**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF GEORGIA**
**ATLANTA DIVISION**

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| RANDALL CALLAHAN, *et al.*,<br><br>Plaintiffs,<br><br>v.<br><br>UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, through ALEX M. AZAR II in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED NETWORK FOR ORGAN SHARING,<br><br>Defendants. | CIVIL ACTION NO.<br>1:19-CV-1783-AT<br><br>**EMERGENCY RELIEF REQUESTED** |

**MEMORANDUM OF LAW IN SUPPORT OF PROPOSED INTERVENOR-DEFENDANTS' EMERGENCY MOTION TO INTERVENE**

April 25, 2019

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## PRELMINARY STATEMENT

This lawsuit challenges the implementation of a revised liver allocation policy that was approved by a supermajority of the Board of Directors of the Organ Procurement and Transplantation Network (OPTN) and scheduled to be implemented on April 30, 2019 (April 2019 Policy). The April 2019 Policy was necessitated by the undisputed reality that the current policy is illegal and inconsistent with the National Organ Transplant Act (NOTA). The relief Plaintiffs seek is untenable because by any measure the April 2019 Policy is more appropriate than a policy that definitively violates NOTA.

Intervention is both necessary and appropriate, on an emergency basis, for several reasons.

First, Proposed Intervenor-Defendants (Movants), who are patients on the liver transplant waitlist in California and New York, have an obvious interest in making sure the liver allocation system, which impacts if or when they receive a donor liver, is legal and consistent with NOTA. In this regard, Movants are no different that the patient Plaintiffs who brought this suit and certainly have a greater interest than the transplant center Plaintiffs whose interest is primarily economic.

Second, Movants' interest is in making sure the current, illegal policy is replaced by a legal policy as soon as possible. Movants are concerned their

interest is not adequately represented by the existing parties to the suit because the current parties either benefit from the current, illegal policy or have allowed the current, illegal policy to remain in effect for the last twenty years. The new policy was only passed after Movants filed suit in New York to declare the current policy illegal, and it is that same interest they seek to protect as Intervenor-Defendants.

Third, although Plaintiffs currently appear to oppose Movant's application, they previously took the position that intervention was necessary under FRCP 24 when Movant Jackson was litigating the liver allocation process before another Court. Specifically, Plaintiff, University of Kansas Hospital Authority affirmatively argued that intervention was needed to "present this Court with a fuller development of the underlying factual issues in this action at a local and national level, to lead to a just and equitable adjudication of the matter at hand." *Cruz et. al. v. U.S. Dept. of Health and Human Serv. et. al.* (S.D.N.Y. 18-CV-6371(AT)) (*Cruz* Action), Doc. No. 9 at. 2. Suffice it to say, if Plaintiffs are truly interested in "a just and equitable adjudication of the matter at hand" they would not oppose Movants' request.

## STATEMENT OF FACTS

1. Proposed Intervenor-Defendants

Proposed Intervenor-Defendant Susan Jackson is a resident of southern California, who has been on the liver transplant waitlist at a California liver transplant center. Ms. Jackson is also a plaintiff in the *Cruz* Action pending in the Southern District of New York. Fruchter Decl. Ex. 1 (*Cruz* Complaint). Proposed Intervenor-Defendant Charles Bennett, is a New York resident who was added to the liver transplant waitlist in February 2019 and is currently hospitalized at a New York liver transplant center.

2. The Liver Distribution and Allocation System

Over thirty years ago, Congress passed NOTA to make clear that donated organs are a national resource that must be equitably distributed on a nationwide basis. The law is clear and unequivocal: allocation of donated organs "[s]hall not be based on the candidate's place of residence or place of listing." 42 C.F.R. § 121.8(a). The purpose of the law was unambiguous – to save as many lives as possible. It is equally clear that the law is not currently being followed.

In direct contravention of the law, the allocation of deceased donor organs is currently highly dependent on where a candidate lives. Indeed, one's place of residence or place of listing is the single largest determining

factor in a candidate's likelihood of survival. *Cruz* Complaint ¶ 88 and Exhibit M thereto. As a result, Congress' effort to save lives has been thwarted and people who could be saved are dying needlessly.

Livers from deceased donors are portable and can be safely preserved for up to 12 hours. *Cruz* Complaint ¶ 73. Livers from California and Arizona can be and have been successfully transplanted in New York, and livers from Virginia and New York have been successfully transplanted in California, Utah, and Texas. Despite the portability of livers, Movants who are registered for liver transplants in California and New York will likely need to wait several years for a transplant, while less-sick candidates 500 or 1,000 miles away will receive transplants in several weeks or months. This disparity results in the death of many waitlist candidates and is the direct result of the current illegal and inequitable liver allocation policy.

The illegality of the current allocation policy has been well recognized by all parties. Notwithstanding the illegality and inequity of the current liver allocation policy, the current and illegal system has been in place for the last two decades.

The medical priority of an adult liver transplant candidate is measured using a MELD score (Model for End-Stage Liver Disease). MELD is a numerical scale, ranging from 6 (least ill) to 40 (gravely ill), that measures

how urgently a candidate needs a liver transplant within the next three months. A candidate's MELD score is an objective measure of medical need, reflecting the urgency with which the candidate needs a transplant. Without a liver transplant, candidates with a MELD score of 35 or higher have a less than 50% chance of surviving three months while candidates with a MELD score of 20 have an over 90% three-month survival rate. Candidates with a life expectancy of less than seven days are given Status 1A priority.

Defendant, the United States Department of Health and Human Services (HHS) operates the nation's Organ Procurement and Transplantation Network (OPTN) through a contract with Defendant United Network for Organ Sharing (UNOS). The OPTN has 58 Organ Procurement Organizations (OPOs) throughout the United States. OPOs are responsible for procuring deceased donor organs for transplantation and each OPO operates in an arbitrarily-determined geographic area called a Donation Service Area (DSA). The 58 DSAs are further grouped into 11 regions (Regions).

The size and scope of the DSAs and Regions bear no relationship to population, geography, transportation logistics or medical need. Some DSAs are 1,000 miles wide while others are less than 100 miles wide. Some DSAs have populations as small as 1.4 million, others as large as 20 million.

Similarly, one of the 11 Regions contains only two OPOs with a total population of 14 million, while another contains 10 OPOs with a population of 49 million or more.

Current OPTN policy – which Plaintiffs' ask this Court to keep in place – allocates livers by MELD score within the DSA or Region before being offered nationally. When a liver becomes available, it must first be made available to candidates within the arbitrary boundaries of the donor's Region with priority status 1A. The liver is then made available to candidates in the donor's DSA and Region with a MELD score of 40, then 39, then 38 and so on until MELD score 15. Only if there are no matching candidates in the DSA or Region with a MELD score of 15 or more is the liver offered nationally.

Given the admittedly arbitrary nature of the DSAs' and Regions' geographic area, the candidate receiving the liver may be both less sick and geographically further away from the donated liver than a candidate with higher medical priority.

The illegality of the current policy has been exploited by transplant centers, like Plaintiffs, to shorten their wait times and encourage those with financial resources to engage in domestic transplant tourism. Unfortunately, for liver waitlist candidate around the country, the current policy is often

fatally flawed because they do not have the financial means to move to areas of the country with shorter wait times.

Over the last three decades much discussion has been had and many studies have been conducted but the OPTN's institutional paralysis, fostered by Plaintiffs, has prevented it from implementing a liver policy that complies with the legislative mandate of nationwide – not "local first" – organ distribution.

3. The *Cruz* Action

In November 2017, litigation was commenced by a lung transplant candidate challenging the use of DSAs and Regions in lung allocation. *Holman v. U.S. Dept. of Health and Human Services* (S.D.N.Y. 17-CV-9041). Within days the OPTN Executive Committee made emergency changes to remove the use of DSAs in lung allocation.

Following the *Holman* matter, in May 2018, a formal challenge to the current liver allocation policy was made in the form of a critical comment to the Secretary of HHS. *Callahan* Complaint Ex. 7. That challenge was followed by the filing of the *Cruz* Action on July 16, 2018, on behalf of six individuals on the liver transplant waitlist in California, Massachusetts, and New York. *Cruz* Complaint. The *Cruz* Action maintained that the current

liver allocation policy is illegal because it is based on arbitrary geographic boundaries in direct contravention of NOTA. *Id.*

As a direct result of the *Cruz* Action, HHS, OPTN and UNOS undertook a formal review of the current liver allocation policy, which resulted in a July 31, 2018 direction from the Secretary of HHS that "the OPTN has not justified and cannot justify" current liver policy and must revise the policy by December 2018. *Callahan* Complaint Ex. 7. The illegality of the current policy has also been recognized by Plaintiffs who commented on November 1, 2019 that they "appreciate the criticisms against DSAs."[1]

The new liver policy was passed by a supermajority of the OPTN Board of Directors on December 3, 2018, and scheduled to be implemented on April 30, 2019. Judge Torres agreed to maintain the *Cruz* Action pending implementation of the new liver policy on April 30, 2019.

The *Cruz* Action specifically sought a declaration that OPTN liver distribution policy based on arbitrarily-drawn DSAs or Regions violates

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[1] Public comment of Indiana University Health; The University of Kansas Health System; Vanderbilt University Medical Center; Washington University in St. Louis/Barnes-Jewish Hospital Transplant Center, 11/01/2018. Accessible at: https://optn.transplant.hrsa.gov/governance/public-comment/liver-and-intestine-distribution-using-distance-from-donor-hospital/. (Last accessed on April 25, 2019.)

NOTA. Movants thus have a clear interest in the outcome of this lawsuit as the policy that Plaintiffs advocate remain in place is a policy based entirely on arbitrarily-drawn DSAs or Regions in direct violation of NOTA.

4. Plaintiff's Motion to Intervene in the *Cruz* Action

On July 17, 2018, Plaintiff, University of Kansas Hospital Authority, filed a motion to intervene in the *Cruz* Action claiming intervention as of right under FRCP 24 because, among other things, it was necessary to "present this Court with a fuller development of the underlying factual issues in this action at a local and national level, to lead to a just and equitable adjudication of the matter at hand." *Cruz* Action, Doc. No. 9 at. 2. The *Cruz* plaintiffs did not oppose the University of Kansas Hospital Authority's motion to intervene. Instead, nearly two months after the April 2019 Policy was approved by the OPTN Board of Directors, and presumably in anticipation of this litigation, the University of Kansas Hospital Authority withdrew its motion to intervene in the *Cruz* matter.

## ARGUMENT

### I. Movants Are Entitled to Intervention as a Matter of Right.

A party seeking intervention as a matter of right under Fed. R. Civ. P. 24(a) must demonstrate that: "(1) his application to intervene is timely; (2) he has an interest relating to the property or transaction which is the subject

of the action; (3) he is so situated that disposition of the action, as a practical matter, may impede or impair his ability to protect that interest; and (4) his interest is represented inadequately by the existing parties to the suit." *Stone v. First Union Corp.*, 371 F.3d 1305, 1308 (11th Cir. 2004) (quoting *Worlds v. Dept. of Health and Rehabilitative Servs.,* 929 F.2d 591, 593 (11th Cir.1991). Movants satisfy all of these factors.

A. The Movants' Application is Timely

When considering whether a motion to intervene is timely, courts consider several factors:

> (1) the length of time during which the proposed intervenor knew or reasonably should have known of the interest in the case before moving to intervene; (2) the extent of prejudice to the existing parties as a result of the proposed intervenor's failure to move for intervention as soon as it knew or reasonably should have known of its interest; (3) the extent of prejudice to the proposed intervenor if the motion is denied; and (4) the existence of unusual circumstances militating either for or against a determination that their motion was timely.

*Georgia v. U.S. Army Corps of Engineers*, 302 F.3d 1242, 1259 ("*U.S. Army Corps*") (11th Cir. 2002). Movants' motion is unquestionably timely.

Only two days passed between Movants' learning of this case and the filing of this motion to intervene. This case was filed on Monday, April 22, 2019. Although Movant's engaged with Plaintiffs even before the filing of the Complaint, and specifically requested to be informed of the filing, Plaintiffs

affirmatively refused to inform Movants of the filing. Notwithstanding, Movants immediately sought leave to appear at the telephonic conference scheduled for Wednesday, April 24, 2019, attended that conference, and filed this emergency motion to intervene the next day.

B. The Movants Have a Direct, Substantial, and Legally Protectable Interest in this Matter That Will Be Impaired if Plaintiffs Are Granted the Relief They Seek

"[A] party is entitled to intervention as a matter of right if the party's interest in the subject matter of the litigation is direct, substantial and legally protectable." *U.S. Army Corps*, 302 F.3d at 1249. This is a flexible inquiry. *Chiles v. Thornburgh*, 865 F.2d 1197, 1215 (11th Cir. 1989).

Movants, who are patients awaiting liver transplants, will be directly affected by the failure to implement the new liver allocation policy. Without the implementation of the April 2019 Policy, Movants will be subjected to an illegal liver allocation policy and stand a lower likelihood of receiving an organ for transplant and thus surviving. Plaintiffs have acknowledged that this kind of bodily harm is precisely the kind that merits intervention as of right. *Cruz* Action, ECF No. 9, at 8.

Additionally, courts have found that participation in the process leading to the challenged agency action is a factor in establishing the prospective intervenor's interest in the action. *See, e.g.*, *Idaho Farm Bureau*

*Fed'n v. Babbitt*, 58 F.3d 1392, 1398 (9th Cir. 1995) (allowing intervention in an action challenging the legality of a measure the proposed intervenor had supported). Here, Movants should be entitled to intervene in this matter since it was, at least in part, the filing of the *Cruz* Action that led to the development of the new liver allocation policy to which Plaintiffs object. Indeed, after not having gotten their way in connection with that earlier action, Plaintiffs have filed this case in an effort to override the decision of the OPTN Board of Directors and preserve an illegal liver allocation policy that suits their business interests.

C. The Movants' Interests Are Not Adequately Protected by the Parties to this Action

Where a proposed intervenor's interests may not be adequately represented by the existing parties, it may intervene as a matter of right. The burden associated with showing that a proposed intervenor's interests are not adequately protected by the parties "should be treated as minimal" and will be "satisfied if the [proposed intervenor] shows that representation of his interest 'may be' inadequate." *Chiles v. Thornburgh*, 865 F.2d 1197, 1214 (11th Cir. 1989) (quoting *Trbovich v. United Mine Workers of America,* 404 U.S. 528, 538 n. 10, 92 S.Ct. 630, 636 n. 10, 30 L.Ed.2d 686 (1972)).

Here, although Movants and Defendants share an interest in implementing the April 2019 Policy, their interests are not perfectly aligned. As evidenced by the April 24, 2019 telephonic conference, Defendants have both institutional and procedural concerns that may implicate the manner in which approach the defense of this case. Movants have a single interest: To change the current, illegal liver allocation policy to the legal liver allocation policy. In the *Cruz* Action, Movants had to sue Defendants with regard to this very issue and have every interest in asserting the illegality of the current liver policy – the very policy that Plaintiffs seek to continue – in this case. Further, courts have noted that "The fact that the interests are similar does not mean that approaches to litigation will be the same." *Id*.

**II. Alternatively, the Court Should Permit Movants to Intervene.**

Rule 24(b)(1)(B) provides that, upon timely motion, a court may provide for permissive intervention to applications who have "a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1). When exercising this discretion, "the court must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(3). This Court has previously outlined that:

> the determination of whether permissive intervention is proper in a case is a two-step process. The court must first determine whether the applicant's claim or defense and the main action share common questions of law or fact. If this requirement is fulfilled the court must exercise its discretion in determining whether intervention should be allowed.

*Georgia Aquarium, Inc. v. Pritzker*, 309 F.R.D. 680, 690 (N.D. Ga. 2014). The intervenor need not have "direct personal or pecuniary interest in the subject of the litigation" but "must demonstrate more than a general interest in the subject matter of the litigation before permissive intervention is allowed." *Id.* (citing *In re Estelle,* 516 F.2d 480, 485 (5th Cir. 1975)). The circumstances in this case counsel the same result.

First, Movants' claims contain common questions and law and fact as those raised by this case. Specifically, Movants have an interest in whether the April 2019 Policy will be implemented and whether the current, illegal policy will be changed.

Second, Movants have a significant interest in the subject matter of this litigation. Just as in *Georgia Aquarium*, Movants are not merely asserting a "generalized interest" in the subject matter of this litigation. *Georgia Aquarium,* 309 F.R.D. at 691. Rather, Movants were instrumental in convincing Defendants that the current liver allocation policy is illegal and must be changed. That Plaintiffs now seek to undo that effort and

undermine the work of Defendants to implement a new legal liver policy counsels heavily in favor of allowing intervention, especially where, as here, "allowing intervention by Movants will not unduly delay or prejudice the adjudication of [Plaintiffs'] claims as this litigation is in a relatively nascent stage and none of the deadlines approved in the [] Scheduling Order have passed." *Id.*

## III. Movants Have Shown Good Cause for Emergency Relief.

Under Local Civil Rule 7.2, a "Court may waive the time requirements of this rule and grant an immediate hearing on any matter requiring such expedited procedure" upon a showing of good cause. As has already been outlined above, a new liver allocation policy was set to go into effect on April 30, 2019. Due to Plaintiffs' motion for a temporary restraining order at the "11th hour plus fifty-nine minutes," that implementation date has already been pushed back to May 8, 2019 at the earliest. *See* Transcript of the April 24, 2019 Hr'g before Hon. Amy Totenberg, at 6:8; Order (ECF No. 16), at 2. This Court has set a hearing on Plaintiffs' temporary restraining order for May 7, 2019, and under the current Order, Defendants are required to submit briefs in opposition to Plaintiffs' motion by May 1, 2019. To allow Movants adequate opportunity to participate in the May 7 hearing and submit opposition papers in connection therewith, it is imperative that

Movants' motion to intervene is resolved on an emergency basis. In the absence thereof, Movants will have to rely on the Defendants to adequately represent their interests, which as set forth above, they may not do. While certainly HHS and UNOS have the interests of patients in mind, they are not themselves facing imminent harm due to the failure to implement the new liver allocation policy. *See* Section I.C., *supra*. On that basis, Movants have demonstrated good cause that this motion to intervene should be resolved on an expedited basis and in favor of intervention.

## CONCLUSION

Having demonstrated good cause consistent with Local Civil Rule 7.2(B), Movants respectfully request that the Court waive the ordinary time requirements for motion practice, grant an immediate hearing on this Emergency Motion to Intervene, and permit Movants to participate fully as defendants to this action for the reasons set forth above.

Respectfully submitted,

Dated: April 25, 2019

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**CERTIFICATE OF SERVICE**

I hereby certify that I electronically filed the foregoing MEMORANDUM OF LAW IN SUPPORT OF PROPOSED INTERVENOR-DEFENDANTS' EMERGENCY MOTION TO INTERVENE, with the Clerk of the Court using the CM/ECF system which will automatically send email notifications of such filing to all attorneys of record.

Dated: April 25, 2019

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**CERTIFICATION OF FONT**

This certifies that pursuant to LR 5.1, N.D. Ga., the above and foregoing MEMORANDUM OF LAW IN SUPPORT OF PROPOSED INTERVENOR-DEFENDANTS' EMERGENCY MOTION TO INTERVENE, has been prepared using Century Schoolbook font, 13 point.

Dated: April 25, 2019

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