No. 21-1589

In The

United States Court of Appeals for the Eighth Circuit

ADVENTIST HEALTH SYSTEM/SUNBELT, INC., doing business as ADVENTHEALTH ORLANDO; BOARD OF TRUSTEES OF THE UNIVERSITY OF ALABAMA, on behalf of UNIVERSITY OF ALABAMA HOSPITAL; MEDICAL UNIVERSITY HOSPITAL AUTHORITY; UNIVERSITY OF IOWA; UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, a body politic and corporate and an independent instrumentality of the State of Kansas; UNIVERSITY OF KENTUCKY; ALEXANDER BERRIOS, JR.,

Plaintiffs-Appellants,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Secretary, XAVIER BECERRA; HEALTH RESOURCES AND SERVICES ADMINISTRATION, Acting Administrator, DIANA ESPINOSA; UNITED NETWORK FOR ORGAN SHARING,

Defendants-Appellees.

On Appeal from the Southern District of Iowa,
Case No. 3:20-cv-00101-SMR-SBJ

BRIEF FOR APPELLANTS

Glenn L. Krinsky
JONES DAY
555 South Flower Street, 50th Floor
Los Angeles, CA 90071
Telephone: 1.213.243.2540
Facsimile: 1.213.243.2539
glkrinsky@jonesday.com

Michael A. Carvin
Yaakov M. Roth
JONES DAY
51 Louisiana Avenue, NW
Washington, DC 20001
Telephone: 1.202.879.3939
Facsimile: 1.202.626.1700
macarvin@jonesday.com
yroth@jonesday.com

Counsel for Appellants
(additional counsel on inside cover)

Peter C. Canfield
JONES DAY
1420 Peachtree Street, N.E., Suite 800
Atlanta, GA 30309
Telephone: 1.404.521.3939
Facsimile: 1.404.581.8330
pcanfield@jonesday.com

Courtney A. Carrell
Kelsey L. Smith
JONES DAY
2727 North Harwood Street
Dallas, TX 75201
Telephone: 1.214.969.3939
Facsimile: 1.214.969.5100
ccarrell@jonesday.com
ksmith@jonesday.com

Stephen H. Locher
Ryan G. Koopmans
BELIN MCCORMICK, P.C.
666 Walnut Street, Suite 2000
Des Moines, IA 50309
Telephone: 1.515.283.4610
Facsimile: 1.515.558.0610
shlocher@belinmccormick.com
rkoopmans@belinmccormick.com

Counsel for Appellants

SUMMARY OF THE CASE

This expedited appeal challenges a new policy governing the allocation of donated kidneys. Known as the Fixed Circle Policy, the new policy recklessly and unreasonably abandons the system that has governed kidney allocation for thirty years. It was adopted by a non-profit entity, Defendant-Appellee United Network for Organ Sharing ("UNOS"), and ratified by Defendant-Appellee U.S. Department of Health and Human Services ("HHS"). Plaintiffs-Appellants are hospitals whose operations and patients will be disadvantaged by the policy change ("the Hospitals"), joined by an exemplar patient on the kidney waiting list (Mr. Berrios). Plaintiffs sought to preliminarily enjoin implementation of the policy, but the district court denied relief.

This Court should reverse. Plaintiffs' challenge is likely to succeed because the new policy suffers from fatal procedural and substantive flaws. Procedurally, the policy is a "significant" one that HHS was required by its own regulations to refer to an advisory committee and publish for public comment. Yet the agency did neither. Substantively, the policy is arbitrary and capricious, because Defendants' own modeling—and real experience with other organs—shows that the Fixed Circle Policy will *reduce* the number of successful transplants. Yet the policy was rushed through on the now-contradicted premise that the existing regime could not be justified on any grounds. In this context, preserving the longstanding status quo will not only prevent irreparable harm to the Hospitals and their patients but also demonstrably advance the public interest.

Plaintiffs believe oral argument of 20 minutes per side would benefit the Court.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, Appellants submit the following statement:

Appellants are governmental entities or natural persons except for Adventist Health System/Sunbelt, Inc. d/b/a AdventHealth Orlando. Adventist Health System Sunbelt Healthcare Corporation is the sole member of the nonprofit corporation Appellant Adventist Health System/Sunbelt, Inc. No publicly held corporation owns 10% or more of the stock of Adventist Health System/Sunbelt, Inc.

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JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. § 1331. It denied a preliminary injunction on March 12, 2021. Add.1. Plaintiffs timely noticed an appeal on March 14, 2021. ECF 86. This Court has jurisdiction under 28 U.S.C. § 1292(a)(1).

STATEMENT OF ISSUES

I. Did the district court legally err by concluding that Plaintiffs had not made a sufficient showing on the merits of their Administrative Procedure Act ("APA") challenges to the Fixed Circle Policy? 42 C.F.R. § 121.4(b); *id.* § 121.8; 5 U.S.C. § 706; *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983).

II. Did the court also err by concluding that Plaintiffs had not shown irreparable harm and that the balance of equities did not favor an injunction? *Kai v. Ross*, 336 F.3d 650 (8th Cir. 2003); *Kroupa v. Nielsen*, 731 F.3d 813 (8th Cir. 2013).

STATEMENT OF THE CASE

I. STATUTORY AND REGULATORY BACKGROUND.

Enacted in 1984, the National Organ Transplant Act established a framework for regulation of the then-new field of transplant medicine. The Act directed creation of the Organ Procurement and Transplantation Network ("OPTN") to establish medical criteria for distributing organs, set up a national computer system to match donors with patients, and generally coordinate organ donations and transplants. 42 U.S.C. § 274(b). Defendant UNOS has operated the OPTN under a contract with Defendant HHS's Health Resources Services Administration ("HRSA") since 1986. A.23.

Under the Act, HHS is to exercise oversight over the OPTN, including by reviewing "critical comments" relating to how the OPTN is carrying out its duties. 42 U.S.C. § 274(c). HHS has promulgated detailed regulations governing the OPTN's operations and the agency's oversight functions. *See* 42 C.F.R. pt. 121. This collection of regulatory provisions is commonly known as the "Final Rule."

At issue in this appeal are two related parts of the Final Rule. Section 121.4 (titled "OPTN policies: Secretarial review and appeals") sets forth in general terms the process by which the OPTN must develop policies and the manner in which HHS reviews them. Section 121.8 (called "Allocation of organs") is addressed specifically to organ allocation policies, the most fundamental policies that the OPTN develops. This case involves Defendants' construction and application of those provisions.

A. Starting with § 121.4, the regulation begins in subsection (a) by empowering the OPTN to develop policies in a series of enumerated areas. 42 C.F.R. § 121.4(a)(1)-(6). Reflecting its primary importance, the first category of policies that the OPTN must develop is for "equitable allocation of cadaveric organs in accordance with § 121.8." *Id.* § 121.4(a)(1). The latter are known as organ allocation policies. The OPTN must also develop policies relating to, among other things, training of transplant surgeons and a system for nominating its own members and officers. *See id.* § 121.4(a)(4), (5). Under a catch-all provision, *id.* § 121.4(a)(6), the OPTN has also developed policies on more mundane and ministerial topics, like travel expense reimbursements and protocols for data submission. *See* ECF 58-1 at 321, 332.

Subsection (b) governs the *process* for adopting these policies. The OPTN must provide its members and other interested parties with an opportunity for comment. 42 C.F.R. § 121.4(b)(1). In addition, the OPTN must provide two types of policies to HHS "at least 60 days prior to their proposed implementation" to allow for agency review. *Id.* § 121.4(b)(2). *First*, that requirement applies to policies the OPTN "recommends to be enforceable," meaning non-compliance could result in termination of the hospital's Medicare or Medicaid participation. *See id.*; *id.* § 121.10(c). *Second*, the OPTN must also provide to HHS its proposed policies "on such other matters as the Secretary directs." *Id.* § 121.4(b)(2). The application of that second provision is in dispute here.

Upon receipt of proposed policies, HHS "*will* refer significant proposed policies" to the Advisory Committee on Organ Transplantation, created under § 121.12 of the Final Rule, and "publish them in the Federal Register for public comment." *Id.* (emphasis added). If the proposed policies are *not* "significant," HHS "may" (but need not) take those steps. *Id.* Either way, HHS must ensure that the policies comply with the Act. *Id.* In addition, HHS must consider and respond to any "critical comments" that parties may submit concerning the OPTN's duties. *See id.* § 121.4(d).

B. Turning next to § 121.8, that provision establishes a host of requirements for allocation policies in particular. Section 121.8 links back to § 121.4 by directing the OPTN to develop organ allocation policies "in accordance with the policy development process described in § 121.4." *Id.* § 121.8(a). It then adds special further procedural and substantive requirements.

Substantively, § 121.8(a) imposes eight requirements, only a subset of which bear on this case. Organ allocation policies must, among other things: (i) "be based on sound medical judgment"; (ii) "seek to achieve the best use of donated organs"; and (iii) "be designed to avoid wasting organs ... and to promote the efficient management of organ placement." *Id.* § 121.8(a)(1), (2), (5). Conversely, allocation policies shall *not* "be based on the candidate's place of residence or place of listing, *except to the extent required by*" the factors above, *id.* § 121.8(a)(8) (emphasis added). In other words, geography can play a role in allocation, but only insofar as geographic units help to advance the other enumerated objectives of the regulation.

The regulation also outlines "performance goals" for allocation policies, "designed to achieve equitable allocation of organs among patients consistent with" the above. *Id.* § 121.8(b). Reinforcing the above, the performance goals include "[d]istributing organs over *as broad a geographic area as feasible*," consistent with the requirements set forth above (*i.e.*, promoting "best use" of the organs and not "wasting" them or interfering with "efficient management"). *Id.* § 121.8(a), (b)(3) (emphasis added).

Each allocation policy must also include "performance indicators" that measure how well the policy is achieving goals set forth in the regulation. *Id.* § 121.8(c)(1). To evaluate performance, the OPTN must provide HHS with "data to assist the Secretary in assessing organ procurement and allocation, access to transplantation, [and] the effect of allocation policies on programs performing different volumes of transplants." *Id.* § 121.8(c)(3).

Procedurally, § 121.8(f) refers to "Secretarial review of policies." It requires the OPTN to submit to HHS proposed allocation policies, performance indicators, and data to enable the agency to assess compliance with the Final Rule. To be precise, it directs that the "transmittal to the Secretary of proposed allocation policies and performance indicators shall include such supporting material, including the results of model-based computer simulations, as the Secretary may require to assess the likely effects of policy changes and as are necessary to demonstrate that the proposed policies comply with" the Final Rule. *Id.* § 121.8(f). When the OPTN revises its allocation policies, it must also "consider whether to adopt transition procedures" to protect those "on the waiting list"; and any such "transition procedures shall be transmitted to the Secretary for review together with the revised allocation policies." *Id.* § 121.8(d)(1).

II. KIDNEY ALLOCATION POLICIES.

A. Historically, Organs Are Allocated Using DSAs and Regions.

Since 1987, organ allocation policy has relied on two geographic constructs, called Donation Service Areas (or "DSAs") and Regions. There are 57 DSAs, many of which roughly follow state lines, each served by a single "organ procurement organization" or "OPO," which is responsible for procuring organs in its service area and facilitating their transport to recipients. The statute contemplates these service areas: Each OPO "has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs." 42 U.S.C. § 273(b)(1)(E). The DSAs are then grouped into 11 larger Regions. *See* A.185 (map).

Under the longstanding kidney policy, transplant candidates are categorized and prioritized based on certain medical criteria, including blood type, length of time on the waitlist, and age. A.210-15. Within each medical category, kidneys are generally distributed first to transplant candidates at hospitals in the same DSA as the donor's hospital. If the organ is not accepted by any hospitals in the DSA, then the kidney is generally offered next to candidates at hospitals in the same Region, and finally offered nationally. A.217-22, 378-79. That prioritization reflects the fact that the longer an organ is outside of the donor's body, including transit time to the transplant center, the lower the chance of a successful organ transplant. *See* A.378; *infra* at 12.

Because organ allocation policies have for three decades prioritized transplant candidates within the same DSA as the organ donor, the relationships that developed between OPOs and transplant hospitals within their service area have become critically important to effective organ allocation. Whatever the origins of the DSA boundaries, at this point there is no question that "the local OPO knows what organs its local centers will take as well as the centers' preferred approaches to handling and pumping the organ." A.247. UNOS itself has recognized that DSAs have "historically been relied upon" to "avoid organ wastage and to promote the efficient management of organ placement, consistent with the OPTN Final Rule." A.270.

Distributing organs beyond the service area of the OPO that procured the organ complicates the medical and logistical task of getting the organ to the right place at the right time, which heightens the risk of waste. That is why, as UNOS has admitted,

replacing DSAs "carries the potential risk of decreased organ utilization ... and/or increased organ discard ... due to the added complexity of including multiple OPOs and transplant centers in the procurement process." A.272.

This is not mere speculation: When UNOS in recent years abandoned the DSA system for liver and lung allocation, the result was an increase in the "discard rate" for both organs. A.206, 256, 261; *see also* A.306 (lung policy changes "increased the death rate," "decreased the transplant rate," and "increased the national discard rate," among other negative results). And such waste is even more likely to occur with kidneys because, unlike other organs, they are often not assigned an intended recipient until after they are removed from the donor, and they are more likely to travel on commercial aircraft. *See* ECF 56-1 at 3. Physician testimony below thus explained that "distributing kidneys across a broader geographic area results in increased kidney wastage." A.390.

B. In 2018, HHS Directs the Abandonment of DSAs.

Although the DSA system has built-in efficiencies for reasons just explained, it is also true that some OPOs are more effective than others, both at recruiting donors and at distributing organs to patients. *See* ECF 56-1 at 100 (CMS observing "wide range of performances" by OPOs). In recent years, hospitals located in DSAs with ineffective OPOs (such as New York) have criticized the DSA boundaries as arbitrary and leading to geographic unfairness, and have sought to replace them with an allocation system that would be more geographically "equitable" by redistributing donated organs from high-functioning OPOs to locations where the OPOs have struggled.

In May 2018, an attorney funded by New York hospitals sent a "critical comment" to HHS regarding UNOS's liver allocation policy, arguing that DSAs and regions are "arbitrary" and so any allocation policy relying on those constructs "will not comply with the law." A.119. The next day, UNOS's General Counsel sent HRSA an unsolicited opinion that "Regions and DSAs are arbitrary and capricious." A.371.

One week later, HRSA formally asked the OPTN to provide its views on whether "using DSAs as units of allocation" and "using OPTN regions as units of allocation" was consistent with the statute and Final Rule. A.265-66. UNOS responded with a half-hearted defense. A.268-73. While it contended that it was reasonable to include DSAs in conjunction with other factors, UNOS also stated that the "disparate sizes, shapes, and populations of DSAs as drawn today" made them irrational units. A.269.

On July 31, 2018, HRSA issued its response to the critical comment, not only directing that the liver allocation policy be revised to eliminate DSAs and Regions, but also concluding that their use "in all other (non-liver) organ allocation policies *has not been and cannot be justified* under the OPTN final rule." A.128-32 (emphasis added). The agency acknowledged that the Final Rule permits the use of geographic constructs to the extent required by factors like "sound medical judgment," ensuring "the best use of donated organs," avoiding "wast[e]," and promoting "efficient management of organ placement." A.129; 42 C.F.R. § 121.8(a)(8); *see also supra* at 4. But HHS determined that UNOS had failed to establish that DSAs and Regions were indeed "justified under such requirements." A.130.

In light of that determination, HRSA "direct[ed] further OPTN action"—more specifically, submission of a detailed report "outlining the OPTN's plans to eliminate DSAs and Regions from other (non-liver) organ-specific allocation policies." A.128, 132. That directive kick-started UNOS's policy development process for a replacement kidney allocation policy (A.291), resulting in the Fixed Circle Policy at issue here.

C. UNOS Adopts the Fixed Circle Policy.

Immediately upon the HRSA directive, the OPTN Kidney-Pancreas Workgroup began to discuss what "leadership believes is the best option to replace DSA and regions in kidney allocation"—namely, use of fixed-distance circles around the donor's hospital. A.368. In response to questions about why they were pursuing this "short-term fix" on "an aggressive timeline," UNOS staff advised that the HRSA letter "calls on the OPTN and UNOS to remove DSA and region from distribution models." *Id.*

Indeed, throughout the policy process, the OPTN understood its order from HHS to be the elimination of DSAs and Regions. *See* A.134 (meeting minutes that describe the "task" as "to remove DSA and regions from kidney allocation policy"); A.395 (OPTN "directed the organ-specific committees to pursue removal of DSA and regions"); A.364 (physician on Kidney Committee stating her understanding that "it was mandatory that DSAs could not be included in any new policy"). Underscoring the OPTN's objective, its ultimate proposal was entitled: "Eliminate the Use of DSA and Region in Kidney Allocation Policy." A.179; *see also* A.288-89 (describing the "purpose" of proposal as "to remove DSA and region as a unit of allocation").

UNOS also insisted that the dismantling of DSAs and Regions had to be done on an "aggressive timeline." A.289. That constrained the scope of policy options that it considered. For example, some experts recommended distributing kidneys based on each organ's risk of post-transplant failure, but UNOS responded that accounting for that admittedly "important consideration" would be "prohibitive given the timeline and the goals of the Workgroup to replace DSA and region." A.406. Other allocation models were likewise never considered because "doing so would not be feasible in the timeline" for "removing DSA and region." *Id.*; *see also* A.390 (affidavit from physician stating that "UNOS forced the Fixed Circle Policy upon the community by repeatedly representing that the kidney allocation had to be changed promptly because the current policy was illegal"). Even the UNOS committee chair, when asked if his work felt too "rushed," admitted "we can do a whole lot more if given the time." A.314-15.

UNOS ultimately proposed the "Fixed Circle Policy," which abandons DSAs and instead gives priority to candidates at transplant centers within a 250-nautical-mile circle around the donor's hospital. A.198-200. The geographic effect of that change is significant: It would divert 497 more kidneys per year to New York, whereas Arkansas, Nebraska, and Missouri are predicted to lose 160 organs annually. A.253.

As required by the Final Rule, UNOS submitted its policy proposals for computer-simulated modeling. A.137-38; 42 C.F.R. § 121.8(f). These simulations are performed by the Scientific Registry of Transplant Recipients ("SRTR"), under contract with HHS. *See* 42 U.S.C. § 274a.

The initial modeling results, reported in December 2018, were alarming: Due to the logistical challenges of allocating organs across OPO service lines—and, on average, farther from donors—the 250-nautical-mile circle option was predicted to result in an average of 1,492 *fewer* kidney transplants per year. A.142.[1] Not surprisingly, that report "was negatively received" by the transplant community "due to notable decreases in the number of transplants." A.148.

UNOS responded to that problem not by revisiting the 250-nautical-mile circle or the elimination of DSAs, but by jiggering the *modeling*. In the original model, a hospital was logically predicted to be more likely to accept an organ offered locally, from its own DSA. UNOS now decided that assumption was anachronistic, and that it should be omitted from the simulation. A.403. To replace it, SRTR staff presented two options for models that did not use DSAs as a predictive factor. *Id.* The first option took into account the distance the organ would have to travel to the recipient in predicting whether a hospital would accept it. By contrast, the second model omitted distance entirely as a relevant factor. *Id.* Without any explanation as to why it was appropriate to entirely exclude the distance the organ would travel, UNOS apparently instructed the SRTR to "rerun" the simulation using that second model, which omitted not only DSAs but distance entirely as a predictive factor. A.149.

[1] The modeling estimated 13,373 to 13,536 kidney transplants per year absent a policy change (average: 13,473), versus 11,894 to 12,084 per year upon implementation of the 250-nautical-mile construct (average: 11,981). A.142.

That change bought UNOS a reduction in projected waste, but only at the expense of medical reality. The distance an organ must travel to reach its recipient is "absolutely a factor that physicians take into consideration when determining whether or not to accept an organ." A.247-48. Because organs are limited in how long they are viable outside of the body, surgeons must consider how long it will take the offered organ to reach the hospital when deciding whether or not the organ is appropriate for their patient. *Id.* The revised data model irrationally ignores this. It assumes the University of Iowa is just as likely to accept an organ from Des Moines as it is to accept the same organ from Rhode Island—which is plainly fallacious. *Id.*; *see also* A.113, 389.

In any event, even under that flawed, revised model, the Fixed Circle Policy is still projected to result in 250 *fewer* kidney transplants per year (from an average of 13,080 to an average of 12,830). A.161.[2] UNOS argued below that some of those lost transplants would be offset by a projected increase in kidney-pancreas transplants. ECF 68 at 19. But even combining the figures, Defendants' models still predict a net decrease in transplants—as well as an increase in the number of patients expected to die on the waitlist each year—under the Fixed Circle Policy. *See* A.195-96.[3]

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[2] The revised modeling estimated 12,982 to 13,166 kidney transplants per year (average: 13,080) absent a change in policy, versus 12,730 to 12,928 (average: 12,830) under the Fixed Circle Policy. *See* A.163 (labeling status quo as "BL" and Fixed Circle Policy as "250.250.2.4").

[3] Under the Fixed Circle Policy, average waitlist deaths are predicted to increase by 24 per year, from 5,237 to 5,261. *See* A.163.

Nevertheless, because the OPTN Board believed it had no choice but to abandon DSAs, it adopted the Fixed Circle Policy in December 2019, and indicated an "intent" to implement the policy "late in 2020." A.275. Shortly thereafter, the COVID-19 pandemic began. Although UNOS repeated its intent to implement the policy change in late 2020, it offered no specific date, and many hospitals expected delays given the immense stress on the health-care system. A.172-73, 365. On October 20, 2020, UNOS finally announced the Policy would take effect on December 15, 2020. A.280. At no point during this period did HHS refer the policy to the Advisory Committee on Organ Transplantation or publish it for comment in the Federal Register.

III. PROCEDURAL HISTORY.

On December 1, 2020, shortly after UNOS announced the implementation date for the Fixed Circle Policy, the Hospitals submitted a critical comment to HHS, setting forth their procedural and substantive objections. A.99. Eight OPO leaders filed their own critical comment with HHS around the same time. ECF 67-2 at 48-52.

With their critical comment pending and implementation looming, Plaintiffs filed this case on December 9, 2020, in the District Court for the Southern District of Iowa. A.17. Plaintiffs are six transplant hospitals (AdventHealth Orlando, University of Alabama Hospital, Medical University of South Carolina, University of Iowa, Kansas University Medical Center, and the University of Kentucky) as well as one patient on the kidney transplant waitlist (Mr. Berrios). They sued UNOS, HHS, and HRSA in addition to the relevant officials (in their capacity as such). A.20-22.

The Complaint alleged that Defendants violated the APA because (i) they did not follow the procedures in 42 C.F.R.§ 121.4(b)(2) for "significant" proposed OPTN policies, and (ii) the Fixed Circle Policy was arbitrary and capricious. A.42-48. Plaintiffs also moved for a preliminary injunction. ECF 3. Just 30 minutes before the motion hearing, HHS directed the OPTN to delay implementation until at least February 13, 2021, while the agency reviewed the critical comments. ECF 40. Defendants agreed to stay implementation for 30 days after any HHS decision on the critical comments, to allow for judicial review. ECF 50.

On February 12, 2021, Acting HHS Secretary Norris Cochran rejected Plaintiffs' critical comment. A.343. Plaintiffs promptly renewed their motion for injunctive relief. ECF 66. After expedited briefing, the district court denied that motion on March 12, 2021. Add.1. The court concluded that neither the Hospitals nor their patients were at risk of suffering irreparable harm, even though it was undisputed that the former would perform fewer transplants and the latter would languish longer on the waiting list under the Fixed Circle Policy. Add.17-19. The court also held that the § 121.4(b)(2) procedures did not apply and that adoption of the Fixed Circle Policy was not arbitrary or capricious, and therefore that Plaintiffs were not likely to prevail. Add.24-42. And the court held that the public interest did not support an injunction, despite the ongoing pandemic and expected increase in mortality under the new approach. Add.42-44.

Plaintiffs immediately sought a stay pending appeal, which the district court (A.96) and this Court denied. This Court, however, agreed to expedite this appeal.

SUMMARY OF ARGUMENT

I. It is not this Court's role to set organ allocation policy. But it decidedly is this Court's role to ensure that Defendants abide by the law, follow the procedures required by statute and regulation, and engage in reasoned decision-making. In rushing to adopt the Fixed Circle Policy, Defendants fell short, and Plaintiffs' challenge is therefore likely (and certainly presents a fair chance) to prevail on the merits.

First, reading the regulatory scheme as a whole, it is clear that when the OPTN sets or revises organ allocation policies, it must submit those proposals to HHS for advance review. HHS, in turn, must refer "significant" organ allocation policies to an advisory committee, and publish them for public comment. Nobody disputes that the Fixed Circle Policy is "significant," yet here HHS took neither of those steps. It proffered a strained and bizarre construction of the rules, under which the *most* important policies that the OPTN proposes are subject to the *least* scrutiny. That makes no sense, and the district court erred as a matter of law by embracing that "loophole" interpretation.

Second, Defendants also acted arbitrarily and capriciously by insisting that the DSA system be abandoned as unjustifiable—and then neglecting to revisit or reconsider that edict even after it became clear that the suggested alternative would (by all accounts) lead to *fewer* transplants and *more* waitlist deaths. Defendants, of course, are empowered to balance the competing interests implicated by organ allocation, including the idea of geographic "equity." But it is irrational to definitively rule out the status quo without regard to how it stacks up against the alternatives on all of the relevant metrics.

II. Plaintiffs will suffer irreparable harm absent an injunction. It is undisputed that the Hospitals will perform fewer transplants under the Fixed Circle Policy. The resulting harm to their mission and financial bottom-line cannot be remedied later, in light of sovereign immunity. Nor will adequate relief be available for their patients, like Plaintiff Berrios, who will have to spend a longer time waiting for a kidney donation. The district court erred by discounting these harms for inapposite legal reasons.

III. Finally, given the undisputed fact that the Fixed Circle Policy will cause more patients to die while waiting for a kidney—and Defendants' inability to show any harm from a temporary injunction—enjoining the policy would further the public interest.

ARGUMENT

I. STANDARD OF REVIEW

Whether to grant a preliminary injunction turns on four factors: "(1) the threat of irreparable harm to the movant; (2) the state of the balance between this harm and the injury that granting the injunction will inflict on other parties litigant; (3) the probability that movant will succeed on the merits; and (4) the public interest." *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981) (en banc).

The third factor—the probability of success on the merits—is typically the "most important." *Jet Midwest Int'l Co. v. Jet Midwest Grp., LLC*, 953 F.3d 1041, 1044 (8th Cir. 2020). This Court has long held that a plaintiff need not show "a greater than fifty per cent likelihood." *Id.* at 1044-45. Rather, "a *fair chance* of prevailing" suffices. *Heartland Acad. Cmty. Church v. Waddle*, 335 F.3d 684, 690 (8th Cir. 2003) (emphasis added); *see also D.M. v. Minn. State High Sch. League*, 917 F.3d 994, 999-1001 (8th Cir. 2019).

This Court has imposed a higher, likely-to-prevail threshold when a plaintiff seeks to enjoin "a duly enacted state statute," the product of "democratic processes." *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 731-33 (8th Cir. 2008); *see also Richenberg v. Perry*, 73 F.3d 172, 173 (8th Cir. 1995) (per curiam). The district court wrongly applied that standard here. Add.20-21. The Fixed Circle Policy is not a statute. And the heightened standard applies to other government acts only if "'the full play of the democratic processes' was involved." *Richland/Wilkin Joint Powers Auth. v. U.S. Army Corps of Eng'rs*, 826 F.3d 1030, 1040 (8th Cir. 2016). That is not the case here. While the OPTN was *created by* Congress (Add.21), it is operated by a private non-profit entity. Its policy proposal did not benefit from any "lengthy public debate involving both the legislative and executive branches," and its leaders are not "democratically elected officials." *D.M.*, 917 F.3d at 1000. As for HHS, mere ratification of an "expert agency recommendation" does not trigger the heightened standard. *Richland*, 826 F.3d at 1040-41. And that is particularly true here, where Plaintiffs' primary argument is that HHS did not follow even the fairly limited procedural requirements—referral to an advisory body, and publication for notice-and-comment—that the Final Rule imposes to ensure that policy decisions of this type are adequately vetted. *See infra* Part II.A.

This Court reviews denial of a preliminary injunction for "abuse of discretion," and such an abuse occurs if the court rested on "erroneous legal conclusions." *Minn. Citizens Concerned for Life, Inc. v. Swanson*, 692 F.3d 864, 870 (8th Cir. 2012) (en banc). Those legal conclusions are reviewed "de novo" on appeal. *D.M.*, 917 F.3d at 999.

II. PLAINTIFFS ARE LIKELY TO PREVAIL ON THE MERITS, AND CERTAINLY HAVE A "FAIR CHANCE" OF DOING SO.

Whatever the applicable standard for Plaintiffs' showing on the merits, the outcome is the same: This element of the preliminary-injunction test has been satisfied. HHS did not follow the regulatory procedures designed to ensure that "significant" proposed policies like the Fixed Circle Policy are thoroughly vetted, and that is basis enough for relief. Moreover, the Policy itself is arbitrary and capricious. HHS insisted that DSAs be abandoned because they supposedly could not be justified as advancing the Final Rule factors (including efficiency and avoiding wastage), and the OPTN ran with that mandate. Yet the rushed result of that process was a policy that Defendants' own model (and real data from its experience with other organs) shows will result in *fewer* transplants and *more* deaths. Undisputed data about the Fixed Circle Policy thus refute the premise that spurred its creation, but Defendants irrationally pressed ahead unfazed.

A. HHS Did Not Follow the Required Regulatory Procedures.

At the outset, the APA requires vacatur of any agency action undertaken "without observance of procedure required by law." 5 U.S.C. § 706(2)(D). Here, the regulations governing the OPTN's policy proposals require HHS to refer "significant" ones to an advisory committee and subject them to notice-and-comment. Yet it is undisputed that HHS bypassed these steps for the Fixed Circle Policy, even though organ allocation policies are by far the *most significant* policies that the OPTN develops. By reading the regulations to permit that circumvention, the district court legally erred.

Plaintiffs' argument is explained in detail below. But the important building blocks are the following: Section 121.8 provides for the OPTN to submit its allocation policies to HHS for review, as one would expect for policies of this significance. That regulatory directive means that organ allocation policies are among those "the Secretary directs" that the OPTN "provide to the Secretary," under the more general provision governing the agency's review process, § 121.4(b)(2). And that, in turn, means that "significant" such policies must be referred by HHS to an advisory committee and published in the Federal Register for public review and comment. All of that stands to reason and makes the different parts of the Rule fit together seamlessly—unlike the Defendants' strained construction, which *exempts* the most significant OPTN policies from review and leaves inexplicable, gaping holes in both of these regulatory provisions.

1. As described above, the Final Rule lays out a process for review and approval of the OPTN's policy proposals. In particular, two sets of "proposed policies" must be provided to HHS at least 60 days prior to their implementation. The first set, which is not at issue here, comprises policies that the OPTN "recommends to be enforceable under § 121.10." 42 C.F.R. § 121.4(b)(2).[4] The second set of policies that must be so

[4] Section 121.10 provides that HHS may terminate participation in Medicare or Medicaid if an OPO or transplant hospital fails to comply with a policy designated as "enforceable." To date, the OPTN has never recommended making a policy enforceable in that way. In practice, however, all OPTN allocation policies must be complied with. By law, OPOs and transplant hospitals must be members of the OPTN, 42 U.S.C. § 273(b)(3)(H), and the OPTN Bylaws require compliance with all OPTN policies, even those that are not "enforceable." *See* ECF 4-4 at 200.

submitted are those "on such other matters as the Secretary directs." *Id.* The Rule then proceeds to instruct that HHS "will refer *significant* proposed policies to the Advisory Committee on Organ Transplantation ... and publish them in the Federal Register for public comment." *Id.* (emphasis added). If the policies are not deemed "significant," HHS "may" take those steps, but is not required by the rule to do so. *Id.*

Starting with the latter two sentences, there is no question that an organ allocation policy, like the Fixed Circle Policy here, qualifies as "significant." After all, allocation policies are the first enumerated category of policies that the OPTN must develop, *id.* § 121.4(a)(1), because setting "criteria for allocating organs" is central to the OPTN's statutory role. 42 U.S.C. § 274(b)(2)(B). If an organ allocation policy is not "significant" for the purposes of this scheme, then it is difficult to imagine what would be.

Indeed, Defendants have not denied that the Fixed Circle Policy is "significant" in the abstract. Instead, they have contended that not all "significant" OPTN policies are subject to the procedural requirements set forth in § 121.4(b)(2). In their view, those requirements apply exclusively to the two categories of policies—identified in the two prior sentences of the regulation—that the OPTN is required to submit to HHS before implementation. One Court of Appeals has agreed with that construction, describing § 121.4(b)(2) as a "funnel" that first identifies two categories of policies that the OPTN must submit to HHS, and then further subdividing those proposed policies into the "significant" and non-significant sets. *See Callahan v. U.S. Dep't of Health & Human Servs.*, 939 F.3d 1251, 1260-61 (11th Cir. 2019).

Even accepting that interpretation of § 121.4(b)(2), it does not change the outcome here. The Fixed Circle Policy—like all organ allocation policies—*is* a proposed policy that HHS directed the OPTN to submit for review. It fits squarely within the scope of § 121.4(b)(2)'s "funnel" and therefore triggers its procedural requirements.[5]

The critical sentence of § 121.4(b)(2) directs the OPTN to "provide to [HHS], at least 60 days prior to their proposed implementation, proposed policies on such other matters as the Secretary directs." That plain language requires that when HHS "directs" the OPTN to "provide" it with "proposed policies" on certain matters, the OPTN must do so. And HHS has directed the OPTN to so provide any organ allocation policies. HHS did so in § 121.8(f), which explains what the OPTN's "transmittal to the Secretary of proposed allocation policies" must "include" for agency review. 42 C.F.R. § 121.8(f).

To repeat, § 121.4(b)(2)—at minimum, and by all accounts—requires referral to the advisory committee and publication in the Federal Register of any "significant" policies that are submitted at HHS's direction to HHS for review. And organ allocation policies are the prime example of such policies, since § 121.8 expressly contemplates transmittal to HHS of "proposed allocation policies" for review. Accordingly, a "significant" organ allocation policy that the OPTN develops under § 121.8 must be submitted to HHS and then proceed through the heightened procedures of § 121.4(b)(2).

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[5] In *Callahan*, it was "undisputed" that the challenged policy fit into "neither" of the two categories of policies identified by § 121.4(b)(2). 939 F.3d at 1258. So the court in that case did not have occasion to construe or apply those categories.

Canons of construction confirm this interpretation, and refute any reading that would exempt organ allocation policies from the § 121.4(b)(2) procedures. Again, these are by far the OPTN's most important policy undertakings. If the Advisory Committee on Organ Transplantation, which was created precisely to comment on "proposed OPTN policies," *id.* § 121.12, need not be consulted on organ allocation policies, why have one at all? And if any OPTN policies are going to be subject to the notice-and-comment procedures that are a baseline of administrative law, surely *the most important* of the policies would be included. Reading the Final Rule to exempt allocation policies from these procedures makes nonsense of the regulatory scheme. *See Darling v. Bowen*, 878 F.2d 1069, 1075-76 (8th Cir. 1989) (despite deference to "agency's construction," courts must remain "mindful" of need to "avoid absurd results and deal with internal inconsistencies"); *cf. Strand v. Diversified Collection Serv., Inc.*, 380 F.3d 316, 318 (8th Cir. 2004) (rejecting an interpretation that would "create bizarre results").

Nor is it possible to construe § 121.8 as establishing its own distinct, albeit equally meaningful, procedures for agency review of allocation policies. While that regulation repeatedly refers to the submission of proposed policies and other materials to HHS for review, *it nowhere actually provides for that review*. The OPTN must "provide ... data" to HHS about organ allocation policies. 42 C.F.R. § 121.8(c)(3). If it develops any "transition procedures" to go along with revised allocation policies, they "shall be transmitted to the Secretary for review together with the revised allocation policies." *Id.* § 121.8(d)(1). The OPTN's "initial revised policies," after promulgation of the Final

Rule, were to be transmitted for review by dates certain. *Id.* § 121.8(e). And any later transmittals of "proposed allocation policies" must include a host of "supporting material" to allow for secretarial review. *Id.* § 121.8(f). Yet nothing in § 121.8 actually provides for any HHS review of the proposed allocation policies or accompanying materials. *That is found only in § 121.4(b)(2).* Treating allocation policies as exempt from the latter would thus turn the Final Rule into a staircase to nowhere: The OPTN must compile and submit a long list of materials to the agency—yet HHS does not need to do *anything at all* with the package. That is simply not a plausible interpretation.

Only Plaintiffs' reading makes sense of the regulatory scheme as a whole. On this reading, § 121.8 *supplements* § 121.4; it does not *replace* it. That is why § 121.8 references § 121.4 no fewer than six times as the source for the OPTN's "policy development process" (§ 121.8(a), (g)) and for the secretarial "review" process (§ 121.8(e)(1), (2), (g)). Section 121.8 is properly read as building on § 121.4's standard process by establishing additional substantive and procedural requirements for organ allocation policies, in light of their importance. It does not thereby *exempt* those major policies from the default procedures of § 121.4, bizarrely leaving a no-review vacuum in its place.

2. The district court's reasons for rejecting Plaintiffs' construction of the regulation (Add.39-41) are unpersuasive and not responsive to the above.

First, the district court denied that § 121.8 requires the OPTN to submit proposed allocation policies to HHS at all. The court carved § 121.8 into isolated subsections, ignored key language, and failed to construe the regulation as a sensible whole.

The court began with § 121.8(d), which directs the OPTN to consider adopting "transition procedures" to protect patients who are already on the waiting list when allocation policies are revised. In that scenario, those transition procedures "shall be transmitted to the Secretary for review *together with the revised allocation policies*." 42 C.F.R. § 121.8(d)(1) (emphasis added). The district court reasoned that this subsection applies only if the OPTN *chooses* to adopt transition rules, but does not require its transmission of "any and all organ allocation policies." Add.39-40.

The district court also distinguished § 121.8(e). That subsection governs the "initial review" that the OPTN was to undertake of its "existing allocation policies" following promulgation of the Final Rule, and required the OPTN to "transmit initial revised policies ... to the Secretary for review" by particular dates. The district court correctly observed that this subsection, "standing alone," does not apply to anything beyond the OPTN's *initial set* of revised allocation policies. Add.40.

Sandwiched between those two subsections, the court included just six words about § 121.8(f), which is the provision that speaks directly to "proposed allocation policies." The court stated only this: "The same reasoning extends to § 121.8(f)." Add.40.

This analysis does not add up. Regulations, like statutes, must be construed "as a whole" and "in connection with every other part," not "in isolation." *Thomas & Wong Gen. Contractor v. The Lake Bank, N.A.*, 553 F.3d 650, 653 (8th Cir. 2009); *see also Clark v. U.S. Dep't of Agric.*, 537 F.3d 934, 940 (8th Cir. 2008) ("[W]e do not read individual words in isolation, but rather, we read them in the context in which they are used and

in the context of the statute as a whole."). The district court disregarded that cardinal principle. On its fragmented interpretation, the OPTN must submit for agency review (i) its initial set of revised allocation policies, and (ii) any subsequent revised allocation policies that include transition procedures—*but not* any revised policies for which the OPTN declines to adopt transition procedures. There is no sense to that. Why would HHS require submission of allocation policies for review *only* if the OPTN felt the need to adopt transition procedures at the same time? The transition policies are the tail; the allocation policies are the dog. The requirement that the former be submitted naturally presupposes the latter will be submitted as a matter of course, and that is exactly what § 121.8(d)(1) contemplates by referencing the transmittal of the transition procedures "together with the revised allocation policies."

More importantly, the district court offered no serious response to § 121.8(f), which is the subsection that expressly speaks to "transmittal to the Secretary *of proposed allocation policies*" and elaborates on what materials the OPTN must "include" in that transmittal. As noted, the district court said only this: "The same reasoning extends to § 121.8(f)." Add.40. That is a puzzling sentence. Section 121.8(f) has nothing to do with transition procedures (covered by § 121.8(d)) or initial allocation policies (covered by § 121.8(e)). Nor can § 121.8(f) plausibly be construed to apply, toothlessly, only if the OPTN *chooses* to submit its proposed policies to HHS. The provision—and, for that matter, § 121.8 generally—makes sense only as a mandate to submit proposed organ allocation policies for agency review in accordance with § 121.4(b)(2).

Second, the district court defended its construction against the obvious attack that it eliminates "[m]eaningful Secretarial review of proposed organ allocation policies," by observing that HHS can still intervene using the "critical comment process." Add.40. That proves too much, as an interested party can file a "critical comment[]" about *any* aspect of the OPTN's "duties." 42 C.F.R. § 121.4(d). If that were sufficient, then § 121.4(b)—and its mandate that "significant" policies be referred to the advisory committee and published for public comment—would be redundant. That is to say, § 121.4(b)(2) makes clear that some policies demand more agency attention than merely responding, after-the-fact, to hypothetical comments. Likewise, it cannot suffice that HHS may *choose* to follow heightened procedures. The Final Rule does not grant HHS unfettered discretion; if proposed policies are significant, it *must* take certain steps that are otherwise optional. The court's reasoning nullifies that distinction. *Solis v. Summit Contractors, Inc.*, 558 F.3d 815, 823 (8th Cir. 2009) ("We also should 'avoid a [regulatory] construction that would render another part of the same [regulation] superfluous.'").

All of this is to say that heightened scrutiny is *required* for certain policies. Section 121.8, by requiring the OPTN to provide its allocation policies and related information to HHS as a matter of course, confirms both in text and in spirit that organ allocation policies are among them. The district court thus missed the forest for the trees. Read as a whole, § 121.8 plainly requires the OPTN to submit its proposed allocation policies for agency review. That, in turn, engages the procedural requirements of § 121.4(b)(2). Since HHS did not abide by those requirements, Plaintiffs are likely to prevail.

B. The Fixed Circle Policy Is Also Substantively Invalid.

Plaintiffs recognize the obvious: Organ allocation is a complex undertaking; there is no "right" answer; and both the OPTN and HHS are entitled to deference as to how they balance competing considerations in settling on a policy choice. This Court cannot mandate that DSAs be retained or that all alternative systems be eschewed.

At the same time, agency action must be reasonable and considered. It cannot be arbitrary and capricious. *Michigan v. EPA*, 576 U.S. 743, 750 (2015); *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43. Here, the OPTN's policy development process began with a directive from HHS to abandon DSAs because they supposedly could not be justified under the regulatory factors. So UNOS took DSAs off the table and "rushed" (A.314) to find a replacement. But Defendants' own modeling then revealed that the new policy will *reduce* the total number of transplants and *increase* mortality. That data exposed objective metrics—some might say the most critical metrics under the Final Rule—on which the DSA model plainly and undeniably beats the new proposal.

This does not mean DSAs must be retained. But it does mean the agency's premise, that DSAs were unjustifiable, was wrong. At minimum, Defendants had to revisit that starting point, and genuinely consider whether to increase waste and mortality, while decreasing efficiency and the transplant rate—just to improve geographic "balance." Whether or not such a decision would be reasonable, it is not one that Defendants ever made, because they continued to insist that DSAs were illegal even after that premise was refuted, blindly pushing ahead with their pre-ordained abandonment.

1. To understand just how backwards the agency action here is, it is important to see that the agency's policy development process *began* with its *conclusion*: that DSAs as a system are categorically unjustifiable under the Final Rule and therefore had to go.

It was HHS that drove this policy process through its July 2018 directive to the OPTN. In that directive, the agency declared that "the use of DSAs and Regions in all ... organ allocation policies has not been *and cannot be* justified under the OPTN final rule." A.132 (emphasis added). HHS explained, correctly, that the Final Rule allows organ allocation to take into account geographic boundaries only "to the extent such reliance is required by" other factors, including "sound medical judgment," ensuring "the best use of donated organs," "avoid[ing] wasting organs," and promoting "efficient management of organ placement." A.129; 42 C.F.R. § 121.8(a). The agency concluded that the OPTN had "failed to provide a justification as to how DSAs and Regions meet" that test. A.129. Again: HHS admitted that "geographic constraints may be appropriate if they can be justified in light of the regulatory requirements," but found that DSAs "have not been and cannot be justified under such requirements." A.130. In other words, the agency believed DSAs had not been shown to be "required by" the other regulatory factors, like efficiency, and thus were unlawful.

Based on that conclusion, HHS expressly directed the OPTN "to remove DSAs and Regions from all organ allocation policies." A.132. Of course, the agency did not direct "any particular policy outcome or allocation scheme." A.130. But it did make one thing very clear: DSAs and Regions were out of contention.

UNOS proceeded accordingly. At a meeting of its Kidney-Pancreas Workgroup just over a week later, the discussion began with "a reminder of our task: to remove DSA and regions from kidney allocation policy." A.134. This mandate was reinforced throughout the policymaking process and understood to be an inviolable premise and end result. *See, e.g.*, A.147 (minutes of a later meeting, where in response to concerns, "UNOS staff explained the mandate was to eliminate DSA and region"). When UNOS ultimately issued its Fixed Circle Policy, it openly explained that the proposal was designed to "address the problem that 'the use of DSAs and Regions in ... organ allocation policies has not and cannot be justified under the OPTN Final Rule." A.201 (quoting HHS). Indeed, the formal name of the policy is literally "Elimination of DSA and Region from Kidney Allocation Policy." *Id.*; *see also* A.234.

In short, Defendants did not set out to develop the best kidney allocation policy, in light of all the facts and regulatory parameters. Rather, they set out to *replace* DSAs on an "aggressive," "rushed" basis. A.289, 314. And they did so on the premise that there was no way to justify DSAs as "required by" the Final Rule's factors.

2. After taking DSAs off the table and rushing to find a replacement, the OPTN adopted the Fixed Circle Policy. Yet then, when Defendants began to model the impact of the policy, it turned out the new system would *underperform* the DSA approach that supposedly could not be justified. In particular, the DSA system outperforms the Fixed Circle from the perspective of (at least) "avoid[ing] wasting organs" and promoting "the efficient management of organ placement." 42 C.F.R. § 121.8(a)(5).

Specifically, Defendants' own modeling shows the Fixed Circle Policy will result in *fewer* successful transplants than the status quo, even holding constant the number of donated kidneys, while deaths on the waitlist will increase. A.163. The precise *degree* of that decline is disputed. The first round of modeling showed that the reduction could be nearly 1,500 transplants per year. A.142. Defendants' response to that shocking figure was to alter the modeling assumptions by *completely removing* the distance between the donor hospital and transplant center as a factor in predicting whether the surgeon would accept the organ. *See* A.148-49, 403. That itself was arbitrary and capricious, because it is well-accepted that the farther an organ must travel for a transplant, the longer the trip is likely to take, the less likely that the transplant will be successful, and thus the less likely a transplant surgeon will accept the organ. *See* A.247-48, 378-79, 387-89; *supra* at 12.[6] Defendants fudged the analysis by excising that consideration from their model. But the Court need not wade into this debate, as even Defendants' revised figures show an undenied *decrease* in total transplants: a 250-transplant decline, offset only in part by 241 more kidney-pancreas transplants. *See supra* at 12.

[6] Defendants have argued that the original modeling overstated this effect, because it treated the DSA boundaries as predictive—a relic of the DSA system in which an organ offered beyond those lines is likely to have been already rejected and therefore be a poor candidate for transplant. *See* Add.32. But even if so, the contractor offered to run an alternative model that ameliorated that effect yet continued to account for distance as a predictive factor. A.403. The OPTN declined even to run those numbers. *See* A.148-49; *supra* at 11-12. Again, that is arbitrary and capricious. *See MCI Telecomms. Corp. v. FCC*, 842 F.2d 1296, 1303-04 (D.C. Cir. 1988) (agency's "willful blindness" to certain economic data "fully deserves the label 'arbitrary and capricious'").

To be sure, Defendants speculate that the policy will do better in practice than in their own modeling. But wishful thinking is not a reasonable basis for agency decision-making. *Audubon Soc'y of Cent. Ark. v. Dailey*, 977 F.2d 428, 433 (8th Cir. 1992) (agency acted arbitrarily where it "chose to ignore what it saw" in its own "projections"). And *actual data* from the experience with lung and liver transplants following similar policy changes points the *opposite* way. For liver allocation, Defendants projected a decrease of 8 transplants annually; actual experience showed a loss of 100 transplants during the first nine months of the new policy alone. A.420-21; ECF 82 at 16-17; ECF 76 at 116.[7] Similarly, implementation of a fixed circle allocation policy for lung transplants caused "a statistically significant increase in the discard rate." A.261; *see also* A.306 ("increased the death rate"; "decreased the transplant rate"). There is thus every reason to believe that Defendants' models *understate* the damage the Fixed Circle Policy will cause. Indeed, if their kidney projections are wrong to the same degree as their liver projections, the Fixed Circle Policy will result in 750 fewer transplants, and 300 excess deaths, over a five-year period. *See* ECF 82 at 16-20. *Cf. Wallace v. Colvin*, 193 F. Supp. 3d 939, 941 (N.D. Ill. 2016) ("Albert Einstein said that the definition of insanity is doing the same thing over and over again and expecting a different result.").

[7] Defendants have tried to explain this decline away by attributing it to the COVID-19 pandemic. *See* A.420. Yet at the same time, they deny that the pandemic has any bearing on whether to proceed with implementation of the Fixed Circle Policy and insist that transplants have proceeded unimpeded. ECF 68 at 24-25; ECF 69-1 at 30-32. They cannot have it both ways.

3. Putting these two points together, the problem is obvious. Defendants chose to adopt a new policy on the assumption that the existing DSA system was unjustifiable. So they admittedly rushed through the process, artificially foreclosing consideration of sticking with (or even tweaking) the status quo. Yet the result of that flawed process was a new approach that data showed would be *demonstrably worse* than DSAs on central metrics of performance required by the Final Rule, like efficiency and waste.

That means the original premise of the entire effort was mistaken: For all their perceived problems, DSAs get the job done and result in more successful transplants than the proposed alternative. At minimum, that means they *could be* justified under the Final Rule: It would be perfectly reasonable and lawful for Defendants to decide that, given their superior performance on the metrics of transplant rates, efficiency, and the avoidance of waste, using DSAs and Regions is "required by" those regulatory factors. 42 C.F.R. § 121.8(a)(8). But because that option was taken off the table from the outset, Defendants *never even considered it*. And they never *revisited* their erroneous starting point in view of the data later exposed by the modeling of their alternative.

That was arbitrary and capricious. Agencies must be open to considering what the data show. They cannot blindly follow their original path even after it has been exposed as misguided. *See Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018) ("agency cannot ignore evidence that undercuts its judgment; and it may not minimize such evidence without adequate explanation"); *Citizens Telecomms. Co. of Minn., LLC v. FCC*, 901 F.3d 991, 1000 (8th Cir. 2018) (agency cannot rest on "explanation ... that runs

counter to the evidence"). When the modeling revealed the DSA system had important advantages, Defendants were obligated to take that into account—not ignore it and cling to a pre-ordained objective of replacing the DSA system at all costs.

Of course, total number of transplants is not the *only* consideration under the Final Rule. And just because DSAs *could be* justified on grounds of efficiency and avoiding waste does not mean that the OPTN or HHS is *required* to maintain them. Defendants are also entitled to consider a range of other factors, including the "best use of donated organs" and "equitable allocation ... among patients." 42 C.F.R. § 121.8(a)(2), (b). And it may be that Defendants would be free to conclude that greater geographic "equity" as between Missouri and New York, for instance, justifies a new system even that would increase mortality and reduce the number of successful transplants. *Cf. Sw. Bell Tel. Co. v. FCC*, 153 F.3d 523, 539 (8th Cir. 1998) (deferring to agency's "reasonable exercise of ... discretionary authority to balance competing statutory goals").

But what is clear from this record is that neither UNOS nor HHS ever made that honest policy judgment. Instead, they took the current system off the table prematurely, on a premise that turned out to be wrong. And then they neglected to revisit the issue when the error was exposed, continuing even now to insist DSAs are "unlawful." ECF 69-1 at 32. They plunged ahead with the Fixed Circle Policy because it was the best alternative they could quickly develop as a replacement for DSAs, without recognizing that the original impetus for devising that alternative had now been contradicted and that the status quo deserved serious consideration on its own merits.

Again, that was arbitrary and capricious. When a "flawed premise is fundamental" to an agency's action, the action is necessarily unreasonable. *Safe Air for Everyone v. EPA*, 488 F.3d 1088, 1101 (9th Cir. 2007). Even if the agency could reach the same result "in the exercise of its discretion," its action must be vacated if based on an "unjustified assumption." *Transitional Hosps. Corp. of La., Inc. v. Shalala*, 222 F.3d 1019, 1029 (D.C. Cir. 2000); *see also, e.g.*, *Prill v. NLRB*, 755 F.2d 941, 948 (D.C. Cir. 1985) (vacating agency decision that "stands on a faulty legal premise and without adequate rationale"). That is what occurred here. HHS believed—and UNOS then took as a given—that DSAs were a non-starter. As a result, they never considered retaining them, even after the emergence of data brutally at odds with the decision to require their replacement.

4. The district court held that Defendants "reasonably found" that DSAs hindered "the equitable allocation" of organs. Add.28. But the court, like HHS, based that on the limited record that existed *in 2018*. That misses the point. Perhaps it was fair to say, at that time, that DSAs "cannot be justified under the Final Rule." Add.27. But it was arbitrary and capricious not to revisit that conclusion after the modeling showed that fixed circles decreased the number of transplants and increased mortality.

Similarly, the court reasoned that it was within the agency's discretion to weigh the competing considerations and approve the Fixed Circle Policy. *See* Add.27-29. Again, perhaps so—but the problem is that Defendants wrongly ruled out a DSA system and thus irrationally skewed the decision-making process. They never actually weighed the competing considerations of retaining DSAs in light of the complete data.

Just as with the procedural claim, the district court hyper-focused on discrete issues and failed to appreciate the bigger picture. That bigger picture leaves no doubt that the process Defendants followed was unreasonable, unlawful, and cannot stand.

* * *

It is assuredly the role of the OPTN and HHS to devise organ allocation policies. And courts are understandably hesitant to intervene in complex policy judgments made by elected officials or their designees. At the same time, agencies must respect the procedures set forth by law. And courts are charged under the APA with ensuring that agencies follow basic principles of reasoned decision-making. Both requirements are critical to ensuring the integrity and legitimacy of the agency's policy outcomes. Yet both were flouted here. HHS skirted the hardly-onerous procedures that the Final Rule demands, using an attenuated and legalistic construction of the regulation that renders it all but superfluous. And Defendants did not stop to consider the implications of their own new data on the very premise of their policymaking endeavor, instead forging ahead to comply with a directive that arguably no longer made sense.

Organ allocation is complicated, and it is clear that this Court is not going to solve the puzzle in this case. But what is equally clear is that Defendants' efforts to date are wholly inadequate and must be redone. This Court should hold that Plaintiffs are likely to prevail on the merits, and direct the OPTN and HHS to try again—this time by following the regulatory procedures and giving serious, open, reasoned consideration to both the longstanding DSA system as well as any proposed alternatives.

III. ABSENT RELIEF, PLAINTIFFS WILL SUFFER IRREPARABLE HARM.

Of course, it is not enough to show likely success on the merits—a plaintiff must also show it would suffer irreparable harm absent an injunction, *i.e.*, that relief at the end of the litigation would be inadequate. *Dataphase*, 640 F.2d at 113. But that requisite is also plainly satisfied here. It is undisputed that the Hospitals and their patients will be disadvantaged by the Fixed Circle Policy compared to the existing DSA system. And the harm wrought by the change cannot be remedied later. For one thing, the Hospitals will have no recourse against HHS for harm to their mission or the negative financial consequences of the change. For another, the Hospitals can represent the interests of their patients, for whom being passed over on the kidney waiting list could well be a life-or-death matter. All of this is quite straightforward, and the district court legally erred by holding that Plaintiffs did not demonstrate irreparable harm.

A. The Hospitals and Their Patients Face Irreparable Harm.

The reason why Plaintiffs would suffer irreparable harm absent preliminary relief is neither disputed nor complicated. Replacement of the DSA system with the Fixed Circle Policy for allocating kidneys will redistribute those organs away from the DSAs where the Hospitals operate and thus reduce the number of transplants they perform. *See* A.167, 171-72, 251-253. Defendants did not dispute that fact in their briefing below. And the district court expressly acknowledged it. *See* Add.19 (finding "injury in fact" based on Plaintiffs' claim "they are expected to perform 300 fewer kidney transplants per year under the Fixed Circle Policy").

The consequences of that undisputed fact are plain. If the Hospitals perform fewer kidney transplants, not only will their mission be impaired, but they will suffer financial losses too. A.167. And those losses are irreparable, because sovereign immunity will preclude compensatory damages against Defendants if this challenge succeeds. 5 U.S.C. § 702 (waiving immunity in APA actions only for suits seeking relief "other than money damages"); *Baker Elec. Coop., Inc. v. Chaske*, 28 F.3d 1466, 1473 (8th Cir. 1994) (finding irreparable injury where plaintiff "would be unable to recover any damages" due to "sovereign immunity ... in suits requesting money damages"); *Granville House, Inc. v. Dep't of Health & Human Servs.*, 715 F.2d 1292, 1298 (8th Cir. 1983) (injury to plaintiff's mission of serving the indigent). That alone suffices as irreparable injury.

Moreover, the necessary consequences of the same fact—the Hospitals' reduction in kidney transplants—is that the Hospitals' *patients* will spend more time on waiting lists, face a reduced opportunity to be matched with a donor, and be at an increased risk of dying without a transplant. Those are irreparable harms too, because a court cannot award after-the-fact relief that will compensate for additional months or years spent on dialysis—and even that is assuming that the patient survives the delay and ultimately obtains a life-saving transplant. *See Kai*, 336 F.3d at 656 (recognizing that "danger to plaintiffs' health, and perhaps even their lives, gives them a strong argument of irreparable injury"); *Ferry-Morse Seed Co. v. Food Corn, Inc.*, 729 F.2d 589, 592 (8th Cir. 1984) (calling lost opportunity and "competitive disadvantage" a "classic situation for preliminary injunctive relief").

For both reasons, the irreparable injury caused by the Fixed Circle Policy is manifest and stems directly from a single fact that neither Defendants nor the district court ever challenged. This is more than enough to satisfy this prong of the test.

B. The District Court Erred by Disregarding These Harms.

In holding otherwise, the district court erred. The court dismissed the harm to the Hospitals themselves based on a complete *non-sequitur*—the court's view that Plaintiffs should have filed their suit earlier in advance of the Fixed Circle Policy implementation date. And the court misunderstood the law of third-party standing in concluding that the Hospitals could not invoke the harms to their patients.

1. With respect to the Hospitals, the court acknowledged that they stood to suffer "decrease[d] revenue" both because of the reduction in number of transplants and by virtue of increased operational costs for the transplants "that do occur." Add.19. And the court agreed that was "sufficient" to establish Article III "injury." *Id.* Yet instead of then asking whether the injury was irreparable—which it is, for reasons explained above—the court abruptly ruled that the harm was nonetheless insufficient because of Plaintiffs' supposed "significant delay in mounting their legal challenge." *Id.*

That was legally confused. Delay bears on irreparable harm only where the plaintiff delays *despite suffering the harm*—because that course of conduct discredits the plaintiff's claim that the injury is serious and irreparable. So, for example, in *Hubbard Feeds, Inc. v. Animal Feed Supplement, Inc.*, this Court agreed that the plaintiff's two-decade delay in challenging the defendant's use of a contested trademark "belies any claim of irreparable

injury" in the form of consumer confusion. 182 F.3d 598, 603 (8th Cir. 1999). But that principle has no relevance here, because Plaintiffs sued *before* the Fixed Circle Policy was scheduled to take effect. Whether they should have filed *even sooner*, as the district court apparently believed, simply has nothing to do with irreparable injury. And the only case that the district court cited on this point, *Roudachevski v. All-American Care Ctrs., Inc.*, 648 F.3d 701 (8th Cir. 2011), is inapposite. That decision did not address delay at all, but rather denied injunctive relief because the supposed injuries either had not been shown to exist or would not have been remedied by an injunction anyway. *Id.* at 706-07.

It is true that courts have discretion to deny injunctive relief based on the plaintiff's lack of "reasonable diligence," even if the ordinary four-factor standard is satisfied. *Benisek v. Lamone*, 138 S. Ct. 1942, 1944 (2018). But the district court did not deny the injunction on that basis; instead, it invoked delay only to undermine Plaintiffs' showing of irreparable harm—which does not follow. Nor could the alleged delay alone justify denial of an injunction here, absent a showing that Defendants "were prejudiced by the delay." *Kroupa*, 731 F.3d at 821; *see also id.* (affirming injunction where district court found delay was "not a sufficient basis to deny preliminary injunctive relief"). Far from being prejudiced, *Defendants themselves offered to delay implementation of the policy*—and defer the adjudication of Plaintiffs' claims—until after HHS had more time to review and respond to the critical comments that were filed by Plaintiffs and by other parties. *See* ECF 40. Given that procedural history, the objection that Plaintiffs should have filed their lawsuit *even earlier* is really a red herring.

Beyond the district court's legal confusion, its complaints about Plaintiffs' timing are also factually unreasonable. Although UNOS announced the Fixed Circle Policy in December 2019, it did not "officially" set an implementation date until October 20, 2020. Add.16; *see also* A.280-83. Until that time, Plaintiffs—who, as hospitals, were under enormous strain from the COVID-19 pandemic—hoped that informal advocacy would reverse the decision, and in any event any lawsuit would have been unripe. *See Neb. Pub. Power Dist. v. MidAmerican Energy Co.*, 234 F.3d 1032, 1038 (8th Cir. 2000) (explaining that ripeness requires consideration of "immediacy" of harm). Once the official date was announced, Plaintiffs proceeded promptly to file a critical comment and to sue. That was diligent. *See Kroupa*, 731 F.3d at 821 (affirming injunction, despite eight-month delay, where plaintiff still sued "before important ... livestock competitions occurred"). And again, there turned out to be more than ample time for adjudication, as Defendants voluntarily deferred implementation by 90 days.

2. The district court further erred by disregarding the irreparable injuries that the Fixed Circle Policy threatens to the Hospitals' patients, who will be less likely to secure kidney transplants or forced to spend longer on waiting lists (and perhaps never make it to a transplant). On that issue, the court acknowledged that a plaintiff is entitled to raise harm to third parties if it has a "close relationship" to those third parties, who face "hindrance" in suing on their own. Add.17 (quoting *Campbell v. Louisiana*, 523 U.S. 392, 397 (1998)). Yet the court found that principle inapplicable here, for three reasons. All are mistaken.

First, the court declared that the Hospitals' patients were "hypothetical." Add.18. But the record makes clear—and it is not disputed—that the Hospitals regularly perform kidney transplants and treat many patients on the waitlist. A.171, 377, 390-91, 412. Nor is there any dispute that the Hospitals will perform *fewer* such transplants under the new policy. *See supra* at 36. It follows that the Hospitals' patients, on average, will suffer harm, either by facing longer waits or losing their chance at an donation altogether. These are projections, of course, but they are not "hypothetical."

Insofar as the district court meant that specific patients had to be *identified by name*, no such requirement exists. This Court has allowed third-party standing even where the third parties were unidentified. *E.g.*, *Planned Parenthood of Minn., Inc. v. Citizens for Cmty. Action*, 558 F.2d 861, 865 n.3 (8th Cir. 1977). The district court cited one case in which the plaintiffs identified, by pseudonym, a few patients who were harmed by a prohibition on assisted dying. *See Compassion in Dying v. Washington*, 79 F.3d 790, 795 (9th Cir. 1996). But that decision never suggested that doing so was legally *necessary*. To the contrary, it held that the doctors had properly been granted standing to assert the rights of "terminally ill patients *in general*," such that the deaths of the named patients did not moot the case. *Id.* (emphasis added). *Compassion in Dying* therefore *supports* the Hospitals' ability to invoke the rights of their transplant patients "in general."

Second, the court objected that Plaintiffs here are "hospitals" rather than "transplant doctors" who actually have the doctor-patient relationship. Add.18. Again, the district court invented that distinction—this time with no citation at all. The law is clear that

hospitals and clinics, not only the doctors that work there, may invoke the rights of their patients. *E.g.*, *Planned Parenthood*, 558 F.2d at 865 n.3 (granting third-party standing to clinic); *Reprod. Health Serv. v. Webster*, 851 F.2d 1071, 1083 n.16 (8th Cir. 1988) (granting third-party standing because "plaintiff Reproductive Health Services has performed abortions"); *June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103 (2020).

Finally, the district court reasoned that because Mr. Berrios joined the litigation, there must be no "practical barriers" to patients exercising their own rights. Add.18. That is overstated. Mr. Berrios' presence may preclude the Hospitals from asserting *his* rights, because *he* is evidently able to vindicate them himself. *Hodak v. City of St. Peters*, 535 F.3d 899, 905 (8th Cir. 2008). But that does not mean that *all* patients are similarly situated; many do face obvious obstacles to suing on their own, and courts have never sworn off third-party standing categorically just because *some* third parties manage to sue in their own right. *See, e.g.*, *Singleton v. Wulff*, 428 U.S. 106, 117-18 (1976) (allowing physician to assert patients' rights, even though the obstacles to patient suits are "not insurmountable" and have "frequently" been overcome).

In all events, the court then contradicted itself by ignoring the irreparable harm to Mr. Berrios, denigrating him as a "nominal" plaintiff. Add.18. The court cannot have it both ways: Either patients face barriers to vindicating their own rights on an individual level (in which case the Hospitals may protect their interests) or else they must sue on their own (in which case Mr. Berrios is a legitimate plaintiff in his own right). Either way, the harm to patients is also properly before the courts here.

* * *

Any change to an organ allocation policy is going to have winners and losers. There is no dispute, as a factual matter, that the Hospitals and their patients (including Mr. Berrios) are the losers in this instance. And if the Fixed Circle Policy is implemented and remains in effect during this litigation, the harms they will suffer cannot later be remedied. That alone does not entitle them to relief. But it does mean they have met the irreparable injury element of the preliminary-injunction standard. And because Plaintiffs have also shown a sufficient likelihood that their challenge to the Fixed Circle Policy will succeed on the merits, the Court should reverse the decision below and instruct that implementation of the policy be enjoined pending this suit. The alternative is to leave in effect a likely-unlawful policy and deprive the Hospitals and their patients of any adequate remedy for the serious harms it will indisputably cause.

IV. THE BALANCE OF EQUITIES STRONGLY SUPPORTS PRESERVATION OF THE LONGSTANDING STATUS QUO WHILE THIS LITIGATION PROCEEDS.

Finally, the Court must consider whether "the balance of harms" and overall "public interest" support injunctive relief. *D.M.*, 917 F.3d at 1003-04. Those factors "merge" when the party opposing injunctive relief is the Government. *Nken v. Holder*, 556 U.S. 418, 435 (2009); *see also Glenwood Bridge, Inc. v. City of Minneapolis*, 940 F.2d 367, 372 (8th Cir. 1991); *accord* Add.43. Here, a refusal to preserve the longstanding kidney allocation policy while this suit proceeds would impair the public interest. The balance of equities therefore points decisively in favor of temporary injunctive relief.

1. Starting with the benefits to the public of temporarily preserving the status quo during the pendency of this lawsuit, there are three important considerations—each of which the district court ignored or misunderstood.

First, and foremost, preserving the longstanding status quo during the pendency of this litigation is in the public interest because, as Defendants' own figures predict and as discussed above, the new policy will decrease the total number of transplants each year while increasing the number of patients who will die on the waiting list. A.141-42, 161; *supra* at 30. This is no mere speculation—similar changes to lung and liver allocation policies caused an increased number of discarded organs. *See supra* at 31. Individuals in need of a kidney transplant are the members of the public most directly affected by the allocation policy, and it cannot be disputed that a policy under which hundreds more people each year receive a life-sustaining kidney confers greater benefits than a policy under which those kidneys go to waste and two dozen more people die.

The district court inexplicably ignored this concrete public-interest factor. Instead, it treated the change in allocation policy as zero-sum, explaining that "it is not clear that the interests of those patients under the current policy [who stand to lose under the new policy] … outweigh those who stand to benefit from its revision." Add.43. Even on its own terms, that would merely suggest that the public interest does not cut either way, not that it militates against relief. More important, that reasoning wrongly assumes that the "winners" under the Fixed Circle Policy fully offset the "losers." In fact, it is undisputed that there will be *more* "losers" than "winners."

The district court observed that the new policy "anticipates greater equity in the distribution of the organs." Add.43. In other words, even if fewer kidney transplants are performed, those who obtain the transplants will arguably be more "deserving" in some subjective sense, because their geography will play a less significant role. But even if that were true,[8] it does not change the objective fact that fewer members of the public will benefit from the new policy than the status quo. Organs are in limited supply and everyone on the waitlist needs one. A change in policy that leads to hundreds more organs being *discarded*, and more people *dying*, fundamentally disserves the public.

Second, the ongoing COVID-19 pandemic further heightens the public interest in preserving the status quo. The healthcare system, including the transplant community, has faced tremendous strain and uncertainty over the past year, and those conditions will make it harder to successfully implement (and monitor the effects of) a dramatically new allocation policy. Even absent the pandemic, implementing the Fixed Circle Policy while this litigation is ongoing would not be in the public interest. With the pandemic, doing so is a clear abuse of discretion. The district court rejected the claim that adopting this new policy mid-pandemic, an admittedly "formidable" task, was itself arbitrary and capricious. Add.37. Even if so, it is a relevant public-interest consideration.

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[8] There are good reasons to doubt it. A report analyzing the effect of shifting lung allocation from DSAs to a fixed-circle model shows that while the change increased the discard rate, UNOS's own "equity" metric (the "access to transplant" score) remained static—and continued to be most correlated with geography. A.423-24; ECF 82 at 14. The "equity" benefits of the shift are thus speculative and dubious.

Finally, a preliminary injunction is in the public interest not only because of the substantive stakes but also because such an injunction would ensure that the new allocation policy (if it is not ultimately set aside) will be implemented only in the event that Defendants have acted lawfully in adopting it. *See League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) ("[T]here is a substantial public interest 'in having governmental agencies abide by the federal laws that govern their existence and operations.'"). Even if the omitted procedures would not "have changed the substantive result," "the public interest is served from the proper process itself." *E. Bay Sanctuary Covenant v. Trump*, 950 F.3d 1242, 1280-81 (9th Cir. 2020). The district court wrongly paid no heed to this important consideration either.

2. Turning to the harms to Defendants that an injunction would cause, the only one identified below was the administrative difficulty of postponing the implementation date. That is demonstrably overblown. Defendants themselves chose to postpone implementation in December 2020—a delay that lasted three months—and identify no particularized cost to that or any additional postponement.

The district court speculated that "confusion will be sown" among transplant hospitals "if [the Fixed Circle Policy] is enjoined at the last possible minute." Add.43-44. But nothing in the record suggests that continuation of the longstanding policy would lead to any "confusion," particularly given that Defendants themselves already postponed the Fixed Circle Policy *the day before* it was set to be implemented. Whether an injunction issues or not, the fate of the Fixed Circle Policy remains uncertain—and

the transplant community remains "in limbo"—so long as this litigation continues, so that cuts neither way. Moreover, contrary to what the district court appeared to assume (Add.43), there is no reason to think that transplant centers or other interested parties on the whole would prefer to see the Fixed Circle Policy implemented just because they "expected and planned for" this policy change. Nor is there any reason to think that any preparations that have already been made in anticipation of the policy change will go to waste if the Fixed Circle Policy is implemented *after* this litigation.

In evaluating the equities, the district court also reasoned that Plaintiffs' ostensible "delay" in seeking relief "weighs heavily" against an injunction. Add.43. That was another legal misuse of the unfair "delay" charge. *See supra* at 38-39. Delay might be relevant to the equities or public interest if, as a result of the delay, an injunction would be more costly or confusing than it otherwise would have been. As just explained, that is simply not the case here. So even if the district court were correct that Plaintiff could or should have sued earlier, that is irrelevant to whether a preliminary injunction is now appropriate. In any event, as discussed above, the district court was wrong: Plaintiffs acted promptly and diligently once their claims became ripe. *See supra* at 40.

In sum, the balance of harms and the public interest support preliminary injunctive relief, and the district court again erred in concluding otherwise.

CONCLUSION

For these reasons, the Court should reverse the order below and remand for entry of a preliminary injunction against implementation of the Fixed Circle Policy.

Dated: April 5, 2021

Glenn L. Krinsky
JONES DAY
555 South Flower Street, 50th Floor
Los Angeles, CA 90071
Telephone: 1.213.243.2540
Facsimile: 1.213.243.2539
glkrinsky@jonesday.com

Peter C. Canfield
JONES DAY
1420 Peachtree Street, N.E., Suite 800
Atlanta, GA 30309
Telephone: 1.404.521.3939
Facsimile: 1.404.581.8330
pcanfield@jonesday.com

Stephen H. Locher
Ryan G. Koopmans
BELIN MCCORMICK, P.C.
666 Walnut Street, Suite 2000
Des Moines, IA 50309
Telephone: 1.515.283.4610
Facsimile: 1.515.558.0610
shlocher@belinmccormick.com
rkoopmans@belinmccormick.com

/s/ Yaakov M. Roth
Michael A. Carvin
Yaakov M. Roth
JONES DAY
51 Louisiana Avenue, NW
Washington, DC 20001
Telephone: 1.202.879.3939
Facsimile: 1.202.626.1700
macarvin@jonesday.com
yroth@jonesday.com

Courtney A. Carrell
Kelsey L. Smith
JONES DAY
2727 North Harwood Street
Dallas, TX 75201
Telephone: 1.214.969.3939
Facsimile: 1.214.969.5100
ccarrell@jonesday.com
ksmith@jonesday.com

Counsel for Appellants

CERTIFICATE OF COMPLIANCE

I hereby certify that, in accordance with the type-volume limitation set forth in Federal Rule of Appellate Procedure 28.1(e)(2) and the general requirements set forth in Federal Rule of Appellate Procedure 32(a)(7)(C), this brief is proportionately spaced, has a typeface of 14-point Garamond, contains 12,981 words, and was prepared using Microsoft Office Word 2016. Further, the brief and addendum have been scanned for viruses with the Windows Defender anti-virus program and are virus-free.

Dated: April 5, 2021

Respectfully submitted,

/s/ Yaakov M. Roth

Counsel for Appellants

CERTIFICATE OF SERVICE

I hereby certify that on April 5, 2021, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Yaakov M. Roth

Counsel for Appellants