UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

JANET AND FRANCIS MURNAGHAN 1024 Arbor Way Newtown Square, Pa 19073	:	Civil Action No. _____
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.	:	

ORDER

The Plaintiffs in this matter have moved on an emergency basis under Rule 65(b), Fed. R. Civ. P., for a temporary restraining order to prevent the Secretary of the United States Department of Health and Human Services (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") on the grounds that their 10-year-old daughter Sarah may soon die if she does not receive new lungs and that every hour that she can participate in the OPTN's system for allocating lungs without being forced to stand at the back of the line for the much larger pool of lungs donated from adults (more than 50 times greater than the pool of lungs donated from children under 12) could save her life. The Plaintiffs contend, *inter alia*, that the Under 12 Rule violates the command of the National Organ Transplant Act of 1984, 42 U.S.C. § 274(b)(2) that the system for allocating donated organs be "equitable" and address "the unique

health care needs of children" as well as the Secretary's own regulation, 42 C.F.R. § 121.8(b), which requires OPTN's policies to give greatest consideration to allocating organs based on medical urgency, and that the Secretary's refusal to set aside the Under 12 Rule to protect the very few children nationally who are subject to it, despite evidence showing that the Rule discriminates against children and serves no purpose, is arbitrary, capricious, and an abuse of discretion. AND NOW, having considered the matter, including the Declarations of Sharon Ruddock and Arthur Baines, it is hereby ordered that the motion for a TRO is granted and that the Secretary shall immediately cease application of the Under 12 Rule so that children under 12 can be considered as recipients for donated lungs from adults based on the medical severity of their conditions as compared to the medical severity of persons over 12 in the OPTN system. This Order shall remain in effect unless and until the Court orders otherwise at the conclusion of the hearing on a preliminary injunction.

_____

J.

UNITED STATES DISTRICT COURT
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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. _____

EMERGENCY MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

For the reasons set forth in the accompanying brief, Plaintiffs Janet and Francis Murnaghan hereby move under Rule 65(b), Fed. R. Civ. P., on an immediate and emergency basis for a temporary restraining order and preliminary injunction to prevent the Secretary of the United States Department of Health and Human Services (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").

Plaintiffs' 10-year-old daughter Sarah may soon die if she does not receive new lungs and every hour that Sarah can participate in the OPTN's system for allocating lungs without being forced to stand at the back of the line for the much larger pool of lungs donated from adults (more than 50 times greater than the pool of lungs donated from children under 12)

could save her life. That is why this motion is being brought on an immediate, emergency basis.

This Court has the authority to grant a temporary restraining order ("TRO") and preliminary injunction in exceptional cases, like this one, where the plaintiffs have a likelihood of success on the merits, immediate and irreparable harm is probable if relief is not granted, greater injury would result from refusing a TRO than from granting it, and the public interest is served by granting the TRO.

Plaintiffs, Sarah's parents, have a reasonable probability of successfully showing the Under 12 Rule is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The Under 12 Rule is "not in accordance with law" because it violates several express requirements of the National Organ Transplant Act of 1984 ("NOTA"), the regulations governing the OPTN, and the United States Constitution. First, because the Under 12 Rule discriminates against children under 12 for no reason, it violates requirements in NOTA and the regulations that OPTN distribute organs equitably among transplant patients. 42 U.S.C. § 274(b)(2)(D); 42 C.F.R. § 121.4(a)(1); *Id.* at § 121.8(a). Second, the Under 12 Rule violates NOTA's requirement that OPTN "adopt criteria, policies, and procedures that address the unique health needs of children." 42 U.S.C. § 274(b)(2)(M). Third, the Under 12 Rule violates 42 C.F.R. § 121.8(b)(2), which directs that OPTN's allocation policies should give greatest consideration to allocating organs to those with the greatest medical urgency. Fourth, the Under 12 Rule is unlawful because it, like all OPTN policies, was not published in the Federal Register, in violation of 42 C.F.R. § 121.4(b) and and 5 U.S.C. § 553(b). The Under 12 Rule also deprives Sarah and children like her of life without equal protection and due process of law in violation of the Fifth Amendment to the U.S. Constitution.

The Under 12 Rule is also arbitrary and capricious. OPTN's data show that segmentation by age could lead to significant disparities, even among adults. OPTN's data also show that children under 12 are being treated not only differently, but much worse. Further, the only rationale suggested for the policy— that OPTN did not know if the Lung Allocation System ("LAS") would be useful for children in 2004—does not make sense. And the Under 12 Rule provides no flexibility: it sentences 10- and 11-year-olds like Sarah to the back of the adult transplant line, regardless of their physical attributes, regardless of their need, and regardless of the recommendations and beliefs of their doctors.

Finally, Plaintiffs meet the remaining requirements for a TRO and preliminary injunction. Sarah will suffer irreparable harm if she is denied relief. Without a lung transplant, she will die. Nobody would be significantly harmed by the elimination of the Under 12 Rule because there are probably fewer than twenty children in the entire country in Sarah's situation. Also, the rejection of the Rule would not give these children priority over adults and adolescents, but would merely give them an equitable chance to receive a lung, based on the severity of their medical condition, their doctors' recommendations, and other factors. And, the public interest is served by a fair allocation system that does not discriminate against children.

Date: June 5, 2013

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Defendant.	:	

BRIEF IN SUPPORT OF EMERGENCY MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Date: June 5, 2013

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I. INTRODUCTION

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.

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"). Every hour that Sarah can participate in the OPTN's system for allocating lungs without being forced to stand at the back of the line for the much larger pool of lungs donated from adults (more than 50 times greater than the pool of lungs donated from children under 12) could save her life, and that is why this motion is being brought on an immediate, emergency basis.

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.

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.

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).

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).

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 to Complaint.) 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.

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.

II. BACKGROUND

A. Factual Background

1. The UNOS, the OPTN, and the Under 12 Rule

Organ donation in the United States is operated 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, including Policy 3.7 entitled "Allocation of Thoracic Organs." (*See* Exh. B to Complaint.)

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.

Adults 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. (Id. ¶ 9.) The LAS was meant to allocate lungs with preference to the most severe cases. (Id.)

2. Sarah's Story

Sarah Murnaghan is a 10-year-old girl who was diagnosed with Cystic Fibrosis when she was 18 months old. (Ruddock Dec. ¶ 1 (*see* Exh. E to Complaint).) Sarah has been in and out of hospitals since she was first diagnosed, with multiple trips to the hospital each year for 3 to 4 days at a time. (*Id.* ¶ 3.) Sarah's condition grew worse about 18 months ago as her lung capacity diminished to about 30% of its normal capacity. (*Id.* ¶ 4.) She needed constant supplemental oxygen and was permanently put on an oxygen machine. (*Id.*) For the past 106 days, she has been in the intensive care unit at Children's Hospital of Philadelphia ("CHOP"). (*Id.* ¶ 1.) On December 7, 2011, Sarah was put on the pediatric lung transplant list, which means that she was then eligible to receive donated lungs from a child donor. (*Id.* ¶ 4.) Under Policy 3.7, Sarah was eligible only for lungs donated from a child, until November 2012, when Sarah's doctors approved her to receive an adult lung through the OPTN. (Id. ¶ 7.)

Sarah's doctors at CHOP have provided the results of medical tests to UNOS to calculate Sarah's LAS. (*Id.*) In fact, UNOS has been tracking Sarah's LAS since she was

placed on the adult transplant waiting list. (*Id.*) In addition, Sarah's family has used Sarah's LAS score to communicate with many hospitals about possible lung donors. (*Id.*) When Sarah first became listed on the adult list, her LAS was 40. (*Id.*) Over time, that number grew into the 50s, then 60s, as Sarah's condition grew worse. (*Id.*)

Sarah has been in CHOP on this most recent stay for 106 days as of today. (*Id.* ¶ 11.) About two weeks ago, she took a turn for the worse and was admitted into the ICU. (*Id.*) At that time, she had a significant and permanent loss of hearing because of the side effects of the antibiotics she must take. (*Id.*) As of two days ago, Sarah's LAS is 66. (*Id.*)

Sarah's doctors at CHOP have advised that she may have only weeks to live. (*Id.* ¶ 13.) If Sarah could be considered for a lung transplant under OPTN Policy 3.7 without regard to the Under 12 Rule, there is a good chance that she would receive a compatible and medically appropriate set of adult lungs that would save her life or at least her chance of receiving one would be greatly increased. (*Id.*) With an LAS of 66, if Sarah were an adult (or if the Under 12 Rule were eliminated) she would be very likely to receive a donated lung. (*Id.* ¶ 12.) In 2011 (the last full year for which UNOS data is available) a LAS of 50 would put Sarah in the top 6% of organ donor candidates. (*Id.*) Assuming those numbers are similar for 2013, Sarah would be very near the top of the list, based on the severity of her condition. (*Id.*) Unfortunately, Sarah is not at the top of the list, she is instead at the very back of the list, because OPTN Policy 3.7 discriminates against children under 12.

To date, Sarah has not had any offers of donated adult lungs through OPTN. (*Id.* ¶ 17.) Through Sarah's doctors at CHOP, Sarah's family has twice asked the Thoracic Committee of UNOS/OPTN if an appeal could be made to the OPTN Lung Review Board. (*Id.*

¶ 18.) 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.*)

Sarah's doctors told her family 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 be greatly increased. (*Id.* ¶ 21.) They also advised that at this time Sarah's chances for successful lung transplant surgery are good. (*Id.*)

3. The Discriminatory Effect of the Under 12 Rule

The information on the UNOS website and the website of the Scientific Registry of Transplant Recipient ("SRTR"), a national database of transplantation statistics based on data from the OPTN, shows that children active on the lung transplant waiting list die at more than twice the rate as adults active on the lung transplant list. (*Id.* ¶ 14; *see also* Exh. B to Ruddock Dec. (showing that the death rate for children is 62% vs 26% for adults in 2011).[1] The 2007-11 three-year average death rate is 46% for children versus 28% for adults. (Ruddock Dec. ¶ 14.) These conclusions are statistically significant. This same data for the years 1999 – 2011 shows a marked increase in the death rate for children since the OPTN implemented the Under 12 Rule in 2005. (*Id.*)

The success rate for children on the lung transplant list was 32%, while the success rate for the adults was 50%. (Baines Dec. ¶ 3.) Success rate is the percentage of adults who get a lung transplant as compared to the total number of adults who were on the transplant list at any time during the year. (Ruddock Dec. ¶ 15.) Since the Under 12 Rule was instituted,

[1] Attached as Exhibit H to the Complaint 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.

adults have experienced a substantial increase in success in receiving a transplant from 29% in 2004 to 51% in 2011, while children are left behind with a success rate of 30%. (*Id.*)

The total number of lungs available for children in need of transplant is very small. (*Id.* ¶ 16.) UNOS data shows that there were only 23 lungs available in 2011. (*Id.*) Given the limitations of blood type, size, and geographic range, a total pool of only 23 lungs is likely to result in no lung donations for a child on the lung transplant waiting list. (*Id.*) In comparison, the adult transplant pool had 1,573 lungs available in 2011. (*Id.*)

Segmentation by age can lead to significant statistical disparities between age groups. (*Id.*) UNOS data for 2011 shows that if lungs were allocated within age segments of the 12 and over population, there would be significant statistical disparities. (*Id.*)

4. The Secretary's Action

On May 29, 2013, Secretary Sebelius wrote a letter to John Roberts, M.D., President of the OPTN Board of Directors noting the intense attention Sarah's case had generated from the national media, Congress, and others and requesting further information about the OPTN's policies with respect to child patients. (*See* Exh. F to Complaint.) After receiving Roberts' response (Exh. C to Complaint), Secretary Sebelius on May 31, 2013 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 (Exh. G to Complaint). Unfortunately, that process will take months and Sarah and other children under 12 currently standing at the back of the line waiting to be considered for donation of lungs cannot wait. They will die in the meantime.

Therefore, on June 3, 2013, counsel for Sarah's parents wrote a letter to Secretary Sebelius requesting that the Secretary "take immediate action and direct the Organ Procurement and Transplantation Network ("OTPN") to set aside that portion of OPTN Policy

3.7 that discriminates against children under 12 in the system established by law for allocating donated lungs." (*See* Exh. A to Complaint.) That letter explicitly did not seek preferential treatment, but rather requested that HHS direct UNOS and OPTN to set aside the Under 12 Rule on an emergency basis for all children. (*Id.*) 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.

B. Legal Background

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."

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, polices, and procedures that address the unique health care needs of children*
>
> . . . .

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

Acting pursuant to its authority under the NOTA, since 1986 the Secretary of the 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. 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) (emphasis added).

The regulations also govern the content of the policies to be developed by the OPTN. These, like § 121.4(a)(1), emphasize the OPTN's responsibility to assist in the equitable allocation of organs, based on recipients' medical conditions and medical judgment. For example, § 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). Section 121.8(a)(6) provides that these equitable policies "[s]hall be reviewed periodically and revised as appropriate." Section 121.8(b)(2) 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.

III. ARGUMENT

The issuance of a TRO and a preliminary injunction is necessary in this case because Sarah's parents have demonstrated in their Complaint and this Motion and Brief: (1) a likelihood of success on the merits; (2) the probability of irreparable harm if relief is not granted; (3) that granting the relief will not result in greater harm to another party; and, (4) that granting the relief is consistent with the public interest. *Bieros v. Nicola*, 857 F. Supp. 445, 446 (E.D. Pa. 1994) (noting that the standard for a TRO is the same as the standard for a preliminary injunction) (*citing Frank's GMC Truck Ctr., Inc.v. G.M.C.*, 847 F.2d 100, 102 (3d Cir. 1988)).

A. Sarah's Parents Are Likely to Prevail on the Merits.

1. This Court has Authority to Review the Action of the Secretary Because It is a Final Agency Action.

The Administrative Procedure Act provides for judicial review of "agency action made reviewable by statute and final agency action[2] for which there is no other adequate remedy in a court." 5 U.S.C. § 704. An agency action is final if (1) it marks "the consummation of the agency's decisionmaking process," and (2) "rights or obligations have been determined" by the actions or "legal consequences will flow" from it. *Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1037 (D.C. Cir. 2002) (citing *Bennett v. Spear*, 520 U.S. 154 (1997)). "[T]he question is whether the agency has imposed an obligation, denied a right, or fixed some legal relationship . . . ." *Role Models America, Inc. v. White*, 317 F.3d 327, 331 (D.C. Cir. 2003) (internal quotation marks and citations omitted).

The Supreme Court has instructed courts to apply the finality requirement in a "flexible" and "pragmatic" way. *Ciba-Geigy Corp. v. E.P.A.*, 801 F.2d 430, 435-36 & n.7 (D.C.

[2] The definition of "agency action" "includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." 5 U.S.C. § 551(13). It is clear that the Secretary's decision not to respond to Plaintiffs' June 3, 2013 letter was an agency action because it was, in effect, a denial of their request for emergency relief and also a "failure to act."

Cir. 1986) ("Congress gave no indication that it intended the finality requirement to be applied in [a] hypertechnical fashion . . . To the contrary, the legislative history of § 704 suggest that Congress was merely codifying the self-imposed judicial practice of exercising restraint in reviewing tentative agency action."). Thus, to be a final action, an agency decision need not be made pursuant to an adjudicative or rulemaking proceeding. *See Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1037 (D.C. Cir. 2002). Further, an agency's action may be final even if it is not the result of formal procedures and even if the decision is memorialized in an informal letter. *See Ciba-Geigy Corp. v. E.P.A.*, 801 F.2d 430 (D.C. Cir. 1986). And, "to be final, an action need not be the last administrative action contemplated by the statutory scheme." *Role Models*, 317 F.3d at 331.

An agency's intent to continue considering an issue does not mean that its decision is not final. In *Environmental Defense Fund, Inc. v. Hardin*, five organizations petitioned the Secretary of Agriculture to (1) issue notices of cancellation for all economic poisons containing the chemical DDT, and (2) suspend registrations for all such products pending the conclusion of cancellation proceedings. 428 F.2d 1093, 1095-96 (D.C. Cir. 1970). The Secretary issued notices of cancellation for four uses of DDT, solicited comments regarding the remaining uses, and took no action on the organizations' request for interim suspension. *Id.* at 1096. The D.C. Circuit rejected respondents' argument that, because the Secretary indicated that he was considering further compliance with the organizations' request and neither granted nor denied much of the relief requested, the decision was not reviewable. *Id.* at 1098.

> An order expressly denying the request for suspension or for cancellation would clearly be ripe for review. The doctrines of ripeness and finality are designed to prevent premature judicial intervention in the administrative process, before the administrative action has been fully considered, and before the legal dispute has been brought into focus. *No subsequent action can sharpen the controversy arising from a decision by the*

> *Secretary that the evidence submitted by petitioners does not compel suspension or cancellation of the registration of DDT. In light of the urgent character of petitioners' claim, and the allegation that delay itself inflicts irreparable injury, the controversy is as ripe for judicial consideration as it can ever be.*

Id.

Similarly, in *Fox Television*, the D.C. Circuit held that the Federal Communications Commission's 1998 decision not to repeal or modify the national television station ownership rule ("NTSO") and the cable/broadcast cross-ownership rule were final agency actions under the APA. 280 F.3d at 1037-38. The FCC had undertaken a review of these rules because a provision of the Telecommunications Act of 1996 required it to review all its ownership rules biannually, "determine whether any of such rules are necessary in the public interest as the result of competition," and "repeal or modify any regulation it determined to be no longer in the public interest." *Id.* at 1033-34 (quoting the Telecommunications Act of 1996, § 202h). The FCC decided not to modify the NTSO Rule because, *inter alia*, it wanted to observe the effects of recent changes to the rules before making any further amendments. *Id.* at 1036. The Court rejected the FCC's argument that the agency's decision—memorialized in its *1998 Report*—was not final because it intended to continue considering the ownership rules.

> [T]he agency['s] inten[t] to continue considering the ownership rules . . . does not mean the determination is not "final" as a matter of law. The *1998 Report* is the Commission's last word on whether, as of 1998, the Rules were "still necessary in the public interest as a result of competition."

Id. at 1036.

By submitting their June 3, 2013 letter to Secretary Sebelius, Plaintiffs followed the proper procedure for bringing critiques of the OPTN before HHS. The regulations promulgated by the Secretary and NOTA itself (1) authorize interested individuals to petition

the Secretary to alter the way the OPTN is administered, and (2) recognize that the Secretary has the authority to direct the OPTN to take action, even on an emergency basis, in response to such a petition. Section 121.4(d) of the regulations provides as follows:

> *Any interested individual or entity may submit to the Secretary in writing critical comments related to the manner in which the OPTN is carrying out its duties or Secretarial policies regarding the OPTN.* Any such comments shall include a statement of the basis for the comments. The Secretary will seek, as appropriate, the comments of the OPTN on the issues raised in the comments related to OPTN policies or practices. *Policies or practices that are the subject of critical comments remain in effect during the Secretary's review, unless the Secretary directs otherwise based on possible risk to the health of patients or to public safety.* The Secretary will consider the comments in light of the National Organ Transplant Act and the regulations under this part and may consult with the Advisory Committee on Organ Transplantation established under § 121.12. After this review, the Secretary may:
>
> (1) Reject the comments;
>
> (2) *Direct the OPTN to revise the policies or practices consistent with the Secretary's response to the comments*; or
>
> (3) Take such other action as the Secretary determines appropriate.

42 C.F.R. 121.4(d) (emphasis added); *see also* 42 U.S.C. § 274(c) (providing statutory authorization for 42 C.F.R. 121.4(d)).

Despite the Secretary's authority to issue an order directing the OPTN to set aside the Under 12 Rule, 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.

Secretary Sebelius's May 31 letter remains the Agency's last word on the subject. That letter directs 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. It does not grant emergency relief to children under 12 who, like Sarah, will likely die before such a fulsome review is completed.

Secretary Sebelius's decision *not* to grant the requested emergency relief, but instead to continue the agency's review of the OPTN, was a final decision. As explained in *Environmental Defense Fund, Inc. v. Hardin* and *Fox Television*, a decision that emergency relief is not warranted is a final decision, even where the agency continues a deliberative process. Like in *Environmental Defense Fund, Inc. v. Hardin*, a judicial determination would not be premature because "[n]o subsequent action can sharpen the controversy arising from a decision by the Secretary that the evidence submitted by petitioners does not compel" immediate suspension of the Under 12 Rule. 428 F.2d at 1098. In other words, and as explained in *Fox Television*, Secretary Sebelius's decision is final because no later review by HHS will revise what Secretary Sebelius has already decided: that the evidence submitted by Plaintiffs was insufficient to merit an immediate suspension of the Under 12 Rule "based on possible risk to the health of patients or to public safety." 42 C.F.R. 121.4(d).[3]

2. The Secretary's Action is Not in Accordance with the Law.

This Court has the authority and should set aside the Secretary's action on the ground that it is "not in accordance with law." 5 U.S.C. § 706(2)(A) (providing grounds for judicial relief from an agency decision).

Children are being treated very differently than adults under the Under 12 Rule, they are suffering because of it, and there is no sound reason for discriminating against children in lung allocation. Under OPTN Policy 3.7, lungs are allocated by the age of the donor. The

[3] Moreover, because of Sarah's critical need for a lung transplant, the Secretary's intent to review the matter further makes no difference for Sarah. She would likely die before that process concluded.

Policy essentially sets up three different waiting lines: one for lungs donated by adults (age 18 and over), one for lungs donated by adolescents (age 12-17), and one for lungs donated by children (age 11 and under). Lungs donated by adults are offered preferentially to adults and adolescents based on location, compatibility, and LAS, which is "a calculation of illness severity and projected posttransplant survival that was intended to place the sickest candidates with the best chance of survival at the top of the waiting list." Colvin-Adams, M, Valapour, et al, *Lung and Heart Allocation in the United States*, Am. J. Transplant 2012; 12:3213-3234, 3214. The Under 12 Rule forces children under 12 to stand at the back of the line for access to pool of lungs donated from adults, which is more than 50 times larger than the pool donated form children. It should be obvious that with a critical need for lung donations, all of the adults on the waiting list do not decline a set of lungs unless the lungs are of very poor quality, such as lungs from a heavy smoker or person with a compromised immune system. As a practical matter, being at the very back of the line is nearly the same as not being in the line. This cannot be justified on the grounds that children under 12 stand in a different line, because the data shows that the rates at which children succeed in getting donated lungs is much lower than the success rate for adults and the rate at which children die while standing in line is much higher than the rate at which adults die.

The Under 12 Rule—which the Secretary has chosen to continue by denying emergency relief—violates the National Organ Transplant Act of 1984 ("NOTA") and the regulations governing the OPTN. First, because the Under 12 Rule discriminates against children under 12 for no good reason, it violates requirements in NOTA and the regulations that OPTN "assist organ procurement organizations in the nationwide distribution of organs *equitably* among transplant patients." 42 U.S.C. § 274(b)(2)(D) (emphasis added); *see also* 42

C.F.R. § 121.4(a)(1) (requiring the OPTN Board of Directors to be responsible for developing "[p]olicies for the *equitable* allocation of cadaveric organs") (emphasis added); *Id.* at 121.8(a) (similar); *Id.* at 121.8(a)(6) (providing that these equitable policies "[s]hall be reviewed periodically and revised as appropriate").

Second, the Under 12 Rule violates NOTA's requirement that OPTN "adopt criteria, policies, and procedures that address the unique health needs of children," 42 U.S.C. § 274(b)(2)(M), because it fails to address the health care needs of children and causes children as a group to suffer dramatically worse outcomes than adults.[4]

Third, the Under 12 Rule violates 42 C.F.R. § 121.8(b), which directs that OPTN's allocation policies should give greatest consideration to allocating organs to those with the greatest medical urgency. The proposed final rule promulgated on April 2, 1998 underscores this priority: "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. Although Sarah has only weeks to live, she stands in line behind adults and adolescents with less pressing needs as measured by LAS, despite the recommendations of her doctors at the Children's Hospital of Philadelphia ("CHOP"), who believe her chances of surviving a transplant with adult lungs are good. (Ruddock Dec. ¶ 21.)

Fourth, the Under 12 Rule is unlawful because it, like all OPTN policies, was not published in the Federal Register. This is a violation of 42 C.F.R. § 121.4(b), which requires the OPTN to provides its policies to the Secretary at least 60 days in advance of their implementation and requires the Secretary to "refer significant proposed policies to the

[4] A strong argument could be made that, for sound policy reasons and because of the statutory command that the policies must address the unique health care needs of children, the OPTN policies should give children preference in organ allocation. Sarah's parents are not, however, seeking preference for children; they are instead seeking to ensure that the OPTN policies do not unfairly discriminate against children.

Advisory Committee on Organ Transplantation established under § 121.12, and publish them in the Federal Register for public comment." It also violates 5 U.S.C. § 553(b), which provides that "[g]eneral notice of proposed rule making shall [generally] be published in the Federal Register."

Fifth, the Secretary's refusal to grant Sarah and other children under 12 emergency relief from the Under 12 Rule deprives them of life without due process of law in violation of the Fifth Amendment to the U.S. Constitution. That protection requires the federal government to treat similarly situated people equally. *See Bolling v. Sharpe*, 347 U.S. 497, 499-500 (1954). Whenever the federal government classifies people to ration a resource, the classification is subject to scrutiny. *See, e.g.*, *Bowen v. Gilliard*, 483 U.S. 587, 597-98 (1987) (applying equal protection analysis to Congress's decision to amend the allocation procedures for Federal Aid to Families with Dependent Children benefits). When the government classifies by race, alienage, national origin, or sex—or limits fundamental rights—courts apply heightened scrutiny to the classification. *Zablocki v. Redhail*, 434 U.S. 374, 388 (1978) ("When a statutory classification significantly interferes with the exercise of a fundamental right, it cannot be upheld unless it is supported by sufficiently important state interests and is closely tailored to effectuate only those interests."); *Frontiero v. Richardson*, 411 U.S. 677, 682 (1973) (stating that classifications based upon race, alienage, national origin, and sex are "inherently suspect and must therefore be subjected to close judicial scrutiny"). Otherwise, rational basis scrutiny applies. *See Lyng v. Castillo*, 477 U.S. 635, 638 (1986) (applying rational basis scrutiny to Congress's definition of a "household"). In this case, the federal government has rationed the cadaveric lungs that people, like Sarah, need to live by discriminating based on age. While courts have acknowledged that rational basis scrutiny applies to classifications based on

age, heightened scrutiny should apply where, as here, the rationed resource is required to sustain human life. *See Dandridge v. Williams*, 397 U.S. 471, 522 & nn.17-18 (1970) (Marshall, J., dissenting) ("And this Court has already recognized several times that when a benefit, even a 'gratuitous' benefit, is necessary to sustain life, stricter constitutional standards, both procedural and substantive, are applied to the deprivation of that benefit."). And, even if heightened scrutiny does not apply, the Secretary's refusal to set aside the policy is still not in accordance with the law because, as explained below, the action is arbitrary, capricious, and not rational.

Sixth, the Under 12 Rule violates Sarah's procedural due process right to be treated equitably and to have life-saving organs allocated as specified in the NOTA: based on medical severity. Moreover, Sarah has been denied the place on the waiting list for donated lungs to which she is entitled without a hearing. Through Sarah's doctors at CHOP, Sarah's family has twice asked the Thoracic Committee of UNOS/OPTN if an appeal could be made to the OPTN Lung Review Board. (*Id.* ¶ 18.) 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.*) Similarly, by failing to grant Sarah's emergency request that the Under 12 Rule be suspended without initiating a hearing, HHS practically ensured that Sarah objections would not be heard before it is too late.

3. The Secretary's Action is Arbitrary, Capricious, and an Abuse of Discretion.

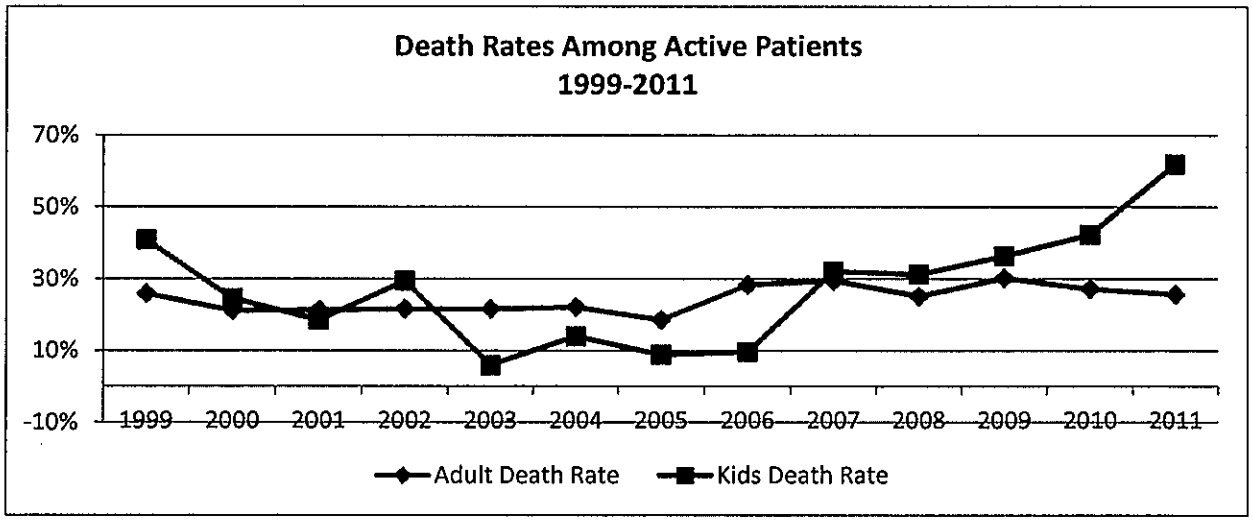
The Secretary's action to allow UNOS, a private entity HHS controls, to continue an unlawful policy that discriminates against children and deprives them of life-saving organs is "arbitrary, capricious, [and] an abuse of discretion," 5 U.S.C. § 706(2)A), especially because the Murnaghan family has brought serious flaws in the policy to the Secretary's attention. In his June 3 letter (Exh. A to Complaint), counsel for Sarah's parents brought to the

Secretary's attention the multiple statutory and regulatory violations inherent in the Under 12 Rule. *See* Section III(A)(2), *supra.*

The June 3 letter also pointed out that significant disparities are the natural result of a system that allocates resources by segmenting the population based on age. The letter pointed out that UNOS data shows that in 2011, the last year for which data is available, segmentation by age could lead to significant disparities. (Ruddock Dec. ¶ 18.) 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. (*Id.*) This shows that it would be extremely unfair to allocate lungs within the adult population based on age.

The June 3 letter explained that disparate outcomes for children are not just likely, they are real. UNOS' own data shows that the death rate (i.e., the percentage of people on the waiting list that die while waiting for a lung transplant) for children in 2011 (the last year for which data is available) is 62% versus 26% for adults. (Ruddock Dec. ¶ 15.) The 2009-11 three year average death rate for children is 46% versus 28% for adults. (*Id.*) These results are statistically significant. (*Id.*)

The June 3 letter included UNOS data about the death rates for the years 1999 to 2011. The data show that 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.*)



The June 3 letter also pointed out that UNOS data on the share of patients receiving a donated lung tells a similar story. In every year since 2005 the rate of adults receiving a donated lung is much higher than the rate of children receiving a donated lung. Ruddock Dec. ¶ 16.

The June 3 letter highlighted the difficulty in discerning a purpose for the Under 12 Rule because none of the OPTN policies, including Policy 3.7, was published in the Federal Register, in violation of 42 C.F.R. § 121.4(b) and 5 U.S.C. § 553(b). The June 3 letter also showed that the ostensible purpose for the Under 12 Rule, as set forth in Dr. Roberts' letter of May 30, 2013, cannot withstand scrutiny . Dr. Roberts suggested that when the OPTN developed Policy 3.7 in 2004 it did not have data to make a decision about applying the LAS system to children and therefore decided to allocate lungs to children based on time in the waiting line, in clear violation of the Secretary's direction to the OPTN to develop a system for allocating organs based on medical urgency.

Counsel showed that it makes no sense for the OPTN to continue 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, when there is no dispute that Sarah is very sick now and could die very soon.

Counsel also showed that the Under 12 Rule is completely inflexible and leaves no room for medical judgment. It had appeared that the Secretary appreciated the benefits of a nuanced approach: she stated in her May 31, 2013 letter that "decisions about who should receive a particular organ in a particular situation involve levels of detail, subtlety and urgency that must be judged by transplant professionals." (*See* Exh. G to Complaint.) But that is precisely what is *not* happening at present. The OPTN has set up an inflexible system that treats children much differently and worse than adults and precludes transplant professions from exercising any discretion in the matter.

There is no question that Sarah needs a lung transplant; the question is why OPTN and HHS continue to enforce the Under 12 Rule when they know it severely prejudices children—a group that should at the very least be treated equally with adults—when the only justification for the Rule is that OPTN did not know if LAS would be useful for children when it developed Policy 3.7 and when at least one young person's life hangs in the balance. The answer seems to be that the OPTN built no flexibility into the Under 12 Rule when it developed it in 2004 or at any time since and neither OPTN nor HHS see fit to develop any flexibility now.[5] But if the Under 12 Rule is hurting children – and doing so for no good reason – then it

[5] 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, et al, *Lung and Heart Allocation in the United States*, Am. J. Transplant 2012; 12:3213-3234, 3218. 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. (*See* Ruddock Dec. ¶ 20.) 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 existing lung allocation policy." *See* OPTN, Health Resources and Services Administration, OPTN Statement Regarding Lung Transplantation and Pediatric Priority, *available at* http://optn.transplant.hrsa.gov/news/newsDetail.asp?id=1595.

is the very definition of arbitrariness for the Secretary to refuse to set it aside on an emergency basis.

B. A TRO and Preliminary Injunction Are Necessary to Prevent Immediate and Irreparable Harm that Cannot be Adequately Compensated by Damages.

A TRO and preliminary injunction are necessary to prevent immediate and irreparable harm that cannot be compensated by damages because, Sarah's doctors at CHOP have advised that she may have only weeks to live if she does not receive a lung transplant. (Ruddock Dec. ¶ 24.) A risk of irreparable harm exists if a plaintiff shows that enforcement of a rule "may deny [plaintiff] needed medical care." *Beltran v. Myers*, 677 F.2d 1317, 1322 (9th Cir. 1982); *see also Dozsa v. Crum & Forster Ins. Co.*, 716 F. Supp. 131, 133 (D.N.J. 1989) (holding that a patient who needed a bone marrow transplant would suffer irreparable injury without an injunction compelling his insurer to cover the treatment because, without prompt surgery, the patient would die). If Sarah could be considered for a lung transplant under OPTN Policy 3.7 without regard to the Under 12 Rule, there is a good chance that she would receive a compatible and medically appropriate set of adult lungs that would save her life or at least her chance of receiving one would be greatly increased. (Ruddock Dec. ¶ 23) Based on 2011 data, Sarah's LAS of 66 would put her in the top 6% in the country, greatly increasing her chances of a receiving a donated lung. (*Id.*)

Sarah is very unlikely to receive viable lungs if the Under 12 Rule remains in effect. UNOS data shows that there were only 23 lungs from child donors available in 2011. (*Id.*) Given the limitations of blood type, size, and geographic range, a total pool of only 23 lungs is likely to result in no lung donations for a child on the lung transplant waiting list. (*Id.*) In comparison, the adult transplant pool had 1,573 lungs available in 2011. (*Id.*) Sarah is unlikely to obtain adolescent or adult lungs of an acceptable quality through the OPTN because,

for that to happen, the lungs would need to be rejected by every adolescent (in the case of an adolescent donor) or every adolescent *and* adult (in the case of an adult donor).

Thus, a TRO is necessary to prevent immediate and irreparable harm because the life of a ten-year-old girl who may have only days or weeks to live hangs in the balance. We cannot overstate the urgency of this case. Sarah could take a turn for the worse at any time and then a lung donation might be too late. The Under 12 Rule should be set aside immediately to ensure that Sarah has a fair chance to continue her life while the Court decides this case.

C. Granting the Requested Relief Will Not Result in Greater Harm to Another Party and the Public Interest Would be Served by Eliminating the Under 12 Rule.

Granting Sarah's parents the relief they request would not result in greater harm to another party, including the adults and adolescents waiting for a lung transplant, or upset the administration of the OPTN. There are very few children under 12 seeking donations of adult lungs, based on medical determinations by their doctors. (*Id.* at 22.) The UNOS data do not show the number of children under 12 seeking donation of adult lungs, but they do show the number of children aged 6-10 seeking lungs from any age donor, which is currently 16. (*Id.*) In 2011, that number was 18. (*Id.*) This shows that there are not many children seeking lung donations overall, and the number seeking adult lungs would be even less. (*Id.*) There may be a few more such children between 10 and 12, but in any event, it is a very small number in relation to the number of adults seeking lung transplants which is currently 1,637. (*Id.*) Thus, eliminating the Under 12 Rule would help children a great deal and do little to affect the chances of adult and adolescent candidates to receive donated lungs.

Eliminating the Under 12 Rule is also consistent with the public interest. It is in the public interest to ration access to vital organs for transplantation in an equitable way, and it

is an affront to community expectations for a civilized society to subject any group of citizens to an arbitrary, capricious, and unlawful rule that decreases their chances of survival.

IV. CONCLUSION

For the foregoing reasons, Janet and Francis Murnaghan request that this Court enter a temporary restraining order on an immediate and emergency basis to ensure that Sarah has a chance to be considered for donation of a set of lungs while the Court considers this matter more fully. Every hour that she has a fair chance to be considered for new lungs may save her life.

Date: June 5, 2013

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