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## WHAT SCRIBNER WROUGHT: HOW THE INVENTION OF MODERN DIALYSIS SHAPED HEALTH LAW AND POLICY

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### I. INTRODUCTION

In March 1960, Clyde Shields, a machinist dying from incurable kidney disease, was connected to an “artificial kidney” by means of a U-shaped Teflon tube that came to be known as the Scribner shunt.<sup>1</sup> By facilitating long-term dialysis, Dr. Belding Scribner’s invention changed chronic kidney failure from a fatal illness to a treatable condition.<sup>2</sup> A half-century after this milestone, there are now more than 1.6 million people throughout the world on maintenance dialysis.<sup>3</sup>

This medical advancement has, in turn, had a profound impact on key areas of health law and policy. This paper focuses on the historical roots and current context of three interrelated areas: ethical allocation of scarce medical resources; public financing of expensive health care; and decisions to stop treatment for non-medically indicated reasons.

One of the earliest issues raised by the invention of modern dialysis was the determination of who would receive the life-saving treatment when there were more medically eligible patients than could be accommodated.<sup>4</sup> To make these difficult decisions, the medical team in Seattle turned to an anonymous, unpaid group of community members who came to be known as the “God Committee.”<sup>5</sup> The work of this

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1. ALBERT R. JONSEN, *THE BIRTH OF BIOETHICS* 211 (1998).

2. *Id.*

3. Christopher Blagg, *The First Dialysis for Chronic Renal Failure 50 Years Ago*, 14 *HEMODIALYSIS INT’L* 1, 2 (forthcoming Jan. 2010).

4. JONSEN, *supra* note 1, at 212.

5. Shana Alexander, *Thirty Years Ago*, 23 *HASTINGS CTR. REP. (SPECIAL SUPPLEMENT)* S-5 (Nov. 1993).

committee, and the public controversy about it, has been cited as marking the birth of bioethics.<sup>6</sup>

The public controversy regarding the limited access to dialysis inspired the only disease-specific coverage under Medicare.<sup>7</sup> The unexpectedly high costs of this program have served as a cautionary tale for other attempts to establish public funding for catastrophically high medical expenses. Today, ameliorating the impact of catastrophic expenses on individuals is a focus of the health reform effort.

The expansion of dialysis services, particularly with the establishment of Medicare coverage, forced the question whether treatment could be stopped for non-medically indicated reasons.<sup>8</sup> Dealing with difficult, noncompliant patients tested emergency obligations and the law on patient abandonment.<sup>9</sup> Those legal issues are now at the forefront of a lawsuit involving undocumented immigrants whose dialysis facility recently closed for economic reasons.<sup>10</sup>

Inevitably, lawmakers, courts, and laypeople will continue to grapple with issues raised by new, expensive, life-saving technology for chronic conditions. The adoption of national health insurance reform may well ameliorate cost and access concerns for millions of individual patients and their families. It is also likely, however, to heighten those concerns on a general, societal level. Thus, at the fiftieth anniversary of the invention of the Scribner shunt, it is appropriate to consider the history and current context of a medical advance that has raised challenging legal, ethical, and policy issues in spades.

## II. THE SCRIBNER SHUNT

“When you haven’t kidneys (via trauma, surgery or disease) you aren’t anymore in a matter of days.”<sup>11</sup> These two fist-size organs remove waste products from the blood, regulate the salt and water balance in the body, and rid the body of excess fluid.<sup>12</sup> One or both can

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6. Report of the Conference, *The Birth of Bioethics*, 23 HASTINGS CTR. REP. (SPECIAL SUPPLEMENT) S-1 (Nov. 1993) [hereinafter “*The Birth of Bioethics*”].

7. JONSEN, *supra* note 1, at 214.

8. *See generally id.* at 233.

9. *See infra* Part V.A.

10. Kevin Sack, *Hospital Falers as Refuse for Illegal Immigrants*, N.Y. TIMES, Nov. 21, 2009, at A1.

11. George E. Schreiner, *How End-Stage Renal Disease (ESRD)-Medicare Developed*, 35 AM. J. KIDNEY DISEASES (SUPPLEMENT 1) 37, 37 (2000).

12. Nat’l Kidney Found., *How Your Kidneys Work*, [http://www.kidney.org/kidneydisease/how\\_kidneyswrk.cfm](http://www.kidney.org/kidneydisease/how_kidneyswrk.cfm) (last visited Mar. 15, 2010).

fail, either temporarily or permanently, for reasons that include congenital abnormalities, primary kidney disease, diabetes, toxins, high blood pressure, and trauma.<sup>13</sup> The permanent failure of both kidneys is known as End-Stage Renal Disease (“ESRD”).<sup>14</sup> Until fifty years ago, it was invariably fatal.

Dr. Willem J. Kolff developed the first effective “artificial kidney,” a hemodialysis machine, in 1939 in the Netherlands during the Nazi Occupation.<sup>15</sup> The basic function of Kolff’s machine is the same as in modern hemodialysis processes (“dialysis”): blood circulates from the patient’s body into the machine, passing alongside a membrane through which the toxins and excess fluid exit into the dialysate fluid, and then the blood, enriched by needed chemicals, is returned to the patient’s body.<sup>16</sup> Connecting a patient to Kolff’s machine required surgery that destroyed an artery and a vein each time it was done. Thus, it was an option only for patients with acute, reversible kidney failure (such as from trauma or poisoning) whose blood could be cleansed in a few treatments and whose kidneys likely would resume functioning on their own.<sup>17</sup> For decades following Kolff’s invention, vascular access was the Achilles heel of chronic dialysis.

Dr. Belding H. Scribner, a University of Washington nephrologist, awoke one night in 1960 troubled by this Achilles heel in the case of a particular patient. This patient, an otherwise healthy man in his thirties, had been diagnosed with irreversible kidney failure and thus sent home from the hospital to die, which he did within two weeks.<sup>18</sup> As Dr. Scribner relayed in an interview: “I woke up and groped for a piece of paper to jot down the basic idea of the shunted cannula which would make it possible to treat people like Joe Saunders again and again with the artificial kidney without destroying two blood vessels each time.”<sup>19</sup>

A permanent U-shaped tube (a cannula), partially indwelling and partially external, would connect an artery to a vein at the arm or leg,

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13. *Id.*

14. Nat’l Kidney Found., End Stage Renal Disease in the United States (Mar. 2008), [http://www.kidney.org/news/newsroom/fs\\_new/esrdinus.cfm](http://www.kidney.org/news/newsroom/fs_new/esrdinus.cfm) (last visited Mar. 15, 2010).

15. JONSEN, *supra* note 1, at 211. Dr. Kolff later immigrated to the United States and practiced at the Cleveland Clinic, where he continued to do ground-breaking work in the development of artificial organs. RENÉE C. FOX & JUDITH P. SWAZEY, THE COURAGE TO FAIL: A SOCIAL VIEW OF ORGAN TRANSPLANTATION AND DIALYSIS 215, 335 (1974).

16. Nat’l Kidney Found., Treating Kidney Failure with Hemodialysis, [http://www.kidney.org/patients/plu/plu\\_hemo/pluo\\_3.cfm](http://www.kidney.org/patients/plu/plu_hemo/pluo_3.cfm) (last visited Mar. 15, 2010).

17. *Id.*

18. FOX & SWAZEY, *supra* note 15, at 202.

19. *Id.*

with a valve allowing repeated access to the dialysis machine.<sup>20</sup> Another physician suggested to Dr. Scribner during a hallway consultation, that he use tubing made of Teflon, a recent invention.<sup>21</sup> University of Washington mechanical engineer Wayne Quinton, who was the head of the Medical Instrument Shop, worked with the substance to arrive at an appropriate shape, a milestone in the now-robust field of bioengineering.<sup>22</sup> The shunt

consisted of 2 Teflon cannulas with tapered tips to insert in the artery and vein, a stainless-steel arm plate to which were attached quick connectors (Swagelok stainless-steel standard plumbing devices) to enable connection of the cannulas and the shunt so the latter could be readily removed to allow connection of the artery and vein to the dialyzer.<sup>23</sup>

On March 9, 1960, David Dillard, M.D., a pediatric cardiac surgeon, sutured this device, which came to be known as the Scribner shunt, into the forearm of thirty-nine-year-old machinist Clyde Shields, who was dying of irreversible kidney failure.<sup>24</sup> It worked. His initial dialysis session lasted seventy-six hours.<sup>25</sup> Thereafter, Mr. Shields received regular dialysis, initially once a week and later two or three times a week for up to twelve hours at a time, and lived eleven more years.<sup>26</sup> The fifth patient treated by the team lived thirty-six years after his shunt was implanted.<sup>27</sup> Vascular access is still a critical issue in maintenance dialysis.<sup>28</sup> The Scribner shunt evolved and has been replaced by the

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20. Thomas R. McCormick, *Ethical Issues in Caring for Patients with Renal Failure*, 20 NEPHROLOGY NURSING J. 549 (1993).

21. *Id.* Teflon was originally suggested because this inert substance did not cause tissue reaction. An important, and initially unrecognized, benefit of the material is that its non-stick properties prevented blood clotting in the tubing. See Videotape: Medicare + Medicaid at 40 (Kaiser Family Found. 2005), available at <http://www.kff.org/medicaid/40yearsvideo.cfm>.

22. Blagg, *supra* note 3.

23. *Id.*

24. *Id.* at 1. The team did not test the shunt in an animal first, as would be required under current regulations. Dr. Scribner later said that if they had, it might not have worked. That is because a dog would probably have been used, and a canine clots more readily. Interview by Christopher Blagg, M.D. with Belding Scribner, M.D., Albert Babb and Wayne Quinton, Nw. Kidney Ctrs., in Seattle, WA (1982) (on file with author).

25. Blagg, *supra* note 3, at 1.

26. *Id.*

27. Lawrence K. Altman, *Dr. Belding H. Scribner, Medical Pioneer, Is Dead at 82*, N.Y. TIMES, June 22, 2003, at A34. The original shunts had a variety of problems and needed to be replaced frequently. *See id.*

28. Vinod K. Bansal, *Vascular Access: Early Nephrology Referral, Team Approach, and Access Preservation Are Key*, 2 NEPHROLOGY TIMES 16, 16 (2009), available at [http://journals.lww.com/nephrologytimes/Fulltext/2009/03000/Vascular\\_Access\\_\\_Early\\_Nephrology\\_Referral\\_Tea](http://journals.lww.com/nephrologytimes/Fulltext/2009/03000/Vascular_Access__Early_Nephrology_Referral_Tea)

arteriovenous fistula.<sup>29</sup> In this procedure, an artery and vein, usually in the arm, are sewn together, to create a connection (a fistula); arterial pressure eventually enlarges the vein allowing it to accommodate dialysis cannulas.<sup>30</sup> Worldwide, there are now more than 1.6 million people on maintenance dialysis.<sup>31</sup>

In January 1962, the Seattle Artificial Kidney Center opened in the basement of a building associated with Swedish Hospital near downtown Seattle.<sup>32</sup> The world's first out-of-hospital dialysis center initially had three machines and the ability to treat approximately nine patients in total with biweekly overnight dialysis.<sup>33</sup>

### III. ALLOCATION OF SCARCE MEDICAL RESOURCES

#### A. The “God Committee”

One of the earliest issues was the determination who should receive the life-saving treatment. There were more medically eligible patients than the original few dialysis machines could treat, even when knowledge of this treatment breakthrough was limited and “medically eligible” was narrowly defined to include only patients who had no other complicating conditions.<sup>34</sup> Those involved with the new center reasoned that selection amongst the eligible patients should not be left to physicians and should reflect community input.<sup>35</sup>

Thus, the executive committee of the King County Medical Society established a selection committee comprised of seven unpaid, anonymous community members.<sup>36</sup> Officially named the “Admissions and Policies Committee of the Seattle Artificial Kidney Center at Swedish Hospital,” in various accounts it was termed the “Life or Death

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29. *Id.*

30. This technique was first described in a 1966 *New England Journal of Medicine* article. Michael J. Brescia et al., *Chronic Hemodialysis Using Venipuncture and a Surgically Created Arteriovenous Fistula*, 275 *NEW ENG. J. MED.* 1089 (1966).

31. Blagg, *supra* note 3.

32. *Id.*

33. McCormick, *supra* note 20, at 549. Its name was later changed to the Northwest Kidney Centers. See Northwest Kidney Centers, <http://www.nwkidney.org/> (last visited Mar. 15, 2010).

34. Christopher Blagg, *The Early History of Dialysis for Chronic Renal Failure in the United States: A View from Seattle*, 49 *AM. J. OF KIDNEY DISEASES* 482, 485 (2007).

35. McCormick, *supra* note 20, at 550.

36. Blagg, *supra* note 34.

Committee,”<sup>37</sup> the “Seattle Committee,”<sup>38</sup> the “God Squad,”<sup>39</sup> and the “God Committee.”<sup>40</sup>

This committee received a great deal of attention, in both the popular media and in academic circles. *Life* magazine sent journalist Shana Alexander to report on the invention of the Scribner shunt and its life-saving potential.<sup>41</sup> Ms. Alexander shifted the story’s focus and wrote an article for the November 9, 1962 issue that centered on the committee and its decision-making process.<sup>42</sup> Most of the opening two pages of her article are taken up with a picture of the committee’s members sitting in shadows and the article’s title: “They Decide Who Lives, Who Dies: Medical Miracle and a Moral Burden of a Small Committee.”<sup>43</sup> At 10,000 words, this was the longest article ever published in *Life*.<sup>44</sup>

Ms. Alexander’s article describes the “Life or Death Committee” as consisting of “a lawyer, a minister, a banker, a housewife, an official of state government, a labor leader and a surgeon.”<sup>45</sup> Except for the housewife, all were men.<sup>46</sup> They were given very little guidance by the medical team on what selection criteria to use.<sup>47</sup> Ms. Alexander quotes a committee member as saying that at the first meeting they considered selecting candidates by lottery.<sup>48</sup>

Ultimately, however, they decided to consider a number of factors, including: “age and sex of patient; marital status and number of dependants; income; net worth; emotional stability, with particular regard to the patient’s capacity to accept the treatment; educational

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37. Shana Alexander, *They Decide Who Lives, Who Dies*, LIFE, Nov. 9, 1962, at 106.

38. David Sanders & Jesse Dukeminier, Jr., *Medical Advance and Legal Lag: Hemodialysis and Kidney Transplantation*, 15 UCLA L. REV. 357, 378 (1967).

39. Albert R. Jonsen, *The God Squad and the Origins of Transplantation Ethics and Policy*, 35 J.L. MED. & ETHICS 238, 238 (2007).

40. Alexander, *supra* note 5.

41. *Id.*

42. *Id.*

43. Alexander, *supra* note 37, at 102–03.

44. Videotape: Excerpts from Conference on the Birth of Bioethics (Univ. of Wash. Health Scis. Ctr. for Educ. Res. 1992) (on file with the Univ. of Wash. Library) [hereinafter “1992 Conference”]. In her presentation to this 1992 conference, Ms. Alexander recalled this as “the most awesome and disturbing story I have ever worked on.” *Id.*

45. Alexander, *supra* note 37.

46. *Id.* at 102–03.

47. *Id.* at 106. The medical team recommended that the committee reject candidates over the age of forty-five, because of the likelihood of other serious medical complications, and reject children, because of likely treatment difficulties. *Id.* The committee decided to further limit the pool to only Washington state residents. *Id.* The committee members decided that they wanted to remain anonymous and to not know the names of the patients whose applications came before them. *Id.*

48. *Id.* at 123.

background; nature of occupation, past performance and future potential; and names of people who could serve as references.”<sup>49</sup> They struggled with whether the goal should be to select those whose lives had the greatest potential or those whose deaths would impose the greatest burden.<sup>50</sup> Renée Fox and Judith Swazey’s 1974 book *The Courage to Fail: A Social View of Organ Transplants and Dialysis* includes a detailed, compelling chapter on the Seattle Committee, the patients it considered, and its decision-making process.<sup>51</sup>

In the deliberations portrayed in the *Life* article, the committee is to select for dialysis two out of five candidates, all of whom they are to assume will die within a few weeks without treatment.<sup>52</sup> The housewife comments that considering the highest potential to serve society suggests choosing the most highly educated, who are a chemist and an accountant.<sup>53</sup> The banker counters that perhaps these two should be ruled out because they are well-off, have made provisions for their families, and thus their deaths will not cause a burden on society.<sup>54</sup>

The surgeon notes that the small businessman is active in his church, which perhaps indicates character and moral strength that would be useful in dealing with the significant difficulties of dialysis.<sup>55</sup> The lawyer responds that being active in church might actually help him endure an early death.<sup>56</sup> And the minister, the chair of the committee, notes that some churches are more active than others.<sup>57</sup> All comment on the number and ages of the patients’ children, with the labor leader suggesting that “a woman with three children has a better chance to find a new husband than a very young widow with six children.”<sup>58</sup> After weighing these and a variety of other factors, the committee selects for dialysis the businessman active in his church and the aircraft worker with six children.<sup>59</sup> Not chosen are the chemist, the accountant, and a

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49. *Id.* at 106.

50. *Id.* at 110.

51. FOX & SWAZEY, *supra* note 15, at 240–80.

52. Alexander, *supra* note 37, at 110.

53. *Id.*

54. *Id.*

55. *Id.*

56. *Id.*

57. *Id.* The minister, John Darrah, wrote a very interesting article, published in 1987, about his time on the committee. John B. Darrah, *The Committee*, 33 TRANS. AM. SOC. ARTIFICIAL INTERNAL ORGANS J. 791 (1987).

58. Alexander, *supra* note 37, at 110.

59. *Id.*

housewife (who seemed to lack the financial resources to move to Seattle for treatment.)<sup>60</sup>

This type of selection process reflects an “ethical muddle, and worse,” charged David Sanders and Jesse Dukeminier in their influential 1967 law review article.<sup>61</sup> The *Life* piece and a similar one in *Redbook*<sup>62</sup> provide “numbing accounts of how close to the surface lie the prejudices and mindless clichés,” that measure worth by a “middle-class suburban value system” and would disfavor creative non-conformists.<sup>63</sup> “The Pacific Northwest is no place” they write, “for a Henry David Thoreau with bad kidneys.”<sup>64</sup>

Publicity about the promises and challenges of dialysis received further airing in a 1965 NBC documentary entitled “Who Shall Live?”<sup>65</sup> The documentary is similar in style to the *Life* magazine article (including the depiction of the committee in shadows) but adds an extra focus on the costs of treatment. The documentary notes that the Seattle Artificial Kidney Center received significant grants and donations, but, even so, patients were expected to guarantee \$10,000 a year for three years.<sup>66</sup> In 2009 dollars, using the Federal Reserve inflation calculator, that amount would be about \$68,000 a year.<sup>67</sup>

The documentary discusses how patients raised the needed money, or not. It features the efforts of the small, scenic town of Shelton, Washington to raise \$30,000 for a young milkman named Buddy Franklin.<sup>68</sup> The “Bucks for Buddy” campaign included pancake breakfasts, bake sales, and a radio announcer’s daily pitches for support. “Buddy Franklin is going to die,” says the radio announcer, “unless you

60. *Id.* The article includes pictures of the businessman, John Myers, with his three young children and describes his experience with thrice-weekly dialysis and other rigors of the treatment. *Id.*

61. Sanders & Dukeminier, *supra* note 38, at 357. This article also considers the emerging legal questions surrounding allocation of organs for transplant and the salvaging of cadaver organs as well as, briefly, a person’s right to have life-sustaining medical care withdrawn. *Id.*

62. Jhan Robbins & June Robbins, *The Rest Are Simply Left to Die*, REDBOOK, Nov. 1967, at 80, 81. This article focused on a 29-year-old life-long diabetic living in Maryland who was deemed not a good medical risk for dialysis given the scarcity of machines. *Id.*

63. Sanders & Dukeminier, *supra* note 38, at 377–78.

64. *Id.*

65. *Who Shall Live?* (NBC television broadcast 1965) ([hereinafter “1965 Documentary”]. The documentary’s title, and that of Ms. Alexander’s *Life* article are drawn from the Jewish New Year reading that Ms. Alexander quotes as: “Who shall live and who shall die; who shall attain the measure of man’s days and who shall not attain it; who shall be at ease and who shall be afflicted.” Alexander, *supra* note 37.

66. 1965 Documentary, *supra* note 65.

67. See Fed. Reserve Bank of Minneapolis, What is a Dollar Worth?, <http://www.minneapolisfed.org/index.cfm> (lasted visited Mar. 15, 2010).

68. 1965 Documentary, *supra* note 65.



and I and everyone else in this town gets behind a nice guy who just wants to go on living.” The “Bucks for Buddy” campaign does raise enough money, and he is selected. Two other patients are depicted in the documentary as not raising sufficient funds, including a WWII veteran who says he does not want to take charity from neighbors and then withdraws his application.<sup>69</sup>

In one dramatic (and clearly staged) scene, patient Donald Duff leaves the Seattle Artificial Kidney Center after an overnight dialysis session as the unseen narrator is heard asking, “Mr. Duff, when you filed your application for the kidney machine, were you the only applicant at the time?” “No,” he replies, “there were several others.” “Were they all accepted?” “No, only two of us were accepted.” “You mean,” and here the narrator pauses, “some of the others were turned down?” “Two or three others were rejected,” says Mr. Duff, “I don’t know why—either for medical reasons or psychological reasons or just didn’t have the \$30,000.” “Mr. Duff,” the narrator asks, “what happened to those who were turned down?” Mr. Duff turns as he starts to walk out the door, and replies, “They’re dead.”

The only woman on the committee, who is described as a housewife, is filmed in shadows saying, “I feel that in our economy, in our time, it just should not have to be that we should have to be deciding who could live and who could die when it’s a mechanical thing, it’s been proven. And it’s just one of the things that I hope will end very soon.”<sup>70</sup>

Sanders and Dukeminier grant that when the committee began its work, chronic dialysis was truly an experimental program and broad selection discretion was perhaps justified. Once it is no longer experimental, however, they argue that justice requires a transparent and fair selection process.<sup>71</sup> The law does not, they note, provide much specific guidance here, although principles underlying the Constitution’s

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69. *Id.* The other is Phyllis Miller, a twenty-eight-year-old housewife and mother of three. Her husband says that he has a gross income of \$4,000 a year and when told it would take \$10,000 a year to keep his wife alive said, “I don’t make that kind of money and I don’t know anyone who does.” The documentary does not make clear whether Ms. Miller ultimately received dialysis. *Id.* Former Director of the Northwest Kidney Centers, Christopher Blagg, M.D., recalls that she did. Interview with Christopher Blagg, M.D., Former Dir., Nw. Kidney Ctrs. (Jan. 5, 2010).

70. 1965 Documentary, *supra* note 65.

71. Sanders & Dukeminier, *supra* note 38. The committee’s selection activities ceased in 1971, as financial support from the State of Washington, private insurance, and community donations were then sufficient to support treatment of all referred, medically eligible patients. Nw. Kidney Ctrs., Our History, <http://www.nwkidney.org/nkc/aboutUs/ourHistory.html> (last visited Mar. 15, 2010).

equal protection clause “may require a more impersonal method of selecting who is to be saved from among the dying.”<sup>72</sup>

Similarly, they argue that commentary on the imperfectly analogous shipwreck cases would seem to proscribe ad hoc comparisons of the social worth of candidates. The shipwreck cases were murder trials in which people apparently doomed to die in an overcrowded lifeboat decide which of their number to kill.<sup>73</sup> The American courts and commentators suggest that a lottery might be appropriate as procedurally fair and giving all an equal chance, while the English courts rejected that idea, finding that all should die or be rescued together.<sup>74</sup> Sanders and Dukeminier consider a variety of other selection criteria and conclude that while none is perfect, and they do not know which is best, any are preferable to selection by ad hoc comparative judgments of social worth.<sup>75</sup>

Scholars from a variety of fields weighed in on the committee’s work and on how to devise appropriate selection criteria.<sup>76</sup> In addition to the immediate and well-publicized issue of allocating dialysis services, kidney and other organ transplantation was on the near horizon. Transplantable organs would no doubt be scarce, as has proved to be the case.<sup>77</sup> It was clear that significant, difficult ethical issues would persist. As Dukeminier and Sanders wrote:

Never before has the treatment of one disease brought to the fore vexing questions in so many fields of law: torts, contracts, property, taxation, wills, criminal law, social welfare law, and constitutional law. Nonetheless, the

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72. Sanders & Dukeminier, *supra* note 38, at 374.

73. *Id.*

74. *Id.* Sanders and Dukeminier’s discussion of the shipwreck cases, with its focus on procedural fairness, calls to mind a scene relayed in Nathaniel Philbrick’s *In the Heart of the Sea: The Tragedy of the Whaleship Essex*. Philbrick’s nonfiction book retells the story that is said to have inspired Herman Melville’s *Moby Dick*. After their whaling boat was rammed and sunk by a whale, the survivors spent several months in small boats in the South Pacific, many of them succumbing to hunger, thirst, and disease. NATHANIEL PHILBRICK, *IN THE HEART OF THE SEA: THE TRAGEDY OF THE WHALESHIP ESSEX* 176 (2001). Desperate survivors in one lifeboat drew lots to see who would be killed and eaten so that the others would survive. *Id.* When the lot fell to Owen Coffin, he is reported to have said of his fate, “I like it as well as any other.” *Id.*

75. Sanders & Dukeminier, *supra* note 38, at 380.

76. See JONSEN, *supra* note 1, at 211–31 (collecting commentary).

77. See, e.g., Govind Persad et al., *Principles for Allocation of Scarce Medical Interventions*, 373 *LANCET* 423, 426–27 (2009) (discussing organ shortage and allocation systems).

issues raised by the invention of the artificial kidney and by kidney transplantation betoken the future.<sup>78</sup>

Scholars have cited the work of this committee, and the controversy it generated, as marking the birth of the modern field of bioethics.<sup>79</sup> Biomedical ethicist Albert Jonson has written that the public and scholarly grappling with this “radically new problem” sparked national interest and activity in the nascent field.<sup>80</sup> Furthermore, the treatment of chronic renal failure raised other, more broadly applicable ethical issues, including patient termination of care (“dialysis suicide”).<sup>81</sup> In attempting to pinpoint the origins of the modern bioethics, some bioethicists point to other mid-twentieth century events—the 1946 Nuremberg Doctor Trials<sup>82</sup> or the 1975 *Quinlan* case<sup>83</sup>—but consider the beginnings of maintenance dialysis to be a defining event.<sup>84</sup> The questions it raised were novel, difficult, public, and not going away any time soon.

#### B. Ventilator Shortage During a Pandemic

Questions about how to appropriately allocate scarce life-saving resources present persistent ethical challenges. The years since the work of the Seattle Committee have seen prominent issues involving organs for transplant,<sup>85</sup> antiretroviral therapy in resource-poor areas,<sup>86</sup> and certain vaccines.<sup>87</sup> Recently, public health departments, hospitals, and

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78. Sanders & Dukeminier, *supra* note 38, at 358.

79. 1992 Conference, *supra* note 44; see also *The Birth of Bioethics*, *supra* note 6, at S-1.

80. *The Birth of Bioethic*, *supra* note 6, at S-2.

81. See JONSEN, *supra* note 1, at 213.

82. See THE NAZI DOCTORS AND THE NUREMBURG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION (George J. Annas & Michael A. Grodin eds., 1992) (describing atrocities committed by Nazi doctors and researchers, their criminal trials, the development of the Nuremberg Code and its impact). Nazi medical experimentation included work on kidneys. A recent newspaper article reports that Yitzhak Ganon avoided doctors for sixty-five years until he became very weak and his wife insisted he seek medical attention. Grist, *Heart Treated, Old Wound Opened*, N.Y. TIMES, Dec. 13, 2009, at WK3. Mr. Ganon ultimately had five cardiac stents placed in a procedure made more risky because he had only one kidney. *Id.* He had only one kidney and had avoided doctors for sixty-five years because while he was held at the Auschwitz concentration camp, Joseph Mengele, M.D., operating without anesthesia and purely for experimental purposes, removed the other one. *Id.*

83. *In re Quinlan*, 70 N.J. 10, 355 A.2d 647 (N.J. 1976) (considering right to withdraw life-sustaining treatment).

84. *The Birth of Bioethics*, *supra* note 6, at S-3 (summarizing presentations).

85. Persad et al., *supra* note 77 (discussing the point system used by the United Network for Organ Sharing and differences depending on the type of organ involved).

86. Laura J. McGough et al., *Which Patients First? Setting Priorities for Antiretroviral Therapy Where Resources Are Limited*, 95 AM. J. PUB. HEALTH 1173 (2005).

87. Jan Medlock & Alison Galvani, *Optimizing Influenza Vaccine Distribution*, 325 SCI. 1705 (2009).

academics have considered how to respond to ventilator and critical care shortages that might be created by an influenza pandemic. The threat is that “a public health disaster similar in magnitude to the 1918 influenza pandemic would require 400% of current U.S. intensive care beds and 200% of all mechanical ventilators. Even a smaller epidemic could be grave, because U.S. intensive care units typically run at greater than 90% occupancy and have little surge capacity.”<sup>88</sup>

What if there are more desperately sick patients than ventilators? Who decides and on what basis? The Centers for Disease Control and Prevention (“CDC”) in October 2009 issued a draft guidance document intended to provide ethical guidance “specific to allocation of mechanical ventilators during a severe pandemic influenza.”<sup>89</sup> The guidance document considers various principles that might guide these difficult allocation decisions, with reference to the body of bioethics scholarship over the past fifty years.<sup>90</sup>

The authors explicitly draw lessons from “the public firestorm” in response to the Seattle Committee’s consideration of broad social worth.<sup>91</sup> Among the lessons drawn is that considering an individual’s overall worth to society raises so many ethical and practical difficulties that the principle should not be utilized in responding to pandemic influenza.<sup>92</sup> “In our morally pluralistic society, there has been widespread rejection of the idea that one individual is intrinsically more worthy of saving than another.”<sup>93</sup>

A somewhat related social worth criteria is not rejected outright, but is presented as “highly controversial.”<sup>94</sup> That is the idea of prioritizing

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88. Douglas B. White et al., *Who Should Receive Life Support During a Public Health Emergency? Using Ethical Principles to Improve Allocation Decisions*, 150 ANNALS OF INTERNAL MED. 132, 132 (2009) (citations omitted). A number of other scholars have also addressed this allocation issue. See, e.g., Michael D. Christian et al., *Development of a Triage Protocol for Critical Care During an Influenza Pandemic*, 175 CAN. MED. J. ASS’N. 1377 (2006); Tia Powell et al., *Allocation of Ventilators in a Public Health Disaster*, 2 DISASTER MED. PUB. HEALTH PREPAREDNESS 20 (2008).

89. ETHICS SUBCOMM. OF THE ADVISORY COMM. TO THE DIR., CTRS. FOR DISEASE CONTROL & PREVENTION, ETHICAL CONSIDERATIONS FOR DECISION MAKING REGARDING ALLOCATION OF MECHANICAL VENTILATORS DURING A SEVERE INFLUENZA PANDEMIC: DRAFT 7–9 (Oct. 30, 2009), available at [http://s3.amazonaws.com/propublica/assets/docs/Vent\\_Guidance\\_draftoc2008pdf.pdf](http://s3.amazonaws.com/propublica/assets/docs/Vent_Guidance_draftoc2008pdf.pdf) [hereinafter “CDC REPORT”].

90. *Id.*

91. *Id.* at 13. This and other sections of the draft report draw on a January 2009 *Annals of Internal Medicine* article that makes the same point. See White et al., *supra* note 89. One of the authors of that article, Bernard Lo, is also on the CDC Subcommittee which issued the draft guidance.

92. CDC REPORT, *supra* note 89, at 13.

93. *Id.*

94. *Id.* at 14.

individuals who are essential to the pandemic response (such as public health and health care workers) based on “instrumental value,” also known as “the multiplier effect” or “narrow social utility.”<sup>95</sup> The argument is that by prioritizing certain key individuals many more lives will ultimately be saved.<sup>96</sup> It is this principle that underlies priority influenza vaccination for health care workers.<sup>97</sup> This narrow social utility principle is more problematic in the context of ventilator scarcity, however, given that its justification requires “good evidence that the measure is *necessary* and will be *effective*.”<sup>98</sup>

The CDC Subcommittee identifies several other ethical considerations that would be useful in guiding decision-making about ventilator allocation. Among these are saving the most lives, saving the most life-years, and “grant[ing] each individual an equal opportunity to live through the various phases of life.”<sup>99</sup> Ultimately, the Subcommittee suggests that a “multi-principle allocation system may best reflect the diverse moral considerations relevant to these difficult decisions.”<sup>100</sup> The Subcommittee further stresses the importance for the perception of fairness that there be community involvement and transparency in establishing specific allocation criteria.<sup>101</sup>

The ventilator-allocation question is speculative and driven by a predicted physical shortage of health care devices. For those reasons, it is in many ways easier than the broader question of how to allocate health care dollars, which are not scarce, but are not unlimited. This question is actual and driven by financial limitations. Noted health economist Uwe Reinhardt has said, quite rightly, that health care can legitimately absorb any dollar it is allocated.<sup>102</sup> Given that reality, countered with the budgetary need to limit the dollars allocated, it is inevitable that treatment and coverage choices will have to be made.

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95. *Id.* at 13–14.

96. *Id.* at 13.

97. White et al., *supra* note 88, at 134–35.

98. CDC REPORT, *supra* note 89, at 14 (internal citation omitted).

99. *Id.* at 11–14. This latter principle is termed “the life-cycle principle.” The authors acknowledge that it gives relative priority to younger individuals over older individuals and defend that prioritization on a variety of grounds. See White et al., *supra* note 89, at 134–35.

100. CDC REPORT, *supra* note 89, at 21. In advocating for a multiprinciple allocation system, the CDC Report echoes the conclusions of a *Lancet* article published earlier in 2009. See Persad et al, *supra* note 77 (considering several allocation principles and their use in specific contexts).

101. CDC REPORT, *supra* note 89, at 21.

102. *Healthcare Crisis: Who's at Risk?* (PBS television broadcast 2000), available at <http://www.pbs.org/healthcarecrisis/> [hereinafter “2000 Documentary”].

No matter how health care reform evolves, difficult cost- and efficacy-related decisions will need to be made (and are being made). Those involved with the creation of maintenance dialysis fifty years ago were correct in arguing that allocation of scarce medical resources was not merely a medical question. Just what kind of question it is and who should be involved in answering it are issues that are likely to only grow in import as we increasingly recognize the need to control health care expenditures.

#### IV. PAYING FOR EXPENSIVE, ONGOING MEDICAL CARE

##### A. The Only Bank that Can Afford It

As the 1965 NBC documentary “Who Shall Live” stated the problem, making dialysis a routine treatment would cost lots of money—“so much that there’s only one bank that can afford it.”<sup>103</sup> That bank, the documentary shows as the voiceover fades, is the United States Congress.<sup>104</sup> In 1966, not long after the documentary aired, the Bureau of the Budget appointed a committee to provide advice on federal efforts related to dialysis and transplantation.<sup>105</sup> The Committee on Chronic Kidney Disease (also known as the “Gottschalk Committee”<sup>106</sup>) issued a report recommending a national, federally funded treatment program.<sup>107</sup>

George E. Schreiner, M.D., the President of the National Kidney Foundation from 1969 to 1970, has written about the extensive citizen and interest group lobbying effort to obtain federal financial support for treatment of end-stage renal disease (“ESRD”).<sup>108</sup> He writes about testifying before Congress thirty times, and arguing that a conventional legislative approach, with biennial funding, would be untenable given the chronic nature of the disease and the fact that the potential patient population for dialysis and transplant would only expand.<sup>109</sup>

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103. 1965 Documentary, *supra* note 65.

104. *Id.*

105. Blagg, *supra* note 34, at 490.

106. So called because it was chaired by eminent renal physiologist Carl Gottschalk. *See id.*

107. *Id.*

108. Schreiner, *supra* note 11.

109. *Id.* at 41.

At one particularly dramatic hearing, a patient was dialyzed in front of the House Ways and Means Committee.<sup>110</sup> Dr. Schreiner writes that he thought this a “risky and foolish venture” and tried to talk to the patient out of this publicity stunt, but the patient, who was on home-dialysis, would not be dissuaded.<sup>111</sup> The demonstration was cut short (though this seems not to have been apparent to the Representatives) when the patient developed ventricular tachycardia and a serious drop in blood pressure.<sup>112</sup>

At the same time as these ESRD-specific lobbying efforts, there was a major push to expand Medicare to cover at least some Americans with disabilities. Medicare was established in 1965 to provide public health insurance for nearly all Americans over age sixty-five.<sup>113</sup> Companion legislation created the Medicaid program, which provides a federal framework and federal financing to support state programs that provide health insurance for categories of low-income people.<sup>114</sup> Within a few years of the establishment of these milestone entitlement programs, Congress had before it a number of amendments related to them.

House Bill 1, a huge multi-faceted bill, incorporated many of these proposed changes, most prominently the inclusion in Medicare of people under sixty-five who had been eligible for Social Security Disability Insurance (“SSDI”) for twenty-four months.<sup>115</sup> James Mongan, M.D., a former Senate Finance Committee staff member, recalled that the twenty-four-month waiting period “dramatically cut the cost of adding the disabled. It was kind of a Darwinian cost-cutting mechanism; half of the disabled died before they reached the two-year period.”<sup>116</sup> An amendment to the Senate’s companion bill drew on this provision for coverage of people with disabilities and added coverage for citizens under age sixty-five with ESRD, but without such a long waiting period.<sup>117</sup> Senate staffer Dr. Mongan recalled that many on the Hill believed that a general catastrophic-coverage bill would be passed before long, and that coverage for ESRD might serve as a “pilot or

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110. *Id.*

111. *Id.* at 43.

112. *Id.*

113. Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified at 42 U.S.C. §§ 1395–1396 (2006)).

114. *Id.*

115. *Id.*

116. Interview with James Mongan, Former Staff Member, Senate Fin. Comm. (2005) [hereinafter “2005 Interview”].

117. *Id.*

demonstration program for the inevitable broader catastrophic bill to come.”<sup>118</sup>

Another significant amendment to the approved Senate bill that—as with the ESRD coverage—was not in the House version was coverage of outpatient prescription medications.<sup>119</sup> The House Conference Committee took up the drug coverage issue first, with Senator Long working hard to get it included. “[The outpatient prescription drug coverage provision] was thrown out in the Conference with the House, and about an hour later, the kidney provision came up, and Senator Russell Long looked at Chairman Mills and said ‘Look, you didn’t give me drugs, you gotta give me the kidneys.’”<sup>120</sup>

He got the kidneys. On October 30, 1972, President Richard Nixon signed the Social Security Amendments of 1972.<sup>121</sup> One of its many provisions expanded Medicare to provide coverage for people with permanent kidney failure who are eligible for social security benefits by virtue of their work history or their parents’ work history.<sup>122</sup> For those not already on Medicare, coverage begins on the first day of the third month following the initiation of a course of dialysis and ends many months after either dialysis terminates or the individual has a kidney transplant.<sup>123</sup> The ESRD program thus dealt directly with the scarcity problem by providing significant federal financial support for kidney dialysis and kidney transplantation.

The program grew in numbers of patients served and in dollars spent far beyond what anyone predicted. It grew from approximately 16,000 patients and \$229 million in 1974 to 135,000 patients and \$3 billion (\$1.3 billion in 1974 dollars) in 1988.<sup>124</sup> By 2007, there were 437,000

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118. Charles L. Plante, *1971 Medicare Amendment: Reflections on the Passage of the End-Stage Renal Disease Medicare Program*, 35 AM. J. KIDNEY DISEASES (APR. SUPPLEMENT) S45, S47 (2000) (quoting from a speech by Dr. Mongan).

119. 2005 Interview, *supra* note 116.

120. *Id.* Expansion of Medicare to provide coverage for outpatient prescription drugs was not realized until the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 42 U.S.C.).

121. Social Security Amendments of 1972, Pub. L. No. 92-603, § 2991, 86 Stat. 1329, 1463–64 (codified as amended at 42 U.S.C. § 426 (2006)).

122. *Id.*

123. *Id.* The termination of coverage can lead to financial hardship because anyone who has had a kidney transplant (unless from an identical twin) will need to be on expensive anti-rejection medications for life. There have been several unsuccessful legislative attempts to extend Medicare coverage for these medications. *See, e.g.*, Immunosuppressive Drug Coverage Act of 2003, S. 191, 108th Cong.

124. INST. OF MED., KIDNEY FAILURE AND THE FEDERAL GOVERNMENT 28 & tbl.1-1 (Richard A. Rettig & Norman G. Levinsky eds., 1991).



patients on the program, which cost \$23.9 billion (\$5.7 billion in 1974 dollars).<sup>125</sup> Of course, the total costs for treatment of ESRD are substantially higher, as Medicare does not cover all the costs for either dialysis or transplantation.<sup>126</sup> Premiums, co-pays, and deductibles are paid from other sources, such as Medicaid, private insurance, or out-of-pocket.

Federal payment for kidney dialysis and transplant rapidly and markedly increased the availability of these services. “Much of the urgency of the debate over egalitarian and utilitarian principles dissipated; the government had opted for the egalitarian way and had chosen to pay for it.”<sup>127</sup> A primary reason for Congressional hesitancy to expand coverage to other diseases, or even to transplants besides kidneys, has been the high costs of Medicare’s ESRD program, far exceeding initial estimates.<sup>128</sup> At more than \$24 billion a year today, this program is a significant, and growing, federal expense.<sup>129</sup> One reason the costs exceeded estimates by so much is that there were many more patients than anticipated.<sup>130</sup>

As medical ethics scholar Thomas McCormick has noted, once dialysis machines were no longer scarce and the treatment no longer experimental, the universe of “medically eligible” patients expanded significantly.<sup>131</sup> No longer was treatment limited, as in the early years of the Seattle Kidney Center, to people between eighteen and forty-five with no complicating medical or psychological conditions.<sup>132</sup> Older people, children, those with other serious medical conditions, drug abusers, the mentally ill—the patient population expanded far beyond the young milkman featured in the “Bucks for Buddy” campaign of the 1965 NBC documentary.

The Gottschalk Committee in 1966 predicted that the number of new patients per year suitable for dialysis would be less than forty patients per million population.<sup>133</sup> Currently, the incidence rate for ESRD care

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125. U.S. RENAL DATA SYS., ANNUAL DATA REPORT (2009), available at [http://www.usrds.org/2009/pdf/V2\\_11\\_09.PDF](http://www.usrds.org/2009/pdf/V2_11_09.PDF) [hereinafter “2009 REPORT”]. The 2007 dollars were converted using the Federal Reserve inflation calculator. See *supra* note 67. For a good discussion of the growth of the program and the initial underestimation of costs, see JONSEN, *supra* note 1, at 218.

126. 2009 REPORT, *supra* note 125.

127. JONSEN, *supra* note 1, at 218.

128. 2009 REPORT, *supra* note 125.

129. *Id.*

130. *Id.*

131. McCormick, *supra* note 20, at 552.

132. *Id.*

133. Felix Knauf & Peter S. Aronson, *ESRD as a Window into America’s Cost Crisis in Health Care*,

in the United States is approximately 400 patients per million population, and the fastest growing category of patient is people over seventy-five years of age.<sup>134</sup> The median age of those entering treatment is now over sixty-four, and co-morbidities, such as heart disease or diabetes, are the norm.<sup>135</sup>

#### B. Last Train out of the Station?

“Ironically, rather than serving as a demonstration or pilot, the ESRD legislation proved to be the last train out of the station for national health insurance. No other group has had a chance to get aboard,” Dr. Mongan stated.<sup>136</sup> Since the enactment of this Medicare expansion, concerns about how to pay for expensive, life-saving treatments have increased. A decade after this legislation, organ transplantation had become accepted medical practice. “The transplanters moved into new fields—pancreas, bowel, segmental lung, block transplantation of multiple organs—and each move raised questions about experimentation, efficacy, cost and consent.”<sup>137</sup> In addition, treatment discoveries have transformed other fatal illnesses into treatable, chronic conditions.

This was and remains the only disease-specific public insurance. There have been legislative attempts to provide similar coverage for HIV/AIDS and for non-kidney transplants.<sup>138</sup> In recent years, there have been a few limited disease-specific tweaks to the Medicare and Medicaid. For example, uninsured women with breast or cervical cancer are an optional coverage category under Medicaid,<sup>139</sup> and the twenty-four-month waiting period for Medicare disability coverage is waived for those with Lou Gehrig’s disease.<sup>140</sup>

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20 J. AM. SOC’Y NEPHROLOGY 2093, 2094 (2009).

134. *Id.*

135. *Id.*

136. Plante, *supra* note 118, at S48 (quoting from a speech by Dr. Mongan).

137. JONSEN, *supra* note 1, at 223. The list of organs that can be transplanted is now much longer and significantly includes hearts and livers. *Id.*

138. *See, e.g.*, H.R. 6196, 110th Cong. (2008) (heart transplants); Insulin-Free World Medicare Pancreas Transplantation Coverage Act of 2001, H.R. 1361, 107th Cong. (pancreas transplants); AIDS Treatment and Assistance Act of 2000, H.R. 4557, 106th Cong. (2000) (attempting to waive the twenty-four-month waiting period for individuals disabled because of AIDS).

139. Medicaid was expanded to include this optional coverage pursuant to the Breast and Cervical Cancer Prevention and Treatment Act of 2000, Pub. L. No. 106-354, 114 Stat. 1381 (2000) (codified at 42 U.S.C. §§ 1396a, 1396b, 1396d, 1396r-1b (2006)).

140. In 2000, the waiting period was waived for those with this rapidly progressing degenerative disease, whose proper name is amyotrophic lateral sclerosis or ALS. Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, § 1(a)(6), 114 Stat. 2763, 2763A-474 (2000) (codified at 42 U.S.C. § 426 (h) (2006)).

How to respond to individually catastrophic health care expenses has continued to present a significant national policy challenge. In 1988 Congress passed and President Ronald Reagan signed into law the Medicare Catastrophic Coverage Act (“MCCA”).<sup>141</sup> Congress intended the MCCA to shift the burden of Medicare recipients’ financially catastrophic out-of-pocket medical costs onto the public system, with a particular focus on long hospital stays, skilled nursing care, and nursing home coverage under Medicaid.<sup>142</sup> Funding for the expanded coverage depended on increased taxes and Part B premiums.<sup>143</sup> This funding mechanism drew fervent objection,<sup>144</sup> and the law was repealed after less than a year.<sup>145</sup>

The recent health reform debate featured proposals to protect privately insured people from the consequences of extremely high medical care costs. In his November 9, 2009 speech to Congress on health reform, President Barack Obama said that a primary goal of the legislation is to provide security from catastrophic expenses for those who have health insurance. “[Insurance companies] will no longer be able to place some arbitrary cap on the amount of coverage you can receive in a given year or a lifetime. We will place a limit on how much you can be charged for out-of-pocket expenses, because in the United States of America, no one should go broke because they get sick.”<sup>146</sup>

The Affordable Health Care for America Act,<sup>147</sup> which passed the House on November 7, 2009, includes a variety of reforms to the private insurance market. One provision caps annual out-of-pocket spending and another prohibits policies from imposing annual or lifetime coverage limits.<sup>148</sup> The Patient Protection and Affordable Care Act,<sup>149</sup> which passed the Senate on December 24, 2009, includes similar

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141. Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 100-360, 102 Stat. 683 (1988) (repealed by the Medicare Catastrophic Repeal Act of 1989, Pub. L. No. 101-234, 103 Stat. 1980 (1989)).

142. William Aaronson et al., *The Success and Repeal of the Medicare Catastrophic Coverage Act: A Paradoxical Lesson for Health Reform*, 19 J. HEALTH POL’Y PLAN. & L. 753,756 (1994).

143. See, e.g., Editorial, *A Catastrophic Health Care Law*, CHI. TRIB., Dec. 29, 1988, at 22; Editorial, *The AARP Tax*, WALL ST. J., June 17, 1988.

144. *A Catastrophic Health Care Law*, *supra* note 143.

145. Medicare Catastrophic Repeal Act of 1989, Pub. L. 101-234, 103 Stat. 1980 (1989).

146. President Barack Obama, Remarks to Joint Session of Congress on Health Care (Nov. 9, 2009), available at [http://www.whitehouse.gov/the\\_press\\_office/remarks-by-the-president-to-a-joint-session-of-congress-on-health-care/](http://www.whitehouse.gov/the_press_office/remarks-by-the-president-to-a-joint-session-of-congress-on-health-care/).

147. Affordable Health Care for America Act, H.R. 3962, 111th Cong. (2009).

148. See, e.g., *id.* §§ 716, 9815, 2709.

149. The Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. (2009).

provisions.<sup>150</sup> These prohibitions on annual and lifetime limits, combined with provisions to limit out-of-pocket expenses will certainly help insure that no American citizen goes broke because of illness. Their impact on insurance premiums and on health care expenditures as a whole is harder to predict. Protecting individuals from catastrophic costs given political and economic realities will continue to be a challenge regardless of how health reform evolves.

The nation also continues to grapple with the appropriate role of for-profit entities in health care and their impact on costs. Dr. Scribner did not patent his invention and strongly believed that kidney dialysis should not be a for-profit endeavor: “I just don’t think doctors should be involved in making profit on the same thing that they’re doing as doctors. It’s like doctors owning drug stores and things like that. I’m against it.”<sup>151</sup> Although the original Seattle facility remains not-for-profit, kidney dialysis is now primarily a for-profit business, with two companies dominating the field.<sup>152</sup>

## V. DECIDING TO NO LONGER TREAT PATIENTS

### A. A Case that Challenges the Law’s Abilities

The repeated and essential nature of maintenance dialysis raised the question from the very beginning of whether it could be stopped for non-medically indicated reasons. When it became clear that the Scribner shunt worked and that patients might be able to live for years, University of Washington administrators questioned whether it was appropriate to take on new patients without a corresponding firm commitment to continue treatment for as long as necessary, potentially

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150. *Id.* § 2711 (“no lifetime or annual limits”).

151. *60 Minutes: What Price Medicine?* (CBS television broadcast 1979). Dr. Scribner was speaking particularly about the issue of home dialysis, of which he was a strong advocate. Home dialysis was significantly less expensive and was a better option, for many, though not all, patients. At the time of the *60 Minutes* broadcast, more than eighty percent of Seattle patients were on home dialysis, and, in the rest of the country, more than eighty percent were in centers. The show raised the question of whether home dialysis was not more widely utilized elsewhere partly because it was not as profitable as center-based dialysis. Today, only a small percentage of patients are on home dialysis, and Northwest Kidney Centers continues to be a leader in this less-common treatment modality. See Christopher Blagg, *It’s Time to Look at Home Dialysis in a New Light*, HEMODIALYSIS HORIZONS 22 (2006), available at <http://www.aami.org/publications/HH/Home.Blagg.pdf>.

152. 2009 REPORT, *supra* note 125, at tabl.J.8 (listing dialysis and transplant facilities, by ownership type, collecting data though 2001), available at [http://www.usrds.org/2009/re/J\\_Ref\\_09.pdf](http://www.usrds.org/2009/re/J_Ref_09.pdf).

for the patient's natural life-span.<sup>153</sup> Concluding that it could be inappropriate to stop treatment for financial reasons, they maintained that funding sources had to be found before more patients would be added to the program.<sup>154</sup>

These university leaders were thinking mostly that lack of money might make it difficult to continue treatment.<sup>155</sup> Other issues can make this difficult, including a patient's extreme lack of cooperation.<sup>156</sup> Dukeminier and Sanders in their 1967 UCLA Law Review article posit a hypothetical patient who is "uncooperative, does not stay on the diet, and upsets the nurses and other patients with his hostility . . . ."<sup>157</sup> Would the patient's doctors be justified in stopping treatment, or would that be common law abandonment?

*Payton v. Weaver*, a frequent teaching case from 1982,<sup>158</sup> raised just this question as well as the question of what constitutes an emergency medical condition.<sup>159</sup> John Weaver, M.D., informed Brenda Marie Payton, a thirty-five-year-old woman with ongoing addictions to alcohol and heroin, that he would no longer provide her outpatient dialysis services because of her intensely uncooperative behavior, antisocial conduct, and refusal to follow instructions despite several years' efforts following the failure of her first transplanted kidney.<sup>160</sup> Ms. Payton regularly arrived for treatment high on drugs, missed appointments, cursed at staff members, pulled the dialysis needle from her leg causing blood to spray, and, on occasion, exposed her genitals to other patients.<sup>161</sup> "Despite these difficulties," the California Court of Appeals noted, "she appears from the record to be a marvelously

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153. McCormick, *supra* note 20, at 550; *see also* Blagg, *supra* note 34, at 485.

154. Blagg, *supra* note 34, at 485. The Hartford Foundation then provided a crucial grant of \$100,000 a year for three years; other private and federal grants followed. *Id.*

155. McCormick, *supra* note 20, at 550.

156. Another potentially difficult situation, though quite different, is a patient's decision to discontinue treatment because its rigors and the challenges of underlying diseases outweigh the value of continuing. This was an early grappling with patient autonomy and the right to stop life-sustaining treatment. Fox and Swazey's 1974 book contains an extended discussion of the views of patients and physicians on "the right to die" in the context of a patient's decision to discontinue dialysis treatments. FOX & SWAZEY, *supra* note 15, at 273-79.

157. Sanders & Dukeminier, *supra* note 38, at 382.

158. *See, e.g.*, J. STUART SHOWALTER, THE LAW OF HEALTHCARE ADMINISTRATION 31 (5th ed. 2008); BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 202, 607 (6th ed. 2008).

159. *Payton v. Weaver*, 182 Cal. Rptr. 225 (Cal. Ct. App. 1982).

160. *See generally id.* at 228.

161. *Id.*

sympathetic and articulate individual who in her lucid moments possesses a great sense of dignity and is intent on preserving her independence . . . .”<sup>162</sup>

Ms. Payton sued to compel Dr. Weaver to keep treating her.<sup>163</sup> The parties settled by a stipulated order that Dr. Weaver would continue to treat Ms. Payton if she met specified conditions of cooperation.<sup>164</sup> Ms. Payton’s abusive, uncooperative behavior did not change, and Dr. Weaver again notified her that he would stop treating her and gave her a list of other dialysis providers in the area, none of whom would accept her.<sup>165</sup> Ms. Payton again sued, arguing that his conduct constituted abandonment and that two hospitals that refused to provide her outpatient dialysis services were violating their state-mandated emergency care obligations.<sup>166</sup>

“Occasionally,” noted the court, “a case will challenge the ability of the law, and society, to cope effectively and sensitively with the fundamental problems of human existence. This is such a case.”<sup>167</sup> The court agreed with the trial court that the physician’s notice was sufficient to end the treatment relationship and that he was not responsible for the fact that no other clinic would accept her as a patient.<sup>168</sup> The court also agreed that there was no emergency under the terms of the California statute, as she was not in immediate danger.<sup>169</sup>

What alternatives then existed for her? The court suggested that an involuntary or voluntary conservatorship could assure that she receive the mental health and dialysis treatment she needed.<sup>170</sup> According to a newspaper article about the case, psychiatrists examined Ms. Payton and determined that she did not meet the standards for a conservatorship.<sup>171</sup> At one point, she fell into a coma, was rushed to the emergency room, and received emergency dialysis.<sup>172</sup> She died not long after.<sup>173</sup>

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162. *Id.* at 227.

163. *Id.*

164. *Id.*

165. *Id.*

166. *Id.*

167. *Id.*

168. *Id.* The court praised the doctor’s efforts to help her, stating that he and the clinic “behaved according to the highest standards of the medical profession,” and quoting the trial judge’s statement that Dr. Weaver “has the patience of Job.” *Id.*

169. *Id.*

170. *Id.*

171. Spencer Sherman, *A Case the Law Can’t Cure*, UNITED PRESS INT’L, July 16, 1982.

172. *Id.*

173. E-mail from Stephen Peck, Attorney, Hanson Bridgett LLP, to Geoffrey William Hymans, Health

With thrice-weekly treatments and the likelihood of death within weeks of stopping treatment, dialysis presents the patient abandonment issue in stark terms.<sup>174</sup> After fifty years of experience<sup>175</sup> with noncompliant and sometimes abusive patients, there now exists a body of practical as well as regulatory guidance on how to manage these types of patients.<sup>176</sup> It is not easy, however, and there will always be patients who are uncooperative, abusive, and/or threatening. In deciding whether and how to cease treatment, physicians and dialysis centers will be guided by the patient abandonment standards shaped, in part, by previous dialysis patients.

In addition, despite near universal coverage under Medicare's ESRD program, there continue to be patients who present no treatment challenges other than their lack of ability to pay. For these patients, the abandonment standard and, particularly, the determination of an "emergency condition" are evolving issues.

#### B. Grady Memorial Closes Outpatient Dialysis Clinic

A recent challenging situation of this sort involves Grady Memorial Hospital's decision to close its outpatient dialysis unit.<sup>177</sup> Grady, which was founded in 1892 with a mission to care for Atlanta's poor and underserved, is the region's Level I trauma facility as well as its major safety net hospital.<sup>178</sup> As of 2008, it is no longer owned by the county and is part of a private not-for-profit health care system.<sup>179</sup>

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Law LLM Student, Univ. of Wash. Sch. of Law (Dec. 10, 2009, 11:28 PDT) (on file with author).

174. Elizabeth B.D. Ripley, *Where does the Nephrologist Stand With A Non-Compliant Abusive Dialysis Patient*, 5 INTERNET J. NEPHROLOGY (Jan. 5, 2010).

175. One of the earliest dialysis patients in 1960 had difficulty complying with the restrictions imposed by the treatment. Among other things, he played basketball with a Scribner shunt newly installed in his leg, requiring that the shunt be reinserted the following day. FOX & SWAZEY, *supra* note 15, at 270.

176. *See, e.g.*, Ripley, *supra* note 175 (referencing guidance documents and regulations promulgated by the Centers for Medicare and Medicaid Services).

177. Kevin Sack, *Atlanta Judge Rules Dialysis Unit Can Be Closed*, N.Y. TIMES, Sept. 26, 2009, at A10.

178. Grady Health Sys., About Grady, <http://www.gradyhealthsystem.org/About/> (last visited Mar. 15, 2010).

179. According to its website, "Grady Health System today continues to maintain its strong commitment to the health-care needs of Fulton and DeKalb counties underserved, while also offering a full-range of specialized medical services for all segments of the community." *See* Press Release, Grady Health Sys., Grady Memorial Hospital Corporation Set to Assume Responsibility for Health System Operation May 20 (May 18, 2008), available at [http://qa.gradyhealthsystem.org/News/press\\_release41.asp](http://qa.gradyhealthsystem.org/News/press_release41.asp). The transition to a not-for-profit corporation occurred on May 20, 2009; *see also* Complaint, *Andrade v. Grady Mem'l Hosp. Corp.*, No. 2009CV175156 (Ga. Fulton County Super. Ct. Sept. 16, 2009) (on file with author).

As with many urban, safety net hospitals, Grady is facing serious financial challenges. According to a spokesperson, its outpatient dialysis unit had been losing between \$2 and \$4 million a year, primarily because many of its patients lacked public or private insurance.<sup>180</sup> A *New York Times* article quotes a hospital official as saying, “Years and years of providing this free care has led Grady to the breaking point. If we don’t make the gut-wrenching decisions now, there won’t be a Grady later. Then, everyone loses.”<sup>181</sup>

Among those impacted by the unit’s closing in October 2009 were fifty-one indigent, uninsured patients.<sup>182</sup> Most of the fifty-one are undocumented immigrants, though a few are in this country legally, but not long enough to qualify for Medicare or Medicaid.<sup>183</sup> Despite Grady’s efforts to relocate them, these patients will have great difficulty finding on-going dialysis services elsewhere. Medicare and Medicaid coverage is generally limited to otherwise eligible citizens and those who have been legal residents for at least five years.<sup>184</sup> Federal law does provide, however, matching funds under a state’s Medicaid program for emergency treatment of any individual whose income is sufficiently low to otherwise qualify.<sup>185</sup> An emergency medical situation is defined by the statute as an acute condition that, without immediate care, would seriously jeopardize a patient’s health or impair bodily functions, parts, or organs.<sup>186</sup>

Whether maintenance dialysis of a particular patient meets the definition of emergency treatment is debatable. In 2001, the Center for Medicare and Medicaid Services (“CMS”) issued a regulation clarifying that reimbursable emergency services must involve the “sudden onset” of an acute, severe condition.<sup>187</sup> “Subsequent legal actions and intense debate have led to variability across states as to whether dialysis services

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180. Craig Schneider, *N.J.: No Care for Grady Dialysis Patients*, ATLANTA J.-CONST., Sept. 18, 2009, available at <http://www.ajc.com/news/atlanta/n-j-no-care-141664.html>.

181. Kevin Sack, *Hospital Falters as Refuge for Illegal Immigrants*, N.Y. TIMES, Nov. 21, 2009, at A1.

182. *Id.*; see also Kevin Sack, *Immigrants Cling to Fragile Lifeline at Safety-Net Hospital*, N.Y. Times, Sept. 24, 2009, at A16.

183. Kevin Sack, *Immigrants Cling to Fragile Lifeline at Safety-Net Hospital*, N.Y. Times, Sept. 24, 2009, at A16.

184. Social Security Act of 1965, 42 U.S.C. §1395o (2006).

185. *See id.* § 1396b(v).

186. *Id.* § 1396b(v)(3)(A)-(C). This is the same definition used in the Emergency Medical Treatment and Labor Act, which requires each Medicare-participating hospital that maintains an emergency room to provide a medical screening to any individual who comes to the emergency room, to provide stabilizing treatment if an emergency condition exists and, generally, to transfer or discharge the patient only if stabilized. *See id.* § 1395dd(b)(1).

187. 42 C.F.R. § 440.255(c)(1) (2009).



are interpreted to be either emergency or chronic care, and to variability in state policies for reimbursement to dialysis providers.”<sup>188</sup>

A federal lawsuit in Arizona resulted in a 2007 consent decree by which Arizona’s Medicaid program was required to cover outpatient kidney dialysis as an emergency medical service.<sup>189</sup> Other courts have held that maintenance dialysis treatment is not emergency treatment for Medicaid purposes.<sup>190</sup> Most states do *not* cover the treatment—either under their Medicaid programs or under purely state-funded programs.<sup>191</sup> In November 2009, Washington State cited federal law in its decision to stop covering dialysis for undocumented immigrants under its Medicaid program and switch to coverage to a state-dollars only program.<sup>192</sup> Georgia’s decision in 2006 to end its Medicaid coverage for dialysis, and not set up alternate coverage, precipitated the crisis at Grady.<sup>193</sup>

Two Grady patients sued on behalf of themselves and others similarly situated, challenging the scheduled closing of the dialysis unit.<sup>194</sup> In their complaint, they argued that the decision to close the clinic was a state action that violated their procedural and substantive due process rights under the Georgia Constitution, constituted patient abandonment, and

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188. Barry M. Straube, *Reform of the US Healthcare System: Care of Undocumented Individuals with ESRD*, 53 AM. J. KIDNEY DISEASES 921, 922 (2009).

189. Padilla v. Rodgers, No. CIV 02 176 TUC FRZ (D. Ariz. 2007), available at [http://op.bna.com/hl.nsf/id/psts-6zfs2y/\\$File/padilla.pdf](http://op.bna.com/hl.nsf/id/psts-6zfs2y/$File/padilla.pdf). The consent decree expired in February 2009, but the State has apparently continued to comply with its terms. E-mail from Ellen Sue Katz, Attorney, William E. Morris Inst. for Justice, to Sallie Thieme Sanford, Acting Assistant Professor, Univ. of Wash. Sch. of Law (Dec. 10, 2009, 8:33 PDT) (on file with author); see also Jane Perkins, *Medicaid Coverage of Emergency Medical Conditions: An Update*, 38 CLEARINGHOUSE REV. 384 (2004) (collecting cases involving undocumented immigrants and emergency care).

190. Quiceno v. Dep’t. of Soc. Servs., 45 Conn. Supp. 580, 728 A.2d 553 (1999). The *Quiceno* court noted that its decision was compelled by the Second Circuit’s decision in the leading case of Greenery Rehab. Group, Inc. v. Hammon, which held that patients with severe brain injuries, who were in “more fragile health” than Quintero, were not receiving care for “an emergency medical condition” under the plain meaning of the federal statute. 150 F.3d 226 (2d Cir. 1972).

191. The *Atlanta Journal-Constitution* reported that Grady had identified eleven states which do provide coverage for ongoing dialysis care for undocumented immigrants and suggested that the patients could relocate to those states for covered care. When the newspaper contacted officials from several of those states, however, the officials disputed that characterization of their Medicaid programs and said they covered only immediate, acute emergency care. Schneider, *supra* note 181; see also Alan Zarembo & Anna Gorman, *States Find Dialysis for Illegal Immigrants a Costly Dilemma*, SEATTLE TIMES, Nov. 9, 2008, available at [http://seattletimes.nwsources.com/html/nationworld/2008369322\\_immigdialysis09.html](http://seattletimes.nwsources.com/html/nationworld/2008369322_immigdialysis09.html).

192. Alien Medical for Dialysis and Cancer Treatment (State-Only), WASH ADMIN CODE § 388-438-0120 (2009) (promulgated on an emergency basis).

193. Kevin Sack, *Hospital Falters as Refuge for Illegal Immigrants*, N.Y. TIMES, Nov. 21, 2009, at A1 (decision “sent waves of uninsured dialysis patients from across the region to Grady”).

194. Kevin Sack, *Immigrants Lose Lawsuit against Atlanta Hospital*, N.Y. TIMES, Dec. 16, 2009, at A32.

breached the contract between the county and the hospital, to which the patients are third party beneficiaries.<sup>195</sup>

In October 2009, the Fulton County Superior Court allowed Grady's outpatient dialysis center to close, although the lawsuit continued until the court dismissed it in December 2009.<sup>196</sup> "At least 51 patients had their life support system unplugged today," said the patients' attorney responding to the decision allowing the facility to close.<sup>197</sup> Without treatment, these patients will see the toxins accumulate to fatal levels, likely sending them to emergency rooms, where federal law requires they be treated.<sup>198</sup>

Grady took steps, some in response to the lawsuit, that undercut charges of patient abandonment. Months in advance of the closure, Grady stopped taking new outpatient dialysis patients, sent letters to current patients warning of the closure, arranged to pay for several months of treatment at private facilities, suggested relocation to states that might provide coverage, and offered to pay for and coordinate sending the undocumented immigrants back to Mexico or Central America.<sup>199</sup> There are few dialysis services available in those countries for uninsured people, however, and those who have returned have fared poorly.<sup>200</sup>

No likely health reform scenario includes coverage for undocumented immigrants with serious chronic conditions.<sup>201</sup> Thus, the challenging legal and ethical questions remain: whether to treat them on a non-emergency basis and, if treatment is provided, how to pay for it. The

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195. Complaint, *Andrade v. Grady Mem'l Hosp. Corp.*, No. 2009CV175156 (Ga. Fulton County Super. Ct. Sept. 16, 2009) (on file with author).

196. Sack, *supra* note 194.

197. Sack, *supra* note 177.

198. The federal Emergency Medical Treatment and Labor Act requires each Medicare-participating hospital that maintains an emergency room to provide a medical screening to any individual who comes to the emergency room, to provide stabilizing treatment if an emergency condition exists, and generally to transfer or discharge the patient only if stabilized. *See* 42 U.S.C. §1395dd (2006).

199. Motion to Dismiss of Defendant at 10-12, *Andrade v. Grady Mem'l Hosp. Corp.*, No. 2009CV175156 (Ga. Fulton County Super. Ct. Dec. 30, 2009) (on file with author); *see also* Kevin Sack, *Hospital Falters as Refuge for Illegal Immigrants*, N.Y. TIMES, Nov. 21, 2009, at A1.

200. *See, e.g.*, Guillermo Garcia-Garcia et al., *Renal Replacement Therapy Among Disadvantaged Populations in Mexico: A Report from the Jalisco Dialysis and Transplant Registry (REDTJAL)*, 68 KIDNEY INT'L SUPPLEMENT S58 (2005); *see also* Kevin Sack, *For Sick Illegal Immigrants, No Relief Back Home*, N.Y. TIMES, Jan. 1, 2010, at A1 (describing experience of former Grady patients with dialysis in Mexico).

201. To the contrary, recent efforts at amending the major bills have aimed to insure that only U.S. citizens will be able to buy subsidized or unsubsidized plans on the insurance exchange. Julia Preston, *Health Care Debate Revives Immigration Battle*, N.Y. TIMES, Sept. 5, 2009, at A22.

fifty-one Grady dialysis patients are only the most recent to grab headlines. Other prominent cases have involved cancer, high-risk pregnancy, and long-term rehabilitation following accidents.<sup>202</sup> Given the current pressures on state budgets and the effective tightening of Medicaid emergency reimbursement standards, we are likely to see more situations like that involving the Grady patients.<sup>203</sup>

## VI. CONCLUSION

In their 1967 law review article, Sanders and Dukeminier write that the ethical, legal, and policy issues raised by the invention of maintenance dialysis “betoken the future.”<sup>204</sup> They were correct. The future is here, and in the realm of health law and policy, this half-century old invention hath betokened our current challenges. This paper focused on the history and current context of merely a few of those challenges.

How should scarce life-saving resources be allocated? Those involved with the first maintenance dialysis reasoned that this was not merely a medical question but one that ought also to have community input.<sup>205</sup> Although the Seattle Committee ceased selecting “who should live and who should die” decades ago and there has been a great deal of scholarly discussion on the topic prompted by the committee’s work, the issue periodically resurfaces.<sup>206</sup> The recent guidance related to potential ventilator shortages provides one example.<sup>207</sup>

More broadly, though, given the need to slow the growth of health care expenditures, we as a society will need to grapple more seriously with the accepted criteria for treatment and coverage decisions. Health care dollars are not scarce, but neither are they unlimited. Treatment and coverage decisions do now, and will into the future, include factors other than the strictly medical.

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202. See, e.g., Deborah Sontag, *Immigrants Facing Deportation by U.S. Hospitals*, N.Y. Times, Aug. 3, 2008, at A1; see also *Greenery Rehab. Group, Inc. v. Hammon*, 150 F.3d 226 (2d Cir. 1972) (coverage dispute involving three immigrant patients in long-term care following serious and sudden head injuries).

203. Indeed, in early January 2010, another safety-net hospital system, this one in Florida stopped paying for dialysis for the indigent. Kevin Sack, *Hospital Cuts Dialysis Care for Poor in Miami*, N.Y. TIMES, Jan. 8, 2010, at A14.

204. Sanders & Dukeminier, *supra* note 38, at 358.

205. McCormick, *supra* note 20, at 550.

206. See JONSEN, *supra* note 1, at 211–31.

207. See CDC REPORT, *supra* note 89.

Who should bear the burden of catastrophically high health care expenses? In the context of kidney dialysis and transplant, this was answered by the creation of a public program for which nearly everyone in the country is eligible.<sup>208</sup> Because Medicare's ESRD program has been so much more costly than anticipated, it has served not as a model for general catastrophic care coverage but as a cautionary tale.<sup>209</sup>

One of the goals of the current health reform effort is that no American should face financial ruin due to illness or injury.<sup>210</sup> To meet this goal, the new legislation aims to significantly increase the percentage of Americans covered by private insurance, prevent that insurance from imposing annual or lifetime coverage limits, and cap out-of-pocket payments.<sup>211</sup> These provisions certainly will protect individuals from catastrophic health care expenses; their impact on insurance premiums and on health care expenditures as a whole is harder to predict.

When is it appropriate to stop treatment for non-medically indicated reasons? With frequent treatments and the likelihood of death within weeks of stopping treatment, dialysis presents in stark terms the issues of patient abandonment and mandated emergency treatment.<sup>212</sup> Early cases involved noncompliant, abusive patients.<sup>213</sup> More recent cases involve undocumented immigrants, whose primary treatment challenge is their lack of ability to pay.<sup>214</sup>

No likely health reform scenario expands coverage for undocumented immigrants with chronic, life-threatening health conditions. Indeed, the recent trend is towards less coverage, with a tightening interpretation of emergency coverage under Medicaid and more limited state-only coverage. How these political realities interplay with the law is sure to be considered by courts in the coming years.

By inventing the shunt that allowed repeated, successful dialysis, what Dr. Scribner wrought is a wealth of legal, ethical, and policy issues. These issues will become more common, not less, as medicine advances and health care budgets tighten. Recalling how society grappled with

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208. See Blagg, *supra* note 34, at 485.

209. See *id.*

210. See President Barack Obama, Remarks to Joint Session of Congress on Health Care (Nov. 9, 2009), available at [http://www.whitehouse.gov/the\\_press\\_office/remarks-by-the-president-to-a-joint-session-of-congress-on-health-care/](http://www.whitehouse.gov/the_press_office/remarks-by-the-president-to-a-joint-session-of-congress-on-health-care/).

211. See *id.*

212. See FOX & SWAZEY, *supra* note 15, at 273–79.

213. See *id.*

214. See Sack, *supra* note 182.

them in the early years of maintenance dialysis can inform this century's health law and policy challenges.