No. 25-10182

IN THE

United States Court of Appeals for the Fifth Circuit

STATE OF TEXAS,

Plaintiff-Appellant,

v.

PFIZER, INCORPORATED,

Defendant-Appellee.

On Appeal from the United States District Court for the Northern District of Texas, Lubbock Division, No. 5:23-cv-312

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* SUPPORTING DEFENDANT-APPELLEE

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CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record for amicus curiae certifies that the following listed persons and entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1, in addition to those listed in the parties' Certificates of Interested Persons, have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

Amicus: The Chamber of Commerce of the United States of America ("Chamber") is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber.

Counsel for Amicus: Jeffrey S. Bucholtz and Matthew V.H. Noller of King & Spalding LLP, and Jennifer B. Dickey and Andrew R. Varcoe of the Chamber of Commerce of the United States of America.

Date: June 23, 2025

s/Jeffrey S. Bucholtz
Jeffrey S. Bucholtz

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INTEREST OF *AMICUS CURIAE*[1]

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 curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

The Chamber has a strong interest in this appeal. The scope of immunity and preemption provided under the Public Readiness and Emergency Preparedness ("PREP") Act, 42 U.S.C. § 247d-6d, affects Chamber members that mobilized during a global pandemic to develop, manufacture, distribute, and administer vaccines, treatments, and

[1] No counsel for any party authored this brief in whole or in part, and no entity or person, aside from *amicus curiae*, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to the filing of this brief.

protective equipment that reduced the likelihood of contracting COVID-19 and the chance of severe illness or death from the virus. The Chamber has filed several briefs addressing the scope of PREP Act immunity and preemption in federal and state appellate courts.[2] More generally, the Chamber has a strong interest in ensuring that immunity and preemption provisions in federal statutes are correctly interpreted to provide the full scope of protection for private parties that Congress intended in enacting those provisions.

INTRODUCTION AND SUMMARY OF ARGUMENT

The COVID-19 pandemic called for an all-hands-on-deck approach to protect the public health, allow Americans to return to work and school, and bring life back to normal. To do so, the nation undertook a "unified whole-of-nation response . . . among federal, state, local, and private-sector entities." 85 Fed. Reg. 79,190, 79,191 (Dec. 9, 2020).

[2] *E.g.*, *Nowacki v. Gilead Sci., Inc.*, No. 367271 (Mich. Ct. App. Aug. 22, 2024); *M.T. ex rel. M.K. v. Walmart Stores, Inc.*, No. 22-125151-A (Kan. Ct. App. Oct. 14, 2022); *Hudak v. Elmcroft of Sagamore Hills*, No. 21-3836 (6th Cir. June 8, 2022); *Saldana v. Glenhaven Healthcare LLC*, No. 20-56194 (9th Cir. Mar. 30, 2022); *Martin v. Petersen Health Operations, LLC*, No. 21-2959 (7th Cir. Jan. 31, 2022); *Mitchell v. Advanced HSC, L.L.C.*, No. 21-10477 (5th Cir. Aug. 10, 2021).

Specifically, the government launched Operation Warp Speed, a congressionally funded partnership with private industry designed to enable faster development and approval of a COVID-19 vaccine. As a direct result of Operation Warp Speed, the U.S. Food and Drug Administration swiftly approved three COVID-19 vaccines, including one manufactured by Defendant-Appellee Pfizer, Inc.

The achievements of Operation Warp Speed would not have been possible without the PREP Act. Enacted in 2005, nearly 15 years before the COVID-19 pandemic struck, the PREP Act encourages the development and distribution of pandemic "countermeasures" such as vaccines by affording broad immunity from tort liability to entities involved in the manufacture, distribution, marketing, allocation, administration, and use of such countermeasures. 42 U.S.C. § 247d-6d(a). To further prevent evasion of that immunity, the PREP Act also contains an express preemption clause prohibiting states from establishing or enforcing any law that differs from or conflicts with "any requirement applicable under" the PREP Act's provisions. *Id.* § 247d-6d(b)(8). Congress recognized that, without these protections, private manufacturers would not "take on the tremendous liability risks" of producing life-saving

medications and vaccines. 151 Cong. Rec. H12244-03, H12264, 2005 WL 3466298 (daily ed. Dec. 18, 2005) (statement of Rep. Nathan Deal).

In this case, the district court correctly applied the PREP Act to dismiss Texas's claims against Pfizer. There is no dispute that Pfizer's COVID-19 vaccine is a "covered countermeasure" under the PREP Act, entitling Pfizer to the PREP Act's protections. 42 U.S.C. § 247d-6d(a), (i)(1)-(2). And Texas seeks to hold Pfizer liable for its "marketing [and] promotion" of the vaccine, placing its claims squarely within the PREP Act's immunity and preemption provisions. 42 U.S.C. § 247d-6d(a), (b)(8).

Texas's contrary arguments misunderstand the statutory text. For example, Texas's brief asserts that the PREP Act's immunity provision "applies only to claims for 'loss' (physical harm or mental anguish) resulting from the 'administration . . . of a covered countermeasure' (such as injection of a vaccine) to an 'individual.'" Br. 16. (quoting 42 U.S.C. § 247d-6d(a)(1)). But the immunity provision applies to "*any type* of loss," not just to physical or mental injury. 42 U.S.C. § 247d-6d(a)(2)(A) (emphasis added). And the provision applies to far more conduct than just "the physical act of directly injecting a particular person with a vaccine." *Maney v. Brown*, 91 F.4th 1296, 1300-01 (9th Cir. 2024). Indeed,

the Act expressly immunizes the "marketing, promotion, [and] sale" of vaccines, which is the very conduct that Texas challenges in this case. 42 U.S.C. § 247d-6d(a)(1), (2)(B).

Texas similarly misunderstands the Act's preemption provision. Texas argues that its claims are not preempted because they are consistent with "federal law" generally. *E.g.*, Br. 3. But the PREP Act preempts state laws that are "different from, or [are] in conflict with, any requirement applicable *under this section*"—meaning specifically *the PREP Act*'s requirements. 42 U.S.C. § 247d-6d(b)(8)(A) (emphasis added). That prevents states from seeking to undermine or evade "the [Act's] granted immunity," as Texas does here. *Hughes v. Terminix Pest Control, Inc.*, 2024 WL 3440465, at *1 (5th Cir. July 17, 2024) (per curiam). Courts thus agree that the Act preempts state-law claims "with respect to the administration of covered countermeasures." *E.g.*, *Leonard v. Ala. St. Bd. of Pharmacy*, 61 F.4th 902, 915 (11th Cir. 2023). Texas's claims, therefore, are preempted.

Texas's arguments to the contrary, if adopted, would undermine Congress's purpose in enacting the PREP Act. The Act reflects Congress's judgment that pandemics require a rapid national response involving

close coordination between the government and private industry. But private businesses likely would not take the risk of developing and distributing life-saving vaccines and treatments if they could—unlike government officials—be second-guessed later and sued for their conduct. The PREP Act thus ensures that the nation's pandemic responses will not be impaired by the threat of liability against the government's private-sector partners. For this reason, and because the text of the statutory immunity and preemption provisions applies to Texas's claims, this Court should affirm the district court's decision dismissing the claims.

ARGUMENT

The district court correctly dismissed Texas's claims against Pfizer as barred under the PREP Act. By its plain terms, the Act immunizes Pfizer and preempts claims like Texas's. Texas's contrary arguments both misconstrue the Act's text and would undermine its purpose of encouraging the development of life-saving pandemic countermeasures.

I. The plain text of the PREP Act's immunity and preemption provisions bars Texas's claims.

Because this case turns on the interpretation of the PREP Act, the Court "begin[s] with the text of the statute." *United States v. Nature's Way Marine, L.L.C.*, 904 F.3d 416, 420 (5th Cir. 2018). And here, the

Court should end with the text because the PREP Act's immunity and preemption provisions unambiguously bar Texas's claims. The Act's immunity provision applies because Texas brings "claim[s] for loss that has a causal relationship with the . . . marketing, promotion, [and] sale" of Pfizer's COVID-19 vaccine, "a covered countermeasure." 42 U.S.C. § 247d-6d(a)(1), (2)(B). The Act's preemption provision also applies because, in suing Pfizer for its marketing of its COVID-19 vaccine, Texas seeks to enforce a "provision of law or legal requirement that . . . is different from, or is in conflict with," the PREP Act's "requirement[s]." *Id.* § 247d-6d(b)(8). Under either or both provisions, the Court should affirm the district court's dismissal of Texas's claims.

1. The Act immunizes Pfizer from Texas's claims.

The PREP Act's immunity provision is "broad." *Mitchell v. Advanced HCS, L.L.C.*, 28 F.4th 580, 585-86 (5th Cir. 2022); *M.T. ex rel. M.K. v. Walmart Stores, Inc.*, 528 P.3d 1067, 1073 (Kan. Ct. App. 2023). The Act provides that "a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure." 42 U.S.C.

§ 247d-6d(a)(1). This immunity extends to "any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, *including a causal relationship with the . . . marketing, promotion, [or] sale . . . of such countermeasure*." *Id.* § 247d-6d(a)(2)(B) (emphasis added). For purposes of immunity, "the term 'loss' means *any* type of loss." *Id.* § 247d-6d(a)(2)(A) (emphasis added).

By its plain terms, the PREP Act's immunity provision applies to Texas's claims against Pfizer. Texas does not dispute that Pfizer is a "covered person" or that Pfizer's COVID-19 vaccine is a "covered countermeasure." *See* Br. 28 (quoting 42 U.S.C. § 247d-6d(a)(1)).[3] But Texas seeks to recover for "injury, loss, and damage" that Texas claims it and the public suffered as a result of statements Pfizer made when marketing, promoting, and selling its vaccine. *See* Br. 9-14; ROA.43 ¶ 8. Texas thus brings "claim[s] for loss that has a causal relationship with the . . . marketing, promotion, [or] sale" of a "covered countermeasure." 42 U.S.C. § 247d-6d(a)(2)(B). The Act unambiguously immunizes Pfizer

[3] In March 2020, the Secretary of Health and Human Services declared COVID-19 a public-health emergency and designated COVID-19 vaccines "covered countermeasures" protected by the PREP Act. *See Hudak v. Elmcroft of Sagamore Hills*, 58 F.4th 845, 849-50 (6th Cir. 2023).

from such claims. *Id.* § 247d-6d(a); *see Nowacki v. Gilead Scis., Inc.*, --- N.W.3d ---, 2025 WL 1056691, at *6 (Mich. Ct. App. Apr. 8, 2025) (holding that "[t]he plain language of the PREP Act clearly" immunized manufacturer from claim related to COVID-19 treatment).

In arguing otherwise, Texas appears to ignore key portions of the statutory text. For example, Texas asserts that the Act's immunity provision is limited to claims "resulting from the 'administration . . . of a covered countermeasure' (such as injection of a vaccine) to an 'individual.'" Br. 16.[4] But the immunity provision in fact bars any "claim[] for loss caused by, *arising out of, relating to, or* resulting from the administration to or the use by an individual of a covered countermeasure," which the Act broadly defines to encompass any claim with a "causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, *packaging, marketing, promotion, sale*, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure." 42 U.S.C. § 247d-6d(a) (emphasis added). That language unambiguously "expands

[4] *See also* Br. 28 (same); Br. 30 ("[T]he PREP Act's immunity language blocks only claims 'from the administration' of a covered product to 'an individual.'" (quoting 42 U.S.C. § 247d-6d(a)(1))).

the conduct within the Act's scope of immunity" beyond "the physical act of directly injecting a particular person with a vaccine." *Maney*, 91 F.4th at 1300-01. Most relevant here, the Act expressly immunizes the "marketing, promotion, [or] sale" of covered countermeasures, 42 U.S.C. § 247d-6d(a)(2)(B), which is the precise conduct Texas challenges.

Texas also misreads the PREP Act's definition of "loss." Without quoting that definition in full, Texas repeatedly asserts that it is limited to "physical harm or mental anguish," Br. 16, 28; "specific ailments or physical harm," Br. 16; "personal injury," Br. 28-29; and "physical or mental 'loss' suffered from vaccine side effects," Br. 29. But the Act expressly defines "loss" as encompassing "*any type* of loss," with personal injury being just one of several non-exhaustive examples. 42 U.S.C. § 247d-6d(a)(2)(A) (emphasis added); *accord M.T.*, 528 P.3d at 1073. The Act even identifies "loss of or damage to *property*" as an example of "loss," making clear that the definition is not limited to personal injury, but also extends to economic harms. 42 U.S.C. § 247d-6d(a)(2)(A) (emphasis added).

Texas also argues that the Act's immunity provision does not apply because the Texas Deceptive Trade Practices Act (DTPA) does not require proof of any loss, Br. 16. But in this lawsuit, Texas expressly seeks to

recover for "loss" allegedly caused by Pfizer's statements about its COVID-19 vaccine. ROA.43 ¶ 8; *see* Br. 9-14.

In sum, the PREP Act "unequivocally extend[s] immunity to scientists, pharmaceutical companies, and other healthcare providers who grappled with the unprecedented nature of the COVID-19 pandemic." *Nowacki*, 2025 WL 1056691, at *6. Texas's claims fly in the face of that immunity, so the district court properly dismissed them.

2. The PREP Act preempts Texas's claims.

The PREP Act's preemption provision is just as "sweeping" as the Act's immunity provision. *M.T.*, 528 P.3d at 1073. It provides that "no State . . . may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement" that (1) is "different from, or is in conflict with, any requirement applicable under this section," and (2) "relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure." 42 U.S.C. § 247d-6d(b)(8).

The district court correctly held that this provision bars Texas's claims against Pfizer. Because the PREP Act "contains an express preemption clause, the court does not indulge any presumption against preemption but instead focuses on the plain wording of the clause." *Young Conservatives of Tex. Found. v. Smatresk*, 73 F.4th 304, 311 (5th Cir. 2023) (cleaned up) (quoting *Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 579 U.S. 115, 125 (2016)). And the "plain wording," *id.*, of the Act's preemption provision easily covers Texas's claims. Texas's claims "relate[] to the . . . marketing [and] promotion . . . of [a] covered countermeasure," and the DTPA provisions Texas seeks to enforce do not mirror any provision of the PREP Act. 42 U.S.C. § 247d-6d(b)(8). Texas thus seeks to "enforce . . . a[] provision of law or legal requirement that . . . is different from, or is in conflict with, [the] requirement[s] applicable under" the PREP Act. *Id.*

That triggers the Act's preemption provision. Courts agree that the clause preempts state-law claims "with respect to the administration of covered countermeasures." *Leonard*, 61 F.4th at 915; *e.g.*, *Hogan v. Lincoln Med. Partners*, 331 A.3d 463, 470 (Me. 2025); *de Becker v. UHS of Del., Inc.*, 555 P.3d 1192, 1201-02 (Nev. 2024); *Politella v. Windham*

Se. Sch. Dist., 325 A.3d 88, 97-98 (Vt. 2024); *Parker v. St. Lawrence Cnty. Pub. Health Dep't*, 102 A.D.3d 140, 144 (N.Y. App. Div. 2012). For all the reasons above, Texas's claims relate to the "administration" of "covered countermeasures" as the PREP Act defines those terms. The PREP Act thus preempts Texas's claims.

Texas contends that the preemption provision "preempts only state laws 'different from, or in conflict with' federal law," and argues that the DTPA does not conflict with "federal law" because it is consistent with the federal FTC Act and Food, Drug, and Cosmetic Act. *E.g.*, Br. 3, 21. But the PREP Act preempts state laws that differ from or conflict "with[] any requirement *under this section*." 42 U.S.C. § 247d-6d(b)(8)(A) (emphasis added). The phrase "this section" unambiguously refers to the PREP Act itself. So even if a state-law claim might be consistent with some other federal law, the PREP Act preempts that claim if it differs from or "conflict[s] with 'requirements' *of the PREP Act*." *Leonard*, 61 F.4th at 914 (emphasis added); *see also Solomon v. St. Joseph Hosp.*, 62 F.4th 54, 61 (2d Cir. 2023) ("The PREP Act further provides a specific preemption provision applicable to certain state laws that conflict *with the Act*." (emphasis added)).

Any state-law claim that would hold a manufacturer liable for alleged loss related to the administration or use of a covered countermeasure conflicts with the PREP Act.[5] The entire point of the PREP Act is to broadly immunize companies from claims related to the "design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use" of covered countermeasures. 42 U.S.C. § 247d-6d(a)(1), (2)(B). The preemption provision reflects the same scope, targeting state laws "relate[d] to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or

[5] *See Hogan*, 331 A.3d at 470 (holding that the Act preempts state laws "to the extent that they allow recovery for claims against defendants administering vaccines who, under the federal statute, are immune from suit or liability"); *de Becker*, 555 P.3d at 1202 (holding that "the Act preempts all state law tort claims arising from the administration of covered countermeasures" (cleaned up)); *Politella*, 325 A.3d at 98 (holding that "state-law claims against immunized defendants cannot proceed in state court in light of the PREP Act's . . . preemption provision[]"); *Parker*, 102 A.D.3d at 144 ("Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures").

administration by qualified persons of the covered countermeasure." *Id.* § 247d-6d(b)(8)(B). Accordingly, as this Court has recognized, the PREP Act's "preemption provision displaces state law that would otherwise conflict with the [Act's] granted immunity." *Hughes*, 2024 WL 3440465, at *1.

Texas's claims against Pfizer plainly "conflict with the [Act's] granted immunity." *Id.* Even if (contrary to fact) Texas law somehow escaped the Act's immunity provision, the Act's preemption provision exists precisely to prevent such end-runs around immunity. Because Pfizer's development, marketing, and sale of its COVID-19 vaccine fall within the heart of what Congress enacted the PREP Act to protect, holding Pfizer liable for that conduct would conflict with the Act. For that reason, the district court correctly found Texas's claims to be preempted.

II. Texas's claims conflict with the PREP Act's purpose to encourage private development of vaccines and medications during pandemics.

In addition to conflicting with the statute's plain text, Texas's interpretation of the PREP Act's immunity and preemption provisions would defeat the important purpose for which Congress enacted the Act:

to ensure that, in the event of a pandemic, American businesses will step up and deliver life-saving vaccines and medications.

In public health emergencies, the government must work hand-in-hand with private sector partners. *See* Statement of Interest of the United States at 2, *Bolton v. Gallatin Ctr for Rehab. & Healing, LLC*, No. 3:20-cv-00683 (M.D. Tenn. Jan. 19, 2021), ECF No. 35-1 ("[s]uccessful distribution and administration of [pandemic] countermeasures . . . depends on the cooperation of private-sector partners"). Such private actors generally lack the liability protections enjoyed by public officials. Peggy Binzer, *The PREP Act: Liability Protection for Medical Countermeasure Development, Distribution, and Administration,* 6 Biosecurity & Bioterrorism 293 (2008). But just as a lack of immunity for public officials 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) (quotation marks omitted).

That is why Congress provided through the PREP Act a mechanism to afford immunity to covered persons for the entire process leading up to and following the administration of a covered countermeasure, such as a vaccine.

A different Congress might have preferred a different mechanism to support the goal of encouraging the private development and administration of covered countermeasures. Perhaps Congress could have chosen a narrower approach than categorically barring claims that otherwise might be deemed meritorious. But Congress instead chose to enact language unambiguously providing for sweeping immunity from and preemption of all state law claims. That language, which courts must follow as Congress wrote it, ensures that a federal or state court may not later second-guess the decision to pursue covered countermeasures by holding a company liable for a covered activity.

When the COVID-19 pandemic struck, the PREP Act worked exactly as Congress intended. Vaccinating tens of 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. at 79,191. The HHS Secretary used the PREP Act's immunity provision to

ensure that the government's 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." 86 Fed. Reg. 14,462, 14,464 (Mar. 16, 2021). That immunity proved crucial to America's integrated national response to COVID-19. For example, the lack of equivalent protections in other countries hindered the rollout of vaccines that, by contrast, quickly became available in the United States.[6]

We may not know what the next pandemic will be or when it will occur—but when it does, the nation will almost certainly again have to rely on American businesses to play crucial roles in the public health response, whether by producing vaccines and other medications or by other mechanisms. Without the PREP Act's protections, however, the number of companies willing to take such actions would shrink. Adopting Texas's interpretation of the Act would dramatically increase the risks for businesses asked to help the government respond to national health emergencies—and, therefore, would impede the efficacy and swiftness of

[6] *See, e.g.*, Neha Arora et al., *India, Pfizer seek to bridge dispute over vaccine indemnity*, Reuters (May 21, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/india-pfizer-impasse-over-vaccine-indemnity-demand-sources-2021-05-21/.

any national response to such crises. That is not the result that Congress intended in enacting the Act and is not consistent with the text of the law.

CONCLUSION

This Court should affirm the district court's judgment.

Respectfully submitted,

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June 23, 2025

CERTIFICATE OF SERVICE

I certify that on June 23, 2025, I caused the foregoing amicus brief to be filed with the Court electronically using the CM/ECF system. All counsel will receive service through the CM/ECF system.

Date: June 23, 2025

s/Jeffrey S. Bucholtz
Jeffrey S. Bucholtz

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(b)(4), because it contains 3,661 words, as counted by Microsoft Word, excluding the parts of the brief excluded by Fed. R. App. P. 32(f). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6), because it has been prepared using Microsoft Word in Century Schoolbook 14-point font.

I further certify that (1) required privacy redactions have been made, 5th Cir. R. 25.2.13; (2) the electronic submission is an exact copy of the paper document, 5th Cir. R. 25.2.1; and (3) the document has been scanned with the most recent version of Microsoft Defender and is free of viruses.

Date: June 23, 2025

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Jeffrey S. Bucholtz