., Aug. 15, 2021. Time was of the essence for saving lives, allowing Americans to go back to school and work, restarting the economy, and returning a sense of normal life.

The situation in Kansas mirrored that of the country. Kansas hospitals faced staffing shortages, and their beds filled with COVID-19 patients. *See* Assoc. Press, *Hospitals in Kansas Report Spike in COVID Cases*, Dec. 20, 2021 (reporting on staffing shortages and that COVID patients filled more than one quarter of beds at Olathe Health); *see also* Glenn E. Rice et al., *One Kansas City Hospital Sees Number of COVID Cases More Than Double Since Last Month*, Kansas City Star, Oct. 6, 2021 (reporting a jump in COVID-19

hospitalizations at Kansas City area-hospitals). At the time Plaintiff's daughter received her vaccine, more than 220,000 Kansans had been hospitalized for COVID-19 and about 5,700 died. *See* Johns Hopkins Univ. & Medicine, Coronavirus Resource Center: Kansas, <https://coronavirus.jhu.edu/region/us/kansas> (last visited Oct. 10, 2022). Also, the week she received a vaccine, the Johnson County Health Department notified parents of 455 students who attended a clinic that anyone not fully vaccinated had to quarantine for up to 14 days after three attendees tested positive for the virus. *See* Heidi Schmidt & Monica Castro, *Dozens of Teenagers Exposed to COVID-19 at Weekend Cheer Clinic in Johnson County*, Fox4, Sept. 16, 2021. Overall, nearly 10,000 Kansans and over one million Americans have died from COVID-19. *See* Centers for Disease Control & Prevention, COVID Data Tracker, <https://covid.cdc.gov/covid-data-tracker/> (last visited Oct. 10, 2022); Kan. Dep't of Health & Env't., COVID-19 Dashboard, <https://www.coronavirus.kdheks.gov/160/COVID-19-in-Kansas> (last visited Oct. 10, 2022).

To cope with these circumstances, many Americans attempted to follow evolving guidance from public health officials on key issues ranging from the utility of face masks, to how the virus was transmitted, to the unprecedented restrictions on business operations and social gatherings. The federal government also established Operation Warp Speed, which invested billions of dollars into research, development, and building manufacturing capacity for a diverse portfolio of vaccine candidates that showed promise. *See generally* U.S. Gov't Accountability Office, *Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges*, GAO-21-319 (Feb. 2021). This funding allowed manufacturers to produce millions of COVID-19

vaccine doses while clinical trials proceeded so that the federal government would be ready to distribute vaccines as soon as the FDA approved their use.

As planned, COVID-19 vaccinations began immediately after the U.S. Food and Drug Administration issued an Emergency Use Authorization (EUA) on December 11, 2020, approving the Pfizer-BioNTech COVID-19 vaccine for individuals 16 years of age and older to prevent “a serious or life-threatening disease or condition” from contracting COVID-19. U.S. Food & Drug Admin., Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Pfizer-BioTech COVID-19 Vaccine), Dec. 10, 2020, at 54. The FDA expanded this authorization to individuals 12 through 15 years of age on May 10, 2021. *See* Letter from RADM Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Pfizer Inc., May 10, 2021.

Vaccinating millions of Americans required a “unified whole-of-nation response to the COVID-19 pandemic among Federal, state, local, and private-sector entities.” 85 Fed. Reg. 52,136, 52,138 (Aug. 24, 2020) (Third Amendment). To facilitate the rapid administration of the vaccines, the federal government had partnered with 21 national pharmacies and independent pharmacy networks with more than 40,000 stores. These partners included traditional pharmacies, supermarkets, and major retailers such as Walmart, the defendant in this case. *See* Centers for Disease Control & Prevention, The Federal Retail Pharmacy Program for COVID-19 Vaccination. The federal government also distributed vaccines directly to states, tribal health programs, community-based health centers, and rural health clinics in medically underserved communities. *See* U.S. Dep’t of

Health & Human Servs., COVID-19 Vaccines, <https://www.hhs.gov/coronavirus/covid-19-vaccines/index.html> (last reviewed Aug. 31, 2022) (providing information on each program).

The Secretary used the PREP Act to ensure these partners would “have the greatest flexibility in mobilizing the workforce they will need to engage in the largest vaccination effort in our Nation’s history.” *Id.* For example, by early 2021, the Secretary had found “an urgent need to expand the pool of available COVID-19 vaccinators in order to respond effectively to the pandemic.” 86 Fed. Reg. 7,872, 7,873 (Feb. 2, 2021) (Fifth Amendment). The government was concerned that “[a]s vaccine supply is made more widely available over the coming months, health care system capacity and the vaccination workforce are likely to become increasingly strained throughout the Nation.” *Id.* Accordingly, the Secretary authorized additional healthcare professionals to contribute to this goal, offering them protection from lawsuits and regulatory action by:

- authorizing healthcare professionals licensed in one state to prescribe, dispense, and administer COVID-19 vaccines in other jurisdictions, *see id.*;
- allowing healthcare professionals with expired licenses to prescribe, dispense, and administer COVID-19 vaccines, *see id.*;
- authorizing federal employees, contractors, and volunteers that the United States deployed to administer COVID-19 vaccinations, *see* 86 Fed. Reg. 9,516, 9,517 (Feb. 16, 2021) (Sixth Amendment); and
- permitting healthcare professionals who do not ordinarily administer vaccines, students in certain training programs, and veterinarians to administer vaccines, *see* 86 Fed. Reg. 14,462, 14,464 (Mar. 16, 2021) (Seventh Amendment); U.S.

Dep't of Health & Human Servs., Requirements for Joining the Expanded COVID-19 Vaccination Workforce.

Pharmacies were key to this effort. As the Secretary stated, “[p]harmacists are well positioned to increase access to vaccinations, particularly in certain areas or for certain populations that have too few pediatricians and other primary-care providers, or that are otherwise medically underserved.” 85 Fed. Reg. at 52,138. In September 2021, when the vaccine at issue here was administered, the Secretary reemphasized that pharmacists, pharmacy technicians, and pharmacy interns were playing “a critical role in this pandemic in overseeing COVID-19 testing and vaccine administration.” 86 Fed. Reg. 51,160, 51,162 (Sept. 14, 2021) (Ninth Amendment).

Further, in repeatedly expanding the class of persons who could administer vaccines, the federal government understood that mistakes would happen and used the PREP Act, as Congress intended, to maximize participation by promising participants that they would not face liability for any such errors. It is for that reason that the Secretary repeatedly revisited and updated the PREP Act Declaration to ensure that the Act’s liability protection applied to all who played a part in this nationwide effort.

II. THE PREP ACT’S LIABILITY PROTECTIONS COVER MISTAKES MADE DURING THE ADMINISTRATION OF A VACCINE

A. Congress Enacted the PREP Act for Precisely These Types of Circumstances

The PREP Act was enacted with strong bipartisan support shortly after an earlier coronavirus outbreak, the SARS epidemic of 2003. *See* H.R. 2863 (Pub. Law No. 109-148), 119 Stat. 2680, 2818. Congress understood that the massive, rapid mobilization

needed to effectuate a national response to a public health emergency could create circumstances like the one at bar, where a person administering a vaccine is accused of making a mistake. Congress appreciated that healthcare providers and pharmacies might not be willing to participate under the shadow of such liability claims. *See* 151 Cong. Rec. 30,409 (2005) (statement of Rep. Nathan Deal, chairman of the Health Subcommittee of the Committee on Energy and Commerce) (health care providers, including pharmacies, need these protections to be “willing to give [a vaccine] when the time comes”). Congress therefore shielded those on the front lines of responses to such emergencies—those involved in manufacturing, distributing, or administering countermeasures such as vaccines, tests, and surgical masks—from liability that might prevent or deter them from continuing to operate and perform their critical functions.

The PREP Act does not preempt all claims arising from a pandemic. Application of the Act hinges upon a declaration of the Secretary. *See* 42 U.S.C. § 247d-6d. As relevant here, liability protections are extended to “*all claims* for loss caused by, arising out of, *relating to*, or resulting from the administration” of a vaccine that has been declared a “covered countermeasure” by the Secretary. 42 U.S.C. 247d-6d(a)(1) (emphasis added). The term “relating to” with regard to preemption has especially broad meaning. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383-84 (1992) (collecting cases); *see also Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 47 (1987) (explaining the “expansive sweep” of this language). To this end, the Declaration itself defines “administration” of a vaccine to include both the “physical provision of the countermeasure to recipients” and “activities and decisions directly relating to . . . dispensing of the countermeasures to

recipients.” 85 Fed. Reg. 15,198, 15,202 (Mar. 17, 2020). Thus, PREP Act immunity covers the management of vaccination programs and locations, not just the physical injection or medical issues allegedly caused by that shot.

To illustrate this point, the Secretary provided two examples of losses that are causally connected to the administration of a covered countermeasure and thus subject to PREP Act immunity: “the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control.” 85 Fed. Reg. 15,198, 15,200 (Mar. 17, 2020).

In addition, Congress was deliberate in establishing a “sole exception” to the immunity conferred by the Prep Act: “an exclusive Federal cause of action” for claims of willful misconduct causing death or serious injury. 42 U.S.C. § 247d-6d(d)(1). The exclusive venue for such claims is the U.S. District Court for the District of Columbia. *See id.* at § 247d-6d(e)(1),(e)(5). Also, for certain claims within the scope of the immunity provision, namely where someone has sustained serious physical injury or death directly caused by the administration or use of a covered countermeasure, the Act allows the person to file a claim with a federal “Covered Countermeasure Process Fund.” *Id.* at 247d-6e. This Fund is designed to provide “timely, uniform, and adequate compensation” through a no-fault claims process. *Id.* § 247d-6e(a). That federal remedy, too, is “exclusive.” *Id.* § 247d-6d(d)(1). Thus, individuals with serious injuries have access to an available remedy.

As envisioned by Congress, PREP Act immunity has proved crucial to America’s COVID-19 response. Indeed, the lack of similar protections in other countries hindered their rollout of vaccines. *See, e.g.,* Neha Arora et al., *India, Pfizer Seek to Bridge Dispute Over Vaccine Indemnity*, Reuters, May 21, 2021. But here, this immunity helped drive the public-private partnership that led to the creation and distribution of COVID-19 vaccines. America is a litigious country, and businesses may not have been so ready to help in a first-of-its-kind effort without appropriate protection from litigation targeting aspects of their responses to the national emergency. Courts must apply PREP Act according to its terms, which includes applying the immunity provision to its proper and full extent.

B. The Trial Court Erred in Significantly Narrowing the Scope of the PREP Act’s Liability Protections

Here, the trial court improperly limited the scope of PREP Act immunity to injuries directly caused by “the vaccine itself.” The court wrongly reasoned that Congress never intended to interfere with the practice of medicine or pharmacy, including the age of consent. This reasoning disregards not only congressional intent but the text of the statute, which expressly provides immunity from “*all* claims for loss” relating to a covered countermeasure. 42 U.S.C. 247d-6d(a)(1) (emphasis added).

The PREP Act prohibits a state from enforcing “*any* provision of law or legal requirement that . . . relates to . . . prescribing, dispensing, or administration by qualified persons of the covered countermeasure” subject to a PREP Act declaration. 42 U.S.C. § 247d-6d(b)(8) (emphasis added). Such preemption inherently interferes with laws governing the practice of medicine or pharmacy to some extent. For example, the Secretary

amended the PREP Act Declaration multiple times to authorize individuals to administer the vaccine who otherwise would not be allowed to give a vaccine under state law. These measures were necessary to effectuate the PREP Act's fundamental understanding that this national public health emergency required a single, concerted national response that was not stymied by endless permutations of state and local laws.

The situation at bar has arisen in the past. The New York courts addressed a nearly identical case to the one here in response to the public health emergency arising out of the H1N1 influenza virus. *See Parker v. St. Lawrence Cnty. Pub. Health Dep't*, 102 A.D.3d 140 (N.Y. App. Div. 2012). In 2009, the Secretary of Health and Human Services declared a public health emergency and recommended the administration of the applicable vaccine. *See id.* at 141 (citing 74 Fed. Reg. 50,968 (2009); 74 Fed. Reg. 51,153 (2009)). A child was administered a vaccine without the parent's consent, and the parent filed a claim for negligence. The New York Appellate Division held that the claim was preempted under the plain meaning of the PREP Act. *See id.* at 142.

The New York court explained that preemption applied to common law duties, just as with statutes and regulations: "Considering the breadth of the preemption clause together with the sweeping language of the statute's immunity provision, we conclude that Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures by a qualified person pursuant to a declaration by the Secretary, including one based upon a defendant's failure to obtain consent." *Id.* at 142-43. The court "presume[d] that Congress fully understood that errors in the administering a vaccination program may have physical as well as emotional consequences," and it concluded that

“potential tort liability must give way to the need to promptly and efficiently respond to a pandemic or other public health emergency.” *Id.* at 144.

III. THE TRIAL COURT’S DECISION JEOPARDIZES THE NATION’S ABILITY TO RESPOND TO FUTURE PUBLIC HEALTH EMERGENCIES

If not corrected on appeal, the trial court’s limitation of PREP Act immunity to only injuries from “the vaccine itself” will have adverse implications for the ability to respond to future pandemic and other public health emergencies. Kansas businesses asked to partner with the government to provide access to life-saving vaccines and other countermeasures may hesitate before agreeing to accept this responsibility if they can be subject to liability for negligent or other nonwillful conduct that occurs during the program.

In public health emergencies, the government must work hand-in-hand with private sector partners. Whereas public health officials have other liability protections under existing law, the private sector may not. *See* Peggy Binzer, *The PREP Act: Liability Protection for Medical Countermeasure Development, Distribution, and Administration*, 6 *Biosecurity & Bioterrorism* 293 (2008). And just as a lack of immunity for public officials exercising discretionary functions may result in “the diversion of official energy from pressing public issues, and the deterrence of able citizens from acceptance of public office,” *Harlow v. Fitzgerald*, 457 U.S. 800, 814 (1982), insufficient protection for private parties that assist the government in times of need may result in “unwarranted timidity” and a failure to act “with the decisiveness and the judgment required by the public good,” *Filarsky v. Delia*, 566 U.S. 377, 389-90 (2012) (quoting *Richardson v. McKnight*, 521 U.S. 399, 409 (1997) and *Scheuer v. Rhodes*, 416 U.S. 232, 240 (1974)).

Pharmacies, retailers, supermarkets, and others would need to consider numerous potential liability-inducing scenarios before agreeing to partner with the government to administer a vaccine, provide testing services, or offer other counter-measures during a national public health emergency. Such scenarios are entirely predictable, yet nearly impossible to avoid in their entirety. *See, e.g.,* Erin Schumaker, *Long Lines for COVID-19 Vaccines Build in Florida, Tennessee, Puerto Rico*, ABC News, Dec. 31, 2020; Rachel Weiner, *As Cases Surge, Lines for Coronavirus Tests Sometimes Stretch Miles in the Summer Heat*, Wash. Post, July 1, 2020. If nothing else, labor shortages, which are particularly likely during a public health emergency, can impact the ability to staff a site, which can increase the chance of accidents or mistakes. *See* Allana Akhtar, *The Labor Shortage is Reportedly Creating Longer COVID-19 Wait Times at CVS and Walgreens*, Insider, Dec. 3, 2021. Already, trial lawyers have spent tens of millions of dollars on advertisements related to COVID-19, *see* Am. Tort Reform Ass'n, COVID-19 Legal Services Television Advertising (2021), and some 17,000 COVID-related lawsuits have been filed across the country, *see* Hunton Andrews Kurth, COVID-19 Complaint Tracker, <https://www.huntonak.com/en/covid-19-tracker.html> (last visited Oct. 11, 2022).

As Congress appreciated, liability protection is critical for a national pandemic response. That is why Congress provided a mechanism for the Secretary to afford immunity to covered persons for the entire process leading up to and following the administration of a vaccine. This includes the chance that a pharmacist misunderstands or negligently misapplies a state law related to the administration of the vaccine, including those involving parental consent. To hold to the contrary would jeopardize the willingness of

businesses to partner with the federal government to quickly respond to future public health emergencies and would limit the public's access to vital healthcare services.

CONCLUSION

The Court should reverse and remand with instruction to dismiss all claims.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing amicus brief was filed electronically on this 14th of October 2022, which sent notification to all counsel of record. Additionally, a courtesy copy by personal service was sent via email to the following counsel of record:

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