UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

MILAGROS MARTINEZ 10030 E. 228th Street, Bronx NY 10466	
Plaintiff, v.	Civil Action No. _____
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.	

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

INTRODUCTION

1. Plaintiff Milagros Martinez is the mother of 11-year-old Javier Acosta, who is now in the intensive care unit at Children's Hospital of Philadelphia ("CHOP") hoping to receive a lung transplant. Javier is severely ill and if he does not receive a donated set of lungs very soon he will die. 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 Javier Acosta.

2. Javier's mother brings 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. Javier's doctors have decided that transplantation of a set of lungs from an adult is appropriate in his case. Javier went on the active waiting list to receive a lung transplant in 2010. He got a little better in 2010 and the doctors moved him to the inactive waiting list. But then he got sick again in 2011 and in early 2012 the doctors placed him back on the active waiting list. He 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 Javier 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. The undersigned counsel appeared before this Court yesterday, June 5, 2013, to request that a temporary restraining order and preliminary injunction be issued to prevent the Secretary from applying 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"). In that case, counsel argued that the Under 12 Rule should be set aside immediately to allow 10-year-old

Sarah Murnaghan a fair chance to be considered for receipt of donated lungs from adults based on the medical severity of her condition, and not her age. After hearing from both parties—and after acknowledging the government's position that any relief granted to Sarah should apply to her only—this Court entered a temporary restraining order enjoining HHS from applying the Under 12 Rule as to Sarah.

8. Following the hearing, Plaintiff requested that the undersigned counsel represent her in seeking similar relief for Javier.

9. The grounds presented here are as compelling as those presented by the Sarah Murnaghan case. Javier is a patient of Dr. Goldfarb at the Children's Hospital of Philadelphia ("CHOP"). Javier needs a lung transplant to survive. Without one he will most likely die before his 12th birthday in August. He could die sooner, much sooner, if his conditions were to suddenly deteriorate, which is within the range of realistic possibilities. Dr. Goldfarb and Javier's other doctors have determined that transplantation of a set of lungs from an adult is appropriate in his case. And Javier, like all children under 12 who have been approved by their doctors for receipt of adult lungs—except, now, for Sarah—is treated differently and worse from similarly situated adults. That is because the Under 12 Rule effectively prevents Javier 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.

10. What makes Javier's situation even more heartbreaking is that Javier's brother—another son of Plaintiff Milagros Martinez—died two years ago at the age of 11 while waiting for a lung transplant that could have saved his life. If Milagros Martinez is to lose another son, it should not be because of the Under 12 Rule, an arbitrary and capricious policy

that violates multiple statutes and regulations and the United States Constitution by discriminating against children in the allocation of vital organs.

11. For the foregoing reasons, the undersigned counsel is prepared to appear in court with Dr. Goldfarb. Milagros Martinez respectfully requests that this Court enter a temporary restraining order on an immediate and emergency basis at that time to ensure that Javier has a chance to be considered for donation of a set of lungs while the Court considers this matter more fully. Every hour that Javier has a fair chance to be considered for new lungs may save his life.

PARTIES

12. Plaintiff is the mother of 11-year-old Javier Acosta, who is now in the intensive care unit at CHOP hoping to receive a lung transplant that will save his life. Plaintiff resides at 10030 E. 228th Street, Bronx, New York 10466.

13. 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

14. 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.

15. 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."

16. 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.

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

18. 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

19. 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 Javier's case is Policy 3.7 entitled "Allocation of Thoracic Organs." *See* Exh. B (Policy 3.7).[1]

20. Under Policy 3.7, Javier 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 Javier 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.

21. 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.

22. 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,

[1] The Exhibits to this Complaint are exactly the same as the Exhibits to the Complaint filed in the case of Sarah Murnaghan, No. 13-cv-03083-MMB (ED Pa.). Rather than duplicate all of those Exhibits, they are incorporated as if attached hereto.

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."

23. 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).

24. 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.

25. 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).

26. 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.

27. 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.

28. 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"[2] 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.

[2] 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.

29. 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 Javier 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 Javier access to the much larger pool of lungs donated by adults.

30. 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.[3] *See* Exh. C.

31. 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 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

[3] *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.

existing lung allocation policy."[4]

B. Javier's Story

32. Javier was diagnosed in utero with cystic fibrosis. The doctors tested for it while Plaintiff was pregnant because Plaintiff had another son, named Jovan, who had cystic fibrosis.

33. Jovan died on August 15, 2009, at a hospital in New York while waiting for a liver and lung transplant. Once he was hospitalized, he just kept getting sicker and he did not get the transplants he needed and then he died. He was 11 years old at the time.

34. Until 2010, Javier had a relatively normal life except that he was hospitalized for several days two to three times a year. Other than when he was hospitalized, he went to school, played, and engaged in physical activity.

35. In 2010, Javier got sick and became a patient at CHOP. At that time, he went on the active waiting list to receive a lung transplant. He got a little better in 2010 and the doctors moved him to the inactive waiting list. But then he got sick again in 2011 and in early 2012 the doctors placed him back on the active waiting list.

36. Javier has been hospitalized at CHOP continuously for 7 weeks at this point, following two weeks in a hospital in New York. He is under the care of the CHOP physicians, including Dr. Samuel Goldfarb, the same physician that testified before this Court in the related Sarah Murnaghan case.

37. Javier has end stage cystic fibrosis and without a lung transplant, he will never go home from the hospital but instead will die. The plan is that if Javier gets a set of lungs donated from an adult they will be adjusted to fit into his chest.

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[4] *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.

38. Javier's condition could deteriorate at any time, putting him days or weeks away from death. Without a new set of lungs his condition will deteriorate and he will die and he has weeks or at best months to live.

C. The Secretary's Action

39. On May 29, 2013, the Secretary wrote Dr. John Roberts, M.D., President of the OPTN Board of Directors, noting the media attention the Under 12 Rule 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.*

40. 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.

41. 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.

42. At the Sarah Murnaghan June 5th Hearing, counsel for the DOJ informed the court and Plaintiff, for the first time, that a Special Committee would meet the following Monday to re-evaluate the Under 12 Rule. Counsel for the DOJ, however, did not provide a deadline by which a decision on whether to set-aside the Under 12 Rule would be made. Javier cannot wait and his life hangs in the balance.

43. Counsel for Sarah, who is also counsel for Javier, 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.

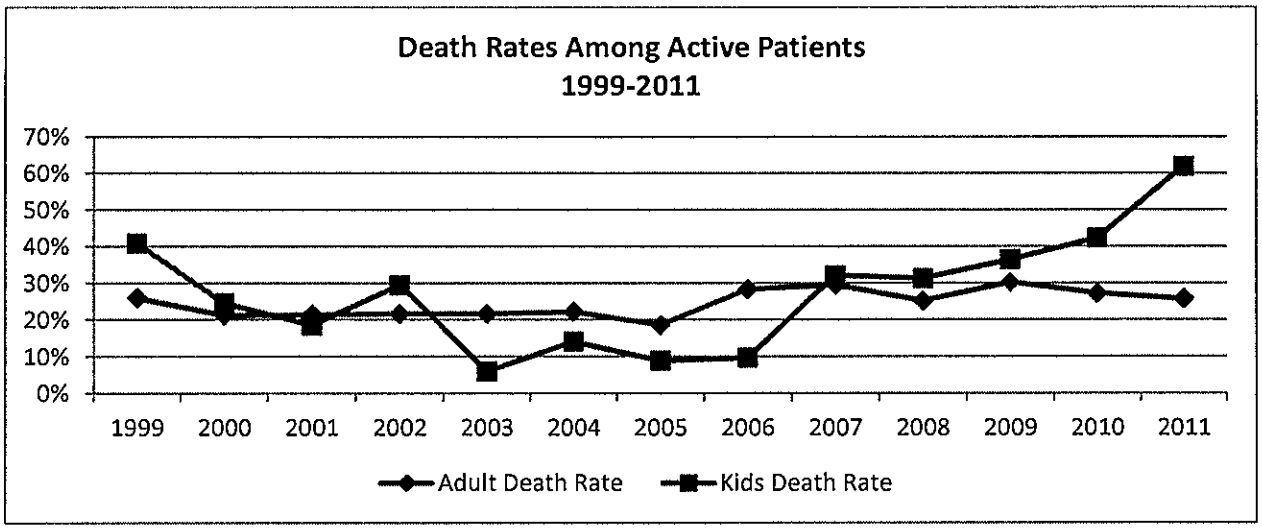
44. As of the time of the filing of this Complaint, the Secretary has not responded to the June 3 letter, which is in effect a denial of the request in that letter.

D. The Effect of the Under 12 Rule

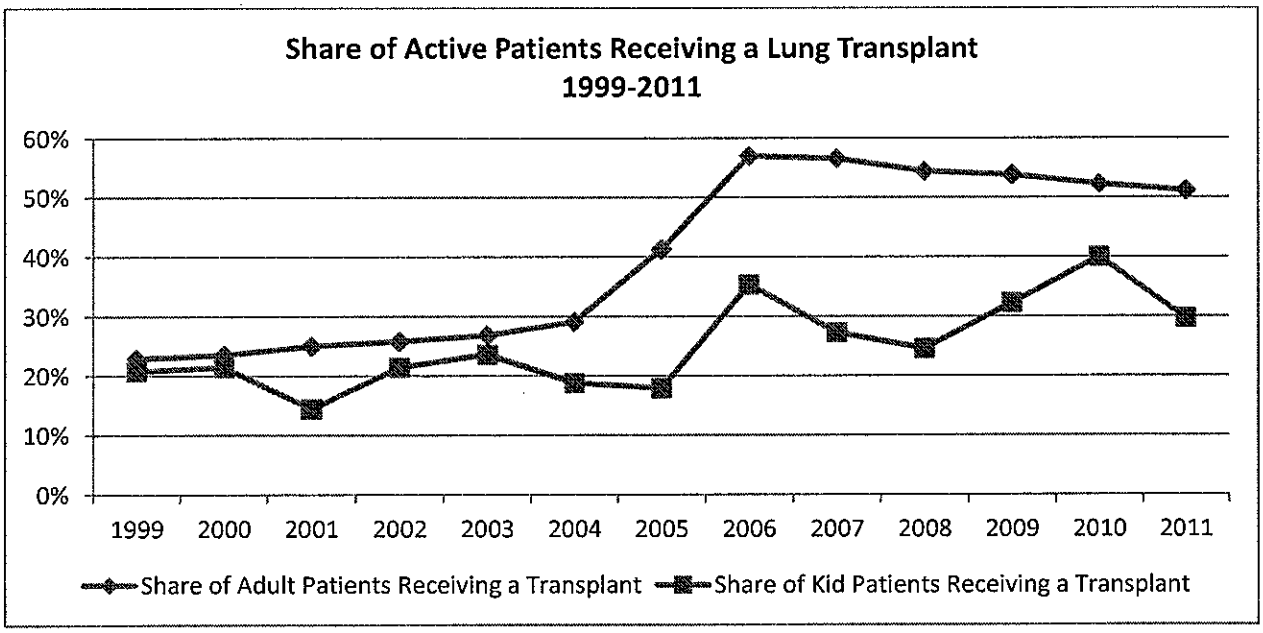
45. The Scientific Registry of Transplant Recipient ("SRTR"), a national database of transplantation statistics based on data from OPTN, works closely with UNOS and is responsible for ongoing data analyses designed to provide policy makers with information needed to make decisions. Data from the UNOS 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 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:

[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.



46. 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:



47. 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.

48. 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 Donated by Group	Percentage of Lung Transplants received 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%

49. 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

50. Plaintiffs repeat and incorporate by reference the allegations contained in paragraphs 1- 49 above.

51. 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).

52. 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.

53. The Under 12 Rule is not in accordance with law because it threatens to deprive Javier Acosta of his life without due process of law in violation of the Fifth Amendment to the United States Constitution.

54. 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).

55. 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).

56. 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).

57. 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).

58. 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

59. Plaintiffs repeat and incorporate by reference the allegations contained in paragraphs 1- 58 above.

60. 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, Plaintiff Javier's mother requests 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 Javier and the very few other children in his circumstances can be treated fairly in the system of

allocating adult lungs without being disqualified because of their age.

Date: June 6, 2013

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