UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC., *et.al.*, *Plaintiffs*, –v– NORRIS COCHRAN, *et al.*, *Defendants*.	Civil Action No. 3:21-cv-00806-FLW-LHG

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

Justin P. Walder
James W. Boyan III
PASHMAN STEIN WALDER HAYDEN
A Professional Corporation
Court Plaza South
21 Main Street, Suite 200
Hackensack, NJ 07601
Telephone (201) 488-8200
Facsimile (201) 488-5556
jboyan@pashmanstein.com

William B. Schultz (*pro hac vice forthcoming*)
Margaret M. Dotzel (*pro hac vice forthcoming*)
Casey Trombley-Shapiro Jonas
(*pro hac vice forthcoming*)
ZUCKERMAN SPAEDER LLP
1800 M Street NW, Suite 1000
Washington, DC 20036
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
mdotzel@zuckerman.com
cjonas@zuckerman.com

Ariella Muller (*pro hac vice forthcoming*)
ZUCKERMAN SPAEDER LLP
485 Madison Avenue, 10th Floor
New York, New York 10022
Tel: (212) 704-9600
Fax: (917) 261-5864
amuller@zuckerman.com
Attorneys for Proposed Intervenors

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American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges, National Association of Children's Hospitals d/b/a 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 the latter 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 Novo Nordisk Inc., ("Novo"), 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. For example, Critical Access Hospitals (small hospitals in rural areas) report 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]

Plaintiff's 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 —

[1] *See* Declaration of James W. Boyan III in Support of Proposed Intervenors' Motion to Intervene, Mar. 1, 2021 ("Boyan Decl."), Ex. A (Declaration of Maureen Testoni in Support of Proposed Intervenors' Motion to Intervene, Feb. 24, 2021 ("Testoni Decl.") ¶¶ 4–6.

which it is not apparent the government Defendants 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 Novo'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 Plaintiff 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 Novo's would be incented to adopt one, resulting in even greater losses of 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 Novo from denying Proposed Intervenors' members the statutory discounts to which they are entitled. Alternatively, because Proposed Intervenors and Plaintiff both seek to have this Court resolve the same question of law – namely whether the 340B statute requires Plaintiff 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, Eli Lilly and Company ("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

[2] Boyan Decl., Ex. C (First Am. Compl., Ex. E (Attach. 1), *Eli Lilly & Co. v. Cochran*, No. 1:21-cv-81-SEB-MJD (S.D. Ind. Jan. 25, 2021), ECF No. 17-6).

illegal,[3] Lilly was emboldened to expand its discount denials to all of its drugs.[4] On December 1, 2020, Novo announced that as of January 1, 2021, it would join the other drug manufacturers in imposing restrictions related to 340B contract pharmacies, effectively denying 340B hospitals the discounts for 340B drugs dispensed through contract pharmacies. Novo has stated that its restrictions will apply only to hospitals and will include an exception for hospitals that do not have their own on-site pharmacy.[5] To date, four other drug companies have implemented similar policies.[6]

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

[3] Boyan Decl., Ex. D (First Am. Compl., Ex. C, *Eli Lilly & Co. v. Cochran*, No. 1:21-cv-81-SEB-MJD (S.D. Ind. Jan. 25, 2021), ECF No. 17-4).

[4] Boyan Decl., Ex. E (First Am. Compl., Ex. G, *Eli Lilly & Co. v. Cochran*, No. 1:21-cv-81-SEB-MJD (S.D. Ind. Jan. 25, 2021), ECF No. 17-8).

[5] *See* Boyan Decl., Ex. J (Notice Regarding Limitation on Hosp. Contract Pharm. Distribution, Novo Nordisk (Dec. 1, 2020)).

[6] *See* Boyan Decl., Ex. F (Am. Compl., Ex. A at 2, *AstraZeneca Pharms. LP v. Cochran*, No. 1:21-cv-00027-LPS (D. Del. Feb. 12, 2021), ECF 13-1); Boyan Decl., Ex. K (Sanofi Notice (July 2020)); Boylan Decl., Ex. L (New policy related to the 340B program, Novartis Statement (Oct. 30, 2020)); Boylan Decl., Ex. M (Mem. from Kevin Gray, SVP, United Therapeutics Corp. to 340B Covered Entities (Nov. 18, 2020)).

(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 Novo 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., *Am. Hosp. Ass'n v. Azar*, No. 4:20-cv-8806 (N.D. Cal. Dec. 11, 2020), ECF No. 1.[7] Novo and three of the other drug companies with similar contract pharmacy policies filed motions to intervene in those cases. Proposed Intervenor-Defendant Novo Nordisk Inc.'s Not. of Mot., Mot., & Mem. in Supp. of Mot. to Intervene, *Am. Hosp. Ass'n*, No. 4:20-cv-8806 (N.D. Cal. Jan. 10, 2021), ECF No. 62; Mot. of Sanofi-Aventis U.S. LLC to Intervene as a Def., *Ryan White Clinics*, No. 1:20-cv-2906 (D.D.C. Nov. 20, 2020), ECF No. 13; AstraZeneca LP's Mot. to Intervene as Def., *Ryan White Clinics*, No. 1:20-cv-2906 (D.D.C. Nov. 24, 2020), ECF No. 29; Eli Lilly & Co.'s Mot. to Intervene as Def., *Ryan White Clinics*, No. 1:20-cv-2906 (D.D.C. Nov. 20, 2020), ECF No. 12; Proposed Intervenor-Def. Sanofi-Aventis U.S. LLC's Not. of Mot., Mot. to Intervene, & Mem. of P. & A. in Supp., *Am. Hosp. Ass'n*, No. 4:20-cv-8806 (N.D. Cal. Dec. 28, 2020), ECF No. 38; AstraZeneca LP's Not. of Mot., Mot., &

[7] On February 17, 2021, the court dismissed this action without prejudice, ruling "plaintiffs may be able to maintain a narrower action seeking general enforcement of the statute in the future . . . ." ECF No. 91 at 13.

Mem. in Supp. of Mot. to Intervene, *Am. Hosp. Ass'n*, No. 4:20-cv-8806 (N.D. Cal. Dec. 28, 2020), ECF No. 35; Proposed Intervenor-Def. Eli Lilly & Co.'s Not. of Mot., Mot., & Mem. in Supp. of its Mot. to Intervene, *Am. Hosp. Ass'n*, No. 4:20-cv-8806 (N.D. Cal. Dec. 28, 2020), ECF No. 28.

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* Boyan Decl., Ex. G (*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, Novo challenges the December 30, 2020 Advisory Opinion. ECF No. 1. At this point no additional motions have been filed and the Court has not yet entered a Scheduling Order. As such, intervention at this preliminary stage of the case would not affect or delay any matters currently before the Court, or otherwise prejudice the parties.

ARGUMENT

"Rule 24(a) of the Federal Rules of Civil Procedure provides that, 'on timely motion, the court must permit anyone to intervene who: (1) is given an unconditional right to intervene by a federal statute; or (2) claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest.'" *Pa. Prison Soc'y v. Cortes*, 622 F.3d 215, 232 (3d Cir. 2010) (alteration omitted) (quoting Fed. R. Civ. P. 24(a)). "Rule 24(b) provides in relevant part that 'on timely motion, the court may permit anyone to intervene who: (A) is given a conditional right to intervene by a federal statute; or (B) has a claim or defense that shares with the main action a common question of law or fact." *Id.* (alteration omitted) (quoting Fed. R. Civ. P. 24(b)). 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).

The Third Circuit requires that the following four elements be met from an applicant seeking intervention as of right: "(1) a timely application for leave to intervene; (2) a sufficient interest in the litigation; (3) a threat that the interest will be impaired or affected, as a practical matter, by the disposition of the action; and

(4) inadequate representation of the prospective intervenor's interest by existing parties to the litigation." *Clean Earth, Inc. v. Endurance Am. Ins.*, Civ. No. 15-6111, 2016 WL 5422063, at *3 (D.N.J. Sept. 28, 2016).

As in most other circuits, the Third Circuit courts "liberally construe Rule 24(a) in favor of intervention." *ACR Energy Partners, LLC v. Polo N. Country Club, Inc.*, 309 F.R.D. 191, 192 (D.N.J. 2015) (alteration and citation omitted). In considering motions to intervene, "courts should adhere to the elasticity that Rule 24 contemplates and may examine pragmatic considerations." *Clean Earth*, 2016 WL 5422063, at *3 (citations omitted); *see also Harris v. Pernsley*, 820 F.2d 592, 597 (3d Cir. 1987) (noting that courts must "consider the pragmatic consequences of a decision to permit or deny intervention").

A. Timeliness

The Third Circuit considers three factors to determine whether a motion to intervene is timely: "(1) the stage of the proceeding; (2) the prejudice that delay may cause the parties; and (3) the reason for the delay." *Wallach v. Eaton Corp.*, 837 F.3d 356, 371 (3d Cir. 2016) (citation omitted). In addition, timeliness is ascertained from the complete set of circumstances, and the inquiry "is essentially a test of reasonableness," *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 223 F.R.D. 326, 328 (D.N.J. 2004) (citation omitted). Where intervention "will cause no delay

to the parties," the timeliness prong has been met. *See Glover v. Ferrero USA, Inc.*, No. 11-1086, 2011 WL 5007805, at *3 (D.N.J. Oct. 20, 2011).

Novo filed its complaint challenging the December 30, 2020 Advisory Opinion on January 15, 2021. ECF No. 1. Proposed Intervenors have promptly moved to intervene. Pursuant to Fed. R. Civ. P. 12(a)(2), Defendants' Answer is not due until the third week of March 2021, at the earliest. As noted above, there currently is no schedule in place and Proposed Intervenors are prepared to participate in the case on whatever schedule the Court sets. Moreover, Proposed Intervenors have attached their Answer to the Complaint to their Motion to Intervene. Boyan Decl., Ex. B. Novo 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) is that the proposed intervenor must "have an interest 'relating to the property or transaction which is the subject of the action' that is 'significantly protectable.'" *Clean Earth*, 2016 WL 5422063, at *3 (citation omitted). Further, at issue must be "a legal interest as distinguished from interests of a general and indefinite character." *Id*. (citation omitted).

Proposed Intervenors and their members have a direct and "significantly protectable" legal interest in obtaining discounts to which they are entitled under the

340B statute.[8] 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 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; (4) develop and maintain targeted programs to serve vulnerable patients; and (5) keep their doors open. Boyan Decl., Ex. A (Testoni Decl.) ¶ 8.

These discounts are precisely the subject of the General Counsel's Advisory Opinion that Novo challenges. Novo 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.

[8] "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 Envtl Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000).

C. Interest Impaired

In assessing whether a proposed intervenor's interests will be impaired, courts in the Third Circuit look to the "practical consequences of denying intervention." *Clean Earth*, 2016 WL 5422063, at *4 (citation omitted). The disposition of Novo's lawsuit in Novo's favor would adversely affect Proposed Intervenors' members, and the communities they serve. If Novo 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. Boyan Decl., Ex. A (Testoni Decl.) ¶¶ 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 Third Circuit has 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. *Pennsylvania v. President of the U.S.*, 888 F.3d 52, 60 (3d Cir. 2018) (citations omitted); *see also Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538 n.10 (1972). Representation is considered inadequate where, "although the applicant's interests are similar to those of a party, they diverge sufficiently that the existing party cannot devote proper attention to the applicant's interests." *Granillo v. FCA US LLC*, No. 16-153, 2018 WL 4676057, at *9 (D.N.J. Sept. 28, 2018) (quoting *Brody v. Spang*, 957 F.2d 1108, 1123 (3d Cir. 1992)).

There is no doubt that HHS interests diverge sufficiently from the interests of Proposed Intervenors in this case. Since Novo and other drug companies 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.[9] Despite periodically stating that it was looking into the issue,[10] 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 and even that process has been unilaterally placed on hold.[11] 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.

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[9] *See, e.g.*, Boylan Decl., Ex. N (Letter from 340B Coalition to Alex M. Azar, Secretary, HHS (July 16, 2020)); Boylan Decl., Ex. O (Letter from Thomas P. Nickels, EVP, AHA to Alex M. Azar, Secretary, HHS (July 30, 2020)); Boylan Decl., Ex. P, Letter from Bruce Siegel, President & CEO, AEH to Alex Azar, Secretary, HHS (Aug. 28, 2020); Boylan Decl., Ex. Q (Letter from Richard J. Pollack, President & CEO, AHA to Alex M. Azar, Secretary, HHS (Sept. 8, 2020)); Boylan Decl., Ex. R (Letter from Richard J. Pollack, President & CEO, AHA to Alex M. Azar, Secretary, HHS (Oct. 16, 2020)).

[10] *See, e.g.*, Boyan Decl., Exs. H and I (First Am. Compl., Exs. K and L, *Eli Lilly & Co. v. Cochran*, No. 1:21-cv-81-SEB-MJD (S.D. Ind. Jan. 25, 2021), ECF Nos. 17-12, 17-13).

[11] Boylan Decl., Ex. S (Cathy Kelly, *340B Dispute Resolution Process On Ice As Feuds Between Pharma, Providers, HHS Heat Up*, Pink Sheet (Jan. 22, 2021)).

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). The requirements are that "(1) the motion to be timely; (2) an applicant's claim or defense and the main action have a question of law or fact in common; and (3) the intervention may not cause undue delay or prejudice to the original parties' rights." *King v. Christie*, 981 F. Supp. 2d 296, 309 (D.N.J. 2013). So long as these threshold requirements are met, the decision to allow permissive intervention is left to the sound discretion of the court. *Id.*

"Rule 24(b), unlike intervention as of right under Rule 24(a), 'is expressly concerned with consolidating common legal or factual issues," *Hemy v. Perdue Farms, Inc.*, No. 11-888, 2011 WL 6002463, at *8 (D.N.J. Nov. 30, 2011) (alteration and citation), and "the court has broad discretion to permit intervention by anyone who 'has a claim or defense that shares with the main action a common question of law or fact,'" *Tansey v. Rogers*, No. 12-1049-RGA, 2016 WL 3519887, at *2 (D. Del. June 27, 2016) (quoting Fed. R. Civ. P. 24(b)(1)(B)). 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 Novo 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: March 2, 2021

Respectfully submitted,

/s/ James W. Boyan III
James W. Boyan III
Justin P. Walder
PASHMAN STEIN WALDER HAYDEN, P.C.
Court Plaza South
21 Main Street, Suite 200
Hackensack, NJ 07601
Telephone (201) 488-8200
Facsimile (201) 488-5556
jboyan@pashmanstein.com
jpwalder@pashmanstein.com

William B. Schultz (*pro hac vice forthcoming*)
Margaret M. Dotzel (*pro hac vice forthcoming*)
Casey Trombley-Shapiro Jonas (*pro hac vice forthcoming*)
ZUCKERMAN SPAEDER LLP
1800 M Street NW, Suite 1000
Washington, DC 20036
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com

mdotzel@zuckerman.com
cjonas@zuckerman.com

Ariella Muller (*pro hac vice forthcoming*)
ZUCKERMAN SPAEDER LLP
485 Madison Avenue, 10th Floor
New York, NY 10022
Tel: (212) 704-9600
Fax: (917) 261-5864
amuller@zuckerman.com

Attorneys for Proposed Intervenors