UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MIRIAM HOLMAN, Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES through ERIC HARGAN in his official capacity as Acting Secretary of the United States Department of Health and Human Services, Defendant.	Civil Action No.:

VERIFIED COMPLAINT FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF

1. Plaintiff, Miriam Holman, is a 21-year-old woman who suffers from a rare form of pulmonary hypertension for which there is no medical therapy and which is rapidly fatal without lung transplantation. Miriam is currently on an artificial lung machine in the intensive care unit at Columbia University Medical Center in New York (CUMC). Miriam files this emergency Complaint seeking a temporary restraining order, a preliminary injunction and a permanent injunction to require the Acting Secretary of the United States Department of Health and Human Services (HHS) to allocate available donor lungs based on medical priority instead of the current antiquated and arbitrary system that gives priority based on a candidate's place of residence.

2. HHS operates the nation's Organ Procurement and Transplantation Network (OPTN) through a contract with the United Network for Organ Sharing (UNOS). By legislative mandate, OPTN policy requires available organs be prioritized among potential candidates by

medical priority. With regard to lungs, medical priority is determined by a candidate's Lung Allocation Score (LAS), which is a priority ranking of 1 to 100.

3. The OPTN has 58 Organ Procurement Organizations (OPOs) throughout the United States. Each OPO operates within an arbitrarily-determined geographic area called a Donation Service Area (DSA). OPTN's current policy provides that, when a lung becomes available, it must first be made available to candidates within the boundaries of the donor's DSA even if there are candidates with a higher medical priority, *i.e.*, a higher LAS, within a logistically reasonable range of the lung (or even geographically closer to the donor than local DSA candidates) (DSA Priority). Only after making donor lungs available to candidates in the local DSA is a donor lung offered to other candidates in an allocation system that prioritizes allocation to candidates in transplant hospitals within 500 miles (Zone A), 1,000 miles (Zone B), 1,500 miles (Zone C), 2,500 miles (Zone D) and more than 2,500 miles (Zone E).

4. By prioritizing available lungs to candidates in the local DSA, OPTN policy limits the number of lungs available to high priority transplant candidates like Miriam and effectively allocates available lungs based on a candidate's place of residence instead of medical priority. This policy is in direct contravention of both the OPTN's legislative mandate and sound medical judgment.

5. By way of example, Miriam has an LAS of over 90, which indicates an extremely high level both of medical need for a transplant and of prospective benefit from a transplant. Miriam's LAS ranking puts her in the top 1% of patients awaiting lungs. Miriam is registered as a candidate at CUMC, which is located in the DSA for southeastern New York. That DSA is serviced by LiveOnNY, the DSA's OPO. The geographic regions that encompass the LiveOnNY DSA are entirely arbitrary and encompass New York City, Long Island, five New

York counties north of New York City (Westchester, Dutchess, Orange, Putnam, Rockland), and Pike County, PA.

6. If a pair of lungs suitable for Miriam became available from a donor in Fort Lee, New Jersey (a three mile drive from CUMC), the lung would be offered first to all suitable candidates in the DSA encompassing Northern and Central New Jersey, even if those candidates have lower LAS – even much lower – than Miriam's. Moreover, given the arbitrary nature of the DSA's geographic area, that candidate would likely be *geographically further away* from the donated lung than Miriam.

7. There is no medical basis to offer an available lung to a candidate with a lower LAS (and potentially geographically further away). The current system is flawed – and for candidates like Miriam it may unfortunately be fatally flawed. Without judicial intervention, Miriam may lose an opportunity for a lung transplant. Absent a transplant Miriam will likely die.

8. Miriam is not looking for any special treatment. She is only asking that available lungs be allocated by medical priority as required by OPTN policy and legislative mandate. Specifically, Miriam is requesting that the DSA Priority provided for in Classifications 1 through 6 of Table 10-9 (Allocation of Lungs from Deceased Donors at Least 18 Years Old) be removed, and that lungs be allocated by zone without the DSA Priority starting with Classification 7.

9. The DSA Priority violates the National Organ Transplant Act of 1984 (NOTA) and discriminates against individuals like Miriam by allocating lungs based on geographic priority instead of medical priority. On November 16, 2017, Miriam asked the Acting Secretary to set aside the DSA Priority. A copy of the letter to the Acting Secretary is attached as Exhibit 1. As of the filing of this suit the Acting Secretary has refused to do so. Miriam now asks this

Court to enter a temporary restraining order and preliminary and permanent injunctions, to the extent necessary, to enjoin the Acting Secretary and the OPTN (which is under HHS's authority and control) from applying the DSA Priority to Miriam's detriment. This would allow Miriam to be treated fairly and for lungs to be allocated based on medical priority. Setting aside the DSA Priority would make more lungs available for high-priority candidates like Miriam and greatly increase Miriam's chances of receiving a set of lungs. Setting aside the DSA Priority would have no adverse effect on the public or anyone else.

10. Emergency relief is warranted because lungs donor lungs must be transplanted within hours and if Miriam does not soon receive a set of donated lungs she will die.

PARTIES, VENUE AND JURISDICTION

11. Plaintiff Miriam Holman is a resident of New York and currently resides in the intensive care unit at Columbia University Medical Center on West 168th Street, New York, NY 10032.

12. Defendant Eric Hargan is the Acting Secretary of the United States Department of Health and Human Services, located at 200 Independence Ave., S.W., Washington, DC 20201. Defendant Hargan is sued in his official capacity.

13. This action arises under the National Organ Transplant Act, 42 U.S.C. § 274, *et seq.*, the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq.*, Federal Regulations 42 C.F.R. part 121, *et seq.*, and the Due Process Clause of the Fifth Amendment to the United States Constitution.

14. Jurisdiction is present under 28 U.S.C. § 1331 because the "district courts have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States."

15. Jurisdiction is also present under the APA, which authorizes a court to "compel agency action unlawfully withheld or unreasonably delayed," 5 U.S.C. § 706(1); authorizes a court to "set aside agency action, findings, and conclusions of law found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "without observance of procedure required by law," *id* § 706(2); and provides a right to judicial review of "final agency action for which there is no other adequate remedy in a court," *id.* § 704.

16. This Court has authority to issue a declaratory judgment and injunctive relief pursuant to 28 U.S.C. §§ 2201-2202.

17. Venue is proper before this Court pursuant to 28 U.S.C. § 1391(e)(1) because plaintiff currently resides in this district, there is no real property involved in the action, and defendants are officers or employees of the United States or agencies thereof and acting in their official capacities.

BACKGROUND

A. HHS Is Responsible For the United States' Organ Transplant Network

18. HHS is responsible for managing the United States' organ donation and transplant network. HHS contracts administration of the OPTN to UNOS. OPTN has developed and published organ transplant policies. The complete OPTN policy is available on the OPTN website – https://optn.transplant.hrsa.gov. The specific policy at issue in Miriam's case is Policy 10.4.C., entitled "Allocation of Lungs from Deceased Donors at Least 18 Years of Age." Policy 10.4.C. is attached to Exhibit 1.

19. NOTA created the OPTN (42 U.S.C. § 274). NOTA requires that the Secretary establish and operate the OPTN in accordance with the requirements of NOTA. Pursuant to NOTA, HHS has promulgated regulations that govern the OPTN (42 C.F.R § 121). These

regulations provide, among other things, that OPTN's Board of Directors shall be responsible for developing policies for the operation of the OPTN, including "[p]olicies for the equitable allocation of cadaveric organs in accordance with §121.8." 42 C.F.R. §121.4(a)(1).

20. Specifically, 42 C.F.R. § 121.8(a) provides as follows:

(a) *Policy development.* The Board of Directors established under § 121.3 shall develop, in accordance with the policy development process described in § 121.4, policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies:

(1) Shall be based on sound medical judgment;

(2) Shall seek to achieve the best use of donated organs;

(3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with § 121.7(b)(4)(d) and (e);

(4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;

(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;

(6) Shall be reviewed periodically and revised as appropriate;

(7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program; and

(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.

42 C.F.R. §121.8(a) (emphasis added).

B. <u>The Final Rule</u>

21. Before the passage of 42 C.F.R § 121 (<u>Final Rule</u>), organs donated in the United States were largely distributed locally or regionally. As a result, donated organs often went to local patients who needed them less urgently than a patient outside the region. The local

allocation of organs resulted in a discrepancy between the availability of organs in states with larger donor banks and those with smaller donor banks.

22. In 1998, HHS Secretary Donna Shalala issued a Final Rule designed to distribute organs more equitably by replacing the local allocation system with a national one. The goal of the Final Rule, which was eventually implemented into law, is to allocate organs based on medical priority over as broad a geographic area as feasible. A copy of the Final Rule is attached as Exhibit 2.

23. The Final Rule recognized that "[h]uman organs that are donated for transplantation are a public trust. These regulations are intended to ensure that donated organs are equitably allocated among all patients, with priority to those most in need in accordance with sound medical judgment." Final Rule at 16298. Consistent with this principle, the Final Rule quoted a Report of the Task Force on Organ Transplantation, recognizing that "[o]rgans and tissues ought to be distributed on the basis of objective priority criteria, and not on the basis of accidents of geography." *Id*.

24. The Final Rule identified several principles that should govern OPTN policy. One of these principles is the equitable allocation of organs, which is described in the Final Rules as follows (*id*. at 16296-7):

> Equitable Allocation—The OPTN is required to develop equitable allocation policies that provide organs to those with the greatest medical urgency, in accordance with sound medical judgment. This increases the likelihood of patients obtaining matching organs, and gives all patients equal chances to obtain organs compared to other patients of equal medical status, wherever they live or list.
>
> By requiring common criteria for listing eligibility and medical status, and by requiring that organs be directed so as to equalize waiting times, especially for those with greatest medical need, this rule is designed to provide patients awaiting transplants with equal access to organs and to provide organs to sickest patients first, consistent with sound medical judgment. While present OPTN policies give weight to medical need, the ''local first'' practice thwarts organ allocation over a

> broad area and thus prevents medical need from being the dominant factor in allocation decisions.
>
> Under the provisions of this rule, it is intended that **the area where a person lives or the transplant center where he or she is listed will not be primary factors in how quickly he or she receives a transplant. Instead, organs will be allocated according to objective standards of medical status and need**. In this way, suitable organs will reach patients with the greatest medical need, both when they are procured locally and when they are procured outside the listed patients' areas. This objective reflects the views of many commenters on the proposed regulations, as well as the finding of the American Medical Association in its Code of Medical Ethics: **"Organs should be considered a national, rather than a local or regional resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation."** (emphasis added)

25. NOTA and regulations promulgated thereunder require that OPTN policies for organ allocation be equitable, that they provide for organ allocation based on medical priority, and that they *not* base organ allocation on a candidate's place of residence or listing.

C. OPTN's Lung Allocation System

26. OPTN's policies for allocation of donated lungs are set forth in OPTN Policy 10 (Allocation of Lungs). Policy 10.1 (Priorities and Score Assignments for Lung Candidates) provides that lung candidates 12 years or older "use a Lung Allocation Score (LAS) to determine lung allocation, as well as geography and blood type." Policy 10.4.C. (Allocation of Lungs from Deceased Donors at Least 18 Years Old) governs the allocations of adult lungs.

27. The Lung Allocation System is described in UNOS literature (attached as Exhibit 3) as follows:

> Every lung transplant candidate age 12 and older receives an individualized lung allocation score []. The lung allocation score is an important factor in determining priority for receiving a lung transplant when a donor lung becomes available. The lung allocation system determines the order of everyone awaiting a lung transplant by their lung allocation score, blood type, and the distance between the candidates and the hospital where the lung donor is located. …

The lung allocation system uses medical information about each lung transplant candidate. This information includes lab values, test results, and disease diagnosis. This medical information is used to calculate a lung allocation score from 0 to 100 for each transplant candidate. The lung allocation score estimates the severity of each candidates' illness and his or her chance of success following a lung transplant. All candidates are placed in order for compatible lung offers according to their score: a candidate with a higher lung allocation score will receive higher priority for a lung offer when a compatible lung becomes available in the same geographic zone.

28. OPTN Policy 10.4.C. and Table 10-9 sets forth a 36 tier ranking system for lung candidates as follows:

10.4.C Allocation of Lungs from Deceased Donors at Least 18 Years Old

Single and double lungs from deceased donors at least 18 years old are allocated according to *Table 10-9* below.

Table 10-9: Allocation of Lungs from Deceased Donors at Least 18 Years Old

Classification	Candidates that are included within the:	And are:
1	OPO's DSA	At least 12 years old, blood type identical to the donor
2	OPO's DSA	At least 12 years old, blood type compatible with the donor
3	OPO's DSA	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
4	OPO's DSA	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
5	OPO's DSA	Priority 2, blood type identical to the donor
6	OPO's DSA	Priority 2, blood type compatible with the donor
7	Zone A	At least 12 years old, blood type identical to the donor
8	Zone A	At least 12 years old, blood type compatible with the donor
9	Zone A	Priority 1 and *one* of the following:

Classification	Candidates that are included within the:	And are:
		• Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
10	Zone A	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
11	Zone A	Priority 2, blood type identical to the donor
12	Zone A	Priority 2, blood type compatible with the donor
13	Zone B	At least 12 years old, blood type identical to the donor
14	Zone B	At least 12 years old, blood type compatible with the donor
15	Zone B	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
16	Zone B	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
17	Zone B	Priority 2, blood type identical to the donor
18	Zone B	Priority 2, blood type compatible with the donor
19	Zone C	At least 12 years old, blood type identical to the donor
20	Zone C	At least 12 years old, blood type compatible with the donor
21	Zone C	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
22	Zone C	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor

Classification	Candidates that are included within the:	And are:
		• At least 1 year old and eligible for intended blood group incompatible offers
23	Zone C	Priority 2, blood type identical to the donor
24	Zone C	Priority 2, blood type compatible with the donor
25	Zone D	At least 12 years old, blood type identical to the donor
26	Zone D	At least 12 years old, blood type compatible with the donor
27	Zone D	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
28	Zone D	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
29	Zone D	Priority 2, blood type identical to the donor
30	Zone D	Priority 2, blood type compatible with the donor
31	Zone E	At least 12 years old, blood type identical to the donor
32	Zone E	At least 12 years old, blood type compatible with the donor
33	Zone E	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
34	Zone E	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
35	Zone E	Priority 2, blood type identical to the donor
36	Zone E	Priority 2, blood type compatible with the donor

29. Classifications 1 through 6 are geographic rankings that take priority over any medical rankings. By implementing classifications 1 through 6, OPTN policy imposes the DSA Priority to limit the availability of lungs by geography based on the candidate's place of residence or place of listing. The DSA Priority requires lungs to first be offered to candidates within the donor's donation service area (DSA) without any consideration for medical priority or the viability of the lung.

D. The OPO and DSA System

30. An OPO is an organization authorized by the Centers for Medicare and Medicaid Services, under § 1138(b) of the Social Security Act, to procure organs for transplantation. There are currently 58 OPOs in the United States. Each OPO has its own donation service area, or DSA. Some states have one OPO but many states like California and New York have as many as five OPOs.

31. CUMC is within the DSA of OPO LiveOnNY (OPO Code: NYRT) which serves New York City (Manhattan, Brooklyn, Queens, the Bronx, and Staten Island), Long Island (Nassau and Suffolk counties), five New York counties north of New York City (Westchester, Dutchess, Orange, Putnam, Rockland), and Pike County, PA. In 2016, there were 67 lungs recovered for transplant within LiveOnNY's DSA. *See* Exhibit 4 at 14. In 2015, there were 57 lungs recovered for transplant and 27 in 2014. *See* Exhibits 5 and 6 at 14. Lungs from the LiveOnNY DSA were transported all over eastern portion of the U.S. as far as Tampa, FL. *See* Exhibit 5 at 24.

32. Within 500 miles of CUMC there are an additional 14 OPOs. Within 1,000 miles of CUMC, there are 31 additional OPO as follows:

OPO Name	City	Distance from CUMC
LiveonNY	New York, NY	2 miles
New Jersey Organ and Tissue Sharing Network	New Providence, NJ	24 miles
Gift of Life Donor Program	Philadelphia, PA	84 miles
Life Choices Donor Services	Bloomfield, CT	99 miles
Center for Donation and Transplant	Albany, NY	131 miles
The Living Legacy Foundation of Maryland	Baltimore, MD	178 miles
New England Organ Bank	Waltham, MA	218 miles
Washington Regional Transplant Community	Annandale, VA	218 miles
Finger Lakes Donor Recovery Network	Rochester, NY	247 miles
Upstate New York Transplant Services Inc.	Buffalo, NY	291 miles
Lifenet Health	Virginia Beach, VA	299 miles
Center for Organ Recovery and Education	Pittsburgh, PA	310 miles
LifeBanc	Cleveland, OH	394 miles
Carolina Donor Services	Greenville, NC	404 miles
Lifeline of Ohio	Columbus, OH	480 miles
Life Connection of Ohio	Maumee, OH	508 miles
Gift of Life Michigan	Ann Arbor, MI	515 miles
Lifeshare of the Carolinas	Charlotte, NC	539 miles
LifeCenter Organ Donor Network	Cincinnati, OH	569 miles
LifePoint	Charleston, SC	642 miles
Kentucky Organ Donor Affiliates	Louisville, KY	643 miles
Indiana Donor Network	Indianapolis, IN	649 miles
Lifelink of Georgia	Norcross, GA	732 miles
Gift of Hope Organ & Tissue Donor Network	Itasca, IL	734 miles
Wisconsin Donor Network	Milwaukee, WI	738 miles
Tennessee Donor Services	Nashville, TN	763 miles
UW Health Organ and Tissue Donation	Madison, WI	811 miles
Alabama Organ Center	Birmingham, AL	865 miles
Mid-America Transplant Services	St. Louis, MO	878 miles
LifeQuest Organ Recovery Services	Gainesville, FL	901 miles
Iowa Donor Network	Noth Liberty, IA	918 miles
Translife	Winter Park, FL	941 miles
Mid-South Transplant Foundation	Cordova, TN	945 miles

33. The OPTN and Scientific Registry of Transplant Recipients (SRTR) publishes data on the organ availability by OPO. SRTR data for 2016 shows the following number of lungs available within the southeastern New York DSA and the respective radii of Zone A and Zone B for a candidate listed for transplant in New York City:

	Lungs Recovered For Transplant in 2016
Local OPO / DSA	67
OPOs within Zone A (500 miles)	1,121
OPOs within Zone B (1,000 miles)	2,457
All 58 OPOs	4,340

E. Discriminatory Operation of the DSA Priority

34. The DSA Priority contradicts the fundamental objective of OPTN policy, namely, to allocate organs by medical priority – not by where the candidate happens to live or is listed.

35. Under the current system, if a lung is accepted for a candidate within the local DSA, it is never offered to a candidate in the broader reach of the organ even if that non-local DSA candidate has a greater medical need and stands to get greater benefit from transplant, i.e., if that candidate has a higher LAS. Moreover, because of the arbitrary boundaries of DSAs, an available lung may not even be offered to the candidate closest to the donor hospital even if that candidate has a higher LAS. Instead of following such a patently illogical allocation priority rule, UNOS should make available to candidates with a recognized level of transplant need all medically compatible lungs that are donated within a logistically reasonable radius of her transplant hospital.

36. By eliminating the DSA Priority, more lungs would be made available to candidates. Using 2016 SRTR data, elimination of the DSA Priority would have made an additional 1,054 lungs available to candidates in CUMC – an increase of 1,573%.

37. Moreover, the DSA Priority has no correlation to organ viability. Indeed, the DSA Priority will often prioritize candidates further from the donor facility. The arbitrary nature of the DSA Priority leads to tragic, arbitrary, and absurd results. If a lung becomes available from a donor located mere miles away from Miriam in New Jersey or Connecticut, all suitable

candidates in that donor's DSA will be prioritized to receive the lungs ahead of Miriam, even if those candidates' LAS are lower than hers and even if Miriam is geographically closest to the donated lung.

38. There is no legitimate justification for DSA Priority. At best, it appears to be based on the local OPO's administrative or political convenience. Neither of those interests provides an objectively legitimate basis for prioritizing the allocation of life-saving organs. Nor is administrative convenience or political convenience of OPOs recognized by HHS as a valid basis for deciding the OPTN's policies. *See* 42 C.F.R. § 121.4(a); 42 U.S.C. § 274(b)(2).

F. Medical Studies Confirm the Inadequacy and Inequity of Providing DSA Priority

39. The medical community has likewise recognized the fundamental flaws in DSA Priority. A study in the *Annals of Thoracic Surgery* published in 2013 (the 2013 Study) concluded that "the locally based lung allocation system results in a high frequency of events whereby an organ is allocated to a lower-priority candidate while an appropriately matched higher priority candidate exists regionally. This may result unnecessarily in the death of higher priority candidates, thus diminishing waiting list outcomes and the net benefit of transplantation." (Exhibit 7)

40. Specifically, the 2013 Study found that in the United States in 2009, 580 double lung transplants (DLT) were performed on candidates located in the same DSA as their respective donors – termed here a "locally allocated DLT." *Id*. at 1232 (2013 Study). Among those 580 locally allocated DLTs, there were 3,454 instances in which suitable DLT candidates in the same UNOS Region[1] as a DLT donor had an LAS higher than the candidate who actually

[1] The 58 DSAs in the United States are divided into 11 UNOS Regions. The 2013 study compared allocation in UNOS Regions to allocation in DSAs because that data was readily

received the DLT. *Id.* The study termed such instances "events." *Id.* There was therefore an average of nearly six events for each locally allocated DLT performed in 2009. *Id.* at 1232-33. Put another way, there were on average six higher-scored suitable regional candidates available for each locally allocated DLT. Moreover, for 480 (82.8%) of the 580 locally allocated DLTs, there was at least one higher-scored candidate in the region waiting for a DLT. *Id.*

41. The same study came to the conclusion that: (i) 555 (16.1%) of the 3,454 events in 2009 involved a regional candidate who did not receive a transplant and ultimately died on the waiting list; and (ii) those 555 events affected 185 separate candidates who died without getting access to a potentially life-saving transplant. *Id.*

42. The findings of the 2013 Study have a troubling relationship with other observed waiting list outcomes. *Id.* Each year, hundreds of candidates for lung transplants die while on the waitlist. Exhibit 8 at 690 (2016 Study). According to a study published in 2016 in *Clinical Transplantation* (2016 Study), sixty percent of those candidates are high-priority candidates– those with an LAS greater than 75 – even though those high-priority candidates make up less than ten percent of total candidates on the waitlist. *Id.* (2016 Study at 690). The 2016 Study further found that "within the locally based lung allocation system, close to half of donor lungs go to patients with an LAS <50 and, in instances of broader geographical sharing, that proportion decreases." *Id.* (2016 Study at 688). Accordingly, the 2016 Study concluded that broader geographic allocation, which ending DSA Priority would accomplish, "may result in an increase in the proportion of high-priority candidates being transplanted." *See id.* (2016 Study at 690).

available. A study making the same comparison between intra-DSA allocation and, for example, allocation within Zone A or national allocation would almost certainly show a *higher* number of "events" as defined in the 2013 Study. (Exhibit 7 at 1234)

43. The studies confirm the necessity of ending any policy that prevents candidates with the highest LAS from receiving transplants. "[W]aiting list survival among patients with an LAS less than 50 is approximately 4 years; those with an LAS 50 to 74 is approximately six months; and those with an LAS 75+ is less than 30 days." Exhibit 7 at 1233 (2013 Study). As a result, and as the 2013 Study further notes, "low-priority candidates [i.e. those with lower LAS] rarely die while awaiting transplantation," and "less than 10% of candidates with an LAS less than 50 die on the waiting list." *Id.* Similarly, a separate study using data from between 2005 and 2009 showed that candidates who received lung transplants and had an LAS at or below 49 received little or no net survival benefit from transplantation. Exhibit 9 at 1274 (2011 Study); Exhibit 8 at 690 (2016 Study).

44. The results of the 2013 Study show that DSA Priority's limitation of the initial pool of lung transplant candidates to those in the donor's DSA distorts the allocation of donated lungs. In far too many cases, DSA Priority leads to fatal results while undermining the explicit goal of HHS and OPTN to distribute organs over as broad a geographic area as feasible to those candidates with the greatest medical urgency. *See* Exhibit 7 (2013 Study).

45. Finally, because the DSA Priority effectively grants a right of first refusal to all suitable candidates within a donor's DSA, it follows that when a donor's lungs ultimately are offered outside the donor's DSA there is a greater likelihood that those lungs are damaged or less suitable for successful transplantation. Ending DSA Priority for lung allocation will therefore lead to allocation of higher-quality lungs to those with the highest LAS – those who, by definition, both have the most urgent medical need and stand to benefit the most from a transplant.

G. Miriam Holman

46. Miriam is a 21-year-old woman who suffers from a rare form of pulmonary hypertension, which is a type of high blood pressure that affects the arteries in one's lungs. Miriam's form of pulmonary hypertension has no therapy or cure and without a lung transplant is fatal. Miriam is only alive today because she is on an artificial lung, called an ECMO (extracorporeal membrane oxygenation). ECMO can only work for a limited time, and every day she is not transplanted she is at risk for dying

47. Miriam has a family history of pulmonary hypertension. Miriam's sister passed away from pulmonary hypertension at the age of 10, about 13 years ago.

48. Miriam was first diagnosed with pulmonary hypertension in 2014, while studying abroad. Over the last three years she has been in and out of hospitals and has undergone various procedures. She has been under constant medical attention as the pulmonary hypertension has caused loss of consciousness and seizures.

49. Miriam has been in the medical intensive care unit at CUMC since September 24, 2017, and was listed for a lung transplant on October 6, 2017.

50. Miriam has an LAS of over 90, which puts her in the top 1% of patients awaiting an organ based on the urgency of her medical need and her prospective benefit from a transplant. On any given day, her LAS would more likely than not put her at the *very top* of the list for her blood type in the DSA for southeastern New York, as well as the Zone A and Zone B around New York City.

51. On November 16, 2017, Miriam's attorneys sent a letter to HHS on her behalf requesting an end to the DSA Priority in OPTN Policy 10.4.C on the bases identified in this

Complaint. (Exhibit 1.) HHS has refused to act on that request although each day without a transplant may be Miriam's last.

52. In correspondence and phone discussion with Miriam's attorneys, both UNOS and HHS have been unable to point to any rational justification for DSA Priority in the allocation of lungs. HHS and UNOS have defended their present inaction only on the basis of the administrative hassle of re-configuring the present illogical system due to: (i) the purported complexity of UNOS allocation computer programs; and (ii) the presumed existence of transplant candidates who would be disadvantaged by the revision Miriam requests be made to the existing illogical DSA Priority rule.

53. Both objections are unavailing. The existence of the distance-based Zone A, Zone B, etc. allocation rules in Policy 10.4.C. all but conclusively shows that HHS and UNOS are equipped to bypass application of DSA Priority in lung allocation with minimal administrative effort. Moreover, administrative or political convenience is clearly *not* a proper basis for organ allocation under NOTA. And even if there are candidates who would be disadvantaged by the change Miriam requests the Secretary make, both the requirements of NOTA and simple public policy logic dictate that DSA Priority should end to favor those who, by definition, both have the most urgent medical need and would benefit most from transplant.

CLAIMS FOR RELIEF

COUNT I – ADMINISTRATIVE PROCEDURES ACT, 5 U.S.C. § 706(2)(A)-(D) THE ACTING SECRETARY'S ACTIONS ARE NOT IN ACCORDANCE WITH LAW

54. Plaintiff repeats and incorporates by reference the allegations contained in prior paragraphs.

55. Under the APA, a court reviewing a final agency action must "hold unlawful and set aside agency action, findings, and conclusions found to be (A) arbitrary, capricious, an abuse

of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; and (D) without observance of procedure required by law." 5 U.S.C. § 706(2)(A)-(D).

56. The DSA Priority is not in accordance with law because it arbitrarily deprives candidates with the greatest medical need for lung transplants of opportunities to receive such transplants.

57. The DSA Priority is not in accordance with law because it threatens to deprive Miriam Holman of her life without due process of law in violation of the Fifth Amendment to the United States Constitution.

58. The DSA Priority is not in accordance with law because it fails to promote the nationwide distribution of organs *equitably* among transplant patients, as required by 42 U.S.C. § 274(b)(2)(D).

59. The DSA Priority Rule is not in accordance with law because the policy does not result in the equitable allocation of cadaveric organs, as required by 42 C.F.R. § 121.4(a)(l).

60. The DSA Priority is not in accordance with law because it fails to achieve and in fact directly undermines the "performance goal" of "[d]istributing organs over as broad a geographic area as feasible . . . and in order of decreasing medical urgency," as required by 42 C.F.R. § 121.8(b)(3).

COUNT II – ADMINISTRATIVE PROCEDURES ACT, 5 U.S.C. § 706(2)(A)
THE ACTING SECRETARY'S ACTIONS ARE
ARBITRARY, CAPRICIOUS, AND AN ABUSE OF DISCRETION

61. Plaintiffs repeats and incorporates by reference the allegations contained in prior paragraphs.

62. The Acting Secretary's action not to set aside the DSA Priority was arbitrary, capricious, and an abuse of discretion because the Acting Secretary had no sound reason for leaving in place a policy that serves no valid purpose, affords no flexibility or exceptions in special cases or circumstances, and violates legal and regulatory requirements.

PRAYER FOR RELIEF

WHEREFORE, Miriam Holman respectfully requests that this Court enter a temporary restraining order and preliminary and permanent orders enjoining the Acting Secretary and the OPTN over which he has authority and control from applying the DSA Priority, so that Miriam and others in her circumstances can be treated fairly in OPTN's system of lung allocation without the arbitrary limitation of the geographic boundaries of the DSAs in which they are located.

Dated: Armonk, New York
November 19, 2017

By: s/*Motty Shulman*

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VERIFICATION

STATE OF NEW YORK
COUNTY OF NEW YORK

I, Glen Holman, am the father of Miriam Holman, the Plaintiff in this action. I, along with my wife, have been responsible for Miriam's care as it relates to the matters in this Verified Complaint for Te Jorary Restraining Order and Preliminary and Permanent Injunctive Relief dated November'}{', 2017. I have read the foregoing Complaint and know the contents thereof. The contents are true to my own knowledge except as to matters therein stated to be alleged upon information and belief, and as to those matters I believe them to be true.

Glen H6liiian

Subscribed and affirmed under penalty of perjury before me on November, 2017

Notarization

MORDECHAI SHULMAN
Notary Public, State of New York
Qualified in New York
LIC. #02SH6088506
My Commission Expires 5/24/18