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

ELI LILLY AND COMPANY,
Lilly Corporate Center
893 Delaware Street
Indianapolis IN 46225, *et al.*,

Plaintiffs,

–v–

NORRIS COCHRAN
200 Independence Avenue, SW
Washington, DC 20201, *et al.*,

Defendants.

Case No. 1:21-cv-81-SEB-MJD

THE AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS, THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES, THE CHILDREN'S HOSPITAL ASSOCIATION, AND THE AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACIST'S MEMORANDUM IN SUPPORT OF THEIR MOTION TO INTERVENE

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The American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, National Association of Children's Hospitals d/b/a the Children's Hospital Association, and American Society of Health-System Pharmacists (collectively the Proposed Intervenors) move this Court, pursuant to Federal Rule of Civil Procedure 24(a), or in the alternative pursuant to Federal Rule of Civil Procedure 24(b), for an Order granting their Motion to Intervene in this lawsuit regarding the 340B Drug Discount Program.

The 340B Program, established by section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires, as a condition of participating in Medicaid and Medicare Part B, that pharmaceutical manufacturers sell outpatient drugs at a discounted price (no more than the 340B ceiling price) to certain public and not-for-profit hospitals, community health centers, and other federally funded clinics that serve communities with a large numbers of low income patients ("340B providers" (described in the statute as "covered entities")) in order to increase the funding these entities have available to meet the needs of their patients.

Since the beginning of the program, 340B providers have dispensed covered outpatient drugs to their patients through in-house pharmacies and through community pharmacies that have entered into written contracts with hospitals and other providers ("contract pharmacies"). Under such arrangements, the 340B provider orders and pays for the 340B drugs, which are then shipped to the contract pharmacy where the drugs are dispensed to the 340B provider's patients. For more than 20 years, all drug companies, including Eli Lilly and Company ("Lilly"), worked cooperatively with 340B providers that dispensed discounted drugs to their patients through contract pharmacies. Overall, a quarter of the benefit that 340B hospitals receive from the 340B discount comes from 340B drugs dispensed through contract pharmacy arrangements. This varies

by hospital type, with Critical Access Hospitals (small hospitals in rural areas) reporting that an average of 51% of their 340B benefit from the 340B discount comes from drugs distributed through contract pharmacies, while Disproportionate Share Hospitals (DSH hospitals) (hospitals that serve a significantly disproportionate number of low-income patients) report that an average of 61% of their 340B benefit from the 340B discount comes from drugs distributed through contract pharmacies.[1]

Plaintiffs' complaint requests the Court to adopt an implausible interpretation of the 340B statute that would deny Proposed Intervenors' members access to drug discounts for drugs dispensed to their patients at most contract pharmacies. Intervention by Proposed Intervenors is necessary to protect their members' interests in this lawsuit and to ensure that patients have adequate access to 340B drugs — which it is not apparent the government defendant will sufficiently do — and to defend the correct interpretation of the 340B statute to include the availability of discounts when distribution is through contract pharmacies. The Proposed Intervenors have standing to intervene because at least one or more of each association's members has been and continues to be significantly harmed by Eli Lilly's failure to offer 340B drug discounts to 340B covered entities when drugs are dispensed through contract pharmacies.

Proposed Intervenors meet the standard for intervention of right. First, Proposed Intervenors' members clearly have a direct stake in the outcome. If Plaintiffs were to obtain a ruling adopting their (incorrect) interpretation of the statute, Proposed Intervenors' members' 340B savings will continue to diminish, seriously hampering their ability to serve vulnerable communities as Congress intended. Moreover, the drug companies that have not already adopted policies comparable to Lilly's would be incented to adopt one, resulting in even greater losses of

[1] *See* Ex. A Testoni Decl., ECF No. 39-1, ¶¶ 4–6.

the 340B discounts and the services to the communities those discounts fund. Likewise, there is no question that an adverse outcome in this case would impair Proposed Intervenors' members' interests—not just in the correct interpretation and application of federal law, but in receiving the discounts to which they are entitled. Defendants cannot adequately defend Proposed Intervenors' interests. In fact, to date, the Department of Health and Human Services (HHS) has refused to take any action to stop Lilly from denying Proposed Intervenors' members the statutory discounts to which they are entitled. Alternatively, because Proposed Intervenors and Plaintiffs both seek to have this Court resolve the same question of law – namely whether the 340B statute requires Plaintiffs to provide covered entities covered outpatient drugs at or below the 340B ceiling price when dispensed through a contract pharmacy – Proposed Intervenors also meet the standard for permissive intervention. Accordingly, the Court should grant Proposed Intervenors' motion to intervene.

BACKGROUND

Seven months ago, Lilly became the first drug company to abandon its 20-year compliance with the statutory requirement to provide 340B providers with drugs at or below 340B ceiling prices when dispensed through contract pharmacies. In May 2020, Lilly floated the idea of applying its "no contract pharmacy" policy to a single drug, Cialis® with the division of HHS that administers the 340B program, the Health Resources and Services Administration (HRSA).[2] When HRSA failed even to inform Lilly that this practice would be illegal,[3] Lilly was emboldened to

[2] Letter Re: Availability of 340B-Priced Cialis® (tadalafil) Erectile Dysfunction Presentations to Contract Pharmacies, Lilly (May 18, 2020), https://www.dropbox.com/s/ttjou3z9zo7q33w/Lilly%201etter%20to%2OHRSA%2005.18.2020.pdall=0.
[3] Ex. C to Pls.' Am. Compl., ECF No. 17-4.

expand its discount denials to all of its drugs.[4] Not surprisingly, to date, five other drug companies followed suit with similar policies.[5]

HRSA's inaction precipitated three lawsuits. Two lawsuits challenged HRSA's failure to issue an Administrative Dispute Resolution (ADR) regulation, which they alleged was needed to resolve the disagreement over contract pharmacy arrangements. *See Ryan White Clinics for 340B Access v. Azar*, No. 1:20-cv-2906 (D.D.C.); *Nat'l Ass'n of Cmty. Health Ctrs. v. Azar*, No. 1:20-cv-3032 (D.D.C.). In addition, Proposed Intervenors and three hospitals filed suit to obtain a ruling that the refusal by Lilly and the other drug companies to provide 340B providers 340B discounts for drugs dispensed through contract-pharmacies was illegal and to require HHS to develop an enforcement plan aimed at stopping the drug companies from continuing to implement these illegal policies. *See* Compl., ECF No. 1, *Am. Hosp. Ass'n v. Azar*, No. 4:20-cv-8806 (N.D. Cal. Dec. 11, 2020). Lilly and three of the other drug companies with similar contract pharmacy policies filed motions to intervene in those cases. Eli Lilly & Co.'s Mot. to Intervene as Def., ECF No. 12, *Ryan White Clinics*, No. 1:20-cv-2906 (D.D.C. Nov. 20, 2020); Mot. of Sanofi-Aventis U.S. LLC to Intervene as a Def., ECF No. 13, *Ryan White Clinics*, No. 1:20-cv-2906 (D.D.C. Nov. 20, 2020); AstraZeneca LP's Mot. to Intervene as Def., ECF No. 29, *Ryan White Clinics*, No. 1:20-cv-2906 (D.D.C. Nov. 24, 2020); Proposed Intervenor-Def. Eli Lilly & Co.'s Not. of Mot., Mot., & Mem. in Supp. of its Mot. to Intervene, ECF No. 28, *Am. Hosp. Ass'n*, No. 4:20-cv-8806 (N.D. Cal. Dec.

[4] Limited Distribution Plan Notice for Eli Lilly and Company Products, https://www.340bhealth.org/files/200901_Eli_Lilly_and_Company_Limited_Distribution_Plan_Public_Notice.pdf.

[5] *See* Sanofi Notice (July 2020), https://www.340bhealth.org/files/Sanofi_Notice_10_1_20.pdf; Letter Re: 340B Contract Pharmacy Pricing, AstraZeneca (Aug. 17, 2020), https://www.dropbox.com/s/gethwns6m7zzkoh/AstraZeneca%20Retail%20Communication%20-%20340B%20-%20Final.pdfld1=0; New policy related to the 340B program, Novartis (Oct. 30, 2020), https://www.novartis.us/news/statements/new-policy-related-340b-program; Letter Re: United Therapeutics Corporation 340B Contract Pharmacy Policy Effective November 20, 2020, United Therapeutics Corp. (Nov. 18, 2020), https://www.dropbox.com/s/swyrookjcwqxe58/United%20Therapeutics%20Letter%2011.20.2020%20%281%29.pdf?dl=0; Notice Regarding Limitation on Hospital Contract Pharmacy Distribution, Novo Nordisk (Dec. 1, 2020), https://www.340bhealth.org/files/Novo_Nordisk_12-1-2020.pdf.

28, 2020); AstraZeneca LP's Not. of Mot., Mot., & Mem. in Supp. of Mot. to Intervene, ECF No. 35, *Am. Hosp. Ass'n*, No. 4:20-cv-8806 (N.D. Cal. Dec. 28, 2020); Proposed Intervenor-Def. Sanofi-Aventis U.S. LLC's Not. of Mot., Mot. to Intervene, & Mem. of P. & A. in Supp., ECF No. 38, *Am. Hosp. Ass'n*, No. 4:20-cv-8806 (N.D. Cal. Dec. 28, 2020); Proposed Intervenor-Defendant Novo Nordisk Inc.'s Not. of Mot., Mot., & Mem. in Supp. of Mot. to Intervene, ECF No. 62, *Am. Hosp. Ass'n*, No. 4:20-cv-8806 (N.D. Cal. Jan. 10, 2021).

In response to these lawsuits, HHS did two things. First, it finalized the proposed ADR regulation (which had been withdrawn). *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020) (to be codified at 42 C.F.R. pt. 10). And, on December 30, 2020, its General Counsel issued an Advisory Opinion recognizing that the 340B statute requires drug companies to offer 340B discounts to covered entities for drugs dispensed through contract pharmacies. *See Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (Dec. 30, 2020). Nevertheless, even though it stated that the drug company policies with respect to contract pharmacies are illegal, HHS has taken no action to enforce the statute. *Id.*

In its complaint, Eli Lilly challenges the December 30, 2020 Advisory Opinion. ECF No. 1. Subsequently, Eli Lilly filed an amended complaint which includes additional claims related to HRSA's ADR regulations. ECF No. 17. At the same time, Lilly filed a motion seeking to preliminary enjoin HRSA from implementing the ADR regulation. ECF No. 18.

Proposed Intervenors' interest in this lawsuit relates only to Lilly's claims regarding the Advisory Opinion. Intervention in this case would thus not affect or delay this Court's resolution of Lilly's motion for a preliminary injunction which addresses a different issue, namely the legality of the recently issued ADR regulation.

ARGUMENT

"Intervention of Right should be permitted upon timely application 'when the applicant claims an interest relating to the property or transaction which is the subject of the action and the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest, unless the applicant's interest is adequately represented by existing parties.' A party may be permitted to intervene in an action (upon timely application) when 'an applicant's claim or defense and the main action have a question of law or fact in common.'" *Am. Std. Ins. Co. of Wis. v. Rogers*, 123 F. Supp. 2d 461, 469 n.5 (S.D. Ind. 2000) (quoting Fed. R. Civ. P. 24(a)(2), (b)(2)). Proposed Intervenors meet both of these standards because the Advisory Opinion, which Plaintiffs challenge, impacts their members' right to statutory discounts under the 340B program.

I. Proposed Intervenors Have a Right to Intervene Under Rule 24(a).

Pursuant to Federal Rule of Civil Procedure 24(a)(2), "a party seeking intervention of right must show: (1) timeliness; (2) an interest relating to the subject matter of the main action, (3) at least potential impairment of that interest if the action is resolved without the intervenor, and (4) lack of adequate representation by existing parties." *Buquer v. City of Indianapolis*, No. 1:11-cv-708, 2013 WL 1332137, at *2 (S.D. Ind. Mar. 28, 2013) (citation omitted); *see also Planned Parenthood of Wis., Inc. v. Kaul*, 942 F.3d 793, 797 (7th Cir. 2019). "The rule is straightforward: the court *must* permit intervention" if those four factors are met. *Driftless Area Land Conservancy v. Huebsch*, 969 F.3d 742, 746 (7th Cir. 2020).

As in most other circuits, the Seventh Circuit courts construe Rule 24(a)(2) motions liberally. *Elouarrak v. Firstsource Advantage, LLC*, No. 1:19-cv-3666, 2020 WL 291364, at *1 (N.D. Ill. Jan. 21, 2020) (citing *Planned Parenthood of Wis.*, 942 F.3d at, 799; *Lopez-Aguilar v. Marion Cty. Sheriff's Dep't*, 924 F.3d 375, 391 (7th Cir. 2019)). Courts should resolve doubts in

favor of allowing intervention. *Michigan v. U.S. Army Corps of Eng'r's*, No. 10-cv-4457, 2010 WL 3324698, at *2 (N.D. Ill. Aug. 20, 2010).

A motion to intervene as a matter of right, therefore should not be denied unless "it appears to a certainty that the intervenor is not entitled to relief under any set of facts which could be proved under the complaint." *State v. City of Chicago*, 912 F.3d 979, 984 (7th Cir. 2019) (citations omitted). Courts "must accept as true the non-conclusory allegations of the motion." *Id.* (citations omitted). A court should not deny a motion to intervene "unless it is certain that the proposed intervenor cannot succeed in its case under any set of facts which could be proved under the complaint." *Michigan*, 2010 WL 3324698, at *2 (citations omitted).

A. Timeliness

The Seventh Circuit considers four factors to determine whether a motion to intervene is timely: "(1) the length of time the intervenor knew or should have known of his interest in the case; (2) the prejudice caused to the original parties by the delay; (3) the prejudice to the intervenor if the motion is denied; and (4) any other unusual circumstances." *Sokaogon Chippewa Cmty. v. Babbitt*, 214 F.3d 941, 949 (7th Cir. 2000) (alteration and citation omitted). In addition, the "test for timeliness is essentially one of reasonableness: 'potential intervenors need to be reasonably diligent in learning of a suit that might affect their rights, and upon so learning they need to act reasonably promptly.' We further note that, when intervention of right is sought, because 'the would-be intervenor may be seriously harmed if intervention is denied, courts should be reluctant to dismiss such a request for intervention as untimely, even though they might deny the request if the intervention were merely permissive." *Lopez-Aguilar*, 924 F.3d at 388–89 (citations omitted).

Lilly filed its complaint challenging the December 30, 2020 Advisory Opinion on January 12, 2021 and filed an amended complaint and a motion for preliminary injunction related to the ADR process on January 25, 2021. Proposed Intervenors have promptly moved to intervene.

According to the Court's recently issued scheduling order, Defendants' response to the preliminary injunction motion was due February 16, 2021. ECF No. 27. As noted above, however, Proposed Intervenors will not be responding to that motion which relates only to the ADR regulation. With respect to the remaining claims for relief (regarding the Advisory Opinion), there currently is no schedule and Proposed Intervenors are prepared to participate in that aspect of the case on whatever schedule the Court sets. Moreover, Proposed Intervenors have attached their Answer to the First Amended Complaint to its Motion to Intervene. Ex. B ECF No. 39-2. Lilly therefore would not be prejudiced because there would be no delay. If the motion were denied, however, Proposed Intervenors would be prejudiced. Thus, the timeliness requirement is met.

B. Interest

The second element under Rule 24(a)(2) is that "the proposed intervenor must have a direct, significant, and legally protectable interest in the question at issue in the lawsuit," which "must be unique to the proposed intervenor" meaning it is "based on a right that belongs to the proposed intervenor rather than to an existing party in the suit." *Elouarrak*, 2020 WL 291364, at *2 (alterations and citations omitted). "Interest in 'the subject of the action' is a broad formulation." *Nat'l Fire Ins. Co. of Hartford v. Tri-State Hose & Fitting, Inc.*, No. 06 C 5256, 2007 WL 9814578, at *4 (N.D. Ill. June 21, 2007).

Proposed Intervenors and their members have a direct, significant and legally protected interest in obtaining discounts to which they are entitled under the 340B statute.[6] Proposed Intervenors' member hospitals use the benefit from 340B discounts for 340B drugs dispensed through contract pharmacies to support programs and services offered by 340B hospitals. These

[6] "An association has standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests at stake are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000).

discounts, for example, allow them to (1) provide and maintain more patient care services; (2) provide and maintain more uncompensated and unreimbursed care; (3) provide and maintain more services in underserved areas; and (4) develop and maintain targeted programs to serve vulnerable patients; and (5) keep their doors open. Testoni Decl., Ex. A ECF No. 39-1 ¶ 8.

These discounts are precisely the subject of the General Counsel's Advisory Opinion that Lilly challenges. Lilly seeks an outcome directly contrary to the Advisory Opinion (*i.e.*, that it not be required to provide discounts for covered outpatient drugs when such drugs are dispensed through a contract pharmacy). Defendants' interests also diverge, as they disagree with Proposed Intervenors that HHS has the authority and obligation to enforce this requirement. Accordingly, the interest factor is met.

C. Interest Impaired

The disposition of Lilly's lawsuit in Lilly's favor would adversely affect Proposed Intervenors' members, and the communities they serve. If Lilly were to successfully convince this Court to adopt its (incorrect) interpretation of the statute, Proposed Intervenors' members would continue to lose access to 340B discounts when their covered outpatient drugs are dispensed from a contract pharmacy. This would not only encourage the other five drug companies with similar policies to continue their policies, but it would likely encourage other drug companies to adopt the same types of policies. This would significantly, adversely impact the services all 340B covered entities provide to vulnerable populations. Testoni Decl., Ex. A ECF No. 39-1 ¶¶ 7, 9. This hardship, which 340B providers are already facing due to the six drug companies' current policies, comes amidst a pandemic that is putting an enormous strain on hospitals' financial resources and accordant ability to care for their patients. On the other hand, if Plaintiffs' claims were rejected, then Proposed Intervenors' members would be able to continue receiving the discounts to which they are entitled and have received since the beginning of the 340B program.

D. Inadequate Representation

The government Defendants in this lawsuit do not adequately represent Proposed Intervenors' interests. The Seventh Circuit held that the burden of making this showing should be treated as "minimal," and that a party seeking intervention as of right must only make a showing that the representation "may be" inadequate. *Ligas ex rel. Foster v. Maram*, 478 F.3d 771, 774 (7th Cir. 2007) (quoting *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538 n.10 (1972)).

There is no doubt that HHS has different interests than the Proposed Intervenors in this case. Since Lilly first instituted the contract pharmacy policy at issue, Proposed Intervenors, 340B covered entities and other 340B covered entity trade associations have been trying to get the government to take action.[7] Despite periodically stating that it was looking into the issue,[8] and after its General Counsel issued an Advisory Opinion agreeing with Proposed Intervenors' statutory interpretation, HHS has never taken the position that it can or will enforce the statutes as interpreted. The only thing HHS has done is to issue the ADR regulation that is being challenged in several lawsuits, including this one, and even that process has been unilaterally placed on hold.[9] Finally, Proposed Intervenors have brought suit against HHS asserting that the Department has

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[7] *See, e.g.*, Letter Re: Recent Actions by Pharmaceutical Manufacturers Eli Lilly and Merck Impacting 340B Covered Entities, 340B Coalition (July 16, 2020), https://nysarh.org/wp-content/uploads/2020/08/340B-Coalition-Letter-Final-7.16.20.pdf; Letter, AHA (July 30, 2020), https://www.aha.org/system/files/media/file/2020/07/aha-urges-hhs-take-action-against-drug-manufacturers-for-limiting-distribution-340b-drugs-letter-7-30-2020.pdf; Letter Re: Pharmaceutical Company Actions Undermining 340B Drug Pricing Program, AEH (Aug. 28, 2020), https://essentialhospitals.org/wp-content/uploads/2020/08/AEH-Letter-340B-Contract-Pharmacy-8-28-20.pdf; Letter, AHA (Sept. 8, 2020), https://www.aha.org/system/files/media/file/2020/09/aha-again-urges-hhs-to-protect-340b-program-from-drug-companies-actions-letter-9-8-20.pdf; Letter, AHA (Oct. 16, 2020), https://www.aha.org/system/files/media/file/2020/10/aha-urges-hhs-stop-drug-companies-refusal-provide-required-340b-discounts-letter-10-16-20.pdf.

[8] *See, e.g.*, Letter from Robert Charrow to Anat Hakim, Lilly (Sept. 21, 2020) https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf; Letter from Krista M. Pedley to Maureen Testoni (Dec. 9, 2020), https://www.340bhealth.org/files/HRSA_Response_Letter_-_12-09-2020.pdf.

[9] Cathy Kelly, *340B Dispute Resolution Process On Ice As Feuds Between Pharma, Providers, HHS Heat Up*, Pink Sheet, https://pink.pharmaintelligence.informa.com/PS143652/340B-Dispute-Resolution-Process-On-Ice-As-Feuds-Between-Pharma-Providers-HHS-Heat-Up (Jan. 22, 2021).

acted contrary to law and/or unlawfully withheld agency action. *See Am. Hosp. Ass'n v. Cochran*, No. 4:20-cv-8806 (N.D. Cal.). It is therefore not only possible but quite conceivable that the government's defense of its right to implement and/or enforce the December 30 decision, as the Plaintiffs seek to bar it from doing, may be inadequate. That alone is sufficient to demonstrate that the government cannot and will not adequately represent the interests of Proposed Intervenors.

In sum, Proposed Intervenors have met the requirements for intervention of right.

II. Alternatively, Proposed Intervenors Should be Permitted to Intervene Under Rule 24(b).

Proposed Intervenors also satisfy the requirements of Federal Rule of Civil Procedure 24(b). Under Rule 24(b), on "timely motion" the Court "may permit anyone to intervene" who "has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1)(B). Permissive intervenors must (1) share a common question of law or fact with a party, (2) be timely in their pursuit of intervention; and (3) not cause prejudice to existing parties. *Randall v. Rolls-Royce Corp.*, No. 1:06-cv-860, 2010 WL 1948222, at *3 (S.D. Ind. May 13, 2010); *see also Planned Parenthood of Wis.*, 942 F.3d at 803.

"The inquiry into whether a common claim or defense exists is a broad one." *Joe Sanfelippo Cabs Inc. v. City of Milwaukee*, No. 14-cv-1036, 2015 WL 1728123, at *2 (E.D. Wis. Apr. 15, 2015) (citing *Bond v. Utreras*, 585 F.3d 1061, 1070 (7th Cir. 2009)). As this Court has noted, "if there are issues of fact and/or law in common, it is the timeliness of the intervention request which is scrutinized most closely." *Walker v. Floyd Cty.*, No. 4:07-cv-14, 2009 WL 2222886, at *1 (S.D. Ind. July 22, 2009) (citations omitted). The common question of law in this case is whether the 340B statute requires pharmaceutical manufacturers to offer 340B discounts to covered entities that dispense their 340B drugs through contract pharmacies. For the reasons described above, *see* Sec. I.A., this motion is timely and thus will not delay the proceedings or

prejudice Lilly or the Defendants. Accordingly, at a minimum Proposed Intervenors should be permitted to intervene under Rule 24(b).

CONCLUSION

For the foregoing reasons, Proposed Intervenors request the Court to grant their motion to intervene of right under Rule 24(a) or, in the alternative, to allow Proposed Intervenors to intervene under Rule 24(b).

Dated: February 19, 2021

Respectfully submitted,

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