IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its member organizations, their members, and these members' patients, et al.,

Plaintiff,

v.

CASE No. 2:22-cv-00223-Z

U.S. FOOD AND DRUG ADMINISTRATION, et al.

Defendants

Unopposed Motion Of Ethics And Public Policy Center For Leave To File A Brief As *Amicus Curiae* In Support Of Plaintiffs' Motion For Preliminary Injunction and Brief in Support Thereof

Pursuant to Federal Rule of Civil Procedure 7 and this Court's local civil rule 7.1, movant Ethics and Public Policy Center ("EPPC") respectfully seeks this Court's leave to file the accompanying brief as an amicus curiae in support of plaintiffs' motion for preliminary injunction (ECF #6). With respect to Local Rule 7.1(a) and (b), movant's counsel have been informed by plaintiffs' counsel that plaintiffs and defendants have mutually consented to the filing of amicus briefs and related motions on or before February 10, 2023. On that basis, movant's counsel attach a Certificate of Conference stating that defendants do not oppose this motion. A proposed Order is also submitted with this motion. Oral argument is not requested.

¹ Consistent with FED. R. APP. P. 29(a)(4)(E), counsel for amicus authored this brief in whole; no counsel for a party authored this brief in any respect; and no person or entity — other than amicus, its members, and its counsel — contributed monetarily to this brief's preparation or submission.

IDENTITY AND INTERESTS OF MOVANT

Movant EPPC is a nonprofit research institution that is based in Washington, D.C., and that is dedicated to defending American ideals and to applying the Judeo-Christian moral tradition to issues of public policy. EPPC works to promote a culture of life in law and policy and to defend the dignity of the human being from conception to natural death. EPPC has filed amicus curiae briefs in other cases involving abortion and drugs that might operate as abortifacients, including Dobbs v. Jackson Women's Health Organization, 597 U.S. (2022), Zubik v. Burwell, 578 U.S. (2016), and Burwell v. Hobby Lobby Stores, 573 U.S. 682 (2014).

REASON TO GRANT MOVANT'S AMICUS CURIAE STATUS

Movant EPPC respectfully submits that its proffered brief will assist the Court on the disputed legal question whether and to what extent federal criminal statutes prohibit sending mifepristone by U.S. mail or by common carrier and bring several relevant matters to the Court's attention. Movant EPPC therefore respectfully requests that this Court grant the motion for leave to file the accompanying amicus curiae brief.

Respectfully submitted,

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CERTIFICATE OF CONFERENCE

Pursuant to Local Rule 7.1(b), the undersigned counsel has been informed by plaintiffs' counsel that plaintiffs and defendants have mutually consented to the filing of amicus briefs and related motions on or before February 10, 2023. On that basis, movant's counsel certifies that defendants do not oppose this motion.

/s/ Charles W. Fillmore
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CERTIFICATE OF SERVICE

I certify that this document has been served on all parties via the court's ECF system on this 10th day of February, 2023.

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Plaintiff,

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U.S. FOOD AND DRUG ADMINISTRATION, et al.

Defendants

AMICUS BRIEF ON BEHALF OF ETHICS AND PUBLIC POLICY CENTER IN SUPPORT OF PLAINTIFFS

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INTERESTS OF AMICUS CURIAE

The Ethics and Public Policy Center, based in Washington, D.C., is a nonprofit research institution dedicated to defending American ideals and to applying the Judeo-Christian moral tradition to issues of public policy. Amicus works to promote a culture of life in law and policy and to defend the dignity of the human being from conception to natural death.

SUMMARY OF ARGUMENT

Federal criminal statutes broadly prohibit sending abortion drugs by U.S. mail or by common carrier. The FDA claims that these criminal statutes have no bearing on its authority to direct manufacturers of mifepristone to distribute that drug by mail or by common carrier to doctors who prescribe mifepristone for abortion and to pharmacies that dispense it for that purpose. But the recent Office of Legal Counsel opinion that the FDA recites and relies on is irredeemably flawed.

ARGUMENT

SECTION 1461 AND SECTION 1462 OF TITLE 18 BROADLY BAR SENDING ABORTION DRUGS BY U.S. MAIL OR BY COMMON CARRIER.

Federal criminal statutes broadly prohibit sending abortion drugs by U.S. mail or by common carrier. Section 1461 of Title 18 states in relevant part:

Every article or thing designed, adapted, or intended for producing abortion ... and [e]very article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion ... [i]s declared to be nonmailable matter and shall not be conveyed in the mails or delivered from any post office or by any letter carrier.

Whoever knowingly uses the mails for the mailing, carriage in the mails, or delivery of anything declared by this section ... to be nonmailable ... shall be fined under this title or imprisoned not more than five years, or both, for the first such offense, and shall be fined under this title or imprisoned not more than ten years, or both, for each such offense thereafter.

Section 1462 of Title 18 similarly prohibits anyone from "knowingly us[ing] any express company or other common carrier" to send or receive "any drug, medicine, article, or thing designed, adapted, or intended for producing abortion." It imposes the same set of penalties.

In its opposition brief, the FDA claims that these criminal prohibitions have no bearing on its authority to direct manufacturers of mifepristone to distribute that drug by mail or by common carrier to doctors who prescribe mifepristone for abortion and to pharmacies that dispense it for that purpose. The FDA recites and rests on the deeply flawed legal advice that the Office of Legal Counsel (OLC) of the U.S. Department of Justice set forth in a recent opinion. *See* Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction at 28-29 (citing OLC opinion titled "Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions" (dated Dec. 23, 2022)).

A. The OLC Opinion Would Eviscerate Section 1461 and Section 1462.

OLC opines that "section 1461 does not prohibit the mailing, or the delivery or receipt by mail, of mifepristone or misoprostol where the sender lacks the intent that the recipient of the drugs will use them unlawfully." OLC Opinion at 1-2 (emphasis added). It asserts that section 1462 is subject to the same prohibition-canceling exception. And it likewise contends that a person who orders or receives abortion drugs by mail or by common carrier does not violate section 1461 or section 1462 if that person "does not intend that they [the drugs] be used unlawfully." *Id.* at 2 n. 3.

OLC proceeds to boast that its reading—or, rather, its *wholesale rewriting*—of these statutes would eviscerate them. Focusing its illustrations on those who send or deliver mifepristone or misoprostol by mail, OLC observes that such persons "typically will lack complete knowledge of how the recipients intend to use them and whether that use is unlawful under relevant law." OLC

Opinion at 17. Therefore, it contends, even a sender's or deliverer's knowledge that a package contains mifepristone or misoprostol that "will be used to facilitate an abortion" is *not* "a sufficient basis for concluding that section 1461 has been violated." *Id.* OLC provides a laundry list of "illustrative uses for mifepristone and misoprostol that the law of a given state would not prohibit": before a gestational limit in some states, for "potentially life-threatening" conditions or other statutory exceptions in others, and so on. *Id.* at 18-20. It concludes that "in light of the many lawful uses of mifepristone and misoprostol, the fact that these drugs are being mailed to a jurisdiction that significantly restricts abortion is not a sufficient basis for concluding that the mailing violates section 1461." *Id.* at 20-21.

OLC's exception would render section 1461 a virtual nullity, even for mailings to states in which abortion is broadly unlawful. Even apart from OLC's illustrations, it would be rare indeed that the sender of abortion drugs would ever have "the *intent* that the recipient of the drugs will use them unlawfully." A typical shipper of abortion drugs wouldn't care one bit whether the recipient uses them for an unlawful abortion or flushes them down the toilet or feeds them to a pet. Even ideological shippers (e.g., abortion activists) would presumably intend at most only that the ultimate recipient have the ability to use the drugs unlawfully if she chooses to go ahead with the abortion, not that she necessarily actually use them.

As OLC explains, section 1461 is derived from the original Comstock Act that Congress enacted in 1873, and section 1462 is derived from an 1897 enactment that extended the mailing prohibitions of the original Comstock Act to common carriers. OLC Opinion at 4, 5 n. 7. In repeatedly referring to the provisions as the Comstock Act, OLC seems eager to draw on the notoriety of their draftsman Anthony Comstock. But there is a striking disconnect between Comstock's

reputation for severity and the lax (if not empty) meaning that OLC would assign to sections 1461 and 1462. Indeed, under OLC's intent test, even at its inception, the original Comstock Act could rarely if ever have been enforced against anyone who mailed abortion drugs. To apply OLC's own statement: In light of the universal exclusion of life-threatening conditions from state abortion laws, anyone who mailed abortion drugs in 1873 "typically [would] lack complete knowledge of how the recipients intend to use them and whether that use [would be] unlawful under relevant law." Plus, for the reasons set forth in the preceding paragraph, it would be rare that a sender in 1873 would ever have an *intent* that the drugs be used unlawfully. Further, under OLC's test, if a state in 1873 had adopted broadly permissive abortion laws, the supposedly draconian Comstock Act would have allowed a sender to mail drugs to that state with the specific intent that they be used for non-lifesaving abortions.

B. The OLC Opinion Is Poorly Supported and Unsound.

There is no meaningful support for OLC's claim that section 1461 does not apply when "the sender lacks the intent that the recipient of the drugs will use them unlawfully." OLC contends that there was a "well-established, consensus interpretation" among the federal appellate courts on such an exception by the middle of the 20th century and that Congress somehow ratified the supposed consensus by "perpetuating the wording" of section 1461's abortion language. But far from there being such a consensus, the cases that OLC cites do not remotely support its position. Congress could not have ratified a supposed "consensus interpretation" that never existed. And OLC's ratification claim is rife with other problems, including the fact that Congress in the 1970s unsuccessfully tried to modify section 1461 to say what OLC claims it already meant.

1. There was no "consensus interpretation" that supports OLC's position.

OLC invokes rulings from a grand total of four circuit courts from the first half of the 20th century in support of its supposed "well-established, consensus interpretation." *None* of these cases that OLC cites stand for the proposition that the Comstock Act provisions bar the mailing of abortion drugs only when the sender intends that the drugs be used unlawfully. Let's run through these cases one by one, in the order in which OLC discusses them.

The Seventh Circuit's ruling in *Bours v. United States*, 229 F. 960 (7th Cir. 1915), actually cuts strongly and directly against OLC's position—a problem that OLC obscures by its brazenly misleading selective quotations. In that case, the Seventh Circuit held that the term *abortion* in the statute that is now codified as section 1461 "must be taken in its general medical sense" to exclude "the necessity of an operation to save life"—i.e., a procedure necessary to save the life of the mother. *Id.* at 964.

In a passage that OLC doesn't quote or even acknowledge, the Seventh Circuit declared that this statute "indicates a national policy of discountenancing abortion as inimical to the national life." *Id.* The court reasoned that while "the letter of the statute would cover all acts of abortion, the rule of giving a reasonable construction *in view of the disclosed national purpose* would exclude those acts that are in the interest of the national life." *Id.* (emphasis added.) It was on that basis that the court determined that the statutory term *abortion* "must be taken in its general medical sense" to exclude "the necessity of an operation to save life"—i.e., a procedure necessary to save the life of the mother. *Id.*

OLC somehow quotes the phrase "reasonable construction" in isolation—without the Seventh Circuit's accompanying language "in view of the disclosed national purpose"—and it

omits any mention of the inconvenient fact that the Seventh Circuit discerned that "national purpose" to be "discountenancing abortion as inimical to the national life." *See* OLC Opinion at 5-6.

Further, far from limiting the statute (as OLC would) to abortions that are unlawful under the laws of the particular state in which the alleged violation occurred, the Seventh Circuit declared that "it is immaterial what the local statutory definition of abortion is, what acts of abortion are included, or what excluded." 229 F. at 964. OLC does quote this passage, but gives it no attention.

Bours is the only case that OLC cites in support of its "well-established, consensus interpretation" of section 1461 that actually involves abortion. Far from supporting OLC's position, Bours emphatically repudiates it. Bours stands for the propositions that section 1461 should be construed to implement "a national policy of discountenancing abortion as inimical to the national life" and that state laws governing which acts of abortion are lawful and which are unlawful are "immaterial" to the meaning of section 1461.

OLC next states that in Youngs Rubber Corp. v. C.I. Lee & Co., 45 F.2d 103 (2d Cir. 1930), the Second Circuit "reasoned in dicta that the statute could not be construed as expansively as its language might suggest." OLC Opinion at 6. Fair enough. But the Second Circuit's dicta are more confused than OLC acknowledges. As OLC notes, the Second Circuit observes that the statutory language, "[t]aken literally, ... would seem to forbid the transportation by mail or common carriage of anything 'adapted,' in the sense of being suitable or fitted, for preventing conception or for any indecent or immoral purpose, even though the article might also be capable of legitimate uses and the sender in good faith supposed that it would be used only legitimately." 45 F.2d at 108 (emphasis added). The Second Circuit could have adequately addressed this concern by reasoning that such "legitimate uses" should be excluded from the scope of the statute. That would mean, for example, that

misoprostol, which, as OLC notes, "is commonly prescribed for the prevention and treatment of gastric ulcers," OLC Opinion at 20, could be mailed for that use. Instead, the Second Circuit sloppily speculated that "[i]t would seem reasonable" to construe the statute "as requiring an intent on the part of the sender that the article mailed or shipped by common carrier be used for *illegal* contraception or abortion or for indecent or immoral purposes." 45 F.2d at 108 (emphasis added). Even worse, it mistakenly cited *Bours* as authority for this proposition. *See id*.

In the next case discussed by OLC, *Davis v. United States*, 62 F.2d 473 (6th Cir. 1933), the Sixth Circuit faulted the district court for not admitting evidence that would "show absence of intent that the goods shipped were to be used for other than a *legitimate* medical or surgical purpose." *Id.* at 474 (emphasis added). At issue were promotional mailings for "rubber sundries," which the defendant contended were not for contraceptive purposes but instead had "a legitimate medical and surgical use in treatment and prevention of disease." *Id.* The Sixth Circuit held that "intent that the articles described in the circular or shipped in interstate commerce were to be used for *condemned* purposes is a prerequisite to conviction." *Id.* at 475 (emphasis added). So although the Sixth Circuit approvingly cited the *Youngs Rubber* dicta at length, its holding reflects the position that *legitimate* uses—uses beyond the purposes that the statute condemns—should be excluded from the scope of the statute, *not* that whatever uses are *lawful under state law* should be.

The Second Circuit's opinion in *United States v. One Package*, 86 F.2d 737 (2d Cir. 1936), which concerned the import of pessaries "for contraceptive purposes," also does not reflect the "consensus interpretation" that OLC posits. OLC contends in particular that the court in *One Package* "adopted *Youngs Rubber*'s dicta as a holding." OLC Opinion at 7. But the Second Circuit in *One Package* read *Youngs Rubber*'s dicta to mean that the statute does not apply when the drugs

are "not intended for an *immoral* purpose." *Id.* at 739 (emphasis added). It declared that the Comstock Act enacted in 1873 "embraced only such articles as Congress [in 1873] would have denounced as immoral if it had understood all the conditions under which they were to be used." *Id.* at 739. The court opined that the "design" of the statute "was not to prevent the importation, sale, or carriage by mail of things which might intelligently be employed by conscientious and competent physicians for the purpose of saving life or promoting the well being of their patients." *Id.* At a time when abortion remained broadly unlawful, the court observed that "[t]he word 'unlawful' would make this clear as to articles for producing abortion." *Id.* In other words, the court was observing that the then-existing laws barring abortion were compatible with what the Congress that enacted the Comstock Act in 1873 "would have denounced as immoral if it had understood all the conditions under which they were to be used." That is a far cry from suggesting that section 1461 should apply only to whatever abortions the various states render unlawful at a particular time.

Two years later, in *United States v. Nicholas*, 97 F.2d 510 (2d Cir. 1938), the Second Circuit, citing *Youngs Rubber* and *One Package*, stated that it had "twice decided that contraconceptive [sic] articles may have lawful uses and that statutes prohibiting them should be read as forbidding them only when unlawfully employed." OLC acknowledges in a footnote that the court in *Nicholas* "described the relevant inquiry as being whether the articles were 'unlawfully employed,' rather than whether the sender *intended* that they be used unlawfully—the touchstone the court had adopted in *Youngs Rubber* and *One Package*"—but it argues that "this difference in phrasing does not reflect a departure relevant to our analysis." OLC Opinion at 9 n. 10.

OLC's argument is slipshod: First, the Second Circuit did not "adopt[]" any "touchstone" in *Youngs Rubber*. Its discussion was dicta, as OLC elsewhere acknowledges. Second, as

discussed above, the Second Circuit in *One Package* did *not* adopt *Youngs Rubber*'s dicta. Third, it's sophistry to concoct a supposed "consensus interpretation" by breezily dismissing material differences in interpretation.

The last circuit-court case that OLC cites is the D.C. Circuit's 1944 opinion in *Consumers Union v. Walker*, 145 F.2d 33 (D.C. Cir. 1944). There the D.C. Circuit held merely that "Congress did not intend to exclude from the mails properly prepared information for properly qualified people." It cited *Nicholas*, *Davis*, *Youngs Rubber*, and *One Package* as support for that narrow proposition.

OLC notes in a footnote that the "leading cases" for its supposed "consensus interpretation" "each involved items that could be used to prevent conception rather than to produce abortion." But it blithely contends that this distinction is irrelevant, even as it badly misrepresents the one case (*Bours*) that involves abortion and even as it completely ignores the passage from *One Package* (on what the 1873 Congress "would have denounced as immoral if it had understood all the conditions under which they were to be used") that renders that distinction critical.

In sum, none of these circuit-court cases stands for the proposition that section 1461 and related Comstock Act provisions bar the mailing of abortion drugs only when the sender intends that the drugs be used unlawfully. Nor, of course, do they remotely establish a "consensus interpretation" supporting such a proposition.

2. Congress did not ratify such an interpretation.

It would of course have been impossible for Congress to ratify a "consensus interpretation" that never existed. So that's one fatal flaw in OLC's argument.

There are plenty of other problems that would defeat OLC's ratification argument even if a "consensus interpretation" had existed. Among them:

a. OLC claims that its ratification argument "is strongly reinforced by the Historical and Revision Note that was included in the 1945 report of the House Committee on the Revision of the Laws when Congress enacted title 18 of the U.S. Code into positive law." OLC Opinion at 12. But that note does nothing more than quote the dicta from *Youngs Rubber* and briefly describe the holdings of *Nicholas* and *Davis*, all of which concern contraception. The note makes only a single mention of abortion, in its quotation of the *Youngs Rubber* dicta. It's farfetched to think that anyone who read that note would be on notice that enactment of Title 18 would mean that Congress was abandoning the "national policy of discountenancing abortion as inimical to the national life."

b. Even if you were to accept OLC's misreading of these rulings from *four* circuit courts, there were *nine* circuit courts when the Seventh Circuit issued its ruling in *Bours* and *ten* circuit courts when the other rulings were issued. So even if OLC's account of these rulings were accurate, it would be odd to find a "consensus interpretation" from a *minority* of circuit courts.

OLC quotes Justice Scalia's legal treatise (Reading Law: The Interpretation of Legal Texts (2012), co-authored with Bryan Garner) for this proposition: "If a word or phrase has been ... given a uniform interpretation by inferior courts ..., a later version of that act perpetuating the wording is presumed to carry forward that interpretation." OLC Opinion at 11-12 (quoting Reading Law at 322). But it ignores Scalia's query three pages later as to "how numerous must the lower-court opinions be ... to justify the level of lawyerly reliance that justifies the canon." Reading Law, at 325. Scalia opines that "seven courts" might be enough but that he "cannot give conclusive numbers." Id.

c. The most obvious way for Congress to have ratified the supposed "consensus interpretation" would have been to add the word unlawful to section 1461 (e.g., "for producing unlawful abortion"). It's heads-we-win-tails-you-lose gamesmanship to contend that making that change and *not* making that change would have the same effect.

d. Congress in fact *unsuccessfully* tried to make such a change on at least one occasion. A House subcommittee report from December 1978 proposed to modify section 1461 so that it prohibited mailing drugs (and other items) "intended by the offender ... to be used to produce an illegal abortion." *See Report of the Subcommittee on Criminal Justice on Recodification of Federal Criminal Law*, 95th Congress, 2d Session (Dec. 1978) (available at https://www.ojp.gov/pdffiles1/Digitization/63344NCJRS.pdf), at 40 (proposing to substitute a new section 6701 in lieu of section 1461). In support of that proposed change, the House subcommittee report states:

[U]nder current law, the offender commits an offense whenever he "knowingly" mails any of the designated abortion materials. Section 6701 of revised title 18 requires proof that the offender specifically intended that the mailed materials be used to produce an illegal abortion. An abortion is "illegal" if it is contrary to the laws of the state in which it is performed. [Underlining added.]

e. As OLC notes, the House report that accompanied Congress's amendment of section 1461 in 1971 flatly states: "Existing statutes *completely prohibit* the importation, interstate transportation, and mailing of contraceptive materials, or the mailing of advertisement or information concerning how or where such contraceptives may be obtained or how conception may be prevented." See H.R. Rep. No. 91-1105, at 2 (1970) (emphasis added). OLC contends that that statement "plainly was a reference to the literal text of their provisions, as opposed to their settled meaning." OLC Opinion at 14 n. 17. But OLC's anti-textual reading of the House report is not "plain[]" at all.

C. The FDAAA Did Not Impliedly Preempt Sections 1461 and 1462.

The FDA also invokes the Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub. L. No. 110-85, against AHM's reading of section 1461. Opposition Brief at 29-30. Insofar as the FDA is arguing that Congress somehow impliedly repealed section 1461 with respect to abortion drugs generally or mifepristone specifically, the argument is farfetched. As the Supreme Court recently re-affirmed, "repeals by implication are not favored" and will not be held to have occurred "unless Congress' intention to repeal is clear and manifest, or the two laws are irreconcilable." *Maine Community Health Options v. United States*, 104 S. Ct. 1308 (2020); *see also In re Lively*, 717 F.3d 406, 410 (5th Cir. 2013) ("Repeals by implication are disfavored and will not be presumed unless the legislature's intent is 'clear and manifest'"). It would be especially extraordinary to have a grandfathering-of-regulations provision impliedly repeal a criminal statute.

The OLC Opinion makes a far more modest use of the FDAAA. It asserts that the FDAAA's treatment of mifepristone is "consistent with the understanding that the Comstock Act does not categorically prohibit the covered modes of conveying abortion-inducing drugs" and "suggests that Congress did not understand the Comstock Act to invariably prohibit the conveyance by mail or common carrier of drugs intended to induce abortions." OLC Opinion at 14 & n.

18. But this assertion rests on the false predicate that Congress can plausibly be determined to have ratified a "consensus interpretation" that never existed.

OLC thinks it significant that no one "in the congressional debate [over the FDAAA] mentioned the Comstock Act, even though it would have been natural to assume that the FDA's 2000 approval had resulted in the distribution of mifepristone to certified physicians through the mail or by common carrier." OLC Opinion at 14 n. 18. But the FDAAA was merely grandfathering certain

existing regulatory restrictions on drugs. It was not specifying a statutory regime for any drug. So it is neither surprising nor meaningful that the Comstock Act was not discussed.

By: M. E. Whola The

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CERTIFICATE OF SERVICE

I certify that this document has been served on all parties via the court's ECF system on this 10th day of February, 2023.

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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS AMARILLO DIVISION

on behalf of itself, its member organizations, their members, and these members' patients, et al.,	
Plaintiff, v.	Case No. 2:22-cv-00223-Z
U.S. FOOD AND DRUG ADMINISTRATION, et al.	
Defendants	

ALLIANCE FOR HIDDOCRATIC MEDICINE

ORDER GRANTING UNOPPOSED MOTION OF
ETHICS AND PUBLIC POLICY CENTER
FOR LEAVE TO FILE A BRIEF AS AMICUS CURIAE
IN SUPPORT OF PLAINTIFFS'
MOTION FOR PRELIMINARY INJUNCTION

Before the Court is the Unopposed Motion of Ethics and Public Policy Center to File a Brief as Amicus Curiae in Support of Plaintiffs' Motion for Preliminary Injunction ("Motion"). The Court **GRANTS** the Motion.

SO ORDERED.				
February, 2023.				
	MATTHEW J. KACSMARYK			
	UNITED STATES DISTRICT JUDGE			