United States Court of Appeals
For the Eighth Circuit

No. 21-1589

Adventist Health System/SunBelt, Inc., et al.

Plaintiffs - Appellants

v.

United States Department of Health and Human Services, et al.;
United Network for Organ Sharing

Defendants - Appellees

Appeal from United States District Court
for the Southern District of Iowa - Eastern

Submitted: June 17, 2021
Filed: November 8, 2021

Before LOKEN, KELLY, and ERICKSON, Circuit Judges.

LOKEN, Circuit Judge.

The Organ Procurement and Transplantation Network ("OPTN") is a private, non-profit entity established at the direction of Congress to perform essential functions in implementing the National Organ Transplant Act of 1984, 42 U.S.C. § 273 *et seq*. ("Transplant Act"). See § 274. One of OPTN's statutory responsibilities is to "assist organ procurement organizations in the nationwide

distribution of organs equitably among transplant patients." § 274(b)(2)(D). In December 2019, OPTN adopted a new policy that significantly changes the method for allocating donated kidneys to kidney transplant patients.

In December 2020, days before the new policy's scheduled implementation, plaintiffs -- adversely affected hospital systems and a patient on the kidney waitlist (collectively, the "Hospitals") -- sued to enjoin the new policy as unlawful under the Transplant Act and the Administrative Procedure Act, 5 U.S.C. § 701 *et seq*. ("APA"). After expedited briefing, the district court[1] denied the Hospitals' Motion for Temporary Restraining Order and Preliminary Injunction. Adventist Health Sys./SunBelt, Inc., et al. v. U.S. Dep't of Health & Human Servs., et al., No. 3:20-cv-00101, Order (S.D. Iowa Mar. 12, 2021). The court's forty-five-page Order concluded that plaintiffs failed to satisfy any of the well-established factors relevant in determining whether to issue a preliminary injunction. See Dataphase Sys., Inc. v. C L Sys., Inc., 640 F.2d 109, 113 (8th Cir. 1981) (en banc). The Hospitals appeal. Reviewing the denial of a preliminary injunction for abuse of discretion, we affirm. See Wise v. Dep't of Transp., 943 F.3d 1161, 1165 (8th Cir. 2019) (standard of review).

I. Background

Amending the Public Health Service Act, the Transplant Act codified a major federal public-private effort to reduce chronic shortages of donated organs urgently needed by patients awaiting transplants. The Act authorizes the Secretary of the Department of Health and Human Services (HHS) to provide grants and other payments to a national network of non-profit organizations tasked with acquiring, preserving, and transporting donated organs, and allocating each donated organ to the

[1]The Honorable Stephanie M. Rose, United States District Judge for the Southern District of Iowa.

highest priority patient on the transplant waiting list for that organ. This is an incredibly complex effort, even for a single organ such as kidneys. And the scope of the Transplant Act is far broader -- the term "organ" includes "the human kidney, liver, heart, lung, pancreas, and any other human organ (other than corneas and eyes) specified by the Secretary by regulation," including bone marrow. 42 U.S.C. § 274b(d)(2).

A. A brief review of the private sector organizations involved in the effort to improve kidney transplants will help put the regulatory issues presented by this appeal in perspective. At the center of the effort is the OPTN. The Transplant Act provides that the Secretary will contract for the establishment and funding of this non-profit entity. 42 U.S.C. § 274(a). The OPTN "shall have" a board of directors "that includes representatives" of the other key private sector players -- "organ procurement organizations [OPOs], transplant centers, voluntary health associations, and the general public." § 274(b)(1)(B). OPTN's prescribed, wide-ranging functions include establishing a national list of persons who need organs, a system to match organs and individuals, and medical criteria for allocating organs; adopting quality standards for the acquisition and transportation of donated organs; coordinating the transportation of organs from OPOs to transplant centers; assisting OPOs "in the nationwide distribution of organs equitably among transplant patients"; and "work[ing] actively to increase the supply of donated organs." § 274(b)(2)(A), (B), (D), (E), (G), (K). The Act requires the Secretary to establish procedures for receiving and considering "critical comments" from interested persons "relating to the manner in which [OPTN] is carrying out [its] duties under subsection (b)." § 274(c). Since the Act's passage in 1984, defendant United Network for Organ Sharing ("UNOS") has served as the OPTN.

In 1998, the Secretary promulgated regulations governing OPTN's operations, known as the "Final Rule." See 42 C.F.R. pt. 121. The Final Rule provides that OPTN "shall establish" committees necessary to perform its duties, whose members

include transplant coordinators, OPOs, transplant hospitals, and transplant candidates and donors. 42 C.F.R. § 121.3(a)(4)(i). The OPTN has established a Kidney Transplantation Committee and a Pancreas Transplantation Committee. In addition, the Final Rule provides that the Secretary will establish an Advisory Committee on Organ Transplantation ("ACOT"), 42 C.F.R. § 121.12, "will refer significant proposed policies" to the ACOT and publish them for comment in the Federal Register, and "may seek the advice" of the ACOT on other proposed policies, § 121.4(b)(2). The Final Rule also provides that the OPTN and the Scientific Registry of Transplant Recipients ("SRTR"), a transplant data-gathering entity established by the Transplant Act, will provide the Secretary annual reports containing information "necessary to assess the effectiveness of the Nation's organ donation, procurement and transplantation system." § 121.11(b)(1)(i)(A); see 42 U.S.C. § 274a.

At the local level, the Transplant Act authorizes the Secretary to certify qualified OPOs to receive federal grants. 42 U.S.C. § 273. Among other qualifications, an OPO must have an agreement with the Secretary to be reimbursed under Title XVIII of the Social Security Act (Medicare), must meet the Secretary's performance standards for a qualified OPO, must have "a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs," and must have a staff "necessary to effectively obtain organs from donors in its service area." § 273(b)(1)(C), (D), (E), and (F). An OPO shall also "have effective agreements, to identify potential organ donors, with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations." § 273(b)(3)(A). An OPO's required functions include providing quality standards and arranging for the acquisition and preservation of donated organs, participating in "systematic efforts" to acquire usable organs from potential donors, maintaining "a system to allocate donated organs equitably among transplant patients according to established medical criteria," arranging for

transportation of donated organs to transplant centers, and participating in the OPTN. § 273(b)(3)(B), (C), (E), (F), (H).

B. The Transplant Act explicitly requires a qualified OPO to have a "defined service area" (DSA) and "effective agreements" with a substantial majority of the health care entities in its service area that "have facilities for organ donation." § 273(b)(1)(E), (b)(3)(A). Thus, it is hardly surprising that the policies initially adopted by the OPTN board of directors for acquiring and allocating donated kidneys were built around the relationships between OPOs and the transplant facilities in their DSAs. There are currently 58 DSAs designated by the Centers for Medicare and Medicaid Services. Each area -- usually statewide or metropolitan -- serves one OPO, one or more transplant programs, and one or more donor hospitals. The initial OPTN allocation policies, which persisted for three decades, provided that donated kidneys were first offered to transplant candidates *in the donor hospital's DSA* who are in the same medical category and priority.[2] If no transplant center in the DSA accepted the kidney, it was then offered to candidates in the same OPTN Region before being offered to candidates nationally. There are eleven geographic OPTN Regions, each consisting of DSA clusters.

The Transplant Act initially acknowledged that existing DSA relationships would be the basis for allocating donated organs -- it provided that the OPTN shall "assist [OPOs] in the distribution of organs *which cannot be placed within the service areas of the organizations*." Pub. L. 98-507, Tit. III, § 372(b)(2)(C), 98 Stat. 2344 (1984). Concerns about potential inequities inherent in a DSA-Region allocation model quickly surfaced. Congress responded by striking the italicized portion of this provision in 1988. Pub. L. 100-607, Tit. IV, § 403(a)(2), 102 Stat. 3115. The Senate Committee on Labor and Human Resources Report explained:

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[2]A multitude of complex medical factors determine a transplant candidate's priority on the OPTN waitlist and medical category within the waitlist.

> The bill would also clarify and refine two aspects of the existing responsibilities of the OPTN. The OPTN is currently required to assist OPOs in the distribution of organs "which cannot be placed within the service areas of the organizations." This phrase is deleted, so as to remove any statutory bias respecting the important question of criteria for the proper distribution of organs among patients. . . . Patient welfare must be the paramount consideration. *The Committee does not wish the statute to be read as establishing a preference for, or against, distribution within the service area of the OPO.*

S. Rep. No. 100-310 at p.14, reprinted in 1988-6 U.S.C.C.A.N. 4236, 4241-42 (emphasis added). In 1990, Congress further clarified its nationwide focus on patient welfare and fairness by amending this provision to the language presently found in 42 U.S.C. § 274(b)(2)(D) -- the OPTN shall "assist [OPOs] in the *nationwide* distribution of organs *equitably among transplant patients*." Pub. L. 101-616, Tit. II, § 202(b)(1), 104 Stat. 3284 (language added italicized). Consistent with this focus, the 1998 Final Rule provided that OPTN's cadaveric organ allocation policies "shall not be based on the [transplant] candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." 42 C.F.R. § 121.8(a)(8).

Despite these warning signals from Congress and HHS, the OPTN board of directors stayed with an allocation model based on DSA and Region preferences. Cries for reform grew louder. ACOT and the American Medical Association argued that DSAs' priority role in distributing organs resulted in geographic inequities and might violate the Final Rule's prohibition against prioritizing candidate location. OPTN data showed geographic disparities in transplant candidate wait times, with median times for kidney transplants varying widely across DSAs. Research indicated that differences in DSA composition and performance were the largest contributor to disparities in kidney allocation. OPTN further concluded that DSAs were "not a good proxy for geographic distance between donors and transplant candidates because [their] disparate sizes, shapes, and populations . . . are not rationally determined in

a manner that can be consistently applied equally for all candidates," and that Regions were ill-suited for organ distribution because they were designed for other purposes such as collecting public comments and allotting seats on the OPTN board.

Critics like ACOT and OPTN called for eliminating DSAs from organ allocation policy because they are not a "good proxy" for distance between donor and patient and lead to "geographic disparities in patient access to transplantation." Two examples illustrate these disparities. The district court noted, quoting the Acting Secretary's response to the Hospitals' critical comment, that under the DSA model a kidney donated in Minneapolis could be offered to a candidate in Bismarck (383 miles away) before a candidate in Des Moines (234 miles). The Eleventh Circuit noted an even more graphic example in Callahan v. U.S. Dep't of Health & Human Servs. Through Alex Azar II, 939 F.3d 1251, 1255 n.3 (11th Cir. 2019): "Under the current, DSA-based policy, if a liver becomes available in Charleston, South Carolina, it would be offered to a moderately ill patient in Memphis, Tennessee (600 miles away) before a critically ill patient in Atlanta, Georgia (266 miles away) -- and indeed, would have to be flown directly over Atlanta en route to Memphis."

C. Despite this widespread criticism, the DSA-Region model persisted, supported by strong defenders among the OPTN membership such as the Hospitals. The current policy conflict and accompanying litigation began in May 2018 when the Health Resources and Services Administration ("HRSA"), the HHS agency that oversees the OPTN, received a well-researched critical comment on behalf of liver transplant candidates in New York. These candidates contended that the DSA-Region allocation model violates the Final Rule to their disadvantage by arbitrarily prioritizing geography at the expense of medical and other appropriate criteria enumerated in § 121.8(a). After directing OPTN to respond, HRSA's Administrator wrote OPTN's President a July 31, 2018 letter, which Count I of the Hospitals' Complaint now seeks to have declared unlawful under § 706(2) of the Administrative Procedure Act. Briefly summarizing the five-page letter, HRSA stated that OPTN

"has not justified and cannot justify" the use of DSAs and Regions in its revised liver allocation policies, and "over the course of many years . . . has failed to [justify] how DSAs and Regions meet the requirements of the OPTN final rule." "On this basis, the OPTN Board is directed to adopt a liver allocation policy that eliminates the use of DSAs and OPTN Regions and that is compliant with the OPTN final rule." "For the same reasons described above concerning liver allocation, HRSA finds that the use of DSAs and Regions in all other (non-liver) organ allocation policies has not been and cannot be justified under the OPTN final rule."

In August 2018, as directed by UNOS, the OPTN Kidney and Pancreas Transplantation Committees formed a Kidney-Pancreas Workgroup to develop alternatives to the use of DSAs and Regions. In December, the Workgroup released for 60-day public comment a concept paper outlining five new policy variations of a "Fixed Circle Policy." See 42 C.F.R. § 121.4(b)(1). After considering statistical modeling data from the SRTR, in August 2019 the Kidney Committee published for public comment a proposed Fixed Circle Policy that gave kidney allocation priority to candidates within 500 nautical miles of the donor's hospital and eliminated use of OPTN Regions. After receiving public comments expressing logistical concerns, the Committee reduced the proposed priority distance to 250 nautical miles and provided a second 60-day public comment period. The Hospitals submitted negative public comments. In November 2019, by a vote of 13 to 4, the Kidney Transplantation Committee recommended the revised 250-mile Fixed Circle Policy to the OPTN Board. On December 3, 2019, the OPTN Board adopted the 250-mile Fixed Circle Policy by a vote of 34 to 5. OPTN then engaged in extensive outreach efforts to prepare the transplant community for the transition, advising it would implement the Fixed Circle kidney allocation policy by the end of 2020 despite the emergence of COVID-19. In late October 2020, OPTN announced an implementation date, December 15, 2020.

On December 1, 2020, the Hospitals submitted a critical comment to HRSA objecting to implementation of the Fixed Circle Policy. They argued an immediate change was ill-advised given the impact of COVID-19 on the transplant community. Procedurally, they argued Fixed Circle was a "significant" proposed policy and therefore HHS must refer it to ACOT and publish it in the Federal Register for public comment. See 42 C.F.R. § 121.4(b)(2). Substantively, they argued that SRTR modeling on which OPTN relied showed the new policy would result in fewer total kidney transplants, worse outcomes, and greater donated kidney wastage. Before HHS could respond to their critical comment, the Hospitals filed this action on December 9 and moved for an emergency temporary restraining order and preliminary injunction to prevent the policy from going into effect the following week.

On December 14, just before a hearing on the Hospitals' motion, HRSA directed OPTN to stay implementation of the Fixed Circle Policy to allow the agency time to consider the Hospitals' critical comment. HRSA ordered OPTN to provide its views on the critical comment. After OPTN explained why it concluded the Hospitals' claims were unfounded, HHS rejected the critical comment and declined to rescind OPTN's Fixed Circle Policy. See 42 C.F.R. § 121.4(d)(1).

After expedited briefing, the district court denied the Hospitals' motion for preliminary injunctive relief in a thorough, well-reasoned opinion. The court concluded that the Dataphase preliminary injunction factors weighed decisively against an injunction. The Hospitals appeal the denial of a preliminary injunction, which we have jurisdiction to review. See 28 U.S.C. § 1292(a)(1). On March 14, 2021, we denied the Hospitals' request for a stay of the Fixed Circle Policy pending appeal. The Policy went into effect as scheduled on March 15.

II. Analysis

A party seeking a preliminary injunction bears the burden of satisfying the four Dataphase factors. The district court flexibly balances the "particular circumstances" in each case to determine whether the movant is entitled to injunctive relief. Dataphase, 640 F.2d at 113. In determining whether the court abused its discretion in denying an injunction, we examine whether the court based its balancing of the Dataphase factors on clearly erroneous factual findings or on an erroneous legal conclusion. See Wise, 943 F.3d at 1165.

"The threshold inquiry [for preliminary injunctive relief] is whether the movant has shown the threat of irreparable injury." Gelco Corp. v. Coniston Partners, 811 F.2d 414, 418 (8th Cir. 1987). Thus, in many cases, irreparable injury is the first Dataphase factor that is addressed. But here, the district court concluded, and we agree, that the Hospitals have shown injury in fact, but not irreparable injury warranting the preliminary injunctive relief they seek. Having shown at least some monetary injury, the Hospitals argue that HHS did not follow *mandatory* regulatory procedures, and therefore the district court erred in denying a preliminary injunction because the APA *requires* vacatur of an agency action taken "without observance of procedure required by law." 5 U.S.C. § 706(2)(D). "[A]n injunction cannot issue if there is no chance of success on the merits." Jet Midwest Int'l Co. v. Jet Midwest Grp., LLC, 953 F.3d 1041, 1044 (8th Cir. 2020), quoting Mid-Am. Real Estate Co. v. Iowa Realty Co., 406 F.3d 969, 972 (8th Cir. 2005). So we begin by addressing the Hospitals' likelihood of success on the merits, which includes this procedural issue.

A. Likelihood of Success on the Merits. The Hospitals argue they are likely to succeed on the merits of two claims -- that HHS violated the APA when it failed to comply with the procedural requirements of the Final Rule in 42 C.F.R. part 121,

and that the Fixed Circle Policy is substantively invalid because OPTN and HHS acted arbitrarily and capriciously in adopting it.

1. The APA Procedural Claim. Section 121.4(b) of the Final Rule prescribes the procedures the OPTN Board of Directors "shall" follow in developing policies within its statutory mission. Subsection 121.4(b)(1) requires the Board to provide its members and "other interested parties" an opportunity to comment on *all* proposed policies and requires the Board to take those comments into account in developing and adopting policies. Subsection 121.4(b)(2) provides that the OPTN Board will refer to the Secretary, at least 60 days prior to implementation, two types of proposed policies: those the Board "recommends to be enforceable under § 121.10," and "proposed policies on such other matters as the Secretary directs." At issue here is the following sentence in this lengthy subsection:

> The Secretary will refer significant proposed policies to the [ACOT] established under § 121.12 and publish them in the FEDERAL REGISTER for public comment.

The Hospitals argue the Secretary's failure to follow those procedures before the kidney Fixed Circle Policy was implemented renders this an agency action taken "without observance of procedure required by law" that must be vacated under § 706(2)(D) of the APA. Like the district court, we disagree.

More background is relevant to this issue. In April 2019, a group of hospitals and individual patients that included some of the plaintiff hospitals in this case, represented by mostly the same attorneys, commenced an action in the Northern District of Georgia seeking to enjoin implementation of OPTN's new liver allocation policy. Plaintiffs alleged, *inter alia*, that this fundamental change in liver allocation procedures was a "significant policy" unlawfully adopted without compliance with the § 121.4(b)(2) procedures. The district court denied a preliminary injunction, rejecting this interpretation of § 121.4(b)(2), and plaintiffs appealed. On September

25, 2019, the Eleventh Circuit affirmed the district court's interpretation of the regulations, rejecting plaintiffs' contention that § 121.4(b)(2) requires the Secretary to refer to ACOT and publish for public comment *all* proposed policies determined to be "significant." Callahan, 939 F.3d at 1258-65. Agreeing with the Secretary's interpretation -- applying "traditional tools of [statutory] construction," rather than deference to the agency[3] -- the court concluded:

> [T]he significant-proposed-policies sentence's [ACOT] referral and publication requirements are triggered *only* in the two circumstances specified in § 121.4(b)(2)'s opening clauses: (1) when the policy at issue is one that the OPTN's Board "recommends to be enforceable . . . or (2) when the policy at issue is one that relates to "such other matters as the Secretary directs . . . ."

Id. at 1258-59. As it was "undisputed that neither of those two conditions obtained," the Court upheld the district court's ruling that plaintiffs failed to demonstrate a substantial likelihood of success on the merits of this APA procedural claim. Id. at 1258, 1265.[4]

In this case, the Hospitals, no doubt correctly anticipating we would agree with the Eleventh Circuit's careful textual analysis of § 121.4(b)(2), specifically alleged that the kidney Fixed Circle Policy "is significant *and on a matter the Secretary directs*." Complaint ¶ 74 (emphasis added). The Hospitals base this new "Secretary directs" argument on a strained interpretation of § 121.8, a section of the Final Rule titled "Allocation of organs" that was not even mentioned in Callahan.

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[3]As the district court noted, HHS in this case again does not seek what has long been referred to as Auer deference to its interpretation of the Final Rule. See Kisor v. Wilkie, 139 S. Ct. 2400, 2413-14 (2019) (plurality opinion).

[4]The Eleventh Circuit remanded for further consideration of other substantive APA and due process claims.

Subsection 121.8(a) enumerates criteria to guide OPTN's Board of Directors in developing allocation policies. For example, it specifies that policies "[s]hall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement." 42 C.F.R. § 121.8(a)(5). Subsection 121.8(f) provides:

> The OPTN's 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 performance indicators and transition procedures of paragraphs (c) and (d) of this section.

The Hospitals argue that, because § 121.8(f) requires OPTN to transmit all proposed organ allocation policies to the Secretary, *every* transmitted proposed allocation policy is a matter submitted "as the Secretary directs" and therefore is eligible to be a "significant policy" within the meaning of § 121.4(b)(2).

We conclude this argument is even less persuasive than the "all policies are significant" argument rejected by the Eleventh Circuit in Callahan. Section 121.8(f) does not use the word "direct" and does not refer to § 121.4(b)(2). It recognizes the reality that OPTN will transmit its policy proposals to the Secretary as part of HHS's oversight role and specifies what "supporting material" shall be included.[5] Section 121.4(b)(2) gives the Secretary the discretion to "refer" some proposed policies that are "significant" enough to warrant the additional, time-consuming procedures of referral to ACOT and publishing for public comment. The Hospitals' interpretation would eliminate this discretion and mandate procedures that no proposed allocation

[5]The record reflects that representatives of the Secretary sit as non-voting members of the OPTN Board and on every OPTN committee responsible for developing organ allocation policies.

policy has ever gone through. If HHS intended in the Final Rule that all proposed organ allocation policies be subject to § 121.4(b)(2)'s enhanced procedures, it would have explicitly referred to § 121.4(b)(2) in § 121.8(f). Cf. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 468 (2001) ("Congress . . . does not, one might say, hide elephants in mouseholes.").

The Hospitals argue the district court's interpretation of the Final Rule creates a "no-review vacuum" for proposed organ allocation policies. But as the district court and the decision in Callahan both noted, the Secretary has discretion under § 121.4(b)(2) to refer proposed policies to ACOT and publish them in the Federal Register. See 939 F.3d at 1264-65. HHS may also elicit feedback on proposed organ allocation policies using the critical comment process outlined in § 121.4(d), as it did in this case. The Hospitals suggest that our interpretation nullifies ACOT's role, but the Final Rule provides that the Secretary "may" seek ACOT's comment on any non-significant policy OPTN proposes. See 42 C.F.R. § 121.12. In addition, the district court noted, since 2010 ACOT has recommended that the Secretary "take steps to ensure the OPTN develops evidence-based allocation policies which are not determined by arbitrary administrative boundaries such as [the DSA/Region model]." Adventist Health Sys., Mar. 12, 2021 Order at p.8.

The district court did not err in concluding that the Hospitals failed to show that their procedural APA claim is likely to succeed on the merits.

2. Substantive Challenges to the Fixed Circle Policy. The Hospitals argue that defendants acted arbitrarily and capriciously throughout the Fixed Circle Policy's development process, violating the Transplant Act and § 706(2)(A) of the APA. Arbitrary and capricious is a highly deferential standard of review. We defer to agency action so long as "an agency 'examine[d] the relevant data and articulate[d] a satisfactory explanation for its action." Org. for Competitive Mkts. v. U.S. Dep't of Agric., 912 F.3d 455, 459 (8th Cir. 2018), quoting FCC v. Fox Television Stations,

Inc., 556 U.S. 502, 513 (2009). A court cannot "substitute its judgment for that of the agency." Id. at 513, quoting Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1987). This is particularly true "when the resolution of the dispute involves primarily issues of fact and analysis of the relevant information requires a high level of technical expertise" by an agency acting within its sphere of expertise. Voyageurs Nat'l Park Ass'n v. Norton, 381 F.3d 759, 763 (8th Cir. 2004) (cleaned up).

The Hospitals attack the OPTN and HHS procedures and analysis as well as the merits of the Fixed Circle Policy on multiple grounds. On appeal, they emphasize their contention that the agency action was arbitrary and capricious because the policy development process *began* with its *conclusion* "that the use of DSAs and Regions in all . . . organ allocation policies has not been *and cannot be* justified under the OPTN final rule," quoting the HRSA Administrator's July 31, 2018 letter to OPTN. Thus, the Hospitals argue, the long-followed DSAs and Regions option "was taken off the table from the outset, Defendants *never even considered it*." As the Brief for Government Appellees did not directly respond to this argument -- indeed the APA was not even *cited* in their Brief -- we think the argument requires specific attention.

It is essential to recall the context for the July 2018 letter. In December 2017, the OPTN Board published a new liver allocation policy recognizing that "[r]egional and donation service area (DSA) boundaries determine current liver distribution" but adding a "150-nautical mile radius proximity circle around the donor hospital." As recounted above, New York objectors submitted a May 30, 2018 critical comment complaining that Congress, the Final Rule, ACOT, and the OPTN itself had been arguing for decades that OPO regions and DSAs are arbitrary geographic boundaries that violate the Final Rule. The comment explained why the new liver policy did not comply with the law and asked that the Secretary, acting under 42 C.F.R. § 121.4(d), "[d]irect the OPTN to revise the policies or practices consistent with the Secretary's response to the comments."

Consistent with § 274(c) of the Transplant Act, the Final Rule provides that, when interested parties submit critical comments, "[t]he Secretary will consider the comments in light of the National Organ Transplant Act" and after review may "[d]irect the OPTN to revise the policies or practices consistent with the Secretary's response to the comments." 42 C.F.R. § 121.4(d)(2). It is undisputed that use of the DSAs and Regions model to determine allocation priorities for donated organs had been repeatedly attacked for decades by OPTN, ACOT, and others as contrary to the command of Congress, reflected in the Final Rule, that allocation policies "[s]hall not be based on the [transplant] candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." § 121.8(a)(8). Yet the OPTN Board had not effectively responded, seemingly paralyzed by influential members who benefitted from the status quo. Viewed in this light, it is apparent that HRSA did not arbitrarily and capriciously "beg[i]n with its conclusion." The merits of the conclusion were well understood and supported by a majority of the transplant community. The Secretary exercised oversight authority over OPTN that Congress explicitly granted in enacting the Transplant Act's public-private effort. In doing so, HHS did not direct "any particular policy outcome or allocation scheme," only that the DSA model could not be used.

The Hospitals further argue that, even if Defendants were not arbitrary and capricious in beginning from the premise that the DSA model must be replaced, they were arbitrary and capricious in ignoring the fact that the SRTR modeling data on which they relied then established that the Fixed Circle Policy produced a *worse* result. To avoid this bad news, the Hospitals argue, Defendants "fudged" their analysis of SRTR data to fit their predetermined result, then ignored the fact that even this flawed data showed the new policy will decrease total kidney transplants, increase donated kidney wastage, and reduce transplant efficiencies. The district court explained in great detail why it rejected these contentions, noting that HHS in responding to the Hospitals' critical comment rationally explained why it disagreed with the assertion that the Fixed Circle Policy would "result in fewer kidney

transplants, increased wastage, or increase discard of viable kidneys," and why the Secretary therefore declined to rescind the Policy. Adventist Health Sys., Mar. 12, 2021 Order at pp.19-37. The court further concluded that the agency's procedures were consistent with Final Rule requirements:

> Statistical modeling was conducted and analyzed by SRTR. The Kidney Committee issued extensive and detailed concept papers to the transplant community and to the public. Public comments were received and taken under consideration. And the OPTN received thorough briefing papers explaining the scientific basis for the proposed policy revision. The disagreements advanced by [the Hospitals] were adequately addressed by SRTR's data modeling and OPTN's briefing papers, upon which the Acting Secretary relied.
>
> Based on the OPTN's expertise in the area of transplant organ allocation, HHS reasonably concluded the Fixed Circle Policy will not result in significantly fewer kidney transplants.

Id. at 30 (citations omitted). After careful review, for the reasons stated by the district court, we agree that the Hospitals failed to demonstrate they are likely to succeed on the merits of their claim that adoption of the Fixed Circle Policy was arbitrary and capricious agency action.

B. Irreparable Harm. At the initial hearing on the Hospitals' motion for a temporary restraining order, the district court observed that the Hospitals' long delay in bringing suit was a "tough hurdle" and it expected them "to pay a great deal of attention to that particular issue." True to its word, the district court denied the Hospitals a preliminary injunction based in part on the fact that their delay in bringing suit until one year after Fixed Circle's adoption, and fewer than five days before its scheduled implementation, undercut their allegations of irreparable harm. Without question, "[a] long delay by plaintiff after learning of the threatened harm . . . may be taken as an indication that the harm would not be serious enough to justify a

preliminary injunction." Wright & Miller, 11A Fed. Prac. & Proc., § 2948.1 & n.13 (3d ed. 2013); see Hubbard Feeds, Inc. v. Animal Feed Supplement, Inc., 182 F.3d 598, 603 (8th Cir. 1999). "[A] party requesting a preliminary injunction must generally show reasonable diligence." Benisek v. Lamone, 138 S. Ct. 1942, 1944 (2018).

On appeal, the Hospitals argue, without direct supporting authority, that they sought to enjoin the Fixed Circle Policy before it took effect, and "[d]elay bears on irreparable harm only where the plaintiff delays despite suffering the harm." We reject this implausible assertion of law. Moreover, at least in this case, it would be outweighed by the third Dataphase factor, "that the balance of equities tips in [the Hospitals'] favor." Wise, 943 F.3d at 1165, quoting Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 20 (2008). The record establishes that, in the year after the Fixed Circle Policy was adopted but before implementation, OPTN engaged in extensive outreach efforts to prepare the transplant community for the coming changes, working with OPOs and transplant centers to run simulated previews of the Policy. Knowing of these collaborative efforts, and no doubt participating in them to some extent, the Hospitals would not have delayed in seeking injunctive relief that would nullify these costly efforts if their alleged financial harms were truly irreparable. (As the district court noted, the balance of the harms for patients on the kidney transplant waitlist is basically a wash -- some will receive kidney transplants more quickly under the Fixed Circle Policy, while others may have a longer wait.)

The Hospitals further argue that claims of delay are overblown because OPTN only announced the Fixed Circle Policy implementation date in October 2020, and they promptly filed a critical comment in early December. This contention is factually unpersuasive. OPTN communicated its intention to eliminate DSAs and Regions from its kidney allocation policy in August 2018. Plaintiffs in Callahan commenced their action to enjoin the new liver allocation policy in April 2019. The Hospitals submitted adverse public comments to the proposed kidney policy later in

2019. OPTN adopted the Fixed Circle Policy in December 2019 and consistently maintained it would be implemented by the end of 2020, notwithstanding COVID-19's impact on healthcare.

Highly relevant in our view was the Hospitals' delay in submitting a critical comment until a mere two weeks before the Policy's implementation. The Transplant Act and Final Rule require OPTN and HHS to solicit and respond to public comments to optimize final adopted policies. See 42 U.S.C. § 274(b)(2)(B), (c); 42 C.F.R. § 121.4(b)(1), (d). Here, the Hospitals knew of the Fixed Circle Policy's alleged drawbacks well in advance but chose not to bring their substantive critiques to the attention of HHS until the eve of implementation.

In these circumstances, the district court did not abuse its discretion in concluding that the Hospitals' *one-year* delay refuted their allegations of irreparable harm. See Novus Franchising, Inc. v. Dawson, 725 F.3d 885, 889, 894 (8th Cir. 2013) (seventeen-month delay); Tough Traveler, Ltd. v. Outbound Prods., 60 F.3d 964, 968 (2d Cir. 1995) (nine months), cert. denied, 527 U.S. 1036 (1999); cf. Hubbard Feeds, 182 F.3d at 602 (nine years). The failure to show irreparable harm is an "independently sufficient basis upon which to deny a preliminary injunction." Sessler v. City of Davenport, 990 F.3d 1150, 1156 (8th Cir. 2021), quoting Watkins Inc. v. Lewis, 346 F.3d 841, 844 (8th Cir. 2003).

C. Balance of Equities and Public Interest. As we explained in Part II.B., the Hospitals' unreasonable delay in submitting an adverse public comment and filing this lawsuit means that the balance of equities favors the denial of a preliminary injunction, as in Benisek, 138 S. Ct. at 1944. As for the public interest, the Fixed Circle Policy has been in effect since mid-March of this year, so forcing the transplant community to revert to the DSA model would disrupt, not preserve, the status quo of a program intended by Congress to increase the number of kidneys donated for transplant and to equitably allocate donated kidneys to the highest priority patients

on a nationwide basis. We agree with the district court that the public interest weighs in favor of denying the requested preliminary injunction because "allowing the Fixed Circle Policy to proceed as-planned maintains the status quo for every other interested party that has prepared for it." Order at p.44; see Benisek, 138 S. Ct. at 1945.

III. Conclusion

The district court's March 12, 2021 Order denying the Hospitals' Motion for Temporary Restraining Order and Preliminary Injunction is affirmed.
