IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, and LILLY USA, LLC Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	No. 1:21-cv-81-SEB-MJD

DEFENDANTS' OPPOSITION TO MOTION TO INTERVENE

Proposed intervenors in this case already have tried—and failed—to litigate the legality of Plaintiff Eli Lilly ("Lilly") and other drug manufacturers' unilaterally imposed restrictions on 340B drug discounts in another federal district court. Proposed intervenors neglect to tell this Court that *every one* of the associations seeking to intervene here (hereinafter collectively "Covered Entities") was a plaintiff in a suit, dismissed less than a month ago, that sought unsuccessfully to commandeer Defendants' ("HHS's") enforcement of the 340B statute against Lilly and other pharmaceutical companies. Ignoring that court's straightforward holding that the legality of Lilly and its peers' recent restrictions must be decided, in the first instance, in HHS's ADR process (*not* in federal court), the Covered Entities now seek a second bite at the apple by intervening in this suit to again press their interpretation of the statute. But the Covered Entities are no more entitled to litigate the proper interpretation of the 340B statute in this suit than in the one that was just dismissed, and intervention should be denied for several reasons.

First, the Supreme Court unequivocally has held that covered entities, like those seeking to intervene here, *cannot* litigate purported 340B violations because "Congress vested authority to oversee

compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 117 (2011). The Covered Entities' attempt to intervene as *defendant* here, in place of the agency charged with enforcing the statute, is simply a creative recasting of precisely the type of suit *Astra* forbade. Second, this Court should not even reach the motion to intervene, because the Court should first address HHS's forthcoming motion to dismiss for lack of subject-matter jurisdiction, which will demonstrate why this Court lacks jurisdiction to review the interpretation set forth in the Advisory Opinion. Intervention is improper when a court lacks subject-matter jurisdiction over the original action, and the intervention of a new party cannot cure a lack of jurisdiction. Third, even were the Court to reach the motion to intervene, the Covered Entities still do not have an interest in the outcome that is sufficient to meet the requirements of Federal Rule of Civil Procedure 24(a)(2). The Covered Entities have no independent right to defend the legality of government action, and their interests are adequately represented because the government is defending this suit vigorously and seeks the same outcome as would proposed intervenors—a complete denial of relief for the plaintiff. Instead, the Covered Entities seeking to intervene should present their views as *amici curiae*—as other groups of identically situated parties already have. Fourth, the Covered Entities cannot even meet the requirements for permissive intervention because they do not have any "claim or defense" for which there is an independent basis for jurisdiction, as required by Rule 24(b)(1)(B). The Covered Entities do not seek to assert any claim or defense of their own in this action; instead, the "defenses" listed in their proposed pleading merely consist of defenses they believe HHS should raise against the claims presented by Lilly. And both *Astra* and the Covered Entities' own recent, failed suit demonstrate that the Covered Entities *cannot* present any claim for 340B violations against either drug manufacturers or HHS.

This Court should delay consideration of the Covered Entities' motion to intervene until it has decided HHS's forthcoming motion to dismiss, but if the Court reaches the motion to intervene,

it should be denied. As HHS already has communicated to the Covered Entities, the Government does not oppose participation by the proposed intervenors as *amici curiae*.

BACKGROUND

The relevant statutory and regulatory background is detailed in HHS's Opposition to Lilly's Motion for Preliminary Injunction, *see* ECF No. 32 at 2-7, and the factual context surrounding Lilly's unilateral contract-pharmacy restrictions was discussed at length during this Court's February 26, 2020 oral argument. For brevity, HHS includes here only background specifically relevant to the Covered Entities' intervention.

On December 11, 2020, each of the Covered Entities seeking to intervene here sued HHS in the Northern District of California. ECF No. 1, Compl., *Am. Hosp. Ass'n v. HHS*, No. 20-cv-8806 (N.D. Cal. Dec. 11, 2020). That same day the Covered Entities moved for emergency injunctive relief, seeking to compel HHS to enforce the 340B statute against Lilly and other manufacturers, including orders "to require the Drug Companies to provide covered outpatient drugs at or below 340B ceiling prices to covered entities when they dispense those drugs through contract pharmacies," along with orders for drug companies to issue refunds, and referral of Lilly and other companies' restrictions for the assessment of significant civil monetary penalties. *Id.*, ECF No. 7, Mot. for Prelim. Inj.

In addition to opposing the Covered Entities' emergency motion, HHS moved to dismiss the suit in its entirety, arguing that claims for 340B violations must be decided, in the first instance, through HHS's newly available ADR process. HHS's motion demonstrated (1) that, under *Astra*, Covered Entities may not sue to enforce 340B requirements (regardless whether the agency or a drug manufacturer is named as the nominal defendant); (2) the Covered Entities could not establish jurisdiction under the Administrative Procedure Act ("APA") because they did not challenge any final agency action; and (3) no jurisdiction exists for a court to review HHS's enforcement of the statute because such decisions are committed to agency discretion under *Heckler v. Chaney*, 470 U.S. 821

(1985). Only two days after HHS filed its motion, the court issued a show-cause order to the Covered Entities, ordering them "to show cause in writing why this case should not be dismissed for lack of subject-matter jurisdiction." *Id.* ECF No. 64 (casing fixed). The court also suspended hearing the Covered Entities' preliminary-injunction motion until HHS's motion to dismiss had been decided.

Facing near-certain dismissal, the Covered Entities disavowed their previous request for sweeping injunctive relief requiring HHS to take specified enforcement actions, and instead recast their suit as one seeking to compel HHS to develop a new "enforcement policy." *Id.* ECF No. 81, Resp. to Order to Show Cause and Opp. to Mot. to Dismiss.

The Covered Entities' attempt to transform their suit was unavailing: Less than one month ago, the Northern District of California dismissed the case, specifically agreeing with each of HHS's jurisdictional arguments. *See Am. Hosp. Ass'n v. Dep't of Health & Human Servs.*, No. 4:20-cv-08806-YGR, 2021 WL 616323 (N.D. Cal. Feb. 17, 2021). Importantly for the present action, the court found the Covered Entities' claims barred by *Astra*'s holding that litigation to enforce 340B requirements is "incompatible with the statutory regime" and that Congress had mandated resolution of disputes under the 340B Program in the agency's ADR process. *Id.* at *5-6. Even though the Covered Entities had "creatively recast their claims," the court found, they "seek precisely that which *Astra* forbids: the *private* enforcement of 340B program requirements." *Id.*. The court then explained:

> Congress made explicit that alleged 340B Program violations are to be first adjudicated by HHS through an established ADR process. This process provides the agency an initial opportunity to develop rules and regulations applicable to the enforcement of the 340B Program requirements. Moreover, the panel consists of decisionmakers *with intimate familiarity, technical knowledge, and understanding of the nuances inherent* in the 340B Program. The judiciary has a prescribed role in this process, but its role comes *only after* the parties have participated in this ADR process. This Court will not otherwise short-circuit the foundational regime that Congress has enacted in the 340B Program.

Id. at *6 (first emphasis added). The court further agreed with HHS that the Covered Entities had not challenged any final agency action, as required to maintain an APA suit, and that the relief sought would invade the unreviewable realm of prosecutorial discretion—even after the Covered Entities had

"backtrack[ed] from their own requests for emergency relief." *Id.* at *8.

In the meantime, several covered entities or associations of the same have moved to participate in this action as *amici curiae*, a role which permits them to provide this Court with potentially useful information regarding the real-world consequences and purported harms inflicted by Lilly's unilateral restrictions on access to discounted drugs. *See* Mot. for Leave to File Amicus Brief, Little Rivers Health Care et al., ECF No. 43; Mot. for Leave to File Amicus Brief, Nat'l Ass'n of Comm. Health Ctrs., ECF No. 46. But, despite undersigned counsel having communicated to counsel for proposed intervenors that the government would not oppose their request to similarly participate as *amici*, the Covered Entities instead have moved to intervene as a defendant—a posture which would allow them to sidestep *Astra* and litigate claims under the 340B statute directly against Lilly.

ARGUMENT

1. Intervention by the Covered Entities is barred by *Astra*.

Even after *explicitly* being told by the Northern District of California that their challenge to the legality of Lilly's new restrictions must be adjudicated, in the first instance, in HHS's ADR Process—not in federal court—the Covered Entities doggedly (and inexplicably) continue to instead pursue the same verboten result: private enforcement of 340B requirements, in direct contravention of Supreme Court authority. The procedural posture of this case, in which the Covered Entities wish to participate as defendants litigating 340B requirements against drug makers, is significantly *more on-point* with *Astra* even than the recent suit against HHS dismissed on these same grounds last month. Intervention must be denied because covered entities, like proposed intervenors here, cannot litigate 340B requirements outside the ADR process.

The Supreme Court expressly confirmed that covered entities may not litigate 340B program requirements in *Astra*. *See generally* 563 U.S. 110. In that case, a collection of covered entities had sued drug manufacturers for purported overcharges on 340B-covered drugs. The Court rejected as

"incompatible with the statutory regime" the covered entities' efforts to sue to enforce 340B requirements, regardless of the legal theory on which they based their claim. *Id.* at 113. This is because "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities." *Id.* at 117. The Court further made clear that the legal theory relied on by covered entities mattered not, in light of the evident "incompatibility of private suits with the statute Congress enacted." *Id.* at 121; *see also id.* at 120 ("Far from assisting HHS, suits by 340B entities would undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis," and create a "substantial" "risk of conflicting adjudications").

Finally, the Court noted that Congress had responded to reports of inadequate 340B oversight and enforcement, not by authorizing private suits by covered entities, but instead by providing for the establishment of an ADR process within the agency. *Astra*, 563 U.S. at 121-22, *citing* 42 U.S.C. § 256b(d). "Congress thus opted to strengthen and formalize" the agency's enforcement, the Court found, "to make the new adjudicative framework the proper remedy for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements,'" with the agency's resolution of ADR complaints subject to review under the APA. *Astra*, 563 U.S. at 121-22.

The Covered Entities' request to intervene here is barred by this unmistakable Supreme Court precedent. The calculus is not altered by the fact that the Covered Entities purport to ask this Court to allow them to defend the agency's statutory interpretation; intervention will still permit covered entities and manufacturers to litigate between them claims for 340B program violations (here, the legality of Lilly's restrictions), which is precisely what the Supreme Court forbade. Stated plainly, *Astra* confirmed that covered entities simply may not sue, on any legal theory, to enforce their statutory entitlement to 340B discounted drugs (and instead must bring claims for violations in the ADR Process). Permitting associations of covered entities here to litigate the correctness of the HHS

General Counsel's statutory interpretation *against a drug manufacturer* would flout this precedent. Intervention must be denied because it is HHS, not the Covered Entities, to which Congress has assigned oversight and enforcement of 340B. *Id.* at 118 ("A third-party suit to enforce" 340B requirements "is in essence a suit to enforce the statute itself," and "[t]he absence of a private right to enforce the statutory ceiling-price obligations would be rendered meaningless if 340B entities could overcome that obstacle by suing" under creative legal theories). Indeed, the Covered Entities' recent attempt to force HHS to take specified actions against Lilly failed on this same ground. *See Am. Hosp. Ass'n*, 2021 WL 616323 ("Although plaintiffs here have similarly and creatively recast their claims as an APA action against HHS and the Secretary of HHS, this action is nothing more than an *indirect action* against the drug manufacturers themselves.").[1]

2. The Court should consider HHS's forthcoming motion to dismiss before ruling on the Covered Entities' motion, because there is no basis for intervention in a suit over which the Court lacks subject-matter jurisdiction.

The Court should not even reach the motion to intervene, because intervention is not proper in a case where a court lacks subject-matter jurisdiction. The Court should address HHS's forthcoming motion to dismiss for lack of subject-matter jurisdiction and failure to state a claim first; HHS respectfully contends that this motion will be meritorious and will demonstrate why the Court lacks jurisdiction to decide, in the first instance, the correctness of the General Counsel's statutory interpretation.

A court generally should resolve issues of subject-matter jurisdiction before it considers other issues. Moreover, intervention does not affect the jurisdictional analysis. "Intervention cannot cure any jurisdictional defect that would have barred the federal court from hearing the original action.

[1] The Covered Entities may respond that nothing in *Astra* abrogated the ability to bring APA claims related to the 340B Program. That is true, but irrelevant, since the Covered Entities are not suing HHS under the APA (that attempt already has failed) but instead seek to participate as *defendants*, against drug maker Eli Lilly—which is precisely what the Supreme Court forbade.

Intervention presupposes the pendency of an action in a court of competent jurisdiction and cannot create jurisdiction if none existed before." 7C Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 1917 (3d ed. 2007) (footnote omitted); *Buckley v. Ill. Judicial Inquiry Bd.*, 997 F.2d 224, 227 (7th Cir. 1993) (noting that entry of an intervening plaintiff cannot cure lack of jurisdiction); *see also Bodimetric Health Servs., Inc. v. Aetna Life & Cas.*, 903 F.2d 480, 490 & n.10 (7th Cir. 1990) (upholding district court's decision to dismiss for lack of subject-matter jurisdiction and noting that ruling made it unnecessary to consider Government's motion to intervene, which had been denied); *Lardas v. Grcic*, 847 F.3d 561, 571 (7th Cir. 2017) (affirming dismissal of original action for lack of standing and holding proposed intervenor was thus left with "no live case in which he might intervene").

In response to Lilly's complaint, HHS expects to present the Court with strong grounds for dismissal. In particular with regard to the Advisory Opinion the Covered Entities seek to "defend," HHS will show that no jurisdiction exists under the APA because the Advisory Opinion is not final agency action and because an adequate alternate remedy has been provided by Congress; that the Opinion does not exceed statutory authority because the only obligations imposed on Lilly flow directly from the 340B statute; and that Lilly cannot maintain a Takings Clause claim because binding circuit precedent establishes that voluntary participation in a regulated government program cannot establish a "taking" as a matter of law. This Court therefore should delay resolution of the Covered Entities' motion until it rules on HHS's forthcoming motion to dismiss, which should be granted.

3. The Covered Entities' interests are adequately represented by HHS.

A separate reason the Covered Entities fail to qualify for intervention as of right is that their interests are adequately represented by HHS—which shares the Covered Entities' goal of repelling this lawsuit. It is the Department of Justice, not private parties like the Covered Entities, which is charged by Congress with the responsibility of defending federal agencies' interpretation of federal

law. *See* 28 U.S.C. § 516. Any unique views the Covered Entities wish to present to the Court should be provided through an amicus brief, not participation as a party, because the Department of Justice's representation of HHS's statutory interpretation is more than adequate.

In *Solid Waste Agency v. U.S. Army Corps of Engineers*, 101 F.3d 503 (7th Cir. 1996), a village government and a citizen group sought to intervene in a suit alongside the federal government defendants. *Id.* at 504. The Seventh Circuit held that the proposed intervenors failed to show that they were not adequately represented by the government, because "[w]here the interests of the original party and of the intervenor are identical—where in other words there is no conflict of interest—adequacy of representation is presumed." *Id.* at 508. The court noted that the proposed intervenors had the same primary goal as the federal government—to "defeat [the plaintiff's] effort to invalidate" the federal government's action. *Id.* The court acknowledged that the United States likely had "additional interests" not shared by the proposed intervenors, but it held that that "diversity of … interests" was not enough to establish that the proposed intervenors were not adequately represented. *Id.*

The same reasoning led to the same result in *Wisconsin Education Association Council v. Walker*, 705 F.3d 640 (7th Cir. 2013). Municipal employees sought to intervene to join the defense of a state statute. *Id.* at 644. The Seventh Circuit held that the employees could not intervene, in part because they were adequately represented by the government in defending the suit. *Id.* at 659. The court observed that the employees and the government had "exactly the same goal" in the litigation—"protecting the [challenged statue] against the [plaintiffs'] constitutional challenge." *Id.* In other words, a presumption of adequate representation exists where "the prospective intervenor and the named party have the same goal," and intervention will not be granted unless that presumption is overcome by the demonstration of some actual conflict. *Id.* "[Q]uibbles with the state's litigation strategy," the court held, were not enough to demonstrate a conflict of interest. *Id.*

This case is on all fours with *Solid Waste Agency* and *Wisconsin Education Association Council*. The Covered Entities and HHS have the same primary goal in the litigation—to repel Lilly's challenge to the Advisory Opinion. This triggers a presumption of adequate representation. HHS's general need to weigh other competing interests and the possibility that the Covered Entities may disagree with HHS about the minutiae of litigation strategy do not come close to rebutting that presumption.

The Covered Entities make no serious attempt to address this standard. Instead, they assert in conclusory fashion that "Defendants' interests [] diverge, as they disagree with Proposed Intervenors that HHS has the authority and obligation to enforce" the Advisory Opinion. Mot. 9. This assertion is patently false; in defending *both* against the Covered Entities' suit in the Northern District of California *and* Lilly's emergency motion in this Court, HHS repeatedly has confirmed that covered entities must challenge Lilly's recent restrictions—as Congress mandated—in the agency's ADR Process. Once an ADR Panel has determined whether Lilly's policy comports with the 340B statute, either side can seek judicial review of that ruling under the APA *and* HRSA can pursue various types of enforcement action if a violation is found. The Covered Entities' suggestion that HHS has abdicated responsibility for enforcing the statute is meritless. Moreover, the Covered Entities purport to seek intervention to defend the legality of the statutory interpretation set forth in the Advisory Opinion—*not* to relitigate the scope of HHS's enforcement efforts. HHS has not backed away from the Advisory Opinion's interpretation in any way and will rely on that reasoning in its motion to dismiss Lilly's suit, so there is no divergent interest whatsoever between the Covered Entities and HHS regarding the only matter about which the Covered Entities seek to intervene.

The Covered Entities also claim that because they "have brought suit against HHS asserting that the Department has acted contrary to law and/or unlawfully withheld agency action," "[t]hat alone is sufficient to demonstrate that the government cannot and will not adequately represent the interests" of covered entities. Mot. 10-11. This assertion is baseless. The Covered Entities fail to

mention that their suit against HHS has been dismissed in its entirety (and that that court *agreed with HHS* that the Covered Entities must pursue relief in the ADR Process, not in federal court, yet they still inexplicably refuse to do so). More importantly, HHS vigorously is defending this suit, and soon will file a meritorious motion to dismiss for lack of jurisdiction. The Covered Entities' threadbare speculation that "[i]t is … quite conceivable that the government's defense … may be inadequate" is wrong as a matter of law—since HHS, the agency charged by Congress with implementing and enforcing the 340B statute, fully is defending its interpretation of the statute. It also is wrong factually, in light of HHS's forceful defense both of Lilly's suit and those brought by other manufacturers in other districts. Equally false is the Covered Entities' assertion that "HHS has never taken the position that it can or will enforce the statutes as interpreted." Mot. 10. HHS successfully rebutted that same assertion in the Northern District of California litigation, and it is the Covered Entities that inexplicably refuse to bring a claim for relief before the agency where the legality of Lilly's policy and, if necessary, appropriate enforcement must be decided.

To the extent that the Covered Entities may be seeking intervention in a misguided attempt to once again litigate *against HHS*—for example, by moving for relief enjoining HHS to enforce the 340B statute in the manner, and on the timeframe, the Covered Entities prefer—any such attempt would once again be barred by *Astra* and principles of agency discretion and, now, *res judicata* to boot.

The Covered Entities therefore cannot meet the standard for intervention as of right under Federal Rule 24(a)(2). Moreover, any interest they have in providing to the Court *facts* in their possession regarding the harms inflicted by Lilly's restrictions can adequately be protected by filing a brief as *amici curiae*, as have other covered entities already. The Covered Entities seeking to intervene are in no way differently situated than other covered entities who have, consistent with the will of Congress, filed claims against Lilly and/or other manufacturers in the ADR Process while seeking leave to participate as *amici* here.

4. The Covered Entities cannot seek permissive intervention because they have no "claim or defense" of their own for which there would be an independent basis for jurisdiction.

The Covered Entities also do not meet the requirements for permissive intervention under Rule 24(b)(1)(B) because they do not seek to present any claim or defense for which there is independent jurisdiction.

Under Rule 24(b)(1)(B), a person seeking permissive intervention must present a "claim or defense." *Id.* It must be the kind of claim or defense "that can be raised in courts of law as part of an actual or impending lawsuit," *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 623 n.18 (1997) (internal quotation omitted), and for which the court has "independent jurisdiction," *Ligas ex rel. Foster v. Maram*, 478 F.3d 771, 775 (7th Cir. 2007). In this case, there are no claims that have been raised or could be raised between Lilly and the Covered Entities. Again, the dispute between those parties *must* be decided in the agency's ADR process. *Astra*, 563 U.S. at 122. The Covered Entities lay out what they call "defenses" in their proposed answer, but these are not defenses that could be asserted by Covered Entities against claims brought by Lilly. *See* Proposed Answer in Intervention, ECF No. 39-2. Rather, they can only be viewed as defenses that the Covered Entities wish for HHS to raise against Lilly's claims. The Covered Entities have no authority whatsoever to raise defenses on the government's behalf—nor to defend a federal agency's interpretation of a federal statute on the agency's behalf—and intervention does not give them any such authority. This principle is illustrated by the fact that the Covered Entities seek to file an *answer* to Lilly's complaint—which would tee up resolution by this Court of the merits of the contract-pharmacy dispute—whereas HHS repeatedly has explained (and will demonstrate in its forthcoming motion to dismiss) that the matter must be decided, in the first instance, in HHS's ADR process, not by this Court.

At bottom, the Covered Entities could not state a claim (or raise a defense) against Lilly, because litigation by covered entities over 340B Program violations unequivocally is foreclosed by

Astra. And the Covered Entities cannot state a claim (or raise a defense) against HHS for similar reasons, as borne out by the recent dismissal of the Covered Entities' attempt to do just that. The Covered Entities' proposed "defenses" set forth in their proposed answer thus cannot support permissive intervention, because there is no claim the Covered Entities could litigate (as plaintiff or defendant) under the 340B statute over which the Court would have jurisdiction, unless and until an ADR Panel renders a final agency decision that may be challenged under the APA. Stated plainly, the Covered Entities have no "claim or defense" in common with HHS or Lilly and therefore cannot meet the prerequisite for permissive intervention. The Covered Entities' statutory *right* to 340B-discounted drugs does not give them a *claim* capable of resolution in federal court. *Astra*, 563 U.S. at 121. The Covered Entities could serve a helpful role as *amici*, fleshing out the facts surrounding the 340B Program—but cheering on HHS and hoping it prevails in litigation does not justify participation as a party in this litigation.

Even if the Covered Entities could meet the requirement for intervention—and they cannot—the Court should exercise its discretion to deny permissive intervention given the potential for the addition of another party to complicate the proceedings and further burden the Court and the parties. "Permissive intervention under Rule 24(b) is wholly discretionary." *Sokaogon Chippewa Cmty. v. Babbitt*, 214 F.3d 941, 949 (7th Cir. 2000). This is particularly true when the agency already is burdened by defending similar, meritless suits, brought by separate pharmaceutical companies, now pending in various district courts.

Finally, the Court should deny permissive intervention for the additional reason that allowing private parties, like the Covered Entities, to litigate the proper interpretation and application of a federal statute alongside the agency charged with implementing that statute would severely curtail the discretion and authority Congress bestowed. As will be demonstrated in HHS's forthcoming motion to dismiss, the proper application of the 340B statute to Lilly's restrictions must be decided, in the

first instance, by the agency—not in this Court, in competing briefs between interested parties such as the Covered Entities and Lilly. The attendant harms that may accrue to the agency from the Covered Entities' participation is borne out by their attempt to *answer* Lilly's complaint, whereas HHS intends to demonstrate that the Advisory Opinion is not reviewable final agency action subject to challenge in this Court.

CONCLUSION

The Court should delay resolution of the Covered Entities' intervention request until it has resolved HHS's forthcoming motion to dismiss for lack of jurisdiction. If the Court reaches the motion to intervene, the request should be denied because the Covered Entities do not meet the requirements for intervention. Conversely, the Covered Entities should, if they choose, move to participate as *amicus curiae* as other covered entities already have done.

Dated: March 9, 2021

Respectfully submitted,

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