

THE LUNG LAWSUIT: A CASE STUDY IN ORGAN ALLOCATION POLICY AND ADMINISTRATIVE LAW

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In November 2017, twenty-one-year-old Miriam Holman, was waiting for a lung transplant.¹ Miriam was suffering from a rare form of pulmonary hypertension for which there is no medical therapy, and which is rapidly fatal without lung transplantation. Miriam was on an artificial lung machine in the ICU at Columbia Medical Center in New York where she was listed for organ transplantation.²

Organ allocation policies are, under federal law, designed to balance equity and utility principles based on medical criteria to rank order patients waiting for suitable organs to be available that are a biological match.³ Allocation policy therefore, incorporates factors such as (1) how critically ill the patient waiting is; (2) how long the patient has been waiting; and (3) for some organs allocation policies, the relative magnitude of the

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¹ Complaint at 18, *Holman v. Secretary of HHS*, No. 17-cv-09041 (S.D.N.Y. filed Nov. 11, 2017) (describing the plaintiff's medical history).

² *Id.* at 1 (explaining the plaintiff's need to file a complaint). See *Pulmonary Hypertension*, MAYO CLINIC (Dec. 28, 2017), <https://www.mayoclinic.org/diseases-conditions/pulmonary-hypertension/diagnosis-treatment/drc-20350702> (clarifying how a doctor finds diagnose and treatment for patients with pulmonary hypertension).

³ See 42 U.S.C. § 274 (2)(B) (2018) (legislating organ donation and transplants). See also 42 C.F.R. § 121.8 (2018) (creating policy on the allocation of organ donations). E.g. *How Organ Allocation Works*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, <https://optn.transplant.hrsa.gov/learn/about-transplantation/how-organ-allocation-works/> (last visited May 2, 2018) (examining the balance between equity and necessity in organ donation).

predicted medical benefit of the transplant as measured by survival for that patient given the patient's current status. When a donor organ becomes available, a list of patients waiting that are a match (based on blood type and other factors such as organ size) is instantly generated in priority order according to allocation policy. The match list is also organized according to distribution criteria; the geographic area within which the organ will be allocated in priority order per allocation policy. This is what prevents organs in Boston from routinely being offered to patients in San Francisco. Some geographic restrictions are necessary to reduce travel and thus ensure the organ remains viable for transplant and the efficient management of the organ allocation system.

As of the beginning of November, when Miriam was listed, donor lungs were distributed "local" first in a priority order determined by lung allocation policy and then in wider concentric circles.⁴ The term "local" as used in the field means an Organ Procurement Organization's ("OPO") designated service area ("DSA"). OPOs are non-profit organizations designated by the Center for Medicare and Medicaid Services ("CMS") to coordinate deceased organ donation for transplantation within a specified geographic area – the DSA.⁵ There are fifty-eight OPOs in the country that collectively work with every acute hospital creating a network to maximize organ donation for transplantation. OPOs are required by law to follow the allocation and distribution

⁴ See UNITED NETWORK FOR ORGAN SHARING: ORGAN PROCUREMENT TRANSPLANTATION NETWORK, LUNG ALLOCATION, POLICY 10 (May 2, 2018), https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_10 (analyzing the policies surrounding organ transplantation).

⁵ See 45 C.F.R. § 486.303 (2018) (describing the certification procedures for organ transplantation). See 45 C.F.R. § 486.304 (2018) (specifying the requirements for designating an organ to an OPO). *E.g.* 45 C.F.R. § 486.308 (2018) (regulating designations and service terms for OPO's).

policies of the Organ Procurement and Transplantation Network (“OPTN”).⁶ Accordingly, when an OPO recovers a donated organ for transplant, a match list is instantly generated by the OPTN given the specific factors that donor organ with potential recipients prioritized in accordance with allocation and distribution policy. For lungs, at the time Miriam was listed, a patient who was a match and at the highest allocation priority *within the OPO’s DSA* would receive the organ offer first. Only after the entire list of patients waiting for lungs in the DSA was exhausted would the lungs then be offered to patients listed outside of the DSA.

This may seem like it makes some sense – prioritizing “local” first may mean that the organs do not travel as far, which reduces damage to the organ and improves outcomes. It may also mean that OPOs and the transplant centers in the DSA can foster close working relationships for more efficient organ placement. However, the DSA was never intended to be used for purposes of organ distribution. DSAs are geographic boundaries that were created for CMS administrative purposes to define which hospitals OPOs are responsible for working with to coordinate donation. At the time they were put in place, DSAs primarily reflected existing catchment areas OPOs were working within prior to the establishment of a national system formalized under federal law. As a result, there is wide variation in the size of DSAs and even patchwork patterns in which a single DSA is comprised of non-contiguous service areas. DSAs range in size from four thousand square miles – the OPO based in Washington DC – to eight hundred thousand square miles – the OPO based in Washington state. Some DSAs serve multiple states

⁶ See 45 C.F.R. § 486.320 (2018) (determining when OPO’s are complying or violating requirements for organ procurement). See also *Organ Procurement Organization (OPO) Reports: OPO Statistics*, SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS, <https://www.srtr.org/reports-tools/opo-specific-reports/> (last visited May 2, 2018) (listing each OPO in the U.S. by state).

and include many transplant centers – such as the New England Organ Bank DSA that serves six states and twelve transplant centers – and some serve a single state with only one or two transplant centers. And some states like Ohio and Texas have multiple DSAs some of which cover non-contiguous areas.

For patients like Miriam, the idea of “local” for purposes of organ distribution does not make much sense. It means that a donor lung could become available across the river less than four miles away, but because that is a different DSA and therefore not “local,” it will be offered to every patient waiting for lungs in the New Jersey OPO’s DSA – even those patients who are much further away and far less medically critical – before it is offered to Miriam. This is why the term “local” as used within the transplant community to mean “within the DSA” is not, a good proxy for “geographically close by.”

I. WHY DOES IT MATTER?

In a system of scarce resource where demand outpaces supply significantly, tough decisions have to be made every time an organ becomes available. As a matter of national policy as established through the National Organ Transplant Act (“NOTA”) and its implementing regulations (the “Final Rule”), the system seeks to maximize the number of lives saved through transplantation in as fair a manner as possible by balancing utility with equity. The legislative intent was that “allocation of scarce organs would be based upon common medical criteria, not accidents of geography.”⁷ That directive, codified in the

⁷ See INST. OF MED. COMM. ON ORGAN PROCUREMENT AND TRANSPLANTATION POL’Y, ORGAN PROCUREMENT AND TRANSPLANTATION: ASSESSING CURRENT POLICIES AND THE POTENTIAL IMPACT OF THE DHHS FINAL RULE 1-38 (1999) (explaining the committee’s proposal and policies decision). “The Final Rule provides a framework within which the transplant system would operate.” *Id.* at 2. “The stated principles underlying the Final Rule include the need for oversight in a system that permits variance in individual medical practice and the creation of a ‘level playing field; in organ allocation-that is, organs are allocated based on patients’ medical

Final Rule, states that allocation “shall not be based on a candidate’s place of residence or listing” with an explicit policy goal that organs be distributed “over as broad a geographic area as feasible”.⁸

II. WHY IS THAT INCLUDED?

The founding principle under the federally established framework is that donated organs are a national resource and should be allocated based on a system that is focused on the patients. And because, as it turns out, there is significant variation in the demand as well as the supply of organs. The burden of end stage organ failure across the country is not evenly distributed (demand) and neither is donor potential (supply).⁹ This means there are areas of the country where patients – with similar medical acuity – wait much longer for organ transplantation than in other areas of the country because organ distribution has prioritized patients as “local” to the donor first through the use of DSAs. By definition allocation and distribution policy is about determining where a defined pool of a resource goes. It is a zero-sum game. This does not mean efforts should not be focused on increasing the organ pool, but whatever size the pool is, the allocation and distribution policies are designed to rank order patients to receive actual organs that become available.

This policy has been the subject of an ugly, prolonged debate within the

need and less emphasis is placed on keeping organs in the local area where they are procured.” *Id.* “A primary stated objective is to equalize waiting times among different areas of the country.” *Id.*

⁸ 42 C.F.R. § 121.8(a)(8) & (b)(3) (1999) (finding priority not to be based on geographic location but rather medical necessity).

⁹ See Jack Lake et al., *Geographic Variation in Liver Supply and Demand*, SCI. REGISTRY OF TRANSPLANT RECIPIENTS, available at <https://www.srtr.org/media/1154/geographic-variation-in-liver-supply-and-demand.pdf> (last visited May 2, 2018) (optimizing district boundaries to improve geographic disparity in supply and demand).

transplant community regarding proposed changes to liver allocation and distribution policy.¹⁰ Proposals to change liver allocation over the past five years have included priority to offer livers first to the sickest patients even if those patients were outside of the “local” DSA from where the organ was recovered. There were many permutations of these proposals – concentric circles, districts, and mathematically optimized areas. The proposals were designed to ensure some geographic constraint to promote efficiency and reduce wastage while providing for a more patient focused allocation recognizing that organs do not belong to a DSA or a particular center. All of the proposals engendered fierce debate and none of them achieved community consensus.

With this in the backdrop, two weeks before the OPTN Board of Directors was scheduled to meet and vote on the liver allocation and distribution proposal, Miriam’s lawyer went to federal court and filed suit in the Southern District of New York. At an emergency hearing on November 20, 2017, they argued for a temporary restraining order to set aside the distribution criteria for livers on the basis that utilizing a DSA as the first unit of distribution was in violation of NOTA and the Final Rule.¹¹

Courts provide significant deference to agency rules if there is a reasonable basis supporting the rule at issue.¹² Under the Administrative Procedures Act (“APA”), the

¹⁰ See Rob Stein, *Searching For a Fairer Way to Distribute Donor Livers*, NPR (Sep. 26, 2017), <https://www.npr.org/sections/health-shots/2017/09/26/549224583/searching-for-a-fairer-way-to-distribute-donor-livers> (exploring novel ways to make organ donation fair); Jordan Michael Smith, *The Gross Inequality of Organ Transplants in America*, NEW REPUBLIC (Nov. 8, 2017), <https://newrepublic.com/article/145682/gross-inequality-organ-transplants-america> (finding that income disparities may affect patients that are in the organ waiting list).

¹¹ See Complaint at 3, *Holman v. Secretary of HHS*, No. 17 Civ. 09041 (S.D.N.Y. filed Nov. 19, 2017) (arguing that DSA is in violation of NOTA and Final Rule); Letter from George Sigounas, Admin’r, Health Res. & Serv. Admin., to Yolanda Becker, President, OPTN (Nov. 24, 2017) (on file with author) (explaining outcome of filed complaint).

¹² See *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984). The Court holds that courts may defer to the judgement of a governmental agency in defining language in its policies, as they are in the best position to know what they are talking about. *Id.* at 866.

standard of review in such cases is that the agency rule will be upheld unless it is arbitrary and capricious.¹³ In Miriam’s case, the lawyers argued that the use of the DSA as the first unit of distribution was arbitrary and capricious because (1) DSAs were not constructed for organ distribution purposes and are arbitrary boundaries that are not consistent in size (e.g. geographically, population, patients waiting, donors, number of programs); and (2) using DSAs for distribution has no correlation to organ viability and results in allocation of organs based on a candidate’s place of residence or listing in direct conflict with the mandates of the Final Rule.¹⁴ The plaintiff requested that the current lung allocation be set aside in favor of distribution of lungs in 500 mile concentric circles.¹⁵

At the initial hearing, the court denied the plaintiff’s petition for a restraining order, but ordered the U.S. Department of Health and Human Services (“HHS”) to undertake an immediate review of the lung allocation policy in light of the Final Rule requirements and file a report with the Court in seven days as to whether, and to what extent, the lung allocation policy would be changed including a timetable for implementation.¹⁶ The plaintiff immediately appealed, where upon the Second Circuit directed HHS to provide the report in three days – by November 24, 2017.

Upon receiving this instruction, the Secretary of HHS directed the OPTN to conduct an emergency “review of the use of DSAs in Lung Allocation Policy in accordance with the requirements of the OPTN final rule” and “inform HHS whether

¹³ 5 U.S.C. § 706(2)(A)-(D) (1966) (defining the scope of review allowed by courts for review of cases).

¹⁴ See Complaint at 14, *Holman*, No. 17 Civ. 09041 (addressing the complaint how the current practice is discriminatory).

¹⁵ *Id.* at 2 (describing current OPTN policies).

¹⁶ Order at 14, *Holman v. Secretary of HHS*, No. 17 Civ. 09041 (S.D.N.Y. Nov. 20, 2017) (denying the restraining order, but ordering an emergency review of HHS’s current allocation policy).

the use of DSAs in Lung Allocation Policy is consistent with the requirements of the OPTN [F]inal [R]ule.”¹⁷ The Executive Committee of the OPTN Board, in the days during the Thanksgiving holiday, conducted an analysis and completed a report concluding that “a policy that does not depend on DSA[s] as the primary unit of allocation of lungs is more consistent with the OPTN Final Rule than a policy that shares first exclusively within the DSA.”¹⁸ The OPTN Executive Committee recommended changing lung distribution to a 250 mile concentric circle. This would provide a consistent geographic constraint nationwide supported by factors including transportation logistics (ground versus air), efficiency, and the need to proceed cautiously to avoid unintended consequences given the extreme time compression; the change would occur without the benefit of full vetting. The new lung distribution criteria would be temporary pending the formal public comment, review and approval process.¹⁹ On this basis, the Secretary of HHS ordered the OPTN to make the recommended change effective immediately.²⁰ This obviated the need for further court intervention and the case was subsequently dismissed.²¹

It took the field ten years to make a significant change to kidney allocation and the community had been debating liver allocation for over five years. With a single lawsuit and a HHS directive, lung allocation was changed in a week.

¹⁷ Letter from George Sigounas, Admin’r, Health Res. & Serv. Admin., to Yolanda Becker, President, OPTN (Nov. 21, 2017) (on file with author) (requesting review of OPTN’s policy and outlining the requirements for the review and any changes).

¹⁸ EXECUTIVE COMMITTEE REPORT, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (2017).

¹⁹ *Id.* (assessing new standards for the lung allocation).

²⁰ George Sigounas, U.S. DEPT. OF HEALTH AND HUM. SERVS. 1, 1 (2017) (requesting that Yolanda Becker, MD, President of the OPTN make the recommendation).

²¹ *See* Complaint at 22, *Holman*, No. 17-cv-09041 (withdrawing the case from November 24, 2017).

Two weeks later, the liver allocation proposal was approved by the OPTN Board.²²

The swift action by the OPTN Board to rectify the distribution criteria in the lung allocation policy has since been criticized by some in the community because it occurred emergently and outside of the usual public comment process designed for consensus. There is, however, no question it precluded inevitable court action ordering change. Judicial precedent of a court-ordered organ distribution policy would have been damaging to the community's core ability to self-govern in a highly complex area requiring significant expertise; a hallmark of organ allocation for the OPTN under the Final Rule and a key power of agency rule-making under the APA.

Innovation in how organs are allocated and distributed is coming. The primary legacy of the lung lawsuit is that organ distribution policy must rely on geographic constraints that are directly and rationally tied to the Final Rule requirements. As a result, the way the field of donation and transplantation thinks about "local" distribution of organs must be reconsidered. Standardized geographic constraints that can be consistently applied nationwide will best meet the legal requirements of the Final Rule and the policy directive to consider organs a national resource to be shared as broadly as possible. The past paradigm based on balancing multiple considerations related to distribution is legally insufficient. Any limitations to broad sharing must be justified by specific and identified factors consistent with the Final Rule mandate in order to meet the rational basis test under an APA legal analysis. For example, criteria for a defined geographic boundary of distribution may be based on organ viability (if reasonably supported by current data

²² *Enhancing Liver Distribution*, U.S. DEPT. OF HEALTH AND HUM. SERVS. (Dec. 2017), <https://optn.transplant.hrsa.gov/governance/public-comment/enhancing-liver-distribution>.

related to travel time of an organ between surgical recovery and transplant) consistent with the Final Rule provision as a component of allocation policy necessary to avoid wastage. In response to these events, the OPTN formed a Geography Committee to propose a set of foundational principles and possible frameworks of distribution that provide a rational basis for geographic constraint to be applied to all organ allocation policies. The Committee is expected to report to the OPTN Board in June 2018 and provide a path forward to ensure organ allocation policies utilize distribution criteria supported by principles consistent with the Final Rule.

As of the time of this publication, there have not been any reports as to whether Miriam received a lung transplant. But the change in lung distribution has meant that the sickest patients waiting within 250 miles of a donor are offered available lungs first regardless of which DSA the patient is listed in. Miriam's case not only changed lung distribution. The lawsuit was also a catalyst for greater change, in liver allocation and ultimately in the OPTN rule-making approach to distribution policy. To ensure the system is better aligned with legal requirements, organs are to be allocated in a manner that maximizes lives saved, in as fair a manner as possible, and minimizes the impact of a patient's geographic location.