UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

JANET AND FRANCIS MURNAGHAN 1024 Arbor Way Newtown Square, Pa 19073 Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES; KATHLEEN SEBELIUS, in her official capacity as Secretary of the U.S. Department of Health & Human Services; 200 Independence Ave., S.W., Room 120F Washington, D.C. 20201 Defendant.	:	Civil Action No. _____

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

INTRODUCTION

1. Plaintiffs Janet and Francis Murnaghan are the parents of 10-year-old Sarah Murnaghan, who is now in the intensive care unit at Children's Hospital of Philadelphia ("CHOP") hoping to receive a lung transplant. She is severely ill with Cystic Fibrosis and if she does not receive a donated set of lungs very soon she will die, possibly in a matter of weeks or sooner. Federal law requires equitable allocation of donated organs, but under the policies currently in effect, that requirement is not satisfied for children under 12, including Sarah Murnaghan.

2. Sarah's parents bring this action against defendant Kathleen Sebelius, Secretary of the United States Department of Health & Human Services (the "Secretary") under 5 U.S.C. § 702, seeking judicial review of the Secretary's decision not to terminate application of that aspect of Policy 3.7 of the Organ Procurement and Transplantation Network (the "OPTN")

that discriminates against children under 12 in the system established by law for allocating donated lungs (the "Under 12 Rule").

3. Donated lungs are a scarce resource for persons in need of them, but the scarcity is much greater for children than for adults. The pool of lungs donated from adults is more than 50 times larger than the pool of lungs donated from children. As a result, in a very small number of cases, transplantation professionals exercising medical discretion choose to downsize appropriately sized lungs from adults for use with children under 12. The procedure cannot be used with very small children and of course the lungs have to be compatible in size (there are limits to downsizing) and blood type as well as medically suitable. The procedure has been accomplished numerous times, particularly outside the United States, with outcomes comparable to transplantation of lungs from children.

4. Sarah's doctors have decided that transplantation of a set of lungs from an adult is appropriate in her case. She has been on the waiting list for child-donated lungs since December 2011. She has not yet received a medically suitable set of lungs from a child, even though children under 12 have preference over adults for the very few lungs donated from other children under 12. The Under 12 Rule effectively prevents Sarah from receiving lungs donated from an adult because it allocates lungs from adults to children under 12 only after they have been offered to and declined by every adult and adolescent, regardless of medical necessity in the same geographic zone. As a practical matter, very few if any lungs from adults ever get to children under 12 or if they do they are often medically unsuitable.

5. Under the National Organ Transplant Act of 1984 ("NOTA"), 42 U.S.C. § 274(b)(2), donated organs are required to be allocated equitably by the OPTN. In 1999, the Secretary promulgated regulations under NOTA that implement the statute by requiring that the

OPTN develop policies that provide organs to those with the greatest medical urgency. 42 C.F.R. § 121.8(b).

6. The Under 12 Rule violates the statute and regulation because it puts children at the very back of the line for lungs from adults regardless of medical urgency. Any adult or adolescent has priority over every child under 12 regardless of severity of their respective conditions. Further, the Under 12 Rule serves no purpose. The OPTN in 2004 decided to put children at the back of the line for organs from adults because it did not have enough data to determine if a scoring system it developed for determining medical severity in adults and adolescents, known as the lung allocation score ("LAS") system, would work with children under 12. There is no evidence that OPTN has reconsidered that decision despite scientific evidence that adult lungs can be successfully transplanted to children under 12, and despite publicly available data that shows that children waiting for lungs are dying at a rate much higher than adults. The 2009-11 three-year average death rate for children is 46% versus 28% for adults. The share of adults receiving a donated lung is also much higher than for children in every year from 2005 to 2011, the last year for which data is available. The Under 12 Rule is also invalid because Policy 3.7 was never published in the Federal Register for public comment, in violation of 5 U.S.C. § 553(b) and 42 C.F.R. § 121.4(b).

7. In the second half of May 2013, after Sarah's condition took a turn for the worse and she was admitted to the ICU at CHOP, her parents submitted a petition to the Secretary through a website called change.org. In response, on May 31, 2013, the Secretary directed the OPTN to study Policy 3.7 and the Under 12 Rule in particular and to make changes after giving an opportunity for comment from doctors and the public. Rightly concerned that any change will not come in time to save Sarah's life, her parents, through counsel, submitted a request on June 3, 2013 to the Secretary under 42 C.F.R. § 121.4(d) that she direct the OPTN to

set aside the Under 12 Policy on an emergency basis. *See* Exh. A. In support of that request, Sarah's parents submitted the statistics summarized above along with an explanation of the flaws in the Under 12 Rule.

8. As of the morning of June 5, 2013, the Secretary has not responded to the June 3 Request or the Secretary's response is inadequate to ensure that Sarah and other children under 12 needing donated lungs from adults are protected from the unfair, discriminatory effects of the Under 12 Rule. Sarah's parents now ask this Court to enter a temporary restraining order and preliminary and permanent orders enjoining the Secretary and the OPTN over which she has authority and control from applying the Under 12 Rule, so that Sarah and the very few other children in her circumstances can be treated fairly in the system of allocating adult lungs without being disqualified because of their age. Immediate termination of the Under 12 Rule would greatly increase Sarah's chances of receiving a set of lungs and would have no adverse effect on the public or anyone else. Sarah's parents are actively pursuing other options, including public solicitation for a directed set of lungs. If Sarah does not soon receive a set of donated lungs she will die, which clearly establishes a right to immediate injunctive relief in this case.

PARTIES

9. Plaintiffs are the parents of 10-year-old Sarah Murnaghan, who is now in the intensive care unit at CHOP hoping to receive a lung transplant that will save her life. Sarah's parents reside at 1024 Arbor Way, Newtown Square, Pa 19073.

10. Defendant Kathleen Sebelius is the Secretary of the United States Department of Health & Human Services ("HHS"), located at 200 Independence Ave., S.W., Room 120F, Washington D.C. 20201. Defendant Sebelius is sued in her official capacity. According to its website, the HHS "is the United States government's principal agency for

protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves."

VENUE AND JURISDICTION

11. 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 regulation 42 C.F.R. part 121, *et seq.*, and the Due Process Clause of the Fifth Amendment to the United States Constitution.

12. 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."

13. 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); provides a right to judicial review of "final agency action for which there is no other adequate remedy in a court," *id.* § 704.

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

15. Venue is proper before this Court pursuant to 28 U.S.C. § 1391(e)(1) because plaintiffs reside 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. Policy 3.7 And The Under 12 Rule

16. Organ donation in the United States is managed by the United Network for Organ Sharing ("UNOS"), a private entity that has a contract with HHS to operate the Organ Procurement Transplant Network ("OPTN"), which was created by Congress. The OPTN has developed and published organ transplant policies which can be found on the OPTN's website. The specific policy at issue in Sarah's case is Policy 3.7 entitled "Allocation of Thoracic Organs." *See* Exh. B (Policy 3.7).

17. Under Policy 3.7, Sarah is eligible for: (1) lungs donated from children under 12 based on time on the waiting list and severity (children are categorized as priority 1 or 2 based on severity) assuming the lungs are compatible in size and blood type; (2) lungs donated from adolescents aged 12 to 17 based on time on the waiting list and severity again assuming the lungs are compatible in size and blood type but only after the lungs are declined by all adolescents in the zone; and (3) lungs donated by adults based on time on the waiting list and severity again assuming the lungs are compatible in size and blood type but only after the lungs are declined by all adults and adolescents in the zone (the "Under 12 Rule"). As a practical matter, the Under 12 Rule prevents children like Sarah from being considered for a donation of lungs from the much larger pool of adult donated lungs or, if children are offered adult lungs after they have been declined by all adults and adolescents in the zone, the lungs are damaged or otherwise medically unsuitable.

18. Adult lungs are allocated based on several factors, including lung compatibility (based on size and blood type), geography (i.e., consideration of how far the donated organ has to be transported), and the lung allocation score ("LAS"), which is a formula that UNOS/OPTN uses to weigh severity and posttransplant survivability. LAS was meant to

allocate lungs with preference to the most severe cases, assuming that the organ candidate had a good chance to live after the transplant.

19. The National Organ Transplant Act of 1984 ("NOTA") created the OPTN. The statute has been amended several times. The current version is codified at 42 U.S.C. § 274, *et seq.* Section 274 provides that "the Secretary shall by contract provide for the establishment and operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b) of this section."

20. Section 274(b)(2) provides, *inter alia*, that the OPTN "shall":

> (A) establish in one location or through regional centers –
>
> (i) a national list of individuals who need organs, and
>
> (ii) a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs,
>
> . . .
>
> (D) assist organ procurement organizations in the nationwide distribution of organs *equitably* among transplant patients,
>
> . . .
>
> (M) *recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children*
>
> . . . .

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

21. Acting pursuant to its authority under the NOTA, since 1986 the Secretary of the Department of Health and Human Services ("HHS") through the Health Resources and Services Administration ("HRSA") has contracted with the United Network for Organ Sharing

("UNOS"), a non-profit private organization, to operate the OPTN. The Secretary has also promulgated regulations at 42 C.F.R. part 121 that govern the OPTN.

22. The regulations promulgated by the Secretary provide 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 . . . ." 42 C.F.R. § 121.4(a)(1).

23. The regulations also govern the content of the policies to be developed by the OPTN. Section 121.8(a) provides that OPTN's Board of Directors "shall develop, in accordance with the policy development process described in § 121.4, policies for the *equitable allocation* of cadaveric organs among potential recipients." (emphasis added). And Section 121.8(b) directs that the allocation policies should be designed to give greatest consideration to allocating organs based on the severity of illness. As noted in the proposed final rule promulgated on April 2, 1998: "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." 63 Fed. Reg. 16296.

24. The OPTN regulations, namely, 12 C.F.R. § 121.4(b), require the OPTN to provide its policies to the Secretary of the HHS at least 60 days in advance of their implementation and requires the Secretary to "refer significant proposed policies to the Advisory Committee on Organ Transplantation established under § 121.12, and publish them in the Federal Register for public comment." None of the OPTN policies were published in the Federal Register.

25. When the OPTN developed Policy 3.7 in 2004 it decided that "waiting time for this population [i.e., children] should remain the method of prioritizing patients in this

group"[1] because there were not that many of them and some of them had diseases not found in the adult population. *See* Exh. C, May 30 letter from Dr. Roberts. OPTN felt it did not have a basis to make a decision about using the LAS with children.

26. OPTN continues to subject children to unfair discrimination in lung allocation simply because it could not prove that the LAS worked for children when it developed the LAS in 2004. OPTN presumes that it cannot tell how sick Sarah really is in comparison to adults and adolescents despite the real world use by doctors of the LAS as a measure of illness severity and on that basis OPTN continues to deny children like Sarah access to the much larger pool of lungs donated by adults.

27. In the past, it may have been the case that complications involved with downsizing an adult lung for transplantation into a child presented a serious obstacle to the surgery, but that is no longer the case. Doctors do these surgeries and "[m]edical literature suggests that outcomes (survival, complications) are comparable when lobes rather than whole lungs are transplanted," although the studies involve small numbers.[2] *See* Exh. C.

28. OPTN Policy 3.7.6.4 provides for "special review of exceptional cases when the treating transplant team believes that the assigned LAS or priority level does not appropriately reflect the severity of the case, or when essential clinical values must be estimated to assign a score." Colvin-Adams, M, Valapour, M, et al, *Lung and Heart Allocation in the United States*, Am J. Transplant 2012; 12:3213-3234, 3218. *See* Exh. D. But the OPTN has categorically refused to consider any exception in Sarah's case and has taken the position that Policy 3.7 does not permit special exceptions to the Under 12 Rule. In a statement issued by the

[1] This clearly violated the Secretary's announced policy decision in favor of "equitable allocation policies that provide organs to those with the greatest medical urgency, in accordance with sound medical judgment." 63 Fed. Reg. 16296.

[2] *See, e.g.,* Keating DT, et al, *Long-term outcomes of cadaveric lobar lung transplantation: helping to maximize resources* J Heart Lung Transplant; 2010 Apr; 29(4):439-44.

OPTN on May 27, 2013, the OPTN stated: "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."[3]

B. Sarah's Story

29. Sarah has been in and out of hospitals since she was first diagnosed with Cystic Fibrosis, with multiple trips to the hospital each year for 4 to 5 days at a time.[4] Exh. E ¶ 4. She has also needed additional medical care at home. Despite her condition, until about 18 months ago she attended school and had a relatively normal life. *Id.*

30. Sarah's condition grew worse about 18 months ago as her lung capacity diminished to about 30% of its normal capacity. *Id. at* ¶ 4. She needed constant supplemental oxygen and was permanently put on an oxygen machine. She has required supplemental oxygen 24 hours a day since then. *Id.*

31. On December 7, 2011, Sarah was put on the pediatric lung transplant list, which means that she was then eligible to receive donated lungs preferentially from a child donor under 12 years of age. *Id.* ¶ 5.

32. In November of 2012 in order to increase the size of the donor pool Sarah's doctors increased the height range for Sarah's listing thus allowing her to receive organs from larger donors. Exh. E Dec. ¶ 8. If Sarah were to receive an offer from a larger donor her surgeons would downsize the donor lungs to fit Sarah's smaller body. *Id.*

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[3] *See* OPTN, Health Resources and Service Administration, OPTN Statement Regarding Lung Transplantation and Pediatric Priority, *available at* http://optn.transplant.hrsa.gov/news/newsDetail.asp?id=1595.

[4] Attached to this Complaint is the Declaration of Sharon Ruddock. *See* Exh. E. Sharon is the sister of Sarah's mother, Janet Murnaghan. She is very familiar with the background of this matter and has been asked by Sarah's parents to work directly with their as they are busy with Sarah and her doctors.

33. For lung transplants, the size of the donated lung has to fit the thoracic cavity of the candidate for donation, but Sarah's parents have been advised that an adult lung can be downsized by the doctors and that although this may be a complicating factor the likely outcome of the transplant surgery of a downsized adult lung is as good as with a lung that did not need to be downsized. *Id.* ¶ 5.

34. Sarah is categorized as priority 1 for child lungs. *Id.* ¶ 11. Sarah has received an LAS since the date she was listed for a lung transplant. *Id.* When she first went on the adult list it was 40. Over time, Sarah's LAS grew into the 50s, then 60s, as Sarah's condition grew worse. *Id.* To date, Sarah has not had any offers of donated adult lungs through OPTN. She has received three offers of donated lungs from children, but her doctors advised against taking any of them on the grounds that they were not medically suitable. *Id.*

35. As of today, Sarah has been in CHOP for 106 consecutive days. Exh. E ¶ 12. About two weeks ago, she took a turn for the worse and was admitted into the ICU. At that time, she had a significant and permanent loss of hearing because of the side effects of the antibiotics she must take. As of two days ago, Sarah's LAS is 66. *Id.*

36. With an LAS of 66, if Sarah were an adult she would be very likely to receive a donated lung. *Id.* ¶ 13. According to the data available on the UNOS website, for 2011 (the last full year for which data is available) an LAS of 50 would put her in the top 6% of organ donor candidates. Assuming those numbers are similar for 2013, Sarah would be very near the top of the list, based mainly on the severity of her condition. *Id.*

37. Unfortunately, Sarah is not at the top of the list, she is instead at the very bottom of the list, because the Under 12 Rule discriminates against children under 12. Exh. E ¶ 14.

38. Sarah's doctors have told Sarah's parents that if Sarah could be considered as a candidate for an adult lung, without regard to her age, all other factors remaining equal, the chance of her receiving a compatible and medically appropriate adult lung would greatly increase. They have also advised that at this time Sarah's chances for successful lung transplant surgery are good. *Id.* ¶ 23.

39. Through Sarah's doctors at CHOP, Sarah's parents have twice asked the Thoracic Committee of UNOS/OPTN if an appeal could be made to the OPTN Lung Review Board. UNOS/OPTN rejected both requests on the grounds that the OPTN Lung Review Board has no discretion to set aside the Under 12 Rule. *Id.* ¶ 20.

40. Sarah's parents have been advised by her doctors that the medical outcome for Sarah is uncertain and it is possible that she only has weeks to live. *Id.* ¶ 24.

C. <u>The Secretary's Action</u>

41. After Sarah's health deteriorated in mid-May 2013 and she was admitted to the ICU, her parents decided to mobilize support for changing the Under 12 Rule and they started a petition on Change.org in an effort to have the Secretary set aside the Rule.

42. In response to the petition, on May 29, 2013, the Secretary wrote Dr. John Roberts, M.D., President of the OPTN Board of Directors, noting the media attention Sarah's case had generated and requesting further information about the OPTN's policies with respect to child patients. *See* Exh. F. The Secretary requested that Dr. Roberts respond by 5:00 p.m. the following day. *Id.*

43. The next day, on May 30, 2012, Dr. Roberts responded to the Secretary's request for information with a six page letter. *See* Exh. C.

44. On May 31, 2013, Secretary Sebelius directed the OPTN to review Policy 3.7 and the Under 12 Rule in particular as soon as possible but with full consultation with the

OPTN membership and other interested parties. *See* Exh. G. Unfortunately, that process will take months with Sarah and other children under 12 currently standing at the back of the line waiting to be considered for a donation of lungs cannot wait. They will die in the meantime.

45. Rightly concerned that any change will not come in time to save Sarah's life, her parents through counsel on June 3, 2013, submitted a request to the Secretary under 42 C.F.R. § 121.4(d) that she direct the OPTN to set aside the Under 12 Policy on an emergency basis. *See* Exh. A. In support of that request, Sarah's parents submitted the statistics summarized below along with an explanation of the flaws in the Under 12 Rule. They also submitted the Declaration of Sharon Ruddock. *See* Exh. E. Sharon Ruddock is Sarah's aunt and she is very familiar with the background of this case.

46. As of the morning of June 5, 2013, the Secretary has not responded to the June 3 Request or the Secretary's response is inadequate to ensure that Sarah and other children under 12 needing donated lungs from adults are protected from the unfair, discriminatory effects of the Under 12 Rule.

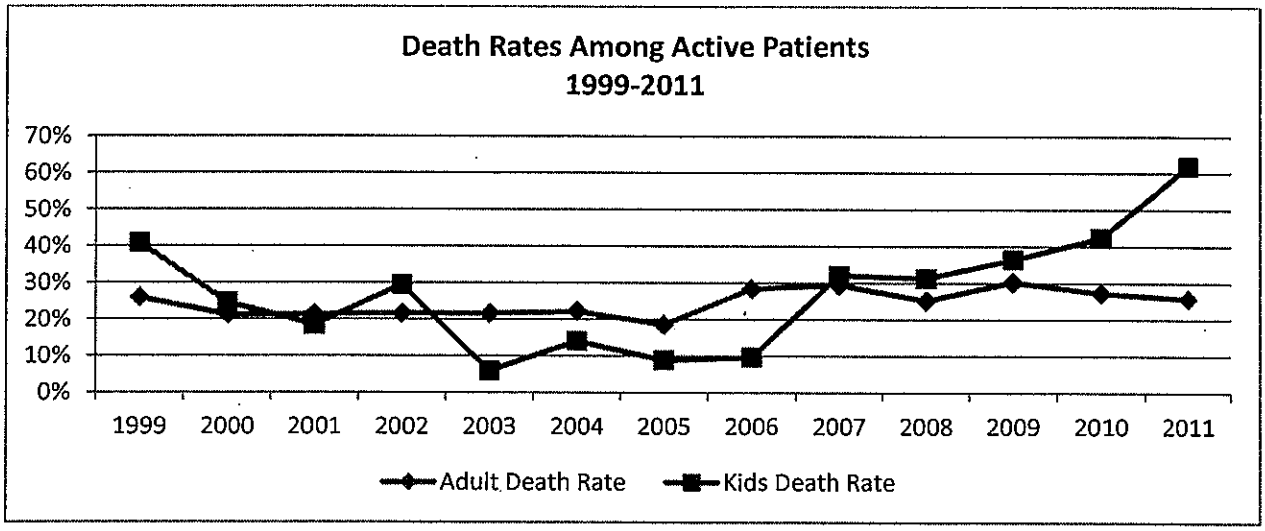
D. <u>The Effect of the Under 12 Rule</u>

47. The Scientific Registry of Transplant Recipient ("SRTR"), a national database of transplantation statistics based on data from OPTN, works closely with UNOS and is responsible for ongoing data analyses designed to provide policy makers with information needed to make decisions. Data from the UNOS website and the website of SRTR shows that children active on the lung transplant waiting list die at more than twice the rate of adults active on the lung transplant waiting list.[5] *See* Exh. E ¶ 15.[6] Attached as Exhibit B to the Ruddock

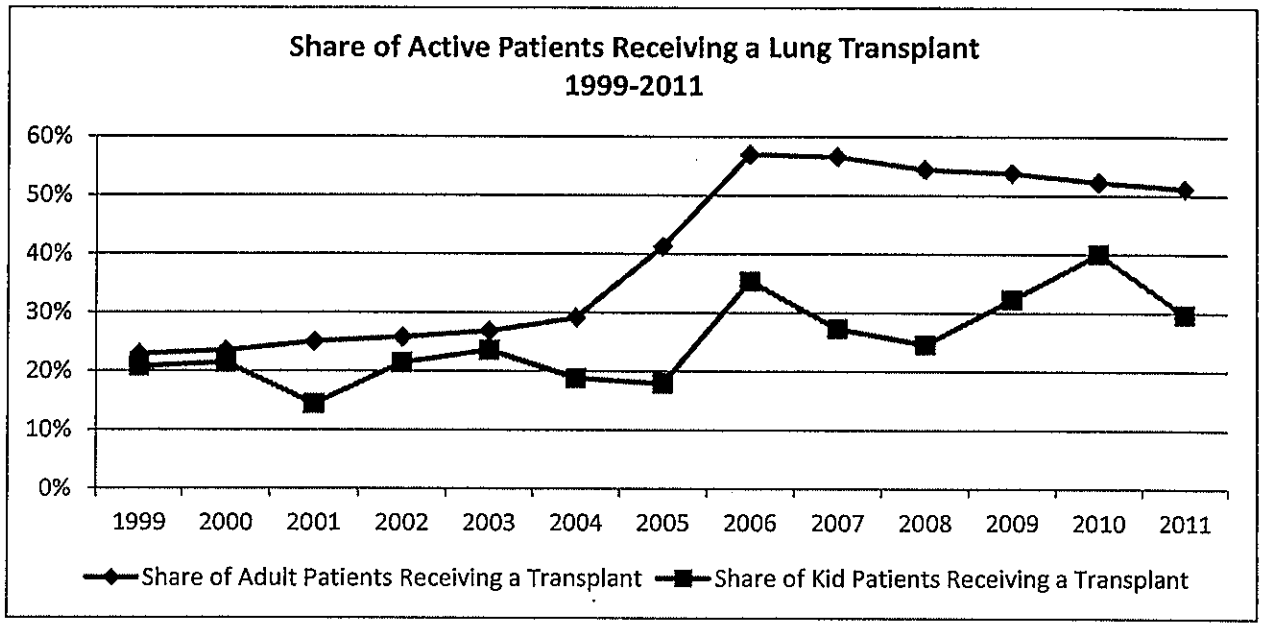
[5] Exhibit A to the Ruddock Declaration explains the use of active versus inactive patients in analyzing death rates.

[6] Attached as Exhibit H is the Declaration of Arthur Baines, an economist with more than 20 years of business, economic and quantitative analysis experience. Mr. Baines corroborates the conclusions about the discriminatory effects of the Under 12 Rule.

Declaration is a table based on SRTR data that shows that the death rate for children is 62% versus 26% for adults in 2011. Also, the 2009-11 three-year average death rate is 46% for children versus 28% for adults. *See* Exh. E ¶ 15. These conclusions are statistically significant. *Id.* Plotting the death rates on a chart for the years 1999 to 2011, since 2005, the year that OPTN implemented the Under 12 Rule, the death rate for children has gone up while the death rate for adults has gone down. *Id.* at ¶ 15-16. This can also be represented graphically, as follows:



48. Success rate is the percentage of people who get a lung transplant as compared to the total number who were on the transplant list at any time during the year. Since the Under 12 Rule was instituted in 2005, adults have experienced a substantial increase in success in receiving a transplant from 29% in 2004 to 50% in 2011, while children are left behind with a success rate of 30% as can be seen from UNOS data, attached as Exhibit C to the Ruddock Declaration. *Id.* This is represented graphically below:



49. The total number of lungs available for children in need of transplant is very small. Current data is not available but UNOS data shows that there were only 23 lungs available in 2011 in the entire country. *See* Exh. E ¶ 17. Given the limitations of blood type, size, and geographic range, a total pool of only 23 lungs is likely to result in few lung donations for a child on the lung transplant waiting list. In comparison, the adult transplant pool had 1,573 lungs available in 2011. *Id.* at ¶ 17.

50. In a May 30, 2013 letter to the Secretary, John P. Roberts, M.D., Chair of the OPTN, suggests that the Under 12 Rule is fair because the demand for donated lungs for children is small and pursuant to Policy 3.7 children get preferential access to lungs donated from children as well as preference behind adolescents to lungs donated from adolescents. As the below chart indicates, however, in 2011, the last year for which data is available, that segmentation by age could lead to significant disparities. For example, in that year, persons aged 18-34 provided 50% of the donated lungs and received 12% of the transplants while persons 65 and over provided 1% of the donated lungs and received 27% of the transplants. This shows that

it would be extremely unfair to allocate lungs within the adult population based on age. Exh. E ¶ 18.

Age Group	Percentage of Lungs Transplanted by Group	Percentage of Lungs Transplanted Successfully by Group
18-34 Yrs Old	50%	12%
35-49 Yrs Old	30%	13%
50-64 Yrs Old	19%	48%
65+ Yrs Old	1%	27%

51. The data proves that outcomes for children are much worse than for adults under Policy 3.7 and the Under 12 Rule. It makes no difference whether Policy 3.7 and the Under 12 Rule are causing this disparity or simply permitting it. Either way, it is a clear violation of the statutory command that the organ allocation system must be equitable and must address the unique medical needs of children.

CLAIMS FOR RELIEF

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

52. Plaintiffs repeat and incorporate by reference the allegations contained in paragraphs 1- 51 above.

53. 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).

54. The Under 12 Rule is not in accordance with law because it unfairly discriminates against children needing donated lungs and thus denies them the equal protection of law guaranteed by the United States Constitution.

55. The Under 12 Rule is not in accordance with law because it threatens to deprive Sarah Murnaghan of her life without due process of law in violation of the Fifth Amendment to the United States Constitution.

56. The Under 12 Rule 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) (emphasis added).

57. The Under 12 Rule is not in accordance with law because it fails to recognize the differences in health and organ transplantation issues between children and fails to address the unique health care needs of children, as required by 42 U.S.C. § 274(b)(2)(M).

58. The Under 12 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)(1).

59. The Under 12 Rule is not in accordance with law because it does not give greatest consideration to allocating organs based on medical urgency, as required by 42 C.F.R. § 121.8(b).

60. The Under 12 Rule is not in accordance with law because Policy 3.7 was never published in the Federal Register for public comment, in violation of 5 U.S.C. § 553(b) and 42 C.F.R. § 121.4(b).

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

61. Plaintiffs repeat and incorporate by reference the allegations contained in paragraphs 1- 60 above.

62. The Secretary's action not to set aside the Under 12 Policy was arbitrary, capricious, and an abuse of discretion because the Secretary had no sound reason for leaving in place a policy that discriminates against children, serves no valid purpose, affords no flexibility or exceptions in special cases or circumstances, and violates legal and regulatory requirements.

PRAYER FOR RELIEF

WHEREFORE, Sarah's parents request that this Court enter a temporary restraining order and preliminary and permanent orders enjoining the Secretary and the OPTN over which she has authority and control from applying the Under 12 Rule, so that Sarah and the very few other children in her circumstances can be treated fairly in the system of allocating adult lungs without being disqualified because of their age.

Date: June 5, 2013

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