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

RANDALL CALLAHAN, *et al.*,	:	
Plaintiffs,	:	
v.	:	
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,	:	CIVIL ACTION NO. 1:19-CV-1783-AT
Defendants.	:	

ORDER

Plaintiffs, Randall Callahan, Katryna Grisson, Candice Seaman and Michael Wingate (the "Patient Plaintiffs") along with Emory University, Henry Ford Health System, Indiana University Health, Oregon Health and Science University, Piedmont Healthcare, The Rector and Visitors of the University of Virginia, The Regents of the University of Michigan, Saint Luke's Hospital of Kansas City, University of Iowa, University of Kansas Hospital Authority, University of Kentucky, Vanderbilt University Medical Center, Virginia Commonwealth University Health System Authority, The Washington University, and Barnes-Jewish Hospital (the "Transplant Center Plaintiffs") (collectively, the "Plaintiffs") filed the instant action against Defendants, the United States

Department of Health and Human Services ("HHS") and United Network for Organ Sharing ("UNOS") (collectively, the "Defendants")[1] alleging that "HHS has failed to follow legally-required procedures in developing the [April 2019 liver allocation] policy, instead choosing to defer virtually all decision-making to a private government contractor, [UNOS], acting in its capacity as the Organ Procurement and Transplantation Network" and that "these actions violate the Administrative Procedure Act [5 U.S.C. Section 706(1), (2)] as well as the Due Process Clause of the Fifth Amendment." *See* Complaint ("Compl") (Doc. 1). Plaintiffs request that the Court find that the April 2019 Policy is violative of the National Organ Transplant Act ("NOTA") along with the regulations promulgated thereunder as well as the Due Process Clause of the Fifth Amendment of the U.S. Constitution. On this basis, Plaintiffs ask the Court to enjoin the April 2019 Policy from being implemented or otherwise taking effect. *Id*. (Prayer for Relief).

Presently before the Court is Plaintiffs' Motion for a Temporary Restraining Order.[2] [Doc. 2]. Plaintiffs "seek an Order from this Court temporarily restraining and enjoining Defendants . . . from implementing [the

[1] "Defendants" as used throughout this Order shall also include Intervenor-Defendants Susan Jackson and Charles Bennett. *See* (Doc. 38, granting motion to intervene). Intervenor-Defendants here are Plaintiffs in a similar lawsuit filed in the Southern District of New York – but they take an opposing view to the Plaintiffs here regarding the merits of the new allocation policy at issue which their legal filings helped to trigger. *See Cruz et al. v. U.S. Dep't of Health and Human Servs. et al.*, No. 18-cv-6371. Based upon administrative actions taken by HHS, the Organ Procurement and Transplantation Network and UNOS following the filing of the instant lawsuit, the *Cruz* action was subsequently stayed pending implementation of the April 2019 Policy, which is the subject of the instant litigation. *See id*.

[2] The Court construes the motion as also requesting a preliminary injunction in accordance with Fed. R. Civ. P. 65.

April 2019 liver allocation policy] . . . or changing the current policy until the Court has ruled on the merits of Plaintiffs' claims." (Doc. 2). According to Plaintiffs, emergency relief is warranted here given that "[a]bsent the Court's intervention, hundreds of liver transplant patients will needlessly die as livers are misdirected and left to languish rather than put to the use intended by their generous donors" and, as a result, "Plaintiffs, including patients waiting for liver transplants, will be subject to irreparable harm and have no adequate remedy at law." *Id*. Defendants oppose the motion in all respects.

In light of the emergency nature of the issues raised in Plaintiffs' motion, the Court held a preliminary conference call with all parties on April 24, 2019. (Doc. 14). Following this telephone conference, the Defendants notified the Court that the liver allocation policy which was scheduled to go into effect on April 30, 2019 would be "postponed until May 14, 2019." (Doc. 15). Following this information, the Court promptly ordered full briefing on the motion. (Doc. 16). Thereafter, on May 7, 2019, the Court held a full-day hearing in order to obtain further clarity and amplification of all relevant issues pertaining to Plaintiffs' motion. (Doc. 63). Following the hearing, the parties were provided with the opportunity to provide supplemental materials to the Court for review, so long as those materials were filed not later than May 8, 2019. *See* (Doc. 66-68) (parties' respective supplemental authority filings). In light of the May 7, 2019 hearing date and given the revised implementation date of the April 2019 liver allocation policy, *see* (Doc. 15), this left the Court with approximately seven (7)

calendar days to reach a decision as to Plaintiffs' motion—which encompasses a wide range of complex scientific subject matter and thorny legal issues.

On May 13, 2019, the Court held a follow-up conference call with all parties in order to ascertain the parties' views as to the implication of an imminent Supreme Court decision in the case of *Kisor v. Wilkie*, No. 18-15, 139 S. Ct. 657 (2018) (Supreme Court's Order granting certiorari) in light of the fact that neither party had discussed or even alluded to the significance of this case to the instant motion either in their briefs or during the May 7, 2019 hearing. Specifically, the Court voiced its concerns that as to the issue of "deference" to an agency's interpretation of its own regulations, as is generally warranted under *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945) and *Auer v. Robbins*, 519 U.S. 452 (1997), there is the potential that this bedrock principle may undergo a significant change both in scope and application in light of the issues raised in the *Kisor* case. Indeed, the Department of Justice argued for modification of established administrative deference principles in its own brief in *Kisor*, filed in the Supreme Court in February 2019. (DOJ Brief attached to Plaintiffs' supplemental filing as Doc. 66-1.) Despite the Court's serious concerns, Defendants' remained steadfast concerning: (1) the high level of deference that should be accorded to HHS here; (2) the minimal impact that *Kisor* would have on their litigating position as to the deference issue; and (3) their unwillingness to move the May 14, 2019 implementation date to a date after the Supreme Court's likely issuance of a decision in *Kisor* in June. For this

reason, the Court is now forced to potentially wade into an area of administrative law (on a preliminary basis) that may see a significant shift in the very near future.

Given the current procedural landscape, the Court is issuing this short Order so as to render a timely decision on Plaintiffs' motion prior to the May 14, 2019 implementation date of the liver allocation policy. However, the Court will issue a detailed and far more extensive decision on the issues before it in the days to come.

The Court conducted: (1) an assiduous review of the parties' briefs, the voluminous materials submitted both in support of and in opposition to the motion and prevailing case law; and (2) a full-day hearing concerning Plaintiffs' motion, which further amplified the parties' positions and crystalized the relevant issues. While appreciating the gravity and seriousness of the subject matter and issues presented in Plaintiffs' motion, the Court finds that Plaintiffs' request seeking a TRO and preliminary injunctive relief [Doc. 2] must be **DENIED** at this time.

The standard for obtaining a temporary restraining order ("TRO") is identical to that of obtaining a preliminary injunction. *Windsor v. United States*, 379 F. App'x 912, 916-17 (11th Cir. 2010). "To support a preliminary injunction, a district court need not find that the evidence positively guarantees a final verdict in plaintiff's favor." *Levi Strauss & Co. v. Sunrise Int'l Trading Inc.*, 51 F.3d 982, 985 (11th Cir. 1995). Instead, it must determine whether the evidence

establishes: (1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable injury if the injunction were not granted; (3) that the threatened injury to the plaintiff outweighs the harm an injunction may cause the defendant; and (4) that granting the injunction would not be adverse to the public interest. *McDonald's Corp. v. Robertson*, 147 F.3d 1301, 1306 (11th Cir. 1998). At the preliminary injunction stage, a district court may rely on affidavits and hearsay materials which would not be admissible evidence for a permanent injunction, if the evidence is "appropriate given the character and objectives of the injunctive proceeding." *Levi Strauss & Co.*, 51 F.3d at 985 (quoting *Asseo v. Pan American Grain Co.*, 805 F.2d 23, 26 (1st Cir. 1986)). *McDonald's Corp. v. Robertson*, 147 F.3d 1301, 1306 (11th Cir. 1998). "A request for equitable relief invokes the district court's inherent equitable powers to order preliminary relief . . . in order to assure the availability of permanent relief." *Levi Strauss & Co.*, 51 F.3d at 987; *Federal Trade Commission v. United States Oil and Gas Corp.*, 748 F.2d 1431, 1433–34 (11th Cir. 1984) (district court may exercise its full range of equitable powers, including a preliminary asset freeze, to ensure that permanent equitable relief will be possible). However, a preliminary injunction "is an extraordinary and drastic remedy not to be granted unless the movant clearly established the 'burden of persuasion' as to the four prerequisites." *McDonald's Corp.*, 147 F.3d at 1306 (internal citations omitted). Significantly, in this Circuit, "a finding of substantial likelihood of success on the merits [is required] before injunctive relief may be provided . . . [and] we have held on occasion that when a

plaintiff fails to establish a substantial likelihood of success on the merits, a court does not need to even consider the remaining three prerequisites of a preliminary injunction." *Pittman v. Cole*, 267 F.3d 1269, 1292 (11th Cir. 2001); *Bloedorn v. Grube*, 631 F.3d 1218, 1229 (11th Cir. 2011) ("If Bloedorn is unable to show a substantial likelihood of success on the merits, we need not consider the other requirements.").

To begin, the Court states up front that it does not enter into this decision lightly and otherwise harbors serious reservations concerning Defendants' position with respect to the level of deference which should be applied here under the guiding principles contained in *Seminole Rock* and *Auer*. The deference to which the Court refers here is solely limited to HHS' interpretation of its own procedural review regulation—specifically 42 C.F.R. Section 121.4(b)(2), which concerns Organ Procurement and Transplantation Network Policies, including Secretarial review and appeals.[3]

Indeed, HHS argues that it is entitled to substantial deference given its "'reasonable, *consistently held* interpretation of its own regulation.'" (Doc. 34 at 17-18) (quoting *INS v. Nat'l Ctr. For Immigrants' Rights, Inc.*, 502 U.S. 183, 189-90 (1991)) (emphasis in original). The "consistently held interpretation" to which HHS refers is its stance that the regulatory review procedures encompassed within 42 C.F.R. 121.4(b)(2) apply only to those policies which OPTN, a private non-profit contractor, recommends to be enforceable under Section 1138 of the

[3] The regulatory process and review question at issue here does not encompass the merits of the allocation policy that the parties also dispute.

Social Security Act and that no organ allocation policy ever recommended by OPTN as adopted and implemented by HHS has ever been recommended to be enforceable. *See* (Doc. 34 at 15-18); Dammons Decl. ¶ 21. However, in order to prop up its position, HHS relies exclusively on: (1) the argument asserted in its opposition brief (Doc. 34); (2) a *post-hoc* Declaration from Cheryl Dammons (Doc. 34-15), Associate Administrator of the Healthcare Systems Bureau with the Health Resources Services Administration, filed on May 1, 2019; and (3) the August 31, 2011 Declaration of Joyce Somsak Associate Administrator of the Healthcare Systems Bureau with the Health Resources Services Administration in an entirely different criminal case context. (Doc. 68-2).[4] After reviewing these three items—none of which are entirely persuasive—the Court is somewhat skeptical that the deference advocated for by HHS is warranted here—especially if the regulatory language at issue is otherwise clear on its face and would otherwise warrant a contrary reading than that espoused by HHS.

After undertaking a searching review of the National Organ and Transplant Act, 42 U.S.C. Section 273 *et seq*., the regulatory language contained in 42 C.F.R. Section 121.4(b)(2), in conjunction with a dissection of 63 Federal Register 16296-16338 (final rule governing operation of OPTN) as well as 64 Federal

[4] The Somsak Declaration was not submitted to the Court as part of the initial briefing in this matter nor was it proffered at the hearing. Rather, this document was submitted in conjunction with HHS' supplemental authority submission. While the Court did not expressly authorize supplementing the evidentiary record, at this preliminary stage, the Court will consider this document to the extent it bears upon the question of "deference." However, the Court may decline to consider this document during a full merits inquiry, should the case proceed to that point.

Register 56650-56661 (setting forth "improvement to the final rule governing operation of the [OPTN], published in 1998" based upon the "advice of a panel convened by the National Academy of Science's Institute of Medicine"), the Court concludes that Defendants' proffered reading of the regulation is difficult to reconcile with various pronouncements in the 1999 Federal Register regarding the overarching intent and requirements of the provisions of the regulation (the "Final Rule"). Despite the Court's significant doubts regarding Defendants' regulatory construction, it recognizes that the language of the Final Rule, when construed with deference to HHS, is open to more than one meaning. Upon conducting its in depth review, the Court is left with the distinct possibility that the 42 C.F.R. Section 121.4(b)(2) is susceptible to two interpretations, one of which, supports, at least minimally, HHS' view as to when the formal procedures contemplated in Section (b)(2) are required to be utilized. *See* 42 C.F.R. § 121.4(b)(2); (*Compare* Doc. 34 at 15-18 [HHS' Opposition Brief], discussing why the more robust procedures set forth in the regulation were not required *with* 64 Fed. Reg. 56650, discussing Congressional intervention after announcement of 1998 Final Rule to ensure greater HHS capacity and engagement in review of organ allocation policies in the 1999 Final Rule).

While the Court has serious reservations that HHS' interpretation does not constitute the best reading of the regulation, especially in light of certain relevant language in the 1999 Federal Register, "[i]t is well established that an agency's interpretation need not be the only possible reading of a regulation—or even the

best one—to prevail. When an agency interprets its own regulation, the Court, as a general rule, defers to it unless that interpretation is plainly erroneous or inconsistent with the regulation." *Decker v. Nw. Envtl. Def. Ctr.*, 568 U.S. 597, 613, 133 S. Ct. 1326, 1337, 185 L. Ed. 2d 447 (2013) (internal quotations and citation omitted); *see Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155, 132 S. Ct. 2156, 2166, 183 L. Ed. 2d 153 (2012). Similarly, such deference is equally due even when the agency's interpretation "is advanced in a legal brief." *Id.*; *Chase Bank USA, N.A. v. McCoy*, 562 U.S. 195, 208, 131 S. Ct. 871, 880, 178 L. Ed. 2d 716 (2011) ("[W]e defer to an agency's interpretation of its own regulation, advanced in a legal brief, unless that interpretation is plainly erroneous or inconsistent with the regulation.").[5]

As such, based upon the information presently in front of the Court and in light of the current state of the law, *see Seminole Rock* and *Auer*, the Court has little choice at this preliminary stage but to accord HHS' interpretation (*i.e.*, that the more robust procedures called for in Section (b)(2) are required only in the event OPTN recommends to the Secretary that a policy be "enforceable") with substantial deference. The Court stresses that while Plaintiffs' have, at present, a

[5] The Court points out that in both *Christopher* and *Chase Bank* the agency's regulatory interpretation was submitted in an *amicus* brief on the part of the agency. Here of course, the landscape is quite different since HHS is a defendant in this action and not just an interested observer. Nevertheless, the Supreme Court has not yet cabined this rule to include only those briefs submitted by *amici* and the Court declines to read in such a limitation. Moreover, at this early stage of the litigation, the Court is not entirely convinced that "[t]he Secretary's position is . . . a '*post hoc* rationalizatio[n]' advanced by an agency seeking to defend past agency action against attack." *Chase Bank USA, N.A.*, 562 U.S. at 209, 131 S. Ct. at 881, 178 L. Ed. 2d 716. Indeed, there is at least some indication that HHS has never utilized the more formal procedures outlined in Section (b)(2) in conjunction with adopting and implementing an organ allocation policy. *See* Dammons Decl. ¶ 21.

high mountain to climb in terms of ultimately prevailing on the merits based upon this particular legal theory, it is entirely possible that, in short order, there may be a substantial change in deference jurisprudence as relates to agency interpretations of regulations. In such a case, the landscape may shift in Plaintiffs' favor based upon the Supreme Court decision in *Kisor*. Or not.

Based upon the above threshold legal analysis, the Court denies Plaintiffs' request for preliminary injunctive relief at this time, even if some of the other emergency injunctive relief standards indeed might warrant the Court's issuance of an injunction to maintain the current liver allocation policy pending further review of this matter. The Court remains deeply concerned that the Government's decision to proceed at this juncture — when the Supreme Court's decision in *Kisor* is imminent and the record here bears some real peculiarities and problems — may itself cause disruption in equitable and efficient liver transplant administration and allocation down the line. But that is for another day now. The Court will issue its more detailed decision in the interim, and this case will continue to proceed in litigation on the merits if Plaintiffs choose to pursue it further. Accordingly, Plaintiffs' Motion for a Temporary Restraining Order [Doc. 2] is **DENIED**.

IT IS SO ORDERED this 13th day of May, 2019.

AMY TOTENBERG
UNITED STATES DISTRICT JUDGE