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2015

## Rules Are Meant To Be Broken: The Organ Procurement And Transplantation Network Should Allow Pediatric Transplantation Of Adult Lungs

Ciera Parish

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### Recommended Citation

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**RULES ARE MEANT TO BE BROKEN: THE ORGAN  
PROCUREMENT AND TRANSPLANTATION  
NETWORK SHOULD ALLOW PEDIATRIC  
TRANSPLANTATION OF ADULT LUNGS**

CIERA PARISH\*

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I. INTRODUCTION

Imagine being told that your dying child could potentially be saved; however, a single regulation prevents doctors from doing so.<sup>1</sup> Imagine being told that your child

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<sup>1</sup> Organ Procurement and Transplantation Network Policies, *Policy 10.1 Priority and Score Assignments for Lung Candidates* (March 31, 2015) available at [http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Policies.pdf](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf).

has only days to live and the life-saving procedure is not available to your child simply because of his or her age.<sup>2</sup> This is exactly what happened to Janet Murnaghan and her dying ten-year-old daughter, Sarah.<sup>3</sup> Diagnosed with cystic fibrosis as an infant, Sarah Murnaghan spent most of her life in and out of hospitals.<sup>4</sup> At the young age of ten years old, Sarah found herself clinging to life in desperate need of a lung transplant for survival.<sup>5</sup> However, this life-saving procedure was within Sarah's reach yet still escaping her grasp.

Due to the extreme shortage of pediatric donors in the United States, Sarah's doctors knew that she would die waiting for a pair of life-saving pediatric lungs.<sup>6</sup> Exploring all options, Sarah's doctors proposed a solution that would save her life: pediatric transplantation of adult-sized lungs.<sup>7</sup> Without this solution, Sarah may have never seen her eleventh birthday.<sup>8</sup> However, this new-found hope was shattered when the Murnaghan's were told that the life-saving procedure was prohibited by a discriminatory and arbitrary regulation: the "Under 12 Rule."<sup>9</sup>

Enacted in 2005, The Organ Procurement and Transplant Network's "Under 12 Rule" essentially prohibits children under the age of twelve from ever receiving a set of adult donor lungs, regardless of physician recommendation or medical necessity.<sup>10</sup> Desperate to keep their child alive, Sarah's parents sought relief through the justice

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<sup>2</sup> *See id.*

<sup>3</sup> *See* Complaint for a Temporary Restraining Order and Preliminary and Permanent Injunctive Relief at 1, *Murnaghan v. United States Department of Health & Human Services*, No. 13-3083 (D. Pa. June 5, 2013), available at <http://docs.justia.com/cases/federal/district-courts/pennsylvania/paedce/2:2013cv03083/477750/1> (moving 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 from applying that aspect of Policy 3.7 of the Organ Procurement and Transplantation Network that discriminates against children under 12 in the system established by law for allocating donated lungs, the "Under 12 Rule." This policy number has been since changed to Policy 10.1 of the Organ Procurement and Transplantation Network as of March 31, 2015. However, its language remains the same).

<sup>4</sup> *See id.* at 10.

<sup>5</sup> *See id.* at 1.

<sup>6</sup> *See id.*

<sup>7</sup> *See id.* at 11.

<sup>8</sup> *See id.* at 4.

<sup>9</sup> Organ Procurement and Transplantation Network Policies, *Policy 10.1 Priority and Score Assignments for Lung Candidates* (March 31, 2015) available at [http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Policies.pdf](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf); *See* Complaint for a Temporary Restraining Order and Preliminary and Permanent Injunctive Relief at 2, *Murnaghan v. United States Department of Health & Human Services*, No. 13-3083 (D. Pa. June 5, 2013), available at <http://docs.justia.com/cases/federal/district-courts/pennsylvania/paedce/2:2013cv03083/477750/1>.

<sup>10</sup> *See* Complaint for a Temporary Restraining Order and Preliminary and Permanent Injunctive Relief at 3, *Murnaghan v. United States Department of Health & Human Services*, No. 13-3083 (D. Pa. June 5, 2013), available at <http://docs.justia.com/cases/federal/district-courts/pennsylvania/paedce/2:2013cv03083/477750/1>.

system. On June 5, 2013, United States District Judge Michael M. Baylson sparked controversy when he temporarily suspended the “Under 12 Rule,” permitting dying ten-year-old Sarah Murnaghan to be placed on the adult lung transplant waitlist.<sup>11</sup> The Pennsylvania District Court Judge ordered Health and Human Services Secretary, Kathleen Sebelius, to direct the Organ Procurement and Transplant Network (“OPTN”) to place Sarah on the adult waitlist, a placement that became effective with the OPTN at 10:34 p.m. that same night.<sup>12</sup>

Following Judge Baylson’s order, the OPTN called an emergency meeting to reevaluate transplant allocation laws in the United States.<sup>13</sup> Unfortunately, not much change was made.<sup>14</sup> The “Under 12 Rule” remains in place, but now, as a result of Judge Baylson’s order, children under twelve awaiting a lung transplant may now elect to have their cases reviewed by a national board of lung transplant surgeons.<sup>15</sup> However, this “review board,” policy change is set to expire in September of 2015 again threatening the availability of adult donor lungs for children under the age of twelve.<sup>16</sup> Due to the limited availability of pediatric lungs, stories such as Sarah’s are becoming far more common.<sup>17</sup> After Sarah’s success, an increasing number of parents have turned to federal courts to keep their dying children alive.<sup>18</sup>

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<sup>11</sup> See *Murnaghan v. United States Dep’t of Health & Human Servs.*, No. 13-3083 (D. Pa. June 5, 2013), available at <http://www.paed.uscourts.gov/documents/opinions/13D0477P.pdf> (granting Murnaghan’s request for a temporary restraining order, requiring Health and Human Services Secretary, Kathleen Sebelius, to direct the OPTN to place Sarah Murnaghan on the adult transplant waiting list, while she was also to remain on the pediatric waiting list).

<sup>12</sup> See *id.*; see also JoNel Aleccia, *Dying Girl Who Sparked Debate Gets Lung Transplant From Adult Donor*, NBC NEWS HEALTH (June 12, 2013), [http://vitals.nbcnews.com/\\_news/2013/06/12/18919724-dying-girl-who-sparked-debate-gets-lung-transplant-from-adult-donor?lite](http://vitals.nbcnews.com/_news/2013/06/12/18919724-dying-girl-who-sparked-debate-gets-lung-transplant-from-adult-donor?lite) (confirming that 10-year-old Sarah Murnaghan underwent six hours of surgery to receive two lobe transplants on June 12, 2013).

<sup>13</sup> See *Pa. Girl’s Double-Lung Transplant Deemed Success*, CBS NEWS (June 11, 2013), <http://www.cbsnews.com/news/pa-girls-double-lung-transplant-deemed-success/>; Sydney Lupkin, *Girl Prompts Small Change to Organ Transplant Policy*, YAHOO NEWS (June 11, 2013), <http://gma.yahoo.com/girl-prompts-small-change-organ-transplant-policy-165437602--abc-news-wellness.html> (providing that the transplant network convened an emergency meeting of its executive committee to evaluate the Under 12 Rule, a little-known organ transplant policy that a Pennsylvania couple brought to national attention after arguing that it had been pushing their dying 10-year-old to the bottom of the adult lung transplant waiting list).

<sup>14</sup> See Lupkin, *supra* note 13.

<sup>15</sup> *Id.*

<sup>16</sup> See United Network for Organ Sharing, Policy Notice (July 1, 2014), available at [http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Policy\\_Notice\\_07-01-2014.pdf](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policy_Notice_07-01-2014.pdf).

<sup>17</sup> See *Second US Family Urges Change to Children’s Organ Transplant Policy*, FOX NEWS (June 10, 2013), <http://www.foxnews.com/health/2013/06/10/second-us-family-urges-change-to-children-organ-transplant-policy/> (providing that a second family has stepped forward in the public fight to change a donor-organ policy that places sick children younger than 12 years of age at the bottom of the adult transplant list, regardless of the severity of their illness).

<sup>18</sup> See *id.*

This note analyzes the “Under 12 Rule” and advocates for its abolishment. This note analyzes the consequences and discrimination faced by children under the age of twelve since its enactment in 2005 as well as the benefits stemming from the allowance of using adult lungs for pediatric transplantation. Part II discusses the history of organ transplantation law and the current organ transplantation laws as they stand. Part III provides statistical data demonstrating the disparity between pediatric lung transplant candidates and adult lung transplant candidates. Part IV discusses the reasons for the implementation of the “Under 12 Rule,” and analyzes the emerging study associated with the benefits of a lung transplantation using larger lungs. Part V discusses the litigation which ensued due to the “Under 12 Rule,” and the legal arguments that were raised. Part VI proposes a new regulation for the pediatric allocation of donor lungs, and Part VII concludes this Note, advocating for the abolishment of the Organ Procurement and Transplant Network’s “Under 12 Rule.”

## II. ORGAN TRANSPLANTATION IN THE UNITED STATES

The United Network for Organ Sharing (“UNOS”) is a non-profit private organization based in Richmond, Virginia, that manages the organ donation, organ procurement, and organ transplantation system in the United States.<sup>19</sup> UNOS originated in 1977 as an initiative of the South-Eastern Organ Procurement Foundation, the first organization to develop a computerized system used to match organ donors with transplant candidates.<sup>20</sup> The South-Eastern Organ Procurement Foundation established a Kidney Center in 1982, which eventually evolved into the UNOS organ center. In 1984, UNOS was formally incorporated into a non-profit, private organization.<sup>21</sup>

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<sup>19</sup> See *About Us*, UNITED NETWORK FOR ORGAN SHARING, <http://www.unos.org/about/index.php>

(last visited March 7, 2014) (providing an informational for users stating that the United Network for Organ Sharing is the private, non-profit organization that manages the nation's organ transplant system under contract with the federal government); see also *Directions*, UNITED NETWORK FOR ORGAN SHARING, [http://www.unos.org/docs/unos\\_directions.pdf](http://www.unos.org/docs/unos_directions.pdf) (last visited March 2, 2015).

<sup>20</sup> See *UNOS Facts and Figures*, UNITED NETWORK FOR ORGAN SHARING (2013), available at [https://www.unos.org/docs/UNOS\\_FactsFigures.pdf](https://www.unos.org/docs/UNOS_FactsFigures.pdf). The United Network for Organ Sharing developed an online database system, called UNet. *Id.* at 2. This online data based is currently used to collect, store, analyze and publish all of the Organ Procurement and Transplantation Network’s data that pertains to the patient waiting list, organ matching, and transplants. See *Data*, UNITED NETWORK FOR ORGAN SHARING, <http://www.unos.org/donation/index.php?topic=data> (last visited Mar. 26, 2015).

Launched on October 25, 1999, this system contains data regarding every organ donation and transplant event occurring in the United States since 1986. UNet is a fail-safe, 24/7, secure Internet-based transplant information database. It enables the nation's organ transplant institutions to: register patients for transplants, match donated organs to waiting patients, and manage the time-sensitive, life-critical data of all patients, before and after their transplants. *Id.*

<sup>21</sup> See *UNOS Facts and Figures*, *supra* note 20 at 5.

Following its incorporation, The United States Congress enacted the National Organ Transplant Act of 1984.<sup>22</sup> In addition to prohibiting the sale of human organs, the Act called for a unified transplant network to be operated by a private, non-profit organization under federal contract.<sup>23</sup> UNOS was the recipient of this contract and the Organ Procurement and Transplantation Network (“OPTN”) was formed.<sup>24</sup> Through this contract with the federal government, UNOS was given the authority to oversee the operation of the OPTN and was given the main task of developing equitable organ distribution policies for the OPTN.<sup>25</sup> To date, UNOS is the only organization to ever operate the OPTN.<sup>26</sup>

#### A. Governance of the United Network for Organ Sharing

UNOS is led by a forty-two-member board of directors who meet twice a year, overseeing management of the organization.<sup>27</sup> It is composed of a wide-range and diverse pool of professions in order to capture different viewpoints within the field of organ transplantation.<sup>28</sup> The board determines and constantly reviews the policies for transplants of the kidney, pancreas, liver, intestine, heart, lung or a combination of two.<sup>29</sup> UNOS has a different transplantation policy for each organ.<sup>30</sup> When making these policy determinations, UNOS receives input from more than twenty permanent and ad-hoc committees.<sup>31</sup> These committees were formed to address specific perspectives and interests including: patient and donor family issues, medical issues specific to the various transplantable organs, needs and concerns of ethnic minorities and children needing transplants, technical aspects of organ recovery and matching, ethical principles, and the collection and reporting of scientific data.<sup>32</sup>

The UNOS board also acts as the board of directors for the OPTN.<sup>33</sup> Through the UNOS’s collaborative policy development, monitoring and enforcement processes

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<sup>22</sup> *See id.*

<sup>23</sup> *See id.*

<sup>24</sup> *See id.*

<sup>25</sup> *See id.*

<sup>26</sup> *See id.*

<sup>27</sup> *See Governance, UNITED NETWORK FOR ORGAN SHARING*, <http://www.unos.org/about/index.php?topic=governance> (last visited March 7, 2014) (stating that the United Network for Organ Sharing is led by a Board of Directors, which oversees management of the organization. This site also provides sections that assist with learning more about UNOS’ governance principles such as key staff, bylaws, corporate policies, best practices, and financial statements); *see also UNOS Facts and Figures*, *supra* note 20, at 6.

<sup>28</sup> *See UNOS Facts and Figures*, *supra* note 20, at 6.

<sup>29</sup> *See id.*

<sup>30</sup> *See id.* at 9.

<sup>31</sup> *See id.* at 6.

<sup>32</sup> *See id.*

<sup>33</sup> *See id.* at 6-7.

have been put in place for the OPTN.<sup>34</sup> Accordingly, the overall purpose of the OPTN is to help ensure the success and efficiency of the United States organ transplant system.<sup>35</sup> Consistent with this purpose, the OPTN has several duties including: facilitating the organ matching and placement process through the use of the computer system, maintaining a fully staffed Organ Center operating 24 hours a day, developing consensus based policies and procedures for organ recovery, overseeing the distribution of organs, and transportation of organs.<sup>36</sup> The OPTN is also tasked with collecting and managing scientific data about organ donation and transplantation; providing transplant data to the government, the public, students, researchers, and the Scientific Registry of Transplant Recipients; developing and maintaining a Web-based computer system that maintains the nation's organ transplant waiting list and recipient/donor organ characteristics; and providing professional and public education about donation and transplantation.<sup>37</sup>

*B. Policy 3.7 "Organ Distribution: Allocation of Thoracic Lungs"*

To ensure that these duties are fulfilled, the OPTN has created several policies, regulations, and bylaws governing the organ transplant process. Accordingly, Policy 3.7 "Organ Distribution: Allocation of Thoracic Lungs" was created.<sup>38</sup> Within this policy, however, lies an arbitrary and discriminatory regulation responsible for the controversy in Sarah Murnaghan's case: the "Under 12 Rule."<sup>39</sup>

Prior to 2005, the "Under 12 Rule" was nonexistent.<sup>40</sup> Before Policy 3.7 was revised to include this rule, lung allocation was based on how long a patient had been on the waiting list.<sup>41</sup> This applied to all lung transplant candidates, regardless of age. Doctors, however, began to realize that this system had many disadvantages. People who were less ill and could afford to wait longer, received transplants first only because they were on the transplant waiting list longer.<sup>42</sup> People who suddenly became very ill and joined the list had virtually no chance of receiving a lung transplant in time to save their lives.<sup>43</sup> Thus, in 2005 the system was redesigned.<sup>44</sup>

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<sup>34</sup> See *id.* at 8.

<sup>35</sup> See *id.* at 5-6.

<sup>36</sup> See *id.*

<sup>37</sup> See *id.* at 3.

<sup>38</sup> Organ Procurement and Transplantation Network Policies, Policy 10.1 Priority and Score Assignments for Lung Candidates (March 31, 2015) available at [http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Policies.pdf](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf).

<sup>39</sup> See Complaint *supra* note 1, at 1-2.

<sup>40</sup> See Complaint *supra* note 1; see *Questions & Answers for Transplant Candidates about Lung Allocation Policy*, UNITED NETWORK FOR ORGAN SHARING, available at [http://www.unos.org/docs/Lung\\_Patient.pdf](http://www.unos.org/docs/Lung_Patient.pdf) (last visited March 7, 2014) [hereinafter *Q & A Lung Allocation*] (providing lung transplant candidates and their families with a booklet containing common questions and answers regarding lung allocation policy in the United States).

<sup>41</sup> See Complaint, *supra* note 1

<sup>42</sup> See *Q & A Lung Allocation*, *supra* note 40, at 1.

<sup>43</sup> See *id.*

This new redesign was implemented to take into account the severity of a candidate's illness, rather than base lung allocation on how long a candidate was on the transplant waiting list.<sup>45</sup> This redesign, however, only applied to adults and children ages twelve and older.<sup>46</sup> Instead, children under the age of twelve fall victim to the UNOS priority system, a discriminatory system which will be explained at length below.<sup>47</sup>

Regardless of age, when a deceased lung donor becomes available, a transplant coordinator from an organ procurement organization enters medical information about the donor into the UNOS computer system.<sup>48</sup> The system then matches the deceased lung donor's medical characteristics with the medical information of candidates awaiting a lung transplant.<sup>49</sup> The UNOS computer system generates a ranked list of patients for the lungs recovered from the donor.<sup>50</sup> The first candidate on the transplant waiting list is offered a set of donor lungs as they become available.<sup>51</sup> This does not ensure, however, that the first candidate on the waiting list will receive the donor lungs. The donor lungs may be given to the next candidate on the waiting list if the first candidate cannot be located in time for the procedure or is too sick to receive the transplant.<sup>52</sup> If this occurs, the donor lungs continue to be offered to the next lung transplant candidate until the organ is placed.<sup>53</sup> Explained above, as of 2005, the first candidate on the waiting list is no longer determined by time spent on the waiting list; rather, candidates ages twelve and older are given a special score in order to determine their ranking.<sup>54</sup>

### *C. Allocation of Thoracic Lungs for Candidates Ages Twelve and Older*

Because of this new design, candidates ages twelve and older undergo a different process for lung allocation than pediatric candidates under twelve.<sup>55</sup> In the new lung

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<sup>44</sup> See Organ Procurement and Transplantation Network Policies, Policy 10.1 Priority and Score Assignments for Lung Candidates (March 31, 2015) available at [http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Policies.pdf](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf); See Complaint, *supra* note 1, at 14.

<sup>45</sup> See Organ Procurement and Transplantation Network Policies, *Policy 10.1 Priority and Score Assignments for Lung Candidates* (March 31, 2015) available at [http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Policies.pdf](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf).

<sup>46</sup> See *id.*

<sup>47</sup> See *Q & A Lung Allocation*, *supra* note 40, at 3.

<sup>48</sup> See *UNOS Facts and Figures*, *supra* note 20, at 10.

<sup>49</sup> See *id.*

<sup>50</sup> See *id.*

<sup>51</sup> See *id.*

<sup>52</sup> See *id.*

<sup>53</sup> See *id.*

<sup>54</sup> See *Q & A Lung Allocation*, *supra* note 40, at 1.

<sup>55</sup> See Organ Procurement and Transplantation Network Policies, Policy 10.1 Priority and Score Assignments for Lung Candidates (March 31, 2015) available at [http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Policies.pdf](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf).



allocation system, every lung transplant candidate ages twelve and older receives an individualized lung allocation score.<sup>56</sup> The system determines the order of everyone over the age of eleven awaiting a lung transplant by their lung allocation scores, blood type, and the geographic distance between the candidates and the hospital where the lung donor is located.<sup>57</sup>

The lung allocation system uses medical information specific to each lung transplant candidate.<sup>58</sup> This information includes lab values, test results, and disease diagnosis.<sup>59</sup> This medical information is used to calculate a lung allocation score from 0 to 100 for each transplant candidate.<sup>60</sup> The lung allocation score represents an estimate of the severity of each candidate's illness and his or her chance of success following a lung transplant.<sup>61</sup> All candidates are placed in order for compatible lung

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<sup>56</sup> *At-a-Glance*, UNITED NETWORK OF ORGAN SHARING POLICY 3.7.6: LUNG ALLOCATION, available at [http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub\\_305.pdf](http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_305.pdf) (last visited Mar. 26, 2015).

Candidates waiting for lung transplants receive priority for deceased donor lung offers based on Lung Allocation Score (LAS) if they are at least 12 years of age. Candidates less than 12 years of age receive deceased donor lung offers based on medical urgency priority. *Id.*

*At-a-Glance*, UNITED NETWORK OF ORGAN SHARING POLICY 3.7.6.1: LUNG ALLOCATION SCORE (LAS) SYSTEM FOR CANDIDATES AT LEAST 12 YEARS OF AGE, available at [http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub\\_305.pdf](http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_305.pdf) (last visited Mar. 26, 2015).

Candidates who are at least 12 years of age receive offers for deceased donor lungs based on LAS, as well as geography and blood type. Candidates with higher LAS's receive higher waiting list priority.

<sup>57</sup> See *Q & A Lung Allocation*, *supra* at 1.

<sup>58</sup> *Report to the Board of Directors*, UNITED NETWORK OF ORGAN SHARING POLICY 3.7.6.1.1: THE LAS CALCULATION, available at [http://optn.transplant.hrsa.gov/converge/CommitteeReports/board\\_main\\_ThoracicOrganTransplantationCommittee\\_11\\_14\\_2012\\_11\\_39.pdf](http://optn.transplant.hrsa.gov/converge/CommitteeReports/board_main_ThoracicOrganTransplantationCommittee_11_14_2012_11_39.pdf) (last visited Mar. 26, 2015).

The LAS calculation uses all of the following:

Waitlist Urgency Measure, which is the expected number of days a candidate will live without a transplant during an additional year on the waiting list.

Post-transplant Survival Measure, which is the expected number of days a candidate will live during the first year post-transplant.

Transplant Benefit Measure, which is the difference between the Post-transplant Survival Measure and the Waitlist Urgency Measure.

The LAS is determined by normalizing the Raw Allocation Score to a continuous scale of 0 to 100. The Raw Allocation Score is the difference between the Transplant Benefit Measure and the Waitlist Urgency Measure. *Id.*

<sup>59</sup> See *Q & A Lung Allocation*, *supra* note 40, at 1.

<sup>60</sup> See *id.*

<sup>61</sup> See *id.*

offers according to their score: a candidate with a higher lung allocation score will receive higher priority for a lung offer when a compatible lung becomes available.<sup>62</sup>

Candidates, ages twelve and over, receive a lung allocation score calculated using thirteen factors. First, the candidate is given a lung function test that measures the maximum amount of air the candidate can breathe out after he or she breathes in as deeply as possible.<sup>63</sup> This is known as forced vital capacity.<sup>64</sup> The pulmonary artery pressure, or the pressure the heart must generate to pump blood through the lungs, is also measured.<sup>65</sup> Doctors also test a candidate's oxygen at rest, which is the amount of oxygen needed at rest to maintain adequate oxygen levels in the blood.<sup>66</sup> The candidate's age and body mass index at the time lungs are offered is also factored into the lung allocation score.<sup>67</sup> When determining a candidate's lung allocation score, doctors also take into consideration whether the candidate has diabetes or requires the use of assisted ventilation.<sup>68</sup>

Next, doctors determine a candidate's functional status which measures the effects that lung disease may have on a person's ability to perform routine daily tasks.<sup>69</sup> This measurement is also calculated depending on how far a candidate can walk in six minutes.<sup>70</sup> A candidate is also given a pulmonary capillary wedge pressure test, and their serum creatinine levels are measured.<sup>71</sup> The candidate's current PCO<sub>2</sub> and change in PCO<sub>2</sub> are both considered in the lung allocation score calculation.<sup>72</sup> This is done by performing a blood gas test to measure the amount of CO<sub>2</sub> in the blood.<sup>73</sup> Finally, the candidate's medical diagnosis is factored into the calculation of the lung allocation score.<sup>74</sup>

#### *D. The "Under 12 Rule"*

Children under the age of twelve, however, are not given lung allocation scores under this new system unless these children receive an approved adolescent

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<sup>62</sup> *See id.*

<sup>63</sup> *See id.* at 2.

<sup>64</sup> *See id.*

<sup>65</sup> *See id.*

<sup>66</sup> *See id.*

<sup>67</sup> *See id.*

<sup>68</sup> *See id.*

<sup>69</sup> *See id.*

<sup>70</sup> *See id.*

<sup>71</sup> *See id.*

<sup>72</sup> *See id.*

<sup>73</sup> *See id.*

<sup>74</sup> *See id.*

classification exception.<sup>75</sup> Instead, these children fall victim to the UNOS priority system.<sup>76</sup> The UNOS priority system is based on a candidate's medical condition.<sup>77</sup> A candidate's medical severity is used to place pediatric lung candidates in order. These candidates are listed as "Priority 1" or "Priority 2".<sup>78</sup> Candidates that meet criteria reflecting a more urgent status are listed as Priority 1, and all remaining lung candidates in this age range are labeled Priority 2.<sup>79</sup>

To meet a Priority 1 status, a candidate must demonstrate either respiratory failure, pulmonary hypertension, or have prior approval through the Lung Review Board, a national group of transplant physicians and surgeons who consider special circumstances.<sup>80</sup> All other candidates that do not meet the criteria for a Priority 1 classification are classified as a Priority 2 candidate.<sup>81</sup> When a potential match is run in the UNOS organ allocation computer system, a candidate's priority status is used in combination with a candidate's blood type and geographic area.<sup>82</sup> These factors determine the order for making offers to pediatric lung candidates.<sup>83</sup> Priority 1 status, however, does not guarantee the donation of any lungs, let alone adult lungs. And because of the shortage of pediatric lungs described below, a Priority 1 pediatric candidate may never receive a life-saving donation in time.

Under Policy 3.7 a pediatric candidate under the age of twelve is technically eligible for donor lungs from three classes of age groups: pediatric donors under twelve, adolescent donors between the ages of twelve to seventeen, and adult donors ages eighteen and older, however you will see how the "Under 12 Rule" makes this virtually impossible.<sup>84</sup> A pediatric candidate under the age of twelve may receive lungs donated from a pediatric donor under the age of twelve based on the UNOS Priority classification system explained above.<sup>85</sup> Although lungs from pediatric donors are offered first to pediatric transplant candidates, the fact still remains that there are just not enough pediatric donor lungs to go around. Because of this fact, a pediatric candidate under the age of twelve may also receive lungs donated from

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<sup>75</sup> See Organ Procurement and Transplantation Network Policies, *Policy 10.1D Candidates at Least 12 Years Old- LAS* (March 31, 2015) available at [http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Policies.pdf](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf).

<sup>76</sup> See United Network for Organ Sharing, *Questions and Answers for Transplant Professionals About Lung Allocation*, available at [https://www.unos.org/docs/Lung\\_Professional.pdf](https://www.unos.org/docs/Lung_Professional.pdf).

<sup>77</sup> See *id.*

<sup>78</sup> See *id.*

<sup>79</sup> See *Q & A Lung Allocation*, *supra* note 40, at 3.

<sup>80</sup> See UNOS Policy 3.7.6.2, *supra* note 76.

<sup>81</sup> See *id.*

<sup>82</sup> See *Q & A Lung Allocation*, *supra* note 40, at 3.

<sup>83</sup> See *id.*

<sup>84</sup> See Organ Procurement and Transplantation Network Policies, *Policy 10.4 Lung Allocation and Classification Ranks* (March 31, 2015) available at [http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Policies.pdf](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf).

<sup>85</sup> See *id.*

adolescent donors between the ages of twelve to seventeen, based on the amount of time on the waiting list and severity, but only after the lungs are declined by all adolescents in the same geographic zone.<sup>86</sup> Thus, the chances of a pediatric transplant candidate receiving a set of adolescent donor lungs is very unlikely as, unlike pediatric candidates, adolescents are given a lung allocation score. In addition, every single adolescent in the same geographic zone has to first decline the donor lungs before the pediatric candidates are given any consideration whatsoever.<sup>87</sup>

Policy 3.7 also contains a rule virtually preventing pediatric candidates under the age of twelve from ever receiving a pair of adult donor lungs. This controversial rule has come to be known as the “Under 12 Rule.”<sup>88</sup> Prior to Judge Baylson’s temporary restraining order, which applied only to Sarah Murnaghan, under this rule, a pediatric candidate under the age of twelve could not qualify for a set of adult donor lungs unless eligible adolescent transplant candidates and adult transplant candidates in the same geographic zone had first turned them down.<sup>89</sup> Because of the shortage of pediatric lungs, pediatric candidates were, and still are, last in line for a pair of adult donor lungs, subject to the bottom of the waitlist. In fact, the OPTN has reported that only one lung transplant in the United States has occurred from a transplant donor older than age eighteen into a transplant candidate younger than twelve since 2007, despite the many pediatric candidates that have died waiting for a donor.<sup>90</sup>

These discriminatory effects of the “Under 12 Rule” resulted in the issuance of Judge Baylson’s temporary restraining order on June 5, 2013. In turn, this order caused the OPTN to call an emergency meeting.<sup>91</sup> The purpose of this emergency meeting was to create a new avenue for pediatric candidates under the age of twelve seeking lung transplants to receive donor lungs.<sup>92</sup> Unfortunately, at the meeting, the rules for lung allocation for children under the age of twelve did not drastically change. The OPTN ultimately voted to allow pediatric candidates under the age of

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<sup>86</sup> *See id.*

<sup>87</sup> *See Q & A Lung Allocation, supra* note 40, at 1.

<sup>88</sup> *See, e.g., Lupkin, supra* note 13.

<sup>89</sup> *See Q & A Lung Allocation, supra* note 40, at 1.

<sup>90</sup> *See* Maggie Fox, *Transplant Experts Agree to Special Consideration for Kids*, NBC NEWS (June 10, 2012), [http://vitals.nbcnews.com/\\_news/2013/06/10/18888114-transplant-experts-agree-to-special-consideration-for-kids?lite](http://vitals.nbcnews.com/_news/2013/06/10/18888114-transplant-experts-agree-to-special-consideration-for-kids?lite) (last visited March 7, 2014) (reporting that the board overseeing organ transplants in the United States voted on Monday, June 10 2013 to allow special consideration for children needing lung transplants after the families of two dying children filed suit).

<sup>91</sup> *See Lupkin, supra* note 13.

<sup>92</sup> *See* Abby Goodnough, *Vote Aids Children Under 12 Seeking Lung Transplant to Have Case Reviewed*, N.Y. TIMES (June 10, 2013), [http://www.nytimes.com/2013/06/11/health/vote-aids-children-under-12-seeking-lung-transplant.html?\\_r=0](http://www.nytimes.com/2013/06/11/health/vote-aids-children-under-12-seeking-lung-transplant.html?_r=0) (discussing the changes made to the pediatric lung allocation policy during an emergency meeting. This meeting was conducted as a response to the widespread attention and the effect that the Sarah Murnaghan and Javier Martinez cases have had on the Organ Procurement and Transplantation Network).

twelve awaiting a lung transplant to have their cases reviewed by a national board of lung transplant surgeons.<sup>93</sup> Based on the severity of their condition, the board may vote to allow such children to get on the adolescent and adult waiting lists for lungs while also keeping their spot on the pediatric list.<sup>94</sup>

Although this may seem like a success to many, pediatric candidates are still denied a lung allocation score, unlike adolescent candidates and adult candidates. In addition, the revision allowing for the review process will expire in September of 2015, leaving the fate of many children in the hands of a medical review board that was forced to implement change by our justice system in the first place.<sup>95</sup> If the national board of lung transplant surgeons chooses not to renew this policy change when it expires in September, the “Under 12 Rule” could revert back to its original state, eliminating the review process and again making it virtually impossible for pediatric candidates under the age of twelve to be eligible for adult lungs. In order to fully appreciate the significance of this troubling possibility, it is important to understand just how difficult it is for a pediatric candidate under the age of twelve to receive a set of donor pediatric lungs.

### III. PEDIATRIC LUNG TRANSPLANTATION DATA

The first successful single lung transplant was reported in 1983.<sup>96</sup> Four years later, the first reported pediatric lung transplantation was performed at the University of Toronto in 1987 on a sixteen-year-old boy with familial pulmonary fibrosis.<sup>97</sup> Ever since, lung transplants have become an accepted therapy for end-stage pulmonary disease in children.<sup>98</sup> However, since 1987, the disparity between the numbers of pediatric lung transplants performed in comparison to the number of adult transplants performed is alarming.

The OPTN's website contains all national data that describe the characteristics of individuals on the candidate waiting list, organ donation and matching, and transplantation.<sup>99</sup> According to the most recent pediatric lung transplantation data report from the Organ Procurement and Transplantation Network, between 1988 and 2013, approximately 1,128 pediatric lung transplants have been performed.<sup>100</sup> This is

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<sup>93</sup> *See id.*

<sup>94</sup> *See id.*

<sup>95</sup> *See id.*

<sup>96</sup> *See UNOS Facts and Figures, supra* note 20, at 4.

<sup>97</sup> *See* Stuart C. Sweet, *Pediatric Lung Transplantation*, 6 *PROC. AM. THORACIC SOC'Y* 122 (2009), available at <http://www.atsjournals.org/doi/full/10.1513/pats.200808-095GO> (Dr. Sweet's article focuses on issues surrounding lung transplantation that are unique to the application of this therapy to infants, children, and adolescents).

<sup>98</sup> *See id.*

<sup>99</sup> *See* US Department of Health and Human Services, *Organ Procurement and Transplantation Network Data*, available at <http://optn.transplant.hrsa.gov/data/>.

<sup>100</sup> *See Data Reports*, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, <http://optn.transplant.hrsa.gov/latestData/rptData.asp> (follow “view data reports” hyperlink; then follow “national data” hyperlink; then select category: transplant; then select organ: lung; follow “build an advanced report” hyperlink; then select age: pediatric/adult; then add every

in stark contrast with the 25,915 adult lung transplants performed between 1998 and 2013.<sup>101</sup> The reason for this difference is simple: there are not enough pediatric lungs to meet the demands of children in need of a lung transplant. According to the OPTN, there were only twenty pediatric lung donors available in 2012.<sup>102</sup> This number was down by three in comparison to the twenty-three pediatric lung donors available in 2011.<sup>103</sup> Because of the variation of blood type, size, and geographic range, a total pool of twenty lungs is likely to result in no lung donations for a child on the lung transplant waiting list. An increase in the amount of pediatric lungs rose to thirty-two pediatric donors in 2013, however, the same fact remains that there are just not enough pediatric donor lungs to go around.<sup>104</sup> In comparison, the adult transplant donor pool had 1,546 adult donors in 2012 and 1,706 adult donors in 2013.<sup>105</sup>

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year through 2013 for pediatrics) (last visited Mar. 7, 2014) (the United Network for Organ Sharing collects and manages all data that pertain to the patient waiting list, organ donation and matching, and transplantation occurring on the Organ Procurement and Transplantation Network, the nation's organ transplant network. This site provides access to national data, which includes the latest data about the status of U.S. organ donation and transplantation on a national level. It provides access to regional data that allows you to view the latest data about the status of United States organ donation and transplantation by the United Network of Organ Sharing region of center. It provides access to state data, which allows you to view the latest data about the status of United States organ donation and transplantation by state of center. It provides access to center data, which includes current and historical information accumulated about individual transplant centers. It also allows you to view the latest data about the status of United States organ donation and transplantation).

<sup>101</sup> See *Data Reports*, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, <http://optn.transplant.hrsa.gov/latestData/rptData.asp> (follow "view data reports" hyperlink"; then select "national data"; then select category: transplant; then select organ: lung; then follow "build an advanced report" hyperlink; then select age: "pediatric/adult"; then add together every year through 2013 for adults) (last visited Mar. 7, 2014).

<sup>102</sup> See *Data Reports*, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, <http://optn.transplant.hrsa.gov/latestData/rptData.asp> (follow "view data reports" hyperlink; then select "national data" hyperlink; then select category: donor; organ: lung; then select "add field to report" and "pediatric/adult"; then add together the number of pediatric lung donors between the ages of 0-10 for 2012) (last visited Mar. 7, 2014).

<sup>103</sup> See *Data Reports*, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, <http://optn.transplant.hrsa.gov/latestData/rptData.asp> (follow "view data reports" hyperlink; then select "national data" hyperlink; then select category: donor, organ: lung; then select "go"; then select "all donors by donor type"; then follow change report to "lung" and under "add field to report" select "age: 9 items"; then select "change report" to "all donors"; then select "go"; .then under "add field to report" select "organ:6 items"; then select "go"; add all categories under 2013 of children from 1-10 in 2012) (last visited Mar. 7, 2014).

<sup>104</sup> See *Data Reports*, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, <http://optn.transplant.hrsa.gov/latestData/rptData.asp> (follow "view data reports link;" then select "national data" hyperlink; then select category: donor, organ: lung; then select "add field to report" and select "pediatric/adult;" then add together the number of pediatric lung donors between the ages of 0-10 for 2013) (last visited Mar. 7, 2014).

<sup>105</sup> See *Data Reports*, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, <http://optn.transplant.hrsa.gov/latestData/rptData.asp> (follow "view data reports" hyperlink; then select "national data" hyperlink; then select category: donor, organ: lung; then select "All

The alarming number of children under the age of twelve who die waiting for a set of lungs is also reported annually. According to the Scientific Registry of Transplant Recipients (“SRTR”), a national database of transplantation statistics based on data from the OPTN, pediatric candidates active on the lung transplantation list die at more than double the rate of adult candidates active on the lung transplant list.<sup>106</sup> In 2011, forty-eight percent of pediatric candidates died while on the lung transplant waiting list.<sup>107</sup> This is in comparison to the thirteen percent of adult candidates who died while on the lung transplant waiting list.<sup>108</sup> This data shows that the 2007-2011 three-year average rates were thirty-three percent for children and only twelve percent for adults.<sup>109</sup> The SRTR’s data also demonstrates a significant increase in the death rate for pediatric candidates since the OPTN implemented the “Under 12 Rule” in 2005.<sup>110</sup>

These numbers demonstrate just how successful adult candidates have been in receiving life-saving lungs in comparison to pediatric candidates. Since 2005, when the “Under 12 Rule” was implemented, adult candidates have experienced an increase in success of receiving life-saving donor lungs.<sup>111</sup> In 2004, there was a twenty-nine percent chance of an adult candidate succeeding in receiving a donor set of adult lungs.<sup>112</sup> After the “Under 12 Rule” was implemented in 2005, this number rose to a significant fifty percent chance of success of receiving life-saving donor

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Donors by Donor Type”; then change report by selecting “lung” and “pediatric/adult”) (last visited Mar. 7, 2014).

<sup>106</sup> *See Reported Deaths and Annual Death Rate Per 1,000 Patients- Years at Risk, 2002 to 2011, Lung Waiting List*, SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS, available at [http://www.srtr.org/annual\\_reports/2011/1203\\_age\\_lu.aspx](http://www.srtr.org/annual_reports/2011/1203_age_lu.aspx) (last visited Mar. 10, 2014). The Scientific Registry of Transplant Recipients is an ever-expanding national database of transplant statistics. *About the SRTR*, SCIENTIFIC REGISTRY FOR TRANSPLANT RECIPIENTS, <http://www.srtr.org/who.aspx> (last visited Feb. 23, 2015). Founded in 1987, the registry exists to support ongoing evaluation of the scientific and clinical status of solid organ transplantation, including kidney, heart, liver, lung, intestine, and pancreas. *Id.* Data in the registry are collected by the Organ Procurement and Transplantation Network from hospitals and organ procurement organizations across the country. *Id.* The SRTR contains current and past information about the full continuum of transplant activity, related to organ donation and wait-list candidates, transplant recipients, and survival statistics. *Id.* This information is used to help develop evidence-based policy, to support analysis of transplant programs and OPOs, and to encourage research on issues of importance to the transplant community). *Id.*

<sup>107</sup> *Compare Waiting List Patient Characteristics at Year-End Lung Waiting List All Waitlist Patients, 2002 to 2011*, *supra* note 106, at [http://www.srtr.org/annual\\_reports/2011/1201c\\_age\\_lu.aspx](http://www.srtr.org/annual_reports/2011/1201c_age_lu.aspx) (stating number of patients on waiting list), with *Data Reports*, *supra* note 101 (Select “Build Advanced Report” then, “Step 1” select “waitlist removal,” “Step 2” select “removal year,” “Step 3” select “removal reason,” and “Choose Organ . . .” select “lung,” then select “Go”)

<sup>108</sup> *See id.*

<sup>109</sup> *See id.*

<sup>110</sup> *See id.*

<sup>111</sup> *See Complaint*, *supra* note 1, at 14.

<sup>112</sup> *See id.*

lungs in 2011.<sup>113</sup> As of 2011, since this rule's implementation, pediatric candidates only have a reported thirty percent chance of success of receiving life-saving donor lungs.<sup>114</sup>

Although these numbers are alarming, there have been countless debates regarding the judicial interference of medical decisions and the organ allocation procedures following Judge Baylson's ruling.<sup>115</sup> Critics state that the courts have no business intervening in complex organ transplant policy and supporters of sick children are saying that the pediatric lung transplantation policies are grossly unfair.<sup>116</sup> Some people want to know why there is so much controversy over a procedure that could potentially save thousands of little lives. Others want to know exactly why the "Under 12 Rule" exists in the first place.

#### IV. PURPOSE OF THE "UNDER 12 RULE"

Dr. Stuart Sweet shed some light on why pediatric candidates were not afforded the same lung allocation policy as adult candidates. Dr. Sweet is the director of the pediatric lung transplant program at Washington University School of Medicine in St. Louis, Missouri who helped to develop the pediatric lung allocation guidelines for the UNOS and the OPTN.<sup>117</sup> According to Dr. Sweet, a prioritization system was not established for pediatric candidates younger than twelve because of a lack of data to allow the use of proper statistical analyses, stating that an "apples-to-apples" comparison of relative illness between the two groups was not possible.<sup>118</sup>

Dr. Sweet argues that officials recently changed the pediatric system to give sicker children higher priorities for transplants and also cast a wider net for suitable candidates, searching beyond existing donor regions to an area 1,000 miles from a donor hospital for a suitable candidate before moving on to adolescent or adult candidates.<sup>119</sup> He disapproves of the District Court's ruling, stating that UNOS cannot make exceptions on a case-by-case basis beyond the exceptions that are built into the existing policy.<sup>120</sup> Thus, because of the diversity in diagnoses and the small numbers of young pediatric patients, accurate models of lung transplant waiting list outcomes could not be developed, leaving pediatric candidates under the age of twelve behind.

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<sup>113</sup> *See id.*

<sup>114</sup> *See id.*

<sup>115</sup> *See Goodnough, supra* note 92.

<sup>116</sup> *See id.*

<sup>117</sup> *See P.A. Parents Say Organ Donation Rules Unfair to Sick 10-year-old, Demand Change*, CBS NEWS (May 28, 2013), <http://www.cbsnews.com/news/pa-parents-say-organ-donation-rules-unfair-to-sick-10-year-old-demand-change/> (reporting that the parents of a ten-year-old Pennsylvania girl are urging officials to change the policy regarding organ transplants to allow the sickest to receive the first available appropriate donation, regardless of age).

<sup>118</sup> *See id.*

<sup>119</sup> *See id.*

<sup>120</sup> *See id.*



But is it enough to potentially discriminate against pediatric candidates simply because there was not enough data available to test whether or not a lung allocation prioritization system would work? There is, perhaps, a more persuasive argument behind the rationale of the UNOS “Under 12 Rule”: the size of the lungs

According to the UNOS and the OPTN, size of the donated lungs and the size of the recipient matters.<sup>121</sup> Size matching between donors and recipients is one of the criteria commonly used for lung allocation.<sup>122</sup> Attempting to match the size of donor lungs to the size of the recipient as closely as possible, transplant teams have employed different measures.<sup>123</sup> In the past, transplant teams have tried to size match donor lungs by measuring the submammary thoracic perimeter, by matching chest x-rays, by anthropometry, and by determining a candidate’s predicted lung size.<sup>124</sup> Presently in the United States, height is used to predict lung size and lung transplant candidates are listed by designated donor height ranges.<sup>125</sup> This size matching was desirable due to the concern that lungs that were too large or too small could lead to potential problems, such as poor lung function and poor outcomes after transplantation.<sup>126</sup>

A study conducted by researchers at Johns Hopkins University School of Medicine may prove otherwise. The study found that over-sized lungs are associated with a thirty-percent increase in the chance of survival after one year of the transplantation<sup>127</sup> Michael Eberlein, M.D., Ph.D., led this breakthrough research.<sup>128</sup> The researchers analyzed data from the UNOS lung transplant registry for all adult

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<sup>121</sup> See *How Organ Allocation Works*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, <http://optn.transplant.hrsa.gov/about/transplantation/matchingProcess.asp> (last visited March 28, 2015). The Organ Procurement and Transplantation Network has provided the public with a useful website that explains how the organ donor matching system works in the United States. *Id.*

<sup>122</sup> See *id.*

<sup>123</sup> See J.P. Ouwens, et al., *Size Matching in Lung Transplantation Using Predicted Total Lung Capacity*, 20 EUR. RESP. J., 1419, 1421-22 (2002), available at <http://www.ersj.org.uk/content/20/6/1419.full.pdf> (last visited Mar. 7, 2014) (arguing that allocation of donor lungs based upon height alone leads to a substantial mismatch in total lung capacity caused by sex mismatch. Concludes that the absence of complications suggests that a greater height donor/recipient discrepancy can be accepted for allocation than previously assumed).

<sup>124</sup> See *id.* at 1419.

<sup>125</sup> See *id.*

<sup>126</sup> See *id.* at 1421.

<sup>127</sup> See *For Lung Transplant, Researchers Surprised to Learn Bigger Appears to be Better*, JOHNS HOPKINS MEDICINE (Aug. 1, 2013), available at [http://www.hopkinsmedicine.org/news/media/releases/for\\_lung\\_transplant\\_researchers\\_surprised\\_to\\_learn\\_bigger\\_appears\\_to\\_be\\_better](http://www.hopkinsmedicine.org/news/media/releases/for_lung_transplant_researchers_surprised_to_learn_bigger_appears_to_be_better) (highlighting the Johns Hopkins-led research which found that larger lungs associated with 30 percent increase in survival at one year); see Rebecca Dezube et al. *The effect of lung-size mismatch on mechanical ventilation tidal volumes after bilateral lung transplantation*, 16 INTERACTIVE CARDIOVASCULAR AND THORACIC SURGERY, 2013, 275-81.

<sup>128</sup> See *id.*

candidates who underwent first-time lung transplantation.<sup>129</sup> Of this pool, 4,520 candidates underwent a double lung transplant and 2,477 candidates underwent a single lung transplant for a total of 6,997 patients included in the study.<sup>130</sup> These transplants were performed between May 2005 and April 2010 in the United States.<sup>131</sup> Eberlein reported that the findings were clearer about the benefits of larger lungs in double lung transplants than in single lung transplants, however, oversized lungs did convey some survival benefit in single lung transplants cases as well.<sup>132</sup>

Rather than using the UNOS size matching criteria, the researchers employed a different approach for size matching the allocation of lungs.<sup>133</sup> Eberlein and his colleagues determined organ size matching using a “predicted total lung capacity” (pTLC) ratio.<sup>134</sup> The pTLC is estimated solely by height and sex. Eberlein found that taller people have larger lungs, and a man’s lungs are larger than the lungs of a woman of the same height.<sup>135</sup> The pTLC-ratio is determined by dividing the donor’s pTLC by the recipient’s pTLC.<sup>136</sup> The researchers defined lung size mismatch as the ratio of the predicted lung capacity of the donor relative to the recipient.<sup>137</sup> A pTLC ratio of 1.0 is a perfect size match.<sup>138</sup> Any number over this ratio indicates that the donor lung is significantly larger than the recipient’s lung.<sup>139</sup>

The patients who underwent a double lung transplant, were found that each 0.1 increase in the pTLC-ratio was associated with a seven percent decrease in the risk of death at 1 year post-transplant.<sup>140</sup> Among the single lung transplant patients, each 0.1 increase in pTLC-ratio was associated with a six-percent decrease in the risk of death at one year post-transplant.<sup>141</sup>

Eberlein’s research suggests that oversized donor lungs may be the best option for patients.<sup>142</sup> However, the study does caution that in some instances lungs can be

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<sup>129</sup> *See id.*

<sup>130</sup> *See id.*

<sup>131</sup> *See id.*

<sup>132</sup> *See id.*

<sup>133</sup> *See id.*

<sup>134</sup> *See id.*

<sup>135</sup> *See id.*

<sup>136</sup> *See Lung Transplant Patients May Fare Better with Larger Organs*, THE SOCIETY OF THORACIC SURGEONS, available at <http://www.sts.org/news/lung-transplant-patients-may-fare-better-larger-organs> (last visited Feb. 23, 2015) [hereinafter Society of Thoracic Surgeons].

<sup>137</sup> *See For Lung Transplant, Researchers Surprised to Learn Bigger Appears to be Better*, *supra* note 127.

<sup>138</sup> *See id.*

<sup>139</sup> *See id.*

<sup>140</sup> *See Society of Thoracic Surgeons*, *supra* note 136.

<sup>141</sup> *See id.*

<sup>142</sup> *See id.*

too large.<sup>143</sup> Eberlien warns that if lungs are beyond a certain size, surgeons could have trouble closing the chest cavity, the lungs could be too compressed and collapse or could weigh too heavily on the heart, causing low blood pressure and other problems.<sup>144</sup> Ashish S. Shah, M.D., surgical director of lung transplantation at The Johns Hopkins University School of Medicine, expresses that despite these potential complications, there is still some benefit to removing age from the equation when allocating lungs, thus putting children and adults into the same pool of donors.<sup>145</sup> Shaw recommends that doctors make decisions based on each individual case and the size of the donor organs that become available.<sup>146</sup> According to Shah, the study shows that rather than looking at age or height alone, physicians should look at “[e]ach patient very carefully and determine what their lung capacity is.”<sup>147</sup> Shaw states that in some instances, oversized adult lungs may be more beneficial for pediatric candidates.<sup>148</sup>

Overall, this research found that double lung transplant recipients who received lungs with an average ratio of 1.3, a 0.3 increase in pTLC, were 30 percent less likely to die in the first year versus double lung transplant recipients who received lungs with a pTLC ratio of 1.0, a perfect size match.<sup>149</sup> Although many may argue that oversized lungs may be problematic, there is no data currently available to substantiate that idea.<sup>150</sup>

Although the OPTN and UNOS have defended the “Under 12 Rule,” stating that its formation was attributed to a lack of data to allow for the use of proper statistical models for pediatric candidates, some families are not satisfied with this reasoning.<sup>151</sup> Despite empirical evidence and recommendations from their physicians, the discriminatory “Under 12 Rule” left two young children to die.<sup>152</sup> The families of the two dying children have come forward, begging our judicial system to intervene.<sup>153</sup>

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<sup>143</sup> See *For Lung Transplant, Researchers Surprised to Learn Bigger Appears to be Better*, *supra* note 127.

<sup>144</sup> See *id.*

<sup>145</sup> See *id.*

<sup>146</sup> See *id.*

<sup>147</sup> See *id.*

<sup>148</sup> See *id.*

<sup>149</sup> See *id.*

<sup>150</sup> See *id.*

<sup>151</sup> See Complaint *supra* note 1, at 3.

<sup>152</sup> See Sydney Lupkin, *Second Child Waiting for Lung Transplant Gets Judge's Reprieve*, ABC NEWS (June 8, 2013), <http://abcnews.go.com/Health/child-waiting-lung-transplant-judges-reprieve/story?id=19350983>.

<sup>153</sup> See *id.*

## V. "UNDER 12 RULE" LITIGATION

Sarah Murnaghan was one of the many children affected by the "Under 12 Rule." Sarah, a ten-year-old girl from Newtown Square, Pennsylvania, was diagnosed with cystic fibrosis at the age of eighteen months.<sup>154</sup> In and out of hospitals since her diagnosis, at the age of ten Sarah's condition grew worse. Her lung capacity diminished to thirty percent of its normal capacity and she was put on a permanent oxygen machine.<sup>155</sup> On December 7, 2011, Sarah was added to the pediatric transplant list and was only eligible for pediatric lungs.<sup>156</sup> This changed in November 2012, when her doctors suggested and was approved to receive adult lungs through the OPTN.<sup>157</sup> Although this life-saving recommendation was made by her physician, the "Under 12 Rule" discussed above made it virtually impossible for Sarah to actually receive the adult donor lungs.

Under the OPTN's lung allocation policy, to receive adolescent lungs, Sarah would have to first wait until all adolescents within her region turned down the donor lungs.<sup>158</sup> In order for Sarah to receive the adult lungs recommended by her physician, Sarah would have to wait until all adolescent candidates and adult candidates within her region turned down the donor lungs. Although Sarah was listed as Priority 1 under the UNOS priority system, there were no pediatric donor matches available. The longer Sarah waited for a new set of lungs, the worse her lung allocation score became.<sup>159</sup> However, pediatric candidates are not prioritized according to lung allocation scores. At the time of suit, Sarah's official lung allocation score was a sixty-six.<sup>160</sup> Had the "Under 12 Rule" not been in effect, this number would have put her in the top six percent of organ donor candidates.<sup>161</sup> Instead, despite Sarah's dangerously high lung allocation score, she was put at the bottom of the waitlist due to the discriminatory effect of the "Under 12 Rule."

Sarah's condition continued to grow worse until she suffered permanent loss of hearing due to the side effects of the antibiotics she was required to take in order to stay alive.<sup>162</sup> In a desperate attempt to keep Sarah alive, Sarah's parents wrote a letter to the UNOS Thoracic Committee twice, begging for the "Under 12 Rule" to be set aside.<sup>163</sup> Both requests were denied although there was medical proof and a recommendation from Sarah's doctors, stating that an adult lung transplant would be successful in Sarah's case.<sup>164</sup>

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<sup>154</sup> See Complaint, *supra* note 1, at 1.

<sup>155</sup> See *id.* at 10.

<sup>156</sup> *Id.*

<sup>157</sup> See *id.*

<sup>158</sup> See *id.* at 7-8.

<sup>159</sup> See *id.* at 11.

<sup>160</sup> See Complaint, *supra* note 1, at 11.

<sup>161</sup> See *id.* at 11.

<sup>162</sup> See *id.*

<sup>163</sup> See *id.* at 12.

<sup>164</sup> See *id.* at 4.

Due to the UNOS Thoracic Committee's denial, on June 3, 2013, Sarah's parents wrote a letter to the Secretary of the United States Department of Health and Human Services, Kathleen Sebelius, requesting that she take immediate action and direct the OPTN to set aside the "Under 12 Rule."<sup>165</sup> Because there was no immediate response from Sebelius, and due to Sarah's limited time, Sarah's parents were forced to take emergency action. On June 5, 2013, Sarah's parents sought the help of our justice system, filing a motion for a temporary restraining order and preliminary injunction in the United States Pennsylvania District Court.<sup>166</sup>

On June 5, 2013, Judge Baylson directed Secretary Sebelius to temporarily suspend the "Under 12 Rule" following an emergency hearing.<sup>167</sup> As a result, Sarah was added to the adult candidate transplant list. Judge Baylson stated that by refusing to set aside the existing rule for children, Sebelius had failed "[t]o protect the very few children nationally who are subject to it."<sup>168</sup> He added that the evidence showed that the rule "[d]iscriminates against children and serves no purpose, is arbitrary, capricious and an abuse of discretion."<sup>169</sup> In order for Sarah to be added to the adult candidate transplant list, medical officials had to "trick" the UNOS computer system into thinking that Sarah was older than twelve.<sup>170</sup> This was accomplished by changing her year of birth in the system, giving Sarah a fake birthday.<sup>171</sup>

Sarah Murnaghan was not the only pediatric candidate discriminated against due to her age, Javier Martinez was also adversely affected by the "Under 12 Rule." Javier Martinez, an eleven-year-old boy from New York, was diagnosed with end stage cystic fibrosis in utero.<sup>172</sup> Sadly, Javier's mother has been in this situation

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<sup>165</sup> See *id.* at 3.

<sup>166</sup> See Complaint, *supra* note 1, at 4.

<sup>167</sup> See *Murnaghan v. United States Dep't of Health & Human Servs.*, No. 13-3083 (D. Pa. June 5, 2013), available at <http://www.paed.uscourts.gov/documents/opinions/13D0477P.pdf> (granting Murnaghan's request for a temporary restraining order, requiring Health and Human Services Secretary to direct the OPTN to place Sarah Murnaghan on the adult transplant waiting list).

<sup>168</sup> See Brett Norman & Jason Millman, *Sarah Murnaghan Lung Transplant Case: Sebelius Ordered to Make an Exception on Transplant*, POLITICOPRO (June 5, 2013), <http://www.politico.com/story/2013/06/sarah-murnaghan-lung-transplant-ruling-kathleen-sebelius-92299.html> (reporting that a federal judge on Wednesday, June 5, 2013 ordered Health and Human Services Secretary, Kathleen Sebelius, to allow ten-year-old Sarah Murnaghan to be moved to the adult lung transplant list, giving her a better chance of receiving a potentially life-saving transplant).

<sup>169</sup> See *id.*

<sup>170</sup> See Lupkin, *supra* note 152 (providing that the transplant network convened an emergency meeting of its executive committee to evaluate the Under 12 Rule, a little-known organ transplant policy that a Pennsylvania couple brought to national attention after arguing that it had been pushing their dying 10-year-old to the bottom of the adult lung transplant waiting list).

<sup>171</sup> See *id.*

<sup>172</sup> See Brief in Support of Emergency Motion for a Temporary Restraining Order & Preliminary Injunction at 4, *Martinez v. United States Department of Health & Human*

before with another one of her sons who fell victim to the “Under 12 Rule.” Javier’s older brother, Jovan, was also diagnosed with cystic fibrosis as an infant.<sup>173</sup> At the young age of eleven years old, Jovan died waiting for a liver and lung transplant that he was never able to receive due to the discriminatory effect of the UNOS “Under 12 Rule.”<sup>174</sup>

In and out of hospitals since his diagnosis, Javier’s condition took a turn for the worse in 2011.<sup>175</sup> In early 2012, Javier was placed on the active lung transplant waiting list where he remained for over a year.<sup>176</sup> At the time of litigation, Javier had been hospitalized continuously for a total of nine weeks.<sup>177</sup> His last seven weeks of hospitalization took place in the same hospital as Sarah Murnaghan, the Children’s Hospital of Philadelphia.<sup>178</sup> At the time Javier’s complaint was filed, his lung allocation score was a thirty-nine.<sup>179</sup> Again, due to the discriminatory effect of the “Under 12 Rule,” Javier was not prioritized according to his lung allocation score.<sup>180</sup> Javier was instead placed at the bottom of the transplant waitlist, essentially left to die.<sup>181</sup> Although Javier’s physician indicated and recommended that lungs donated from an adult would be appropriate for him, the “Under 12 Rule” would have prevented Javier from ever receiving the set of adult donor lungs.

Keeping up-to-date and informed with Sarah Murnaghan’s requests to the UNOS Thoracic Committee and to Secretary Sebelius, Javier’s mother decided to also take action.<sup>182</sup> Desperate not to lose another son to the “Under 12 Rule,” Javier’s mother employed the same attorney working on and representing ten-year-old Sarah Murnaghan, Steven G. Harvey of Pepper Hamilton LLC, located in Philadelphia.<sup>183</sup> On June 6, 2013, a motion was filed for a temporary restraining order and preliminary injunction from the “Under 12 Rule,” also in the Pennsylvania District Court.<sup>184</sup> Again, Judge Baylson directed Secretary Sebelius to temporarily suspend the “Under 12 Rule” for Javier, placing him on the adult candidate transplant list.<sup>185</sup>

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Services, No. 13-3119 (E.D. Pa. June 14, 2013), *available at* <http://www.pepperlaw.com/pdfs/JaviersTROMotion.pdf>.

<sup>173</sup> *See id.* at 4.

<sup>174</sup> *See id.* at 2, 4.

<sup>175</sup> *See id.* at 4.

<sup>176</sup> *See id.*

<sup>177</sup> *Id.*

<sup>178</sup> *Id.* at 2.

<sup>179</sup> *Id.* at 4.

<sup>180</sup> *Id.* at 15.

<sup>181</sup> *Id.*

<sup>182</sup> *See id.* at 2.

<sup>183</sup> *See* Lupkin, *supra* note 152.

<sup>184</sup> *See* Emergency Motion for a Temporary Restraining Order & Preliminary Injunction at 1, 3, *Martinez v. United States Department of Health & Human Services*, No. 13-3119 (E.D. Pa. June 14, 2013), *available at* <http://www.pepperlaw.com/pdfs/JaviersTROMotion.pdf> (moving under Rule 65(b), Fed. R. Civ. P., on an immediate and emergency basis for a

In addition to explaining Sarah's and Javier's situations, Steven Harvey and his legal team also made a series of legal arguments explaining exactly why the "Under 12 Rule" should be abolished.<sup>186</sup> Describing the "Under 12 Rule" as an arbitrary and capricious policy, Harvey argued that the "Under 12 Rule" violated multiple statutes, regulations, and the United States Constitution by discriminating against pediatric candidates with regard to the allocation, of not only lungs, but all vital organs.<sup>187</sup>

Citing the National Organ Transplant Act of 1984 ("NOTA"), codified at 42 U.S.C. § 274, Attorney Harvey explains that the Act requires 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) of NOTA provides 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 . . . .<sup>188</sup>

Harvey argues that Section 274(b)(2) of NOTA has been violated because the OPTN has not adopted criteria, policies, and procedures that address the unique health care needs of children.<sup>189</sup> He argues that the discriminatory effects of the "Under 12 Rule" in and of itself are proof of this.<sup>190</sup>

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temporary restraining order and preliminary injunction to prevent the Secretary of the United States Department of Health and Human Services from applying that aspect of Policy 3.7 of the Organ Procurement and Transplantation Network that discriminates against children under 12 in the system established by law for allocating donated lungs, the "Under 12 Rule").

<sup>185</sup> Brief in Support, *supra* note 172, at 22.

<sup>186</sup> *Id.* at 14-17.

<sup>187</sup> *Id.* at 2-3.

<sup>188</sup> *Id.* at 7 (quoting with emphasis added 42 U.S.C. § 274(b)(2)).

<sup>189</sup> *Id.* at 14-15.

<sup>190</sup> *See id.* at 12, 14.

Harvey explained that the NOTA gives authorization for the Secretary of the United States Health and Human Services to contract with UNOS.<sup>191</sup> As explained in the above history, UNOS in turn operates the OPTN.<sup>192</sup> Pursuant to the Secretary's authority, Harvey argued that the Secretary has promulgated regulations that govern the OPTN.<sup>193</sup> Found at 42 C.F.R. § 121, these regulations provide that the 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."<sup>194</sup> In Harvey's legal analysis, he explains that this regulation has also been violated.<sup>195</sup> He stresses that the "Under 12 Rule" is not a policy that ensures the equitable allocation of all cadaveric organs.<sup>196</sup> He argues that since the 2005 lung allocation policy was revised, children have been treated very differently than adults.<sup>197</sup>

Harvey explains that the regulations promulgated under 42 C.F.R. 21 also govern the content of the policies to be developed by the OPTN.<sup>198</sup> These regulations explain the OPTN's responsibility to assist in the equitable allocation of organs, based on recipients' medical conditions and medical judgment.<sup>199</sup> In his argument, Harvey cites to several sections of the OPTN's regulations and states that UNOS has violated several regulations.<sup>200</sup>

He starts by citing §121.8(a) which provides that the OPTN's board of directors "[s]hall develop, in accordance with the policy development process described in Section 121.4, policies for the equitable allocation of cadaveric organs among potential recipients."<sup>201</sup> It is argued that this regulation has been violated because the policies implemented by the UNOS and the OPTN do not provide for equitable allocation.<sup>202</sup> He argues that the discriminatory effects of the "Under 12 Rule" prove that pediatric candidates do not receive equitable allocation of donor lungs.<sup>203</sup> He cites to Section 121.8(a)(6) which provides that these equitable policies "shall be reviewed periodically and revised as appropriate."<sup>204</sup> He also argues that the UNOS and the OPTN have again violated this regulation, seeing as medical data demonstrates how the "Under 12 Rule" has discriminated against pediatric

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<sup>191</sup> *See id.* at 3, 7-8.

<sup>192</sup> *See id.*

<sup>193</sup> *Id.* at 8.

<sup>194</sup> *Id.* (quoting 42 C.F.R. § 121.4(a)(1)).

<sup>195</sup> *Id.*

<sup>196</sup> *Id.* at 15.

<sup>197</sup> *See id.* at 5.

<sup>198</sup> *Id.* at 8.

<sup>199</sup> *Id.*

<sup>200</sup> *See Id.* at 13-17.

<sup>201</sup> *Id.* at 8.

<sup>202</sup> *Id.* at 14.

<sup>203</sup> *See id.* 13-14.

<sup>204</sup> *Id.* at 14.



candidates; however, no appropriate revisions have been made.<sup>205</sup> Harvey next cites to Section 121.8(b)(2) which states that the allocation policies should be designed to give greatest consideration to allocating organs based on the severity of illness.<sup>206</sup> It is argued that this regulation has been violated because pediatric candidates are not assigned a lung allocation ranking score, and thus the entire pool of donor lungs are not accessible to pediatric candidates regardless of how severe the illness.<sup>207</sup>

Harvey also cites to federal regulations that provide that allocation policies should be based on sound medical judgment.<sup>208</sup> He argues that the UNOS and the OPTN have also violated this regulation, as both Sarah and Javier's physicians recommended, with sound medical judgment, that both pediatric candidates should be placed on the adult donor waiting list.<sup>209</sup> Lastly, Harvey argues that the "Under 12 Rule" also violates NOTA's requirement that OPTN "adopt criteria, policies, and procedures that address the unique health needs of children," found at 42 U.S.C. Section 274(b)(2)(M).<sup>210</sup> Harvey states that the OPTN has failed "to address the health care needs of children and causes children as a group to suffer dramatically worse outcomes than adults."<sup>211</sup>

#### VI. PROPOSED LUNG ALLOCATION LEGISLATION FOR THE OPTN

The "Under 12 Rule" is a discriminatory rule that violates the National Organ Transplant Act of 1984 and the regulations governing the OPTN. Although the UNOS temporarily revised the "Under 12 Rule" by adding a national board of lung transplant surgeons to review special cases, the entire existence of the "Under 12 Rule" is discriminatory in its effect.<sup>212</sup>

##### *A. Why the Lung Allocation Policy Should be Amended*

The National Organ Transplant Act of 1987 assigns several functions to the OPTN.<sup>213</sup> One of these functions requires that the OPTN "assist organ procurement organizations in the nationwide distribution of organs *equitably* among transplant patients".<sup>214</sup> The OPTN has violated this requirement, failing to distribute donor lungs equitably among all transplant patients by creating a different allocation

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<sup>205</sup> *See id.* 15, 18-20.

<sup>206</sup> *Id.* at 8, 15.

<sup>207</sup> *See id.* 19-20.

<sup>208</sup> *Id.* at 8, 15 (referencing Organ Procurement & Transplantation Network 63 Fed. Reg. 16296 (Apr. 2, 1998) (to be codified at 42 C.F.R. § 121)).

<sup>209</sup> *See id.* at 19.

<sup>210</sup> *Id.* at 14-15.

<sup>211</sup> *Id.* at 15.

<sup>212</sup> *See* Lupkin, *supra* note 13.

<sup>213</sup> 42 U.S.C.A § 274(b) (2014).

<sup>214</sup> 42 U.S.C.A § 274(b)(2)(D) (2014).

process applicable only to pediatric candidates under the age of twelve.<sup>215</sup> The OPTN has also violated the requirement directing it to “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”.<sup>216</sup> The “Under 12 Rule” has caused pediatric candidates to suffer dramatically worse outcomes than adults.<sup>217</sup> Despite the overwhelming medical data available to and compiled by the OPTN itself, the OPTN has failed to adopt policies that address the unique health care needs of children.<sup>218</sup> It is a known medical fact that there is an extreme shortage of pediatric donor lungs.<sup>219</sup> Statistics also show that pediatric candidates active on the lung transplantation list die at more than double the rate as adult candidates active on the lung transplant list.<sup>220</sup> Nevertheless, the OPTN continues to employ an arbitrary rule that does not address these unique circumstances, and instead discriminates against all children under the age of twelve.<sup>221</sup>

The “Under 12 Rule” is also in violation of its allocation performance goals set forth in the Code of Federal Regulations.<sup>222</sup> Under these allocation performance goals, the OPTN is required to give greatest consideration in allocating organs to those with the greatest medical urgency in accordance with sound medical judgment.<sup>223</sup> The “Under 12 Rule” prevents the OPTN from fulfilling this requirement.<sup>224</sup> Every day that the “Under 12 Rule” remains enacted, pediatric candidates with more pressing needs are standing in line behind transplant candidates with less pressing needs as measured by their lung allocation scores.<sup>225</sup> In addition, the “Under 12 Rule” leaves no room for sound medical judgment.<sup>226</sup> As demonstrated in the cases explained above, despite the sound medical judgment

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<sup>215</sup> See Organ Procurement and Transplantation Network Policies, *Policy 10.1D Candidates at Least 12 Years Old- LAS* (March 31, 2015) available at [http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Policies.pdf](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf).

<sup>216</sup> See 42 U.S.C.A § 274(b)(2)(M) (2014).

<sup>217</sup> Brief in Support, *supra* note 172, at 18.

<sup>218</sup> *Data Reports*, *supra* note 100.

<sup>219</sup> See Sweet, *supra* note 97.

<sup>220</sup> See *id.*

<sup>221</sup> See Organ Procurement and Transplantation Network Policies, *Policy 10.1D Candidates at Least 12 Years Old- LAS* (March 31, 2015) available at [http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Policies.pdf](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf).

<sup>222</sup> See Organ Procurement & Transplantation Network, 42 C.F.R. § 121.8(b) (Mar. 19, 2015).

<sup>223</sup> See Organ Procurement & Transplantation Network, 42 C.F.R. § 121.8(b)(2) (Mar. 19, 2015).

<sup>224</sup> See Complaint *supra* note 1; Brief in Support, *supra* note 172.

<sup>225</sup> See, e.g. Complaint *supra* note 1

<sup>226</sup> Brief in Support, *supra* note 172, at 19.

given by both Sarah and Javier's physicians, both pediatric candidates were denied access to the adult transplant waiting list prior to litigation.<sup>227</sup>

Because the "Under 12 Rule" violates the National Organ Transplant Act of 1984 and the regulations governing the OPTN, it should be abolished in its entirety. Revising the allocation policy to include a national board of lung transplant surgeons to review special cases is simply not sufficient.<sup>228</sup> Not only does this revision expire in July 2014, potentially threatening the lives of pediatric candidates all over the United States, but the board may still elect to deny pediatric candidates access to adult donor lungs for the same reasons they employed the "Under 12 Rule" in the first place: a lack of data with regard to pediatric candidates and a concern regarding over-sized lungs.<sup>229</sup>

Eberlein's Johns Hopkins study relieves these concerns.<sup>230</sup> There is no data currently available to substantiate the hypothesis that lungs that are too large or too small could lead to potential problems and poor outcomes after a transplant.<sup>231</sup> This study shows that instead of looking at age alone or height alone when determining whether a patient can sustain larger lungs, physicians should carefully look at each patient's case and unique circumstances.<sup>232</sup>

#### *B. Model Lung Allocation Statute*

The OPTN should completely abolish the "Under 12 Rule" and create a uniform policy that distributes organs equitably among all transplant patients regardless of age. By enacting a uniform policy, the disparity between pediatric candidates and adult candidates would no longer exist.<sup>233</sup> Instead of the OPTN's current allocation policy, the OPTN should adopt an allocation policy similar to the following model:

**Lung Allocation:** All candidates, regardless of age, waiting for lung transplants receive priority for deceased donor lung offers based on Lung Allocation Score (LAS), as well as geography and blood type. Candidates with higher LASs receive higher waiting list priority.

**Lung Allocation Score (LAS) System for Candidates Under Twelve Years of Age:** Due to the unique needs of pediatric candidates, children who are under twelve years of age receive offers for deceased donor lungs based on LAS, as well as geography, blood type, and total lung capacity (pTLC). Candidates with higher LASs receive higher waiting list priority.<sup>234</sup>

This proposed regulation would be effective for several reasons. First, pediatric candidates under the age of twelve would now be assigned a lung allocation

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<sup>227</sup> See Complaint *supra* note 1, at 1; Brief in Support, *supra* note 172, at 1.

<sup>228</sup> See Lupkin, *supra* note 13.

<sup>229</sup> See *id.*

<sup>230</sup> See *For Lung Transplant, Researchers Surprised to Learn Bigger Appears to be Better*, *supra* note 127.

<sup>231</sup> See *id.*

<sup>232</sup> See *id.*

<sup>233</sup> See *id.*

<sup>234</sup> See *id.*

score instead of falling victim to the OPTN Priority System, a system that has proven ineffective. By allowing pediatric candidates under the age of twelve to receive a lung allocation score, pediatric candidates with more pressing needs will no longer be behind transplant candidates with less pressing needs. The OPTN will in turn fulfill its requirement to distribute donor lungs equitably among all transplant patients, as mandated under the National Organ Transplant Act of 1984.<sup>235</sup>

In order to address the possibility of over-sized adult donor lungs, this proposed regulation would add an additional, however, non-discriminatory requirement for all pediatric candidates under the age of twelve. These pediatric candidates would receive offers for deceased donor lungs based on lung allocation score, geography, blood type, and the added requirement of total lung capacity. As explained earlier, size-matching in the United States is accomplished by age and height alone.<sup>236</sup> Dr. Eberlein's study demonstrates a more effective way of determining whether or not a set of donor lungs would be appropriately sized for a transplant candidate.<sup>237</sup> Rather than discriminating against children under the age of twelve, the allocation of lungs should take into consideration a pediatric candidate's total lung capacity, to be determined by the candidate's physician.

## VII. CONCLUSION

Despite the regulations mandated to the OPTN by the National Organ Transplant Act of 1984 and the Code of Federal Regulations, the OPTN continues to employ a policy that fails to distribute organs equitably among all transplant patients, regardless of age.<sup>238</sup>

The OPTN has no basis for the employment of this policy. To justify its actions, the OPTN has stated that there just was not enough data to include pediatric candidates in its lung allocation algorithm.<sup>239</sup> In addition, the OPTN has relied on the notion that lungs that are too large or too small could lead to potential problems and poor outcomes after transplantation, an opinion that has yet to be substantiated by medical data.<sup>240</sup>

Several studies have emerged since Judge Baylson's decision on June 5, 2013.<sup>241</sup> These studies demonstrate bigger lungs are, in fact, better.<sup>242</sup> Sarah Murnaghan and Javier Martinez are both living proof that the "Under 12 Rule" has a discriminatory effect that almost cost them their lives.<sup>243</sup> Sarah Murnaghan and Javier Martinez

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<sup>235</sup> See 42 U.S.C.A § 274 (2014).

<sup>236</sup> See *For Lung Transplant, Researchers Surprised to Learn Bigger Appears to be Better*, *supra* note 127.

<sup>237</sup> *Id.*

<sup>238</sup> 42 U.S.C.A § 274 (2014); Brief in Support, *supra* note 172

<sup>239</sup> See Brief in Support, *supra* note 172.

<sup>240</sup> See *How Organ Allocation Works*, *supra* note 118.

<sup>241</sup> See *For Lung Transplant, Researchers Surprised to Learn Bigger Appears to be Better*, *supra* note 127.

<sup>242</sup> *Id.*

<sup>243</sup> See Complaint *supra* note 1, at 1; Brief in Support, *supra* note 172, at 1.

were given days to live. Had it not been for Judge Baylson's issuance of a temporary restraining order, Sarah and Javier would have died. Two families would have had to bury their child, despite sound medical judgment and recommendations by their physicians, stating that both Sarah and Javier were viable candidates for pediatric transplantation of adult lungs. This is simply unacceptable.

The amendment to the "Under 12 Rule" allowing for a national board of lung transplant surgeons to review special cases will be expiring in just a few short months, potentially threatening the lives of pediatric candidates all over the United States.<sup>244</sup> This is a serious threat that simply cannot be ignored. Action to abolish this arbitrary rule must be taken immediately, before our courts are flooded with litigation from parents seeking to keep their dying children alive. To prevent this from happening, UNOS should enact a non-discriminatory regulation providing for true equitable distribution of organs to all transplant candidates, regardless of age. Affording pediatric candidates under the age of twelve the same shot at a life-saving organ as adult candidates will prove to be the best solution for the many problems that will ensue as long as the "Under 12 Rule" remains effective.

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<sup>244</sup> See Lupkin, *supra* note 13.