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## Kidney Transplantation: Only for the Well-to-Do?

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# Kidney Transplantation: Only for the Well-to-Do?

JENNIFER M. SMITH\*

*"To have to worry about how you're going to pay for transplant medications 36 months down the road is a shame."<sup>1</sup>*

## INTRODUCTION

The world of organ transplantation remains a wealthy one, especially in the United States. Well-to-do Americans who need an organ transplant travel to Third World countries to get an organ from some poor, living person, then travel back to the United States for their continued post-operative care.<sup>2</sup> This is especially true for kidney transplantations, which involve the solid organ most in demand.<sup>3</sup>

Increasingly, transplant professionals desperately push for more solutions to overcome the organ transplant shortage that exists in the United States because of the increase in mortality occurring due to

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1. Deborah Shelton, *The Transplant Gap Keeps More Blacks Waiting for Kidneys*, CHI. TRIB., July 8, 2008 (quoting Willa Lang, president and chief executive officer of the National Kidney Foundation of Illinois), available at <http://www.donatelifellinois.org/donatelifelife/news/Tribune07-08-08.pdf>.

2. Vanessa Chandis, *Addressing a Dire Situation: A Multi-Faceted Approach to the Kidney Shortage*, 27 U. PA. J. INT'L ECON. L. 205, 218 (2006) (commenting that kidneys come from people who live in poorer countries, such as India and South America, and are transplanted to people in richer countries, such as the United States).

3. See INT'L ASS'N FOR ORGAN DONATION, UNDERSTANDING: STATISTICS/FACTS, <http://iaod.org/understanding-organ-donation.htm> (last visited Mar. 9, 2009) (reporting that 4066 people died in the United States in 2006 while waiting for a kidney and 1605 people died waiting for a liver).

lack of a kidney transplant.<sup>4</sup> Historically, Americans have objected to the outright sale of human organs because many fear that selling human organs will result in the exploitation of the poor.<sup>5</sup> More recently, however, some scholars have suggested that exploitation of the poor is a ridiculous paternalistic concern that prevents poor people from increasing their wealth by selling their body parts as living donors.<sup>6</sup>

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4. See, e.g., 7 ADVANCES IN BIOETHICS: THE ETHICS OF ORGAN TRANSPLANTATION (Wayne Shelton & John Balint eds., 2001); MARK CHERRY, KIDNEY FOR SALE BY OWNER: HUMAN ORGANS, TRANSPLANTATION, AND THE MARKET (2005); BARRY R. SCHALLER, UNDERSTANDING BIOETHICS AND THE LAW: THE PROMISES AND PERILS OF THE BRAVE NEW WORLD OF BIOTECHNOLOGY (2008); THE ETHICS OF ORGAN TRANSPLANTS: THE CURRENT DEBATE (Arthur L. Caplan & Daniel H. Coelho eds., 1998); ROBERT M. VEATCH, TRANSPLANTATION ETHICS (2000); Gloria J. Banks, *Legal & Ethical Safeguards: Protection of Society's Most Vulnerable Participants in a Commercialized Organ Transplantation System*, 21 AM. J.L. & MED. 45 (1995); E.A. Friedman & A.L. Friedman, *Payment for Donor Kidneys: Pros and Cons*, 69 KIDNEY INT'L 960 (2006), available at <http://www.nature.com/ki/journal/v69/n6/full/5000262a.html>; Alexandra Glazier & Scott Sasjack, *Should It Be Illicit to Solicit? A Legal Analysis of Policy Options to Regulate Solicitation of Organs for Transplant*, 17 HEALTH MATRIX 63 (2007); Michele Goodwin, *The Body Market: Race Politics & Private Ordering*, 49 ARIZ. L. REV. 599 (2007); Richard Schwandt & Aidan R. Vining, *Proposal for a Future Delivery Market for Transplant Organs*, 11 J. HEALTH POL. POL'Y & L. 483 (1987).

5. See CHERRY, *supra* note 4, at 8-9, 76 (stating that one social concern over commercialization is that "cash payments will attract primarily poor and low-income segments of the population, including racial minorities, who will disproportionately bear the health care complications of being vendors, as well as being increasingly subjected to exploitation"); Laura Meckler, *Kidney Shortage Inspires a Radical Idea: Organ Sales*, WALL ST. J., Nov. 13, 2007, at D1, available at [http://online.wsj.com/public/article\\_print/SB119490273908090431.html](http://online.wsj.com/public/article_print/SB119490273908090431.html) (reporting that Francis Delmonico, a transplant surgeon, fears that organ sales "would attract the poor, vulnerable and unhealthy"); Todd Zwillich, *Analysis: Cash Payments for Organs?*, UNITED PRESS INT'L, Apr. 21, 2006, available at [http://www.accessmylibrary.com/coms2/summary\\_0286-14963194\\_ITM](http://www.accessmylibrary.com/coms2/summary_0286-14963194_ITM) (reporting that Robert Veatch, who opposed cash payments for organs for decades because of the potential to exploit poor people, is now calling for experimentation with cash payments for organs because so many people are dying as a result of the organ shortage).

6. See William Barnett II et al., *A Free Market in Kidneys: Efficient and Equitable*, 5 INDEP. REV. 373, 374 (2001), available at [http://www.independent.org/pdf/tir/tir\\_05\\_3\\_barnett.pdf](http://www.independent.org/pdf/tir/tir_05_3_barnett.pdf) ("[T]he prohibition against the purchase and sale of kidneys forecloses [poor people from converting their physical human capital into a more valuable form of wealth], insofar as it involves the sale of a kidney. It effectively prevents [poor people] from making choices that they believe would increase their well-being. The current prohibition is paternalistic, and as such it is dehumanizing. Adults, because they are poor, are treated as if they are incapable of making decisions in their own best interest. Rather, government officials make one-size-fits-all decisions for them, with no knowledge whatsoever—much less personal knowledge—of them as individuals or of

Even if Americans put aside their reservations about the potential exploitation of the poor and embrace this new paradigm shift, which would allow poor citizens to sell their body parts, the poor working class who need kidney transplants—and in fact who would also be the very ones sought after as living kidney donors—could not afford to be a kidney recipient.<sup>7</sup> This is because they would not be able to afford the lifetime cost of the immunosuppressive medication (or anti-rejection drugs) necessary to ensure that their bodies do not reject the “new” kidney.<sup>8</sup>

As it now stands, the federal government pays the costs to maintain individuals on dialysis for life and covers eighty percent of the cost of immunosuppressive drug therapy for Medicare kidney recipients for a life.<sup>9</sup> However, the government only covers the cost of immu-

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their individual situations and values.” (citation and footnote omitted)); AP Monaco, *Rewards for Organ Donation: The Time Has Come*, 69 KIDNEY INT’L 955 (2006), available at <http://www.nature.com/ki/journal/v69/n6/full/5000281a.html> (noting that government efforts to reward organ donors may be viewed as implementing a policy that directly exploits the poor); Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813, 1842-43 (2007) (citing Russell Korobkin, *Buying and Selling Human Tissues for Stem Cell Research*, 49 ARIZ. L. REV. 45 (2007)) (noting that if an organ provider believed that money was worth the small health risk, the government’s interest in protecting the donor against the temptation should not trump the recipient’s medical self-defense right).

7. *But cf.* Barnett et al., *supra* note 6 (concluding that allowing the sale of human organs in the United States would solve the issues surrounding the organ shortage and the wealthy and poor would have access to kidneys, but failing to address the costs associated with maintenance of transplanted kidneys).

8. See discussion *infra* Part I.

9. Alexander S. Goldfarb-Rumyantsev et al., *Role of Socioeconomic Status in Kidney Transplant Outcome*, 1 CLINICAL J. AM. SOC’Y NEPHROLOGY 313 (2006) (“Medicare beneficiaries who are eligible to receive the immunosuppressive medication coverage must still pay 20% of the cost of these medications as Medicare covers only 80% of the total cost.”); see also Elisa J. Gordon, *The Ethics of Medicare Policy: Increasing Transplant Access and Survival*, 55 DEPAUL L. REV. 1045, 1047 (2006) (finding that the twenty percent co-pay that organ recipients must pay during the first thirty-six months places the transplanted kidney at risk of rejection); Bertram L. Kasiske et al., *Payment for Immunosuppression After Organ Transplantation*, 283 JAMA 2445 (2000) (advocating that “Medicare should cover the cost of all immunosuppressive therapy for all solid organ transplant recipients who cannot afford to pay” because currently “Medicare covers most transplantation procedures in the United States, but ends coverage for outpatient immunosuppressive medications after 36 months”); NATCO, POSITION STATEMENT: MEDICARE COVERAGE FOR IMMUNOSUPPRESSIVE DRUGS (2006), available at [http://www.natco1.org/public\\_policy/documents/MedicareDrugCoverage.pdf](http://www.natco1.org/public_policy/documents/MedicareDrugCoverage.pdf) (“[T]he 20% co-pay can be prohibitive and lead to nonadherence with the prescribed medication regime, potential organ dysfunction, organ loss or even death.”).

nosuppressive drug therapy for individuals under sixty-five and not otherwise disabled for three years after a successful kidney transplant.<sup>10</sup> Because these post-transplant anti-rejection medications are so expensive, many people with low or fixed incomes do not meet the financial criteria necessary to qualify to receive a kidney transplant. This is because they will not be able to pay for the cost of maintaining the transplant after government assistance terminates.

Congress has introduced legislation that purports to remedy this situation by providing that the government will pay eighty percent of the cost for the post-transplant medications for life.<sup>11</sup> But unless this bill passes and other needed changes are made, kidney transplantation remains an option primarily for the well-to-do.

## I. CASE STUDIES

Jessica and Emily's stories are not unique. Both need a kidney transplant; neither can afford one.

Jessica is a twenty-year-old Florida resident whose transplanted kidney "shriveled up" soon after she turned eighteen.<sup>12</sup> Since that time, she has spent three hours a day three days a week on kidney dialysis just to stay alive.<sup>13</sup> There is no cost for kidney dialysis for Jessica; the government pays it all.

Jessica received her first kidney transplant at the age of twelve.<sup>14</sup> She appeared to be a model kidney-transplant patient; she is a competitive swimmer, a surfer, and a lifeguard.<sup>15</sup> When Jessica received her donated kidney eight years ago, she was still a minor. The government paid for the kidney transplant, as well as the immunosuppressive medications to keep the transplanted kidney functioning.<sup>16</sup>

But when the kidney failed soon after she turned eighteen, Jessica had other concerns to worry about. Although the government would pay for the cost of the kidney transplant for an adult, the government's

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10. Gordon, *supra* note 9, at 1052-53 ("Based on Medicare policy, patients (who are not disabled or age sixty-five and older) are responsible for covering twenty percent of the costs of immunosuppressive medications for three years and the full costs thereafter.").

11. See discussion *infra* Part II.

12. Harry Wessel, *Struggles Don't End with Transplant*, ORLANDO SENTINEL, Feb. 3, 2008, at A1.

13. *Id.*

14. *Id.*

15. *Id.*

16. *Id.*

post-transplant help with the immunosuppressive medications was significantly curtailed because Jessica was no longer a minor.<sup>17</sup>

Now she has to meet the financial criteria to qualify for a kidney.<sup>18</sup> Jessica is unemployed and supports herself with monthly disability checks.<sup>19</sup> Because the transplant center determined that she would not be able to afford the long-term care of the donated kidney, it notified her that it was removing her name from the kidney-recipient waiting list.<sup>20</sup>

Jessica was disappointed. The average wait in the United States for a kidney is about five years,<sup>21</sup> but in central Florida the wait is approximately one year.<sup>22</sup> With a new kidney, Jessica's life would be significantly improved, but on dialysis, she remains chronically ill.<sup>23</sup>

Jessica has several other medical problems—problems involving her heart, liver, vascular system, and she even had a massive stroke.<sup>24</sup> Yet, she was not removed from the kidney transplant waiting list because of medical issues. Rather, she was involuntarily removed from the list because she did not meet the financial criteria to receive a

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17. *Id.* (“Medicare does not have a three-year limit for minors, but those who have had coverage for at least three years lose it once they turn 18.”); Lisa M. Willoughby et al., *Health Insurance Considerations for Adolescent Transplant Recipients as They Transition to Adulthood*, 11 PEDIATRIC TRANSPLANTATION 127 (2007) (“It is well-recognized that there is insufficient healthcare coverage in the general adolescent population, especially during the transition period into adulthood. The age that this transition occurs is between 18 and 23 [years], depending on whether insurance is provided by the state (Medicaid or the State Children’s Health Insurance Program), Medicare or a private health plan.”).

18. *See, e.g.*, Kidney Transplant Program, Univ. of S. Cal., Financial Considerations, <http://usckidneytransplant.org/financialconsiderations.html> (last visited Mar. 17, 2009) (“Costs related to transplant include evaluation and testing, transplant surgery and hospitalization, follow-up care and medication.”).

19. *See* Wessel, *supra* note 12, at A1.

20. *Id.*

21. Megan Shaughnessy, *A Different Approach to Kidney Allocation in the United States*, 36 DIALYSIS & TRANSPLANTATION 230, 230 (2007) (noting that the wait for a kidney sometimes is as long as ten years); Laura Neergaard, *Therapy Helps Hard-to-Transplant Get a New Kidney*, WASH. TIMES, Oct. 14, 2008 (reporting that the wait for a kidney can be four to five years); Posting of Sally Satel to The Huffington Post, [http://www.huffingtonpost.com/sally-satel/who-wants-to-be-a-kidney-\\_b\\_49910.html](http://www.huffingtonpost.com/sally-satel/who-wants-to-be-a-kidney-_b_49910.html) (May 29, 2007, 21:32 EST) (reporting the average wait for a kidney is five years, but in 2010 the wait may be as long as ten years).

22. *See* Wessel, *supra* note 12, at A1.

23. Rebecca P. Winsett et al., *Kidney Transplantation*, in ORGAN TRANSPLANTATION: CONCEPTS, ISSUES, PRACTICE, AND OUTCOMES (2002), [http://www.medscape.com/viewarticle/443490\\_print](http://www.medscape.com/viewarticle/443490_print) (“[P]atients choose the option of transplantation out of a desire for more normalcy in their lives.”).

24. *See* Wessel, *supra* note 12, at A1.

kidney transplant; she cannot afford the deductibles and co-pays associated with a transplant.<sup>25</sup>

Emily's story is a bit different. She is a twenty-seven year old student in Illinois.<sup>26</sup> She has been on kidney dialysis for years, but over time, dialysis became less effective.<sup>27</sup> While most people waiting for a kidney do all they can to get to the top of the waiting list, even going abroad for a kidney transplant, Emily has delayed trying to get a transplant for several years because she does not believe that she can afford the post-transplant anti-rejection drugs.<sup>28</sup> Although she began the process of obtaining an evaluation for a transplant, she remains torn—how will she pay for the immunosuppressive medications that may average \$15,000 annually?<sup>29</sup>

Jessica and Emily's worries are common in the kidney transplant world. There are also those who work post-transplant and thus do not qualify for government assistance who cannot afford the annual cost of the immunosuppressive drugs. Jessica was removed from the waiting list and Emily is afraid to join the list because neither has the financial means to maintain a kidney post-transplant.<sup>30</sup> Emily remains on dialysis, but that treatment option makes it more likely that she will not be able to work.<sup>31</sup> Further, the chances of receiving a successful transplant decreases with time.<sup>32</sup>

So, many potential kidney recipients cannot receive transplants because they cannot afford the deductibles, co-payments, anti-rejection medications and other costs associated with a kidney transplant. These real life scenarios beg the question: is kidney transplantation only for the well-to-do?

## II. COMPREHENSIVE IMMUNOSUPPRESSIVE DRUG COVERAGE FOR KIDNEY TRANSPLANT PATIENTS ACT OF 2007

Many Americans are living with some form of kidney disease.<sup>33</sup> Years ago, a diagnosis of severe kidney disease or renal disease “sig-

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25. *Id.*

26. Shelton, *supra* note 1.

27. *Id.*

28. *Id.*

29. *See infra* note 121.

30. *Id.*; *see also* Wessel, *supra* note 12, at A1.

31. Winsett et al., *supra* note 23 (“The longer patients remain on dialysis, the more difficult it is to reintroduce the patient to employment.”).

32. Neergaard, *supra* note 21.

33. *See, e.g.*, Erika L. Rager, *The Donation of Human Organs and the Evolving Capacity for Transplantation: Exciting Developments and Future Prospects*, 65 N.C. MED. J. 18 (2004), available at <http://www.ncmedicaljournal.com/jan-feb-04/ar010403.pdf>

naled certain death within a short period of time.”<sup>34</sup> Renal disease occurs when there is a failure of the kidney to properly excrete waste, which causes subsequent accumulation of urea and other nitrogenous waste in the blood.<sup>35</sup> When kidneys permanently fail to function, it is called end stage renal disease (ESRD),<sup>36</sup> which is chronic renal disease that necessitates dialysis or transplantation<sup>37</sup>—the two treatment options for ESRD.<sup>38</sup> However, these options are not mutually exclusive.<sup>39</sup>

The most common option is dialysis, which is a process that cleans excess potassium from a person’s blood.<sup>40</sup> The government currently will pay for a lifetime of dialysis, but dialysis leaves the person chronically ill with a less than adequate quality of life.<sup>41</sup> The preferred option, transplantation, results in a higher quality of life.<sup>42</sup> Patients do

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(noting that by the end of 2003 there were over 85,000 people with end stage renal disease awaiting a transplant in the United States).

34. See COMM. ON NUTRITION SERVS. FOR MEDICARE BENEFICIARIES, INST. OF MED., *THE ROLE OF NUTRITION IN MAINTAINING HEALTH IN THE NATION’S ELDERLY* 132 (2000) [hereinafter *THE ROLE OF NUTRITION*].

35. See *id.* at 133.

36. Sandra J. Carnahan, *Medicare’s Coverage with Study Participation Policy: Clinical Trials or Tribulations?*, 7 *YALE J. HEALTH POL’Y L. & ETHICS* 229, 234 n.20 (2007).

37. *THE ROLE OF NUTRITION*, *supra* note 34, at 133-34 (remarking that ESRD necessitates treatment by dialysis or transplantation); James F. Blumstein, *Government’s Role in Organ Transplantation Policy*, in *ORGAN TRANSPLANTATION POLICY: ISSUES AND PROSPECTS* 5, 8 (James F. Blumstein & Frank A. Sloan eds., 1989) (noting that ESRD is life-threatening absent dialysis or transplantation).

38. Paul W. Eggers, *Medicare’s End Stage Renal Disease Program*, 22 *HEALTH CARE FINANCING REV.* 55, 55 (2000), available at <http://www.cms.hhs.gov/HealthCareFinancingReview/Downloads/00fallpg55.pdf> (“There are two basic treatments available to persons with ESRD—dialysis and transplantation.”); see also Arthur J. Matas, *A Gift of Life Deserves Compensation: How to Increase Living Kidney Donation with Realistic Incentives*, 604 *POL’Y ANALYSIS* 2, 2 (2007) (noting a third option for treatment is no treatment, in which case the patient will eventually die).

39. See Matas, *supra* note 38, at 2 (noting that a patient may begin on dialysis before receiving a transplant, and if the transplant fails, may go back to dialysis).

40. See Sally L. Satel & Benjamin E. Hippen, *When Altruism Is Not Enough: The Worsening Organ Shortage and What It Means for the Elderly*, 15 *ELDER L.J.* 153, 158 (2007).

41. Laura G. Dooley & Robert S. Gaston, *Stumbling Toward Equity: The Role of Government in Kidney Transplantation*, 1998 *U. ILL. L. REV.* 703, 718 (1998) (noting that living on dialysis is constantly onerous).

42. R.M. Jindel et al., *Noncompliance After Kidney Transplantation: A Systematic Review*, 35 *TRANSPLANTATION PROC.* 2868, 2868 (2003) (“Patients with a functioning transplant also have a significantly longer life span than patients on chronic dialysis.”); Matas, *supra* note 38, at 2 (“[C]ompared with dialysis, kidney transplant significantly prolongs life and improves quality of life.”).



not have to rely upon dialysis to continue living. They have a “new” kidney to allow them to function and presumably go back to work. Thus, this is the favored option for ESRD.<sup>43</sup> But with a transplant, the kidney recipient must take immunosuppressive medications faithfully for the lifetime of the transplant to maintain the “new” kidney or risk an organ rejection<sup>44</sup> and perhaps death.<sup>45</sup>

Because of the laws surrounding kidney transplants, many people—particularly low income individuals—do not have access to kidney transplantation. Therefore, either they find themselves involuntarily removed from the transplant waiting lists, like Jessica, or they do not pursue a donated kidney, like Emily, because they know they will not be able to pay for the maintenance of the kidney when the government’s aid ends.

This is not new information. Indeed, this disparity in access to kidney transplantation was the impetus behind the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2007 (the Transplant Drug Act).<sup>46</sup> This has been introduced in both the House<sup>47</sup> and Senate,<sup>48</sup>—same language in each bill<sup>49</sup>—and is now before the Senate’s Committee on Finance.<sup>50</sup> The Transplant Drug Act, if passed, would provide a lifetime of immunosuppressive medications to Medicare kidney transplant recipients whose coverage would otherwise terminate.<sup>51</sup> As proposed, it

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43. Eggers, *supra* note 38, at 56 (recognizing transplantation as the optimal therapy).

44. *Id.*

45. Marie A. Chisholm et al., *Patient Factors Associated with Adherence to Immunosuppressant Therapy in Renal Transplant Recipients*, 62 AM. J. HEALTH-SYS. PHARMACY 1775, 1776 (2005) (noting that nonadherence to immunosuppressant therapy may result in “decreased quality of life, increased health care costs, need for dialysis, morbidity, and mortality”); COMM. ON MEDICARE COVERAGE EXTENSIONS, INST. OF MED., *EXTENDING MEDICARE COVERAGE FOR PREVENTIVE AND OTHER SERVICES 7* (Marilyn J. Field et al. eds., 2000) [hereinafter *EXTENDING MEDICARE COVERAGE*] (noting that experience and evidence confirm that transplant patients eventually lose their grafts due to lack of immunosuppressive therapy, causing them to return to dialysis, receive another transplant, or die).

46. H.R. 3282, 110th Cong. (2007).

47. *Id.*

48. S. 2320, 110th Cong. (2007).

49. See *Bill Eliminating 3-Year Time Limitation on Medicare Coverage for Kidney Transplants Introduced in Senate*, BNET, Dec. 2007, available at [http://findarticles.com/p/articles/mi\\_m0YUG/is\\_12\\_17/ai\\_n24241935](http://findarticles.com/p/articles/mi_m0YUG/is_12_17/ai_n24241935).

50. GovTrack.us, S. 2320: *Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2007: Overview*, <http://www.govtrack.us/congress/bill.xpd?bill=S110-2320> (last visited Jan. 1, 2009).

51. *Id.*

[a]mends SSA title II (Old Age, Survivors and Disability Insurance) (OASDI) to: (1) continue entitlement to prescription drugs used in immunosuppressive therapy furnished to an individual who receives a kidney transplant for which payment is made under Medicare; and (2) extend Medicare secondary payer requirements for end stage renal disease (ESRD) beneficiaries.

Amends title XVIII (Medicare) of SSA to apply special rules to kidney transplant recipients receiving additional coverage for immunosuppressive drugs. Deems such individual to be enrolled under Medicare part B. Makes him or her responsible for the full amount of the applicable premiums. Applies deductible and coinsurance requirements to the provision of such drugs.

Amends the Public Health Service Act, the Employee Retirement Income Security Act of 1974 (ERISA), and the Internal Revenue Code to set forth requirements for group health plans to provide coverage of immunosuppressive drugs for kidney transplant patients.<sup>52</sup>

Medicare's current three year drug coverage entitlement may appear strict, but from an historical perspective, it has tripled what it used to be.<sup>53</sup> It is encouraging to witness Congress's reception to the importance of drug coverage entitlement for kidney transplant recipients because it may signal that Congress will ultimately pass the Transplant Drug Act that is presently before it.

#### A. *Historical Development of Legislation*

Before 1965, health care for the aged and needy was sparse. There were federal and state government programs, helped by local governments, charities, and community hospitals, but they were not meeting the health needs of seniors and low income citizens.<sup>54</sup> Thus, Congress passed the Social Security Act Amendments of 1965, simultaneously creating both Medicare and Medicaid.<sup>55</sup> Specifically, this legislation created:

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52. GovTrack.us, S. 2320: *Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2007: Congressional Research Service Summary*, <http://www.govtrack.us/congress/bill.xpd?bill=S110-2320&tab=summary> (last visited Jan. 1, 2009).

53. See *infra* note 114.

54. Almanac of Policy Issues, Medicaid, <http://www.policyalmanac.org/health/medicaid.shtml> (last visited Jan. 1, 2009); Social Security Online, Social Security Administration History, <http://www.ssa.gov/history/ssa/lbjmedicare1.html> (last visited Jan. 1, 2009).

55. R. A. Rettig, *Socioeconomic Impact of the End Stage Renal Disease Program in the USA. Payment and Quality of Care*, 14 NEPHROLOGIA 14 (1994), available at <http://www.revistanefrologia.com/mostrarfle.asp?ID=1591> (noting Medicare and Medicaid were both adopted in 1965); Almanac of Policy Issues, *supra* note 54; see also EXTENDING

- A hospital insurance program to cover most seniors (Medicare Part A);
- A voluntary supplementary medical insurance program (Medicare Part B);
- An expansion of an existing program to assist seniors with out of pocket costs, such as premiums, deductibles, co-payments, and other uncovered costs; and
- The Medicaid program to cover families with dependent children, the blind and disabled.<sup>56</sup>

Since its enactment, policymakers have been concerned about the lack of sufficient outpatient prescription drug benefits.<sup>57</sup> From the inception, Medicare provided for prescription drugs that were administered in the physician's office to ensure doctors did not hospitalize patients merely for medications.<sup>58</sup> But an outpatient prescription drug benefit, which was considered for Medicare Part B, was not included because of the inability to determine the potential costs of such a benefit.<sup>59</sup>

Under some political pressure to expand Medicare, President Lyndon Johnson called for a task force to determine the viability of a prescription drug benefit under the new Medicare program.<sup>60</sup> Created in 1967 and operating for twenty months, the task force concluded in 1969 that "a drug insurance program under Medicare is needed by the elderly, and would be both economically and medically feasible . . . [and] consideration should be given to providing coverage at the outset

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MEDICARE COVERAGE, *supra* note 45, at 15 (finding that Medicare was created to serve the needs of older Americans who could not pay for health care or obtain private insurance, and Medicaid was created to provide health insurance for low income individuals, mainly poor mothers with children and low-income disabled).

56. Almanac of Policy Issues, *supra* note 54.

57. JENNIFER O'SULLIVAN, MEDICARE PRESCRIPTION DRUG COVERAGE FOR BENEFICIARIES: BACKGROUND AND ISSUES (2003), available at [http://www.house.gov/towns/pdf/prescription\\_drugs.pdf](http://www.house.gov/towns/pdf/prescription_drugs.pdf) ("The absence of an adequate prescription drug benefit has been of concern to policymakers since the enactment of Medicare in 1965.").

58. Thomas R. Oliver et al., *A Political History of Medicare and Prescription Drug Coverage: Missed Opportunities and Muddled Outcomes*, 82 MILBANK Q. 283, 291-92 (2004), available at [http://www.allacademic.com/meta/p\\_mla\\_apa\\_research\\_citation/0/6/1/7/6/pages61760/p61760-1.php](http://www.allacademic.com/meta/p_mla_apa_research_citation/0/6/1/7/6/pages61760/p61760-1.php).

59. *Id.* at 291 ("[T]he outpatient prescription drug benefit for Part B was dropped on the grounds of unpredictable and potentially high costs." (citation and internal quotation marks omitted)).

60. *Id.* at 293 ("In May 1967 [U.S. Department of Health, Education and Welfare] Secretary John Gardner established the Task Force of Prescription Drugs in response to a directive from President Johnson to undertake immediately a comprehensive study of the problems of including the cost of prescription drugs under Medicare." (citation and internal quotation marks omitted)).

mainly for those drugs which are most likely to be essential in the treatment of seniors' illnesses."<sup>61</sup> Nevertheless, no proposal for Medicare drug benefits survived due to congressional inaction, related costs, and industry rebellion.<sup>62</sup> Although Medicare did not offer outpatient prescription drug coverage, Medicaid did so as an optional benefit, which all states chose to offer in introducing their Medicaid programs.<sup>63</sup>

The 1972 Social Security Act amendments fueled renewed interest in a Medicare prescription drug benefit, but again no legislation resulted.<sup>64</sup> However, these amendments, which became effective in 1973, included Medicare coverage for kidney transplantation and dialysis.<sup>65</sup> Specifically, the federal government began paying for dialysis and kidney transplantation for most Americans with ESRD,<sup>66</sup> and anyone who was diagnosed with ESRD automatically qualified for Medicare, irrespective of age or disability.<sup>67</sup> Medicare entitlement, however, was limited to one year following a successful transplant.<sup>68</sup> The legislation was passed with the thought that the ESRD program would "bring great social value at a modest cost" and that implementation of a national health insurance program would occur within one to two years.<sup>69</sup> National health insurance did not become a reality, and still has not although the United States is closer to implementing one, but this legislation saved the lives of over one million people who benefited from renal replacement therapy.<sup>70</sup> Prior to this legislation, hospitals would decide who would receive dialysis; those not selected—frequently seniors, women, and blacks—were simply left to die of renal

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61. *Id.* at 294 (citation omitted).

62. Robin J. Strongin, *Providing Outpatient Prescription Drugs Through Medicare: Can We Afford to? Can We Afford Not to?*, NAT'L HEALTH POL'Y F., Mar. 1999, at 2, available at [http://www.nhpf.org/pdfs\\_bp/BP\\_MedicareOutptRx\\_3-99.pdf](http://www.nhpf.org/pdfs_bp/BP_MedicareOutptRx_3-99.pdf).

63. Oliver et al., *supra* note 58, at 291.

64. Stephen H. Long, *Prescription Drugs and the Elderly: Issues and Options*, 13 HEALTH AFF. 158 (1994).

65. See Blumstein, *supra* note 37, at 7; Allen R. Nissenson & Richard A. Rettig, *Medicare's End Stage Renal Disease Program: Current Status and Future Prospects*, 18 HEALTH AFF. 161 (1999).

66. Dooley & Gaston, *supra* note 41, at 709.

67. See Jonathan Himmelfarb & Glenn M. Chertow, *Medicare ESRD Prospective Payment System: Weighing the Evidence*, 16 J. AM. SOC'Y NEPHROLOGY 1164, 1164-65 (2005), available at <http://jasn.asnjournals.org/cgi/reprint/16/5/1164.pdf>.

68. See Eggers, *supra* note 38, at 56.

69. Himmelfarb & Chertow, *supra* note 67, at 1164.

70. See Eggers, *supra* note 38, at 55.

failure.<sup>71</sup> Thus, there was great social value in providing renal replacement therapy,<sup>72</sup> but at a larger than expected financial cost.<sup>73</sup>

When this Medicare ESRD program began in 1973, transplantation—considered the rarer and riskier procedure at that time—was deemed to be a bridge therapy during gaps of dialysis<sup>74</sup> as a result of low graft survival rates.<sup>75</sup> It was evident even then (some thirty years ago), that because of the low graft survival rates lifetime immunosuppressive drug therapy was needed to ensure that the patient's immune system did not reject the “new” kidney.<sup>76</sup>

By 1978, however, annual Medicare ESRD costs were nearing one billion dollars—well more than expected—and projected costs were estimated to be about triple those figures.<sup>77</sup> Thus, in 1978, leaving intact the basic entitlement portions of the 1972 legislation, Congress responded by passing the ESRD Program Amendment, extending Medicare entitlement following a successful transplant from one year to three years.<sup>78</sup> This amendment was to encourage home dialysis and

71. *Id.* at 57 (reporting that of all persons chosen for dialysis treatment prior to the 1972 legislation, 75% were male, 91% were white, and only 7% were over the age of 55; but by 1978, 50% were female, 35% were black, and 46% were age 55 and older).

72. *Id.* at 56 (reporting that Medicare's ESRD Program generally achieved the intended goal of ensuring access to life sustaining care for many people who would not have received care).

73. MANAGEMENT OF TECHNOLOGY: THE KEY TO PROSPERITY IN THE THIRD MILLENNIUM 499 (Tarek M. Khalil et al. eds., 2001) (stating that estimated costs for the ESRD Program for the initial year were between \$35 million and \$75 million, but that actual costs came to \$240 million and have increased yearly at an annual rate of twenty percent).

74. EXTENDING MEDICARE COVERAGE, *supra* note 45, at 100 (explaining that transplantation was still considered to be rare and risky at the time, and that dialysis was the more fully developed treatment option); Eggers, *supra* note 38, at 56; see also Robert S. Gaston & Carlton J. Young, *African Americans and Renal Transplantation: Disproportionate Need, Limited Access, and Impaired Outcomes*, 323 AM. J. MED. SCI. 94, 95 (2002), available at <http://www.amjmedsci.com/pt/re/ajms/pdfhandler.00000441-200202000-00007.pdf> (noting that thirty years ago, dialysis—not transplantation—was deemed the optimal treatment for chronic renal failure).

75. A “graft” is an organ or tissue that is removed from one person and transplanted into another person. “Graft survival rate” is the percentage of patients who have functioning organs that were transplanted from another at a certain point in time, usually measured in one, three, and five-year time frames. LIVER TRANSPLANT PROGRAM, UNIV. HOSP. OF CINCINNATI, TERMS TO KNOW, [http://www.cincinnati.org/about\\_glossary.htm](http://www.cincinnati.org/about_glossary.htm) (last visited Mar. 19, 2009).

76. EXTENDING MEDICARE COVERAGE, *supra* note 45, at 105; Eggers, *supra* note 38, at 56.

77. THE ROLE OF NUTRITION, *supra* note 34, at 311-12.

78. Eggers, *supra* note 38, at 56.

kidney transplantation.<sup>79</sup> Because patients remained disabled or met the Medicare age requirements, many patients remained on Medicare after three years.<sup>80</sup> This legislation provided Medicare coverage, but outpatient immunosuppressive medications were not addressed.<sup>81</sup>

In the late 1970s, cyclosporine, an immunosuppressive drug, was introduced with great success, changing the entire landscape of organ transplantation.<sup>82</sup> But cyclosporine was so expensive that post-transplant immunosuppressive drug therapy became an issue.<sup>83</sup> Because it was administered as an outpatient drug, and therefore not reimbursable by Medicare, many patients declined the immunosuppression regime prescribed by their physicians.<sup>84</sup>

In 1983, the Food and Drug Administration (the FDA) approved cyclosporine, and it was introduced to the public in 1984.<sup>85</sup> This FDA approval was a major medical advance in transplantation medicine that led to an increase in demand for organ transplants.<sup>86</sup>

Also in 1983, Dr. H. Barry Jacobs attempted to form a company that would purchase kidneys from healthy, but very poor citizens of Third World countries and sell them to wealthy American recipients.<sup>87</sup> Specifically, his proposal included creating the International Kidney Exchange Limited, in which an indigent Third World resident would set a price for a kidney, which Jacobs would then sell and collect a brokerage fee.<sup>88</sup> Americans were outraged by Dr. Jacobs' proposal,<sup>89</sup>

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79. Richard A. Rettig, *Government's Role in Organ Transplantation Policy*, in ORGAN TRANSPLANTATION POLICY: ISSUES AND PROSPECTS, *supra* note 37, at 191, 195.

80. Eggers, *supra* note 38, at 56.

81. THE ROLE OF NUTRITION, *supra* note 34, at 312.

82. Rettig, *supra* note 79, at 193 ("The clinical experience of transplantation was altered markedly by the introduction of cyclosporine into general use."); Rager, *supra* note 33, at 18 ("Cyclosporine dramatically changed the course of organ transplantation.").

83. THE ROLE OF NUTRITION, *supra* note 34, at 313; Oliver et al., *supra* note 58, at 291.

84. Rettig, *supra* note 79, at 193.

85. Eggers, *supra* note 38, at 57.

86. Margaret R. Sobota, Note, *The Price of Life: \$50,000 for an Egg, Why Not \$1,500 for a Kidney? An Argument to Establish a Market for Organ Procurement Similar to the Current Market for Human Egg Procurement*, 82 WASH. U. L.Q. 1225, 1226 (2004).

87. Banks, *supra* note 4, at 72; Steve P. Calandrillo, *Cash for Kidneys? Utilizing Incentives to End America's Organ Shortage*, 13 GEO. MASON L. REV. 69, 79-80 (2004); Samuel Gorovitz, *Is Law the Prescription That Can Cure Medicine?*, 11 J.L. & HEALTH 1, 9 (1996).

88. Shelby E. Robinson, *Organs for Sale? An Analysis of Proposed Systems for Compensating Organ Providers*, 70 U. COLO. L. REV. 1019, 1036 (1999) (citing Susan Hankin Denise, *Regulating the Sale of Human Organs*, 71 VA. L. REV. 1015, 1021 (1985)).

yet wealthy Americans engaged in this transplant tourism then and still do today.<sup>90</sup> As a result, Congress passed the National Organ Transplant Act of 1984 (NOTA),<sup>91</sup> which banned the sale or purchase of human organs for use in human transplantation.<sup>92</sup>

As originally proposed, NOTA provided coverage for cyclosporine.<sup>93</sup> But due to funding concerns, President Ronald Reagan signed the legislation, and NOTA became law in 1984 absent cyclosporine coverage.<sup>94</sup> This was partly because the key supporters of the legislation—United States Congressmen Gore, Kennedy, and Waxman—were more concerned with the bill's central purpose (outlawing the sale or purchase of human organs) than the immunosuppressive drugs that are needed to maintain a kidney transplant.<sup>95</sup> Ultimately, after a political compromise, NOTA retained its core, but funding for cyclosporine—an objectionable provision—fizzled out.<sup>96</sup>

Due to the rising costs of the Medicare ERSD program, the Omnibus Budget Reconciliation Act of 1981 was passed.<sup>97</sup> It included the Medicare secondary payer provision (the MSP), requiring beneficiaries that maintained insurance other than Medicare to seek primary coverage from their private insurers before Medicare for the first twelve months of coverage.<sup>98</sup> The twelve month period was extended to eighteen months in 1990,<sup>99</sup> and thirty months in 1997,<sup>100</sup> lessening the federal government's financial burden.

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89. Laura Meckler, *Kidney Shortage Inspires a Radical Idea: Organ Sales*, WALL ST. J. ONLINE, Nov. 13, 2007, [http://online.wsj.com/public/article\\_print/SB119490273908090431.html](http://online.wsj.com/public/article_print/SB119490273908090431.html).

90. Press Release, Kathleen Maclay, UC Berkeley, UC Berkeley Anthropology Professor Working on Organs Trafficking (Apr. 30, 2004), [http://berkeley.edu/news/media/releases/2004/04/30\\_organs.shtml](http://berkeley.edu/news/media/releases/2004/04/30_organs.shtml).

91. 42 U.S.C. § 274e (2000).

92. Bethany J. Spielman, *Acquiring and Allocating Human Organs for Transplant: U.S. Law*, in LEGAL PERSPECTIVES IN BIOETHICS 143, 146 (Ana S. Iltis et al. eds., 2008).

93. Keith J. Mueller, *The National Organ Transplant Act of 1984: Congressional Response to Changing Biotechnology*, 8 REV. POL'Y RES. 346, 353 (1989).

94. *Id.*

95. *Id.* at 354; Blumstein, *supra* note 37 (“[T]he one explicitly mandatory regulatory provision of the 1984 act was its ban on the purchase or sale of human organs, as that would affect interstate commerce.”).

96. Mueller, *supra* note 93, at 354.

97. Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, § 2146, 95 Stat. 357, 783 (codified at 42 U.S.C. § 1395y).

98. See Eggers, *supra* note 38, at 57; Robert S. Lockridge, Jr., *The Direction of End-Stage Renal Disease Reimbursement in the United States*, 17 SEMINARS IN DIALYSIS 125, 126 (2004).

99. Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4203, 104 Stat. 1388 (codified at 42 U.S.C. § 1395y); Lockridge, *supra* note 98, at 126.

Then, there was a medical breakthrough, albeit limited, allowing access to immunosuppressive medications. Congress passed the Omnibus Budget Reconciliation Act of 1986, covering eighty percent of a Medicare recipient's immunosuppressive drug costs for up to one year after a Medicare-covered kidney transplant<sup>101</sup>—which Congress then amended in the Omnibus Budget Reconciliation Act of 1987, enlarging the coverage from solely “immunosuppressive drugs” to include “prescription drugs used in immunosuppressive therapy.”<sup>102</sup>

Still concerned about the lack of an outpatient prescription drug benefit, Congress passed the Medicare Catastrophic Coverage Act of 1988 (MCCA), which provided prescription drug coverage for the second year and beyond after a successful Medicare transplant.<sup>103</sup> Under MCCA, Medicare covered eighty percent of medication costs after the beneficiary paid a \$600 deductible.<sup>104</sup> However, the proposed financing scheme for MCCA required seniors with higher incomes to pay the lion's share.<sup>105</sup> This was unacceptable and caused public outrage; therefore, MCCA was repealed in 1989 before it could be implemented.<sup>106</sup>

In 1993, President William Clinton advanced the Health Security Act (HSA),<sup>107</sup> which had a comprehensive benefit package.<sup>108</sup> HSA included prescription drugs, outpatient diagnostic testing and rehabilitation services, physician and hospital care, preventive services,

100. Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4631, 111 Stat. 251, 486 (codified at 42 U.S.C. § 1395y); Lockridge, *supra* note 98, at 126.

101. Lockridge, *supra* note 98, at 126; Eugene Yen et al., *Cost-Effectiveness of Extending Medicare Coverage of Immunosuppressive Medications to the Life of a Kidney Transplant*, 4 AM. J. OF TRANSPLANTATION 1703 (2004).

102. Medicare Program; Medicare Coverage of Prescription Drugs Used in Immunosuppressive Therapy, 60 Fed. Reg. 8951 (Feb. 16, 1995) (to be codified at 42 C.F.R. pt. 410).

103. Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 100-360, § 202, 102 Stat. 683 (codified as amended at 42 U.S.C. § 1395x).

104. Oliver et al., *supra* note 58, at 298.

105. *Id.* at 299.

106. Thomas Rice et al., *The Medicare Catastrophic Coverage Act: A Post-Mortem*, 9 HEALTH AFF. 75, 76 (1990). *But see Obama Calls for Overhaul of U.S. Health Care System*, CNN, Mar. 5, 2009, <http://www.cnn.com/2009/POLITICS/03/05/health.care.summit/index.html> (reporting that in President Barack Obama's proposed health care overhaul, he would mandate that “senior citizens making more than \$170,000 annually to pay a greater share of their prescription drug costs under Medicare”).

107. *See* Health Security Act, H.R. 3600, 103d Cong. (1993), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=103\\_cong\\_bills&docid=f:h3600ih.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=103_cong_bills&docid=f:h3600ih.txt.pdf).

108. H. Richard Beresford, *The Health Security Act: Coercion and Distrust for the Market*, 79 CORNELL L. REV. 1405, 1410 (1994).



mental health and substance abuse services, family planning, and hospice and home health care.<sup>109</sup> In particular, the Clinton administration noted that with the inclusion of prescription drug coverage, Medicare would be the largest purchaser of prescription drugs and would use its negotiating power to obtain price reductions from the pharmaceutical companies.<sup>110</sup> After losing public support due to attacks by conservatives and interest groups—claiming that the proposal was too complicated, would restrict health care, and represented too much government—the plan and other major health reform proposals lost steam and died in September 1994.<sup>111</sup>

Meanwhile, the Omnibus Budget Reconciliation Act of 1993<sup>112</sup> gradually phased in additional immunosuppressive medication coverage for patients who received a Medicare-covered transplant.<sup>113</sup> It increased from twelve months to eighteen months in 1995, twenty-four months in 1996, thirty months in 1997, and thirty-six months for every Medicare transplant thereafter.<sup>114</sup>

Congress then passed the Balanced Budget Refinement Act of 1999.<sup>115</sup> This legislation extended Medicare immunosuppressive drug coverage for eight months for those whose coverage would otherwise expire for a period of five years.<sup>116</sup>

Following the aforementioned Acts, Congress then enacted the Beneficiary Improvement and Protection Act of 2000 (BIPA),<sup>117</sup> which provided lifetime immunosuppressive drug coverage to beneficiaries who qualified for Medicare coverage because of age or disability.<sup>118</sup> But ESRD patients who have had a successful kidney transplant are no longer considered disabled because transplantation is considered rehabilitation, thereby presumably allowing patients to go back to work.<sup>119</sup>

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109. H.R. 3600.

110. Oliver et al., *supra* note 58, at 301-02.

111. *Id.* at 302.

112. See Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 312.

113. See Lockridge, *supra* note 98, at 126.

114. *Id.*; HEALTH CARE FINANCING ADMINISTRATION, HCFA LEGISLATIVE SUMMARY: THE OMNIBUS BUDGET RECONCILIATION ACT OF 1993, at 43 (1993), available at <http://www.cms.hhs.gov/relevantlaws/downloads/legislativesummaryforobraof1993.pdf>.

115. Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106-113, § 227, 113 Stat. 1501.

116. Lockridge, *supra* note 98, at 126-27; Press Release, White House, Balanced Budget Refinement Act of 1999: Highlights (Nov. 18, 1999), available at [www.hhs.gov/news/press/1999pres/19991118b.html](http://www.hhs.gov/news/press/1999pres/19991118b.html).

117. Pub. L. No. 106-554, 114 Stat. 2763.

118. Gordon, *supra* note 9, at 1055; Yen et al., *supra* note 101.

119. Gordon, *supra* note 9, at 1055.

Thus, unless ESRD patients continue to qualify for Medicare due to age or disability, their immunosuppression therapy ends three years after the transplant. Even though most kidney transplant patients suffer from a number of physical limitations and symptoms that limit the type and amount of work they can do,<sup>120</sup> they no longer qualify for lifetime immunosuppression drug therapy. As a result, they will have to pay the annual costs of the anti-rejection drugs, which many people of lesser financial means cannot afford because of the high cost of the drugs.<sup>121</sup> Thus, the current law pays for a lifetime of immunosuppressive drugs for those who continue to qualify for Medicare, but not to those younger than sixty-five or who are not otherwise disabled. Seemingly, then, there is not equal access to kidney transplantation.<sup>122</sup>

For years Congress was unsuccessful in trying to pass prescription drug coverage for seniors,<sup>123</sup> but in 2003 President George W. Bush signed into law the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Modernization Act or the MMA).<sup>124</sup> This was considered the most sweeping health care reform legislation since the 1965 passage of Medicare and Medicaid.<sup>125</sup> Although there were several attempts for an outpatient prescription drug benefit since Medicare's enactment, the MMA was the first prescription drug benefit for seniors and persons with disabilities.<sup>126</sup> This act was principally enacted presumably to cure the lack of Medicare coverage for outpatient prescription medications.<sup>127</sup>

In particular, President Bush and Congress stated their concern over the inability of senior citizens to afford prescription medica-

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120. *Id.*

121. EXTENDING MEDICARE COVERAGE, *supra* note 45, at 113 (reporting that costs may be as low as \$5900 to more than \$16,000 per year depending upon the regime that the patient needs); Kasiske et al., *supra* note 9, at 2446 (reporting that annual costs for immunosuppressive drug therapy may be as much as \$10,000 to \$14,000 for kidney transplant recipients); Yen et al., *supra* note 101 (reporting the annual cost of immunosuppressive medications to be between \$5000 to \$13,000).

122. Gordon, *supra* note 9, at 1055 ("This disproportionate coverage (based on disability) calls into question the meaning of entitlement or equity in treatment regardless of financial capacity.").

123. K. Shane Keene & Randy L. Byington, *Weighing in on the Medicare Prescription Drug Benefit Plan*, 4 INTERNET J. HEALTHCARE ADMIN., No. 2 (2007), <http://www.ispub.com/ostia/index.php?xmlFilePath=journals/ijhca/vol4n2/drug.xml>.

124. Pub. L. No. 108-173, 117 Stat. 2066.

125. Keene & Byington, *supra* note 123.

126. William P. Bro, *Importation of Prescription Drugs and Risks to Patient Safety*, 36 CAL. W. INT'L L.J. 105, 107 (2005).

127. Thomas R. Barker, *The Low-Income Subsidy in the New Medicare Drug Benefit*, 1 J. HEALTH & BIOMEDICAL L. 49, 49 (2005).

tions.<sup>128</sup> The MMA's drug benefit, the focal point of the law, took effect in January 2006.<sup>129</sup> Even with the MMA, those kidney recipients who no longer qualify for Medicare remain vulnerable to high medical costs. Further, the MMA banned direct government negotiation with drug manufacturers for lower drug prices,<sup>130</sup>—the very opposite of what the Clinton administration tried to accomplish with the advancement of the HSA.<sup>131</sup> This ban prompted the Democrats to introduce the Medicare Fair Prescription Drug Price Act of 2007, currently before the Senate, which would allow the government to negotiate lower drug prices with drug manufacturers.<sup>132</sup>

The benefits of the MMA are controversial. Some argue that it was a political move by the Republican Party to garner votes from senior citizens, but that both major political parties profited;<sup>133</sup> others found that the MMA provides elusive benefits to seniors and windfalls to the drug manufacturers and insurance companies.<sup>134</sup> What is clear is that still more is needed.

Thus, there have been several Congressional bills for comprehensive immunosuppressive drug therapy,<sup>135</sup> but no legislation has been

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128. *Id.* at 49-50.

129. Robert B. Doherty, *Assessing the New Medicare Prescription Drug Law*, 141 *ANNALS OF INTERNAL MED.* 391, 391 (2004); John K. Iglehart, *The New Medicare Prescription-Drug Benefit—a Pure Power Play*, 350 *NEW ENG. J. MED.* 826, 827 (2004).

130. LAUREN HUTCHENS, *THE HEALTH POLICY LANDSCAPE: 2001 AND BEYOND* 8 (2007), available at [http://www.forumsinstitute.org/pubs/nj/april\\_07.pdf](http://www.forumsinstitute.org/pubs/nj/april_07.pdf).

131. Health Security Act, H.R. 3600, 103d Cong. (1993), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=103\\_cong\\_bills&docid=f:h3600ih.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=103_cong_bills&docid=f:h3600ih.txt.pdf).

132. S. 3, 110th Cong. § 2.

133. See Richard L. Hall & Robert P. Van Houweling, *Campaign Contributions and Lobbying on the Medicare Modernization Act of 2003*, at 4 (May 30, 2006), [http://www.allacademic.com/meta/p\\_mla\\_apa\\_research\\_citation/1/5/0/4/6/pages150461/p150461-1.php](http://www.allacademic.com/meta/p_mla_apa_research_citation/1/5/0/4/6/pages150461/p150461-1.php).

134. See Melissa Ganz, *The Medicare Prescription Drug Act of 2003: Are We Playing the Lottery With Healthcare Reform?*, 2004 *DUKE L. & TECH REV.* 0011 (2004), available at <http://www.law.duke.edu/journals/dltr/articles/2004dltr0011.html>.

135. See, e.g., *Comprehensive Immunosuppressive Drug Coverage for Transplant Patients Act*, S. 173, 109th Cong. (2005); *Comprehensive Immunosuppressive Drug Coverage for Transplant Patients Act*, H.R. 2051, 109th Cong. (2005); *Comprehensive Immunosuppressive Drug Coverage for Transplant Patients Act*, S. 178, 108th Cong. (2003); *Comprehensive Immunosuppressive Drug Coverage for Transplant Patients Act*, H.R. 2223, 108th Cong. (2003); *Comprehensive Immunosuppressive Drug Coverage for Transplant Patients Act*, S. 1204, 107th Cong. (2001); *Comprehensive Immunosuppressive Drug Coverage for Transplant Patients Act*, S. 2399, 106th Cong. (2000); *Comprehensive Immunosuppressive Drug Coverage for Transplant Patients Act*, H.R. 5276, 106th Cong. (2000); *Immunosuppressive Drugs Coverage Act*, S. 631,

enacted. This brings us to where we are today: the Transplant Drug Act before the Senate.<sup>136</sup> The bill was introduced on August 1, 2007 and remains in the embryonic stages of the legislative process.<sup>137</sup> But would passage of the Transplant Drug Act make a difference?

### B. *Would Legislative Changes Make a Difference?*

Immunosuppressive drug therapy is the most significant health care expense after the three year post-transplant.<sup>138</sup> It has swiftly developed “as a major health care issue with implications for chronic rejection and graft loss.”<sup>139</sup> Chronic rejection is known as “any form of nonspecific late graft dysfunction[,]”<sup>140</sup> and is “the leading cause of late graft failure in renal transplant recipients.”<sup>141</sup> Because of the cost of immunosuppressive medications, many fail to comply with their post-transplant medical regimen.<sup>142</sup> Noncompliance with immunosuppressive drug therapy for kidney transplants is the third leading cause of graft loss.<sup>143</sup> Patients who are noncompliant with their immunosuppressive drug therapy lose their transplants or die at rates much greater than patients who comply.<sup>144</sup> Thus, medical compliance after a kidney transplant is critical to the maintenance of the transplanted kidney and the patient’s life.<sup>145</sup>

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106th Cong. (1999); Immunosuppressive Drug Coverage Extension Act, H.R. 1115, 106th Cong. (1999).

136. S. 2320, 110th Cong. (2007).

137. *Id.*

138. Willoughby et al., *supra* note 17, at 128.

139. Jindel et al., *supra* note 42, at 2868.

140. Winsett et al., *supra* note 23, at 19, 21; *see also* Phillip F. Halloran, *Immunosuppressive Drugs for Kidney Transplantation*, 351 *NEW ENG. J. MED.* 2715 (2004) (“The central issue in organ transplantation remains suppression of allograft rejection. Thus development of immunosuppressive drugs is the key to successful allograft function.”).

141. R.B. Isaacs et al., *Noncompliance in Living-Related Donor Renal Transplantation: The United Network of Organ Sharing Experience*, 31 *TRANSPLANTATION PROCEEDINGS* 19S (1999).

142. Yen et al., *supra* note 101, at 1707.

143. B. Siegal & S.M. Greenstein, *Profiles of Noncompliance in Patients with a Functioning Renal Transplant: A Multicenter Study*, 31 *TRANSPLANTATION PROCEEDINGS* 1326, 1326 (1999); *see also* Chisolm et al., *supra* note 45, at 1775 (“Nonadherence to [immunosuppressant therapy] after transplantation is one of the leading causes of allograft rejection, graft loss, and death.”).

144. Yen et al., *supra* note 101, at 1703.

145. Antonio Giuffrida & David Torgerson, *Should We Pay the Patient? Review of Financial Incentives to Enhance Patient Compliance*, 315 *BRIT. MED. J.* 703, 703 (1997) (“Compliance can be defined as the extent to which a patient’s behavior coincides with medical advice.”).

This is important because current Medicare law only allows for immunosuppressive drug therapy for a limited time post-transplant for individuals who no longer qualify for Medicare.<sup>146</sup> Thereafter, those individuals have to pay for the immunosuppressive drug therapy themselves, or with the assistance of others.<sup>147</sup> This is often difficult for those in low-income brackets, as shown by the case studies of Jessica and Emily.<sup>148</sup> “The inability to afford immunosuppressive agents is thought to underlie as many as half of all [noncompliance] cases.”<sup>149</sup> Thus, there is a direct correlation between lack of Medicare-sponsored immunosuppressive medication and noncompliance.

Health professionals have studied the effect of extending coverage of immunosuppressive medications by Medicare for kidney transplants in a variety of settings. By and large, the studies have concluded that Medicare’s extension of coverage of immunosuppressive medications would positively impact graft survival rates for low-income transplant recipients.<sup>150</sup> In fact, the conclusion is that when there is equal access to immunosuppressive medications, there are no differences in graft survival rates for kidney transplant patients.<sup>151</sup>

One study evaluated the last two years in which Medicare paid for immunosuppressive medication for only one year, 1992 to 1993, and the first few years in which Medicare paid for three years of immunosuppressive medication, 1995 to 1997.<sup>152</sup> The study revealed the following: “Low income did affect graft survival in the second and third years post-transplant, but only during the period in which Medicare did not pay for immunosuppressant medications.”<sup>153</sup> Thus, the two year extension that Medicare granted post-1993 was critical to the graft survival of those who could not afford to pay for the medications after the end of the government’s assistance with immunosuppressive medications.

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146. 42 U.S.C. § 1395 (2006).

147. See, e.g., Kasiske et al., *supra* note 9, at 2446.

148. See discussion *supra* Part I.

149. Willoughby et al., *supra* note 17, at 127 (noting also that this noncompliance may be partly a result of loss of or lack of health insurance coverage).

150. See, e.g., Robert S. Woodward et al., *Effect of Extended Coverage of Immunosuppressive Medications by Medicare on the Survival of Cadaveric Renal Transplants*, 1 AM. J. TRANSPLANTATION 69, 73 (2001); Yen et al., *supra* note 101, at 1707.

151. Woodward et al., *supra* note 150, at 73.

152. *Id.* at 70. The study only evaluated those patients who received first cadaveric renal transplants and not patients who received living donor kidneys, multi-organ transplants, or those who had a previous transplant.

153. *Id.*

Based on the results of this study, another group of health professionals conducted a separate study “to estimate the expected economic and clinical effects of extending Medicare immunosuppressive coverage availability from three years to the life of the transplanted kidney.”<sup>154</sup> This study revealed that extending Medicare immunosuppressive coverage for a lifetime will result in societal savings as well as reduced risks of transplant failure and death in those who cannot afford to pay the cost of the immunosuppressive medications—those with low incomes.<sup>155</sup>

Another study revealed that patients who were most likely not to comply with the immunosuppressant regime were younger, female, single, and non-white,<sup>156</sup> but these are generally the very same individuals who make up the low-income population.<sup>157</sup> Moreover, workers in low-income families have more health problems than workers in middle-income families.<sup>158</sup> Therefore, it is not surprising that non-compliance is directly correlated to the inability to afford the immunosuppressive drug therapy. In sum, a lifetime of immunosuppressive drug therapy would have an equally positive impact in kidney transplantation even amongst people with varied incomes.

### C. What Would this Legislative Change Mean?

#### 1. For the Kidney Recipient

Immunosuppressive drug therapy is the most daunting cost for the kidney recipient.<sup>159</sup> However, patients may obtain help in paying for these expensive medications. For example, such assistance may come from employer-sponsored health insurance, private insurance (Medigap insurance, for example), Medicare, Medicaid, charitable organizations, family, or pharmaceutical company assistance programs.<sup>160</sup> Yet, these varying methods of assistance are not guaranteed, are usually for a short term only, and often have income-limits tied to

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154. Yen et al., *supra* note 101, at 1704.

155. *Id.* at 1707.

156. Chisholm et al., *supra* note 45, at 1776 (noting that noncompliance is more common amongst blacks, Hispanics, younger adults, singles, and those who have had their transplants for a longer time and that low income patients were less compliant than patients in higher socioeconomic groups); Jindel et al., *supra* note 42, at 2871.

157. See GREGORY ACS & PAMELA LOPREST, URBAN INST., WHO ARE LOW-INCOME WORKING FAMILIES? 4-6 (2005), available at [http://www.urban.org/UploadedPDF/311242\\_working\\_families.pdf](http://www.urban.org/UploadedPDF/311242_working_families.pdf) (describing low income families as comprising younger adults, minorities and single parents).

158. *Id.* at 6.

159. See Kasiske et al., *supra* note 9.

160. *Id.* at 2446-47; see also Chisholm et al., *supra* note 45, at 1780.

them as well as an application process.<sup>161</sup> Most troubling, when Congress passed BIPA in 2000, some pharmaceutical companies terminated their assistance programs for Medicare beneficiaries *because* the government extended its coverage for the immunosuppressive medications.<sup>162</sup> This means less help for those who need the most help.

In addition to the yearly costs of the anti-rejection medications, there are other costs associated with kidney transplants that are often overlooked. Patients, even those with sufficient health insurance coverage, may also have to pay for transportation, housing, and food for evaluation or follow up visits to the transplant centers; costs for time away from work for them and their family members; insurance premiums; deductibles; and co-payments.<sup>163</sup> Patients may also require other outpatient medications, such as antihypertensive agents and antibiotics for infections, which Medicare does not cover.<sup>164</sup> Thus, passage of the Transplant Act would reduce, but not eliminate, the financial and emotional burdens of kidney recipients, improve patient access, and improve compliance with the immunosuppression regimen.<sup>165</sup> This would then reduce loss of the transplanted kidney, thereby reducing Medicare spending for re-transplantation or dialysis.<sup>166</sup>

## 2. *For the Federal Government*

Congress engaged the Institute of Medicine (IOM) on a few occasions to evaluate the ESRD program and the feasibility of extending the strict time limitations for immunosuppressive drug therapy.<sup>167</sup> IOM recommended more than once that Congress eliminate the three year limit.<sup>168</sup>

In 1987, IOM recommended that "Congress eliminate the three-year limit on Medicare eligibility for ESRD patients who are successful transplant recipients and authorize an entitlement equal to that of ESRD patients who are treated by dialysis."<sup>169</sup> Congress responded by

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161. Kasiske et al., *supra* note 9, at 2446-47.

162. Marie A. Chisholm, *Increasing Transplant Patients' Access to Medications: Medicare and Beyond*, 58 AM. J. HEALTH-SYS. PHARMACY 2081 (2001).

163. Kasiske et al., *supra* note 9, at 2446.

164. EXTENDING MEDICARE COVERAGE, *supra* note 45.

165. *Id.* at 22.

166. *Id.*

167. Kasiske et al., *supra* note 9, at 2446 (referring to a 1987 IOM study to evaluate the ESRD program and a 1997 study to evaluate the extension of immunosuppressant drugs beyond three years).

168. *Id.*

169. *Id.*

extending immunosuppressive drug coverage from one to three years.<sup>170</sup>

Then, in 1997, Congress requested that IOM study the issue of further extending immunosuppressive drug therapy beyond the three years.<sup>171</sup> Two years later, Congress extended the three-year time limit temporarily for another eight months under very limited guidelines.<sup>172</sup> Ultimately, this three-year limit was extended for a lifetime, but only for those who continue to qualify for Medicare due to age or disability.<sup>173</sup> But what about the others like Jessica and Emily who may no longer qualify for Medicare after transplantation?

The main reason that lifetime immunosuppressive therapy has not been granted to all patients qualifying under the ESRD program (irrespective of age or disability) is because of the estimated costs of such an entitlement.<sup>174</sup> But several years ago, IOM engaged a research group to study the estimated costs of such entitlement, and the conclusion was that a *savings* would result because the accessibility of immunosuppressive drug therapy would reduce the kidney allograft failure rate.<sup>175</sup> This study, of course, assumed some variables not currently in play. For example, the study assumed, amongst other variables, that: the MSP requirement would extend from thirty months to an indefinite period, thus reducing by twenty-five percent the number of patients who would burden Medicare; that the annual cost of immunosuppressive drug therapy in 2000 would be \$5400 with a yearly increase of four percent; and that the cost would include a twenty percent co-payment and a five percent wholesale discount.<sup>176</sup> Thus, this resulted in an estimated cost savings of over \$500 million.<sup>177</sup> Another study with present day variables would be beneficial, but nevertheless, it appears that the end result would be a savings to the government.

In addition, for the past several years, Congress has considered several drug bills, often in several iterations, but most of them have

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170. Budget Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 312.

171. Kasiske et al., *supra* note 9, at 2446.

172. *See supra* notes 113-14 and accompanying text.

173. *See supra* notes 115-16 and accompanying text.

174. Kasiske et al., *supra* note 9 (noting that the question of how to pay for immunosuppressive drug therapy, the key to the success to organ transplantation, has plagued Congress for many years).

175. *Id.* at 2448 (emphasis added).

176. *Id.*

177. *Id.* at 2449; *see also* Yen et al., *supra* note 101 (calculating an expected discounted savings to society from lifetime coverage of \$136 million annually).



failed.<sup>178</sup> There are a handful of other bills presently under consideration that impact prescription drugs: Pharmaceutical Market Access and Drug Safety Act of 2007,<sup>179</sup> Pharmaceutical Market Access Act of 2007,<sup>180</sup> Medicare Fair Prescription Drug Price Act of 2007,<sup>181</sup> and Prescription Drug Affordability Act of 2007.<sup>182</sup> Although passage of these bills will not solve America's health care crises, they will allow greater access to cheaper drugs for the American people.

Prescription drugs are one of the fastest growing costs in the health care industry.<sup>183</sup> America can expect some immediate and sweeping changes because President Barack Obama supports access to cheaper drugs for Americans. For example, President Obama believes that the ban on allowing Medicare to directly negotiate with drug companies for cheaper drugs should be repealed.<sup>184</sup> Such a bill is presently pending before Congress in the Medicare Fair Prescription Drug Price Act of 2007.<sup>185</sup> He also supports allowing importation of prescription drugs to the United States.<sup>186</sup> The same drugs sold in the United States are often sold for about sixty percent less in foreign countries, such as Canada and those in Europe.<sup>187</sup> Finally, President Obama advocates the use of generic drugs when available and would prevent the major drug companies from paying generic drug companies from introducing their products to the market so that the brand name drug companies can continue to charge exorbitant prices for drugs.<sup>188</sup> In the first few weeks of his administration, President Obama called for an overhaul of the United States health care system,

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178. See, e.g., Medicare Prescription Drug Price Negotiation Act of 2007, H.R. 4, 110th Cong.; Prescription Drug Affordability Act, H.R. 194, 110th Cong. (2007); Medicare Prescription Drug Price Reduction Act, S. 445, 109th Cong. (2005); Safe IMPORT Act of 2004, S. 2493, 108th Cong.; Pharmaceutical Freedom Act of 2000, H.R. 3636, 106th Cong.

179. Pharmaceutical Market Access and Drug Safety Act of 2007, S. 242, 110th Cong.

180. Pharmaceutical Market Access Act of 2007, S. 251, 110th Cong.

181. Medicare Fair Prescription Drug Price Act of 2007, S. 3, 110th Cong.

182. H.R. 194.

183. KAREN DAVIS ET AL., SLOWING THE GROWTH OF U.S. HEALTH CARE EXPENDITURES: WHAT ARE THE OPTIONS? 4 (2007).

184. BarackObama.com, Barack Obama and Joe Biden's Plan to Lower Health Care Costs and Ensure Affordable, Accessible Health Coverage for All, <http://www.barackobama.com/pdf/issues/HealthCareFullPlan.pdf> (last visited Jan. 2, 2009).

185. S. 251.

186. BarackObama.com, *supra* note 184.

187. PATENTED MED. PRICES REVIEW Bd., ANNUAL REPORT 9 (2002).

188. BarackObama.com, *supra* note 184.

including a reform of our country's prescription drug policies.<sup>189</sup> This is because America's health care system is broken as a whole, and in particular with respect to life-saving prescription drugs for kidney transplantation.

### III. RECOMMENDATIONS

Immunosuppressive medications should be provided by the federal government for people who cannot afford them. Passage of the Transplant Drug Act is a good start, and this would have a significant impact on those who would not qualify for Medicare after the three year limit (like Emily), and thus, would have to pay the full amount for immunosuppressive medications.

However, more is needed. Individuals in Jessica's position, who may continue to qualify for Medicare due to age or disability, are unable to pay the co-payments and deductibles for the immunosuppressive medications.<sup>190</sup> These are often the individuals who have fixed incomes, like a monthly disability check. Thus, Medicare should cover 100% of the cost of immunosuppressive medications, not just eighty percent, as the current Transplant Drug Act pending before the Senate provides.

Prior bills to eliminate the three year time limitation have not passed due to funding concerns,<sup>191</sup> and elimination of the twenty percent co-payments would undoubtedly increase funding concerns. Nevertheless, elimination of the twenty percent contribution is critical as it can "lead to nonadherence with the prescribed medication regime, potential organ dysfunction, organ loss or even death."<sup>192</sup> Further, when considering the costs of re-transplantation and dialysis, as compared to organ transplant maintenance, Congress cannot afford to fail to pass legislation funding the elimination of the three year time limitation, and even the elimination of the twenty percent co-payments.<sup>193</sup>

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189. See *Obama Calls for Overhaul of U.S. Health Care System*, *supra* note 106.

190. Gordon, *supra* note 9, at 1053 (noting that co-payments for immunosuppressive medications may range from \$167 to \$233 per month).

191. *Bill Eliminating 3-Year Time Limitation on Medicare Coverage for Kidney Transplants Introduced in Senate*, TRANSPLANT NEWS, Dec. 2007, [http://findarticles.com/p/articles/mi\\_m0YUG/is\\_/ai\\_n24241935](http://findarticles.com/p/articles/mi_m0YUG/is_/ai_n24241935) ("Legislation eliminating the three-year time limitation on coverage has been introduced in previous congresses wit bipartisan support but there has never been enough money to fund it.").

192. NATCO, *supra* note 9.

193. *GAO Study Finds Lifetime Immunosuppressant Drug Coverage Saves Money, Improves Patient Outcomes*, TRANSPLANT NEWS, Nov. 2007, [http://findarticles.com/p/articles/mi\\_m0YUG/is\\_/ai\\_n27457827](http://findarticles.com/p/articles/mi_m0YUG/is_/ai_n27457827) (reporting that a failed transplant costs 500 percent more than maintenance of a functioning transplant).

Elimination of the co-payments and deductibles is not without precedent. In 1965, the SSA assisted seniors with premiums, deductibles, co-payments and other uncovered costs.<sup>194</sup>

Jessica and Emily's problems also bring into focus something even greater. Even with the passage of the Transplant Act, there is still much to be desired in America's non-existent comprehensive health care coverage for its citizens. Americans need universal health care. Indeed, President Obama believes that "health care is a right for every American."<sup>195</sup> Americans can expect a significant overhaul to its current health care system.<sup>196</sup>

It is understandable that developing countries do not have universal health care, but the United States is the only industrialized country without universal health care.<sup>197</sup> Yet, the United States has access to more advanced medical care than many other countries. That is, in the United States, the poor have very limited or no access to health care and the wealthy have access to as much health care as they desire. This disparity in health care directly impacts ESRD, and the number of people suffering with ESRD is growing rapidly.<sup>198</sup> The ESRD program was passed with the understanding that a national health insurance program was on the way;<sup>199</sup> but to date, Americans still lack universal health care. The ESRD program was also passed in an effort to encourage kidney transplants.<sup>200</sup> But without adequate funding to ensure that those with ESRD can pay for the costly immunosuppres-

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194. Almanac of Policy Issues, *supra* note 54; *see also supra* Part II.A (stating that Congress passed the SSA in 1965, which included "expansion of an existing program to assist seniors with out of pocket costs, such as premiums, deductibles, co-payments, and other uncovered costs").

195. Joe Klein, *The Obama Surge: Will It Last?*, TIME, Oct. 9, 2008, available at <http://www.time.com/time/politics/article/0,8599,1848518,00.html>.

196. *A Start on Health Care Reform*, N.Y. TIMES, Mar. 7, 2009, available at <http://www.nytimes.com/2009/03/08/opinion/08sun1.html> (stating that President Barack Obama has committed to infusing \$634 billion into health care reform over the next ten years).

197. Maxwell J. Mehlman, "Medicover": A Proposal for National Health Insurance, 17 HEALTH MATRIX 1, 3 (2007).

198. David Tuller, *Kidney Disease Takes a Growing Toll*, N.Y. TIMES, Nov. 17, 2008, available at [http://www.nytimes.com/2008/11/18/health/18kidneydisease.html?\\_r=1&scp=2&sq=chronic+kidney+disease&st=nyt](http://www.nytimes.com/2008/11/18/health/18kidneydisease.html?_r=1&scp=2&sq=chronic+kidney+disease&st=nyt).

199. Nancy Kutner, Coverage and Cost: What Has a 30 Year American "Experiment in National Healthcare" Shown? 2 (2005), [http://www.allacademic.com//meta/p\\_mla\\_apa\\_research\\_citation/0/2/1/8/0/pages21809/p21809-1.php](http://www.allacademic.com//meta/p_mla_apa_research_citation/0/2/1/8/0/pages21809/p21809-1.php).

200. Ctrs. for Medicare & Medicaid Servs., Overview ESRD (Jan. 27, 2009), <http://www.cms.hhs.gov/esrdgeneralinformation/>.

sive medications, kidney transplants remain an option primarily for the well-to-do.

#### CONCLUSION

Transplant professionals are aggressively debating overturning the ban of the sale of human organs in the United States, which would presumably result in the rich legally purchasing organs from the poor.<sup>201</sup> But this would be absolute irony: If the United States overturns the ban on the purchase and sale of human organs, as many transplant professionals are proposing, then the group of persons who would be likely targets for selling their organs—poor people—would be most likely not to financially qualify to be a kidney recipient in the event they needed a kidney. There are a limited number of kidneys and they are being doled out to those who can afford to maintain the life of the kidney. Health care in America must be more accessible to more people. And as one senator in favor of passage of one of the earlier ESRD bills asked: “How do we explain that the difference between life and death is a matter of dollars?”<sup>202</sup>

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201. See generally Jennifer M. Smith, “Dirty Pretty Things” and the Law: Curing the Organ Shortage and Health Care Crises in America, 12 *CHAP. L. REV.* 361 (2009).

202. Lisa Raiz, *The Transplant Trap: The Impact of Health Policy on Employment Status Following Renal Transplantation*, 8 *J. HEALTH & SOC. POL’Y* 67, 68 (1997) (quoting Senator Vance Hartke).

