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# ASSESSING PATIENT COMPLIANCE IN THE SELECTION OF ORGAN TRANSPLANT RECIPIENTS

*Ingrid Kinkopf-Zajac\**

## I. INTRODUCTION

**THERE IS A SUBSTANTIAL AMOUNT** of literature addressing many of the issues related to the scarcity of organs for transplantation. A great deal of this material focuses on increasing the supply of organs through various means, which include increasing public education about organ donation, proposals for changing the laws regulating organ donation, and the role of potential donors, family members, and health care providers in the organ donation process.

An equally substantial amount of literature focuses on dealing with the reality of too few organs and the criteria by which they are rationed. As Table 1 below illustrates, there is a significant number of people waiting for organs.<sup>1</sup> Table 2 shows that the rate at which their needs are met is insufficient.<sup>2</sup>

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1. UNITED NETWORK FOR ORGAN SHARING (UNOS), THE NAT'L ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, FACTS ABOUT TRANSPLANTATION IN THE UNITED STATES (1995), listing the number of people waiting for organs as of March 2, 1995. "UNOS policies allow patients to be listed with more than one transplant center (multiple listing), and thus registrations may be greater than the actual number of patients." *Id.*

2. *Id.* These data are based upon the UNOS Scientific Registry as of February 18, 1995 and are "subject to change due to future data submission or correction." Organs for 2550 of these kidney transplants were provided by living related donors.

**Table 1 - UNOS National Patient Waiting List Registrations**

Kidney	27,897
Liver	4,281
Pancreas	238
Pancreas Islet Cell	15
Kidney-Pancreas	1,116
Intestine	73
Heart	3,044
Heart-Lung	207
Lung	1,678
<b>Total</b>	<b>38,549</b>

**Table 2 - Number of Transplants Performed, January-November 1994**

Kidney	9,539
Liver	3,327
Pancreas	93
Kidney-Pancreas	677
Heart	2,151
Heart-Lung	65
Lung	657
<b>Total</b>	<b>16,509</b>

The current system for the selection of organ recipients has suffered from a great deal of criticism, particularly in light of the scarcity of organs. This Note will review the current process by which candidates for organ transplantation are selected as well as identify problems existing within that process.<sup>3</sup>

The body of this Note, however, is devoted to recommendations for significant changes in the current process. This includes the consideration of additional criteria by which trans-

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3. The scope of this Note is limited to the discussion of solid organ transplantation (*i.e.*, pancreas, liver, heart, kidneys, and lungs). It does not address issues related to other transplantable human body parts such as bone, cartilage, bone marrow, and corneas because the transplantation process of such parts varies significantly from that of solid organs.

plant candidates could be selected, in addition to addressing some of the existing problems with the current system. Specifically, this proposal involves establishing uniform guidelines for assessing patients' ability or willingness to comply with post-transplant treatment in the selection of would-be organ recipients. Such a change employs the use of psychosocial factors in assessing patient compliance, and as a result, is very controversial because of the necessary value judgments that often accompany their use. Although there are commentators who advocate the use of psychosocial factors in the allocation of organs, they have not made specific recommendations for their use. The intent of this Note, therefore, is to take the next step, that is, to make specific recommendations for changes to the current system and include the assessment of patient compliance in the selection of organ transplant recipients. It is recommended that this assessment be implemented in all transplant programs; however, because of the implications of this proposal and the unavailability of alternative treatment for some patients, the exclusion of potential recipients should be limited to re-transplant patients and potential kidney recipients only.

The use of psychosocial factors in evaluating potential organ recipients is very unpopular and the arguments against it are difficult to overcome. Therefore, the advantages and disadvantages of such a proposal will be discussed at length. Although the arguments against such a proposal are compelling, it is believed that this proposal represents a legitimate and manageable way of dealing with the scarcity of organs available for transplantation — a reality that has the potential to touch anyone.<sup>4</sup>

## II. THE ROLE OF PATIENT COMPLIANCE IN THE CURRENT PROCESS FOR SELECTING ORGAN TRANSPLANT RECIPIENTS AND UNDERSTANDING PATIENT COMPLIANCE

Before discussing the current system for selecting organ

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4. As of this writing, the author's father had just received his first cadaveric kidney transplant after being on the waiting list for nearly two years. His kidney failure was caused by complications of diabetes mellitus.

transplant recipients and making recommendations for change, it is necessary to define the term "compliance," to understand why compliance is so important for organ recipients, and to identify some factors that may affect patient compliance. For the purposes of this Note, compliance is defined as the willingness or ability to adhere to a prescribed treatment regimen.<sup>5</sup>

Upon receiving a donor organ, a patient takes on a great deal of responsibility to ensure the success of the transplant as well as his or her own well-being. Because the donor organ, no matter how close the match, is foreign to the recipient's body, the patient must take medications to suppress the body's immune system and prevent it from rejecting the organ. This drug therapy continues for the duration of the patient's life.<sup>6</sup> Although this may sound relatively simple, there are several drawbacks to the use of these medications that may affect a patient's compliance in taking them. First, many of these drugs produce undesirable side effects that vary in severity and occurrence from patient to patient.<sup>7</sup> For example, with kidney transplant patients, a typical regimen may include prednisone, cyclosporine, and azathioprine.<sup>8</sup> Side effects caused by the use of prednisone, for example, may include such changes in the patient's physical appearance as "round cheeks, fat deposits on the abdomen and upper back, increased growth of facial and body hair, and acne."<sup>9</sup> More seriously, these drugs produce a generalized immunosuppression in the patient's body rendering him or her susceptible to infection.<sup>10</sup> This requires that the patient take special care to avoid infection and necessitates com-

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5. This definition is purposely broad to address as many of the arguments both for and against such a recommendation.

6. Deborah Mathieu, *Organ Substitution Technology: Identifying and Framing the Key Issues*, in ORGAN SUBSTITUTION TECHNOLOGY: ETHICAL, LEGAL, AND PUBLIC POLICY ISSUES 3,5 (Deborah Mathieu ed., 1988) (discussing the costs and benefits of organ transplantation).

7. See *id.* (listing such serious side effects as "tremors, seizures, kidney and/or liver failure, hypertension, lymphomas, diabetes, vision disorders, and anemia").

8. UNIVERSITY HOSPITALS OF CLEVELAND, KIDNEY TRANSPLANT RECIPIENT INFORMATION 3-5 (n.d.) [hereinafter RECIPIENT INFORMATION] (on file with author) (discussing post-transplant treatment with prednisone, azathioprine, and cyclosporine and the possible side effects to be expected from these medications); See also Nancy L. Ascher, *The Pros and Cons of Cyclosporine*, in ORGAN SUBSTITUTION TECHNOLOGY, *supra* note 6, app. B at 306-07 (presenting empirical evidence of the pros and cons of using cyclosporine as medicine therapy for organ recipients).

9. RECIPIENT INFORMATION, *supra* note 8, at 4.

10. Ascher, *supra* note 8, at 306.

munication with the physician concerning even the slightest infection, both to cover treatment and to rule out possible early rejection.<sup>11</sup> These medications also have been shown to increase the patient's susceptibility to cancers of the lymph system and to have toxic effects on the kidney.<sup>12</sup> The unpleasantness of some of these side effects, particularly those affecting physical appearance, are cited by some patients as reasons for their noncompliance.<sup>13</sup>

Secondly, these drugs are very expensive. The total cost for a medical regimen including the three medications discussed above was estimated at over \$10,000 per year in 1993.<sup>14</sup> For transplant recipients, this financial obligation alone produces real concerns because Medicare coverage of these medications is currently limited to a maximum of the first three years post-transplant.<sup>15</sup> In fact, in a study of transplant patient compliance, the cost of medications was cited by a few patients as the reason for their noncompliance.<sup>16</sup>

Finally, careful monitoring of patients post-transplant is also essential, particularly in the months immediately after surgery. This requires frequent visits to the transplant center for follow-up examinations and blood tests, sometimes as often as twice a week for the first three months after transplant.<sup>17</sup> This follow-up is both to identify possible signs of rejection (which, if it occurs, is most likely to happen within the first year) and

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11. See RECIPIENT INFORMATION, *supra* note 8, at 3 (discussing the increased susceptibility to infection caused by prednisone and azathioprine and the importance of quickly diagnosing a rejection).

12. Ascher, *supra* note 8, at 306-07.

13. See A.E. Bittar et al., *Patient Noncompliance as a Cause of Late Kidney Graft Failure*, 24 TRANSPLANTATION PROC. 2720, 2721 (1992) (discussing findings of a clinical study of the influence of noncompliance on late kidney graft failure); Robert T. Schweizer et al., *Noncompliance in Organ Transplant Recipients*, 49 TRANSPLANTATION 374, 376 (1990) (describing the incidence and reasons for medication noncompliance by transplant recipients).

14. Interview with Marilyn Bartucci, Head Nurse Manager, Transplant Center, University Hospitals of Cleveland, in Cleveland, Ohio (Aug. 27, 1993).

15. 60 Fed. Reg. 8951 (1995). This is a recent change in the Medicare Program, which previously covered immunosuppressant medications for only one year post-transplant.

16. Schweizer et al., *supra* note 13, at 376.

17. RECIPIENT INFORMATION, *supra* note 8, at 5. This is an example of the protocol of one transplant center, whose routine may vary from that of other centers. In general, however, the patient's attendance at outpatient office and laboratory appointments is one way of measuring patient compliance. See Mary Rovelli et al., *Noncompliance in Organ Transplant Recipients*, 21 TRANSPLANTATION PROC. 833, 833 (1989) (discussing empirical study to examine patient noncompliance in organ recipients).

to monitor the patient's response to drug therapy and adjust dosages if necessary.<sup>18</sup>

Most, if not all, commentators agree that the importance of patient compliance with the post-transplant treatment regimen cannot be overemphasized. [T]he medical reality [is] that successful transplantation depends on patient compliance and painstaking follow-up . . . . [M]any good and scarce organs have been lost in patients who failed or forgot to take their immunosuppressive medications, who failed to come to follow-up visits, or who abused drugs or alcohol, with mortal sequelae.<sup>19</sup>

Identifying patients at risk for noncompliance with treatment post-transplant is not an easy task. Whereas compliance can be fairly accurately assessed for re-transplant patients, most patients are first-time organ recipients whose predicted compliance is much more difficult to assess.

In a study of noncompliance in organ transplant recipients, the researchers examined two types of noncompliance — the “failure to comply with the follow-up regimen . . . [and the] failure to take medications as directed.”<sup>20</sup> The researchers found that noncompliance with the follow-up regimen, such as the failure to attend outpatient office visits or laboratory appointments, was easy to determine; however, medication noncompliance was found to be more difficult to confirm.<sup>21</sup> The researchers were able to ascertain several instances of medication noncompliance from patients who readily admitted their noncompliance, relatives providing confirmation of noncompliance, and unexplained decreases or increases in levels of the drug cyclosporine.<sup>22</sup> Such unexplained decreases in cyclosporine can signal the possibility that the patient may be failing to take the medication, whereas unexplained increases

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18. See RECIPIENT INFORMATION, *supra* note 8, at 3-5 (explaining post-transplant treatment).

19. W.C. Waltzer et al., *Equity in Organ Distribution: A Plea for a Return to Reality*, 21 TRANSPLANTATION PROC. 3388, 3389 (1989). See also *Developments in the Law: Medical Technology and the Law*, 103 HARV. L. REV. 1519, 1633 n.128 (1990) (stating that patients' failure to comply with post-operative treatment results in unsuccessful transplantations (quoting NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, TRANSPLANTATION IN NEW YORK STATE: THE PROCUREMENT AND DISTRIBUTION OF ORGANS AND TISSUES 110-11 (1988))).

20. Rovelli et al., *supra* note 17, at 833.

21. *Id.*

22. *Id.*

might demonstrate that the patient may be trying to hide non-compliance by taking high doses immediately prior to clinic visits.<sup>23</sup> For some patients, noncompliance could only be strongly suspected, but not confirmed, because of frequent rejection episodes easily controlled with the administration of immunosuppressants.<sup>24</sup>

Assessment of the risk of noncompliance with a primary (first-time) recipient is more difficult. This requires both an examination of pre-transplant behaviors and predictions about whether the patient will continue to exhibit those behaviors after the transplant. There is a broad range of patients whose post-transplant compliance may be questionable. Such patients include, but are not limited to, the following: those whose financial circumstances impact their ability to comply with treatment, those whose intellectual capacity affects their ability to understand the transplant process and the importance of post-operative treatment, those who engage in behaviors that may affect their judgment or willingness to comply with treatment, and those who merely lack an understanding of their illness and the ramifications of noncompliance.

### III. THE CURRENT PROCESS FOR SELECTING ORGAN TRANSPLANT RECIPIENTS

The process for selecting potential organ recipients has undergone a number of changes in the last fifteen years. In the mid 1980s, a great deal of public concern and outrage about the inequitable distribution of organs led Congress to take action.<sup>25</sup> The public was reacting specifically to the apparent preferential treatment by transplant centers that was being given to the wealthy, including several foreign nationals, when selecting organ transplant recipients.<sup>26</sup> In response, Congress

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23. *Id.*

24. *Id.*

25. Kathleen W. Possai, *A Structural Analysis of the Market for Human Organs* 43-44 (Jan. 1992) (unpublished Ph.D dissertation, Temple University) (describing the history of transplantation regulation).

26. *Id.* See also Esther L. Benenson, *UNOS: Evolution of the Organ Procurement and Transplantation Network*, 20 DIALYSIS AND TRANSPLANTATION 495, 495 (1991) (discussing the organ shortage problem and the subsequent development of the Organ Procurement and Transplantation Network).



enacted the National Organ Transplant Act in 1984 which, among other things, called for the establishment of a task force on organ transplantation by the Secretary of Health and Human Services.<sup>27</sup> The Task Force's primary purpose "was to conduct comprehensive examinations of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation . . . ."<sup>28</sup> Pursuant to the National Organ Transplant Act, the Task Force investigated and ultimately recommended the creation of a National Organ Procurement and Transplantation Network (OPTN).<sup>29</sup> In 1986, the federal government awarded the contract to administer the OPTN to the United Network for Organ Sharing (UNOS), a private, non-profit organization.<sup>30</sup>

The primary responsibilities of UNOS include overseeing all aspects of "organ procurement and transplantation throughout the United States while administering a national organ allocation system based on scientific and medical factors and practices."<sup>31</sup> In conjunction with this role, UNOS has developed policies designed to ensure equitable organ allocation to those registered on the national patient waiting list.<sup>32</sup> To ensure compliance with UNOS policies, Congress made Medicare and Medicaid reimbursement to transplant centers contingent upon OPTN membership and adherence to the rules set forth by UNOS.<sup>33</sup>

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27. National Organ Transplant Act, Pub. L. No. 98-507, § 101(a) (1984), *reprinted in* ORGAN SUBSTITUTION TECHNOLOGY, *supra* note 6, app. D at 309.

28. Task Force on Organ Transplantation, *Organ Transplantation — Issues and Recommendations* (1986), *reprinted in* ORGAN SUBSTITUTION TECHNOLOGY, *supra* note 6, app. A at 297 [hereinafter Task Force].

29. *Id.* at 301.

30. *Developments in the Law*, *supra* note 19, at 1630 n.109. These contracts were renewed for consecutive three-year periods in October, 1990 and 1993. United Network for Organ Sharing (UNOS), General Information on the United Network for Organ Sharing and Its Policies and Programs, United Network for Organ Sharing Fact Sheet (Jan. 1994) (on file with author) [hereinafter UNOS General Information].

31. UNOS General Information, *supra* note 30.

32. *Id.*

33. Several questions have been raised about Congress' ability to delegate power to a private firm and the subsequent authority of UNOS. This topic, however, is not within the scope of this Note. For a discussion of these issues, see Articles of Incorporation of the United Network for Organ Sharing (Nov. 3, 1994) (on file with author and available from UNOS upon request) and James F. Blumstein, *Government's Role in Organ Transplantation Policy*, in *ORGAN TRANSPLANTATION POLICY: ISSUES AND PROSPECTS* 5 (James F. Blumstein et al. eds., 1989) (discussing the federal government's involvement in organ transplantation policy and the

The actual criteria for selecting organ recipients set forth by UNOS is, however, the last part of a three-stage process for selecting potential organ recipients.<sup>34</sup> The first stage involves the referral of a patient with end-stage organ failure to a transplant center. Specifically, it focuses on the question of whether or not a referral actually takes place. Arthur L. Caplan, a prominent figure in the field of biomedical ethics and author of several books and articles on organ procurement and transplantation, emphasizes this stage of the process.<sup>35</sup> Caplan feels that patient referral to a transplant center is not necessarily determined by whether a patient is in need of an organ transplant.<sup>36</sup> Instead, he maintains that referrals occur as a result of multiple factors including "public opinion, the availability of doctors capable of diagnosing end-stage organ failure, political considerations, individual self-perceptions of health, and general beliefs within the medical community about the utility of various kinds of transplants."<sup>37</sup>

Caplan focuses in particular on the private physician's referral of his or her patient to a transplant center. First, Caplan points out that because few patients go directly to a transplant center on their own, a number of patients are unlikely to be referred simply because they have no insurance and, therefore, no private physician to make that referral.<sup>38</sup> Second, Caplan discusses that even those patients with private physicians may not be referred.<sup>39</sup> He attributes this to the following reasons: 1) physicians with no direct connection to, or expertise in transplantation may not be up to date on the latest break-

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relationship between the federal government and UNOS).

34. This process has been described by different commentators as having either two or four stages. See Dan W. Brock, *Ethical Issues in Recipient Selection for Organ Transplantation*, in *ORGAN SUBSTITUTION TECHNOLOGY*, *supra* note 6, at 87 (describing a two-stage process that includes formation of a waiting list and recipient selection from that list when an organ becomes available); ARTHUR L. CAPLAN, IF I WERE A RICH MAN, COULD I BUY A PANCREAS? 164-70 (1992) (describing a four-stage process for the selection of organ recipients: eligibility, admissibility, distribution, and selection). The author of this Note has adopted three stages to aid in focusing on specific issues within the process as well as on the concerns expressed by these other commentators.

35. CAPLAN, *supra* note 34, at 164-67.

36. *Id.* at 164.

37. *Id.*

38. *Id.* at 166-67.

39. *Id.* at 167.

throughs in the field; 2) physicians may be allowing their own views about the uncertainty of a patient's quality of life post-transplant to interfere with the making of referrals; 3) physicians who have a financial interest in one form of therapy, such as dialysis, may not have as great an interest in suggesting alternatives; 4) physicians who are aware of the financial difficulties of their patients may not even raise transplantation as an option because of the expense of the procedure and need for lifelong immunosuppressant therapy; and 5) patients' personality characteristics, such as shyness, fearfulness, noncompliance, or abusiveness, may result in less than enthusiastic referrals, or no referral at all.<sup>40</sup>

Caplan is not alone in his views about this problem. Barbara Levine, a social worker at a local transplant center, revealed her concerns about private physicians acting as gatekeepers for transplant programs.<sup>41</sup> Ms. Levine instead believes that all patients with end-stage organ disease should be referred to a transplant center where experts in the field can evaluate the patients' suitability for a transplant and properly educate them about all of their options.<sup>42</sup> Although it is likely that patient compliance is a factor at this point, it is extremely difficult to identify definitively the role patient compliance actually plays at this initial stage because of: the number and variety of physicians involved in this stage of the process, the fact that many of these patients are never referred for a transplant, and even if the possibility of transplantation is discussed, the reasons why the physician did not make the referral are not disclosed to the patient.

The second stage in the process of selecting potential organ recipients involves what happens after referral to a transplant center.<sup>43</sup> Before beginning this discussion, it should be

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40. *Id.*

41. Interview with Barbara Levine, Social Worker, Transplant Service, University Hospitals of Cleveland, in Cleveland, Ohio (Feb. 13, 1995) [hereinafter Levine Interview].

42. *Id.* Cf. Martin Benjamin et al., *What Transplantation Can Teach Us About Health Care Reform*, 330 NEW ENG. J. MED. 858, 860 (1994) (stating that the role of gatekeeper is difficult but not intolerable as loyalty to the patient can be balanced with responsible allocation of organs).

43. This stage corresponds to the first stage described by Brock, *supra* note 34, at 87-97 (describing criteria to be used in evaluating and selecting organ recipients), and the second stage described by Caplan, *in* CAPLAN, *supra* note 34, at 168 (labeling the second stage as admissibility and describing the factors which may influence it).

pointed out that "[e]ach local transplant team formulates and applies its own criteria for waiting-list placement and patient selection."<sup>44</sup> For this reason, the criteria used generally "vary from center to center, and a candidate rejected at one center may be accepted at another."<sup>45</sup>

Kidney transplantation candidates "undergo an evaluation process in order to identify medical, social, and psychological factors that may affect successful outcome."<sup>46</sup> A survey of all U.S. transplant centers performing kidney transplants falling under UNOS supervision in 1991 was conducted by the Patient Care and Education Committee of the American Society of Transplant Physicians (ASTP).<sup>47</sup> The authors concluded that: 1) there are many situations in which clinical practices differ; and 2) it is likely that each center's selection criteria evolves from that center's prior experience.<sup>48</sup> For example, such differences in clinical practices include the make-up of the evaluation committees,<sup>49</sup> the diagnostic testing performed on patients to determine suitability,<sup>50</sup> patient age limits,<sup>51</sup> and the medical contraindications to transplantation.<sup>52</sup>

These centers were also questioned about some of the factors considered in assessing patient compliance. The results again showed a difference among those responding. For example, eighty-three percent of the centers responding consider the patient's attendance at dialysis in this assessment, but other

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44. *Developments in the Law*, *supra* note 19, at 1630-31.

45. *Id.* at 1631, n.110.

46. Eleanor L. Ramos et al., *The Evaluation of Candidates for Renal Transplantation: The Current Practice of U.S. Transplant Centers*, 57 *TRANSPLANTATION* 490, 490 (1994).

47. *Id.*

48. *Id.* at 493.

49. *Id.* at 491. The list of health care professionals reported by respondent transplant centers as being members of their evaluation committees includes: transplant coordinators, nephrologists, social workers, transplant surgeons, nurses, tissue-typing personnel, urologists, nutritionists, immunologists, psychologists, psychiatrists, and dentists. *Id.*

50. *Id.* at 491-92. For example, cardiac and gastrointestinal testing of patients varies from aggressive testing of all patients, to testing of patients over a certain age, to those patients with significant histories, to symptomatic patients, to no specific policies for testing at all. *Id.*

51. *Id.* at 491. Sixty-six percent of respondent centers report no specific age limits for renal recipients while the remaining 34% have age limits ranging from 48-80 years. *Id.*

52. *Id.* at 495 (discussing several contraindications). For example, over 90% of respondent centers exclude HIV-positive patients because of the fear "that increased immunosuppression may accelerate the conversion to AIDS." *Id.* However, significant differences between centers exist in the exclusion of patients on the basis of underlying cardiac disease and various types of hepatitis. *Id.*

factors that may help to determine patient compliance are inconsistently assessed.<sup>53</sup> The study revealed that centers also vary in their treatment of patients with a history of drug abuse, with some centers requiring a specific period of abstinence prior to transplantation, some requiring both abstinence and a negative drug screen, some excluding patients with a drug history altogether, and some centers having no specific policy at all.<sup>54</sup> Perhaps the most uniform management of patients involves those with a history of psychosis. According to the survey, eighty percent of the responding centers require a psychiatric evaluation in patients with a history a psychosis, whereas only six percent reported no specific policy for this factor.<sup>55</sup> Unfortunately, the survey did not address the weight which centers give to noncompliant behavior (or factors affecting a patient's ability to comply) when assessing a patient's suitability for a transplant.

The lack of uniformity between all transplant centers pointed out by this study is, however, consistent with the findings of other commentators. Another survey examining the psychosocial evaluation of organ transplant recipients was conducted by members of the Medical College of Virginia.<sup>56</sup> In contrast to the ASTP Study discussed above, respondents in this survey identified the weight given to each factor by stating whether the factor would be: 1) an absolute contraindication to transplant; 2) a relative contraindication to transplant; or 3) irrelevant in the consideration of a patient for transplant.<sup>57</sup>

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53. *Id.* at 493. For example, a substantially lower number of centers considered patients signing off dialysis prior to completing the treatment (48%), blood chemistry and cyclosporine levels possibly indicating dietary or medication noncompliance (41% and 50% respectively), and the patient's blood pressure control which also may indicate dietary or medication noncompliance (40%). *Id.*

54. *Id.*

55. *Id.*

56. James L. Levenson & Mary E. Olbrisch, *Psychosocial Evaluation of Organ Transplant Candidates: A Comparative Study of Process, Criteria, and Outcomes in Heart, Liver, and Kidney Transplantation*, 34 *PSYCHOSOMATICS* 314, 314 (1993). In contrast to the ASTP Study which only examined criteria for renal transplants, the Virginia Study includes data about heart, liver, and kidney transplant programs. *Id.* The heart transplant programs surveyed were all U.S. members of the International Society for Heart Transplantation, while the liver and kidney programs were under the supervision of UNOS. *Id.* at 315.

57. Levenson & Olbrisch, *supra* note 56, at 315. Those items which were left blank also were counted in the irrelevant category. *Id.* Contraindication is defined as "a condition or circumstance that indicates a form of treatment . . . is inappropriate in a specific case." THE NEW

Although ideally the amount of weight given to each factor would be more clearly defined, the terms absolute, relative, and irrelevant at least provide some insight into the degree of importance which the transplant centers assign to these factors. Table 3 below summarizes many of the results of the Virginia Study.<sup>58</sup>

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WEBSTER'S MEDICAL DICTIONARY 48 (Donald O. Bolander ed., 1992).

58. Levinson & Olbrisch, *supra* note 56, at 317-19. The results presented in this table can be found within Tables 3-5 of the Levinson & Olbrisch article. *Id.* This single table has been created using those results in an effort to focus on the areas consistent with the purposes and scope of this Note. The values in this table represent percentages of *responding* centers only. *See id.* at 315. In other words, the values for renal transplant programs in this table represent a percentage of only the 71% of renal transplant programs responding to the survey. *Id.* Likewise, as both the cardiac and liver transplant programs had 64% response rates, the cardiac and liver values in this table represent a percentage of only those responding programs. *Id.*

Table 3 -- Psychosocial Contraindications to Transplant

	Cardiac	Liver	Renal		Cardiac	Liver	Renal
<b>No support person</b>				<b>Excessive caffeine use</b>			
Absolute	9.0	6.5	2.6	Absolute	0.0	0.0	0.0
Relative	66.7	67.4	33.5	Relative	29.5	21.7	9.1
Irrelevant	24.4	26.1	63.9	Irrelevant	70.5	78.3	90.9
<b>Current felony prisoner</b>				<b>Current cig. smoking</b>			
Absolute	46.2	39.1	20.6	Absolute	43.6	2.2	1.3
Relative	29.5	30.4	37.4	Relative	47.4	34.8	21.4
Irrelevant	24.4	30.4	41.9	Irrelevant	9.0	63.0	77.3
<b>Hx sig. criminal behavior</b>				<b>Cig. smoking in 6 months</b>			
Absolute	29.5	17.4	5.2	Absolute	2.6	0.0	0.0
Relative	47.4	45.7	52.9	Relative	48.7	28.3	14.9
Irrelevant	23.1	37.0	41.9	Irrelevant	48.7	71.7	85.1
<b>Mental retardation IQ&lt;70</b>				<b>Current heavy alcohol use</b>			
Absolute	25.6	10.9	2.6	Absolute	80.8	80.4	41.6
Relative	59.0	69.6	51.3	Relative	17.9	13.0	42.9
Irrelevant	15.4	19.6	46.1	Irrelevant	1.3	6.5	15.6
<b>Severe retardation IQ&lt;50</b>				<b>Alcohol abuse in 6 months</b>			
Absolute	74.4	45.7	24.0	Absolute	21.8	23.9	14.9
Relative	19.2	41.3	51.9	Relative	69.2	58.7	47.4
Irrelevant	6.4	13.0	24.0	Irrelevant	9.0	17.4	37.7
<b>Significant obesity</b>				<b>Current addictive drug use</b>			
Absolute	25.6	2.2	13.0	Absolute	92.3	84.8	69.5
Relative	59.0	60.9	56.5	Relative	7.7	8.7	24.0
Irrelevant	15.4	37.0	30.5	Irrelevant	0.0	6.5	6.5
<b>Dietary noncompliance</b>				<b>Addictive drug use in 6 months</b>			
Absolute	11.5	8.7	5.2	Absolute	35.9	32.6	17.5
Relative	71.8	56.5	53.2	Relative	56.4	54.3	60.4
Irrelevant	16.7	34.8	41.6	Irrelevant	7.7	13.0	22.1
<b>Medication noncompliance</b>				<b>Denial of illness severity</b>			
Absolute	51.3	32.6	35.7	Absolute	34.6	34.8	18.8
Relative	47.4	60.9	51.9	Relative	55.1	47.8	53.9
Irrelevant	1.3	6.5	12.3	Irrelevant	10.3	17.4	27.3
<b>AMA hosp. discharge Hx.</b>				<b>Transplant not understood</b>			
Absolute	26.9	8.7	5.8	Absolute	21.8	15.2	16.9
Relative	61.5	73.9	58.4	Relative	60.3	71.7	48.7
Irrelevant	11.5	17.4	35.7	Irrelevant	17.9	13.0	34.4

Although these results are significant for a number of reasons, at least three observations immediately stand out: 1) there is an incredible lack of uniformity in the evaluation and weight given to psychosocial criteria; 2) there are organ-specific differences in the evaluation process, with that for cardiac transplants being the strictest and that for kidney transplants being the most lenient; and 3) the evaluation of patient compliance, particularly with medications, is an important consideration in determining a patient's suitability for receiving a transplant.<sup>59</sup>

The authors of the Virginia Study do not attempt to explain these differences, nor do they call for absolute uniformity in the selection process. They do, however, advocate a national or international consensus conference to prioritize the consideration of criteria and to help establish guidelines for transplant centers in the recipient selection process.<sup>60</sup> These authors also attempt to explain the differences observed based upon which organ is transplanted:

It has been noted that criteria within individual transplant programs tend to become more lenient over time. Since kidney transplant programs have existed much longer, this may, in part, explain their greater leniency. Clinicians may also feel less pressured to make an optimal choice of transplant recipient because it does not seem that "squandering" a kidney results in another patient's death.<sup>61</sup>

While this may explain the leniency of kidney transplant programs, it does not explain the differences between liver and heart programs, with heart transplant programs being stricter than liver programs. Since liver transplantation was developed after heart transplantation,<sup>62</sup> the leniency-over-time theory does not apply. Instead, Levenson and Olbrisch suggest that, because a large percentage of the liver patients evaluated have alcohol or substance abuse problems, more leniency is required because of the nature of the population of potential liver trans-

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59. *Id.* at 320.

60. *Id.* at 322.

61. *Id.* at 320. Patients suffering from end-stage renal disease have the alternative of dialysis while patients with end-stage heart or liver disease have no alternative. See *Developments in the Law*, *supra* note 19, at 1632.

62. Levenson & Olbrisch, *supra* note 56, at 320.



plant recipients.<sup>63</sup> In fact, patients with alcohol-related end-stage liver disease represent over fifty percent of the patients with end-stage liver disease.<sup>64</sup>

These studies also demonstrate that patient compliance clearly has a role at this stage of the selection of organ transplant recipients, but because it is not considered equally by all transplant centers (if considered at all), it is, once again, difficult precisely to define the role of patient compliance in this stage of the process. As Table 3 above demonstrates, patient noncompliance, particularly with medications, does weigh very heavily in determining a candidate's suitability for an organ transplant.<sup>65</sup> The most obvious point these studies make, however, is that, like the first stage of selecting potential organ recipients, the second stage lacks uniformity and arguably may be viewed as unfair.

The third and final stage of the overall selection process involves the selection of patients from the waiting list when the organ becomes available.<sup>66</sup> Although, theoretically, this stage of the process is governed by UNOS and its criteria for the distribution of organs, some commentators, notably Arthur L. Caplan, believe that this is not the case.<sup>67</sup>

The selection of organ recipients generally is determined by a point system developed by UNOS which considers both medical and non-medical criteria. Because of the perishable nature of some organs, distance plays a role in the distribution of hearts, livers, pancreas, lungs, and organ combinations.<sup>68</sup>

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63. *Id.*

64. Alvin H. Moss & Mark Siegler, *Should Alcoholics Compete Equally for Liver Transplantation?*, 265 JAMA 1295, 1295 (1991).

65. See *supra* Table 3. Dietary non-compliance was considered an absolute contraindication to transplantation by 11.5% of cardiac transplant programs, 8.7% of liver transplant programs, and 5.2% of renal transplant programs. *Id.* It was considered a relative contraindication by 71.8% of cardiac programs, 56.5% of liver programs, and 53.2% of renal programs. *Id.* Medication non-compliance was weighed even more heavily by the responding centers, with 51.3% of cardiac programs, 32.6% of liver programs, and 35.7% of renal programs reporting it an absolute contraindication. Medication non-compliance was considered a relative contraindication by 47.4% of cardiac programs, 60.9% of liver programs, and 51.9% of renal programs. *Id.*

66. This corresponds to Caplan's fourth stage, labeled as selection, in CAPLAN, *supra* note 34, at 170, and to the second stage described by Brock, *supra* note 34, at 87.

67. CAPLAN, *supra* note 34, at 169 (stating that "[i]ndividual transplant centers, despite the existence of UNOS, frequently claim rights over organs they procure").

68. See Possai, *supra* note 25, at 57-58 (describing the organ allocation point system used

For these organs a specific number of points generally are allowed for blood-type matching, length of time on the waiting list, degree of medical urgency, and patient proximity to the transplant center.<sup>69</sup>

For kidney transplants, the process is somewhat different. Because kidneys can last for approximately forty-eight to seventy-two hours after harvest,<sup>70</sup> and kidney recipients are usually not in a life-threatening situation, extra time is available for more extensive testing of the donor kidney to find the best match possible.<sup>71</sup> The distribution of cadaveric kidneys weighs very heavily on antigen matching. Antigens are specific proteins that "are present on every cell of the [h]uman body, and help the body determine what is . . . 'foreign.'"<sup>72</sup> If the body recognizes something as foreign, an immune response is triggered and antibodies are released to attack the foreign matter.<sup>73</sup> The UNOS system for distribution of cadaveric kidneys gives priority to zero antigen mismatches,<sup>74</sup> which are, theoretically, the least likely to result in rejection. If there is a patient with a zero antigen mismatch and comparable blood type, he or she will be offered the kidney regardless of other factors such as length of time on the waiting list and geographic allocation.<sup>75</sup> If no zero antigen mismatch exists, the quality of antigen matches, length of time on the waiting list, and geographic allocation are awarded points as defined by UNOS and/or the individual transplant center.<sup>76</sup> The patient with the

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by UNOS). See also UNITED NETWORK FOR ORGAN SHARING, FACTS EVERYONE SHOULD KNOW ABOUT ORGAN DONATION AND TRANSPLANTATION (n.d.) [hereinafter UNOS FACTS] (stating the preservation times as follows: four to six hours for hearts, lungs, and heart-lung; 12-24 hours for livers; and 48-72 hours for kidneys).

69. Possai, *supra* note 25, at 57-58; United Network for Organ Sharing, Policies §§ 3.6-3.8 (Nov. 3, 1994) (on file with author and available from UNOS upon request). There are additional factors which may be considered depending upon the organ being transplanted. See generally *id.* §§ 3.5-3.9. For example, the comparison of donor and recipient size is an important consideration in liver distribution. *Id.* § 3.6.1.

70. UNOS FACTS, *supra* note 68.

71. Ian Ayres et al., *Unequal Access to Kidney Transplantation*, 46 VAND. L. REV. 805, 815 (1993) (stating that "[c]urrent UNOS policies explicitly mandate allocation of cadaveric kidneys to potential recipients with antigens similar to those of the donor").

72. Possai, *supra* note 25, at 55.

73. *Id.*

74. United Network for Organ Sharing, Policies, § 3.5.2 (Nov. 3, 1993).

75. *Id.* § 3.5.2.3. See also Ayres et al., *supra* note 71, at 818-19 (describing that, within the UNOS point system for selecting kidney transplant recipients, the greatest weight is placed on the number of antigens matched).

76. United Network for Organ Sharing, Policies, §§ 3.5.3-3.5.6 (Nov. 3, 1993). Patients

highest numerical score is offered the kidney.<sup>77</sup> Although these criteria for organ distribution were initially well-received, advances in the area of immunosuppressant drugs and the inequitable results of this method have resulted in an increasing amount of criticism about them.<sup>78</sup>

Discussion of the current system of recipient selection raises questions about how these scarce organs are distributed and how to improve this process. Ideally, the solution is to increase the supply of organs to avoid making difficult allocation decisions; however, recent efforts geared toward increasing the supply have been unsuccessful and a number of other proposals thus far have been rejected.<sup>79</sup> The failure of these ef-

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may be listed on the local lists of multiple transplant centers and on the UNOS waiting lists multiple times. *Id.* § 3.2.2. In general, kidneys are allocated first locally, then regionally, then nationally. *Id.* § 3.5.3.

77. *Id.* § 3.5.6. For pediatric patients, extra points for kidney allocation based upon the child's age are awarded at the time the patient is initially listed. *Id.* at § 3.5.6.5. These points are retained until the patient turns 18 years of age. *Id.*

78. This criticism generally is related to the racial inequality that results from the current system of organ distribution. For more information on this topic, see Ayres et al., *supra* note 71 (exploring the disparate racial impact of mandated antigen matching and whether this effect is justified given recent technological advances); James F. Childress, *Artificial and Transplanted Organs*, in *BIOLAW: A LEGAL AND ETHICAL REPORTER ON MEDICINE, HEALTH CARE, AND BIOENGINEERING* § 13-6 (James F. Childress et al. eds., 1986) (discussing generally various proposed criteria for the selection of recipients of organ transplants).

79. For further information about organ procurement and the current efforts and proposals geared toward increasing the supply of donor organs, the following references are recommended: United Network for Organ Sharing, Policies, § 2.0 (Nov. 3, 1993) (describing the minimum procurement standards for an organ procurement organization); Linda C. Fentiman, *Organ Donations: The Failure of Altruism*, *ISSUES SCI. & TECH.*, Fall 1994, at 43 (urging an organ donation system based on presumed consent, compensated donation, and community preference); Benjamin et al., *supra* note 42, at 858-59; A.H. Barnett & David L. Kaserman, *The Shortage of Organs for Transplantation: Exploring the Alternatives*, 9 *ISSUES L. & MED.* 117 (1993) (evaluating six currently proposed alternative organ procurement systems); James F. Blumstein, *The Use of Financial Incentives in Medical Care: The Case of Commerce in Transplantable Organs*, 3 *HEALTH MATRIX* 1 (1993) (discussing the advantages of using forward contracts for transplantable cadaveric organs); CAPLAN, *supra* note 34, at 145-70 (discussing the ethics of organ procurement); Teri Randall, *Too Few Human Organs for Transplantation, Too Many in Need . . . and the Gap Widens*, 265 *JAMA* 1223 (1991) (discussing the shrinking supply and increasing demand for organs); Teri Randall & Charles Marwick, *Physicians' Attitudes and Approaches Are Pivotal in Procuring Organs for Transplantation*, 265 *JAMA* 1227 (1991) (discussing ways to increase organ donation); *Developments in the Law*, *supra* note 19, at 1617-30 (discussing attempts to obtain an adequate supply of donor organs); Chad D. Naylor, Note, *The Role of the Family in Cadaveric Organ Procurement*, 65 *IND. L.J.* 167 (1989) (evaluating the role of the family in cadaveric organ procurement and whether this role should be eliminated or recognized in an effort to obtain more organs); Arthur L. Caplan, *Beg, Borrow, or Steal: The Ethics of Solid Organ Procurement*, in *ORGAN SUBSTITUTION TECHNOLOGY*, *supra* note 6, at 59 (discussing the ethical and policy issues facing procurement of scarce organs). See also Thomas D. Overcast, *Legal Aspects of Death and Informed Consent in Organ Transplantation*, in *HUMAN*

forts necessitates dealing with the reality: there are too few organs and too many patients in need. Although dealing with this reality requires making difficult decisions, these decisions often cannot be avoided.<sup>80</sup>

#### IV. A PROPOSAL FOR CHANGING THE CURRENT SYSTEM OF SELECTING ORGAN TRANSPLANT RECIPIENTS

##### A. Defining the Proposal

Before proposing a change in the current system of distributing these scarce organs, one first must look at the goals to be achieved by transplantation. Generally, the ability of a patient to benefit from a transplant and the likelihood of a successful outcome are the goals of transplantation.<sup>81</sup> With these goals in mind, it is recommended that transplant centers uniformly consider a patient's willingness or ability to comply with treatment post-transplant in the selection of organ recipients. This change would be in addition to, and not in lieu of, the medical criteria currently employed in selecting organ recipients.<sup>82</sup> Because of the difficulties in assessing patient compliance discussed above, it is recommended that all patients be assessed for their ability to comply with the treatment, but that

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ORGAN TRANSPLANTATION: SOCIETAL, MEDICAL-LEGAL, REGULATORY, AND REIMBURSEMENT ISSUES 55 (Dale H. Cowan et al. eds., 1987) (discussing various legal issues involved in the retrieval and transplantation of hearts).

80. The author does not recommend forgoing efforts to increase the supply of organs but instead advocates continuing efforts geared toward organ procurement while addressing the immediate problem of scarcity.

81. See J.A. Robertson, *Patient Selection for Organ Transplantation: Age, Incarceration, Family Support, and Other Social Factors*, 21 TRANSPLANTATION PROC. 3397, 3398 (1989) (discussing a wide consensus that medical utility in use of the organ by individual patients represents a minimum threshold); Task Force, *supra* note 28, at 303 (discussing the Task Force's recommendations on what goals must be emphasized when proposing a change in the current system of organ recipient selection).

82. The author acknowledges the controversy surrounding the current medical criteria used for the selection of organ recipients, and the lack of uniformity in their use. See generally Ayres et al., *supra* note 71 (discussing the disparate racial impact of mandated antigen matching and whether this effect is justified given recent technological advances); Ramos et al., *supra* note 46 (presenting the criteria used by various transplant centers to evaluate candidates for renal transplantation). However, it is impossible to address all of these issues in this Note. For the purposes of this Note, therefore, the current medical criteria are accepted as a given, and the assumption is made that these criteria are uniformly applied even though, in reality, this is not the case.

potential exclusion of a patient based on this factor be limited to re-transplant patients and potential kidney recipients only.<sup>83</sup>

Under this proposal, the assessment of re-transplant patients would be carried out in the same manner as noncompliance was assessed for transplant recipients in the Compliance Study, discussed previously.<sup>84</sup> Such an assessment involves an examination of the patient's previous compliance with the follow-up regimen for the prior transplants and a determination of his or her compliance with medications.<sup>85</sup> If the patient's organ rejection, either solely or in part, is a result of noncompliance, he or she would proceed to the second step, which will be described later.

Assessment of the behaviors or circumstances of primary kidney recipients that may affect their post-operative compliance would involve a two-step process. The first step would be to identify patients whose ability or willingness to comply with post-operative treatment is questionable. This conclusion should not be speculative. Rather, it should be based upon evidence obtained during an evaluation process. This evaluation would involve examining each patient's medical history for evidence of recurrent noncompliance in the past.<sup>86</sup> Such evidence could include attendance at dialysis, adherence to a drug regimen, compliance with any dietary restrictions, attendance at appointments, or a history of hospital discharges against medical advice.<sup>87</sup> This evaluation also should include an assessment of the patient's support system, if any, and its role in the

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83. As re-transplant patients have been through the process once, it is easier to determine their potential for noncompliance by examining their behavior and medical records from the prior transplant. However, medication noncompliance sometimes must be based on the weight of the evidence as opposed to its actual confirmation. See Rovelli et al., *supra* note 17, at 833 (discussing the use of confirmation by family members and unexplained increases and decreases in cyclosporine as factors in determining noncompliance). Kidney transplant patients also are good candidates for such a proposal because they have the alternative of dialysis treatment available to them. See *Developments in the Law*, *supra* note 19, at 1632.

84. Rovelli et al., *supra* note 17, at 833.

85. *Id.*

86. Levine Interview, *supra* note 41. Ms. Levine emphasized that isolated instances of noncompliance are not uncommon, particularly with chronically ill patients, and that noncompliance is, to a certain degree, a part of human nature. *Id.* Therefore, for the purposes of this proposal, only repeated instances or patterns of noncompliance should be considered.

87. See Rovelli et al., *supra* note 17, at 833 (discussing the use of adherence to diet, medication, and dialysis schedules and attendance at appointments in assessing and predicting noncompliance-in-treatment patients).

patient's post-transplant life.<sup>88</sup> A support system may include family, friends, agencies, or associations. An analysis of the patient's financial status, including health insurance and its coverage provisions,<sup>89</sup> sources of income, job history and stability, is also recommended.<sup>90</sup> Evaluation of the patient's history further should include determining the existence of any prior or current history of mental health disorders or diminished intellectual capacity, prior or current history of substance abuse,<sup>91</sup> and the ability of the patient, or responsible party, to articulate a basic understanding of the illness and the treatment involved.<sup>92</sup> Because potential organ recipients are in some

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88. Schweizer, *supra* note 13, at 376 (suggesting recommendations for facilitating treatment adherence). An example of this process was discussed during a recent interview. A mentally retarded patient was being evaluated for a possible kidney transplant. The patient was married to a woman who was also mentally retarded. Neither of them was able fully to comprehend the procedure or the post-operative care involved with the transplant. Because there was no other family involved, the transplant center consulted with several agencies working with the patient, none of which would accept responsibility for the patient's care post-operatively. As a result, the patient was ultimately denied placement on the transplant waiting list. Levine Interview, *supra* note 41.

89. A brief discussion of Medicare coverage for end-stage renal patients may be helpful in understanding the financial considerations of potential transplant patients. Patients with a diagnosis of permanent kidney failure or end-stage renal disease (ESRD) become eligible for Medicare under the End-Stage Renal Disease Medicare program established by Congress in 1972. Medicare Part A covers any medically necessary inpatient hospital care. HEALTH CARE FIN. ADMIN., U.S. DEP'T OF HEALTH AND HUMAN SERVS., MEDICARE: COVERAGE OF KIDNEY DIALYSIS AND KIDNEY TRANSPLANT SERVICES 1 (1992) [hereinafter MEDICARE COVERAGE]. For patients with ESRD, however, most of the services and supplies are provided by the elective Part B coverage, which covers outpatient maintenance dialysis. *Id.* at 2. For patients undergoing a transplant, Part A covers the inpatient services related to the actual surgery as well as the hospital services provided in preparation for the transplant, such as the Kidney Registry fee, laboratory services, and other diagnostic testing. *Id.* at 6. Part B covers the surgeon's services for performing the transplant and immunosuppressive medications for up to three years following discharge from the hospital. *Id.* at 7; 60 Fed. Reg. 8951 (1995). For patients entitled to Medicare only because of ESRD, Part A coverage ends 12 months after dialysis is no longer required or 36 months after a kidney transplant. MEDICARE COVERAGE, *supra*, at 2. Part B coverage, which is elective and requires the payment of a premium, may be discontinued by the patient at any time, but is discontinued automatically when Part A coverage terminates under the conditions already discussed. *Id.* Should the need for dialysis recur, as with the failure of the transplant, Medicare coverage is immediately reinstated. *Id.*

90. See Schweizer, *supra* note 13, at 376 (discussing findings of noncompliance in patients of lower socioeconomic status). This will help to identify patients whose financial circumstances may affect their ability to comply with post-transplant treatment, such as those in a middle income bracket who may lack insurance coverage for medications. *Id.* This information also may help to identify potential conflicts patients may have that relate to the need for time off work. *Id.*

91. See Rovelli et al., *supra* note 17, at 833 (stating that the results of the Compliance Study revealed that two definite reasons for noncompliance in organ transplant recipients were mental disease and alcoholism).

92. Interview with Roberta A. Stokes, Clinical Nurse Specialist, Cleveland Clinic Foundation, in Cleveland, Ohio (Feb. 15, 1995) [hereinafter Stokes Interview]. Throughout the

stage of organ failure at the time they are being evaluated, it is likely that most, if not all, of this information would be available to evaluators with the patient's consent.

After primary kidney recipients with potential compliance problems have been identified, the second step would involve discovering the reasons underlying the problems identified. For example, a patient who repeatedly fails to take medication because he or she cannot afford it would have different needs than a patient who repeatedly forgets to take medication because he or she is under the influence of illegal drugs or alcohol. Although both of these hypothetical patients would be considered at risk for noncompliance, once these underlying reasons have been ascertained, those conducting the evaluations can better assess what the patient's specific needs are and how to remedy any existing problems so that the risk is no longer an issue.

### B. Implementing the Proposal

The end result of implementing these changes would be the same three-stage process discussed above, but with significant modifications. Under this proposal, the first stage of the process would continue to involve the patient's private physician. However, these physicians would be required to refer all patients in need of an organ to a transplant center. The private physicians would no longer be serving as gatekeepers, thereby eliminating the danger of legitimate candidates being kept from the resources and treatment they need. Instead, the private physician would explain the reason for the referral and what the referral entails. Documentation of the information given to the patient should be fully detailed in the patient's medical record. The physician also should document if the patient refuses to consent to a referral or otherwise does not follow up with it.

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interview, Ms. Stokes emphasized that patient education is of primary importance for potential organ recipients. *Id.* She recommended that such education be provided at a level which the patient can understand and further be reinforced periodically throughout the pre-operative period. Ms. Stokes pointed out that, because the waiting period for organs can be lengthy, patients often forget what they were told during the initial evaluation, which is the time when most pre-operative education takes place.

These changes would necessitate educating private physicians caring for these patients about the need to refer all patients in end-stage organ failure to a transplant center at the appropriate time,<sup>93</sup> as well as the latest information about transplant center procedures and transplant surgery itself so they can fully inform their patients when making the referral.

Enforcing such a change may be difficult. For primary kidney recipients, ensuring that patients are appropriately referred may be accomplished easily because they are routinely seen at dialysis centers where other health care practitioners could serve as a check. For patients with extrarenal (other than kidney) organ failure, enforcement may not be as easy. One option is to hold these physicians legally liable for failing to make the referral;<sup>94</sup> but realistically, those patients not referred, or their family members, may not have the knowledge or resources to pursue a malpractice claim. Another option would be to subject physicians not making referrals to disciplinary action. Because medical judgment would not be a defense in this case, this may serve as a reasonable incentive for physicians to comply with the referral requirement. However, this again may not be completely effective because complaints about the physician would have to be made before an investigation occurred and the particular patient involved may not know he or she has a legitimate complaint.

It is arguable that the best way to enforce these changes is to educate patients about their rights. Although difficult, this may be accomplished by enhancing public information about organ transplantation. For example, public education could be improved by encouraging, or requiring, health care facilities to expand on their disclosure of patient rights, encouraging professional associations to publicize information about the re-

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93. The timing of referrals for patients with end-stage organ failure is dependent in part upon the organ involved. See Levenson and Olbrisch, *supra* note 56, at 320. For example, cardiac transplantation is considered when the patient has no other options for survival; liver transplantation usually is considered prior to the terminal stage of the disease; and kidney patients are generally considered eligible when they begin dialysis. *Id.*

94. Currently, physicians may be held liable for failing to advise a patient of all treatment alternatives; however, the success of such a suit may be questionable as the physician's medical judgment may not be viewed as unreasonable. There is no guarantee that the patient will definitely receive the organ even if referred, and "many physicians still consider transplantation to be outside of the realm of standard practice." Overcast, *supra* note 79, at 63-64.



sponsibilities of its members, having third-party payers provide educational information to their members, and reinforcing the need overall for members of all health professions to participate in increasing patient education.

This proposal further involves two major changes that would take place during the second stage of the process, which occur after referral to the transplant center. The first change would be the establishment of uniform guidelines for assessing a patient's ability to comply with treatment. To both achieve uniformity and provide an incentive for transplant centers to comply, it is recommended that these guidelines be incorporated into UNOS regulations for OPTN members. The second change involves putting these guidelines to use.

Initially, as a part of these guidelines, the entire evaluation process should be explained to the patient and consent should be obtained whenever applicable. This explanation should include a review of medical records and a discussion with other practitioners caring for the patient.<sup>95</sup> The patient should be encouraged at this point to share what he or she may consider any potential problems that may need to be addressed. Every patient referred to the transplant center would also undergo a mental health evaluation by a mental health professional to determine his or her general mental health, intellectual capacity, and ability to understand both the illness and the commitment required of a transplant recipient. For patients with a history of a mental health disorder or other current mental health problems, this is particularly important because mental illness has been definitively identified as a reason for patient noncompliance.<sup>96</sup> Other members of the transplant team then would review each patient's medical record, communicate with other health care practitioners involved with the patient, and interview the patient and members of his or her support system, if any, to address any other pertinent considerations. The purpose of this evaluation is to determine if compliance with treatment has been a problem for the patient in the

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95. The patient should be informed that a review of his or her past medical history is a necessary part of the evaluation process and that refusal to consent to such a review would remove the patient from consideration for a transplant.

96. Rovelli et al., *supra* note 17, at 833.

past or if there are factors in the patient's life that might affect his or her ability to comply with post-transplant treatment. Ideally, many of these problems can and should be identified by the patient's private physician, and efforts to deal with them already should be underway. Realistically, however, that may not be the case.

After completing the initial evaluation, the transplant team should get together to discuss the collective findings. The team then must decide, assuming the patient otherwise qualifies, whether compliance has been or may be a problem for the patient if a transplant is performed. The presumption is that no problems with compliance exist, and the transplant team has the burden of proving that the patient would be a compliance risk if given a transplant. If the team determines that no potential problems with compliance exist, no further assessment would be necessary. If, however, a history of noncompliance or other factors affecting the patient's ability to comply were identified clearly, then a second, independent evaluation of the patient's problem areas should immediately be arranged. For example, if the patient's mental health evaluation resulted in questions about the patient's compliance, another mental health professional should be consulted for a second opinion.<sup>97</sup>

At this point, the patient should be fully informed of the transplant team's findings, concerns, and any need for additional follow-up. The patient also should be informed of the process by which this decision can be appealed. The patient may either independently seek out evaluation at another transplant center or formally appeal the decision to UNOS, who would then arrange for evaluation at another transplant center at no cost to the patient.<sup>98</sup> If the patient is found to be a suit-

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97. In the Virginia Study, the researchers discovered that a substantial number of the responding centers sometimes or never obtained second opinions when an adverse decision regarding a patient was made. See Levenson & Olbrisch, *supra* note 56, at 317, Table 2. Specifically, 28.2% of cardiac transplant programs, 35.0% of liver transplant programs, and 34.8% of kidney transplant programs stated that they obtain a second opinion only sometimes. *Id.* The factors taken into consideration when determining whether a second opinion would be obtained were not discussed. Second opinions were never obtained by 20.5% of cardiac programs, 7.5% of liver programs, and 80% of kidney programs. *Id.* Although this Note is limited to a discussion of patient compliance, it is recommended that second opinions be obtained whenever adverse decisions regarding a patient are made.

98. This appeal would simply entail a written description of the reasons for the patient's disagreement with the decision. It is not an adjudicatory proceeding, and no formal hearings

able candidate at the second transplant center, he or she then would be listed at that center. If, however, the second center's findings were the same, the patient could choose to either continue to seek evaluation at additional centers at his or her expense or be bound by the decision. In addition to arranging for another evaluation, UNOS also would conduct an investigation of the patient's initial evaluation to ensure that the center adequately complied with the guidelines.<sup>99</sup>

Assuming that the decision was not appealed, patients requiring additional follow-up would be placed on a secondary waiting list. This indicates that they are still considered potential candidates for transplantation, but that they will not be eligible for actual transplant surgery until these problems are resolved.<sup>100</sup> Re-evaluation by the transplant team would depend on the nature of the problem and the steps required to resolve it, and such re-evaluation should occur within six months. If, upon re-evaluation, the patient's compliance is determined no longer to be a problem, he or she would immediately be placed on the primary transplant waiting list in the position he or she would have originally assumed.<sup>101</sup> If, after one year, the patient is still identified as a compliance risk, the patient would be removed from the secondary transplant list. Patients removed from the transplant list would be referred to the appropriate social service agency or other support service at that time to help them work on the problems identified. Removal from the secondary list would not bar the patient from being re-evaluated, but the patient would be limited to re-evaluation every three months and would not be eligible for secondary list placement again.

For patients placed on the secondary list, the focus would be on determining the reasons behind the patient's history of

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would be held. The patient may elect to seek out attorney assistance in the preparation of the written appeal, but it is not required and would be at the patient's expense.

99. UNOS' investigation would be limited to determining compliance with the guidelines, such as ensuring that second opinions were obtained, and would not involve judgments based upon the assessment made or conclusions reached by the transplant center's team members.

100. This would enable the patient to benefit from time spent on the waiting list, under the UNOS point system, while at the same time ensuring that the patient is, in fact, a suitable candidate for surgery.

101. This assumes, of course, that the patient was otherwise determined to be medically eligible for a transplant.

noncompliance or the behaviors determined to affect that patient's ability to comply with post-transplant treatment. The goal of this step is to correct these problems and thereby enable the patient to become eligible for a transplant. For example, if a patient's history of noncompliance was found to be the result of financial difficulties, efforts to provide the patient with the necessary funding or advice about budgeting for the added expenses could be undertaken. If a history of substance abuse is the patient's problem, a three-to-six-month history of sobriety, active participation in a treatment program, and a negative blood alcohol test or drug screen would be sufficient to render the candidate suitable.<sup>102</sup> Those patients not meeting such criteria would be referred to the appropriate rehabilitation program. For patients whose problems were related to a lack of understanding of their illness or the importance of post-operative treatment, aggressive education to increase the patient's level of understanding would be the recommended course of action.<sup>103</sup>

Under this proposal, there would be no changes that would take place during the third stage of the process, which involves the selection of a recipient when an organ becomes available. The only difference from the current system is that UNOS involvement would take place earlier in the process. This earlier involvement of UNOS would include incorporating these guidelines into its regulations and making referrals and conducting investigations for patients appealing the decisions of

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102. This is currently the criteria used by one local transplant center. Levine Interview, *supra* note 41. The required length of abstinence is a controversial topic which has undergone several changes. For example, there are other programs that have defined different prognosis scales for patients with alcoholism in need of a liver transplant. See, e.g., Emmet B. Keeffe & Carlos O. Esquivel, *Controversies in Patient Selection for Liver Transplantation*, W.J. MED. 586, 587-88 (1993).

103. The author recommends aggressive education of all patients and their significant others during the evaluation process, with such education to include introduction to a patient who has previously undergone the same transplant surgery for which this patient is being considered. According to a clinical nurse specialist with a local transplant program, a lack of proper patient education is one of the main problems with transplant patients post-operatively and significantly contributes to noncompliance. Stokes Interview, *supra* note 92. See also Bittar et al., *supra* note 13, at 2721 (encouraging the identification of and a more personal approach to patients at risk for noncompliance); Schweizer, *supra* note 13, at 376 (recommending good communication between patient and physician to help facilitate treatment compliance); Betty C. Irwin, *The Role of the Nursing Professional in Organ Transplantation*, in HUMAN ORGAN TRANSPLANTATION, *supra* note 79, at 99-102 (discussing the role of nursing in the case of organ transplant recipients).

individual transplant centers.

## V. EXAMINING THE ARGUMENTS SURROUNDING THE IMPLEMENTATION OF THE PROPOSED CHANGE

### A. Discrimination Based on Social Worth, Race, Socioeconomic Status, and Disability

#### *Opposing View*

Opponents of this proposal will argue that denying patients access to organ transplants on the basis of psychosocial criteria is treading dangerously close to basing selection on social worth.<sup>104</sup> Determining a person's social worth or value involves the "consideration of a variety of factors, including income, net worth, educational background, community service, and occupation."<sup>105</sup> In short, "[s]ocial value does not measure the goodness of persons but merely how useful they are to society."<sup>106</sup> The use of social worth in selection of organ transplant recipients has been uniformly rejected by practitioners and commentators alike.<sup>107</sup>

Opponents will argue that, under this proposal, the potential for individual biases and prejudices is not removed. Even though the decisions would be made by a transplant team, as opposed to individual practitioners, the team's findings would likely be the result of a compilation of individual team

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104. See *Developments in the Law*, *supra* note 19, at 1636-37 (discussing the detrimental consequences of selection based upon social characteristics).

105. JOHN F. KILNER, WHO LIVES? WHO DIES?: ETHICAL CRITERIA IN PATIENT SELECTION 27 (1990).

106. *Id.*

107. In the early 1970s, kidney dialysis machines were scarce and rationing was necessary. As an example of social worth selection, a Native American named Ernie Crowfeather was denied dialysis because he did not measure up to the social worth criteria established by a committee of Seattle citizens, who had been given the responsibility for choosing the "most appropriate" candidates for dialysis. NANCY NEVELOFF DUBLER & DAVID NIMMONS, ETHICS ON CALL: A MEDICAL ETHICIST SHOWS HOW TO TAKE CHARGE OF LIFE-AND-DEATH CHOICES, 315-18 (1992). After Crowfeather's story was publicized, the medical and ethics communities rejected the social worth criterion as an ethically acceptable method for allocating scarce medical resources. *Id.* at 318.

members' views. The biases or prejudices of any one individual team member could affect the entire team's decision and potentially result in denying the patient what might be life-saving treatment. For example, if a mentally challenged patient were found to be at risk for noncompliance by the person conducting his or her mental health evaluation, that assessment may be based upon a legitimate concern about compliance, or it may represent a judgment about giving a scarce organ to a mentally challenged person.

Similarly, opponents may argue that discrimination against minorities and the poor, even if not intended, is likely to result from the implementation of this proposal.<sup>108</sup> Those with money and resources are more likely to be found suitable recipients because they have the financial means to comply with treatment. In contrast, minorities and the poor are plagued with problems such as financial difficulties, insufficient education, and less stable support systems, all of which may have affected their ability to comply with treatment in the past and/or result in the perception that future compliance might be a problem. This is especially problematic for African Americans who are already at a disadvantage for kidney transplants because of the emphasis on antigen matching and the marked underrepresentation of African Americans in the cadaveric donor pool.<sup>109</sup>

Furthermore, it is arguable that the exclusion, or otherwise different treatment, of patients labelled as noncompliant would constitute violations of the Americans with Disabilities Act of 1990 (ADA).<sup>110</sup> Prior to the enactment of the ADA, the treatment of noncompliant patients was accepted as that defined by the court in *Payton v. Weaver*.<sup>111</sup> In *Payton*, the court held that neither the physician nor the hospital defendants were required to provide further dialysis treatment to the plaintiff because the plaintiff was noncompliant, abusive, and engaged

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108. *Developments in the Law*, *supra* note 19, at 1636-37.

109. Ayres et al., *supra* note 71, at 808, 822. Because African Americans tend to have different antigens than whites, a predominantly white donor pool limits the availability of cadaveric kidneys to African Americans. *Id.* at 822.

110. 42 U.S.C. §§ 12101-12213 (1994) (providing protection and legal remedies for disabled individuals who have been discriminated against).

111. 182 Cal. Rptr. 225 (1982).

in behavior which affected the care provided to other patients.<sup>112</sup> Further, the court held that the physician had provided sufficient notice of his desire to end the relationship, as well as ample time for the patient to find another treating physician, thereby relieving the defendant physician of all obligations imposed by the physician-patient relationship.<sup>113</sup>

With the passage of the ADA, however, it is not clear that the outcome of the *Payton* case would be the same.<sup>114</sup> Generally, the ADA was passed in part "to provide a clear and comprehensive national mandate for the elimination of discrimination against individuals with disabilities."<sup>115</sup> The ADA adopts the definition of disability as is written in the Rehabilitation Act,<sup>116</sup> and thereby defines it in pertinent part as "a physical or mental impairment that substantially limits one or more of the major life activities of such individual."<sup>117</sup> Subchapter III of the ADA clearly includes the provision of services by a hospital or health care provider within the scope of the Act.<sup>118</sup> Although there is no case law which specifically addresses this issue, it is arguable that, under the provisions of the ADA, denying a patient access to a transplant because of established or predicted noncompliance due to a disability, as defined in the Act, would constitute a violation of the Act.<sup>119</sup>

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112. *Id.* at 228-29.

113. *Id.*

114. See David Orentlicher, *Denying Treatment to the Noncompliant Patient*, 265 JAMA 1579, 1580 (1991) (proposing that *Payton* could be decided differently today because the plaintiff now could argue that denial of further dialysis constitutes discrimination on the basis of a psychological disorder under the ADA).

115. 42 U.S.C. § 12101(b)(1) (1994).

116. 29 U.S.C. § 706(8)(B) (West Supp. 1997) (defining the term "individual with a disability," for purposes of the Rehabilitation Act, as "any person who (i) has a physical or mental impairment which substantially limits one or more of such person's major life activities, (ii) has a record of such an impairment, or (iii) is regarded as having such an impairment").

117. 42 U.S.C. § 12102(2)(A).

118. 42 U.S.C. §§ 12181(7)(F), 12182(a) (defining public accommodation to include hospitals and professional offices of health care providers and further prohibiting discrimination on the basis of disability by public accommodations).

119. Orentlicher, *supra* note 114 (proposing that, if a patient's noncompliance reflects psychiatric dysfunction, then a further denial of treatment may be prohibited under the ADA as discrimination based on a psychological disorder).

### Response

In support of this proposal, to make any system of organ distribution work, it first must be recognized that "there are *no* value-neutral selection criteria that could permit bypassing the need to make ethical judgments in the recipient selection process."<sup>120</sup>

One of the first and most basic advantages of this proposal is that it gives priority to those patients who demonstrate a willingness and ability to comply with post-transplant treatment. This is commensurate with the goals of transplantation — the ability of a patient to benefit from the transplant and the likelihood of a successful outcome. These goals are the basis for the medical criteria currently used to identify organ transplant recipients. It is generally accepted that patients excluded from organ transplants on the grounds of medical efficacy are not treated unfairly, and the recommendations under this proposal simply broaden what is considered medically efficacious. This point has been well-articulated in a report on transplantation by the New York State Task Force on Life and the Law:

Failure to comply with post-operative treatment, including the rigorous drug regimen, makes the transplant futile—it results in graft rejection, and, in the case of heart and liver recipients, the patient's death unless another organ is implanted. Hence, psychosocial criteria, used to assess the patient's willingness and ability to comply with treatment protocols, are closely related to an evaluation of medical benefit and outcome.<sup>121</sup>

Further, the fear of prejudice and inappropriate social value judgments, such as discrimination on the basis of race or socioeconomic status, occurring under this proposal is unfounded. Race does not come into play under the recommended changes. Its role and the role of other social characteristics,

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120. Brock, *supra* note 34, at 88.

121. *Developments in the Law, supra* note 19, at 1633, n.128 (quoting NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, TRANSPLANTATION IN NEW YORK STATE: THE PROCUREMENT AND DISTRIBUTION OF ORGANS AND TISSUES 110-11 (1988)). See also TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 294 (3d ed. 1989). "[T]he criterion of [the] likelihood of success is relevant because a scarce medical resource should only be distributed to patients who have a reasonable chance of benefitting from it. Ignoring this factor would be unjust, because it would result in a waste of resources, as in the case of organs that can be transplanted only once." *Id.*



such as lifestyle, social support systems, and alcoholism will only be a factor in the assessment if the medical outcome was or will be detrimentally affected. There is a "mistaken belief that in order to avoid the use of certain kinds of value judgments that seem ethically unjustified, one must avoid *all* value judgments. But this is not necessary — nor is it even possible."<sup>122</sup> While it is true that using factors such as financial status in evaluating organ recipients could be construed as an assessment of one's social worth, it is crucial to determine why such a factor is being used.<sup>123</sup> "If [u]sed because it positively affects the probability of successful patient and graft survival, and if there is adequate evidence that it in fact does so, it is ethically unproblematic."<sup>124</sup> Therefore, because patient compliance is essential to the success of the transplant and, in some instances, to the survival of the patient, the consideration of a patient's ability to comply and the factors potentially affecting it are justifiable.

In addition, this proposal incorporates several safeguards designed to prevent the occurrence of such discrimination. The requirement of second opinions, for example, significantly decreases the likelihood of individual biases or prejudices coming into play. Similarly, the patient's right to appeal the decision and obtain an entirely independent evaluation will likewise remove the danger of discriminatory practices.

It is also unlikely that this proposal will result in violations of the ADA. First, not all patients affected by this proposal have a disability as defined in the Act.<sup>125</sup> For example, those currently engaged in the use of illegal drugs are not considered disabled under the ADA.<sup>126</sup> Such patients are treated in the same manner as those identified as noncompliance risks because of a disability. Second, those patients excluded from consideration for a transplant who do fall within the given disability definition are not removed from such consideration on the basis of their disability, which a violation of

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122. Brock, *supra* note 34, at 89.

123. *Id.* at 89-90.

124. *Id.* at 90.

125. 42 U.S.C. § 12102(2) (defining the term disability for purposes of the ADA).

126. *Id.* § 12210(a).

the ADA would require.<sup>127</sup> Rather, the effects which the disability has on the medical efficacy of a transplant are the reasons for the possible exclusion.<sup>128</sup> Third, even if this is considered discrimination on the basis of a disability, this proposal clearly provides reasonable modifications to minimize any such discrimination,<sup>129</sup> and the criteria as established in the proposal are necessary for ensuring the success of the transplants and the likelihood of patients to benefit from them.<sup>130</sup> Any further steps, such as no consideration of patient compliance, would completely undermine the goals of transplantation and potentially affect the many compliant patients who are awaiting transplants.

As the previous discussion indicated, it is not entirely clear what the outcome of a case alleging a violation of the ADA under this proposal would be. However, it is believed that this proposal, if implemented as prescribed, would not be inconsistent with the ADA.

Furthermore, this proposal would also bring uniformity to the system of selecting potential organ recipients, particularly at the stages of the process where the greatest potential for arbitrariness and prejudice exists. As the ASTP and Virginia Studies demonstrate, there is a significant lack of consistency among transplant centers in how candidates are evaluated for transplantation.<sup>131</sup> These studies have shown that some trans-

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127. *Id.* § 12182(a) (prohibiting denial of the ability fully and equally to participate in the "enjoyment of . . . goods, services, facilities, privileges, advantages, or accommodations" on the basis of a disability).

128. *See id.* § 12182(b)(2)(A)(i) (following the general prohibition against discrimination on the basis of a disability, but allowing the use of eligibility criteria for the purpose of screening out an individual with a disability when "such criteria can be shown to be necessary for the provision of the goods, services, facilities, privileges, advantages, or accommodations being offered").

129. *Id.* § 12182(b)(2)(A)(ii) (stating "a failure to make reasonable modifications in policies, practices, or procedures, when such modifications are necessary to afford such goods, services, facilities, privileges, advantages, or accommodations to individuals with disabilities . . ." is a violation of the ADA "unless the entity can demonstrate that making such modifications would fundamentally alter the nature of such goods, services, facilities, privileges, advantages, or accommodations . . ."). Examples of such reasonable modifications of this proposal include the following: placement on a secondary list, as opposed to outright exclusion, the requirement of second opinions; and the appeals process.

130. The criteria set forth in this proposal are not intended to screen out individuals with disabilities, but rather may affect them just as others without disabilities are affected. These criteria are necessary to optimize the success of transplantation and to facilitate the fair and equitable distribution of organs.

131. This proposal does not address any legitimate differences in criteria based upon the

plant centers have very specific policies relating to the assessment of patient compliance, while others may have no such policies at all.<sup>132</sup> The assessment of compliance in determining the patient's likelihood of benefitting from treatment is not new, particularly when it involves a treatment which someone else might have to wait longer for or forgo altogether. For example, "[m]any rehabilitation programs use psychosocial assessments, including assessment of compliance and motivation, as a standard part of their eligibility determinations in placing would-be patients on their waiting lists, as well as in making decisions to terminate care."<sup>133</sup>

Recognizing the potential problems and inequities in which such assessments could result emphasizes the need for uniformly established guidelines. The incorporation of these guidelines into UNOS regulations would eliminate many of these concerns regarding discrimination. It would, for example, remove the potential biases now exhibited by transplant centers. For instance, "if centers are held accountable for surgical outcome relative to a national standard, this may militate against decisions to include marginal patients. In contrast, if funding agencies require that centers perform a certain annual volume, this may lead to the inclusion of poorer prognosis recipients."<sup>134</sup>

Many of the existing arguments calling for uniformity also emphasize that "[s]ignificant differences between transplant centers in psychosocial criteria and selection rates may encourage patients to shop around . . . . Adherence to at least some agreed-upon psychosocial criteria by all transplant centers would optimize fairness in the allocation of scarce donor organs."<sup>135</sup> This would eliminate the advantages realized by

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organ being transplanted. Rather, the call for uniformity is that programs providing the same services should have the same set of guidelines for assessing patient compliance.

132. See Ramos et al., *supra* note 46, at 493; Levenson & Olbrisch, *supra* note 56, at 319. See also *supra* Table 3 (presenting the weight assigned to various psychological contraindications to transplant).

133. Arthur L. Caplan, *Ethics of Casting the First Stone: Personal Responsibility, Rationing, and Transplants*, 18 ALCOHOLISM: CLINICAL AND EXPERIMENTAL RES. 219, 219 (1994) (discussing the importance of personal responsibility for one's health and its role in both preventing the need for organ transplants and in contributing to transplant failure).

134. Owen S. Surman & Ruth Purtilo, *Reevaluation of Organ Transplantation Criteria: Allocation of Scarce Resources to Borderline Candidates*, 33 PSYCHOSOMATICS 202, 211 (1992).

135. Levenson & Olbrisch, *supra* note 56, at 322. See also Robertson, *supra* note 81, at

those having the knowledge and resources to seek out evaluations at multiple transplant centers over those who, lacking these resources, may be lucky to be listed at even one transplant center.<sup>136</sup> "Although there are sound reasons for some of the variations . . . that exist, their existence gives the public the impression that pettiness or arrogance of providers can be decisive in determining who does and does not gain admission to a [transplant] program."<sup>137</sup>

This leads to yet another issue that must be considered: public perceptions of fairness in selecting organ transplant recipients. Public support of transplantation is essential for two reasons. Currently the public is the only source of organs, and they, both directly and indirectly, also provide the necessary funding for the provision of transplant-related services.<sup>138</sup> According to Caplan, "[i]f the public does not believe the process by which organs are allocated to be fair, they will not support either the procurement of organs on a voluntary, altruistic basis or the continuing commitment of public and private funds to pay for transplants."<sup>139</sup>

In 1994, three telephone surveys were conducted for UNOS by an independent research firm.<sup>140</sup> The surveys focused on the attitudes of the following groups: adult Americans, representing the general consumer group; candidates waiting for a kidney, liver, heart, or lung transplant; and organ

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3402 (concluding that a representative body should set the criteria for determining which patients will receive organs).

136. James F. Childress, *Ethical Criteria for Procuring and Distributing Organs for Transplantation*, 14 J. HEALTH POL., POL'Y & L. 87, 107-08 (1989). See A.P. Monaco, *Comment: A Transplant Surgeon's Views on Social Factors in Organ Transplantation*, 21 TRANSPLANTATION PROC. 3403, 3405 (1989) (discussing the ability of the wealthy to gain greater access to the transplantation process); A.L. Caplan, *Problems in the Policies and Criteria Used to Allocate Organs for Transplantation in the United States*, 21 TRANSPLANTATION PROC. 3381, 3384 (1989) [hereinafter Caplan, PROBLEMS] (stressing that there needs to be equity and uniformity in the allocation of organs).

137. Caplan, PROBLEMS, *supra* note 136, at 3384.

138. *Id.* at 3381.

139. *Id.* at 3387. See also Moss & Siegler, *supra* note 64, at 1296-97 (arguing that alcoholics should receive lower priority for liver transplants because of the effect on public support of transplantation); BEAUCHAMP & CHILDRESS, *supra* note 121, at 296 (stating that public confidence in morally acceptable and fairly applied criteria is essential to the organ donation system).

140. SOUTHEASTERN INST. OF RES., INC., RESEARCH REPORT: PATIENTS AND THE POPULOUS: AMERICAN ATTITUDES TOWARD THE ALLOCATION OF ORGANS IN TRANSPLANTATION 1 (1994) (on file with author).

recipients who already had received a kidney, liver, heart, or lung.<sup>141</sup> Among the findings these surveys yielded was that “[t]here is no clear consensus within any of the three groups as to an organ allocation policy.”<sup>142</sup> Other findings of interest include the fact that a majority of respondents overall agree that the organs available for transplantation are distributed fairly.<sup>143</sup> For the candidates and recipients, those agreeing that there was a fair distribution constituted at least two-thirds of the respondents in each group, while, in the consumer group, not even a majority agreed that the distribution system is fair.<sup>144</sup> In each of the three surveys, more of the disagreement about the fairness of the current allocation system was expressed by minorities.<sup>145</sup>

One final point of interest is the priorities these groups would assign in the allocation of organs. With each survey, the two highest priorities, given in order, would be assigned to “the patient who is the most critically ill” and “the patient who has the best chance of surviving the operation and retaining the organ.”<sup>146</sup>

Arguably, the public support of such a proposal could go either way. If the public felt that denial of a transplant based upon predictions about a patient’s ability to comply with treatment was too speculative or otherwise unfair, public support could suffer.<sup>147</sup> However, if the public believed that this proposal represented necessary steps that must be taken in light of the scarcity of organs, it may improve the public’s support and faith in the distribution of organs for transplantation.

The opposition’s arguments regarding discrimination based on social worth, race, socioeconomic status, and disability are significant, but they ultimately must fail. Although the use of psychosocial factors and the assessment of patient compliance is potentially discriminatory, its use under these circumstances

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141. *Id.*

142. *Id.* at 5.

143. *Id.* at 6-7, 15.

144. *Id.*

145. *Id.* at 10.

146. *Id.* at 16, 19, 23.

147. *See, e.g.,* Carl Cohen & Martin Benjamin, *Alcoholics and Liver Transplantation*, 265 JAMA 1299 (1991) (arguing that alcoholics should not be categorically precluded from receiving liver transplants simply because the public might react negatively if they are included).

is justified. If the proposal is implemented as prescribed, the risk of misuse is effectively eliminated.

### B. Constitutional Safeguards

#### *Opposing View*

A related concern is that the constitutional safeguards against such discrimination, such as those provided by the due process and equal protection clauses, may not apply to the distribution of cadaveric organs. Because these clauses only protect individuals against state action, which is conduct by the government, the necessary element of state action would be missing and patients would have no recourse against such discrimination.<sup>148</sup> For example, in *Blum v. Yaretsky*,<sup>149</sup> a class of Medicaid patients challenged decisions made by the nursing homes in which they resided to discharge or transfer patients without notice or an opportunity for a hearing.<sup>150</sup> The plaintiffs claimed that the extensive regulation of nursing homes in New York State converted this to action by the State for the purposes of the Fourteenth Amendment.<sup>151</sup> The Supreme Court of the United States rejected that argument holding that "[t]he complaining party must . . . show that 'there is a sufficiently close nexus between the State and the challenged action of the regulated entity so that the action of the latter may be fairly treated as that of the State itself.'"<sup>152</sup> This raises the understandable concern that UNOS may not be found to be a state actor; thereby, removing any constitutional safeguards these patients might otherwise enjoy.

#### *Response*

UNOS involvement at all stages of the process may answer the concerns about the lack of constitutional protection instead of raising additional concerns about it. The "nexus between the federal government and UNOS might seem sufficient to implicate the federal government in UNOS decision

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148. *Developments in the Law*, *supra* note 19, at 1637.

149. 457 U.S. 991 (1982).

150. *Id.* at 993.

151. *Id.* at 1003.

152. *Id.* at 1004.

making, making UNOS a de facto state actor.”<sup>153</sup> For example, in *Burton v. Wilmington Parking Authority*,<sup>154</sup> an African American sued a restaurant located in a publicly owned parking building for failure to serve him.<sup>155</sup> Because the restaurant was located in a publicly owned building that was maintained with public funds and the parking service was owned and operated by an agency of the state, the state was held liable for violating the Equal Protection Clause of the Fourteenth Amendment.<sup>156</sup> It is quite possible that the argument would be even stronger in the case of UNOS because “[t]he federal government further implicates itself in UNOS decisions by providing the enforcement mechanism for UNOS policies — federal Medicare and Medicaid eligibility.”<sup>157</sup> Therefore, it is believed that, with the implementation of this proposal and the involvement of UNOS at all stages of the process, patients would be afforded the constitutional protection of the due process clause.

As for the equal protection concern, patients in need of a transplant who are noncompliant are not the same or equal to those who are compliant. In *City of Cleburne, Texas v. Cleburne Living Center*,<sup>158</sup> the Supreme Court of the United States held “that all persons similarly situated should be treated alike.”<sup>159</sup> Because compliant and noncompliant candidates for a transplant are not similarly situated, there is no equal protection issue.

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153. *Developments in the Law*, *supra* note 19, at 1638. See also *Blum v. Yaretsky*, 457 U.S. at 1004 (holding that a sufficiently close nexus must exist between the State and the regulated entity to attribute the regulated entity's action to the State for purposes of the Fourteenth Amendment).

154. 365 U.S. 715 (1961).

155. *Id.* at 716.

156. *Id.* at 716-17.

157. *Developments in the Law*, *supra* note 19, at 1638.

158. 473 U.S. 432 (1985).

159. *Id.* at 439.

### C. Punishment

#### *Opposing View*

Opponents of this proposal will argue that its implementation will, in effect, punish people for behavior that may not be within their control. By even putting patients on notice that compliance is essential to being considered for a transplant, it seems unfair and impossible to require compliance or deterrence of a specific behavior when that behavior may not be voluntary. As one commentator points out, "it is hard to find a lifestyle 'choice' or a health condition that is not, at least in part, a consequence of genetics, family environment, social environment, gender, life trauma, ethnicity, community, education . . . and, probably, most significantly, wealth."<sup>160</sup> Although this commentator acknowledges that there may be some voluntary elements to a patient's conduct that potentially affect the patient's ability to comply, the commentator claims that "[m]ost life style choices . . . are the consequences of a variety of factors, and most commonly we do not know the significance of the different factors."<sup>161</sup> The most often cited condition or life style "choice" to which this argument applies is alcoholism. While the choice to take a drink appears to be voluntary, alcoholism is a product of several forces including genetics, social factors, and familial patterns.<sup>162</sup> In spite of these involuntary components of the disease, opponents will claim that this proposal recommends that patients suffering from alcoholism be treated differently than those whose conditions are unrelated to alcohol because an alcoholic does not have the same chance of controlling his behavior to reduce the risk of noncompliance.<sup>163</sup> Opponents will argue that this proposal, and others like it, fails to consider all the factors affecting a patient's ability to comply with treatment, and that

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160. Robert L. Schwartz, *Life Style, Health Status, and Distributive Justice*, 3 HEALTH MATRIX 195, 204 (1993).

161. *Id.* at 205.

162. *Id.* at 204.

163. See, e.g., Moss & Siegler, *supra* note 64, at 1296-98 (recommending that patients with alcohol-related end-stage liver disease be given lower priority for liver transplants than those patients with non-alcohol-related liver disease).



the patient may be powerless to change such factors. Indeed, even assuming a patient is able to control his or her noncompliance, does that justify the denial of what may be a life-saving organ?<sup>164</sup>

Opponents also will likely make the following slippery slope argument: if organs are rationed on the basis of a patient's behavior or his or her role in the illness, then this may lead to the rationing of health care overall. If it does, few of us would be legitimately eligible for health care.<sup>165</sup> Examples of patients having at least some small role in their illness include firefighters injured in the line of duty, motorcyclists with head injuries due to not wearing helmets, professional athletes injured while competing, and downhill skiers sustaining injuries while on the slopes. All of these patients, arguably, were on notice of the potential consequences of their actions. Currently, there is no indication that anyone believes such patients should be denied access to the care they need, yet if we start rationing organs on the basis of a patient's behavior, would this not be the next logical step? In the interest of fairness to end-stage organ failure patients who are denied access to transplantation, should we not treat others the same? One commentator writes on this issue in the context of alcoholics' eligibility for liver transplants. He states:

If alcoholics should be penalized because of their moral fault, then all others who are equally at fault in causing their own medical needs should be similarly penalized. To accomplish this, we would have to make vigorous and sustained efforts to find out whose conduct has been morally weak or sinful and to what degree. That inquiry, as a condition for medical care or for the receipt of goods in short supply, we certainly will not and should not undertake.<sup>166</sup>

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164. See Schwartz, *supra* note 160, at 211 (discussing problems associated with using the denial of available health care as a punishment for behavior); Cohen & Benjamin, *supra* note 147, at 1299-1301 (arguing against the conclusion that alcoholics' personal failings should be considered in determining entitlement to scarce resources).

165. For an excellent discussion of this argument, see Schwartz, *supra* note 160, at 198-202 (discussing the range of lifestyle choices and their consequences on healthy status).

166. Cohen & Benjamin, *supra* note 147, at 1300. Cf. Robertson, *supra* note 81, at 3400 (suggesting that an allocation scheme which punishes patients for previous behavior may be just only if the patient was clearly culpable and on notice as to the consequences, but further stating that such criteria ultimately may be unacceptable).

Opponents also also argue that, with the exception of re-transplant patients and their histories of noncompliance, there is no definitive way for predicting a patient's noncompliance with post-transplant treatment. This proposal assumes that if there is evidence of noncompliance in the patient's history, he or she will continue to be noncompliant in the future when, in fact, that may not be the case.<sup>167</sup> This is even more problematic for those patients who do not necessarily have a history of noncompliance, but whose life circumstances may raise concerns about their ability to comply with treatment.

This situation bears a striking resemblance to the selective incapacitation of criminals which has gained attention in recent years. With selective incapacitation, "some [criminal] offenders would be imprisoned for a longer period than others convicted of the same offense, because of predictions about their *future* criminality."<sup>168</sup> Among the major objections to selective incapacitation are "1) it is *unfair* to punish people for crimes they have not yet committed, and might not commit if released; [and] 2) it is unjust to incarcerate (or further incarcerate) people on the basis of predictions of future crimes because those predictions are too often wrong."<sup>169</sup> Like selective incapacitation, speculating about the future compliance of organ transplant patients is unfair and cannot be justified.

### *Response*

This proposal does not constitute any form of punishment. Under this proposal, patients would not be flatly rejected for a transplant. Instead, unlike the current system of distribution, patients will be assisted in dealing with whatever problems may affect their ability to comply with the post-transplant regimen.<sup>170</sup> This proposal is designed to encourage compli-

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167. See Levine Interview, *supra* note 41. Ms. Levine claims that many transplant patients view the receipt of an organ as a new lease on life and do everything within their power to make it work.

168. SANFORD H. KADISH & STEPHEN J. SCHULHOFER, *CRIMINAL LAW AND ITS PROCESSES: CASES AND MATERIALS* 162 (5th ed. 1989).

169. *Id.*

170. See Levenson & Olbrisch, *supra* note 56, at 322 (stating that the current system encourages "patients to shop around rather than work on correcting psychosocial contraindications to transplantation"); BEAUCHAMP & CHILDRESS, *supra* note 121, at 296 (suggesting

ance, or deter behaviors affecting compliance, that are within the patient's power to control. Recognizing that factors affecting compliance are not necessarily voluntary, placement on the secondary list involves determining the causes of noncompliance, providing the patient with the means for dealing with those causes, and assisting him or her in any other way possible. For alcoholics, this may mean enrollment in Alcoholics Anonymous or another substance abuse rehabilitation program. For patients with financial difficulties, this may include working with government agencies to get the patient the necessary resources that would enable compliance with treatment or, if applicable, employment assistance.

For those behaviors that are within the patient's control, placement on the secondary list is notice that further consideration for a transplant is dependent upon that patient doing whatever he or she can to correct such problems.<sup>171</sup> This line of thinking is similar to that encountered in our everyday lives. In many facets of our lives we encounter benefits that are conditioned upon our compliance with specific terms. For example, insurance policies often require the insured to comply with specifications in the policy or to abstain from certain behaviors before a claim will be paid. Car warranties cover certain parts or problems provided that the owner has complied with the maintenance requirements outlined in the owner's manual. This idea is not new to our legal system, either. The recent concept of "three strikes and you're out," in which felons convicted of a third felony are sentenced to life in prison, puts these persons effectively on notice of the consequences of continued violations of the law. Even something as simple as a speeding ticket fits into this picture. Drivers are on notice of speed limits and the consequences of failing to comply with them. If they choose not to comply, they receive a speeding ticket.

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that justice requires society to seek alternatives for patients rather than excluding them from transplantation).

171. This is in contrast to the current system in which patients often are not told of the reasons they are being refused for placement on the waiting list, or are merely told they are "medically unsuitable" for consideration. See Levenson & Olbrisch, *supra* note 56, at 317, Table 2 (presenting the inconsistencies, as reported by responding centers, in which potential patients are given a reason for their rejection).

A similar concept has recently come into play in the medical field as well. In the last decade, physicians and other care providers have refused to render treatment to patients on the basis of futility.<sup>172</sup> Although these patients are usually terminally ill, the main idea behind the concept is that the benefits of continuing treatment are negligible or futile, while the burdens of treatment are substantial.<sup>173</sup>

The necessity of compliance in transplant patients has been established. Giving an organ to a patient unable or unwilling to comply with treatment is futile.<sup>174</sup> As the above analysis suggests, the benefits of such a transplant would be negligible, while the burdens would be very substantial. This patient would undergo major surgery and the routine post-operative course only to sustain what may be a fatal bout with rejection. Additionally, another patient will have been adversely affected because he or she was deprived of an organ.

The scarcity of these organs and the need to make difficult decisions are what makes transplantation different from other areas of health care, thereby making the slippery slope argument less of a concern. If there were enough organs to match the number of those in need, allocation decisions would not be an issue. Just as we care for the firefighters, motorcyclists, professional athletes, and skiers without question, all patients in need would be given organs. This is not the reality, however, and each year patients are dying as a result of the scarcity of transplantable organs.<sup>175</sup> The rationing of organs based on psychosocial factors and patient compliance is not taken lightly, nor is it advocated unless necessary. Unfortunately, in the case of organ distribution, it has become necessary.

The criticism with regard to predicting patient compliance

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172. See REBECCA DRESSER, *BIOETHICS AND LAW* (forthcoming, West Publishing Co.) (manuscript on file with author).

173. *Id.*

174. See *Developments in the Law*, *supra* note 19, at 1633 n.128 (discussing the necessity for patients to comply with post-operative treatment (quoting NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, *TRANSPLANTATION IN NEW YORK STATE: THE PROCUREMENT AND DISTRIBUTION OF ORGANS AND TISSUES*, 110-11 (1988))).

175. In the years between 1988 and 1993, the General Accounting Office estimated that over 10,000 people died while on a waiting list to receive an organ. Fentiman, *supra* note 79, at 43. This number, however, does not include the thousands more who never even made it onto a waiting list. *Id.*

is compelling. However, it must be emphasized that the goals of this proposal are to further the goals of transplantation. Mere speculation about a patient's post-transplant compliance would not be enough to remove a patient from consideration for a transplant. The presumption should be that the patient will be compliant. Only in the presence of evidence concerning possible noncompliance would a patient be considered temporarily ineligible. The focus, then, would be on doing whatever is possible to make that person a suitable candidate for transplantation.

Although the situations may seem similar, it is inappropriate to compare this proposed treatment of potential organ recipients to criminals. These patients have not committed any crime, nor does this proposal constitute a form of punishment. In fact, under this proposal, these patients would be given the tools they need for a successful transplant outcome. Granted, some patients would ultimately be excluded from consideration because of these changes, but only after painstaking efforts have been exhausted to help them and to enable them to help themselves.

#### D. Re-Transplant Patients

##### *Opposing View*

Opponents of this proposal also will argue that its treatment of re-transplant patients is unfair. Implementing these changes will result in the assumption that patients labelled as noncompliant with their first transplant will continue to be noncompliant with subsequent transplants. Opponents will argue that it is impossible to determine that the rejection was due to noncompliance when compliant patients also reject organs. Among other things, the patient's noncompliance may have been a result of inadequate education by health care providers after the transplant was performed.

The potential exclusion of re-transplant patients also raises a separate host of issues. The main argument against this exclusion is that it would constitute abandonment of the pa-

tient.<sup>176</sup> This is especially problematic for physicians who are committed to their patients and feel a heightened duty to continue to help patients on whom they have already operated.<sup>177</sup>

The current system of organ distribution also places emphasis on treating patients on the basis of medical urgency. Re-transplant patients usually are much sicker than primary transplant patients.<sup>178</sup> In keeping with the general duty to help the most urgently ill patients, re-transplant patients should not be excluded from another transplant.<sup>179</sup> In addition, unlike kidney patients who have the alternative of dialysis if they reject an organ, those in need of hearts and livers, for example, have no alternative. These patients will die if denied an organ. Even if the patient's noncompliance contributed to the rejection, it arguably is not enough to justify denial of a life-saving organ.<sup>180</sup>

### Response

The situation regarding re-transplant patients is different from that of primary recipients. In addition to the documentation of the patient's prior compliance being readily available, these are patients who have already been given a chance; and in the interest of fairness and the need for equitable allocation, their ability to accept the responsibility which a transplant entails must be taken into consideration, especially since there are so many other patients waiting for their first chance.

Allocation priorities should not be altered on the basis of any special obligations that transplant teams feel to support patients on whom they have already performed transplants. Nor does any sense of justice support a claim that it is unfair to give patients second or third organs while others await their first.<sup>181</sup>

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176. Childress, *supra* note 78, at 318; Brock, *supra* note 34, at 98-99 (discussing arguments against the exclusion of organ recipients from receiving a second organ after a failed graft).

177. See Peter A. Ubel et al., *Rationing Failure: The Ethical Lessons of the Retransplantation of Scarce Vital Organs*, 270 JAMA 2469, 2471 (1993); see also Robertson, *supra* note 81, at 3401 (stating that physicians may exert aggressive efforts for a re-transplant patient "to demonstrate commitment to avoid abandonment"); Brock, *supra* note 34, at 99.

178. Ubel, *supra* note 177, at 2473.

179. *Id.*

180. See Schwartz, *supra* note 160, at 211-12 (implying that the severity of punishment for noncompliant behavior should be in proportion to the egregiousness of the conduct).

181. Ubel, *supra* note 177, at 2473.

It should also be noted that, while re-transplant patients generally are much sicker than primary transplant patients, "[r]etransplantation is an independent risk factor for poor transplant outcome."<sup>182</sup> One commentator describes why the distribution of organs to re-transplant patients may not be commensurate with the goals of transplantation:

At any level of urgency, re-transplant recipients do not do as well as similarly ill primary transplant recipients . . . even after controlling their preoperative status . . . . [T]here is no greater duty to help one group over the other. Thus, efficacy should determine which group has priority in receiving organs. By giving re-transplant candidates equal access to transplantable organs, our present policy does not do all it can to distribute organs efficaciously. We give organs to a group of people who have less chance of gaining long-term survival from a transplant. We ignore our duty to distribute scarce resources in ways that increase the chance that the resources will bring benefit.<sup>183</sup>

Although some commentators would remove re-transplant patients from consideration for another transplant altogether,<sup>184</sup> in the interest of fairness, the recommended changes to the current system of distribution propose that those in search of another transplant be subject to the same compliance assessment as primary recipients. The only differences that would result in the treatment of re-transplant patients is that those who rejected a heart or liver as a result of noncompliance could be potentially excluded from consideration for another transplant, whereas those awaiting their first heart or liver would not be excluded. Because primary heart or liver transplant candidates could die without ever having been given a chance, they are the ones who should be given priority.

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182. *Id.*

183. *Id.*

184. See Monaco, *supra* note 136, at 3405 (stating that noncompliance, having resulted in a failed first transplant, "is a valid means to reject a potential recipient for a second transplant"); Brock, *supra* note 34, at 99 (discussing the author's opinion that candidates who have never received an organ transplant and who will die without the organ should be chosen over those who have received a previously failed transplant).

### E. Cost of Implementation

#### *Opposing View*

Aside from the many ethical questions this proposal raises, the cost of implementing it cannot be overlooked. Transplant centers would need additional staffing to complete these evaluations, handle the necessary administrative matters, and provide the necessary follow-up for the patients on the secondary list. UNOS also would be affected by these costs because of its increased role in the process and the need to implement and maintain the changes it would incur. Since transplantation is directly and indirectly funded by the public, the costs of such extensive changes would be passed along to taxpayers.

#### *Response*

There is no doubt that cost will be a factor in the implementation of this proposal. However, it is likely that these increased costs will be covered by the monies saved as a result of the institution of these changes. In fact, a recent study of the economic impact of noncompliance in kidney transplant patients was conducted by researchers from the Hartford Transplant Center in Hartford, Connecticut.<sup>185</sup> This study specifically compared the hospital admissions of thirty patients determined to be noncompliant (using the criteria from the Compliance Study discussed previously) compared with those of a control group of thirty compliant patients whose specific characteristics were matched as closely as possible.<sup>186</sup> Table 4 below summarizes the findings of this study.<sup>187</sup> In addition to the findings listed in the table, fourteen of the thirty noncompliant patients "lost their kidney transplants from rejection, or died."<sup>188</sup>

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185. M. Swanson et al., *Economic Impact of Noncompliance in Kidney Transplant Recipients*, 24 *TRANSPLANTATION PROC.* 2722, 2722 (1992).

186. *Id.* These characteristics included "age, donor source, race, incidence of diabetes mellitus, and re-transplantation." *Id.* Additionally, all transplants were performed within the same two-year period (1984-86), and all patients received similar immunosuppressive medications post-operatively. *Id.*

187. *Id.*

188. *Id.* (failing to state the number of compliant patients, if any, who may have lost their kidney transplant due to rejection or who died).



**Table 4 - Economic Impact of Noncompliance in Kidney Transplants**

	Noncompliant	Compliant
Number of readmissions	178	76
Mean length of stay upon readmission	11.3 days	8.6 days
Total readmission costs for the group (excluding the transplant itself)	\$1,254,301	\$442,132
Mean cost of readmissions per patient	\$35,602 <sup>1</sup>	\$14,737
Mean cost of readmissions per patient (excluding diabetic recipients who may have had admissions unrelated to the transplant)	\$28,541	\$12,885
Readmissions due to complications arising from treatment for rejection	19	7

<sup>1</sup>This total excludes the effect of two noncompliant patients with extreme numbers of admissions. *Id.*

Because patients with functioning kidney transplants no longer need dialysis, the researchers also examined the savings realized from the elimination of dialysis from the treatment regimen for these patients. First, they determined the cost of hemodialysis to be approximately \$28,000/patient/year.<sup>189</sup> The researchers then calculated the cost of transplant maintenance to be \$10,000/patient/year, which results in a savings of \$18,000/patient/year.<sup>190</sup> Although the definitive cost of implementing the changes recommended in this proposal is not available at this time, it appears that cost would not necessarily be a factor because of the savings that would be realized from the fewer hospitalizations and shorter hospital stays of giving the organs to compliant patients.

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189. *Id.*

190. *Id.*

## VI. CONCLUSION

The amount of literature addressing organ donation and transplantation issues and the current number of patients awaiting organs demonstrate that the scarcity of organs and selection of recipients continue to be controversial issues. The current process for the selection of organ recipients, described here as a three-stage process, lacks uniformity and can be viewed as unfair. A proposal for changing this system to include uniform guidelines for the assessment of patient compliance is one possible alternative to the current system. Because compliance is so important for patients receiving organs, on its face, this seems like a legitimate solution. However, the use of psychosocial factors in determining a patient's ability to comply raise a number of ethical questions and arguments, many of which are compelling. In addition, the fact that it is difficult to predict patient noncompliance, particularly in primary recipients, also must be considered. This proposal addresses these arguments and difficulties by limiting the possible exclusion of primary recipients to those with an alternative treatment available to them. While all potential organ recipients should be assessed for noncompliance, those potentially excluded as a result of unresolved problems with noncompliance would, therefore, be limited to kidney patients and those having undergone a prior transplant.

The scarcity of organs available for transplantation and the need for fairness in the distribution of these scarce resources necessitate making difficult decisions. Although this proposal would require making some of these difficult decisions, it is believed that, overall, it provides a fair and legitimate solution to an unfortunate situation and that it best serves all those suffering from end-stage organ failure.

