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## A Tale of Two Countries: Parallel Visions for Informed Consent in the United States and the United Kingdom

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# A Tale of Two Countries: Parallel Visions for Informed Consent in the United States and the United Kingdom

## ABSTRACT

*In recent years, the proper role of informed consent doctrine in an environment of healthcare cost containment has been a hotly contested legal and policy issue. The purpose of this Note is to probe the current informed consent debate in the United States and the United Kingdom and to draw out the respective roles informed consent ought to play in those two systems. In doing so, this Note draws on the history of the doctrine and several recent scholarly proposals, and offers a modest proposal synthesizing the best aspects of those proposals.*

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## I. INTRODUCTION

The U.S. healthcare system is widely regarded as providing the highest quality healthcare in the world.<sup>1</sup> Its healthcare system, however, is by no means perfect, and it could be argued that it is not the best of all healthcare systems. Although characterized by high quality, U.S. healthcare is also plagued with problems of overspending and relatively low per capita coverage compared to healthcare systems of other developed countries.<sup>2</sup> Therefore, among the primary goals of U.S. healthcare policymakers is to contain healthcare costs while maintaining adequate levels of treatment.

While most would agree that reduction of healthcare costs is a worthy goal, for decades the battle lines have been clearly drawn in the United States between two contrasting visions of healthcare delivery: the economic paradigm and the professional paradigm.<sup>3</sup> Those in the former camp envision a system that allows market forces to perform an automatic regulatory role, such that patients are able to make the kinds of cost-benefit decisions that typically face consumers, while managed care organizations are free to invent delivery structures that encourage cost containment. In other words, the economic paradigm acknowledges a valid economic concern ("Is the treatment worth the cost?") in addition to the traditional medical concern ("Is the treatment beneficial?").<sup>4</sup> In contrast, those who adhere to the professional model would ask only the latter question.<sup>5</sup>

In the United Kingdom, on the other hand, where healthcare is provided through a public delivery system with an overall expenditure cap,<sup>6</sup> problems of overspending are not prevalent. Despite this, British healthcare quality is adequate to serve the needs of its population.<sup>7</sup> Many reasons have been offered for the lower levels of spending in the United Kingdom, and indeed it is likely that U.S. policymakers could learn some valuable lessons from the British

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1. Bureau of Labor Educ., Univ. of Me., *The U.S. Health Care System: Best in the World, or Just the Most Expensive?* 1 (2001).

2. See George J. Annas & Frances H. Miller, *The Empire of Death: How Culture and Economics Affect Informed Consent in the U.S., the U.K., and Japan*, 20 *Am. J. L. & Med.* 357 (1994).

Three years ago, the U.S. spent 131 percent more per capita on health care than did Japan, and almost 200 percent more than did the U.K. For all that expenditure, however, the U.S. trails behind the U.K., Japan, and many other industrialized nations in such basic health-outcome measurements as infant mortality, perinatal mortality, and male life expectancy.

3. James F. Blumstein, *Medicine Isn't an Economics-Free Zone*, *Wall St. J.*, June 22, 2001, at A14.

4. *Id.*

5. *Id.*

6. See Annas & Miller, *supra* note 2, at 369.

7. See *id.* at 377-78.

approach that may inform U.S. policy strategies while leaving the United States' tradition of treating medical care as a private good undiminished.

In the midst of these contrasting systems and the varying ideologies pertaining to healthcare delivery stands the problem of informed consent. What role should informed consent play in each of these different systems? Should its role be the same in both nations, or is its proper function in the United States different from that in the United Kingdom? This Note will summarize the current informed consent debate in the United States and the United Kingdom and draw out the respective roles informed consent should play in those two systems. Part II of this Note describes the history of informed consent law in the United States. Part III discusses current U.S. informed consent proposals and concludes that a contract theory of informed consent, supplemented by professional disciplinary proceedings, is the best approach. Part IV tracks the history of U.K. informed consent law. Finally, Part V discusses the current U.K. informed consent debate and concludes that a model comprised of one-time global disclosure, broad information availability, professional disciplinary proceedings, and a new cause of action based on these new disclosure standards would address the most pressing issues in the current U.K. informed consent debate.

## II. INFORMED CONSENT IN THE UNITED STATES: HISTORICAL BACKGROUND

Many explanations exist for the high level of U.S. healthcare spending. One cultural explanation is the tendency for U.S. doctors to view death as failure, despite death's certain inevitability in the long-run and frequent inevitability in the short-run.<sup>8</sup> The U.S. "frontier spirit" has also been cited for culturally predisposing Americans (and consequently U.S. physicians) toward action in the face of adversity, manifested in the medical care context as a tendency to treat now rather than waiting or acknowledging that further treatment will yield little or no benefit or possibly even do more harm than good.<sup>9</sup> In other words, Americans believe that "the main purpose of a man's life is to solve problems."<sup>10</sup>

Many commentators, however, point to causal connections other than cultural predispositions, such as structural aspects of the U.S. health care system. A classic example of a structural flaw in the U.S. healthcare delivery system is the once dominant fee-for-service model

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8. Annas & Miller, *supra* note 2, at 388.

9. *Id.* at 361.

10. *Id.* at 361-62 (quoting Lynn Payer, *Medicine & Culture* 131 (1988)).

of healthcare delivery. This model engendered a tradition of superfluous delivery of care under the guise of medical necessity, spurred on by the relative ease of passing on costs to both insurance companies and the government, often viewed as impersonal bottomless pits that are unaffected by the individual's relatively small discrete expenditures.<sup>11</sup> While the goal of managed care is to reduce the overspending brought on by the fee-for-service world of yesteryear, old habits die hard and vestiges of the old ways of thinking about healthcare spending still surface in the practice of defensive medicine, the technological imperative, and other common utilization-increasing aspects of our health system.<sup>12</sup>

It is apparent that the doctrine of informed consent is relevant to the U.S. cost-containment debate. One way to illustrate the parallels between informed consent doctrine and the overall approach to healthcare delivery is to look to the lessons of history. The doctrinal roots of informed consent can be traced back at least as far as the eighteenth century ethical debate between Thomas Percival and John Gregory.

Percival's ethics were characterized by opposition to any kind of price or quality competition among physicians.<sup>13</sup> Furthermore, Percival favored monopolistic self-regulation by the medical profession.<sup>14</sup> "For Percival, the Enlightenment and rationality were available only to the elites paternalistically bound to assuming the burden of protecting the public."<sup>15</sup> In contrast, Gregory criticized the monopolistic and paternalistic tendencies of the Percivalean ethic.<sup>16</sup> Gregory believed that the medical profession could benefit, as do other professions, from a dose of competition (what he called "private interest").<sup>17</sup> However, Gregory felt that medical science and practice were kept too secret for the public to adequately judge the merit of particular physicians.<sup>18</sup>

Even today, the tension between Percival and Gregory is felt. The debate between the professional paradigm and the economic paradigm centers on the ability of patients, as consumers, to adequately digest medical information for the purpose of making informed treatment decisions.<sup>19</sup> Proponents of the professional model,

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11. *Id.* at 362.

12. *Id.* at 378.

13. Jeffrey L. Berlant, *Profession and Monopoly: A Study of Medicine in the United States and Great Britain* 82 (1975).

14. *Id.* at 91.

15. *Id.* at 93.

16. *Id.* at 88-97.

17. *Id.* at 91.

18. *Id.*

19. James F. Blumstein, *Health Care Reform and Competing Visions of Medical Care: Antitrust and State Provider Cooperation Legislation*, 79 *Cornell L. Rev.* 1459, 1464 (1994).

for example, tend to point to market failure—asymmetry of information—as engendering the need for a monopolistic substitution for the market in the form of a self-regulated, paternalistic profession.<sup>20</sup> In contrast, supporters of the economic model might look to professionalism as the cause of the market's difficulties, rather than their cure.<sup>21</sup> The roots of professionalism are characterized by a Percivalean tendency to discount the ability of patients to understand medical information; in contrast, Gregory expressed concern that patients were incapable of judging medical skill only because medical information was kept too secret from them.<sup>22</sup>

And yet, the realization that informed consent has significance in the cost-containment debate is not sufficient. This realization leaves unanswered the question, "How should informed consent be structured in the managed-care era?" In Part III, this Note will attempt to answer that question, but first this Note provides an introduction to the historical development of the doctrine of informed consent in the United States.

The doctrine of informed consent in the U.S. healthcare context holds as its driving value the concepts of autonomy and self-determination.<sup>23</sup> These deep-seated values explain why U.S. courts initially analyzed the duty to obtain a patient's consent to treatment under the ambit of the tort of battery.<sup>24</sup> In the 1914 case of *Schloendorff v. Society of New York Hospital*,<sup>25</sup> where a doctor performed surgery on a patient who consented to examination under anesthesia but explicitly stated that "there must be no operation,"<sup>26</sup> Judge Benjamin Cardozo stated: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages."<sup>27</sup> Therefore, plaintiffs in early informed consent cases were

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20. See, e.g., Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 Am. Econ. Rev. 941, 951 (1963).

21. Paul Starr, *The Social Transformation of American Medicine* 226–27 (1982).

22. See *supra* note 18 and accompanying text.

23. Joan H. Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 Iowa L. Rev. 261, 267 (1999).

24. Clark C. Havighurst, James F. Blumstein & Troyen A. Brennan, *Health Care Law and Policy: Readings, Notes, and Questions* 1093–94 (2d ed. 1998).

25. 105 N.E. 92 (N.Y. 1914).

26. *Id.* at 93.

27. *Id.* This is one of the most commonly quoted assertions in U.S. informed consent doctrine. See, e.g., Kathy L. Cerminara, *The Class Action Suit as a Method of Patient Empowerment in the Managed Care Setting*, 24 Am. J. L. & Med. 7, 21 (1998); Grant H. Morris, *Dissing Disclosure: Just What the Doctor Ordered*, 44 Ariz. L. Rev. 313, 317 (2002).

required to show that their doctors made undesired contact with the patient intentionally and without consent.<sup>28</sup>

As surgery became more commonplace and surgeons' work more trusted, however, the fear of unauthorized surgery became less significant.<sup>29</sup> At that time, the judicial focus shifted from the necessity of obtaining consent to that of obtaining adequately informed consent based on full disclosure.<sup>30</sup> This judicial trend toward the "informing" aspect of informed consent began with the famous California case of *Salgo v. Leland Stanford Junior University Board of Trustees* in 1957.<sup>31</sup> Like earlier courts that heard informed consent cases, the *Salgo* court framed its analysis in terms of the battery cause of action; however, it was the first court to discuss what disclosures were necessary to make a patient's consent informed: "A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment."<sup>32</sup>

This new legal issue of determining the proper amount of prior disclosure of medical information naturally led to the recharacterization of the tort as a breach of a professional duty,<sup>33</sup> in other words, a breach of the duty to obtain informed consent before treatment was often treated as a form of professional negligence.<sup>34</sup> This treatment of informed consent under a professional negligence standard began to take hold with the Kansas Supreme Court's 1960 decision in *Natanson v. Kline*,<sup>35</sup> which adopted *Salgo's* reasoning but did so in the malpractice context as opposed to battery.<sup>36</sup> The classification of the doctrine of informed consent under the heading of professional negligence is currently the dominant view,<sup>37</sup> and the battery cause of action is typically reserved for situations where physicians act with no consent at all or with evil intent.<sup>38</sup>

To prevail in a professional negligence case, a plaintiff must show (1) that the physician had a duty to disclose certain types of information to the patient, (2) that the physician breached that duty,

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28. See Restatement (First) of Torts § 13 (1934).

29. Havighurst et al., *supra* note 24, at 1094.

30. *Id.*

31. *Id.*; see *Salgo v. Leland Stanford Jr. Univ. Bd. of Trs.*, 317 P.2d 170 (Cal. Dist. Ct. App. 1957).

32. *Salgo*, 317 P.2d at 181.

33. Havighurst et al., *supra* note 24, at 1094.

34. *Id.*

35. 350 P.2d 1093 (Kan. 1960).

36. *Id.* at 1106 (citing *Salgo* for the rule that physicians have a duty to make only "those disclosures which a reasonable medical practitioner would make under the same or similar circumstances," and thus indicating that a malpractice standard applies in informed consent cases).

37. Havighurst et al., *supra* note 24, at 1094.

38. *Id.*

(3) that the plaintiff sustained an injury, and (4) that the physician's breach of duty proximately caused the injury.<sup>39</sup> The duty and breach issues are usually analyzed together. The existence of a duty on the part of the doctor to make some sort of disclosure tends to be taken for granted; however, the proper standard for determining what disclosure is required is an important matter in malpractice litigation, and a matter on which the states vary.<sup>40</sup> The rule in the majority of states is what one would expect in a professional negligence action, namely that the physician must disclose only the information that a reasonable medical practitioner in the same or similar circumstances would disclose.<sup>41</sup>

Several jurisdictions, however, follow the rule established in *Canterbury v. Spence*.<sup>42</sup> In *Canterbury*, the U.S. Court of Appeals for the D.C. Circuit abjured a standard based on professional custom as "arrogat[ing] the decision on revelation to the physician alone"<sup>43</sup> based on general standards of divulgence, despite the fact "that the myriad of variables among patients makes each case so different that its omission can rationally be justified only by the effect of its individual circumstances."<sup>44</sup> Based on these considerations, the court reasoned that the duty to inform arises from phenomena apart from customary practice<sup>45</sup> and determined that a patient-centered standard was more appropriate given the patient's self-determination interest.<sup>46</sup> Under this standard the physician must disclose all information material to the patient's decision.<sup>47</sup> In addition, the test for materiality is objective, based on a reasonable-person test: "[A] risk is . . . material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy."<sup>48</sup>

Some have argued that despite the move to a patient-based standard, this objective rule is not faithful to the underlying ethical concern for patient self-determination, because it ignores whether the disclosure was adequate for the specific patient making the treatment

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39. *Id.* at 992.

40. *See generally* Havighurst et al., *supra* note 24, at 1094–99.

41. *Id.* at 1094; *see, e.g.*, Natanson, 350 P.2d at 1106.

42. 464 F.2d 772 (D.C. Cir. 1972) (applying District of Columbia law).

43. *Id.* at 784.

44. *Id.*

45. *Id.* at 786.

46. *Id.*

47. *Id.* at 786–87.

48. *Id.* at 787 (quoting Jon R. Waltz & Thomas W. Scheuneman, *Informed Consent to Therapy*, 64 Nw. U. L. Rev. 628, 640 (1970)).

decision.<sup>49</sup> While this is a valid concern, one questions whether imposing liability based on a subjective, patient-based standard of disclosure might render physicians, who typically are unaware of the intricacies of each patient's personal preferences, unable to avoid liability for nondisclosure. Of course, if the ultimate goal is to encourage more disclosure, a subjective rule would likely achieve that end. As far as this Author is aware, there are no courts adopting a subjective disclosure standard.

Managed care raises interesting questions regarding the categories of disclosure that will be required. As noted above, the doctrine of informed consent originated at a time when medicine was less sophisticated and surgery was relatively new.<sup>50</sup> These circumstances combined with the fee-for-service nature of U.S. healthcare delivery for most of the twentieth century, gave rise to a risk of the forcing of unneeded medical care on patients.<sup>51</sup> In the modern managed-care environment, however, where medicine is much more trusted and where physician incentives are to decrease utilization, physicians are often in a position to exploit patients' naiveté by denying them the benefit of needed treatments.<sup>52</sup> Here, the doctrine of informed consent plays a very different role when requiring doctors to ensure that their patients are adequately informed before giving their consent.<sup>53</sup>

Some cases indicate the possibility of physician liability not only for nondisclosure of the risks of recommended treatments, but also for nondisclosure of the risks of nontreatment,<sup>54</sup> for nondisclosure of provider-specific risks,<sup>55</sup> and for financial incentives potentially affecting physician decisionmaking.<sup>56</sup> In *Truman v. Thomas*, for example, the defendant gynecologist testified that he had often recommended to the patient that she get a Pap smear; however, he did not discuss with her the full range of risks associated with the failure to do so.<sup>57</sup> The patient who chose to forego the Pap smear, eventually died of cervical cancer, and her minor children brought suit against the gynecologist.<sup>58</sup> Reasoning that the California requirement that doctors disclose all information material to the patient's decision implied a requirement that the physician share

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49. For a brief discussion of this issue with citations to other commentators, see Havighurst, et al., *supra* note 24, at 1099.

50. *See id.* at 1094 (indicating that the battery characterization of informed consent violations became less apt as surgery became less risky and more accepted).

51. *See id.* at 1125.

52. *Id.*

53. *See id.*

54. *See, e.g., Truman v. Thomas*, 611 P.2d 902 (Cal. 1980).

55. *See, e.g., Johnson v. Kokemoor*, 545 N.W.2d 495 (Wis. 1996).

56. *See, e.g., Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990).

57. 611 P.2d at 904.

58. *Id.*

material information regarding the risks of foregoing the recommended course of treatment, the court held that the physician may have breached the duty of care he owed to the plaintiff.<sup>59</sup> In *Johnson v. Kokemoor*, the plaintiff contended that the patient, who had died as a result of the surgery at issue, should have been informed of the operating surgeon's particular success rates as compared with other surgeons.<sup>60</sup> The Wisconsin Supreme Court agreed, holding that where physicians have substantially different success rates, the choice of physician is a choice between treatment alternatives, triggering disclosure of the success rate data under the Wisconsin informed consent statute.<sup>61</sup> Finally, in *Moore v. Regents of the University of California*, the plaintiff, a leukemia patient, alleged that during the course of his treatment his treating physicians collected samples of his blood, blood serum, skin, bone marrow aspirate, and sperm, and removed his spleen without informing him that his unique blood components likely had great commercial and research value.<sup>62</sup> He further alleged that the physicians went on to patent a cell line using his cells, naming themselves as the inventors.<sup>63</sup> The California Supreme Court held that such allegations of failure to disclose research and economic interests in the plaintiff's treatment established a claim for failure to obtain informed consent.<sup>64</sup> It should be noted, however, that the holdings in *Johnson* and *Moore* are unusual in the medical context,<sup>65</sup> although the Court of Appeals for the Eighth Circuit has handed down a ruling similar to *Moore* for ERISA fiduciaries.<sup>66</sup>

The remaining element of an action for breach of the duty to obtain informed consent to treatment is causation. The plaintiff must show that failure to obtain informed consent was a proximate cause of the injury or, stated differently, the patient would have decided not to undergo the treatment if the patient had been adequately informed of the risk.<sup>67</sup> Alternatively, in the case of a suit for nondisclosure of the risks of non-treatment, the patient would have consented to the

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59. *Id.* at 906–7.

60. 545 N.W.2d at 499–500.

61. *Id.* at 507.

62. 793 P.2d 479, 481 (Cal. 1990).

63. *Id.* at 481–82.

64. *Id.* at 483.

65. Havighurst, et al., *supra* note 24, at 1114 (stating that the holding in *Johnson* “is unusual”); Krause, *supra* note 23, at 340 (“*Moore* is a single case arising in a state with a traditionally broad informed consent doctrine, and no other jurisdiction has adopted its holding to date.”).

66. *See* Shea v. Esensten, 107 F.3d 625, 628–29 (8th Cir. 1997) (holding that an administrator of ERISA plan had duty to disclose compensation arrangement designed to induce physicians to make fewer referrals to specialists).

67. Havighurst et al., *supra* note 24, at 1100.

treatment if adequately informed. An issue exists as to whether the causation element can be satisfied in cases alleging nondisclosure of a risk other than the risk that actually led to the injury.<sup>68</sup>

Just as with the standard for disclosure, states differ as to whether an "objective" or "subjective" causation test is appropriate in informed consent cases.<sup>69</sup> Many courts have adopted an objective test, asking the jury to determine whether, if properly informed, a reasonable, prudent patient would have chosen differently.<sup>70</sup> Such an objective test neutralizes the effects of the plaintiff's testimony regarding causation, which is likely tainted with self interest and "20/20 hindsight."<sup>71</sup> Of course the already injured patient now believes that he would have chosen to forego the harmful treatment if he had known about the risk.

Like the objective disclosure standard, however, the objective test for causation is often criticized as being unfaithful to the underlying ideal of individual autonomy and self-determination.<sup>72</sup> Consequently, many courts have adopted a subjective test for causation, asking instead whether this particular patient would have foregone treatment if adequately informed.<sup>73</sup> While the subjective test satisfies the desire for the furtherance of patient autonomy, it introduces the risk that distorted plaintiff testimony regarding the importance of the omitted disclosure will be given too great an effect. Probably as a result of this tension, the cases seem to evidence a blurring of the distinction between the two tests.<sup>74</sup>

One final aspect of U.S. informed consent doctrine is the enactment in many states of informed consent statutes<sup>75</sup> after the twentieth century trend toward vindicating patient autonomy through more patient-oriented analysis ran against the tort crises of the 1970s and 1980s.<sup>76</sup> Although patients were viewed more as rational consumers of healthcare during this time, the patient autonomy championed by evolving informed consent doctrine was minimized in the face of pressure to limit physician liability.<sup>77</sup>

Over half the states now have informed consent statutes.<sup>78</sup> These statutes tend to take one of two general approaches: (1) listing of the

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68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.*

72. *See id.* ("Is the objective test for causation true to the professed purpose of giving individual patients a chance to choose for themselves?").

73. *Id.*

74. *Id.* at 1101.

75. *See generally id.* at 1116–18 (discussing consent statutes enacted in several states).

76. *Id.* at 1116.

77. *Id.*

78. *Id.*

required types of disclosure coupled with a presumption of informed consent if the enumerated disclosures are made; or 2) listing of the elements of the cause of action based on failure to obtain informed consent as well as the defenses to such a cause of action.<sup>79</sup> Within this basic framework, the statutes address a variety of issues relating to informed consent which are not within the scope of this Note. Suffice it to say that one exhaustive survey of the early informed consent statutes found that they tended to be “little more than window dressing, creating the appearance of change without the substance.”<sup>80</sup> Moreover, many state legislatures attempted to replace subjective, patient-oriented standards with the professional test for appropriateness of disclosure.<sup>81</sup>

### III. WHAT SHOULD INFORMED CONSENT LOOK LIKE IN THE UNITED STATES?

Having become broadly familiar with the current state of U.S. informed consent doctrine, the all-important normative question remains: “What *should* informed consent look like in the United States?” Needless to say, commentators have come forward with many proposals for the role informed consent ought to play in managed care. Four major lines of thinking are outlined this Part.

#### A. *Specific Informed Consent Proposals in Recent Years*

##### i. Mark A. Hall’s Theory of Economic Informed Consent<sup>82</sup>

Professor Hall’s theory of advance contractual consent to nondisclosure argues that when an individual subscribes to a managed care plan, he is in effect consenting to a rationing scheme, or a “bundle of unspecified refusals of marginally beneficial care.”<sup>83</sup> As a basis for this claim, Hall advocates the “global disclosure” of cost containment mechanisms at the time of enrollment and reenrollment, reasoning that despite the rarity of such disclosures in current practice, there is no justification for failing to inform HMO

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79. *Id.*

80. Alan Meisel & Lisa D. Kabnick, *Informed Consent to Medical Treatment: An Analysis of Recent Legislation*, 41 U. Pitt. L. Rev. 407, 562–63 (1980).

81. Havighurst et al., *supra* note 24, at 1118.

82. Mark A. Hall, *Making Medical Spending Decisions: The Law, Ethics, and Economics of Rationing Mechanisms* 194 (1997) [hereinafter Hall, *Making Medical Spending Decisions*]. See generally Susan M. Wolf, *Toward a Systemic Theory of Informed Consent in Managed Care*, 35 Hous. L. Rev. 1631, 1665–68 (1999) (describing Professor Hall’s theory).

83. Hall, *Making Medical Spending Decisions*, *supra* note 82, at 194.

subscribers of plan incentive structures.<sup>84</sup> Hall recommends adding five items of disclosure to current disclosure practices: (1) a common-sense explanation of managed care's broader goal of containing costs through eliminating expensive, marginally-beneficial care; (2) a description of who exercises authority over which medical spending decisions; (3) a general explanation of the sources of the rules that govern decisionmakers, coupled with availability upon request of copies of those rules; (4) a fairly specific description of the financial incentives that affect physicians' recommendations; and (5) an explanation of what patients can expect to be told when treatment options of potential benefit to the patient are not recommended due to cost.<sup>85</sup> As to this fifth recommendation, Hall proposes an example:

Our medical professionals will provide a range of treatment options that is reasonable and standard for this kind of insurance in this part of the country and this practice setting. However, they will not always point out where their professional judgment differs from those who practice under more expensive forms of insurance or who follow different styles of medical practice. Patients are always free to ask questions about their course of recommended treatment. Those questions will be answered honestly and thoroughly, including requests for second opinions or for information about how to obtain treatment that is not available under this insurance plan. However, patients may not demand payment by us for treatment that is more expensive than this plan allows or that, in the view of our medical professionals, exceeds appropriate medical standards.<sup>86</sup>

Hall then asks what effect such prior consent should have on doctors' duty to inform patients of non-treatment decisions under the rationing scheme.<sup>87</sup> He argues that requiring physicians to make such disclosures at the treatment decision point would be impracticable.<sup>88</sup> Physicians will often subconsciously engage in implicit rationing, and if forced to disclose the underlying tradeoffs, they run the risk of undermining patient trust.<sup>89</sup> Furthermore, just as the patient self-determination ideal is often sacrificed because of practical concerns, "pristine informed consent [can] be compromised in the resource allocation situation as well."<sup>90</sup>

Thus, Hall argues that "enrolling with an HMO constitutes blanket advance consent to the subsequent denials of marginally beneficial care brought about by the rules, procedures, and incentives disclosed at the outset (and periodically affirmed through annual open enrollment decisions); thereafter, additional disclosure at the

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84. Mark A. Hall, *A Theory of Economic Informed Consent*, 31 Ga. L. Rev. 511, 520–21 (1997) [hereinafter Hall, *A Theory of Economic Informed Consent*].

85. *Id.* at 582–84.

86. *Id.* at 584.

87. See Hall, *Making Medical Spending Decisions*, *supra* note 82, at 193–239.

88. *Id.* at 204.

89. *Id.* at 205.

90. Hall, *A Theory of Economic Informed Consent*, *supra* note 84, at 551–56.

time of treatment is unnecessary.”<sup>91</sup> This general allowance of nondisclosure does not apply, though, where the patient questions the physician.<sup>92</sup> Nor does Hall insist that this theory of advanced consent ought to apply to all treatment decisions; rather, he excludes from its coverage certain high stakes decisions, such as refusal to consent to life support or treatment decisions having significant consequences on the patient’s ability to make a living.<sup>93</sup> Finally, Hall recognizes that his theory of consent would be illusory if patients were not given choices either between plans or between various options within a plan.<sup>94</sup>

An alternative theory submitted by Professor Hall is the theory of “silent rationing.”<sup>95</sup> Under this theory, subscription to the plan is not viewed as an advance consent to rationing, but rather as “a waiver of the right to be informed when such decisions are made.”<sup>96</sup> The practical result of this waiver theory is the same as that of advanced consent: physicians generally are not required to disclose non-covered treatment options, except in the face of patient questioning or high stakes medical decisionmaking.

## ii. Peter H. Schuck’s Call for Contextualization

Professor Peter Schuck emphasizes “the need to contextualize informed consent” by “tailoring the law’s requirements more carefully to the different settings in which risks arise and are discussed, assessed, and acted upon.”<sup>97</sup> In furtherance of this theme, Schuck proposes a reassessment of informed consent along four paths: (1) subjection of informed consent doctrine to cost-effectiveness analysis, (2) use by physicians of more meaningful and understandable methods of communicating risks to patients, (3) movement away from a monolithic informed consent doctrine inattentive to the variety of contexts in which consent is sought, and (4) legal enforcement of patient-plan contracts over the characteristics of informed consent.<sup>98</sup>

Schuck first argues that informed consent doctrine should be “paid the compliment of taking it seriously” enough to subject it to systematic cost-effectiveness analysis.<sup>99</sup> “Talk, especially busy doctors’ talk, is not cheap. Genuinely probing conversation . . . is

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91. Hall, Making Medical Spending Decisions, *supra* note 82, at 211.

92. *Id.*

93. *Id.* at 226.

94. Hall, *A Theory of Economic Informed Consent*, *supra* note 84, at 576–81.

95. Hall, Making Medical Spending Decisions, *supra* note 82, at 224.

96. *Id.* at 216.

97. Peter H. Schuck, *Rethinking Informed Consent*, 103 Yale L.J. 899, 906 (1994).

98. *Id.* at 905–06.

99. *Id.* at 947.

dearer still.”<sup>100</sup> He argues that the many costs of informed consent, from the costs of doctors’ time to the mental and emotional costs for patients of processing the information, should be weighed against the various benefits of different levels of disclosure.<sup>101</sup> While acknowledging the potential difficulties inherent in attempting to comprehensively estimate the costs and benefits of informed consent, Schuck maintains that there is no principled reason why such an estimation cannot be achieved<sup>102</sup> and recommends two possible starting points: direct time-cost measurements based on physician surveys and cross-national comparative analyses.<sup>103</sup>

Schuck recognizes that in an age of cost containment, current informed consent doctrine may not pass cost-benefit muster given its high costs.<sup>104</sup> However, he argues that such a result is not preordained.<sup>105</sup> Rather, analysis might reveal that approaching the ethically ideal version of informed consent would produce benefits, perhaps in the form of autonomy and outcome enhancement, that are worth the costs.<sup>106</sup>

Schuck’s second recommendation relates to physician communication styles. Reasoning that the goals of informed consent cannot be achieved unless physicians communicate reliable risk information in an intelligible and meaningful fashion, he points to studies and commentary indicating that actual informed consent practices fail to satisfy these minimal standards.<sup>107</sup> Schuck cites language and concepts used by physicians in characterizing risks as an important reason for this failure.<sup>108</sup> General terms such as “high” or “insignificant” and ambiguous terms such as “may” or “probably will” give the patient little basis for assessing risk in a refined way.<sup>109</sup> At the same time, more exact quantitative terminology like numerical percentages is too “remote[] from any referent that is real or palpable to the patient” to be useful as a decisionmaking tool.<sup>110</sup>

To make risk information more meaningful for patients, Schuck asserts that physicians should change the way they describe risk.<sup>111</sup> He recommends that doctors characterize medical risks in terms of other risks that are more accessible to the patient, such as describing

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100. *Id.* at 942.

101. *Id.* at 942–43.

102. *Id.* at 943–44.

103. *Id.* at 944–45.

104. *Id.* at 946.

105. *Id.*

106. *Id.* at 947.

107. *Id.* at 948.

108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.* at 949.

the risk associated with a treatment as being equivalent to the risk of experiencing a collision while driving home at night.<sup>112</sup>

One may question the practicability of such an approach; indeed, Professor Schuck himself indicates that a comparative risk approach is problematic.<sup>113</sup> The first concern is whether comparative risk information can even be made available to physicians in a form they can properly use without committing the statistical fallacies that are common even among experts.<sup>114</sup> Schuck, however, submits that there is no principled reason such information cannot be supplied, particularly since the number of comparisons made available need not be any larger than the number of risk categories physicians already use in discussions with patients.<sup>115</sup> Nevertheless, he concedes that simple equivalences can be dangerous given the fact that the tolerance for particular risks is a personal matter that varies greatly from patient to patient.<sup>116</sup> But he considers this fault acceptable in comparison to the extreme failure of current risk discussions.<sup>117</sup>

Professor Schuck's third proposal involves adaptation of informed consent to the various contexts in which the doctrine is applied.<sup>118</sup> He views current informed consent doctrine as "largely monolithic and noncontextual (except insofar as it employs 'reasonableness' terms and contains certain exceptions to the general duty to disclose)" and indicates a need to contextualize and differentiate the doctrine.<sup>119</sup> Pointing to the tobacco litigation of the 1990s, where jurors imputed informed consent to the plaintiff-victims despite the serious suffering experienced by the victims and the clear evidence of the defendants' causal role in that suffering, Schuck recommends that policymakers consider why informed consent might be more easily imputed in some contexts than in others.<sup>120</sup>

Much as he did with his cost-effectiveness and comparative risk proposals, Schuck concedes that answering this question would be difficult.<sup>121</sup> Still, he maintains that in principle it is not impossible.<sup>122</sup> In support of this claim, he points to anecdotal evidence indicating that mothers retain a great deal more of the information their obstetricians provide about risks, tests, and alternatives than do

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112. *Id.*

113. *Id.*

114. *Id.* at 949–50.

115. *Id.* at 950.

116. *Id.* at 950–51.

117. *Id.* at 951.

118. *Id.* at 952.

119. *Id.* at 951–52.

120. *Id.* at 952–54.

121. *Id.* at 954.

122. *Id.*

patients in most other contexts.<sup>123</sup> He also offers as an example a claim that informed consent should be imputed in the case of mass vaccines, where the risks are low and the benefits are very great to the individual and to others, much more readily than in the case of silicone breast implants, where the risk-benefit relationship is much more questionable and the choice is highly personal.<sup>124</sup> According to Schuck, a properly contextualized informed consent doctrine might vary according to the nature of the treatment, the treatment setting, the number and type of available alternatives, the degree of medical uncertainty, and the special characteristics of the particular patient, among other factors.<sup>125</sup> Additionally, an informed consent doctrine would differentiate between elective and non-elective treatments, between primary- and tertiary-care providers, and between one-time and long-term treatments.<sup>126</sup>

Finally, and perhaps most significantly, Schuck extends his contextualization argument to the realm of individual preferences.<sup>127</sup> In his words,

some patients seem to prefer leaving some or all medical treatment decisions to their physicians, accepting their ignorance about the risks they face but placing trust in their physicians to “do the right thing” for them. Others appear to act in the same way even though they may in fact simply be too intimidated or anxious to behave otherwise. Still others—I call them (us) ‘information junkies’—more closely approximate the conventional “rational consumer” model of decisionmaking, treating medical treatment decisions more or less like other consumption decisions with respect to the information sought.<sup>128</sup>

He criticizes the law’s current treatment of all patients and physician-patient relationships as homogenous, suggesting that this view deprives patients of the right to choose different levels of consent with which they would be more satisfied and for which they would be willing to pay.<sup>129</sup> This result is ironic given the key role choice plays as the underlying rationale for informed consent doctrine in the United States.<sup>130</sup>

Pointing to two advantages of the existing uniform approach, that it is cheaper to know and enforce and that it protects patients against gross inequalities of bargaining power versus providers, Schuck rejects these rationales given the growing organization of the healthcare market and the increasing monopsonistic power held by large group purchasers of healthcare who can act as proxies for their

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123. *Id.*

124. *Id.* at 955.

125. *Id.* at 954.

126. *Id.* at 955.

127. *Id.* at 957.

128. *Id.*

129. *Id.*

130. *Id.* at 957–58.

members.<sup>131</sup> He proposes that under these conditions, such group purchasers should be allowed to bargain over a variety of informed consent issues, such as standard dialogue procedures, amount of discussion, types of disclosures to be made, alternative dispute resolution, institutional liability, and others.<sup>132</sup> In Schuck's view, such bargains should be enforced under appropriate circumstances, such as when the patient is a member of an organization that truly represents the best interests of its members or when the provisions at issue can plausibly be said to have advanced the patient's interests (viewed *ex ante*) and no overreaching or lack of consent is present.<sup>133</sup>

### iii. Susan M. Wolf's Systemic Vision<sup>134</sup>

Professor Susan M. Wolf envisions a systemic theory of informed consent.<sup>135</sup> Criticizing the narrow focus of Hall and others on whether prior or presumed consent reduces the amount of required dialogue at the treatment decision point,<sup>136</sup> Wolf stresses the importance of the flow of events leading up to the treatment decision.<sup>137</sup> First, a worker accepts a job, thereby limiting his health plan options.<sup>138</sup> Next, he chooses a health plan, whether it be one of many available plans or the only plan offered by his employer.<sup>139</sup> Then the subscriber must choose a primary care physician.<sup>140</sup> The treatment decision in the context of a particular health condition arises only after all of these choices have taken place.<sup>141</sup> At every stage of this process, information is being given or withheld that affects the patient's later treatment options and decisions.<sup>142</sup> Thus, the current focus on the point-of-treatment decisionmaking reflects a failure to approach informed consent doctrine systemically.<sup>143</sup>

Wolf first submits that, both before job acceptance and at plan enrollment, the employee should be informed of the content of the health plan or plans offered by the employer, including the plans exclusions and its rationing incentives.<sup>144</sup> It is argued that such

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131. *Id.*
  132. *Id.* at 958.
  133. *Id.* at 958–59.
  134. Wolf, *supra* note 82, at 1631.
  135. *Id.*
  136. *Id.* at 1650–51.
  137. *Id.* at 1653.
  138. *Id.*
  139. *Id.*
  140. *Id.* at 1654.
  141. *Id.*
  142. *Id.*
  143. *Id.* at 1663.
  144. *Id.* at 1675.

disclosures are necessary for the subscriber to subscribe knowingly and select a primary care provider knowledgeably and for the plan to resolve its conflict of interest.<sup>145</sup> Wolf also argues that the prospective primary care provider has a duty to disclose the financial incentives to which he is subject and his particular "rationing and disclosure styles."<sup>146</sup>

Finally, Wolf addresses disclosure at the point of treatment decision.<sup>147</sup> Wolf avers that the patient ought to be informed not only of diagnosis and treatment options, but also of the factors that play into the doctor's decision regarding which treatments he will recommend.<sup>148</sup> Because managed care plans are so large and complex, the patient needs the physician to explain the extent to which plan exclusions and discretionary physician rationing play into the physician's disclosure decisions for the patient to properly evaluate the physician's advice and decide whether or not to get a second opinion.<sup>149</sup> Such disclosure, as well as disclosure of the full range of available treatments, is also necessary for resolving the physician's conflict of interest.<sup>150</sup> In addition to the duty to make such wide-ranged disclosures, Wolf suggests that physicians ought to perform "economic advocacy" for their patients, going to bat for them against the plan when rationing rules threaten inappropriate harm to the patient.<sup>151</sup>

According to Wolf, a patient's need for disclosure is increased by what she calls "feedback loops": informational pathways via which patients are apprised of the facts necessary for determining whether or not to remain with their plan and primary care provider.<sup>152</sup> Without such information, patients as consumers cannot conduct quality control within the healthcare system by walking away from unacceptable plans.<sup>153</sup>

#### iv. Joan H. Krause's Statutory Model

Professor Joan Krause presumes that the major informed consent problem to be dealt with during this era of cost containment is the need for disclosure of noncovered treatment alternatives.<sup>154</sup> She acknowledges that patients in this new era of medical consumerism do not merely have more rights; indeed, they also have more

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145. *Id.* at 1675–76.

146. *Id.* at 1676.

147. *See id.* at 1676–77.

148. *Id.* at 1676.

149. *Id.* at 1676–77.

150. *Id.* at 1677.

151. *Id.* at 1678.

152. *Id.*

153. *Id.*

154. Krause, *supra* note 23, at 292–93.

responsibilities.<sup>155</sup> Patients, however, need access to adequate information, including information about cost containment incentives and excluded, care to make decisions for which they should be held responsible.<sup>156</sup> Krause believes HMOs tend to utilize policies that discourage such disclosure, both explicitly and implicitly.<sup>157</sup>

Despite the great deal of public attention focused on gag clauses in provider-plan contracts, Professor Krause views the gag clause as a "paper tiger, a perfect foil for anti-managed care activists," given evidence that these provisions do not significantly affect physician practice.<sup>158</sup> Rather, she looks to implicit incentives to withhold information, such as "termination without cause" provisions and internalization of cost containment decisions, as the real root of the nondisclosure problem.<sup>159</sup>

Professor Krause concludes that despite the common assumption that physicians are required to disclose treatment alternatives generally, this requirement is rarely given much weight in practice.<sup>160</sup> Therefore, because traditional informed consent law has not been successful at protecting the patient's right to information regarding treatment alternatives generally, it surely cannot be counted on to protect the patient's right to information regarding uncovered alternatives.<sup>161</sup>

Krause criticizes prior contract theories of informed consent and prior proposals to reform tort law as incomplete solutions, although she does seem to think there is a place for such ideas. She first examines Professor Hall's contract theory, concluding that it is impressive but too limited to be effectual.<sup>162</sup> Because Hall would apply his theory only to care that is of marginal benefit and not to high stakes or value-laden treatment decisions, Krause argues that in the end, his proposal is more descriptive than corrective of modern informed consent practices.<sup>163</sup> Furthermore, she claims that to expand Hall's theory to include high-stakes and value-laden decisions would controversially limit patients' informed consent rights.<sup>164</sup> Krause views current proposals to improve tort and ethical doctrines as similarly insufficient, but does advocate two reforms in these

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155. *Id.* at 349.

156. *Id.*

157. *Id.* at 293-305.

158. *Id.* at 296-97 (citing U.S. Gen. Accounting Office, GAO/HEHS-97-175, *Managed Care: Explicit Gag Clauses Not Found in HOM Contracts, But Physician Concerns Remain* (Aug. 1997)).

159. *Id.* at 297-305.

160. *Id.* at 337.

161. *Id.*

162. *Id.* at 360.

163. *Id.*

164. *Id.* at 360-61.

areas.<sup>165</sup> She first recommends a reconfiguration of tort law in terms of emphasizing dignitary interests and the importance of process, with a view to relating tort law more closely to the self-determination interest in which it is rooted.<sup>166</sup> In the ethical arena, Krause advocates a clear bifurcation between the duty to provide information and the duty to provide care, so that the mere inability to provide a certain treatment does not provide an excuse not to disclose the existence of that treatment.<sup>167</sup> In Krause's view, disclosure of beneficial but non-covered treatment options has the potential to protect the relationship of trust between patient and physician, which is sometimes threatened by the existence of financial incentives that create physician self-interest.<sup>168</sup>

Krause's unique contribution to the body of informed consent literature, however, is her reconceptualization of informed consent in statutory terms, based on lessons she has drawn from breast cancer informed consent statutes.<sup>169</sup> She views these statutes as significant because they typically (1) provide for the creation of standardized summaries of treatment alternatives; (2) adopt strictly medical criteria for determining appropriate disclosure; and (3) impose professional discipline penalties, as opposed to restricting patients to tort remedies, against violators.<sup>170</sup>

First, while praising the usefulness of treatment option summaries, Krause acknowledges that it would be virtually impossible to summarize every medical treatment category.<sup>171</sup> In the alternative, she suggests that it might be beneficial to create summaries only for a defined list of medical conditions for which informed consent is considered particularly important.<sup>172</sup> Such a list might include cancer treatment and invasive surgical procedures.<sup>173</sup> While alluding to the possibility that this listing approach might provide a good supplement to a global waiver approach like that espoused by Professor Hall, Krause nevertheless sees this partial listing as unsatisfactory for dealing with day-to-day disclosures regarding minor care.<sup>174</sup>

Krause also argues for the use of exclusively medical criteria, such as "medical viability," for determining the types of disclosure that will be required.<sup>175</sup> Her main concern in making this argument

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165. See *id.* at 364–71.

166. *Id.* at 364–68.

167. *Id.* at 368.

168. *Id.* at 370.

169. See *id.* at 378–85.

170. *Id.* at 380–83.

171. *Id.* at 380–81.

172. *Id.* at 381.

173. *Id.*

174. *Id.*

175. *Id.* at 381–82.

appears to be that other types of standards, like "availability," run the risk of being interpreted as allowing financial considerations to play into the disclosure decision.<sup>176</sup> Moreover, she makes little of the potential for controversy arising from such standards in view of the paucity of case law generated by the breast cancer statutes on the issue of which disclosures are required.<sup>177</sup>

Finally, Krause points to professional discipline provisions as perhaps the most important aspect of the breast cancer informed consent statutes.<sup>178</sup> To the extent that the goal of policymakers is to deter nondisclosure, as opposed to compensating patients who have suffered purely dignitary harms with large monetary awards, professional discipline is a very effective model.<sup>179</sup> Professional discipline relieves the plaintiff of the burden of proving causation and focuses solely on the underlying issue of whether the physician made the proper disclosures.<sup>180</sup> In addition, the dispute would be handled by medical professionals, which Krause argues is more fitting because professionals are more capable of making decisions based on purely medical considerations.<sup>181</sup> Still, Krause does not take the loss of monetary awards lightly, suggesting that perhaps the best approach would be a combination of tort and disciplinary models, with violations resulting in physical harm to patients being actionable in tort.<sup>182</sup> While it is true that this would disadvantage those who have suffered dignitary harms vis-à-vis those who have suffered physical harm, Krause argues that such an approach is desirable because it legitimizes the dignitary interests that underlie informed consent doctrine while minimizing excess tort liability.<sup>183</sup> After all, the tort system is not always the best instrument for protecting patient rights.<sup>184</sup>

### *B. A Synthesizing Approach*

Each of the above proposals has strengths and weaknesses to varying degrees. Might a synthesizing approach combine the strengths of each while minimizing their weaker points? A proposal achieving this result would undoubtedly resemble some of the above proposals more closely than others but could conceivably contain elements of all. This Subpart examines the four proposals outlined

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176. *Id.* at 382.

177. *Id.*

178. *Id.* at 384.

179. *Id.*

180. *Id.*

181. *Id.*

182. *Id.* at 384–85.

183. *Id.* at 385.

184. *Id.*

above and attempts to synthesize them into a finished product that incorporates the best elements of each. The examination begins with a look at some of the perceived shortcomings of the various approaches.

Professor Schuck's contextualization argument is strong but suffers from many drawbacks. The first is found in the following words: "no principled reason why not."<sup>185</sup> Indeed in three of his four major proposals, Schuck indicates that the necessary legwork would be difficult but is not impossible.<sup>186</sup> Meanwhile, he offers very little in the way of explanation as to why these various tasks can in fact be accomplished.

For example, Schuck states that he has been unable to find any quantitative measurement of the costs and benefits of informed consent, but sees no principled reason why such a calculation would be impossible.<sup>187</sup> He does offer direct physician time-cost measurement as a possible approach;<sup>188</sup> however, such an approach would not meet up to his own requirement that all types of cost, including emotional costs and the like, would need to be measured to conduct a truly comprehensive cost-effectiveness analysis.<sup>189</sup> Schuck also suggests that cross-national comparisons might shed some light on the costs and benefits of various informed consent practices,<sup>190</sup> but it is not clear, given the uniqueness of the U.S. healthcare system generally and U.S. informed consent doctrine particularly, that such comparisons would go very far in achieving any kind of genuinely probing analysis of the costs and benefits associated with informed consent. It is a true strength of Schuck's proposal, however, that he seeks to subject informed consent doctrine to the same cost-benefit analyses to which nearly all policy choices are subjected.<sup>191</sup> However, perhaps such analysis need not be directly quantified. Rather it

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185. This claim appears in Schuck's defense of three of his four major proposals. See Schuck, *supra* note 97, at 944 (claiming that there is no reason why costs and benefits of informed consent cannot be quantitatively measured); *id.* at 950 ("There is no reason in principle why health care physicians cannot be supplied with comparative risk information that is systematically designed to be used in conversations with patients."); *id.* at 954 (The question of which factors make differentiation between certain risk contexts appropriate with regard to informed consent standards is difficult, but "can indeed be answered, at least in principle.").

186. *Id.* at 944 ("While the estimation task will be difficult, there is no reason in principle why it cannot be done."); *id.* at 949-50 ("I acknowledge that formulating and applying comparative risk information is problematic," but "[t]here is no reason in principle why health care physicians cannot be supplied with comparative risk information . . ."); *id.* at 954 ("Although this is a difficult question, it is one . . . that cannot be answered.").

187. *Id.* at 943-44.

188. *Id.* at 944.

189. See *id.* at 942-43.

190. *Id.* at 945.

191. *Id.* at 947.

might more appropriately be perceived as an influential background principle that policymakers would do well to keep in mind.

Similarly, Schuck indicates that, although accurate comparative risk information is difficult to convey and difficult to marshal, “there is no reason in principle” why physicians cannot be supplied with such information in a usable form.<sup>192</sup> Statistical risk analysis is notoriously difficult, such that even experts in the field sometimes make common cognitive errors.<sup>193</sup> Thus, while it may be possible to deliver such information to some physicians in a form that they can use,<sup>194</sup> it is doubtful whether all physicians would be able to effectively utilize such risk descriptions to the betterment of their patients’ understanding. In addition, as Schuck acknowledges, the simple equivalencies envisioned by comparative risk discussion are further limited in their effectiveness by the varied ways in which different people view particular risks.<sup>195</sup> Still, comparative risk discussions are not necessarily useless. Perhaps, rather than being viewed as the be-all and end-all of disclosure styles, comparative risk explanation would be more properly treated as a valid and effective option among the various risk disclosure styles available, including explanation in terms of percentages and less specific explanations.

Schuck makes a similarly unsubstantiated claim regarding the capacity (“at least in principle”) of policymakers to ascertain the many factors that contribute to differentiation between informed consent contexts.<sup>196</sup> Schuck himself submits a list of factors that probably should be considered, indicating that there are “perhaps other[s].”<sup>197</sup> Yet it is not evident that all of the factors contributing to differentiation can be readily ascertained. Furthermore, assuming it may be possible to create a comprehensive list of the most important factors informing contextualization, it seems that it would be exceedingly difficult to outline a comprehensive approach to applying those factors to different practice contexts. It is difficult to envision such a comprehensive approach to differentiation being taken up by legislators; however, surely such differentiation is appropriate. Again, perhaps the more appropriate vision is that of a toned-down differentiation between the different contexts in which consent is sought, seen as an appropriate background consideration.

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192. *Id.* at 950.

193. *Id.*

194. *See id.* (“At a minimum, the number of comparisons need be no larger than the number of descriptive categories that physicians already use in discussing risk with patients.”)

195. *Id.* at 950–51.

196. *Id.* at 954 (“Although this is a difficult question, it is one that, like the cost-effectiveness question, can indeed be answered, at least in principle.”).

197. *Id.*

Perhaps the strongest aspect of Schuck's proposal is his call for differentiation in the realm of individual disclosure preferences.<sup>198</sup> Schuck correctly recognizes the differences among individuals with regard to these preferences and importantly notes the irony behind the denial of disclosure choices in the name of informed consent (with its underlying interest of self-determination): in this way, the law denies patient choice in the name of patient choice.<sup>199</sup>

Schuck acknowledges the strengths of a unitary standard of disclosure: it is cheaper to administer, and it protects patients in situations characterized by unequal bargaining strength.<sup>200</sup> He argues, however, that these reasons for uniformity are seriously weakened by the growing complexity of the healthcare market and the increasing bargaining strength of group purchasers acting on behalf of patients.<sup>201</sup> Schuck argues that patient choices regarding desired levels and types of disclosure ought to be enforced where circumstances are appropriate (e.g., where proxies can truly be said to have acted in the interest of their members or where proxies can honestly be said to have advanced the patient's interests).<sup>202</sup>

Professor Wolf's systemic proposal appears to suffer a major fault which largely weakens its force: her vision of informed consent is impracticable because it would consume too many resources, as can be seen from a quick recap of the disclosures she would require. First, Wolf calls for a disclosure at the time of job acceptance of the content of the health plans the employer offers.<sup>203</sup> Next, she asserts the necessity of similar disclosures at the time of plan enrollment.<sup>204</sup> Then, when the plan member begins to shop for primary care providers, each prospective provider is required to share not only the rationing incentives that affect his decisionmaking but also his particular "rationing and disclosure styles."<sup>205</sup> The standards for determining whether a physician has sufficiently disclosed his particular "style" are not elaborated upon, and the costs of conducting such dialogue are not discussed. Finally, at the point of the treatment decision, Wolf demands "physician disclosure of the full roster of relevant treatments as well as the medical and economic considerations affecting the physician's recommendation."<sup>206</sup>

The cost of such far-reaching disclosure requirements cannot be overstated. In the words of Peter Schuck, "Talk, especially busy

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198. *See id.* at 956-59.

199. *Id.* at 957-58.

200. *Id.* at 957.

201. *Id.* at 958.

202. *Id.*

203. Wolf, *supra* note 82, at 1675.

204. *Id.*

205. *Id.* at 1676.

206. *Id.* at 1677.

doctors' talk, is not cheap."<sup>207</sup> The failure of Wolf's proposal to address the cost issues of her widespread disclosure requirements is its primary downfall and cannot be ignored in today's cost-conscious world.

That said, Professor Wolf's proposal does evince two major strong points: (1) its emphasis on systemic thinking and (2) its focus on the importance of feedback loops. First, Wolf reasons that good informed consent policy should take into account the structure of the entire managed care system.<sup>208</sup> It is safe to say that any policy which does not adequately consider the unique structure and aims of managed care runs the risk of failing to adequately address the concerns raised by that structure and those aims. It does not necessarily follow, however, that widespread disclosure at every structural level is the only way to effectively address managed care's systemic concerns. Second, Wolf stresses the importance of feedback loops as a quality control instrument for patients in an age of medical consumerism.<sup>209</sup> This, too, is a useful contribution to the thinking on informed consent. As is the case with systemic analysis, however, extensive disclosure at every step in the health-plan process is not necessarily a prerequisite for enabling the patient to judge the performance of his or her provider and plan.<sup>210</sup>

Professor Krause's narrow focus on disclosure of noncovered treatment options<sup>211</sup> assumes away the difficult question: "Should noncovered options be disclosed?" If a patient specifically asks about noncovered treatment options, surely the physician is required to answer honestly. And if the stakes are very high, surely the physician should discuss every treatment alternative with the patient, even those that are not covered. But what about the day-in, day-out healthcare decisions, in situations where patient concern does not reach a level sufficient to provoke them to ask questions about other options? Under certain circumstances, might full disclosure of all likely beneficial options be excused? These are difficult questions, and the answers are not immediately obvious. Hence, it may be that Krause needs to examine her presuppositions.

Krause, however, does submit some useful ideas. For instance, while she admits that a proposal to create comprehensive treatment-alternative summaries across the board would be impracticable, she seems to hint at the possibility of using summaries in specified high stakes areas to supplement contract-based informed consent

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207. Schuck, *supra* note 97, at 942.

208. Wolf, *supra* note 82, at 1650.

209. *Id.* at 1678.

210. *See id.* ("The patient or subscriber needs to know how well the provider and plan are addressing the individual's medical problems.")

211. *See* Krause, *supra* note 23, at 292.

theories.<sup>212</sup> Whether such a supplementation might indeed be possible is an intriguing question.

Undoubtedly, however, the greatest success of Krause's proposal is its recommendation of the use of professional disciplinary proceedings in policing disclosure.<sup>213</sup> Professional disciplinary proceedings offer the strong advantage of effective deterrence of improper nondisclosure while minimizing stress on the tort system.<sup>214</sup> Simultaneously, professional discipline has the appeal of bringing added legitimacy to dignitary injuries, which the tort system does not strongly protect, but which are at the very heart of the autonomy interests that underlie informed consent doctrine.<sup>215</sup> The idea of using professional disciplinary procedures exclusively except where physical injury results from nondisclosure thus has some promise.<sup>216</sup>

Finally, a criticism of Professor Mark Hall's economic theory may be justifiable. According to Professor Krause, Hall's theory calls for permitting patients and providers to contract out of the tort system; "[t]o the extent that judges are bound by the common law of informed consent, however, it is not clear that they would be free to recognize such a contractual waiver."<sup>217</sup> There is some validity to this point, especially considering the apparent judicial distrust of cost containment incentives affecting disclosure.<sup>218</sup> To the extent that Hall's theory would not be supported judicially, legislative action may be needed. And yet, given the foundational self-determination interests underlying informed consent doctrine in the United States, one could make a strong argument for judicial enforcement of disclosure bargaining. Finally, as Schuck has indicated, one possible bargaining option under a contract theory is bargaining for alternative dispute resolution.<sup>219</sup> Perhaps a forum more disposed to enforcing individual bargaining in this area can be chosen.

Regardless of whether it is judicially or statutorily achieved, however, Professor Hall's economic theory of informed consent offers an appealing analytical framework for analyzing informed consent in today's managed care environment. As Schuck points out, allowing individuals to contract regarding preferred disclosure standards promotes individual autonomy and self-determination, the core

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212. *Id.* at 381 ("To the extent that even commentators such as Professor Hall agree that certain types of conditions are too important to be included within a global waiver of informed consent to cost-conscious decision making, there may some support for this general approach.").

213. *See id.* at 384-85.

214. *Id.*

215. *Id.*

216. *See id.* at 384-85.

217. *Id.* at 361.

218. *See, e.g., Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 484 (Cal. 1990); *see also, e.g., Shea v. Esensten*, 107 F.3d 625, 628-29 (8th Cir. 1997).

219. Schuck, *supra* note 97, at 958.

interests that comprise the foundation upon which informed consent is established in the United States.<sup>220</sup> Thus, under appropriate circumstances, the law should enforce such bargains.<sup>221</sup> It makes no sense for a doctrine which champions choice to limit patients' ability to exercise choice.<sup>222</sup>

Wolf criticizes Hall's formulation of the issue as too narrow: "Is the doctor-patient dialogue required by the doctrine of informed consent at the point of treatment diminished by prior or presumed consent to certain treatment limitations or allocation rules at the point of subscribing to the health plan?"<sup>223</sup> Rather, Wolf claims, a systemic analysis is needed.<sup>224</sup> Hall's informed consent theory, however, arguably addresses systemic concerns by expanding the class of appropriate disclosure settings beyond the point of treatment to include the point of enrollment.<sup>225</sup> To be sure, Hall's proposal advocates more modest disclosure than Wolf's, but it is no less systemic.

Professor Krause adds an additional criticism, namely that Hall's contract theory, which excludes high stakes and value-laden decisions, is so limited in scope as to be more descriptive than prescriptive in nature.<sup>226</sup> The claim is that limitation of the theory to everyday care of marginal benefit does not address the locus of the problem.<sup>227</sup> Is it not beyond argument, however, that such everyday decisions comprise the lion's share of disclosure contexts? And does not a minute of physician dialogue cost the same whether it is spent in discussion of aspirin versus ibuprofen or in discussion of chemotherapy versus radiation therapy? It stands to reason that reducing the level of physician dialogue in the everyday setting goes to the heart of the cost-containment aspiration. Furthermore, it seems apparent that in the context of high stakes decisionmaking, where the informational costs tend to be relatively low in comparison to the likely eventual treatment costs, more robust disclosure is justified, especially given the importance of the decisions being made.

To the extent that physician dialogue currently resembles that envisioned by Hall's proposal, that is well; however, as we have seen, courts' judgments of the sufficiency of such dialogue are unpredictable.<sup>228</sup> In an uncertain and litigious environment, it is

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220. See *id.* at 957–58.

221. *Id.* at 958–59.

222. *Id.* at 957–58.

223. Wolf, *supra* note 82, at 1650–51.

224. See *id.* at 1650.

225. Hall, *A Theory of Economic Informed Consent*, *supra* note 84, at 582.

226. Krause, *supra* note 23, at 360.

227. *Id.* at 360.

228. See, e.g., *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 484–85 (Cal. 1990).

hardly likely that all physicians, whose actions are so often motivated by a desire for liability avoidance, feel free to reduce disclosure even for low stakes decisions. A legal framework that provides certainty for physicians based on contractual disclosure obligations would indeed add value to the current situation.

Furthermore, an economic theory of informed consent, if properly laid down, ought to encourage the development of Wolf's feedback loops, such that medical consumers can exercise informed judgments of plan and provider quality.<sup>229</sup> If patients truly are globally informed at enrollment and reenrollment,<sup>230</sup> and if providers are obliged to respond truthfully to patient questioning,<sup>231</sup> and if complete information regarding rules that govern plan decision makers is made available upon request,<sup>232</sup> patients who desire to gauge the desirability of their plan and provider have all the necessary tools at their disposal. It is true that contractual consent theory likely is not justifiable if full disclosure is not made at the proper times or if information is not readily available to plan members; however, neither Hall nor this Author advocates that plans be free to "hide the ball" in such a way.<sup>233</sup>

Although Krause's article in some ways eschews a contract theory of informed consent, some of her ideas may indeed provide useful building blocks for improving upon such a theory. As noted above, Krause indicated that standardized summaries of treatment options for particular high-stakes medical conditions could supplement a contract model of informed consent.<sup>234</sup> As Hall himself notes, it is likely that medical decisions regarding such conditions necessitate further disclosure, even in the face of the less-disclosure preferences of some patients.<sup>235</sup> Perhaps comprehensive summaries like those contained in the breast cancer statutes could aid disclosure efforts in this context.

Perhaps the most important potential addition to the contract theory would be Krause's suggestion of the use of professional disciplinary proceedings to police some disclosure violations.<sup>236</sup> The beauty of a contract theory of informed consent is its synergy with the traditional doctrine, in that it aims to promote patient autonomy and self-determination. To the extent that patient autonomy is to be furthered, however, the law ought to deter even merely dignitary

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229. See Wolf, *supra* note 82, at 1678.

230. See Hall, *A Theory of Economic Informed Consent*, *supra* note 84, at 582.

231. See *id.* at 584.

232. See *id.* at 583.

233. See *id.* at 583-84.

234. Krause, *supra* note 23, at 381.

235. Hall, *Making Medical Spending Decisions*, *supra* note 82, at 226.

236. See Krause, *supra* note 23, at 384-85.

violations of autonomy.<sup>237</sup> Further strain, however, on the tort system in the current environment of myriad tort reform efforts would seem an improper avenue for vindicating dignitary interests, thus highlighting the need for vamped-up professional discipline. Utilizing professional disciplinary proceedings to address disclosure violations would accomplish the goal of deterrence of such violations while avoiding needless tort litigation.<sup>238</sup> Furthermore, disciplining providers for disclosure violations causing only dignitary harm vindicates and legitimizes autonomy and self-determination.<sup>239</sup> To the extent that physicians cause measurable physical harm to patients by failing to disclose, such violations could be handled under the existing tort system,<sup>240</sup> contractually determined ADR, or statutorily determined mechanisms. Of course, to avoid needless wasting of judicial resources, rules determining the proper forum for dispute resolution would be necessary. Otherwise patients suffering dignitary harms would likely be tempted to seek tort relief in the hopes of receiving monetary damage awards. Perhaps the traditional motion to dismiss for failure to state a claim would be sufficient; however, it may be that a more concrete and uniform standard for determining the appropriate resolution forum would be more suitable.

Thus, this Note concludes that a contract theory of informed consent provides the proper framework for setting disclosure standards in the United States. Such a model achieves a systemic focus while furthering patient autonomy and self-determination by allowing patients to bargain for their preferred types of disclosure. Furthermore, such a model insists on accessibility of information for patients, ensuring that the feedback loops so necessary for consumer quality control are present. Although Professor Hall envisions a judicial enforcement model, it may well be that statutory intervention or contractual choice of forum is necessary to ensure certainty of contractual enforcement. Finally, some supplementary items would arguably approve upon a contract approach. The creation of standardized treatment-option summaries for common high-stakes medical decisions would aid physician efforts to ensure adequate disclosure in these settings. Furthermore, the inclusion of a professional discipline component, perhaps achieved statutorily, in a contract model would further vindicate the autonomy interests that virtually all agree are vital while limiting provider liability for monetary damages.

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237. *See id.*

238. *Id.*

239. *Id.* at 385.

240. *See id.* at 384–85.

#### IV. "INFORMED CONSENT" IN THE UNITED KINGDOM: *BOLAM* AND ITS PROGENY

As stated above, the United Kingdom's healthcare system is not characterized by the drastic spending that plagues the U.S. system. Several aspects of the British system contribute to its manageable spending situation.

The first and most obvious difference between the United Kingdom's healthcare delivery system and that of the United States is that the former is a public system, while the latter is largely private. In the United Kingdom, medical care is viewed as a public good and, as a corollary of that country's governmental provision of healthcare, overall medical spending is limited by a set healthcare budget.<sup>241</sup> Clearly, this capped-spending approach limits healthcare spending across the board, probably affecting every category of medical treatment. Capped spending, however, arguably plays an even greater role in limiting spending in those areas where the cost of treatment probably does not justify its likely benefit. Because of capped spending, U.K. physicians and policymakers are forced to make allocation decisions with regard to concededly scarce resources; in other words, they have to make cost-benefit determinations. Therefore, where treatment costs would naturally tend to exceed treatment benefits—that is, where treatment makes little economic sense—these determinations would result in greatly reduced utilization.

A cultural factor cited as leading to lower spending in the United Kingdom is the fact that British society tends to view death as acceptable, rather than as professional failure.<sup>242</sup> Physicians and patients alike consider death to be both natural and necessary.<sup>243</sup> Thus, British physicians, in addition to being forced to make cost-benefit decisions as to the relative value of potential treatments for dying patients, are also less encumbered by the intense desire to preserve life at all costs which often characterizes U.S. medical care.<sup>244</sup> It is interesting to note that the United Kingdom was the birthplace of the hospice care movement.<sup>245</sup> Annas and Miller correctly characterize the hospice movement as "reject[ing] heroic medical treatment and [as being] openly designed to ease the natural transition to death."<sup>246</sup>

It is also argued that the United Kingdom's more collective notions of healthcare entitlement decrease spending in its healthcare

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241. Annas & Miller, *supra* note 2, at 369.

242. *Id.* at 389.

243. *Id.*

244. *Id.* at 387.

245. *Id.*

246. *Id.*

system. Because Britons do not consider themselves to be autonomous consumers of medical care as a private good, but rather perceive themselves (correctly) as members of a collective pool who have to "divvy up" the scarce healthcare resources with one another, they tend to demand less treatment than their neighbors across the Atlantic.<sup>247</sup>

Relatedly, lower levels of spending in the United Kingdom are often attributed to the more professional-favoring British informed consent standards. English law does not purport to recognize the doctrine of informed consent.<sup>248</sup> Under the oft-cited rule handed down in the *Bolam* case, however, doctors' decisions regarding disclosure of the risks of treatment and non-treatment are handled under the ambit of medical negligence and are traditionally afforded deference so long as the doctors can be said to have acted "in accordance with a practice accepted at the time as proper by a responsible body of medical opinion skilled in [that] particular form of treatment."<sup>249</sup> For the most part, this rule holds true today.<sup>250</sup>

While the *Bolam* test at first appears to be similar to the predominant U.S. disclosure standards (outlined in Part IV), upon further investigation it is seen to be more deferential to the physician. The "reasonable-physician" standard utilized by the majority of U.S. jurisdictions attempts to ascertain a particular disclosure standard attributable to the medical community and holds the physician to that standard, while the second most common U.S. standard, which is patient- rather than professional-based, is even less deferential to physicians. In contrast, the *Bolam* test defers to physicians' disclosure judgments so long as those judgments are accepted by any responsible body of medical men.<sup>251</sup>

*Maynard v. West Midlands Regional Health Authority*<sup>252</sup> clarified the extent of this deference to physicians. In *Maynard*, the House of Lords stated that "a judge's 'preference' for one body of distinguished professional opinion to another also professionally distinguished is not sufficient to establish negligence in a practitioner whose actions have received the seal of approval of those whose opinions . . . were not preferred."<sup>253</sup> In other words, a judge who

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247. *Id.* at 369.

248. Philip M.D. Gundy & Annette P. Gumbs, *Bolam, Sidaway and the Unrecognized Doctrine of "Informed Consent": A Fresh Approach*, 1997 J. Pers. Inj. Litig. 211, 211.

249. *Bolam v. Friern Hosp. Mgmt. Comm.*, (1957) 1 W.L.R. 582, 582 (Q.B.).

250. Nicola Castle, *Applying Bolitho*, 1998 J. Pers. Inj. Litig. 278, 279 ("The 'Bolam test' remains the cornerstone by which the standard of care is measured in medical negligence claims.")

251. *Bolam*, 1 W.L.R. at 582.

252. (1984)1 W.L.R. 634 (H.L.).

253. *Id.* at 639.

deems the patient's evidence more credible than the practitioner's cannot impose liability so long as that practitioner produces any respectable medical opinion approving of his conduct.<sup>254</sup> Taken together with some commentators' observations that defendants often produced rather questionable evidence in the hopes of its being considered respectable, the "*Maynard* principle" operates to tie judges' hands in cases where the defense evidence is much less credible than the plaintiff's evidence but nevertheless is considered part of some respectable body of medical opinion.<sup>255</sup>

The *Defrietas v. O'Brien* case<sup>256</sup> appeared to make it even more difficult for plaintiffs to prevail in English informed consent cases. *Defrietas* seemed to hold that defendants could invoke the *Maynard* principle by merely adducing evidence from one or two experts known to be on the fringes of acceptable medical practice.<sup>257</sup> It appears, however, that *Defrietas* has not had much effect on English informed consent litigation.<sup>258</sup> In fact, the House of Lords has indicated in dictum that the mere fact that the defendant has brought evidence from a number of experts who genuinely believe his decision was appropriate does not require a court to hold that the defendant escapes liability; rather the court must be satisfied that the experts, in reaching their opinions, "have directed their minds to the question of comparative risks and benefits and have reached a defensible conclusion on the matter."<sup>259</sup> The House of Lords has made it clear, however, that defense experts' opinions will fail to defeat the plaintiff's case only in the rare case where a judge determines that those opinions cannot be logically supported.<sup>260</sup>

Some inroads were arguably made into the *Bolam* test's deference to professionals in *Sidaway v. Board of Governors of the Bethlem Royal Hospital*.<sup>261</sup> In *Sidaway*, Lord Bridge and Lord Keith agreed in dictum that when a patient specifically questions a physician about treatment risks, the physician must answer honestly and "as fully as the questioner requires."<sup>262</sup> Furthermore, Lords Bridge, Keith, and Templeman suggested that even where no expert witness contends that the non-disclosure fails to conform to accepted practice, the judge might come to the conclusion that disclosure "was so obviously necessary to an informed choice . . . that no reasonably prudent medical man would fail to make it."<sup>263</sup> The extent to which

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254. See Castle, *supra* note 250, at 279.

255. *Id.*

256. 6 Med. L.R. 108 (1995).

257. Castle, *supra* note 250, at 280.

258. *Id.*

259. See, e.g., *Bolitho v. City and Hackney Health Auth.*, (1998) A.C. 232 (HL).

260. See *id.*

261. [1985] A.C. 871 (H.L.); Gundy & Gumbs, *supra* note 248, at 212-13.

262. *Sidaway*, [1985] A.C. at 898.

263. *Id.* at 900.

judges are free to stray from the *Bolam* test in reality, however, is as yet unclear.

It is not surprising that the United Kingdom affords such great authority to treating physicians in view of the gatekeeping function of British general practitioners.<sup>264</sup> Because physicians control the decision whether a patient will see a specialist for further treatment, and thereby are responsible for controlling costs, they are vested with greater authority relative to patients than their U.S. counterparts. Patient knowledge encourages patient autonomy.<sup>265</sup>

#### V. WHAT SHOULD INFORMED CONSENT LOOK LIKE IN THE UNITED KINGDOM?

Informed consent law in the United Kingdom is understandably less developed than its U.S. counterpart.<sup>266</sup> Some point to the historical need to implicitly ration healthcare resources in a system with capped spending as the explanation for this condition.<sup>267</sup> As was alluded to above, this view is valid. In Britain, where capped public spending is the hallmark of healthcare, general practitioners function as gatekeepers, filtering true patient need from mere patient demand for limited specialty and high-tech care.<sup>268</sup> Such a filtering role naturally engenders a narrower scope for individual decisionmaking.<sup>269</sup> Thus, it is not surprising that English law favors the professional on the disclosure issue.<sup>270</sup> Maintenance of low costs in the British system is achieved in part by discouraging disclosure, which in turn discourages patient autonomy and encourages the collectivist notions that lead British patients to demand less utilization.

Annas and Miller argue that the relative homogeneity of English culture as compared with the United States also argues for reposing more trust in English professionals to make medical decisions for their patients.<sup>271</sup> Where greater homogeneity is present, we expect more cultural agreement regarding treatment decisions, making disclosure less important.<sup>272</sup> In the United States, on the other hand,

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264. Annas & Miller, *supra* note 2, at 379.

265. *Id.* at 377.

266. Mary Anne Bobinski, Book Review, 18 *Hous. J. Int'l L.* 957, 965 (1996) (reviewing Christopher Newdick, *Who Should We Treat? Law, Patients and Resources in the N.H.S.* (1995)).

267. Frances H. Miller, *Denial of Health Care and Informed Consent in English and American Law*, 18 *Am. J.L. & Med.* 37, 67-68 (1992).

268. Annas & Miller, *supra* note 2, at 378.

269. *Id.*

270. *Id.* at 379.

271. *Id.* at 387.

272. *Id.*

where cultural diversity is high and a wider economic and spiritual gulf exists between patients and physicians, the law may need to more carefully protect disclosure given the infrequency of shared values.<sup>273</sup>

Furthermore, increased disclosure despite decreased options due to capped spending could be considered inhumane.<sup>274</sup> With respect to U.S. informed consent policy, it is often argued that paternalistic physicians have no right to neglect to disclose treatment options simply because they are not covered, for the physician never knows what resources the patient might have at his disposal to purchase a noncovered treatment outside of the plan.<sup>275</sup> Such a concern does not apply in a capped public system like that in the United Kingdom, where medical choice is limited by limitations on supply.<sup>276</sup> In such a setting, informing patients about potentially beneficial but financially unattainable treatment options might well be considered inhumane.<sup>277</sup> Of course, this is a paternalistic argument. Standing in contrast to this argument is the argument that nondisclosure of unavailable options forecloses the possibility of procedural coverage appeals<sup>278</sup> or mobilization of public opinion against the noncoverage.<sup>279</sup> These procedural and political concerns do apply in the U.K. context, although the potential to have coverage denials overturned there is unclear. At any rate, the argument for requiring disclosure of noncovered alternatives seems somewhat weaker in the United Kingdom than in the United States.

Still, it can be argued that the United Kingdom's deference to professionals is explainable in less justifiable terms. Specifically, some view this deference as an indefensible carryover from the Victorian era—an extension of the traditional English tenet that “Nanny knows best.”<sup>280</sup> (In fact, an Australian Supreme Court judge criticized the *Bolam* test using these very terms.<sup>281</sup>) The *Bolam* test has been criticized as having grown out of the class hierarchy system of early English society and the unwillingness of the legal profession to allow ordinary people to challenge the rules of the medical profession.<sup>282</sup>

How should disclosure obligations in the United Kingdom compare and contrast with those in the United States? Should not

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273. *Id.*

274. *Id.* at 378.

275. *See, e.g., Krause, supra note 23, at 302–3.*

276. *Annas & Miller, supra note 2, at 378.*

277. *Id.*

278. *See Krause, supra note 23, at 303–04.*

279. *See Annas & Miller, supra note 2, at 378–79.*

280. *See, e.g., Dr. Peter Fenwick, Informed Consent—Should Bolam Be Rejected?*, 16 *Med. & L.* 215, 215 (1997).

281. *Id.* at 219.

282. *Id.*

British patients have the same right of self-determination that American patients enjoy? At the same time, is it not relevant that the role of general practitioners as gatekeepers is necessary in the United Kingdom's public healthcare delivery system?

As Lord Scarman indicated in his *Sidaway* dissent, the right of self-determination inheres in patients in the United Kingdom just as it does in patients in the United States.<sup>283</sup> Scarman recommended a move to a patient-based standard like the one announced in *Canterbury v. Spence*.<sup>284</sup> Such a move would clearly vindicate patient autonomy to a degree, but would arguably fail to adequately serve the need to conserve resources of physician time in a capped-spending environment.

In truth, the United Kingdom's capped spending system operates much like U.S. managed care's capitation model.<sup>285</sup> Britain has indeed been capitating its general practitioners ever since the National Health System (NHS) was created in 1948,<sup>286</sup> so that in many ways the NHS operates as the functional equivalent of an HMO.

It stands to reason, then, that an informed consent proposal in the United States might contain some valuable lessons for the United Kingdom. This Note proposes for the United Kingdom many of the same recommendations asserted for the United States in the area of informed consent. Specifically, this Note prescribes (in addition to current British disclosure practices) the aforementioned concepts of (1) one-time global non-physician disclosure in the year that citizens reach the age of majority, so that citizens fully understand the system in which their medical decisions are being made; (2) the availability upon request of information regarding the rules governing decisionmakers; (3) a requirement of honest answers to patient questioning; and (4) a system of professional discipline to apply where harms caused by nondisclosure are purely dignitary. In addition, a fifth element is advocated for specific application to the U.K. system: establishment of a legal duty of care to comply with disclosure requirements (1), (2), and (3) above in addition to the physician-oriented duty already in place under *Bolam*.

The need for a contract-based approach is not necessary or applicable in the United Kingdom, because cost-containment there is already being achieved pursuant to a longstanding tradition of public

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283. *Sidaway v. Bd. of Governors of the Bethlem Royal Hosp.*, [1985] A.C. 871, 886-87 (H.L.).

284. *Id.* at 888.

285. Frances H. Miller, *Capitation & Physician Autonomy: Master of the Universe or Just Another Prisoner's Dilemma? (What Can Britain's National Health Service Experience Teach Us?)*, 6 Health Matrix 89, 99 (1996).

286. *Id.*

rationing. In the United States, by way of contrast, a longstanding tradition of unlimited spending is being corrected by cost-containment measures in the private sector through managed care, making the contract enforcement theory an essential element of an effective U.S. informed-consent model.

This model would vindicate the autonomy interests of British patients by enabling them to understand the environment in which they are giving or withholding consent. Thus, if a patient prefers to accept the treatment recommended in a particular situation "at face value," he can do so. If, however, he prefers to know more information about treatment options, he is free to ask, and the physician is bound to answer honestly. Furthermore, if he wants to learn more about the rules to which a general practitioner is subject and the incentives that affect his judgment, he can request the appropriate information. Regardless of the patient's choice regarding information in any given treatment setting, it is *his* choice, not the choice of a paternalistic professional.

This model also furthers patient autonomy by providing for the aforementioned employment of professional disciplinary proceedings as a mechanism to deter illegal nondisclosure. As discussed, professional discipline has the value of deterring informed consent violations while conserving the resources of the tort system.

Furthermore, this model is consistent with the need for the efficient use of the U.K.'s capped healthcare resources. Physicians will be free to go about their day-to-day practices as they did before, subject only to the *Bolam* standard. Granted, they will be required to honestly answer patient inquiries regarding unavailable treatment options and risks, but it is doubtful that they are currently legally permitted to lie in the face of direct questioning. Thus, general practitioners' time will be used just as efficiently as it is today. The major costs created by this model are the expense of global disclosure and the expense of litigation under the newly created legal duty.

The expense of global disclosure would not be insubstantial; however, the major portion of the costs will be borne at the outset. Maintaining an already-established global disclosure mechanism should not be overly expensive. Regardless, the cost of one-time global disclosure, coupled with the on demand availability of rule documentation, is a small price to pay for the legitimization of patients' interest in autonomy and self-determination. When such disclosure should take place is a matter which requires consideration. In the managed care context, global disclosure takes place at enrollment and reenrollment.<sup>287</sup> There is no analogous event in Britain, however, where every citizen is covered by NHS from

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287. See Hall, *A Theory of Economic Informed Consent*, *supra* note 84, at 582.

birth.<sup>288</sup> This Author proposes the age of legal majority in the United Kingdom as the proper time for global disclosure to take place. Mechanically, such disclosure could take the form of a mandated, one-day class taught by paraprofessionals from NHS at various locations across the United Kingdom, or perhaps a video distributed to each citizen when he or she attains majority.

The expense of litigation under the new legal duty would likewise be worth the cost. The reasoning behind such a legal duty is that it provides much needed redress for patients who have suffered legitimate physical injuries due to physician nondisclosure. As this Note has discussed, Britain's current deference to physicians in professional negligence cases has the potential to deny redress even to patients who, in the mind of the judge, have been wronged. Under the proposed model however, patients who are harmed as a result of a violation of the legal disclosure standards laid out above would be able to state a *prima facie* case of professional negligence. In this way, the common sense "smell test" would not be subverted as easily by technical application of the *Bolam* test. At the same time, the legal duty would be clear enough to avoid a blurring of the legal standard: any claimant alleging a breach of this duty must prove that his physician violated one of the legal disclosure requirements, as administratively or statutorily written, and that the violation legally caused compensable injury to the plaintiff.

Thus, we see that the models for informed consent in the United States and the United Kingdom can be remarkably similar because of the two systems' shared interests in containing costs and furthering autonomy. One time global disclosure and subsequent full availability of rules, incentives, and structural information enables patients to exercise choice in determining how much they prefer to know about their treatment options and the rules and incentives that affect decision makers and general practitioners. The use of professional disciplinary proceedings deters violations and legitimizes patients' right to self-determination, while not increasing tort liability. Finally, the creation of a new legal standard based on these new disclosure policies enables patients who clearly have been harmed by violative nondisclosure to have redress when the *Bolam* test might not otherwise do so.

## VI. CONCLUSION

As this Note has demonstrated, the U.S. healthcare system is very different from that of the U.K. The U.S. system is largely private, and its informed consent doctrine is highly developed and

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288. See Annas & Miller, *supra* note 2, at 369.

characterized by a strong desire to promote autonomy. In addition, America has only begun in the last half century to pull itself out of a morass of overspending engendered by years of cost-pass-through insurance and fee-for-service medicine. That movement is most strongly evidenced by managed care.

In contrast, the U.K.'s system of capped public spending on healthcare has enabled it to effectively control its costs by controlling the amount spent industry-wide. As healthcare costs rise, however, British concerns to maintain low spending levels are very real. In fact, Britain's gatekeeper approach is functionally equivalent to capitation in U.S. managed care. This brings British concerns in line with American concerns to a large extent. Furthermore, the interests in autonomy and self-determination have been recognized by many in the United Kingdom as important, aligning British aims even more with American aims.

An effective model for informed consent policy in the United States is the contract theory of informed consent. This entails not merely enforcement of contracts over treatment-point disclosure levels, but also global disclosure at enrollment and reenrollment, and effective availability of further information about plan rules and incentives. In addition, assigning a stronger role to professional disciplinary proceedings in the informed-consent context is an effective way to deter improper nondisclosure while avoiding strain on the tort system.

A well-developed model of informed consent in the United Kingdom would incorporate each of these characteristics, with the exception of the contract theory, which is inapplicable to the public health delivery context. Finally, another useful addition to the U.K. informed consent regime would be the creation of a cause of action based on violation of the proposed disclosure standards, so that legitimate claims that slip through the cracks of the *Bolam* test can be properly redressed.

It is possible to achieve patient autonomy and self-determination while effectively containing healthcare costs. Each of these aims is worthy of aspiration, and it is clear that a well-developed theory of informed consent can adequately further both of these objectives.

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