

THE ADMINISTRATIVE LAW IMPLICATIONS OF QUASI-GOVERNMENTAL ORGAN ALLOCATION

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I. THE NETWORK.....	2
II. THE CASE.....	5
A. The Under 12 Rule	6
B. The Secretary	7
C. The Order.....	8
III. NOTA	11
A. Nondelegation	11
B. Constraints	13
i. Expertise.....	13
ii. Insulation.....	15
IV. THE FINAL RULE.....	16
A. Promulgation	16
B. Oversight Provision	19
i. Procedural Oversight.....	19
ii. Substantive Oversight	20
V. ALLOCATION POLICIES	22
A. Notice & Comment	22
i. Law.....	22
ii. Policy	23
B. Deference.....	24
i. <i>Auer</i> and <i>Skidmore</i>	25
ii. <i>Chevron</i>	27
a. Threshold	27
b. Step One.....	29
c. <i>Mead</i>	30
d. Step Two.....	31
C. State Action	32

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2	<i>SETON HALL LEGISLATIVE JOURNAL</i>	[Vol. 41:1
	i. Entwinement	35
	ii. Control	37
	iii. Public Function	38
	iv. Normative Judgment	39
VI.	CONCLUSION.....	40

INTRODUCTION

Congress created the Organ Procurement and Transplantation Network (“the OPTN”), a quasi-governmental agency, to allocate the nation’s supply of deceased-donor organs. But, this agency is a shell. The Human Resources & Services Administration contracts with a private, non-profit corporation (the United Network for Organ Sharing or “UNOS”) to operate the OPTN and to develop allocation policies—based, in large part, on the medical science developed by its own membership—in light of normative mandates from Congress and the Department of Health & Human Services. The District Court for the Eastern District of Pennsylvania skirted several fundamental questions about the legitimacy and constitutionality of this arrangement when it temporarily restrained the OPTN/UNOS from treating a ten-year-old lung transplant candidate differently than adults in her position on the lung waitlist;¹ a subsequent transplant mooted her claim, leaving consideration of its merits to another day. This Article picks up where that transplant candidate’s story left off and is the first to critically examine the OPTN/UNOS vis-à-vis issues of quasi-governmental regulation, political oversight, judicial deference to scientific agencies, and notice-and-comment rulemaking outside the scope of the Administrative Procedure Act.

I. THE NETWORK

In 1984, Congress passed the National Organ Transplant Act (“NOTA” or “the Act”) to facilitate the development of nationwide organ transplantation policies.² The Act created the OPTN, a “private,

¹ This Article treats the OPTN and UNOS as a single entity (“the OPTN/UNOS” or “the Network”), except in cases where it draws legal or factual distinctions between the shell (the OPTN) and its operator (UNOS).

² National Organ Transplant Act, Pub. L. No. 98-507, 98 Stat. 2339 (codified as amended at 42 U.S.C. § 273 *et seq.* (2012)). See generally Jed A. Gross, *E Pluribus UNOS: The National Organ Transplant Act and Its Postoperative Complications*, 8 YALE J. HEALTH POL’Y L. & ETHICS 145 (2013) (providing a comprehensive social, technological, and legislative history leading to the passage of NOTA).

nonprofit entity” charged with establishing both “a national list of individuals who need organs” and “a national system . . . to match organs and individuals included in the list.”³ Until this time, organ sharing had only occurred within a voluntary network of hospitals; NOTA “transformed th[at] voluntary network . . . into a formal [one] with effectively mandatory membership and governance by the OPTN.”⁴ Since 1986, UNOS has been under contract with the Health Resources and Services Administration (“HRSA” is a division of the U.S. Department of Health & Human Services (“HHS” or “the Department”)) to operate the OPTN.⁵

The Act requires that the OPTN’s allocation policies distribute “organs equitably among transplant patients.”⁶ Implementing this directive, the Department published a final rule instructing the OPTN Board of Directors (“the Board”) to draft policies “based on sound medical judgment . . . to achieve the best use of donated organs” (“the Final Rule”).⁷ The Final Rule authorizes the Board—comprised of transplant physicians; transplant candidates, recipients, and family members; and representatives of organ procurement organizations (“OPOs”), transplant hospitals, and the general public—to develop these policies,⁸ and the Board has delegated this authority to various organ-specific and trans-substantive committees.⁹ Those committees utilize

³ 42 U.S.C. § 274(b)(2)(A); *cf.* Gross, *supra* note 2, at 250 (“Congress took pains to emphasize the non-governmental nature of the network, for example, by calling it the ‘Organ Procurement and Transplantation Network’ . . . rather than the ‘United States Transplantation Network’ . . .” (citation omitted)).

⁴ DAVID L. WEIMER, *MEDICAL GOVERNANCE: VALUES, EXPERTISE, AND INTERESTS IN ORGAN TRANSPLANTATION* 73 (2010).

⁵ UNOS is a private non-profit organization. *About*, UNOS, <http://www.unos.org/about/index.php/> (last visited Nov. 7, 2016). UNOS was established in 1977 by the privately incorporated South-Eastern Regional Organ Procurement Foundation—a voluntary network of eighteen transplant centers that had grown out of an organization originally funded by the Public Health Service in 1969—to facilitate donor-recipient organ matching. WEIMER, *supra* note 4, at 45 (“[B]y 1983, UNOS was the only organization operating a nationwide system to support organ sharing.” (citation omitted)). *See generally* Wisconsin v. Shalala, No. 00-C-155-C, 2000 WL 34234002, at *2 (W.D. Wis. Nov. 22, 2000) (noting that the OPTN-operator contract with UNOS has been renewed several times).

⁶ 42 U.S.C. § 274(b)(2)(D) (emphasis added).

⁷ 42 C.F.R. § 121.8(a)(1)–(2) (2015); *see* Organ Procurement & Transplantation Network, 63 Fed. Reg. 16,296, 16,297 (April 2, 1998), codified at 42 C.F.R. § 121.

⁸ *See* 42 C.F.R. § 121.3(a); *id.* § 121.4(a); *see also* *Final Rule*, OPTN, <https://optn.transplant.hrsa.gov/governance/about-the-optn/final-rule/> (last visited Nov. 7, 2016); Stuart C. Sweet & Gena Boyle, *The OPTN/UNOS Policy Development Cycle: Challenges and Opportunities*, 3 CURRENT TRANSPLANTATION REPORTS 75, 75–78 (2016) (describing “the typical policy development process” to include (1) identification of a problem, (2) developing a policy proposal, (3) public comment, and (4) post-implementation monitoring), available at <http://link.springer.com/article/10.1007/s40472-016-0086-9>.

⁹ The organ-specific committees are Kidney, Liver & Intestinal Organ, Pancreas, and

Network-specific notice-and-comment procedures,¹⁰ which allow for input from the Network's membership and other interested parties.¹¹ Yet, the Final Rule purports to establish that "significant" policies promulgated by the Network are not "enforceable" until approved by the Secretary of HHS ("the Secretary").¹²

Regardless, while the Network is responsible for establishing allocation policies, it falls to fifty-eight federally-designated OPOs to apply those policies during the real-time distribution of organs to patients awaiting transplantation ("candidates").¹³ Each of these OPOs facilitates transplants from deceased donors within its exclusive geographically defined donation service area ("DSA") to candidates at transplant centers around the country.¹⁴ Ten years after NOTA was signed into law, Congress amended the Social Security Act to require—as a prerequisite to Medicare and Medicaid reimbursement—that hospitals and OPOs comply with Network policies (including establishing agreements whereby hospitals notify OPOs of potential organ donors).¹⁵

Once a person is consented to be an organ donor,¹⁶ the local OPO

Thoracic Organ. *Committees*, OPTN, <https://optn.transplant.hrsa.gov/members/committees/> (last visited Nov. 7, 2016). And, the trans-substantive committees normally involved in organ allocation policy development include Ethics, Executive, Histocompatibility, Membership & Professional Standards, Minority Affairs, OPO, Patient Affairs, Pediatric Transplantation, and Policy Oversight. *Id.*

¹⁰ 42 C.F.R. § 121.4(b)(1); see *Making OPTN Policy*, OPTN, <https://optn.transplant.hrsa.gov/governance/policies/making-optn-policy/> (last visited Nov. 7, 2016); see also *Policy Notices*, OPTN, <https://optn.transplant.hrsa.gov/governance/policy-notices/> (last visited Nov. 7, 2016); *Public Comment*, OPTN, <http://optn.transplant.hrsa.gov/governance/public-comment/> (last visited Nov. 7, 2016).

¹¹ See Martin A. Strosberg & Ron W. Gimbel, *The Public Administration of Organ Allocation: Maintaining the Public-Private Partnership*, 7 PUB. ADMIN. & MGMT. 229, 232 ("UNOS . . . adopts policies with organized input from the public and the general membership."). The independent organizational members of the OPTN/UNOS include 254 transplant centers, fifty-eight OPOs, fifty-eight histocompatibility laboratories, and thirty professional and voluntary organizations. See WEIMER, *supra* note 4, at 51.

¹² 42 C.F.R. § 121.4(b)(2).

¹³ *About APOO*, ASSOCIATION OF ORGAN PROCUREMENT ORGANIZATIONS, <http://www.aopo.org/about-aopo/> (last visited Nov. 7, 2016); see WEIMER, *supra* note 4, at 49 ("Each OPO has a monopoly over procuring organs from cadavers in hospitals within its geographic area. Fifty of the OPOs are independent organizations that harvest cadaveric organs from multiple hospitals. The other eight are operated by transplant centers based in specific hospitals and do not hold independent membership in the OPTN.").

¹⁴ WEIMER, *supra* note 4, at 49. Transplant centers are hospitals where transplants are performed. 42 C.F.R. § 121.2; see *OPO Report*, SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS, <http://www.srtr.org/cst/current/opo-report.aspx/> (last visited Nov. 7, 2016).

¹⁵ Social Security Act Amendments of 1994, Pub. L. No. 103-432, 108 Stat. 4398 (codified as amended at 42 U.S.C. § 1320b-8(a)(1) (2012)).

¹⁶ This may be either by first-person consent (e.g., during registration at the DMV), or by the consent of the donor's legal next-of-kin.

uploads the donor's social and medical information onto an online UNOS-operated donor-recipient matching system called DonorNetSM.¹⁷ Using DonorNetSM, an OPO representative generates one or more organ-specific "matchruns" that sort and rank all the candidates who may be compatible for each organ to be offered.¹⁸ The sequence of candidates on each unique matchrun is determined automatically based on algorithms that reflect the allocation policies that are operative at the time the matchrun is generated.¹⁹

While the allocation policies vary by organ type, they all share some commonalities.²⁰ First, with few exceptions, organs from deceased donors are initially offered to candidates geographically nearest the donor, then to candidates farther away.²¹ Second, despite the Act's mandate to distribute organs "equitably," the Network is still expected to specifically "address the unique health care needs of children."²² So, all allocation policies include some division between children and adults.²³ Third, all allocation policies provide transplant surgeons discretion when considering offers for candidates listed at their center since "decisions about who should receive a particular organ in a particular situation involve levels of detail, subtlety and urgency that must be judged by transplant professionals."²⁴

II. THE CASE

In December 2011, the transplant team at Children's Hospital of Philadelphia ("CHOP") sought to employ its discretion when it determined that Sarah Murnaghan—a then-ten-year-old girl with cystic fibrosis listed for a bilateral lung transplant—was medically eligible to receive lungs from an adult where the donor's lungs would be "downsized" to fit her.²⁵ Due to her progressively worsening health,

¹⁷ *How organs are matched*, UNOS, <https://www.unos.org/transplantation/matching-organs/> (last visited Nov. 7, 2016).

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ Complaint for a Temporary Restraining Order and Preliminary Injunction [hereinafter Complaint], Exhibit C (Letter from John P. Roberts, President, OPTN/UNOS, to Kathleen Sebelius, Secretary, HHS [hereinafter Roberts] *Murnaghan v. Sebelius*, No. 13-CV-03083, 2013 WL 3363500 (E.D. Penn. June 5, 2013)).

²¹ *See id.* (noting that geographic proximity minimizes organ preservation time and maximizes the chance of a successful transplant).

²² 42 U.S.C. § 274(b)(2)(M).

²³ *See generally Policies*, OPTN, available at <https://optn.transplant.hrsa.gov/governance/policies>.

²⁴ *See Organ Procurement and Transplantation Network*, 64 Fed. Reg. 56,650, 56,652 (Oct. 20, 1999).

²⁵ *See Complaint*, *supra* note 20, at 10–11; *see also Roberts*, *supra* note 20 (noting that

Sarah was admitted to CHOP in May 2013.²⁶ Unfortunately for Sarah, high-quality lungs from adult donors were being routinely accepted for adult candidates who were ranked ahead of her on the waitlist due to the so-called “Under 12 Rule.”²⁷

A. *The Under 12 Rule*

The Network’s lung allocation policy draws a distinction between those individuals age twelve or older and those under twelve years old.²⁸ On the one hand, if a candidate is age twelve or older, their medical team will calculate a lung allocation score (“LAS”), which provides transplant physicians with a quantitative assessment of the candidate’s mortality before—and survival benefit after—transplantation.²⁹ A candidate’s priority on lung matchruns is based on their LAS: candidates with a higher LAS receive offers first within their DSA.³⁰ On the other hand, candidates under age twelve do not receive an LAS score.³¹ As a result, these pre-adolescent candidates are last in line to receive offers from adult donors, after all adolescent and adult candidates have refused.³²

some thoracic transplant surgeons opt to excise one or more lobes from a larger donor’s lungs for transplant into a smaller recipient and that studies have shown that outcomes are comparable to whole lung transplants despite the added complexity).

²⁶ Complaint, *supra* note 20, at 3.

²⁷ Hearing Regarding Motion for Temporary Restraining Order [hereinafter TRO Hearing], *Murnaghan*, 2013 WL 3363500, at 27:00–28:01. In the months following her admission, Sarah’s transplant team received and rejected several lung offers that already had been refused by higher-ranked adult candidates, which they considered to be of inadequate medical quality. *Id.* at 33:10.

²⁸ See generally Sarah O’Brien, *The Impact and Implications of Sarah Murnaghan on the Organ Procurement and Transplantation Network’s Lung Allocation Policy and a Proposal for Further Change*, 18 QUINNIPIAC HEALTH L.J. 99, 111–17 (2015).

²⁹ Roberts, *supra* note 20 (the LAS is based in part on the candidate’s medical diagnosis, blood analyses, and lung function).

³⁰ Roberts, *supra* note 20.

³¹ Why the Under 12 Rule was promulgated is a matter of some debate in the medical community. Compare Keren Ladin & Douglas W. Hanto, *Rationing Lung Transplants—Procedural Fairness in Allocation and Appeals*, 369 NEW ENG. J. MED. 599, 599 (2013) (“Such scores were assigned only to patients 12 or older, because there were insufficient data to support their applicability to younger populations, owing to their different diagnoses and limited outcomes data.” (citation omitted)) with Thomas M. Egan & Stuart C. Sweet, *Rationing Lung Transplants*, 369 NEW ENG. J. MED. 2064, 2064 (2013) (“Ladin and Hanto ignore critical references. The decision to exclude children younger than 12 years of age from receiving allocation scores was based on careful data review; it did not result from insufficient data.”) (citation omitted)). See also Ciera Parish, *Rules Are Meant to Be Broken: The Organ Procurement and Transplantation Network Should Allow Pediatric Transplantation of Adult Lungs*, 28 J.L. & HEALTH 319, 333–36 (2015) (describing the purpose of the Under 12 Rule).

³² Roberts, *supra* note 20.

B. The Secretary

Around the time of her admission to CHOP, Sarah's parents sought to change the Under 12 Rule by publishing a petition to be delivered to Secretary Kathleen Sebelius and Board President Dr. John P. Roberts.³³ In response, the Network stated that the Murnaghans' request for special review could not be considered.³⁴ Nevertheless, on May 31, 2013, Secretary Sebelius directed the Network to "identify[] any potential improvements to th[e lung allocation] policy that would make more transplants available to children, consistent with the requirements of the [Final Rule]."³⁵

On June 3, 2013, Sarah's parents' attorney wrote to Secretary Sebelius, arguing that the Under 12 Rule was flawed and discriminatory, and directly requesting that the Secretary suspend the rule for Sarah on an emergency basis.³⁶ The next day, at an unrelated budgetary hearing before the House Education and Labor Committee, three congressmen pressed Sebelius to grant the Murnaghans' request.³⁷ One congressman, in particular, compared Sarah's situation to "deny[ing] a[n] organ transplant based on somebody's race, . . . skin [color], . . . or gender . . ."³⁸ Sebelius refused, suggesting that the allocation "rules that are in place and reviewed on a regular basis are there because the worst of all worlds in my mind is to have some individual pick and choose who lives and who dies. I think you want a process where it's guided by medical science and medical experts."³⁹

³³ See *Allow Transplant of Adult Lungs to Children*, CHANGE.ORG, <http://www.change.org/petitions/allow-transplants-of-adult-lungs-to-children/> (last visited Nov. 12, 2016).

³⁴ *OPTN statement regarding lung transplantation and pediatric priority*, OPTN (May 27, 2013), <https://optn.transplant.hrsa.gov/news/optn-statement-regarding-lung-transplantation-and-pediatric-priority/> ("OPTN policies allow status adjustments for specifically defined groups of candidates with unique medical circumstances not addressed by the overall policy. A request to adjust the status of a patient under age 12 so that they may be included in the allocation sequence for adolescents and adults is not within the scope of the existing lung allocation policy.")

³⁵ Complaint, Exhibit G (Letter from Secretary Sebelius to Dr. Roberts), *supra* note 20. See generally 42 C.F.R. § 121.4(d) (If "[a]ny interested individual" submits to the Secretary comments critical of the OPTN's policies, the Secretary will consider those comments, and upon review, may take any action the Secretary deems appropriate, including "direct[ing] the OPTN to revise the policies or practices.").

³⁶ Complaint, Exhibit A (Letter from Stephen G. Harvey, attorney representing Sarah Murnaghan, to Secretary Sebelius), *supra* note 20 (noting that the Network's review of the lung allocation policy could take months, during which Sarah would die).

³⁷ See *Rep. John Kline Holds a Hearing on the Dep't of Health & Human Servs. Budget Before the H. Educ. & Labor Comm.*, 113th Cong. (2013) [hereinafter *HHS Hearing*] (statements of Reps. Thomas Price, Lou Barletta, and Glenn Thompson).

³⁸ *Id.* (statement of Rep. Lou Barletta).

³⁹ *Id.* (statement of Sec'y Kathleen Sebelius).

C. The Order

On June 5, 2013, Sarah's parents filed a motion in the District Court for the Eastern District of Pennsylvania for a temporary restraining order ("TRO") enjoining the Secretary and the Network from applying the Under 12 Rule.⁴⁰ The complaint alleged two overarching violations of the Administrative Procedure Act ("APA"): (1) that the Under 12 Rule was "not in accordance with law;" and (2) that the Secretary's failure to set it aside was "arbitrary, capricious, and an abuse of discretion."⁴¹ During a hearing held the same day, Sarah's pulmonologist testified that the Under 12 Rule was "arbitrary;"⁴² that Sarah would only survive two to four more weeks without a transplant;⁴³ and that, were Sarah assigned an LAS, she would have a high chance of receiving lungs before her death.⁴⁴

The court issued the TRO, limiting its application to Sarah.⁴⁵ That night, UNOS adjusted its allocation algorithm to implement the order.⁴⁶ In a supplemental memorandum to its order, the court noted that the TRO did not direct a lung to Sarah, or place Sarah at the front of the line for lungs; rather, the order merely restrained the Network from disadvantaging Sarah based on her age.⁴⁷

On June 6, 2013, the OPTN/UNOS Thoracic and Pediatric Committees convened an emergency joint teleconference to "determine

⁴⁰ Complaint, *supra* note 20, ¶ 18.

⁴¹ *Id.* ¶¶ 52–62.

⁴² TRO Hearing, *supra* note 27, at 17:43.

⁴³ TRO Hearing, *supra* note 27, at 22:30.

⁴⁴ TRO Hearing, *supra* note 27, at 29:00 (noting that Sarah would be listed in the ninety-fifth percentile in terms of medical severity).

⁴⁵ Order, *Murnaghan*, 2013 WL 3363500, at 2 (June 5, 2013). That said, the mother of another child waiting on the lung waitlist—an eleven-year-old named Javier Martinez—obtained a similar TRO and preliminary injunction from the same court the very next day, represented by the Murnaghans' attorney. See Parish, *supra* note 31, at 338–39 (citations omitted).

⁴⁶ Roberts, *supra* note 20.

⁴⁷ Supplemental Mem., *Murnaghan*, 2013 WL 3363500, at 2 (June 7, 2013). This was a repetition of a caveat the court announced during the TRO hearing. See TRO Hearing, *supra* note 27, at 41:57–43:25 ("I want to emphasize what the legal issue on the TRO is, as I understand it. And I think this is very important, that, I am not in a position—nor would I seek to be—to decide who gets a transplant. That's not the function of a judge. The legal issue that's presented is that the Under 12 Rule is an 'arbitrary' and 'capricious' rule that is [*sic*] been improperly put into effect by the Secretary of HHS and that it should not block—it should not be used to block—Sarah from getting a transplant. And that is really the only legal issue. So, if I were to grant the TRO, it would only apply to Sarah. And it would not guarantee that she would get a transplant. It would only mean that the Secretary and the people who administer the donor program could not keep her in a separate category of 'Under 12.' They would have to consider her as equal to adults. So, what I'm being asked to decide here is a narrow legal issue.").

if there was sufficient evidence available to support a recommendation to modify the current pediatric lung allocation policy urgently.”⁴⁸ After a review of data provided by the Scientific Registry of Transplant Recipients, the Committees jointly recommended that “the Executive Committee [not] take any emergency policy actions . . . regarding pediatric lung allocation.”⁴⁹ Likewise, the OPTN/UNOS Ethics Committee saw “significant ethical risk in special review, appeal, or exceptions to allocation policies based on a particular candidate’s circumstance beyond the exception and review procedures already incorporated into Network policy.”⁵⁰ In particular, the Committee expressed concern that the

circumvention of organ allocation through judicial appeals . . . is likely to undermine the main ethical directive of an equitable allocation system to maximize the public good and achieve justice. Politicians and judges who intervene in a complex allocation algorithm may be well-intentioned but fail to consider all the moral variables that must be balanced at the macro level rather than through an individual candidate’s experience.⁵¹

After reviewing these reports, the Executive Committee decided, on June 10, to permit transplant centers the opportunity to seek individual exceptions permitting children below age twelve to avoid the Under 12 Rule.⁵² Sarah’s transplant team immediately sought—and was granted—

⁴⁸ Report of Joint Meeting of the OPTN/UNOS Thoracic and Pediatric Committees to the OPTN/UNOS Executive Committee (June 10, 2013), https://web.archive.org/web/20140818205607/http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Exec_Comm_mtng_materials_06-10-13.pdf/ (“The members of the Committees understood that such an extreme action should be recommended only if the review of current available evidence demonstrated the presence of a systematic, disproportional, imminent disadvantage to children as a result of the current allocation system.”).

⁴⁹ *Id.*

⁵⁰ Memorandum of OPTN/UNOS Ethics Committee to OPTN/UNOS Executive Committee (June 10, 2013) [hereinafter Ethics Memo], https://web.archive.org/web/20140818205607/http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Exec_Comm_mtng_materials_06-10-13.pdf/ (“Appeal to the unique features of specific cases is not an appropriate approach to make fairness claims against the complex algorithm of an allocation policy.”); cf. Cass R. Sunstein, *The Most Knowledgeable Branch*, 164 U. PA. L. REV. 1607, 1610 (2016) (“Judges face their own challenges. . . . [T]heir information is partial and fragmentary, often a kind of cartoon. It is a product of the adversary process, run by lawyers, which can lead to distorted and wildly inadequate perspectives. Judges cannot possibly have an adequate sense of the full range of issues with which executive officials must deal.” (citations omitted)).

⁵¹ Ethics Memo, *supra* note 50; see Ladin & Hanto, *supra* note 31, at 599 (“Appeals waged through federal courts and the court of public opinion . . . undermine fairness. . . . Lawsuits also inappropriately saddle courts with decisions about health policy. Finally, appeals reduce transparency and predictability, undermining the public perception of fairness, which could reduce donation rates.”).

⁵² Summary of Actions Taken at June 10, 2013, OPTN/UNOS Executive Committee Meeting (June 11, 2013), <https://web.archive.org/web/20150415092740>

such an exception.⁵³

No longer encumbered by the Under 12 Rule, Sarah underwent a bilateral lung transplant from an adult donor on June 12.⁵⁴ Unfortunately, those lungs failed almost immediately, forcing Sarah onto a heart-lung bypass machine for three days before she could be re-transplanted with a second pair of adult lungs.⁵⁵ No longer dependent on the operation of the TRO, and hence without the need to convert the TRO into a preliminary injunction, the Murnaghans dismissed their suit.⁵⁶

Due to the dismissal, the court never reached the merits of Sarah's claim, i.e., it never received briefing on NOTA, the OPTN, UNOS, the Final Rule, or the Under 12 Rule. Indeed, the court appears to have issued the TRO on the assumption that organ allocation policies such as the Under 12 Rule are "regulation[s]" due deference under *Chevron*:

[O]ne of the damning aspects of a regulation is that it's arbitrary, and that is an allegation that the plaintiff has made in her complaint here: that it is an arbitrary rule and is without medical basis. And, I think that is something that has a lot of weight. What is a strong factor in favor of the defendant is the concept of judicial deference to administrative rulemaking and administrative agency expertise. This is commonly known as the *Chevron* rule.⁵⁷

The remainder of this Article examines this assumption in the context of a several potentially dispositive legal issues that deserved, but did not receive, attention in *Murnaghan*.

Part III posits that the OPTN is a legally valid quasi-governmental

/http://optn.transplant.hrsa.gov/ContentDocuments/Policy_Notice_06-2013.pdf. Of note, this exception-based scheme has since become a permanent component of Network policy. See O'Brien, *supra* note 28, at 155 ("After a period of public comment and a vote by the OPTN, the temporary mechanism became permanent on June 23, 2014." (citations omitted)); OPTN, POLICY 10: ALLOCATION OF LUNGS, § 10.2.B, *Lung Candidates with Exceptional Cases* (Oct. 1, 2016), https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf ("For lung candidates less than 12 years old, transplant programs may request classification as an adolescent candidate. . . .").

⁵³ Joint Motion to Postpone Preliminary Injunction Hearing and to Extend Temporary Restraining Order, *Murnaghan*, 2013 WL 3363500, at 2 (June 13, 2013).

⁵⁴ Maryclaire Dale & Malcolm Ritter, *Sarah Murnaghan's Surgery Deemed a Success*, HUFFINGTON POST (June 12, 2013), https://web.archive.org/web/20160304104700/http://www.huffingtonpost.com/2013/06/12/sarah-murnaghan-surgery_n_3431653.html.

⁵⁵ Marie McCullough, *Five grave problems reduce Sarah's survival chances*, THE INQUIRER (July 3, 2013) (noting that these lungs would normally have been unsuitable for transplant due to pneumonia in the donor), https://web.archive.org/web/20150920232952/http://articles.philly.com/2013-07-03/news/40331491_1_lungs-transplant-surgery-sarah-murnaghan.

⁵⁶ Notice of Dismissal Without Prejudice, *Murnaghan*, 2013 WL 3363500, at 1 (July 8, 2013).

⁵⁷ TRO Hearing, *supra* note 27, at 47:56–48:41.

agency, and that UNOS, as its operator, is authorized to promulgate binding organ allocation policies. Part IV challenges the Department's Final Rule, arguing that, despite its procedural validity, Congress never authorized the Secretary to substantively intervene in the Network's policymaking. Part V argues that, though the Network's allocation policies are not subject to the APA, they are nonetheless due some equitable form of judicial deference. Finding that these policies reflect the Network's interpretation of a statute (NOTA) and not of a regulation (the Final Rule), this Part concludes that *Chevron* deference may be appropriate on the assumption that a court is willing to suspend the political accountability norm that is normally a prerequisite to deference to agency interpretations of organic statutes.

Finally, after considering whether the Network is a state actor susceptible to constitutional challenges, the Article concludes with a call to balance relief from alleged violations of constitutional rights with the inherently more abstract concerns of next-in-line candidates and the public.

III. NOTA

For the Network's allocation system to survive constitutional scrutiny, two showings must be made. First, NOTA must meet the demands of the Supreme Court's nondelegation doctrine. Second, the Network must be able to prove that its policies are designed with scientific expertise that is insulated from political interference.

A. *Nondelegation*

Eight decades have passed since the Court has struck down a statute for delegating authority either without an "intelligible principle,"⁵⁸ or to a private entity.⁵⁹ Because NOTA requires the Network to distribute "organs equitably among transplant patients" and "address the unique health care needs of children,"⁶⁰ there is unquestionably an "intelligible principle" that the Network must abide.⁶¹

⁵⁸ See *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 474 (2001) ("In the history of the Court we have found the requisite 'intelligible principle' lacking in only two statutes, one of which provided literally no guidance for the exercise of discretion, and the other of which conferred authority to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring 'fair competition.'" (citing *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935) and *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935))).

⁵⁹ See *Carter v. Carter Coal Co.*, 298 U.S. 238 (1936) (noting that delegation of regulatory authority to a private entity is "legislative delegation in its most obnoxious form").

⁶⁰ See 42 U.S.C. § 274(b)(2)(D), (M).

⁶¹ This is not to say that there are not critics of the "intelligible principle" doctrine. See,

And, until very recently, there would be no doubt about Congress's decision to delegate allocative policymaking authority to the Network.⁶² Indeed, *Carter Coal* was considered a "dormant doctrine" until 2013,⁶³ when the Court of Appeals for the District of Columbia Circuit held that Congress had impermissibly delegated legislative power to Amtrak, which was—in the Circuit's view—a private entity.⁶⁴ The Supreme Court ultimately vacated the judgment,⁶⁵ finding instead that Amtrak is a governmental entity,⁶⁶ thereby avoiding the Circuit's attempted revival of *Carter Coal*. In separate concurring opinions, however, two Justices indicated that *Carter Coal*'s ban on private delegation may have traction in future cases.⁶⁷

Emboldened by these concurrences, future lower court decisions may strive to prompt the Court to revive *Carter Coal*. And, given that the Network is almost certainly more private than Amtrak, a case like *Sarah Murnaghan*'s could squarely tee up the nondelegation doctrine.⁶⁸ But, with six sitting Justices silent on the issue, there is no indication that a majority would be willing to strike down NOTA as an unconstitutional delegation of authority to a private entity.

e.g., *Dep't of Transp. v. Ass'n of Am. R.R.s* ("American Railroads"), 135 S. Ct. 1225, 1246, 1250 (2015) (Thomas, J., concurring in the judgment) ("Although the Court may never have intended the boundless standard the 'intelligible principle' test has become, it is evident that it does not adequately reinforce the Constitution's allocation of legislative power. . . . [P]erhaps we deliberately . . . bow[ed] to the exigencies of modern Government that were so often cited in cases upholding challenged delegations of rulemaking authority." (citing, *e.g.*, *Mistretta v. United States*, 488 U.S. 361, 372 (1989) ("[I]n our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power under broad general directives."))).

⁶² See, *e.g.*, Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543, 586 (2000) ("[T]he nondelegation doctrine seems increasingly out of step with modern governance.").

⁶³ Anne Joseph O'Connell, *Bureaucracy at the Boundary*, 162 U. PA. L. REV. 841, 900–01 (2014) (citing Gillian E. Metzger, *Privatization as Delegation*, 103 COLUM. L. REV. 1367, 1440 (2003)).

⁶⁴ See *Ass'n of Am. R.R.s v. U.S. Dep't of Transp.*, 721 F.3d 666, 674–77 (D.C. Cir. 2013), *vacated and remanded sub nom. American Railroads*, 135 S. Ct. 1225.

⁶⁵ *American Railroads*, 135 S. Ct. at 1233–34 (remanding for consideration of the remaining constitutional issues).

⁶⁶ *Id.* at 1228.

⁶⁷ See *id.* at 1237–38 (Alito, J., concurring) ("When it comes to private entities, however, there is not even a fig leaf of constitutional justification. . . . By any measure, handing off regulatory power to a private entity is 'legislative delegation in its most obnoxious form.'" (quoting *Carter Coal*, 298 U.S. at 311)); *id.* at 1252 (Thomas, J., concurring in the judgment) ("Because a private entity is neither Congress, nor the President or one of his agents, nor the Supreme Court or an inferior court established by Congress, the Vesting Clauses would categorically preclude it from exercising the legislative, executive, or judicial powers of the Federal Government.").

⁶⁸ See *infra* Part V.C.2.

B. Constraints

Separate from any private-delegation concerns, the Network operates to some degree as a scientific agency, which means that when developing allocation policy, the Network is constrained by two interrelated “expertise-forcing” requirements:⁶⁹ primarily, its policy choices must be genuinely coupled with “significant expertise;”⁷⁰ and, as a corollary, that expertise must be insulated from the influence of the political branches.⁷¹

i. Expertise

The Court has found evidence of “significant expertise” when Congress requires a medical regulatory “program [to] evolve as technological expertise mature[s].”⁷² Here, Congress expects not only that transplantation medicine will “evolve,” but that the Network itself will be the entity driving “technological expertise matur[ation].”⁷³ Indeed, unlike “[r]egulatory science” agencies, like the EPA, which are “generally not concerned with . . . advancing the pantheon of human knowledge,”⁷⁴ Congress tasked the OPTN’s leadership not only with developing allocation policy, but also with “improv[ing]” the science of

⁶⁹ See Adrian Vermeule & Jody Freeman, *Massachusetts v. EPA: From Politics to Expertise*, 2007 SUP. CT. REV. 51, 52 (2007) (“Expertise-forcing is the attempt by courts to ensure that agencies exercise expert judgment free from outside political pressures, even or especially political pressures emanating from the White House or political appointees in the agencies.”).

⁷⁰ See *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 697 (1991) (“The identification and classification of medical eligibility criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns. In those circumstances, courts appropriately defer to the agency entrusted by Congress to make such policy determinations.”); see also *Gonzales v. Oregon*, 546 U.S. 243, 257 (2006) (“An agency . . . acquire[s] special authority to interpret its own words when . . . using its expertise and experience to formulate a regulation . . .” (citation omitted)).

⁷¹ See *Massachusetts v. EPA*, 549 U.S. 497, 533 (2007) (holding that, where Congress mandates agency action following the agency’s determination of certain circumstances, the agency may not pursue contrary presidential priorities absent a “reasonable explanation as to why it cannot or will not exercise its discretion”); see also *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000) (“[N]o matter how ‘important, conspicuous, and controversial’ the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, an administrative agency’s power to regulate in the public interest must always be grounded in a valid grant of authority from Congress.”).

⁷² See *BethEnergy*, 501 U.S. at 697.

⁷³ Cf. *id.* (deferring to Secretary of Labor’s interpretation of black-lung medical-benefit regulations where the Secretary “will make every effort to incorporate within his regulations . . . to the extent feasible the advances made by medical science . . .” (citation and internal quotation marks omitted)).

⁷⁴ See Louis J. Virelli III, *Scientific Peer Review and Administrative Legitimacy*, 61 ADMIN. L. REV. 723, 736 (2009).

transplantation.⁷⁵ This coupling of responsibilities makes the Network rare (if not unique) among governmental and quasi-governmental entities, and indicates congressional recognition of “significant expertise” sufficient to justify the Network’s authority.⁷⁶

On the other hand, one could reasonably contend that the Network’s ability to “improve” transplantation *science* does not necessarily qualify the Network to develop allocation *policy*.⁷⁷ But, a brief examination of UNOS’s history refutes this argument. Whereas the typical scientific agency regulates entities that have no experience in self-regulation, Congress constructed the OPTN on top of an existing network of transplant centers that—prior to the Federal Government’s involvement—independently and successfully allocated organs.⁷⁸ Indeed, it was this very experience that Congress sought to harness in promulgating NOTA.⁷⁹

⁷⁵ See 42 U.S.C. § 274(b)(2)(I), (N) (“The [OPTN] shall . . . collect, analyze, and publish data concerning organ donation and transplants [and] carry out studies and demonstration projects for the purpose of improving procedures for organ donation procurement and allocation”); *cf. id.* § 274(b)(1)(B) (“The [OPTN] shall . . . have a board of directors that includes representatives of [OPOs], transplant centers, [and] voluntary health associations . . .”).

⁷⁶ The Final Rule takes a similar approach in demanding that the Network consistently review its policies with an eye toward the application of its expertise. See 42 C.F.R. § 121.4(e)(2) (“The OPTN shall implement policies and shall . . . [u]pdate policies developed in accordance with this section to accommodate scientific and technological advances.”).

⁷⁷ See Strosberg & Gimbel, *supra* note 11, at 244 (“[T]ransplant professionals have no particular expertise on deciding on the tradeoffs between utility and equity. These tradeoffs and associated policies are better made by politicians than transplant professionals.” (citing ROBERT VEATCH, *TRANSPLANTATION ETHICS* (2000))). See generally Holly Doremus & A. Dan Tarlock, *Science, Judgment, and Controversy in Natural Resource Regulation*, 26 PUB. LAND & RESOURCES L. REV. 1, 17 (2005) (“[T]he real battleground in arguments about the use of science . . . is typically not the data . . . but the . . . judgments used to interpret and translate the data into regulations.”).

⁷⁸ WEIMER, *supra* note 4, at 95 (“Voluntary sharing by UNOS was already under way when the OPTN was created, so that its members had considerable experience with cooperating as well as plausible starting points from which allocation policy could begin to evolve.”).

⁷⁹ *Hearings Before the Subcomm. on Health & the Env’t of the H. Comm. on Energy & Commerce*, 98th Cong. 175 (1983) [hereinafter *NOTA Hearing*] (statement of Rep. Al Gore) (“We have heard three times now the statement that, what is proposed is a Federal Government takeover of the system when, in fact, nothing of the sort is proposed. The private systems would continue in place. The program would still be run by the same people.”); see David L. Weimer, *Public and Private Regulation of Organ Transplantation: Liver Allocation and the Final Rule*, 32 J. HEALTH POLITICS, POL’Y & L. 9, 44 (2007) (“OPTN committees have a heavy representation of transplant surgeons who bring the sort of tacit knowledge—information and understanding based on firsthand experience and observation—that is extremely useful in identifying potential issues . . . [and] in predicting the likely consequences of proposed rule changes. Many of these surgeons also contribute to the medical literature on transplantation, which gives them considerable experience in dealing with empirical evidence.”). *Contra, e.g., Gonzales*, 546 U.S. at 266–67 (“The structure of the [Controlled

ii. Insulation

But, even Congress's recognition of "significant expertise" is not enough to meet the expertise-forcing requirement unless the Network can also demonstrate that NOTA satisfies the political-insulation corollary in two ways: one legal, one factual. First, as a matter of law, the Network can show that there is no statutory conduit through which political influence may validly affect substantive changes to allocation policy.⁸⁰ Here, NOTA only authorizes procedural checks by the Secretary.⁸¹

Moreover, even assuming that—in certain contexts—a substantive executive regulation may open a conduit for political influence, this is not that context. Though the Final Rule purports to endow the Secretary with substantive override authority, that authority is *ultra vires* of NOTA.⁸² Hence, as a matter of law, the Network is insulated from political influence.

Second, even if, as a matter of law, NOTA did authorize the involvement of the political branches in substantive allocation policymaking, the Network could demonstrate that any particular policy being challenged was, as a matter of fact, promulgated free of such influence.⁸³ During a congressional hearing years after the promulgation of the Under 12 Rule, Secretary Sebelius resisted political pressure to intervene in Sarah's case,⁸⁴ clarifying that "the OPTN . . . is not bureaucrats, it's transplant surgeons and health care providers," and that these experts develop allocation policy "based on their best medical judgment of the most appropriate way to decide allocation in an

Substances Act], then, conveys unwillingness to cede medical judgments to an executive official [the Attorney General] who lacks medical expertise." (emphasis added) (citation omitted)).

⁸⁰ See *Mass. v. EPA*, 549 U.S. at 533 (finding that where congressional design mandates the use of policymaking authority by a scientific agency, contrary political priorities may not interfere); see also Vermeule & Freeman, *supra* note 69, at 89 ("State Farm is expertise-forcing in the sense that the Court expects the agency to make discretionary policy decisions that can be justified by the relevant statutory factors, and not politics."). *Contra* *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 59 (1983) (Rehnquist, J., concurring in part and dissenting in part) ("A change in administration brought about by the people casting their votes is a perfectly reasonable basis for an executive agency's reappraisal of the costs and benefits of its programs and regulations.").

⁸¹ See *infra* Part IV.B.1.

⁸² See *infra* Part IV.B.2.

⁸³ See *State Farm*, 463 U.S. at 42 (holding that "a reviewing court may not set aside an agency rule that is rational [and] based on consideration of the relevant factors").

⁸⁴ See *HHS Hearing*, *supra* note 37 (statement of Rep. Barletta) ("[Y]ou are the one person who has the authority to suspend the current policy until we are confident that children have equal access to lifesaving treatment and aren't discriminated against because of their age. . . . I'm begging you. Sarah has three to five weeks to live. Time is running out. Please, suspend the rules until we look at this policy, which we all believe is flawed.").

impossibly difficult situation.”⁸⁵ In essence, Secretary Sebelius was contending that the Under 12 Rule was an allocation policy promulgated—as a matter of fact—by the Network using its “best medical judgment,”⁸⁶ and that it would be inappropriate for the policy to be superseded by politics.

IV. THE FINAL RULE

The Department’s attempt to establish substantive override authority through the Final Rule, then, was invalid. While the Final Rule was promulgated in technical compliance with the APA, its provision purporting to authorize the Secretary to oversee the substance of the Network’s allocation policies has no statutory foundation and is an example of impermissible self-aggrandizement by an agency.

A. Promulgation

On September 8, 1994, the Department published a notice of proposed rulemaking for a rule governing the operation of the OPTN.⁸⁷ The rule would have required the OPTN to propose policies to the Secretary; and, “[i]f the Secretary object[ed] to a policy, the OPTN may [have] be[en] directed to revise the policy consistent with the Secretary’s direction.”⁸⁸ The proposed rule “recognized the [OPTN]’s exclusive statutory authority to develop organ allocation policy,” but reserved for the Secretary the power to oversee policy development in order to ensure that allocation remained “fair and equitable.”⁸⁹ Most transplant centers

⁸⁵ See *id.* (statement of Sec’y Sebelius). See generally *NOTA Hearing*, *supra* note 79, at 2 (statement of Rep. Henry A. Waxman) (“We must also avoid the chaos and bitterness that inevitably will arise if transplants are available only to . . . those fortunate enough to be singled out by the media for special attention.”). At the time the Secretary made her remarks, she may have been acutely sensitive to the issue of political influence in agency rulemaking. An April 5, 2013 order issued out of the District Court for the Eastern District of New York had included language that her then-recent decision regarding Plan B availability had been “arbitrary, capricious, and unreasonable.” *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 187 (E.D.N.Y. 2013) (“[T]hree distinguished scientists, including the Editor-in-Chief of the *New England Journal of Medicine*, wrote: ‘In our opinion, the secretary’s decision to retain behind-the-counter status for Plan B One-Step was based on politics rather than science.’” (quoting Alastair J.J. Wood, Jeffrey M. Drazen, & Michael F. Greene, *The Politics of Emergency Contraception*, 366 *NEW ENG. J. MED.* 101, 102 (2012))).

⁸⁶ Cf. *HHS Hearing*, *supra* note 37 (statement of Sec’y Sebelius) (“What I have been told by the transplant experts—and I don’t profess to have any expertise in this area—is that . . . a delineation between pediatric and adult lungs [is] based on . . . survivability . . .”).

⁸⁷ Organ Procurement & Transplantation Network, 59 Fed. Reg. 48,482, 46,496 (Sept. 8, 1994).

⁸⁸ *Id.* at 46,498.

⁸⁹ *Wisconsin*, 2000 WL 34234002, at *4.

2017] *QUASI-GOVERNMENTAL ORGAN ALLOCATION* 17

responded “cool[ly],” preferring “minimal federal oversight.”⁹⁰ The Department did not adopt the proposed rule.⁹¹

But, two years later, on November 13, 1996, the Department revived the rulemaking, reopened the docket for comments, and held a three-day hearing where “[m]ore than one hundred witnesses testified, and . . . more than six hundred [unique] letters were submitted”⁹² Nearly ninety-nine percent of physicians, and more than ninety percent of patients and families, opposed a stronger government role in allocation policy development.⁹³

Then, on April 2, 1998, the Department announced a final rule.⁹⁴ In the section “OPTN policies: Secretarial review and appeals,” the regulation read:

The Board of Directors shall . . . [p]rovide . . . proposed policies to the Secretary, who may provide comments and/or objections If the Secretary objects to the policy, the OPTN may be directed to revise the policy consistent with the Secretary’s direction. [I]f the Secretary . . . disagrees with [the revised] content, the Secretary may take such other action as the Secretary determines appropriate.⁹⁵

Then-Secretary Donna Shalala announced that this rule would “vest[] ultimate control of organ allocation policy with [the Secretary] instead of with the [OPTN].”⁹⁶ Resistance to the rule mounted in the transplant

⁹⁰ WEIMER, *supra* note 4, at 77.

⁹¹ *Wisconsin*, 2000 WL 34234002, at *4.

⁹² WEIMER, *supra* note 4, at 78–79.

⁹³ WEIMER, *supra* note 4, at 79 (citation omitted).

⁹⁴ See *supra* notes 7–12 and accompanying text.

⁹⁵ 63 Fed. Reg. at 16,334, codified at 42 C.F.R. § 121.4(b)(2).

⁹⁶ *Wisconsin*, 2000 WL 34234002, at *4; Dulcinea A. Grantham, *Transforming Transplantation: The Effect of the Health and Human Services Final Rule on the Organ Allocation System*, 35 U.S.F. L. REV. 751, 780 (2001) (“This provision gives the Secretary the power to unilaterally accept or reject any policy proposed by OPTN.” (citing 42 C.F.R. § 121.4(b))).

community and Congress.⁹⁷ After nearly two years of delays,⁹⁸ the Department responded by including a new subsection in the Federal Register titled “Discussions with the Transplant Community: Secretarial Oversight and Enforceability of OPTN Policies”:

It is not the desire, nor is it the intention, of the department to interfere in the practice of medicine. Decisions about who should receive a particular organ in a particular situation involve levels of detail, subtlety and urgency that must be judged by transplant professionals. . . . [T]he Secretary’s review is intended to ensure consistency between OPTN policies and [NOTA].⁹⁹

Notwithstanding this protestation, the language of the Final Rule itself nonetheless purports to vest in the Secretary precisely the same oversight authority proposed in 1994, 1996, and 1998.

Procedurally, the consistency of content in the Final Rule satisfies the rather lax “logical outgrowth” doctrine.¹⁰⁰ Under this doctrine, “an agency, in its notice of proposed rulemaking, need not identify precisely every potential regulatory change, [but] the notice must be sufficiently descriptive to provide interested parties with a fair opportunity to comment and to participate in the rulemaking.”¹⁰¹ Here, the only substantive change to the oversight provision from the original proposal was that the Secretary would be required to “refer significant proposed polices to the Advisory Committee on Organ Transplantation” before recommending reconsideration or requiring modification.¹⁰² Given that the transplant community had a full opportunity to—and did—voice its concerns about the Secretary’s claim to substantive oversight, the

⁹⁷ Grantham, *supra* note 96 at 759 (quoting *Putting Patients First: Resolving Allocation of Transplant Organs: Joint Hearing Before the Subcomm. on Health and Env’t of the House Comm. on Commerce and the Sen. Labor & Human Res. Comm.*, 105th Cong. 138 (1998) [hereinafter *Putting Patients First Hearing*] (statement of Dr. Lawrence G. Hunsicker, President, UNOS) (“[T]he proposed HHS [Rule] causes the transplant community great concern.”)); *Wisconsin*, 2000 WL 34234002, at *5 (“An overwhelming majority of leading experts within the transplant community condemned the final rule.”); WEIMER, *supra* note 4, at 88–89 (“Rep. Michael Bilirakis introduced a bill to overturn the HHS Final Rule, stating in the floor debate that medical experts and not Secretary Shalala know best when it comes to transplant policy. [The bill] nullified the rule and prevented HHS from asserting final authority over allocation policies. On April 4, 2000, it passed the House 275 to 147 . . . [but w]ith the anticipated difficulty of resolving the large differences between the House and Senate bills in conference committee, and the promised veto of any bill similar to the House version by President Clinton, the 106th Congress ended without legislation on organ allocation.” (parentheticals and internal quotation marks omitted)).

⁹⁸ See generally *Wisconsin*, 2000 WL 34234002, at *5.

⁹⁹ 64 Fed. Reg. at 56,652.

¹⁰⁰ See *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007).

¹⁰¹ *Chocolate Mfrs. Ass’n of U.S. v. Block*, 755 F.2d 1098, 1104 (4th Cir. 1985) (citations omitted).

¹⁰² 64 Fed. Reg. at 56,659, codified as amended at 42 C.F.R. § 121.4(b)(2).

provision cannot plausibly be argued to be anything but a “logical outgrowth” of the originally noticed proposal.¹⁰³ Nonetheless, even this highly deferential doctrine does not tolerate rules that fall outside the “statutory grant of authority.”¹⁰⁴

B. Oversight Provision

So, the dispositive question is whether NOTA provides a “statutory grant of authority” for the secretarial oversight provision. This Part concludes that NOTA expressly authorizes secretarial review of the Network’s procedures for developing allocation policies, but leaves no room for her to overrule or revise their substance.

i. Procedural Oversight

NOTA authorizes the Secretary to “establish procedures for . . . receiving . . . critical comments relating to *the manner in which* the [OPTN] is carrying out the duties of the Network . . . ; and [for] the consideration by the Secretary of such critical comments.”¹⁰⁵ Since one of the “duties of the Network” is “establish[ing] . . . medical criteria for allocating organs,”¹⁰⁶ the necessary inference is that NOTA empowers the Secretary to consider the procedures by which the Network develops allocation policies. Consistent with this inference, the Final Rule authorizes the Secretary to “revise” those procedures or take “other action as the Secretary determines appropriate.”¹⁰⁷ In *Murnaghan*, Sarah’s parents implicitly relied on this procedural oversight authority when they claimed that the Under 12 Rule violated the Final Rule because it had never been published in the Federal Register for public comment.¹⁰⁸ But,

¹⁰³ See *BASF Wyandotte Corp. v. Costle*, 598 F.2d 637, 642 (1st Cir. 1979) (“Even substantial changes in the original plan may be made so long as they are in character with the original scheme and a logical outgrowth of the notice and comment already given. The essential inquiry is whether the commenters have had a fair opportunity to present their views on the contents of the final plan. We must be satisfied, in other words, that given a new opportunity to comment, commenters would not have their first occasion to offer new and different criticisms which the Agency might find convincing.” (internal citation and quotation marks omitted)).

¹⁰⁴ *Long Island Care*, 551 U.S. at 173–74.

¹⁰⁵ 42 U.S.C. § 274(c) (emphasis added).

¹⁰⁶ *Id.* § 274(b)(2)(B).

¹⁰⁷ See 42 C.F.R. § 121.4(d)(2)–(3).

¹⁰⁸ Complaint, *supra* note 20, ¶ 60. Separately, Sarah claimed that the “Secretary’s action not to set aside the Under 12 Policy was arbitrary, capricious, and an abuse of discretion” *Id.* ¶¶ 13, 62 (citing 5 U.S.C. § 706(2) (2007) (“The reviewing court shall . . . hold unlawful and set aside agency action . . . found to be . . . arbitrary”). However, a decision not to employ enforcement authority is “committed to agency discretion by law.” See *Heckler v. Chaney*, 470 U.S. 821, 832, 835 (1985) (“[A]n agency’s decision not to take enforcement action should be presumed immune from judicial review” (citing 5 U.S.C. § 701(a)(2))).

this claim was without merit.

The Final Rule states that allocation policies will be published in the Federal Register in two circumstances (one mandatory, one discretionary), neither of which were inapplicable with respect to the Under 12 Rule. First, when a policy is “significant,” the Secretary “will . . . publish [it] in the Federal Register for public comment.”¹⁰⁹ Though the Murnaghans noted that “[n]one of the OPTN policies [have been] published in the Federal Register,”¹¹⁰ they failed to demonstrate that either the Under 12 Rule, or the overarching lung allocation policy,¹¹¹ were “significant.”¹¹² Without this affirmative showing, the mandatory Federal Register publication provision does not apply. Second, the Final Rule also states that the Secretary “may” publish “other proposed policies” in the Federal Register.¹¹³ But, a plaintiff cannot establish a cause of action by relying on a regulation that puts unqualified discretion in the hands of an executive officer.¹¹⁴

ii. Substantive Oversight

In the alternative, the Murnaghans claimed that the Under 12 Rule substantively violated the Final Rule.¹¹⁵ Here, the threshold question is whether NOTA empowers the Secretary to overturn the Network’s

So, even assuming, for purposes of Sarah’s claim, that the Secretary actually had authority to override allocation policies, the Department could demonstrate that the Network had, on the Department’s behalf and within NOTA’s parameters, employed its “reasoned” expertise. *See State Farm*, 463 U.S. at 43. And, since the “agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities,” a court should not feel compelled to issue an order requiring the Department to set the Under 12 Rule aside. *Lincoln v. Vigil*, 508 U.S. 182, 192–93 (1993) (finding unreviewable the agency’s redistribution of “lump-sum appropriations,” which allow an agency to “adapt to changing circumstances” (quoting *Heckler*, 470 U.S. at 831)). In the words of Justice Marshall in his concurrence to *Heckler*: “[a]s long as the [Network] is choosing how to allocate finite . . . [transplant organ] resources, [its] choice will be entitled to substantial deference, for the choice among valid alternative . . . policies is precisely the sort of choice over which agencies generally have been left substantial discretion by their enabling statutes. On the merits, then, a decision . . . based on valid resource-allocation decisions will generally not be ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.’” *Cf.* 470 U.S. at 842 (Marshall, J., concurring in the judgment) (citation omitted).

¹⁰⁹ 42 C.F.R. § 121.4(b)(2) (emphasis added).

¹¹⁰ Complaint, *supra* note 20, ¶ 24.

¹¹¹ *Policy 10: Allocation of Lungs*, OPTN, (Oct 1, 2016), available at https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf.

¹¹² This raises several questions: what criteria are used to determine whether an allocation policy is “significant;” who determines those criteria; are those criteria objective or subjective; should a court defer to the Department’s determination that a policy is “significant,” and, if so, what form of deference is appropriate?

¹¹³ 42 C.F.R. § 121.4(b)(2).

¹¹⁴ *See supra* note 108.

¹¹⁵ Complaint, *supra* note 20, ¶¶ 58–59.

allocation policies when, in her estimation, those policies fail to conform with the substantive requirements of the Final Rule. As noted, NOTA authorizes the Secretary to “establish procedures for . . . receiving . . . critical comments relating to *the manner in which* the [OPTN] is carrying out the duties of the Network.”¹¹⁶ As a textual matter, this language cannot be interpreted to provide the Secretary with substantive oversight power.¹¹⁷ To the contrary, according to the United States Court of Appeals for the District of Columbia Circuit, “the manner in which” a duty is carried out is categorically a procedural issue.¹¹⁸

But, even assuming NOTA grants the Department discretion to regulate the substance of Network policies, the question would nevertheless remain: did the Final Rule supply grounds for the Secretary to intrude in Sarah’s situation? The Murnaghans claimed that the Under 12 Rule “did not result in the equitable allocation of cadaveric organs” or “give greatest consideration to allocating organs based on medical urgency.”¹¹⁹ And, indeed, the Final rule requires that the Secretary “assess [whether] proposed policies comply with . . . performance indicators” that “measure how well each policy” is “achiev[ing] equitable allocation of organs among patients” based on “sound medical judgment.”¹²⁰ Yet, fatally to Sarah’s claim, this authority to “assess,” found in § 121.8, is not coupled with authority to override. While the Secretary does have override authority over procedure under § 121.4,¹²¹ it would be unreasonable to graft that authority onto § 121.8, which addresses substance.¹²²

In summary, the Department was never required to publish the Under 12 Rule in the Federal Register. And, even if NOTA gave the Department leeway to promulgate regulations that would grant the Secretary substantive oversight authority (which it does not), the Department’s failure to incorporate that authority into the Final Rule left Secretary Sebelius powerless to overturn the Under 12 Rule.

¹¹⁶ 42 U.S.C. § 274(c) (emphasis added).

¹¹⁷ The legislative history also supports the position that substantive oversight is precluded. See Grantham, *supra* note 96, at 759 n.58 (quoting *Putting Patients First Hearing*, *supra* note 97, at 77 (statement of Sec’y Shalala) (“I reiterate that the Department does not have a preconceived notion of any allocation policies. We are relying on the transplant community to develop the policy.”)).

¹¹⁸ See *Mendoza v. Perez*, 754 F.3d 1002, 1023 (D.C. Cir. 2014) (“Procedural rules . . . alter *the manner in which* the parties present themselves or their viewpoints to the agency.” (emphasis added) (internal quotation marks omitted)).

¹¹⁹ See Complaint, *supra* note 20, ¶ 58 (citing 42 C.F.R. § 121.4(a)(1)); *id.* ¶ 59 (citing 42 C.F.R. § 121.8(b)).

¹²⁰ See 42 C.F.R. § 121.8(a)(1), (b), (c)(1), (f).

¹²¹ See *supra* note 107 and accompanying text.

¹²² *Cf.* 42 C.F.R. § 121.8(a)–(h) (nowhere containing a secretarial override provision).

V. ALLOCATION POLICIES

Though the Secretary lacked authority to rescind the Under 12 Rule, that does not decide the issue whether the court could have struck it down as “not in accordance with law.”¹²³ This Part first argues that the Network, though not subject to the requirements of the APA, employs a parallel notice-and-comment system that nevertheless satisfies the APA’s normative concerns. Second, it propounds a novel threshold test for determining the applicability of *Chevron* deference to quasi-governmental entities, and contends that the Network satisfies that test. Finally, it considers whether, when developing allocation policies, the Network is a “state actor” subject to claims sounding in the Constitution.

A. Notice & Comment

The Murnaghans claimed that “[t]he Under 12 Rule is not in accordance with law because [the lung allocation policy] was never published in the Federal Register for public comment, in violation of 5 U.S.C. § 553(b).”¹²⁴ This claim falters from the start: as a matter of law, the Network is not subject to the APA. Moreover, as a normative matter, the procedures that the Network utilizes to develop allocation policies adequately address the same concerns that drive the APA’s notice-and-comment requirements.

i. Law

NOTA’s requirement that the OPTN operate a unique notice-and-comment system signals congressional intent not to subject the Network to the APA.¹²⁵ Congress controls whether an agency “is subject to statutes that impose obligations or confer powers upon Government entities, such as the [APA].”¹²⁶ While HHS is certainly an “agency” that must conform to § 553(b),¹²⁷ Congress carved out the OPTN from the APA’s informal-rulemaking obligations when it mandated that the OPTN “establish [its own] public comment and hearing process . . . similar to

¹²³ See Complaint, *supra* note 20, ¶¶ 54–60.

¹²⁴ See Complaint, *supra* note 20, ¶ 60.

¹²⁵ Although, there is not much by way of judicial guidance in situations where, as here, Congress has not expressly spoken on the issue. See O’Connell, *supra* note 63, at 917 (“The ultimate result for all of these statutes is similar: there are no bright lines for boundary organizations. This ambiguity derives from a dearth of decisions as well as inconsistency among the tests used and decisions made. Administrative law scholars have said little about this confusion.” (citation omitted)).

¹²⁶ *Lebron v. Nat’l R.R. Passenger Corp.*, 513 U.S. 374, 392 (1995).

¹²⁷ The APA applies to any entity that is an “agency,” i.e., to any “authority of the Government of the United States.” 5 U.S.C. § 551(1) (2007).

the process required of government agencies.”¹²⁸ And, indeed, the Network has complied with its mandate. Its notice-and-comment system is “similar to”—but distinct from—the APA.¹²⁹ So, as a matter of law, allocation policies are not subject to § 553(b).¹³⁰

ii. Policy

But, even though the Network is not subject to the APA, the demand for a similar notice-and-comment process demonstrates congressional intent that the APA’s fundamental principles—transparency, accountability, and participation¹³¹—also undergird allocation policy. For this reason, it is important that the Network avoid two major pitfalls of regulated resource allocation: ossification and capture.

Organ allocation is unlike most decision-making at the federal level, which can result in the ossification of “winners” and “losers.” To take a classic example, environmental protection groups want more stringent emission standards; polluters want more relaxed ones. If the EPA regulates less stringently, the polluters “win,” and the environmental groups “lose.” While each individual organ allocated by the Network similarly generates a “winner” (in the form of that organ’s recipient), the next-in-line “loser” is likely to become the next “winner.” Now, there is no perfectly “fair” way to allocate organs. But, unlike limited-resource scenarios where static policies may ossify resource distribution,¹³² there

¹²⁸ See *Wisconsin v. Shalala*, No. 00-C-155-C, 2000 WL 34234002, at *3 (W.D. Wis. Nov. 22, 2000) (emphasis added).

¹²⁹ Cf. *Policy Notices*, OPTN, <http://optn.transplant.hrsa.gov/governance/policy-notice/> (last visited Nov. 7, 2016) (“Find summaries of all OPTN policy and bylaws changes approved at board and executive committee meetings, including implementation dates and any actions you need to take.”); *Policy Comment*, OPTN, <https://optn.transplant.hrsa.gov/governance/public-comment/> (last visited Nov. 7, 2016) (“The OPTN policy development process incorporates feedback on policy . . . before the proposals go to the OPTN board of directors for approval. Public comment is an essential part of the policy development process. All interested individuals are welcome to participate, especially transplant candidates, who are most affected by policies. The OPTN welcomes public comment on all open policy proposals. We consider every comment we receive about a proposal before the OPTN board of directors votes on it.”).

¹³⁰ If, to the contrary, the Network is subject to the APA, the Author posits that anonymously donated organs are “public property” exempt from requirements of notice-and-comment rulemaking. Compare 5 U.S.C. § 553(a)(2) (“This section applies . . . except to the extent that there is involved . . . a matter relating to . . . public property . . .”) with 63 Fed. Reg. at 16,300 (“Human organs that are given to save lives are a public resource . . .”).

¹³¹ See generally Reeve T. Bull, *Making the Administrative State “Safe for Democracy”*: *A Theoretical and Practical Analysis of Citizen Participation in Agency Decisionmaking*, 65 ADMIN. L. REV. 611, 627 (2013).

¹³² Cf. Craig A. Arnold, *Resilient Cities and Adaptive Law*, 50 IDAHO L. REV. 245, 257 (2014) (“[L]egal protections of private property rights . . . undermine the resilience and functioning of ecosystems by . . . ossifying resource allocations . . . granted long ago.”).

is generally no concern about permanent unfairness in the allocation system,¹³³ particularly since Network policy development is dynamic, cyclical, and ongoing.¹³⁴

Furthermore, by developing allocation policy blind to the identities of the individual candidates that may receive organ offers, the Network steers clear of any capture issue.¹³⁵ Drawing on the same analogy, if the EPA is considering a carbon cap on industrial CO₂ emissions, the EPA knows *ex ante* which players support and oppose the proposal and the impact the proposal would have on those players.¹³⁶ But, allocation policy development is inherently devoid of capture in that they employ general rules that are applied algorithmically to candidates in real time.¹³⁷ In short, Network policymakers have no way of knowing how policy changes will affect particular candidates.

So, while the Network is not subject to the APA's notice-and-comment requirements, its dynamic and blind policy development process is, as a general matter, transparent and procedurally fair. However, a crucial question so far remains unanswered: does the content of the Under 12 Rule fall within the range of acceptable choices delineated by NOTA and the Final Rule?

B. Deference

The Murnaghans' answer was, no, that the Under 12 Rule was substantively "not in accordance with" NOTA or the Final Rule.¹³⁸ Both the Murnaghans and the court oversimplified this allegation, and thereby failed to grapple with the subtle but important issue of whether the Under 12 Rule reflects the Network's interpretation of NOTA *or* its interpretation of the Final Rule. (The court must have presumed that it

¹³³ Yet, if a particular individual is *constantly* a "loser," as the Murnaghans alleged Sarah was in the Under 12 Rule regime, then they may attempt to short-circuit the system through indirect means like judicial review. See WEIMER, *supra* note 4, at 32.

¹³⁴ See *Making OPTN Policy*, OPTN, <http://optn.transplant.hrsa.gov/governance/policies/making-optn-policy/> (last visited Nov. 7, 2016) (providing "a brief look at the process of an idea that transforms from proposal to transplant policy").

¹³⁵ Cf. Marsha Garrison, *Regulating Reproduction*, 76 GEO. WASH. L. REV. 1623, 1650 (2008) ("Certainly, any private entity that makes use of the expertise of interested—and often self-interested—parties is subject to capture by those parties in a way that may distort its public mission.").

¹³⁶ See Rachel E. Barkow, *Insulating Agencies: Avoiding Capture Through Institutional Design*, 89 TEX. L. REV. 15, 21 (2010) ("To achieve either expert or nonpartisan decision making, one must avoid undue industry influence, or 'capture.'").

¹³⁷ See *supra* text accompanying notes 17–19.

¹³⁸ See *Complaint*, *supra* note 20, ¶¶ 56–59.

reflected the former because it found *Chevron*,¹³⁹ but not *Auer*,¹⁴⁰ deference to be a less-than-weighty “factor” in its decision.¹⁴¹) Notwithstanding the court’s—likely unintentional—sidestepping of the question,¹⁴² whether the Network’s gap-filling is done pursuant to a statute versus a regulation matters.

If an allocation policy is an interpretation of NOTA (as this Part argues is the case with respect to the Under 12 Rule), *Chevron* deference may be appropriate.¹⁴³ But, if an allocation policy reflects an interpretation of the Final Rule, then it may be due *Auer* deference, a doctrine that three Justices have questioned categorically.¹⁴⁴

i. *Auer* and *Skidmore*

Even if one assumes the continuing survival of the doctrine (which is considered even more deferential than *Chevron*¹⁴⁵), *Auer* deference is unavailable to Network policies because the Final Rule does no more than “parrot” NOTA.¹⁴⁶ The Final Rule stipulates that allocation policies must

¹³⁹ See *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984) (courts are to defer to agency interpretations of ambiguous *statutes* where the interpretation reasonably resolves the ambiguity).

¹⁴⁰ *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (restating that an agency’s interpretation of its own *regulations* are “controlling unless plainly erroneous or inconsistent with the regulation” (citation and internal quotation marks omitted) (quoting *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945))).

¹⁴¹ See *supra* text accompanying note 57. This Article sets aside the following question: was it appropriate for the court to consider *Chevron* deference as a “factor” in its TRO analysis? Cf. *infra* Part V (discussing the four factors relevant to a preliminary injunction inquiry, none of which relate to *Chevron* deference).

¹⁴² Like the court, one commentator assumed this to be an issue of statutory interpretation without further elaboration. Cf. Michelle DeVito, *The Judge Put Me on the List: Judicial Review and Organ Allocation Decisions*, 65 CASE W. RES. L. REV. 181, 196 (2014) (citation omitted).

¹⁴³ See *infra* Part V.B.2.

¹⁴⁴ See *Perez v. Mortgage Bankers Ass’n*, 135 S. Ct. 1199, 1213 (2015) (Scalia, J., concurring in the judgment) (“I would . . . abandon[] *Auer* and apply[] the [APA] as written. The agency is free to interpret its own regulations with or without notice and comment; but courts will decide—with no deference to the agency—whether that interpretation is correct.”); *id.* at 1225 (Thomas, J., concurring in the judgment) (“[T]he entire line of precedent beginning with *Seminole Rock* raises serious constitutional questions and should be reconsidered in an appropriate case.”); see also *id.* at 1210 (Alito, J., concurring in part and concurring in the judgment) (“I await a case in which the validity of *Seminole Rock* may be explored through full briefing and argument.”).

¹⁴⁵ Hanah M. Volokh, *The Anti-Parroting Canon*, 6 N.Y.U. J.L. & LIBERTY 290, 291–92 (2011).

¹⁴⁶ *Gonzales*, 546 U.S. at 257 (“An agency does not acquire special authority to interpret its own words when, instead of using its expertise and experience to formulate a regulation, it has elected merely to paraphrase the statutory language.”). Were parroting not an issue here, there would still be an issue of author identity: can Network policies receive *Auer* deference as interpreting the Department’s Final Rule? Probably, yes. See John F. Manning,

“result in the equitable allocation of cadaveric organs,”¹⁴⁷ while “giv[ing] greatest consideration to allocating organs based on medical urgency.”¹⁴⁸ In other words, the latter consideration (“medical urgency”) is but one factor that the Network must incorporate into its overall “equitable” allocation scheme. So, on reflection, the Final Rule’s insistence on “equitable allocation” and “medical urgency” simply parrots NOTA’s language, which requires allocation of organs “equitably among transplant patients.”¹⁴⁹ And, this is not even the only example of parroting by the Department.

Like NOTA, which requires the Network to “improv[e] procedures for organ . . . allocation . . . to . . . populations with limited access to transportation,”¹⁵⁰ the Final Rule instructs the Network to “reduce inequities resulting from socioeconomic status.”¹⁵¹ At most, the Department’s focus on this “socioeconomic” class of candidates is simply a highlighting of one subcategory within—i.e., it neither adds to nor subtracts from—NOTA’s broader category of “populations with limited access to transportation.” Since the Final Rule provides no further targets or goals for substantive Network policy development, the entirety of the Department’s substantive regulatory instructions appears to parrot NOTA. And, when parroting, an agency’s interpretation of a statute is assessed with *Skidmore* deference, not *Auer*.¹⁵²

Under *Skidmore*, an interpretation is entitled to respect “proportional to its ‘power to persuade.’”¹⁵³ While the application of the Under 12 Rule may seem normatively unfair out of context,¹⁵⁴ there is no reason to suspect that the rule itself is unpersuasive: the lung allocation system is “highly detailed,”¹⁵⁵ and the Network “benefit[ted]” from the “specialized experience” of the transplant community as it answered “the

Constitutional Structure and Judicial Deference to Agency Interpretations of Agency Rules, 96 COLUM. L. REV. 612, 696 n.104 (1996) (“Authorship is not an essential predicate to deference under [*Auer*]. Rather, the Court has relied on the *Chevron* rationale to defer to an agency’s interpretation of regulations that the agency did not adopt.” (citing, e.g., *BethEnergy*, 501 U.S. at 696–97 (finding judicial deference due to Secretary of Labor’s interpretation of regulations promulgated by Secretary of Health, Education, and Welfare, where congressional delegation “entails the authority to interpret HEW’s regulations and the discretion to promulgate interim regulations based on a reasonable interpretation thereof”))).

¹⁴⁷ Complaint, *supra* note 20, ¶ 58 (citing 42 C.F.R. § 121.4(a)(1)).

¹⁴⁸ *Id.* ¶ 59 (citing 42 C.F.R. § 121.8(b)).

¹⁴⁹ See 42 U.S.C. § 274(b)(2)(D).

¹⁵⁰ See *id.* § 274(b)(2)(N).

¹⁵¹ See 42 C.F.R. § 121.4(a)(3).

¹⁵² See *Gonzales*, 546 U.S. at 268–69.

¹⁵³ *United States v. Mead Corp.*, 533 U.S. 218, 235 (2001) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

¹⁵⁴ Cf. *HHS Hearing*, *supra* note 84.

¹⁵⁵ Cf. *supra* text accompanying notes 29–32.

subtle questions” about pediatric lung transplantation.¹⁵⁶ That said, a court should only rely on *Skidmore* if it has first determined that the policy reflected an interpretation of the Final Rule.

ii. *Chevron*

In the alternative, a court could find that the Under 12 Rule interprets NOTA, which would raise the question whether the policy is due *Chevron* deference. The *Murnaghan* court assumed the applicability of *Chevron*,¹⁵⁷ but failed to note, *inter alia*, that the defendant (the Department) was not, in fact, the author of the policy at issue.¹⁵⁸

a. Threshold

If *Chevron* is going to be applied to a policy like the Under 12 Rule, a court should understand why that is so before deferring to a quasi-governmental entity’s interpretation of its organic statute. Here, the two norms that normally support a finding of *Chevron* deference—namely, expertise and political accountability¹⁵⁹—intersect in such an unusual way that, perhaps, political accountability need not be demonstrated at all.¹⁶⁰ Arguably, since the only interests implicated by allocation policies are those of the candidates, and since Network policies utilize “*medical criteria*” to allocate organs,¹⁶¹ *political* accountability ought to be irrelevant.¹⁶² Consider the following test: where organizational expertise

¹⁵⁶ See *supra* text accompanying notes 75 & 99.

¹⁵⁷ See *supra* text accompanying note 57.

¹⁵⁸ It may be that this is a distinction without a difference, since courts may conclude that an agency has given its sub-agency a “stamp of approval” without “digging” deeply into “where an interpretation originated, or whether the agency was truly the primary interpreter involved.” Aaron R. Cooper, *Sidestepping Chevron: Reframing Agency Deference for an Era of Private Governance*, 99 GEO. L.J. 1431, 1450–51 (2011) (parenthetical omitted) (citing David J. Barron & Elena Kagan, *Chevron’s Nondelegation Doctrine*, 2001 SUP. CT. REV. 201, 204, 234–35 (2001)).

¹⁵⁹ O’Connell, *supra* note 63, at 923 (“[D]eference doctrines draw largely from the perceived institutional characteristics of agencies, notably their accountability and expertise—at least relative to the courts.”).

¹⁶⁰ *But cf.* Kimberly N. Brown, “*We the People*,” *Constitutional Accountability, and Outsourcing Government*, 88 IND. L.J. 1347, 1391 (“Not all government contracts raise accountability issues of constitutional dimension. . . . [A] contract should be initially scrutinized for constitutional accountability if one of two triggers exist: First, a contract delegates to private parties executive power under the Constitution’s express terms, or, second, a contract affords to a private party the ability to exercise enforcement power in a manner that could lead to a realistic risk of interference with civil liberties.”).

¹⁶¹ See 42 U.S.C. § 274(b)(2)(B) (emphasis added).

¹⁶² If, as the *Murnaghan* court presumed, HHS had directly developed the Under 12 Rule, then this analysis would be simpler: as a traditional cabinet department, *Chevron*’s accountability norm would certainly have been triggered, see *Chevron*, 467 U.S. at 865–66 (“While agencies are not directly accountable to the people, the Chief Executive is, . . .”) and

is extraordinary, where Congress justifiably entrusts rulemaking to that expertise, and where the interests implicated by the resulting policies are those of a narrowly defined population, political accountability need not be demonstrated because its value in the *Chevron* calculus approaches zero.

Were it instead necessary to demonstrate political accountability in the context of allocation policies, there would be three potentially insurmountable obstacles to the application of *Chevron* deference.¹⁶³ First, the substantive secretarial oversight provision of the Final Rule is an invalid interpretation of NOTA,¹⁶⁴ so, it cannot be relied upon to establish political accountability as a matter of law. Second, since no Secretary has ever employed the procedural secretarial oversight provision (nor affirmatively approved an allocation policy), no Network policy has ever been generated in a politically accountable atmosphere as a matter of fact.¹⁶⁵ Third, there is no statutory authority granting the President or the Secretary the power to remove any member of the OPTN/UNOS Board.¹⁶⁶

satisfied since the Secretary serves at the pleasure of the President, subject to removal without cause. *Cf.* *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd. (PCAOB)*, 561 U.S. 477, 483 (2010) (“Since 1789, the Constitution has been understood to empower the President to keep these officers accountable—by removing them from office, if necessary.” (citing *Myers v. United States*, 272 U.S. 52 (1926))).

¹⁶³ *Cf.* *Brown*, *supra* note 160, at 1351 (“Inevitably, democratic accountability is compromised with the practice of government outsourcing, which occurs when the government contracts with private parties to provide goods or services for which the government is responsible.”).

¹⁶⁴ *See supra* Part IV.B.2.

¹⁶⁵ *See supra* Part IV.B.1.

¹⁶⁶ *See PCAOB*, 561 U.S. at 496 (“Neither the President, nor anyone directly responsible to him . . . has full control over the Board. The President is stripped of the power our precedents have preserved, and his ability to execute the laws—by holding his subordinates accountable for their conduct—is impaired.”). The *PCAOB* problem may be resolved by the possibility that the President could order termination of the OPTN/UNOS contract. *See* Kimberly N. Brown, *Government by Contract and the Structural Constitution*, 87 *NOTRE DAME L. REV.* 491, 521 (2011). But, if the President were to order termination, the order would first go through the Secretary, who would then have to command HRSA’s contracting officer (“CO”) to terminate the contract with UNOS. And, that Administrator would be obliged to independently investigate before the contract could be terminated for the “convenience” of the Government. *See* 48 C.F.R. § 49.101(b) (2015) (“The contracting officer shall terminate contracts . . . only when it is in the Government’s interest.”); *see also* *TigerSwan, Inc. v. United States*, 118 Fed. Cl. 447, 452 (2014) (“Without question, a CO is granted a great deal of discretion in determining whether it is in the government’s best interest to terminate a contract for convenience. However, while a CO is afforded wide discretion, [s]he is still responsible for making an independent decision with regard to a contract.” (citation omitted)). Thus, even assuming contract termination makes the Network accountable for purposes of *Chevron*, *see* *Brown*, *supra* note 160, at 1403 (“To be sure, there are a number of hurdles that a constitutional accountability doctrine presents. The precise details of what must be included in federal contracts to satisfy an accountability doctrine are

To summarize, if a court found itself unwilling to compromise with respect to the necessity of the political accountability norm, then, for the reasons discussed above, it likely would have to deny *Chevron* deference to the Network for three reasons: (1) the Secretary has no power over the substance of the Network's policies; (2) even if she did, she has essentially waived it; and, (3) neither she nor the President can coerce the Network's leadership for lack of direct removability. What follows assumes that a court has concluded that the Network's expertise is sufficient to outweigh the dearth of political accountability, and therefore that it is necessary to embark upon a *Chevron* analysis.¹⁶⁷

b. Step One

In the case of the Under 12 Rule, the question at *Chevron*'s first step is whether NOTA is "unambiguous[]"¹⁶⁸ in its use of the term "equitably" and the phrase "address the unique health care needs of children."¹⁶⁹ Or, more precisely, "employing traditional tools of statutory construction,"¹⁷⁰ has Congress "directly spoken to the precise question at issue:"¹⁷¹ namely, how should pediatric candidates—or, at a lower level of generalization, how should pediatric *lung* candidates—be treated when compared with adult candidates in the context of adult-donor offers?

To answer this question, one begins by looking at NOTA's text. The Network's allocation policies must not only "distribut[e] organs equitably among transplant patients,"¹⁷² but must also "address the unique health care needs of children."¹⁷³ Without further clarity elsewhere in the statute, NOTA is ambiguous as to how the Network

not immediately apparent and would have to be developed through litigation or legislation, which takes time."), it does not appear the President has direct control over the Network Board through termination and, therefore, the Network cannot avoid the *PCAOB* problem.

¹⁶⁷ Some commentators have expressed categorical resistance to the idea of granting *Chevron* deference to a private entity. See, e.g., A. Cooper, *supra* note 158, at 1460 (citation omitted) ("Structural aspects of privatization suggest that private delegation increases the likelihood that the decision-making values embodied in both *Chevron* and the Constitution will be undermined: values such as transparency, accountability, fairness, and deliberation may all be compromised."). Others would apply *Chevron* deference, at least in this instance. See, e.g., DeVito, *supra* note 142, at 197; Jocelyn Cooper, *Dissecting the Heart of Organ Allocation Policy: Evaluating the Eastern District of Pennsylvania's Grant of Life in Murnaghan v. U.S. Department of Health and Human Services*, 59 VILL. L. REV. 269, 299 (2014).

¹⁶⁸ See *Chevron*, 467 U.S. at 843.

¹⁶⁹ See *supra* text accompanying note 22.

¹⁷⁰ *Chevron*, 467 U.S. at 843 n.9.

¹⁷¹ *Id.* at 842.

¹⁷² 42 U.S.C. § 274(b)(2)(D).

¹⁷³ *Id.* § 274(b)(2)(M).

should treat children vis-à-vis adults.¹⁷⁴ Assuming legislative history may not be considered,¹⁷⁵ it seems the Under 12 Rule easily clears *Chevron*'s first step because it falls within the ambiguity gap established by NOTA—i.e., it demonstrably attempts to ensure “equitabl[e]” organ allocation while also “address[ing] the unique . . . needs” that attend to children who require lung transplants. Before moving on to *Chevron*'s second step, however, a court must engage in the two-part *Mead* inquiry.¹⁷⁶

c. *Mead*

The first prong of *Mead* asks whether Congress delegated authority to make rules “carrying the force of law,” holding that such a delegation “may be shown . . . by an agency’s power to engage in . . . notice-and-comment rulemaking, or by some other indication of a comparable congressional intent.”¹⁷⁷ So, here, the question is whether the Network’s internal notice-and-comment system is “comparable” to the APA notice-and-comment system.¹⁷⁸ NOTA’s text illustrates a striking similarity:

¹⁷⁴ Here, ambiguity is readily apparent due to the potential conflict in allocating “equitably,” while still prioritizing children. In these sorts of circumstances, the Supreme Court “permit[s] the Executive to make trade-offs between competing policy goals.” See *American Railroads*, 135 S. Ct. at 1251 (Thomas, J., concurring in the judgment) (citing, e.g., *Yakus v. United States*, 321 U.S. 414, 420, 423–26 (1944) (approving authorization for agency to set prices of commodities at levels that “will effectuate the [sometimes conflicting] purposes of th[e] Act”) and *Indus. Union Dep’t, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 686–87 (1980) (Rehnquist, J., concurring in judgment) (“It is difficult to imagine a more obvious example of Congress simply avoiding a choice which was both fundamental for purposes of the statute and yet politically so divisive that the necessary decision or compromise was difficult, if not impossible, to hammer out in the legislative forge.”)).

¹⁷⁵ Cf. *Halbig v. Burwell*, 758 F.3d 390, 406–07 (D.C. Cir. 2014) (“One line of cases instructs us to cease our inquiry and give effect to the statute’s unambiguous language. Another tells us to wade into the legislative history in the hope of glimpsing ‘new light on congressional intent.’ . . . [O]ur decision about which path to travel implicates substantial theoretical questions of statutory interpretation, . . .” (citations omitted)), *reh’g en banc granted, judgment vacated*, No. 14-5018, 2014 WL 4627181 (D.C. Cir. Sept. 4, 2014). If a court decides to consider legislative history at Step One, it ought to take note of two key facts. First, NOTA originally did not refer to the “unique health care needs of children;” and the bills, committee reports, and debates surrounding NOTA in the House and Senate fail to make reference to “child” or “children,” outside a general plea to increase the donor pool. See, e.g., 130 Cong. Rec. 29,982 (Oct. 4, 1984) (statement of Sen. Ted Kennedy) (“This bill is a small but very important step toward assisting children and adults dying tragically and unnecessarily because of the lack of needed organs.”). Second, NOTA was amended by the Children’s Health Act of 2000, Pub. L. No. 106-310, 114 Stat. 1101 (2000), to include § 274(b)(2)(M), which calls for the OPTN to be attentive to the “unique health care needs of children[.]”

¹⁷⁶ Cf. O’Connell, *supra* note 63, at 925 (“To the extent that boundary organizations use a wider range of tools to make decisions than the rulemaking and adjudication categories entrenched in the APA, they may have a harder time qualifying for deference under *Mead*.”).

¹⁷⁷ 533 U.S. at 227.

¹⁷⁸ Compare *supra* note 129, with 5 U.S.C. § 553.

“[t]he [OPTN] shall . . . provide to members of the public an opportunity to comment with respect to [allocation] criteria.”¹⁷⁹ It is difficult to imagine that a court would not find such language “comparable” to language directing an agency to utilize APA rulemaking procedures. Indeed, in an opinion handed down seven months before *Mead* (but seemingly prophetic of its holding), one federal district court found that, yes, the language of NOTA indicates the Network’s notice-and-comment system was meant to act in a manner “similar to” informal rulemaking under the APA.¹⁸⁰

What remains is to determine whether the Under 12 Rule, in particular, also satisfies *Mead*’s second prong, which asks whether the policy for which deference is sought was “promulgated in the exercise of [the Network’s notice-and-comment] authority.”¹⁸¹ It was: the Under 12 Rule was made part of the lung allocation policy via the Network’s notice-and-comment system.¹⁸² Having now answered both *Mead* questions in the affirmative, it is appropriate to move on to *Chevron*’s second step.

d. Step Two

Here, courts uphold an interpretation of a statute if that interpretation is “based on a permissible construction of the statute.”¹⁸³ Since *Chevron*’s second step is dramatically more deferential than *Skidmore*, and since it is already evident that the Network’s allocation policies have the *Skidmore*-satisfying “power to persuade,”¹⁸⁴ the Under 12 Rule would

¹⁷⁹ 42 U.S.C. § 274(b)(2)(B).

¹⁸⁰ See *Wisconsin*, 2000 WL 34234002, at *3.

¹⁸¹ See *Mead*, 533 U.S. at 227. One commentator has concluded that the Network’s allocation policies carry the “force of law” and are due *Chevron* deference, in part, because the notice-and-comment procedures described in the Department’s Final Rule (requiring allocation policies to be submitted to the Secretary and published in the Federal Register for comment) are “more suggestive of rulemaking procedures than the creation of non-binding policy statements.” DeVito, *supra* note 142, at 197 (citing *Christensen v. Harris Cnty.*, 529 U.S. 576, 586–89 (2000)). This argument, however, ignores a key fact: allocation policies have never been promulgated pursuant to the Final Rule; indeed, Sarah Murnaghan’s parents contended that this failure to abide by federal regulations was a reason to invalidate the Under 12 Rule. See *supra* text accompanying note 108. Moreover, were the Under 12 Rule examined through the procedural lens of the Final Rule (as the commentator seems to suggest it should be), then the Under 12 Rule necessarily would be invalid since it was not “promulgated in the exercise of [the Final Rule’s] authority.” See *Mead*, 533 U.S. at 227.

¹⁸² Roberts, *supra* note 20. See generally *supra* note 129.

¹⁸³ *Chevron*, 467 U.S. at 843; see Matthew C. Stephenson & Adrian Vermeule, *Chevron Has Only One Step*, 95 VA. L. REV. 597, 599 (2009) (“Subsequent courts and commentators have treated Step Two as a requirement that the agency’s statutory interpretation be ‘reasonable.’”).

¹⁸⁴ See *supra* notes 153–156 and accompanying text.

undoubtedly clear *Chevron*'s second step.¹⁸⁵ In short, assuming that the Network's allocation policies generally may be subject to *Chevron* deference, the Under 12 Rule specifically would satisfy both steps of *Chevron* and, therefore, should be immune from judicial intervention as a matter of administrative law.

C. State Action

But, even *Chevron* deference cannot save a policy that is unconstitutional.¹⁸⁶ In *Murnaghan*, Sarah's parents claimed that the Under 12 Rule violated Sarah's Due Process and Equal Protection rights.¹⁸⁷ However, as a prerequisite to claiming that an allocation policy violates one's constitutional rights, the plaintiff must also allege that the promulgation and/or application of the policy is state action.¹⁸⁸ The Murnaghans avoided this issue altogether by suing the Department. But, the Department is not the entity responsible for allocation policies.¹⁸⁹

¹⁸⁵ See, e.g., *Tualatin Valley Builders Supply, Inc. v. United States*, 522 F.3d 937, 942 (9th Cir. 2008) (where a quasi-governmental regulation survives the "less stringent *Skidmore* analysis," there is no need to conduct *Mead* or *Chevron* Step Two analyses). This Part does not analyze the substance of the Under 12 Rule to determine whether it would survive *Chevron*'s second step as this would involve extensive analysis of the Network's scientific and medical judgments. Helpfully, one commentator has condensed many of the relevant considerations in support of her position that *Chevron* deference would be appropriate. See DeVito, *supra* note 142, at 198–200.

¹⁸⁶ Thomas W. Merrill & Kristin E. Hickman, *Chevron's Domain*, 89 GEO. L.J. 833, 914 (2001) ("Because the Constitution is a form of law superior to a mere statute, . . . there can be no doubt that *Chevron* deference must give way when the agency's policy, although consistent with the statute and otherwise permissible in light of the statutory language and purpose, impinges upon principles that the Court has discerned in the Constitution." (citing *Dickerson v. United States*, 530 U.S. 428, 437 (2000) ("Congress may not legislatively supersede our decisions interpreting and applying the Constitution."))).

¹⁸⁷ Complaint, *supra* note 20, ¶¶ 54–55. Whether this argument would have been successful on the merits is beyond the scope of this Article. But, the intersection of allocation rules and the Constitution has received attention in the literature. See, e.g., O'Brien, *supra* note 28, at 128–33 (analyzing the Network's lung allocation policy in the context of equal protection and concluding that it "passes constitutional muster"); Benjamin Mintz, *Analyzing the OPTN Under the State Action Doctrine—Can UNOS's Organ Allocation Survive Strict Scrutiny?*, 28 COLUM. J.L. & SOC. PROBS. 339, 376–96 (noting a "racially discriminatory effect that results from the factoring of antigen matching in [kidney] allocation decisions," and arguing that such an "allocation system may not be able to survive equal protection strict scrutiny analysis").

¹⁸⁸ *Brentwood Acad. v. Tenn. Secondary Sch. Athletic Ass'n*, 531 U.S. 288, 295 (2001) ("Our cases try to plot a line between state action subject to Fourteenth Amendment scrutiny and private conduct (however exceptionable) that is not." (citations omitted)); see U.S. CONST. amend. XIV, § 1 ("[N]o State shall . . . deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws."); see also *id.* amend. V ("No person shall . . . be deprived of life, liberty, or property, without due process of law . . .").

¹⁸⁹ Query whether the Department was a proper defendant to this lawsuit in the first instance. Cf. *supra* note 146 (discussing the author identity issue). Although the Network

So, the *Murnaghan* court should have addressed whether, when promulgating allocation policy, the *Network*—a quasi-governmental entity—is engaging in state action such that it is subject to claims of constitutional violations. Critically, only a court may answer this question. While Congress has discretion to impose statutory requirements on quasi-governmental entities—e.g., whether to subject them to FOIA¹⁹⁰—Congress receives no deference in the determination

immediately complied with the *Murnaghan* court’s TRO, it is arguable that it need not have done so, since the *Network* was not itself a named party in Sarah’s complaint. See FED. R. Civ. P. 65(d)(2)(A). It is more likely, though, that the *Network* was legally bound to obey the order as an “agent” or “servant” of the Department, see *id.* 65(d)(2)(B), since the *Network* is under contract with HRSA. See *supra* note 5 and accompanying text.

¹⁹⁰ The Freedom of Information Act (“FOIA”) allows any individual to request federal agency records. See generally 5 U.S.C. § 552(a) (2014). HHS, CMS, and HRSA are subject to FOIA and maintain offices to respond to requests. See *Freedom of Information and Privacy Acts Division*, HHS, <http://www.hhs.gov/foia/contacts/index.html> (last visited Nov. 7, 2016). Private entities, on the other hand, are not generally subject to FOIA, *Forsham v. Harris*, 445 U.S. 169, 179–80 (1980), as they do not meet FOIA’s definition of “agencies.” Cf. 5 U.S.C. § 552(f)(1). But, exceptions do exist. See, e.g., *Moye, O’Brien, O’Rourke, Hogan & Pickert v. Nat’l R.R. Passenger Corp.*, 376 F.3d 1270, 1277 n.5 (11th Cir. 2004) (concluding that Amtrak is subject to FOIA though not a federal agency (citing 49 U.S.C. § 24301(e) (2016) (“[FOIA] applies to Amtrak for any fiscal year in which Amtrak receives a Federal subsidy.”))). A two-pronged test determines whether the subject of a FOIA request is an “agency record”: first, an agency must “either create or obtain” the record; second, “the agency must be in control of the requested materials at the time the FOIA request is made.” *Dep’t of Justice v. Tax Analysts*, 492 U.S. 136, 144–45 (1989) (citations omitted). And, the “data generated by a privately controlled organization which has received grant funds from an agency, but which data has not at any time been obtained by the agency, are not ‘agency records’ accessible under the FOIA,” even when the agency subjects the private entity to “some supervision.” *Forsham*, 445 U.S. at 173, 176–78 (parenthetical omitted) (finding that a private research group’s data were not agency records despite agency’s “right of access to the data” because the agency “ha[d] not exercised its right . . . to obtain permanent custody of the data”). The OPTN/UNOS, as its moniker would suggest, has a dual nature: the OPTN is a shell quasi-governmental agency operated by UNOS, an entirely private non-profit entity that existed prior to—and wholly independent of—NOTA. See *supra* Part I. OPOs generate allocation lists in compliance with the policies of UNOS, which then stores and maintains those lists. But, NOTA anticipates that the OPTN will continue to maintain the national organ-matching registry even if UNOS ceases to act as its operator. See Harold J. Krent, *Fragmenting the Unitary Executive: Congressional Delegations of Administrative Authority Outside the Federal Government*, 85 NW. U. L. REV. 62, 96 n.108 (1990) (“HHS . . . may select a different private delegate to discharge those functions currently undertaken by UNOS.”). This in mind, the OPTN—and not UNOS—must be the legal holder of allocation lists; otherwise, UNOS could (arguably) refuse to provide them to any successor-operator. FOIA applies to the OPTN since it is a federal governmental agency, even if only a shell. So, FOIA applies to the records produced by UNOS in its role as OPTN operator. That said, neither UNOS nor the OPTN have a FOIA office. So, as an experiment to determine whether UNOS records can actually be obtained, the Author submitted FOIA requests to HHS, HRSA, and CMS, for the lung allocation lists whence Sarah Murnaghan received her two bilateral lung transplants. HHS immediately responded that it was not the holder of UNOS records, and forwarded the request to HRSA. See Letter from HHS FOIA Office to Author (Dec. 12, 2014) (on file with author). CMS attempted to locate the lists and—upon realizing that it did not hold them—also forwarded

of whether such an entity is a state actor for constitutional purposes.¹⁹¹

The following is an analysis of the Network under three of the Court's tests for determining whether a nominally private entity is engaging in state action:¹⁹² entwinement, control, and public function.¹⁹³

the request to HRSA. *See* Letter from Hugh Gilmore, Director, CMS FOIA Office, to Author (Feb. 23, 2015) (on file with author). HRSA flatly denied the request. *See* Letter from Thomas Flavin, Freedom of Information Officer, HRSA FOIA Office, to Author (March 23, 2015) (on file with author) (“[T]he lung allocation lists . . . are exempt under FOIA Exemption (b)(6), which protects against the release of information about individuals in . . . medical files . . . when the disclosure of such information would constitute a clearly unwarranted invasion of personal privacy.” (internal quotation marks omitted)). It may be inferred from this response that HRSA perceives the Network's allocation lists to be agency records subject to FOIA requests. Otherwise, it seems more likely that HRSA would have responded as HHS and CMS did: by simply dodging the request, rather than citing to a substantive FOIA exemption. Notwithstanding the implication, the Author appealed HRSA's determination, arguing that Exemption (b)(6) does not apply to redacted copies of the allocation lists. *See* Letter from Author to Deputy Chief FOIA Officer, Office of the HHS Assistant Secretary for Public Affairs (April 9, 2015) (on file with author). HHS affirmed HRSA's decision to deny disclosure arguing, first, that FOIA does not demand disclosure for lack of public interest; and, second, that the records themselves “are found in a Privacy Act System of Records (SORN-09-15-0055), Organ Procurement and Transplantation Network (OPTN)/Scientific Registry of Transplant Recipients (STR) Data System,” access to which is limited by the Privacy Act. *See* Letter from Catherine Teti, Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, to Author (Aug. 19, 2015) (citing 5 U.S.C. § 552a and 74 Fed. Reg. 57,184, 57,184–86 (Nov. 4, 2009)). In conclusion, HHS appears to view OPTN/UNOS allocation lists as “agency record[s],” at least for purposes of FOIA. *Cf. Tax Analysts*, 492 U.S. at 144–45.

¹⁹¹ *See American Railroads*, 135 S. Ct. at 1231 (“Congressional pronouncements, though instructive as to matters within Congress' authority to address, are not dispositive of . . . status as a governmental entity for purposes of separation of powers analysis under the Constitution.” (citation omitted)); *see also Brentwood Academy*, 531 U.S. at 296 (“[T]he character of a legal entity is determined neither by its expressly private characterization in statutory law, nor by the failure of the law to acknowledge the entity's inseparability from recognized government officials or agencies.” (citing *Lebron*, 513 U.S. at 399 (“We hold that where, as here, the Government creates a corporation by special law, for the furtherance of governmental objectives, and retains for itself permanent authority to appoint a majority of the directors of that corporation, the corporation is part of the Government for purposes of the First Amendment.”))).

¹⁹² *Cf. Gross*, *supra* note 2, at 238–39 (“Although courts have not had to confront the state actor problem with respect to UNOS, it is academically interesting because it plays on an ambiguity that has persisted since NOTA's enactment: how to characterize the mix of ‘private’ and ‘governmental’ features constituting the OPTN.”).

¹⁹³ This Part does not engage in four other state action tests for various reasons. *See generally* Julie K. Brown, *Less is More: Decluttering the State Action Doctrine*, 73 Mo. L. REV. 561, 581 (2008) (citations omitted) (“The state action doctrine is slowly descending into utter confusion, where private parties remain unaware of what conduct subjects them to Constitutional restrictions, and courts are unclear as to the appropriate state action standard.”). First, the Court has not used the state compulsion test for over half a century. *Id.* at 567 n.60 (citing *Burton v. Wilmington Parking Auth.*, 365 U.S. 715 (1961)). Second, the joint participation test “applies in situations where the state so closely encourages a party's activity that the private actor is said to be ‘cloaked with the authority of the state,’” *id.* at 567 (citation omitted), which is a situation utterly dissimilar from the relationship between the Department

The tests do not formalistically review the organic statutes of quasi-governmental entities;¹⁹⁴ rather, each is highly fact-specific and must be applied on a case-by-case basis.¹⁹⁵

i. Entwinement

This fact-specific inquiry is particularly daunting when trying to predict whether a court would find state action under the entwinement test. Generally, where there is a “pervasive entwinement of [government] officials in the structure of [a nominally private] association,” that “association’s regulatory activity may and should be treated as state action”¹⁹⁶ In *Brentwood Academy*, the Court found state action where a state-wide not-for-profit interscholastic athletic association, which included most of the state’s public schools,¹⁹⁷ acted through those schools’ representatives to regulate athletics “in lieu of the State Board of Education’s exercise of its own authority.”¹⁹⁸

Like in *Brentwood Academy*, where the voting membership of the association’s rulemaking and administrative arms consisted of representatives—e.g., principals—from the member schools,¹⁹⁹ the OPTN/UNOS Board is primarily comprised of transplant surgeons representing the Network’s affiliated transplant centers.²⁰⁰ But, unlike

and the Network. Third, the symbiotic relationship test is “closely related to”—but “more unstructured than”—a fourth test, the nexus test, *id.*, which has already received consideration in the literature as applied to the Network: while “[t]he facts underlying the OPTN scheme legitimate an argument of a sufficient nexus between the OPTN and the government,” it is extremely challenging to predict how the Supreme Court would categorize the relationship “because the determination of a sufficient nexus classifying a private entity as a state actor is heavily fact-driven.” Mintz, *supra* note 187, at 373 (“[D]espite the presence of a relatively significant nexus,” the Court concluded that the United States Olympic Committee was not a state actor; hence “the Court is unlikely to find the OPTN a state actor on the nexus theory since the evidence of a nexus was stronger with respect to the USOC than it is with respect to the OPTN.” (citing *S.F. Arts & Athletics, Inc. v. U.S. Olympic Comm.*, 483 U.S. 522, 542–47 (1987))).

¹⁹⁴ See *Brentwood Academy*, 531 U.S. at 301 n.4 (“[I]f formalism were the *sine qua non* of state action, the doctrine would vanish owing to the ease and inevitability of its evasion, and for just that reason formalism has never been controlling.”).

¹⁹⁵ *Id.* at 295–96 (“[N]o one fact can function as a necessary condition across the board for finding state action; nor is any set of circumstances absolutely sufficient, for there may be some countervailing reason against attributing activity to the government.”); *Burton*, 365 U.S. at 722 (“Only by sifting facts and weighing circumstances can the nonobvious involvement of the State in private conduct be attributed its true significance.”).

¹⁹⁶ *Brentwood Academy*, 531 U.S. at 291.

¹⁹⁷ *Id.* at 299–300 (“Only the 16% minority of private school memberships prevents this entwinement of the Association and the public school system from being total and their identities totally indistinguishable.”).

¹⁹⁸ *Id.* at 291.

¹⁹⁹ See *id.* at 299–300.

²⁰⁰ See *Board of Directors, OPTN*, <https://optn.transplant.hrsa.gov/members/board-of->

the committee members in *Brentwood Academy*, who were employees of the very state (Tennessee) that the Court found the association to be “entwine[d]” with,²⁰¹ the members of the Network committees are citizens of various states and primarily employees of geographically diverse private hospitals, public hospitals, OPOs, and histocompatibility laboratories.²⁰² Moreover, none of the voting members of its Board or committees are employees of the Federal Government.

Also, in *Brentwood Academy*, the Tennessee State Board of Education had historically and expressly designated the association as “the organization to supervise and regulate [interscholastic] athletic activities”²⁰³ Likewise, HHS has consistently designated UNOS to operate the OPTN.²⁰⁴ Finally, as in *Brentwood Academy*, where State Board of Education members were “assigned ex officio to serve as members of the [association’s rulemaking and administrative arms],”²⁰⁵ the HHS Division of Transplantation is represented by ex officio members on the Network Board and on many Network committees.²⁰⁶

Overall, it is an onerous—perhaps impossible—task to anticipate whether a court would find entwinement after weighing these various

directors/ (last visited Nov. 7, 2016).

²⁰¹ *Brentwood Academy*, 531 U.S. at 300.

²⁰² See *Committees*, OPTN, <https://optn.transplant.hrsa.gov/members/committees/committee-q-a/> (last visited Nov. 7, 2016). Worth noting, as an aside, is the Ethics Committee: its composition mirrors almost exactly the hypothetical “Medical Commission” Justice Scalia sketched in a prescient dissent. Compare *Ethics Committee*, OPTN, <https://optn.transplant.hrsa.gov/members/committees/ethics-committee/> (last visited Nov. 7, 2016) (listing the following as members (among others): six transplant centers M.D.’s; two OPO representatives; and three members of the general public, including Georgetown University medical ethicist Robert Veatch, Ph.D.) and *Robert Veatch, Ph.D.*, KENNEDY INSTITUTE OF ETHICS, <https://kenedyinstitute.georgetown.edu/people/robert-veatch/> (last visited Nov. 7, 2016) (“One of the pioneers of contemporary medical ethics, Dr. Veatch served as an ethics consultant in the early legal case of [a] woman whose parents won the right to forgo life-support”) with *Mistretta*, 488 U.S. at 422 (Scalia, J., dissenting) (“If rulemaking can be entirely unrelated to the exercise of judicial or executive powers, I foresee all manner of ‘expert’ bodies, insulated from the political process, to which Congress will delegate various portions of its lawmaking responsibility. How tempting to create an expert Medical Commission (mostly M.D.’s, with perhaps a few Ph.D.’s in moral philosophy) to dispose of such thorny, ‘now-in’ political issues as the withholding of life-support systems”).

²⁰³ *Brentwood Academy*, 531 U.S. at 292 (citation omitted).

²⁰⁴ See *Wisconsin*, 2000 WL 34234002, at *2.

²⁰⁵ *Id.* at 300.

²⁰⁶ See, e.g., *Board of Directors*, OPTN, <https://optn.transplant.hrsa.gov/members/board-of-directors/> (listing Melissa Greenwald (Director, HRSA Division of Transplantation) as ex officio member) (last visited Nov. 26, 2016); *Data Advisory Committee*, OPTN, <https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/> (last visited Nov. 8, 2016) (listing its membership to include Monica Lin and Christopher J. McLaughlin (Division of Transplantation, HHS, Ex Officio-Non Voting)).

facts. All considered, it is unclear which way the entwinement analysis cuts, whereas it is clear the Network is not under control of the Government.

ii. Control

Though decided in substantively distinct constitutional contexts, *Livestock Marketing* (First Amendment²⁰⁷) and *American Railroads* (separation of powers²⁰⁸) are leading examples of the factual and legal circumstances in which a court may find that the Federal Government controls a nominally private entity, thus opening the door to claims that the entity has violated the Constitution.²⁰⁹ While the quasi-governmental entities in those cases share some features with the Network,²¹⁰ key distinctions evidence that the latter is not under the Government's control. In *Livestock Marketing*, the Court found that the Agriculture Secretary intimately and consistently "exercise[d]" authority over the Beef Committee's ultimate advertising message, and therefore held that the "message of the promotional campaigns [was] effectively controlled

²⁰⁷ See *Johanns v. Livestock Mktg. Ass'n*, 544 U.S. 550, 553 (2005).

²⁰⁸ See *American Railroads*, 135 S. Ct. at 1228.

²⁰⁹ Cf. Kevin R. Kosar, CONG. RESEARCH SERV., RL30533, THE QUASI GOVERNMENT: HYBRID ORGANIZATIONS WITH BOTH GOVERNMENT AND PRIVATE SECTOR LEGAL CHARACTERISTICS 2 (2011) (organizing governmental and quasi-governmental entities on a linear spectrum based on "their relationship to the executive branch (and Congress)" as a matter of control). Closest to the government are "highly 'political'" quasi-official institutions that are "subject to pressures not dissimilar to th[ose] encountered by regular executive agencies." *Id.* at 6. Farthest from the government are nonprofit organizations "honorific[ally]" chartered by Congress for "patriotic, charitable, historical, or educational purpose[s]," without conferral of governmental power or benefits. *Id.* at 22–23; see, e.g., *Olympic Committee*, 483 U.S. at 542–43 ("The [United States Olympic Committee] is a 'private corporation established under Federal law.'" (citation omitted)).

²¹⁰ For example, like in *Livestock Marketing*, where the "Beef Committee"—charged with developing generic beef advertisements, 7 U.S.C. § 2904(1), (4)(A)–(B) (2010)—was selected by a board of private geographically representative cattle producers and importers, 7 C.F.R. § 1260.141 (2016), the Network's Board and committees are also geographically representative and composed of private experts moonlighting as policymakers. See *supra* text accompanying note 202. Furthermore, both Amtrak and the Network have large-scale public-benefit goals: Amtrak must "provide efficient and effective intercity passenger rail mobility," 49 U.S.C. § 24101(b), and reduce fares for the disabled and elderly, *id.* § 24307(a); the Network must distribute "organs equitably among transplant patients," 42 U.S.C. § 274(b)(2)(D), and "address the unique health care needs of children." *Id.* § 274(b)(2)(M). And, both are recipients of significant federal financial support. Compare *American Railroads*, 135 S. Ct. at 1232 ("In its first 43 years of operation, Amtrak has received more than \$41 billion in federal subsidies. In recent years these subsidies have exceeded \$1 billion annually." (citation omitted)) with *Justification of Estimates for Appropriations Committees*, HRSA, at 14, <http://www.hrsa.gov/about/budget/budgetjustification2015.pdf/> (last visited Nov. 7, 2016) (HRSA received more than \$23M *per annum* in 2013 and 2014 for transplantation).

by the Federal Government itself.”²¹¹ Likewise, in *American Railroads*, the Court found the political branches “control[led] Amtrak’s . . . Board of Directors [and] exercise[d] substantial, statutorily mandated supervision over Amtrak’s priorities and operations,” and thus concluded that Amtrak was a “governmental entity for purposes of separation of powers analysis under the Constitution.”²¹²

The record here demonstrates the antithesis. The HHS Secretary has never directed the Network to develop any particular policy (nor has she even adopted one promulgated by the Network²¹³), and the Network Board’s members are private actors who have never been subjected to active Executive oversight (nor are those members subject to removal²¹⁴). And, yet, as unlikely as it would be for a court to find on these facts that the Government controls the Network to the extent that it is subject to constitutional claims, there is one more state action test to consider.

iii. Public Function

In order for a private entity to engage in state action under the public function test, the “function performed [must have] been ‘traditionally the exclusive prerogative of the State.’”²¹⁵ Two commentators have suggested that the Network does not perform a public function because “[t]he provision of general medical care is not a traditional public function,”²¹⁶ and because “the private sector has traditionally been

²¹¹ *Livestock Marketing*, 544 U.S. at 560–61 (“[T]he record demonstrates that the Secretary exercises final approval authority over every word used in every promotional campaign. All proposed promotional messages are reviewed by Department officials both for substance and for wording, and some proposals are rejected or rewritten by the Department. Nor is the Secretary’s role limited to final approval or rejection: Officials of the Department also attend and participate in the open meetings at which proposals are developed.” (citations omitted)).

²¹² *American Railroads*, 135 S. Ct. at 1231. Notably, the Court held so despite express statutory language stating that Amtrak “is not a department, agency or instrumentality of the United States Government.” *Id.* at 1233 (internal quotation marks and citation omitted).

²¹³ *Cf. Abood v. Detroit Bd. of Educ.*, 431 U.S. 209, 251 (1977) (“Had the State itself adopted the procedures it approved for the private utility, it would have been subject to the full constraints of the Constitution.”).

²¹⁴ *Contra American Railroads*, 135 S. Ct. at 1231 (“[A]ll appointed Board members are removable by the President without cause.” (citation omitted)); *Livestock Marketing*, 544 U.S. at 560 (“All members of the [Beef] Committee are subject to removal by the Secretary.” (citation and emphasis omitted)).

²¹⁵ *Rendell-Baker v. Kohn*, 457 U.S. 830, 842 (1982) (emphasis omitted) (quoting *Jackson v. Metro. Edison Co.*, 419 U.S. 345, 353 (1974)); *contra, e.g., Olympic Committee*, 483 U.S. at 544–45 (“The [Amateur Sports] Act merely authorized the [Olympic Committee] to coordinate activities that always have been performed by private entities. Neither the conduct nor the coordination of amateur sports has been a traditional governmental function.”).

²¹⁶ *Mintz, supra note 187*, at 367 (citing, e.g., *Taylor v. St. Vincent’s Hosp.*, 523 F.2d 75,

responsible for the procurement and transplantation of organs.”²¹⁷ When considered at a low level of generality, their argument is well taken.

But, at a slightly higher level of generality, the Network serves a different function: it operates to allocate a limited public resource.²¹⁸ And this *is* a function traditionally reserved to the Government.²¹⁹ So, when applying the public function test, the fact that the Network’s functions were previously managed by purely private organizations may be of less importance than the “stark fact . . . that there are not enough organs to go around.”²²⁰ Clearly though, a plaintiff-candidate’s success on a public function theory would depend heavily on the court’s tolerance of high-level generality.²²¹

iv. Normative Judgment

Regardless of the test employed, however, courts are granted considerable discretion to insert their own “normative judgment” when deciding state-action inquiries: “[e]ven facts that suffice to show public action (or, standing alone, would require such a finding) may be

78 (9th Cir. 1975) (holding that operation of a hospital was not a public function)).

²¹⁷ Mintz, *supra* note 187, at 368; *see* Gross, *supra* note 2, at 238 (“One basis for finding state action—if the entity is engaged is an activity traditionally reserved for the state—has questionable applicability to the OPTN because transplantation, and hence organ allocation, is such a recent innovation.”).

²¹⁸ Donated human organs are “a public resource and a public trust.” 63 Fed. Reg. at 16,300; *see* Eric. F. Galen, *Organ Transplantation at the Millennium: Regulatory Framework, Allocation Prerogatives, and Political Interests*, 9 S. CAL. INTERDISC. L.J. 335, 354 n.102 (1999) (“The public trust doctrine, as applied to organs donated for transplant, suggests that donated organs are ‘preserved for public use’ and that the government, ‘as trustee for the people, bears responsibility of preserving and protecting the right of the public to the use’ of such organs.” (quoting BLACK’S LAW DICTIONARY (6th ed. 1991))); *cf.* Roy G. Spece, Jr., *A Fundamental Constitutional Right of the Monied to “Buy Out of” Universal Health Care Program Restrictions Versus the Moral Claim of Everyone Else to Decent Health Care: An Unremitting Paradox of Health Care Reform?*, 3 J. HEALTH & BIOMEDICAL L. 1, 86 (2007) (“Rights to purchase . . . organs for transplantation . . . raise medical, scientific, and policy judgments about the allocation of scarce and uniquely important public resources.”).

²¹⁹ *See* Stephen E. Gottlieb, *Compelling Governmental Interests: An Essential but Unanalyzed Term in Constitutional Adjudication*, 68 B.U. L. REV. 917, 948–49 (1988) (“Legislatures are faced with significant choices in determining how to allocate limited resources in ensuring the[] protections [of life, health, and safety]. Such considerations led the [Constitutional] Convention to define the powers and obligations of Congress in general terms, so as to avoid confining congressional action unnecessarily.” (citing The Federalist No. 44, at 284–85 (James Madison) (Clinton Rossiter ed., 1961))).

²²⁰ *See* Strosberg & Gimbel, *supra* note 11, at 229–30.

²²¹ *Cf.* Frank H. Easterbrook, *Abstraction and Authority*, 59 U. CHI. L. REV. 349, 352 (1992) (“If you assume that the purpose of [an] enterprise is to increase the number of protected interests, then ‘it is crucial to define the liberty at a high enough level to permit unconventional variants to claim protection.’ If you believe that tradition serves to restrict the powers of judges to pursue their vision of a good society, then you will choose a lower level of generality.” (citation omitted)).

outweighed in the name of some value at odds with finding public accountability in the circumstances.”²²² Therefore, even if the Network’s policies qualify as state action under one or more of the above-enumerated tests, a court may nevertheless conclude that the Network is immune from constitutional claims.

VI. CONCLUSION

That all said, just as courts presumably would not categorically dismiss claims that the Network violated NOTA or that the Final Rule is invalid, they likewise should not consider the Network categorically immune from claims that allocation policies are unconstitutional.²²³ But, contrary to *Murnaghan*, courts should not grant relief—regardless of the specific allegations at issue—without a more complete investigation.²²⁴ Indeed, a considered application of the *Winter* factors demonstrates that the TRO in *Murnaghan* was improvidently granted.²²⁵

To begin, the “balance of equities” tipped neither in Sarah’s favor, nor in favor of other candidates. Sarah was not the only individual who could have been irreparably harmed by not receiving a lung transplant. All candidates suffer from the threat of irreparable harm. As far as the court knew, the next candidate—who would have received Sarah’s first pair of lungs but for the suspension of the Under 12 Rule—could have died awaiting another offer.²²⁶ Since, the “balance of equities” were in equipoise in Sarah’s case, granting the TRO was inappropriate.²²⁷

²²² See *Brentwood Academy*, 531 U.S. at 295, 303.

²²³ Cf. J. Cooper, *supra* note 167, at 296 (“[T]he court’s decision [in *Murnaghan*] presents an opportunity for future transplant candidates to request judicial intervention when they are unable to receive an organ thereby increasing the scope and number of individual causes of action.” (citing *Girl’s Need Breathes Life into Debate over Organ Allocation*, NAT’L PUBLIC RADIO (June 6, 2013), <http://www.npr.org/blogs/health/2013/06/10/189270798/Girls-Need-Breathes-Life-Into-Debate-Over-Organ-Allocation/> (“And then I can start to see other people saying, ‘You know what, I need a liver. I need a heart. Where’s a federal judge?’”))).

²²⁴ *Contra DeVito*, *supra* note 142, at 206 (“Judge Baylson was correct in issuing the TRO and suspending the OPTN policy for lung allocation to those under twelve as it applied to Sarah’s circumstances and in refraining from issuing a broad-based ruling about the OPTN under-12 rule in general.”).

²²⁵ See *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008) (“A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.”).

²²⁶ *Contra DeVito*, *supra* note 142, at 206 (“A judge should be allowed to create a temporary solution” (emphasis added)).

²²⁷ The Author recognizes that this situation was terribly fraught for the court: to deny the TRO would have been to close off the last and only avenue of relief to a dying child with a colorable claim of discrimination. Yet, despite the deeply compelling nature of Sarah’s case, a likely dispositive order should not have issued until the court had fully considered the

Furthermore, consideration of the public interest should have prevented the order. In grappling with this factor, the court should have asked, e.g., whether injunctive relief would harm the public's interest in having a neutrally administered allocation system;²²⁸ or, whether an injunction would disrupt the public's trust in the system's fundamental fairness.²²⁹ The problem is that sudden abrogation of policy in individual circumstances could result in a perception that candidates with access to the media, or to politicians, or to the courts, receive preferential treatment—certainly not a result that is in the public interest.

Of course, assuming a showing of a likelihood of success on the merits (as well as satisfaction of the other three *Winter* factors) in a case like Sarah's,²³⁰ a court should grant prospective relief. But, any restraining order or injunction should be stayed, pending an appeal, to ensure thorough consideration.²³¹ Ultimately, relief from the application of Network policy should be reserved for cases in which there is a substantial demonstration of a violated right, and should not be granted in expedited hearings that threaten to irreparably harm unrepresented candidates and traumatize the public's perception of an equitable allocation system.

confluence of policy decisions that resulted in her case being brought at all.

²²⁸ Cf. Ethics Memo, *supra* note 50 (“Politicians and judges who intervene in a complex allocation algorithm may be well-intentioned but fail to consider all the moral variables that must be balanced at the macro level rather than through an individual candidate’s experience.”).

²²⁹ Cf. Ladin & Hanto, *supra* note 31, at 599 (“Appeals waged through federal courts. . . reduce transparency and predictability, undermining the public perception of fairness, which could reduce donation rates.”). By contrast, the *Murnaghan* court improperly conflated the public’s interest with Sarah’s. Cf. Supplemental Mem., *supra* note 47, at 2 (“[T]he TRO was very much in the interest of the public as well as . . . Sarah. If, for example, the OPTN decides to suspend the [Under 12 Rule in the next few days], it would be a tragedy if Sarah were to die prior to the meeting from remaining ineligible for lungs that would have otherwise become available if she were treated as an adult.”).

²³⁰ Cf. *supra* Parts III–V (suggesting responses on the merits to Sarah’s regulatory, statutory, and constitutional claims).

²³¹ At the request of the district court, the Court of Appeals could review this interlocutory decision on an accelerated timetable. See 28 U.S.C. § 1292(b) (2006) (“When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order. The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such order, if application is made to it within ten days after the entry of the order: *Provided, however*, That application for an appeal hereunder shall not stay proceedings in the district court unless the district judge or the Court of Appeals or a judge thereof shall so order.”); cf. *Statistics*, DONATE LIFE, <http://donatelifenet/statistics/> (last visited Dec. 12, 2016) (an average of twenty-two people die every day awaiting a transplant).

