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## ARTICLES

### Medicare's Coverage with Study Participation Policy: Clinical Trials or Tribulations?

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#### INTRODUCTION

The Medicare program has, from its inception, sought to balance its duty to safeguard the Medicare trust, with its statutory obligation to pay only for “reasonable and necessary”<sup>1</sup> health care for Medicare beneficiaries, and to honor the government’s promise that its elderly and disabled citizens will receive the best that modern medicine has to offer.<sup>2</sup> Modern medicine is expensive, and costs continue to rise, fueled by an influx of new medical technology and the fast approach toward Medicare eligibility for millions of baby-boomers.<sup>3</sup> The Centers for Medicare and Medicaid Services (CMS)<sup>4</sup> face legal and political restraints

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1. See 42 U.S.C.A. § 1865y(a)(1)(A) (2003) (providing that “no payment may be made . . . for any expenses incurred for items or services . . . not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”).

2. See S. REP. NO. 89-404 (1965), as reprinted in 1965 U.S.C.C.A.N. 1443, 1465 (expressing congressional intent that the Medicare program would “make the best of modern medicine more readily available to the aged”).

3. See Dep’t of Health & Human Servs., Medicare Enrollment: National Trends 1966-2005, <http://www.cms.hhs.gov/MedicareEnRpts/Downloads/HISMI05.pdf> (last visited May 3, 2007). With the exception of 1984, the number of Medicare beneficiaries has grown each year since its inception in 1965. *Id.* The term “baby boom” refers to the generation born between 1946 and 1964. In 2000, persons between the ages of 65 and 84 made up 10.9% of the U.S. population, but that number is projected to increase to 17% of the total population by 2030. U.S. Census Bureau, Projected Population of the United States, by Age and Sex: 2000 to 2050 (2004), <http://www.census.gov/ipc/www/usinterimproj/> (follow hyperlink to Table 2a).

4. See DEP’T OF HEALTH & HUMAN SERVS., THE NEW CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) (2001), <http://www.hhs.gov/news/press/2001pres/20010614a.html>. Medicare and Medicaid, enacted in 1965, were administered by the Social Security Administration until 1977. In 1977, Medicare and Medicaid were transferred to the Department of Health and Human Services

with respect to its ability to control costs. Although CMS has discretion in determining *how much* it will pay for new items and services, it does not have explicit statutory authority to consider cost when deciding whether to cover the intervention in the first instance.<sup>5</sup> Faced with conflicting obligations and statutory restraints, CMS has endeavored to reduce costs, particularly with regard to expensive new technology, through an initiative known as Coverage with Evidence Development (CED).<sup>6</sup> This new coverage policy, published by CMS on July 12, 2006, consists of two arms.<sup>7</sup> The second, more controversial arm of CED is called Coverage with Study Participation (CSP). Under this program, CMS will pay for certain new medical tests, treatments, and biotechnology products, even though it deems the medical evidence insufficient to merit broad national coverage, provided that the services are received in the context of a prospective clinical trial aimed at generating additional evidence.<sup>8</sup> Thus, CSP would restrict payment for certain services to a limited group of Medicare beneficiaries who “agree” to participate in a clinical trial.

The idea of linking coverage to clinical research is not entirely new. In 1995, CMS conditioned payment for an innovative surgical procedure upon patient participation in a clinical trial. In that instance, CMS commenced a seven year clinical trial to compare the outcomes of emphysema patients who underwent lung volume reduction surgery with those patients who were given comprehensive pulmonary rehabilitation.<sup>9</sup> In the face of vigorous opposition

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(HHS) and to the Health Care Financing Administration (HCFA). In 2001, HHS changed the name to Centers for Medicare and Medicaid Services (CMS). *Id.* Since this Article includes background material and legislative history, the designations CMS, HCFA, and Medicare are used interchangeably.

5. See discussion *infra* Section II.A.

6. CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL COVERAGE DETERMINATIONS WITH DATA COLLECTION AS A CONDITION OF COVERAGE: COVERAGE WITH EVIDENCE DEVELOPMENT (2006), [https://www.cms.hhs.gov/mcd/ncpc\\_view\\_document.asp?id=8](https://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8) [hereinafter CMS, CED GUIDANCE DOCUMENT].

7. See *id.* at pt. V. The first arm is called “Coverage with Appropriateness Determination” (CAD). CMS explains that items or services designated for CAD are backed by sufficient scientific evidence to satisfy the “reasonable and necessary” statutory standard required for coverage purposes, but additional information is needed to assure the intervention is “appropriately provided.” *Id.* CAD may be required as a condition of coverage under the following circumstances: (1) if the new service should be restricted to patients with specific conditions and criteria; (2) if the item or service requires providers with specific training or credentials; (3) when “clinical thought leaders” are concerned there may be substantial opportunities for misuse; or (4) if the coverage determination significantly changes the way providers manage patients using the new service. *Id.* at pt. V.A. Under CAD, CMS will require as a condition of payment (coverage) that the provider must submit to a research database or registry patient information beyond that usually available on the claims forms that are required for payment. *Id.* To the extent that coverage is contingent upon patients providing additional (beyond billing) information to a registry for research purposes, CAD may raise some of the same issues regarding voluntary informed consent that are raised with the second arm of CED, Coverage with Study Participation.

8. See *id.* at pt. V.B.

9. See Sean R. Tunis & Steven D. Pearson, *Coverage Options for Promising Technologies*:



from provider representatives and some members of Congress, CMS restricted payment for lung volume reduction surgery to beneficiaries treated according to a clinical trial protocol.<sup>10</sup> In a 2005 trial involving the use of FDG-PET scans to diagnose certain cancers, CMS conditioned coverage of the scans on participation in a prospective clinical trial or registry.<sup>11</sup> Also in 2005, CMS conditioned coverage of implantable cardioverter defibrillators (ICDs) used for certain indications on participation in a clinical trial or registry.<sup>12</sup> Prior to the publication of its July 2006 "Coverage with Evidence Development" guidelines, however, CMS had not explained its authority for linking coverage with participation in research.

Coverage with Study Participation (CSP) substantially alters the manner in which CMS has traditionally made its national coverage determinations, and raises significant legal and ethical questions. CMS claims that a service designated for CSP does not meet the statutory "reasonable and necessary" standard because, although promising, more evidence is required before the clinical result can be generalized to the Medicare population, or to additional subgroups of Medicare patients.<sup>13</sup> Yet, under CSP, the item or service is somehow boosted to the level of "reasonable and necessary," if provided within the context of a clinical trial.<sup>14</sup>

The statutory authority for CSP is questionable. CMS proposes that a statutory provision permitting payment for research conducted for purposes of quality improvement would also allow it to pay for the CSP clinical trials. This

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*Medicare's Coverage with Evidence Development*, 25 HEALTH AFF. 1218, 1220-21 (2006) (describing the emphysema trial, and other instances of linking coverage to research participation).

10. *Id.* (noting that the emphysema trial went forward despite strong opposition from some members of Congress and provider representatives).

11. See CTRS. FOR MEDICARE & MEDICAID SERVS., DECISION MEMO FOR POSITRON EMISSION TOMOGRAPHY (FDG) FOR BRAIN, OVARIAN, PANCREATIC, SMALL CELL LUNG, AND TESTICULAR CANCERS (2005), available at <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=92>.

12. See CTRS. FOR MEDICARE & MEDICAID SERVS., DECISION MEMO FOR IMPLANTABLE DEFIBRILLATORS (2005), available at <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=148>.

13. CMS, CED GUIDANCE DOCUMENT, *supra* note 6, at pt. V.B ("CSP allows CMS to determine that an item or service is only reasonable and necessary when it is provided within a research setting where there are added safety, patient protections, monitoring, and clinical expertise."). Among the evidentiary findings that may result in a designation of Coverage with Study Participation (CSP) are: (1) Available evidence may be a product of otherwise methodologically rigorous evaluations but may not have evaluated outcomes that are relevant to Medicare beneficiaries; (2) The available clinical research may have failed to address adequately the risks and benefits to Medicare beneficiaries for off-label or other unanticipated uses of a drug, biologic, service or device; and (3) Available clinical research studies may not have included specific patient subgroups or patients with disease characteristics that are highly prevalent in the Medicare population. *Id.*

14. See *id.*

Article posits that the “reasonable and necessary” provision is CMS’s only statutory authority for making coverage decisions, and that CSP represents CMS’s attempt to circumvent the statute’s limitations. Congress has statutorily mandated that CMS withhold payment for Medicare items or services that are not “reasonable and necessary.” If services provided under CSP truly do not meet that standard, then CMS, possibly under intense political pressure, is essentially paying for items or services that are *not* reasonable and necessary, in violation of its statutory mandate.

Moreover, Coverage with Study Participation is ethically questionable, and may violate the United States Health and Human Services’ (HHS) “Regulations for the Protection of Human Subjects,” which require the voluntary consent of subjects prior to research participation. With CSP, a Medicare beneficiary must either participate in a prospective clinical research trial or be denied a service deemed medically appropriate by their personal physician. Under these circumstances, how can the patient’s research participation ever be truly voluntary, as required by the federal regulations, when the price of non-participation is that Medicare will refuse coverage? Moreover, many elderly and disabled Medicare beneficiaries, for various reasons, may be unable or unwilling to participate in medical research.<sup>15</sup> For those patients, non-participation means denial of the service.

Although CMS insists that the goal of CSP is to enhance access to new medical technology and improve health outcomes for Medicare beneficiaries, in the larger context, CSP appears to be an ethically problematic, thinly-veiled effort to control the high cost of new technology by limiting present coverage and arbitrarily elevating the amount of evidence necessary to meet the “reasonable and necessary” standard. The effect of CSP will be to delay, perhaps for years, full and equal access to potentially life-saving new technology. Moreover, given that Medicare is the nation’s largest insurer of health care, and its coverage policies are adopted by many third-party payers and public health insurance programs throughout the nation, CSP has far-reaching implications not only for Medicare beneficiaries, but for millions of others.<sup>16</sup>

Part I of this Article provides a brief overview of Medicare program essentials, reviews the general CMS process for making local and national coverage determinations, and further explains Coverage with Study Participation.

Part II focuses on the Medicare program’s struggle to define its authority. It examines the statutory language, legislative history, the few court opinions, and CMS’s historical attempts at administrative rule-making to determine the limits of CMS’s authority under the “reasonable and necessary” provision. It also

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15. See discussion *infra* Section III.B.

16. See Eleanor D. Kinney, *Medicare Coverage Decision-Making and Appeal Procedures: Can Process Meet the Challenge of New Medical Technology?*, 60 WASH. & LEE L. REV. 1461, 1470 (2003) (“Medicare coverage decision-making influences decisions for public health insurance programs.”).

addresses whether CMS has the statutory authority to require clinical trials for coverage purposes under the Agency for Healthcare Research and Quality (AHRQ) provision.<sup>17</sup> This Part emphasizes the historical role that cost considerations, including cost-effectiveness analysis, have played in determining whether expensive new technology is “reasonable and necessary.” If CMS has no authority to consider cost in making its coverage determinations, then engaging in implicit cost control for the same purpose is equally without statutory support.

Part III examines difficulties with the structure of Coverage with Study Participation, CMS requirements for the inclusion of elderly subjects in clinical trials, and the potential for violating federal regulations protecting the rights of human subjects. This Part concludes that, even if CMS had legitimate statutory authority to conduct clinical trials, the policy itself is flawed.

Part IV of this Article concludes that Coverage with Study Participation is a vehicle through which CMS may slow the path of new technology to the nation's elderly in an implicit effort to reduce program costs. With CSP, CMS has implicitly woven cost considerations into its coverage criteria, which it has no authority to do. If items and services are deemed by CMS to be sufficiently reasonable and necessary for the Medicare population to be approved for Coverage with Study Participation, then they are sufficiently reasonable and necessary to be covered for all Medicare patients who medically require the intervention, whether or not they agree to participate in a trial, and whether or not their physicians participate in data collection activities. CMS can generate additional post-coverage data through other means, without denying beneficial services to Medicare beneficiaries unable to participate in clinical trials. On the other hand, if interventions designated for CSP truly do not meet the “reasonable and necessary” standard due to insufficient data, then the intervention should not be covered, despite political pressure to do so. As it has done in the past, Congress, after robust public debate, must act to define the role of cost in coverage determinations, either by expressly allowing CMS to weave cost-effectiveness into its coverage criteria, or by other means of rationing care.

## I. MEDICARE PROGRAM OVERVIEW

### A. *The Basics*

The Medicare program was signed into law on July 30, 1965,<sup>18</sup> amending

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17. 42 U.S.C.A. § 1395y(a)(1)(E) (2003) authorizes CMS to pay for certain research conducted by the AHRQ. AHRQ conducts research to enhance the quality of medical care, and to development medical practice guidelines. *Id.* § 1320b-12. *See also* discussion *infra* Part IV.

18. Old-Age, Survivors, and Disability Insurance Act of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified as amended at 42 U.S.C. § 1395).

the Social Security Act and bringing federally subsidized health insurance to roughly 19 million elderly Americans.<sup>19</sup> Today, the Medicare program is the nation's largest insurance company, providing health care for over forty million persons who are over age sixty-five, certain disabled persons, and persons with end stage renal disease.<sup>20</sup> The Medicare program falls under the auspices of HHS and is administered through the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA). The scope of benefits is prescribed by law, and is divided into four main parts. Part A, or Hospital Insurance (HI), includes hospital, skilled nursing, home health, and hospice care.<sup>21</sup> Medicare Part B, or the Supplementary Medical Insurance Program (MI), includes physician and other out-patient services.<sup>22</sup> Part C, or Medicare Advantage, is a managed care option added by the Balanced Budget Act of 1997,<sup>23</sup> and includes, at a minimum, Parts A and B, as well as some additional benefits.<sup>24</sup> Part D, the outpatient prescription drug program effective January 1, 2006, was added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).<sup>25</sup>

Most eligible persons are automatically enrolled in Medicare, and are eligible for Part A benefits. Part B benefits are voluntary, and most beneficiaries must pay premiums to obtain Part B benefits. Most eligible persons, however, participate in both Parts A and B.<sup>26</sup>

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19. See Dep't of Health & Human Servs., Medicare Enrollment: National Trends 1966-2005, <http://www.cms.hhs.gov/MedicareEnRpts/Downloads/HI05.pdf> (last visited May 3, 2007).

20. BD. OF TRS. OF THE FED. HOSP. INS. & FED. SUPPLEMENTARY MED. INS. TRUST FUNDS, 2006 ANNUAL REPORT at 2, available at <http://www.cms.hhs.gov/ReportsTrustFunds.tr2006.pdf>. In 2005, Medicare covered 42.5 million people, including 35.8 million aged 65 and older, and 6.7 million disabled or with end state renal disease. *Id.* End stage renal disease is defined as permanent kidney failure requiring dialysis or a kidney transplant. See 42 U.S.C.A. § 1395c (2003).

21. See 42 U.S.C.A. § 1395d (2003).

22. See *id.* § 1395j. Medicare Parts A and B were included in the original Act.

23. See Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4001, 111 Stat. 251, 276 (modifying Social Security Act, §§ 1851-59, to be codified at 42 U.S.C. §§ 1395w-21 to -28 (Medicare Plus Choice plans)).

24. See 42 U.S.C.A. § 1395w-21(a) (West Supp. 2006). Medicare Advantage, formerly called Medicare Plus Choice, offers eligible beneficiaries a "coordinated care plan" through a health maintenance organization, preferred provider organization, or provider-sponsored organization. *Id.*

25. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (to be codified at 42 U.S.C. 1395w-101).

26. In 2005, 42,394,926 people were enrolled in either Part A or Part B. Dep't of Health & Human Servs., HI-SMI Trend Table, <http://www.cms.hhs.gov/MedicareEnRpts/Downloads/HISMI05.pdf> (last visited May 3, 2007). Of these, 42,033,263 (99.1%) were enrolled in Part A, and 39,694,772 (or 93.6%) were enrolled in Part B. Dep't of Health & Human Servs., HI Trend Table, <http://www.cms.hhs.gov/MedicareEnRpts/Downloads/HI05.pdf> (last visited May 3, 2007); Dep't of Health & Human Servs., SMI Trend Table, <http://www.cms.hhs.gov/MedicareEnRpts/Downloads/SMI05.pdf> (last visited May 3, 2007). See generally Dep't of Health & Human Servs., National Trends 1966-2005, <http://www.cms.hhs.gov/MedicareEnRpts> (last visited May 3, 2007).

CMS contracts with local insurance companies to review and process providers' day-to-day claims for reimbursement.<sup>27</sup> These companies are responsible for assuring that payment is made in accordance with Medicare policy, and that payment is made only for items and services covered under Part A or Part B. Companies that process Part A claims are referred to as fiscal intermediaries, and those processing Part B claims are referred to as carriers.<sup>28</sup>

### *B. The Coverage Process*

As the nation's largest health care insurer, Medicare's policies have tremendous effects, influencing the insurance coverage decisions of other public and private payers, including employers who self-insure their workers.<sup>29</sup> Thus, when Medicare determines that it will not cover a particular new technology, that technology will be unavailable not only to Medicare beneficiaries, but to millions of other privately insured persons across the nation. Medicare coverage decisions affect the health care services that physicians order and provide to Medicare beneficiaries. Medicare beneficiaries are free to purchase medical services, including new technology or devices that are available in the marketplace but not covered by Medicare, however they are not likely do so. Given that 19% of Medicare beneficiaries have yearly incomes below \$9000, and over half have incomes below \$19,000, the practical effect of a non-coverage determination would be to deny the new technology or device to the beneficiary.<sup>30</sup>

Moreover, Medicare decision-making criteria may considerably impact our nation's economy, either strengthening or weakening the pharmaceutical, biotechnology, and medical device industries.<sup>31</sup> The Medicare program is the world's largest single payer of health care, and private payers typically adopt

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27. See 42 U.S.C. § 1395h (2000) (regulating CMS contracts pertaining to fiscal intermediaries).

28. See *id.*; *id.* § 1395u (regulating CMS contracts pertaining to carriers).

29. See Sean Tunis, *Why Medicare Has Not Established Criteria for Coverage Decisions*, 350 NEW. ENG. J. MED. 2196, 2196 (2004).

30. See MEDICARE PAYMENT ADVISORY COMM'N, MEDPAC DATA BOOK 2006, at 23 chart 2-5 (2006), available at [http://www.medpac.gov/publications/congressional\\_reports/Jun06DataBookSec2.pdf](http://www.medpac.gov/publications/congressional_reports/Jun06DataBookSec2.pdf) (setting out poverty levels for Medicare beneficiaries for the year 2003); U.S. DEP'T OF HEALTH & HUMAN SERVS., THE 2003 HHS POVERTY GUIDELINES (2003), available at <http://aspe.hhs.gov/poverty/03poverty.htm>; see also Vicki Gottlich, *The Perspective of Medicare Beneficiaries*, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS 87 (Eleanor D. Kinney ed., 2002).

31. See Bradley Merrill Thompson & Brian A. Dahl, *The Perspective of Manufacturers*, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS, *supra* note 30, at 127, 127-28 (explaining that innovative technology plays a role in setting the standard of care in the health care system, and that the quality of care may be impaired when negative coverage decisions block payment).

Medicare coverage policies. Medicare's coverage criteria could potentially reduce the availability of investment capital for medical technology, which in turn could reduce industry incentives to create innovative and potentially life-saving technology, which could lead to reductions in employment and reduced exports.<sup>32</sup>

The starting point for Medicare's coverage determinations is the statutory provision that will hereinafter be referred to as the "reasonable and necessary" provision. It provides that "no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."<sup>33</sup> The "reasonable and necessary" criterion essentially mandates that CMS pay the correct amount to legitimate service providers who furnish services that are reasonable and necessary to meet the medical needs of eligible beneficiaries.<sup>34</sup> The Act lists categories of items and services for which payment may be made, but gives the Secretary the authority to determine which specific items and services within each category will be covered by the program.<sup>35</sup> For example, Medicare will pay for surgery, but it does not specify the particular types of surgery that may be covered. Thus, CMS would allow payment for a gall bladder operation only if that surgery is medically necessary for a particular beneficiary. Most noteworthy, however, is that the statute neither defines "reasonable and necessary" nor provides criteria for making specific coverage determinations, leaving CMS and local contractors substantial discretion in the decision-making process.

Medicare coverage decisions are made both nationally and locally, but the vast majority (about 90%) of coverage determinations are made on the local level.<sup>36</sup> Medicare contracts with private organizations to make Local Coverage Decisions (LCDs), and these contractors develop thousands of local medical review policies to provide guidance to the public and medical community within their geographical area.<sup>37</sup> LCDs apply only within the area served by the local

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32. See Tunis, *supra* note 29, at 2197.

33. 42 U.S.C. § 1395y(a)(1)(A) (2000).

34. See Geraldine Nicholson & Lena Robins, *The Reasonable and Necessary Criterion and Medicare Contractor Review of Claims: Efforts To Combat Fraud, Waste and Abuse in the Medicare Program*, 43 ST. LOUIS U. L.J. 81, 81 (1999).

35. Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55,634, 55,635 (Sept. 26, 2003).

36. CTRS. FOR MEDICARE & MEDICAID SERVS., FACT SHEET: CMS RESPONDS TO STAKEHOLDER FEEDBACK REGARDING COVERAGE WITH EVIDENCE DEVELOPMENT 1-2 (2005), <http://www.cms.hhs.gov/MedicareCoverageGuideDocs/Downloads/guidfactsheet.pdf>.

37. Medicare Program; Procedures for Making National Coverage Determinations, 64 Fed. Reg. 22,619, 22,621 (Apr. 27, 1999) (stating that the purpose of local medical review policies is to explain to the public and the medical community "when an item or service will be considered 'reasonable and necessary' and thus eligible for coverage under the Medicare statute"). See also Susan Bartlett Foote et al., *Variation in Medicare's Local Coverage Policies: Content Analysis of Local Medical Review Policies*, 11 AM. J. MANAGED CARE 181, 181 (2005), available at

contractor.<sup>38</sup>

In contrast, National Coverage Determinations (NCDs) are made by CMS, and may be generated externally or internally. Approximately eighteen to twenty-four NCDs are issued each year, and are published in CMS program manuals.<sup>39</sup> Any interested party, including beneficiaries, may make an external request for a new national coverage determination.<sup>40</sup> Most NCD external requests, however, are made by an organization, such as the manufacturer of a drug, device, or medical product, or by a professional medical organization, a provider, or a supplier.<sup>41</sup> CMS may make an internal request if it determines an NCD is “in the interest of the general health and safety of Medicare beneficiaries.”<sup>42</sup>

An NCD may grant, limit, or deny coverage for a “specific medical item or service.”<sup>43</sup> A limited NCD, also called coverage with conditions, may limit coverage of an item or service to patients with certain diseases or severity levels,

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<http://www.ajmc.com/article.cfm?ID=2820> (noting that “nearly 50 local contracting organizations develop thousands of local medical review policies”).

38. Medicare Program; Procedures for Making National Coverage Determinations, 64 Fed. Reg. at 22,621.

39. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 36, at 2.

40. Medicare Program; Revised Process for Making Medicare National Coverage Determination, 68 Fed. Reg. at 55,638. Section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. No. 106-554, 114 Stat. 2763 app. At 2763A-534 to -543, amended the Social Security Act to allow beneficiaries to request a national coverage determination.

41. See Grant Bagley, *Current Procedures and Standards for Making Medicare Coverage Decisions*, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS, *supra* note 30, at 17, 22.

42. Medicare Program; Revised Process for Making Medicare National Coverage Determination, 68 Fed. Reg. at 55,638. See also CTRS. FOR MEDICARE & MEDICAID SERVS., FACTORS CMS CONSIDERS IN OPENING A NATIONAL COVERAGE DETERMINATION (2006), [https://www.cms.hhs.gov/mcd/ncpc\\_view\\_document.asp?id=6](https://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=6). With respect to items and services that are currently covered, an internal NCD may be generated when significant questions exist as to the health benefits of currently covered services; when new evidence indicates that changes may be warranted; when conflicting local policies are causing significant disparities in care; when significant evidence of variation in billing practices exists; or when conflicting carrier or intermediary policies exist. *Id.* at pts. IV, V. With respect to a new item or service, an internal NCD may be initiated when new technology represents a substantial medical advance and is likely to have significant health benefit if delivered more quickly to beneficiaries; when rapid spread of the technology may have reduce health inequalities or have a significant impact on public policy; or when significant uncertainty exists concerning the health benefits or risks. *Id.* at pt. V.

43. Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. at 55,634; see also Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 731, 117 Stat. 2066 (to be codified at 42 U.S.C. § 1395y) (amending the Social Security Act to define a national coverage determination as “a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this subchapter”).

or to certain providers or facilities that meet specific criteria.<sup>44</sup>

A national coverage decision is binding on all Medicare contractors, and takes precedence over any conflicting local policies once the NCD is effective.<sup>45</sup> CMS may determine whether an item or service is reasonable and necessary (coverage or non-coverage) based on internal staff evaluation of the submitted evidence and a systematic review of the medical literature.<sup>46</sup> Moreover, under certain circumstances, CMS may seek an external health technology assessment to evaluate the performance of a new technology, to appraise the evidence on patient health outcomes as well as its safety and economic impact, or to “identify those areas that need further evidence development.”<sup>47</sup> At the present time, CMS contracts with the AHRQ to perform its external technology assessments.<sup>48</sup>

CMS may also supplement its internal expertise by convening a meeting of the Medicare Coverage Advisory Committee (MCAC) to help determine whether an item or service is “reasonable and necessary.” The MCAC consists of nearly 100 members of varying backgrounds in medicine, the biological and physical sciences, health data and information, patient advocacy, medical ethics, and other related professions, and also includes a smaller representation of industry and

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44. Medicare Program; Revised Process for Making Medicare National Coverage Determination, 68 Fed. Reg. at 55,635.

45. See *id.* at 55,635-36. A national coverage decision may be appealed by an adversely affected Medicare beneficiary. 42 U.S.C.A. § 1395ff(f)(1) (West Supp. 2006) (providing that only eligible Medicare beneficiaries “who are in need of the items or services that are the subject of the coverage determination” have standing to seek review of national or local coverage determinations). A beneficiary may obtain initial review from the HHS Departmental Appeals Board (DAB) and thereafter seek judicial review. *Id.* The law makes no provision for providers, manufacturers, or other affected industry stakeholders to appeal adverse coverage determinations, although they are allowed to submit written or brief oral statements as amici. See 42 C.F.R. § 426.510(f) (2006). Even though only a beneficiary has standing to appeal a national coverage determination, the appeal would likely be sponsored by providers or other interested stakeholders. See BARRY R. FURROW ET AL., *THE LAW OF HEALTH CARE ORGANIZATION AND FINANCE* 365 (5th ed. 2004).

46. CTRS. FOR MEDICARE & MEDICAID SERVS., *FACTORS CMS CONSIDERS IN COMMISSIONING EXTERNAL TECHNOLOGY ASSESSMENTS*, at pt. III (2006), available at [http://www.cms.hhs.gov/mcd/ncpc\\_view\\_document.asp?id=7](http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=7) (defining a systematic review as a comprehensive search of the medical literature, focusing on explicit criteria that can be reproduced, and including an appraisal of the evidence to assess its credibility, usefulness, and importance).

47. *Id.* In general, factors CMS considers when requesting an external technology assessment include when the evidence is so extensive that timely review may not be possible, the evidence is complex or conflicting, experts have differing opinions, specialized methods are required, when the review requires expertise not currently available within CMS staff, or when the topic being considered will be referred to the Medicare Coverage Advisory Committee (MCAC). *Id.* at pt. IV.

48. *Id.* at pt. V. The AHRQ is a federal agency under the auspices of the Department of Health and Human Services. See generally About AHRQ, <http://www.ahrq.gov/about/ataglace.htm> (last visited May 3, 2007). Its purpose is to improve health care quality, safety, efficiency, and effectiveness. AHRQ contracts with CMS to perform technology assessments, which may be performed in-house, or with one of AHRQ’s thirteen Evidence-based Practice Centers (EPCs), located throughout the United States and Canada. See Evidence-based Practice Centers, <http://www.ahrq.gov/clinic/epc/> (last visited May 3, 2007).



consumer interests.<sup>49</sup> MCAC meetings are now conducted in an open public forum, and CMS may seek MCAC advice in addition to commissioning an external technology assessment.<sup>50</sup> Finally, within CMS, the newly-created Council for Technology and Innovation (CTI) assists in coordinating coverage, coding, and payment for new technologies.<sup>51</sup>

In 2000, Medicare extended coverage to the “routine costs” of qualifying clinical trials, including “reasonable and necessary” treatment for complications arising from clinical trial participation.<sup>52</sup> Coverage is limited to services that are generally available to Medicare beneficiaries outside of trials.<sup>53</sup> Payment for the test article or service, however, is excluded.<sup>54</sup> For example, in a clinical trial to test an experimental chemotherapy drug, the cost of the drug would not be covered due to its experimental nature, but costs relating to the administration of the treatment, the appropriate monitoring of efficacy or side effects, and the prevention or treatment of complications would be covered as routine costs of the trial.<sup>55</sup>

It is important to note that the term “national coverage determination” refers only to whether a particular item or service is covered nationally by the Medicare program,<sup>56</sup> and does not include any determination as to how much the

49. See CTRS. FOR MEDICARE & MEDICAID SERVS., FACTORS CMS CONSIDERS IN REFERRING TOPICS TO THE MEDICARE EVIDENCE DEVELOPMENT & COVERAGE ADVISORY COMMITTEE 3 (2005) (draft guidance), available at [http://www.cms.hhs.gov/mcd/ncpc\\_view\\_document.asp?id=10](http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=10) [hereinafter CMS, MCAC DRAFT GUIDANCE]; Medicare Program; Establishment of the Medicare Coverage Advisory Committee, 63 Fed. Reg. 68,780 (Dec. 14, 1998) (announcing the establishment of MCAC).

50. See CMS, MCAC DRAFT GUIDANCE, *supra* note 49, at pts. VI, VII. Factors CMS considers when referring topics to MCAC include significant controversy among experts or “some other significant consideration that would affect whether the item or service is ‘reasonable and necessary’ under the Act;” existing studies are flawed or do not address relevant policy questions; studies are conflicting; CMS requires additional review of TA methods or more information on net health outcomes; the perspectives of affected patients and caregivers may be relevant; the technology is controversial among the general public; clarification in an MCAC public forum may be useful in future NCDs; the use of the technology may have a major impact on the Medicare population or program overall; or the viewpoint of patient advocates or other societal viewpoint may be relevant. *Id.* at pt. V.

51. 42 U.S.C.A. § 1395ee (West Supp. 2006).

52. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE COVERAGE: CLINICAL TRIALS 1 (2000), available at <http://www.cms.hhs.gov/ClinicalTrialPolicies/Downloads/finalnationalcoverage.pdf>.

53. *Id.* at 2.

54. *Id.* See also *infra* text accompanying note 75.

55. See Mark Barnes & Jerald Korn, *Medicare Reimbursement for Clinical Trial Services: Understanding Medicare Coverage in Establishing a Clinical Trial Budget*, 38 J. HEALTH L. 609, 623 (2005).

56. See 42 U.S.C.A. 1395y(I)(6)(A) (West Supp. 2006) (“The term ‘national coverage determination’ means a determination by the Secretary with respect to whether or not a particular

government will pay for a particular covered item or service. The assignment of payment codes and other payment issues are accomplished by a process separate from the coverage determination.<sup>57</sup>

## II. COVERAGE WITH STUDY PARTICIPATION AND THE LIMITS OF STATUTORY AUTHORITY

CMS's Coverage with Study Participation policy is controversial because it allows coverage of certain items or services outside of the "reasonable and necessary" determination that is essential to the national coverage determination process. Statutory support for CSP is uncertain. This uncertainty was highlighted when CMS issued its July 12, 2006 CED Guidance Document, doing a considerable about-face from the stance it took in an earlier CED Draft Guidance as to the statutory authorization for restricting coverage of certain items or services to clinical trials. A comparison of the relevant parts of the Draft Guidance and the CED Guidance best illustrates CMS's unstable statutory position.

### *A. CMS's Search for Statutory Support for Coverage with Study Participation*

CMS published its first public notice draft guidance on April 7, 2005, outlining its intention to link a small number of its national coverage determinations to a requirement for prospective data collection, an approach it termed "coverage with evidence development" (CED).<sup>58</sup> CMS asserted that 42 U.S.C. § 1395y(a)(1)(A), the "reasonable and necessary provision," was the statutory authority to link coverage decisions to additional data collection.<sup>59</sup> CMS explained that the available scientific evidence was such that the item or service would only be "reasonable and necessary" if the service was "delivered in the context of specific data being collected" while the service was being provided.<sup>60</sup> The data collection requirement meant that coverage for certain services would be limited to beneficiaries who enrolled in a clinical trial, or to providers who participated in other prospective data collection activity.<sup>61</sup> The

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item or service is covered nationally under this subchapter.").

57. See Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55,634, 55,635 (Sept. 26, 2003) ("[A]n NCD . . . does not include a determination about which code, if any, is assigned to a particular item or service covered . . . or a determination with respect to the amount of payment for a particular covered item or service.").

58. CTRS. FOR MEDICARE & MEDICAID SERVS., FACTORS CMS CONSIDERS IN MAKING A DETERMINATION OF COVERAGE WITH EVIDENCE DEVELOPMENT (2005), <http://www.cms.hhs.gov/coverage/download/guidanceced.pdf> [hereinafter CMS, DRAFT GUIDANCE].

59. *Id.* at 6. CMS asserts that Section 1862(a)(1)(A) of the Social Security Act is the source of its authority for CED. 42 U.S.C. § 1395y(a)(1)(A) (2000).

60. CMS, DRAFT GUIDANCE, *supra* note 58, at 3.

61. *Id.* at 3.

purpose of CED was to generate sufficient additional evidence to allow CMS, at some point in the future, to make a national coverage determination which, if positive, would extend the service to all beneficiaries for whom it was medically necessary.<sup>62</sup> CMS suggested the alternative to CED would be non-coverage.<sup>63</sup> The CED Draft Guidance drew over 400 pages of published comments from stakeholders and concerned public members, many of whom questioned CMS's statutory authority for linking coverage to prospective data collection, and challenged other legal and ethical aspects of the policy.<sup>64</sup>

In July 2006, in response to stakeholder concerns, CMS published a significantly revised guidance document (the "CED Guidance Document").<sup>65</sup> In this document, CMS announced that its CED policy would have two arms, Coverage with Appropriateness Determination (CAD) and Coverage with Study Participation (CSP). According to CMS, national coverage decisions requiring CAD would encompass those items or services that are supported by sufficient scientific evidence to meet the "reasonable and necessary" standard, but which require the provider to collect additional data at the time the service is provided, and submit the data to a database or registry.<sup>66</sup> The purpose of this additional data collection is to assure CMS that the service it is paying for was provided appropriately to qualifying patients in accordance with the specific national coverage decision.<sup>67</sup>

With respect to Coverage with Study Participation, however, CMS announced the creation of "a new concept of conducting research," and declared a new-found source of statutory authority to support the new policy.<sup>68</sup> Unlike its earlier CED Draft Guidance, CMS now asserted that new items and services designated for Coverage with Study Participation, which includes prospective clinical trials, were *not* supported by sufficient evidence to meet the "reasonable and necessary" standard. CMS purports, however, to have the statutory authority to pay for services under 42 U.S.C. § 1395y(a)(1)(E), which gives CMS the authority to pay for research conducted by the AHRQ.<sup>69</sup> Under this provision,

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62. *Id.* at 4-5.

63. *Id.* at 7.

64. *See, e.g.*, Letter from Daniel J. Popeo & David Price to Dr. Steve Phurrough, Director of CMS Coverage and Analysis Group (June 6, 2005) (on file with author).

65. CMS, CED GUIDANCE DOCUMENT, *supra* note 6.

66. *Id.* at pt. V.A. CMS indicates that Coverage with Appropriateness Determination (CAD) will require providers to supplement the information routinely submitted through claims for services with additional clinical data collected at the time the service is provided. Providers will submit the additional data to databases or registries associated with the NCD in question. *Id.*

67. *Id.*

68. *Id.* at pt. I.

69. *Cf.* 42 U.S.C. § 1395y(a)(1)(E) (2000) ("(a) Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B for any expenses incurred for items or

CMS may pay for research conducted by AHRQ that is reasonable and necessary to meet the needs and priorities of the Medicare program.<sup>70</sup> The work contemplated by the AHRQ research statute, however, pertains to research conducted for the purpose of improving the quality of medical care, developing clinical guidelines for preventing and treating various health conditions, and evaluating the comparative effects of various services.<sup>71</sup> Nothing in the AHRQ research statute authorizes CMS to use the resources of this agency to determine whether an item or service ought to be *covered*. Hence, it appears that CMS is attempting to run around the restrictions of the “reasonable and necessary” provision by using Coverage with Study Participation and the AHRQ research statute as the basis for making coverage decisions.<sup>72</sup>

In its CED Guidance Document, CMS takes the position that it is simply asking AHRQ to act in its normal research capacity to produce additional data that will be publicly available. Then, at some point in the future, CMS may use this data as the basis for a national coverage determination.<sup>73</sup> CMS has no statutory authority to require clinical trials as a prerequisite to a national coverage determination, and CSP appears to be a thinly-masked attempt to appear as though it is not actively involved in conducting research for this purpose; rather, CMS is merely paying for research conducted by AHRQ. With CSP, however, CMS has designed, from start to finish, a research system for the purpose of generating sufficient information for CMS to use in a future national coverage decision. Indeed, CMS has indicated that in order for providers to get paid for studies conducted pursuant to CSP, the study must be “designed to produce evidence that could be used in a future national coverage decision . . . .”<sup>74</sup>

At its core, Coverage with Study Participation is a blueprint for research that allows CMS to pay for an item or service that it deems *not* “reasonable and necessary.” CMS’s interpretation of its authority to pay for AHRQ-conducted research essentially renders meaningless the “reasonable and necessary”

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services . . . (E) in the case of research conducted pursuant to section 1320b-12 of this title, which is not reasonable and necessary to carry out the purposes of that section . . . .”); *id.* § 1320b-12(a) (placing a duty on the Secretary of AHRQ to conduct research on the efficacy of services and procedures, oversee periodic review and updating of guidelines, assess the efficiency of alternative services and procedures, and meet the needs of the Medicare and Medicaid systems).

70. *Id.* § 1320b-12(a).

71. *Id.*

72. *See* CMS, CED GUIDANCE DOCUMENT, *supra* note 6, at pt. V.B (“New evidence that assists in the Medicare coverage process for the item or service is one of the desired results of CSP.”).

73. *Id.* (“If the research results are published in a peer-reviewed journal, the evidence will be used in an NCD reconsideration to determine if a change in Medicare coverage is appropriate under section [1395y](a)(1)(A).”); *id.* at pt. VIII.A (“Because NCD analyses are normally based on a review of publicly available evidence, the results of the trial should be published in the peer reviewed literature to be considered in an NCD reconsideration.”).

74. *Id.* at pt. VI.B (“To qualify for reimbursement, such a study must be designed to produce evidence that could be used in a future national coverage decision that would focus on whether the item or service should be covered by Medicare under [1395y](a)(1)(A).”)

provision, and violates its statutory mandate prohibiting payment for services unless they are “reasonable and necessary.”<sup>75</sup> If the intervention is sufficiently “reasonable and necessary” to be covered within the context of a clinical trial, it ought to be available to all for whom it is medically necessary, without such restriction.

*B. Can CMS Consider Cost When Determining What Is “Reasonable and Necessary”?*

Cost considerations may be a silent, yet principal, driver of Coverage with Study Participation. The manner in which CMS has made its national coverage determinations during the more than forty years of its existence has, for the most part, been less than transparent, due primarily to the uncertain and politically unpopular role that cost considerations have played in coverage decisions. At one point, CMS expressly designated cost-effectiveness as specific criteria to be considered in determining whether expensive new technology would be covered by the Medicare program.<sup>76</sup> At other points, CMS has said specifically that it will not consider cost. In between, CMS has considered cost, but it has done so implicitly, and under other names.<sup>77</sup> Not until recently, with the passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003, has the Secretary been statutorily mandated to make public the factors it uses to determine whether an item or service is reasonable and necessary, and thus covered by Medicare.<sup>78</sup>

This Section examines the legislative history and subsequent court and administrative interpretations to ascertain whether CMS has authority under the reasonable and necessary provision to consider cost in making coverage decisions, or, by extension, to control costs by limiting coverage of certain expensive new technology to clinical trial participants. In support of this Article’s thesis that Coverage with Study Participation is a means of implicit cost control, this Section also highlights the historical tension between CMS and industry

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75. In the CED Guidance Document, CMS indicated its intent to reconsider its Clinical Trial Policy, essentially to encompass payment for CSP trials under (a)(1)(E), which CMS says is the statutory authority for the Clinical Trial Policy. *Id.* at pt. V.B. In that policy, however, CMS is covering only the reasonable and necessary care related to the trial or complications resulting from the trial, but specifically *excludes* the “investigational item or service” itself. Granted, with CSP, the item or service is not experimental, but it *has* been deemed by CMS to be not reasonable and necessary. This remains an apparent attempt to circumvent the limitations of the “reasonable and necessary” coverage provision.

76. See discussion *infra* Subsection II.B.3.

77. See discussion *infra* Subsection II.B.4.

78. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 731, 117 Stat. 2066, 2349 (to be codified at 42 U.S.C. § 1395y(I)(1)).

stakeholders, who have pressed CMS almost since its inception to make public its views regarding the role of cost in making coverage decisions.

*1. Legislative History and the Meaning of "Reasonable and Necessary."*

The "reasonable and necessary" provision provides CMS's only clear statutory authority for making national coverage determinations. It provides that "no payment may be made under part A or part B . . . for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . ."<sup>79</sup> Medicare's architects envisioned bringing to the elderly the same level of health care as was then enjoyed by insured, paying, and younger patients.<sup>80</sup> Although little is officially documented as to the origin of the reasonable and necessary phrase, the common understanding among federal officials who worked on the legislation was that the phrase was adapted from an Aetna plan for federal workers under the Federal Employees Health Benefits Program.<sup>81</sup> One official recalls having had only a single weekend in which to convert the Aetna plan into a federal health care plan, and that "[t]here were no quality standards and no cost controls other than a vague stipulation that services had to be 'medically required.'"<sup>82</sup> No additional language from Congress accompanied the 1965 law; thus, there is no indication that the reasonable and necessary language was ever subjected to serious analysis. The statute is silent as to the process that CMS is to follow in making coverage determinations, and it gives no hint as to what factors CMS may legally use to determine if an item or service meets the statutory standard. Moreover, despite a few attempts, CMS has not successfully engaged in the administrative rule-making process to define its coverage criteria.

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79. 42 U.S.C.A. § 1395y(a)(1)(A) (West Supp. 2006).

80. See Robert M. Ball, *Perspectives on Medicare: What Medicare's Architects Had in Mind*, 14 HEALTH AFF. 62, 67 (1995).

81. See THEODORE R. MARMOR, *THE POLITICS OF MEDICARE* 48 (2d ed. 2000). Professor Marmor notes that in 1965, during the late stages of Medicare drafting, a bill proposed by Republican John Byrnes was discussed before the Ways and Means Committee, "which proposed benefits similar to those offered in the Aetna Life Insurance Company's health plan for the federal government's employees." A modified version of the Byrnes proposal was ultimately reflected in Medicare Part B, adding coverage for the costs of doctor's services. *Id.* at 48-52. One of Medicare's primary drafters, Robert Hoyer, recalls that "the reasonable and necessary provision and other exclusions . . . were taken from an Aetna policy that was available to federal employees at the time . . ." See also Jacqueline Fox, *Medicare Should, but Cannot, Consider Cost: Legal Impediments to a Sound Policy*, 53 BUFF. L. REV. 577, 593 (2005) (interview with Robert Hoyer). Professor Fox reports that the Aetna Life and Casualty policy excluded services and supplies that were "[n]ot *reasonably necessary* for treatment of pregnancy, illness, or injury, or to improve the functioning of a malformed body member," which differs somewhat from the "reasonable and necessary" language of the Medicare statute. *Id.* at 594. See also Tunis, *supra* note 29, at 2196.

82. Ball, *supra* note 80, at 69.

In the original Medicare statute, the terms “reasonable” and “necessary” appear separately, almost entirely in the context of whether a particular treatment is medically necessary, or whether the treatment could reasonably be expected to improve the patient’s condition.<sup>83</sup> The term ‘reasonable’ was used repeatedly in the context of payment—that payment will be made for reasonable charges for non-institutional providers, or for reasonable costs incurred by institutional providers.<sup>84</sup> Although the term “reasonable cost” is specifically defined in the statute, the definition focuses on the methods to be used in establishing cost, and provides little limiting language.<sup>85</sup>

The legislative history supports the meaning of “reasonable” as pertaining to the *amount* to be paid for covered services, as well as services to be included in the future, and the term “necessary” as pertaining to whether the service is medically necessary. For example, the Senate Finance Committee Report which accompanied the original Medicare bill (H.R. 6675) explains that payments to providers would be based on the “reasonable cost” of providing care, and that “reasonable charges” would be the “customary charges for similar services” in the locality.<sup>86</sup> Covered services were to be paid at the “reasonable cost of service ordinarily provided to inpatients by hospitals . . . including new services and techniques as they are adopted in the future.”<sup>87</sup>

In the Senate Report, the phrase “reasonable and necessary” refers to coverage of services that are medically necessary. For example, the report states that “payment could be made for the rental of a special hospital bed to be used by a patient in his home only if it was a *reasonable and necessary* part of a sick person’s treatment,” but “personal comfort items and services [such] as massages and heat lamp treatment would only be covered where they contribute meaningfully to the treatment of an illness or injury or the functioning of a

83. See, e.g., 42 U.S.C. § 1395f(a)(2) (2000) (providing that that payment may be made for inpatient hospital services or diagnostic services were “medically required and such services are or were necessary for such purposes” or where “such treatment can or could reasonably be expected to improve the condition for which such treatment is or was necessary”).

84. See, e.g., *id.* § 1395l(a)(1) (providing that “in the case of services . . . 80 percent of the reasonable charges for the services; except that an organization which provides medical and other health services . . . may elect to be paid 80 percent of the reasonable cost of services”). Although the original Act allowed for payment based on reasonable costs or charges, it was later amended to institute the prospective payment system based on diagnostic related groups (DRGs) for hospital payment, and the Resource-Based Relative Value Scale (RBRVS) for physician reimbursement.

85. See *id.* § 1395x(v)(2)(A) (placing upon the definition of reasonable cost the limitation that payment will be made only for semi-private accommodations, unless private accommodation is medically necessary); *id.* § 1395x(v)(2)(B) (placing upon the definition of reasonable cost the limitation that if a provider furnishes an item or service more expensive than Medicare allows, payment shall be only the reasonable cost of the equivalent item or service).

86. S. REP. No. 89-404 (1965), as reprinted in 1965 U.S.C.C.A.N. 1943, 1949.

87. *Id.* at 1967.

malformed body member.”<sup>88</sup> The Report also cautions fiscal intermediaries to “safeguard[] against unnecessary utilization of covered services.”<sup>89</sup> That the patient’s physician was responsible to determine what was medically necessary is also born out by the first section of Title XVIII of the Social Security Act, which prohibits the government from interfering or exercising any control over the practice of medicine.<sup>90</sup>

Perhaps most indicative of congressional intent is that the “reasonable and necessary” provision falls under the statutory title “[e]xclusions from coverage,” and the statutory subtitle, “(a) Items or services specifically excluded.” Thus, the “reasonable and necessary” clause is expressed as a negative—that “no payment may be made” for services that are “not reasonable and necessary.”<sup>91</sup> The only sensible inference from this congressional directive is that Medicare is presumed to cover all items and services except those that are not reasonable and necessary, or otherwise excluded by statute.

Thus, the language of the statute and its legislative history bear out that the Medicare program is expected to cover items and services that the patient’s physician deems medically necessary, subject to utilization review. Nothing in the legislative history suggests that CMS has the authority under the “reasonable and necessary” provision to consider the cost of items or services in making coverage determinations. And certainly, Congress could not have contemplated that “reasonable and necessary” could be applied to restrict coverage of a beneficial item or service to a limited group of clinical trial participants, as would be the case with Coverage with Study Participation.

## 2. CMS Attempts To Weave Economic Considerations into “Reasonable and Necessary” Determinations

In the years immediately following Medicare’s 1965 enactment, little is documented regarding the interpretation of the reasonable and necessary provision by CMS’s forerunner, the Health Care Financing Administration (HCFA).<sup>92</sup> From its inception, HCFA made “reasonable and necessary” national coverage determinations through an informal process. By the 1970s, however, HCFA had become increasingly concerned over the cost of new technology such

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88. *Id.* at 1989 (emphasis added).

89. *Id.* at 1993.

90. See 42 U.S.C. § 1395 (2000) (“Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or in the manner in which medical services are provided . . .”).

91. *Id.* § 1395y(a); *id.* § 1395y(a)(1)(A) (emphasis added).

92. In 2001, the Department of Health and Human Services changed the name of the Health Care Financing Administration to the Centers for Medicare and Medicaid Services. See Press Release, Dep’t of Health and Human Servs., The New Centers for Medicare and Medicaid Services (CMS) (June 14, 2001), available at <http://www.hhs.gov/news/press/2001pres/20010614a.html>; see also *supra* text accompanying note 4.



as computed tomography (CAT) scanners and kidney dialysis needed for the End Stage Renal Disease Program, which was already facing annual projected costs thirty-five times higher than original estimates.<sup>93</sup> Out of these concerns arose federal agencies to advise Congress and HCFA on coverage issues.<sup>94</sup> It was the coverage of heart transplants, however, that ultimately pushed HCFA to attempt to formalize its national coverage policy through the administrative rule-making process.<sup>95</sup>

The manner in which HCFA handled the matter of heart transplants represents an early agency effort to avoid engaging in direct discussion about the cost of new procedures, but instead to attempt to minimize cost, at least in the short term, by delaying coverage. In 1980, after HCFA discovered that a local administrator had been covering heart transplants performed at Stanford University Medical Center, HCFA announced that heart transplants would be excluded from Medicare coverage, citing concerns over patient selection, as well as social and economic implications.<sup>96</sup> HCFA then contracted for a study of the issues, including patient care costs.<sup>97</sup> Given the charge to consider cost, the study investigator recommended that the economic impact of heart transplants could be significantly limited by creating demanding criteria for facilities wishing to perform the transplant, and by, for example, limiting selection to patients less than sixty-five years old, which would effectively deny access to the vast majority of the Medicare population.<sup>98</sup> Although the directive from senior Medicare officials, as well as the White House, was to limit the potential cost of heart transplantation, the administration took the more politically wise course, and chose to focus not on the cost of transplantation, but on the limited supply of hearts available for transplant.<sup>99</sup> Finally, in 1987, nearly seven years after the first successful procedures had been performed (and many needy beneficiaries denied the procedure), HCFA determined that heart transplants were "reasonable and necessary," but adopted the limiting criteria pertaining to facilities and the age of potential recipients.<sup>100</sup> Instead of admitting that heart transplants were just

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93. See Julie Kosterlitz, *Picking Up the Tab: Medicare Coverage of Heart Transplants*, 18 NAT'L J. 1825, 1827 (1986).

94. See Susan Bartlett Foote, *Why Medicare Cannot Promulgate a National Coverage Rule: A Case of Regula Mortis*, 27 J. HEALTH POL. POL'Y & L. 707, 713 (2002).

95. *Id.*

96. Exclusion of Heart Transplantation Procedures from Medicare Coverage, 45 Fed. Reg. 52,296, 52,297 (Aug. 6, 1980). See also Fox, *supra* note 81, at 580-83 (using heart transplant coverage as an example of the role of cost in Medicare coverage determinations).

97. Exclusion of Heart Transplantation Procedures from Medicare Coverage, 45 Fed. Reg. at 52,297.

98. See Fox, *supra* note 81, at 582.

99. See *id.* at 583.

100. Medicare Program; Criteria for Medicare Coverage of Heart Transplants, 52 Fed. Reg. 10,935 (Apr. 6, 1987).

too expensive to cover for everyone in need, the issue became one of “a blameless tragedy of access to a scarce resource.”<sup>101</sup>

The heart transplant controversy prompted HCFA to attempt to clarify its authority under the “reasonable and necessary” provision in 1980. To that end, HCFA drafted a proposed rule outlining criteria it would use in making coverage decisions that included “safety, economics, and ethical and social factors.”<sup>102</sup> Although the draft was circulated, it was never published, and no rule was ever promulgated, reportedly due to strong opposition from the medical device industry and organized medicine with respect to the economic criteria.<sup>103</sup> Medical device manufacturers were concerned that a formalized process, particularly one that included external technology assessment to evaluate potential economic impact, would result in unfavorable coverage decisions.<sup>104</sup> And so, HCFA continued to make its coverage decisions through an informal internal process that was closed to the public, and that provided little guidance to its stakeholders.

### 3. CMS Attempts To Establish Cost-Effectiveness As a Factor in Determining What Is “Reasonable and Necessary”

The need to formally clarify its authority under the reasonable and necessary provision became increasingly evident to HCFA in 1986 as the result of two significant events. First, in *Bowen v. Michigan Academy of Family Physicians*, the United States Supreme Court held that the statutory bar to federal question jurisdiction did not bar judicial review of Medicare’s administrative standards or policies.<sup>105</sup> Thus, for the first time since its inception in 1965, the door was open to judicial challenge of Medicare’s coverage policies. Second, in *Jameson v. Bowen*, the United States District Court for the Eastern District of California

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101. Fox, *supra* note 81, at 583.

102. Foote, *supra* note 94, at 713.

103. *Id.* at 710-14. Foote’s article provides an insightful account of how stakeholders, particularly the medical device industry, have historically both supported formal rule-making, or opposed rule-making, depending on the industry’s perceived effect such rule-making would have on the development of new technologies.

104. *See id.* at 713-14. Foote writes that in 1981, the National Center for Health Care Technology, whose job it was to advise Medicare on coverage of new technologies, was dissolved, primarily due to pressure exerted on the Reagan administration by the medical device industry and organized medicine.

105. *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667 (1986) (allowing challenge to validity of regulations where no administrative review is available), *limited*, *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 17 (2000). In *Michigan Academy*, an association of family physicians and individual doctors challenged Medicare regulations authorizing payment of benefits in different amounts for similar physicians’ services, depending on whether the physician was board certified, engaged in allopathic medicine, or other criteria. The Court held that the statutory bar applied to judicial review of the amount of benefit determinations, but did not preclude judicial review of the method by which such determinations were made, or of administrative standards. *Michigan Academy*, 476 U.S. at 681.

allowed judicial review of a specific national coverage policy.<sup>106</sup> As part of a settlement agreement in this case, HCFA agreed to prepare and publish a description of the process used to make coverage decisions, including the reasoning behind its decisions against a particular technology.<sup>107</sup> The settlement agreement also required HCFA to allow for public input into the coverage process “where appropriate.”<sup>108</sup> In 1987, in partial settlement of the *Bowen* lawsuit, HCFA published its April 1987 Notice signaling its intent to engage in formal rule-making to provide standards and procedures for making coverage determinations.<sup>109</sup> Although the 1987 Notice indicated that the national coverage process may involve possible referral of the matter to the Public Health Service Office of Health Technology Assessment (the predecessor to the Agency for Health Research and Quality), it contained no provision for general public input into the technology assessment process.<sup>110</sup>

Finally, in 1989, amid intense and growing criticism over the lack of transparency in national coverage policy, and the lack of opportunity for stakeholder input, HCFA published a notice of proposed rule-making relating to coverage criteria for health care technology, promising to establish its coverage criteria and procedures in regulations.<sup>111</sup> In its notice, HCFA suggested that in the past, the public, particularly the device manufacturing industry, may have been confused over its coverage criteria because it used the same “safe and effective” language used by the FDA.<sup>112</sup> Essentially, CMS had said it would consider an item or service to be “reasonable and necessary” if it was safe and effective, and not experimental.<sup>113</sup> HCFA now emphasized that its definition differed from that of the FDA, and that it would consider additional criteria.<sup>114</sup> In

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106. See *Jameson v. Bowen*, No. CV-F-83-547, 1987 WL 108970 (E.D. Cal. Feb. 20, 1987) (settlement agreement and release of claims); see also Foote, *supra* note 94 at 714 (noting that the *Jameson* plaintiff's challenge was to a Medicare policy that denied coverage for angioplasty procedure deemed “experimental”).

107. *Jameson*, 1987 WL 108970 at \*1.

108. *Id.* In settlement of the case, HCFA agreed to publish its coverage process, “including decisions as to whether new procedures are not covered because they have not yet been found to be reasonable and necessary and/or safe and effective.” *Id.*

109. Medicare Program; Procedures for Medical Services Coverage Decisions, 52 Fed. Reg. 15,560, 15,560 (Apr. 29, 1987).

110. *Id.* at 15,562; see also Darrel J. Grinstead, *Evolution of Medicare's Coverage Policy-Making Process*, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS, *supra* note 30, at 1, 9.

111. Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology, 54 Fed. Reg. 4302 (Jan. 30, 1989).

112. See *id.* at 4312.

113. *Id.* at 4304, 4308 (HCFA's historical interpretation of the reasonable and necessary provision was “a test as to whether the service in question was ‘safe’ and ‘effective’ and not ‘experimental’”).

114. *Id.* at 4312.

a clear departure from its historical interpretation, HCFA, for the first time, claimed that the “reasonable and necessary” provision provided authority for it to use cost-effectiveness as a consideration in whether to expand, continue, or terminate coverage of high-cost technology.<sup>115</sup> HCFA announced that the more expensive a service was, the more likely it was to be referred for national determination, which would include an analysis of its cost-effectiveness.<sup>116</sup> Simply stated, cost-effectiveness analysis compares the beneficial effects of a service, such as years of life added by treatment or reduction in infection rates, with its medical and non-medical costs, expressed in dollars.<sup>117</sup> Although careful to note that safety and effectiveness was still the most important criteria, HCFA explained that cost-effectiveness analysis was necessary in light of the “current explosion of high-cost medical technologies,”<sup>118</sup> and it promised to engage in the rule-making process to establish more specific criteria.<sup>119</sup>

Using cost-effectiveness criteria to determine whether an item or service was reasonable and necessary proved extremely controversial, drawing criticism from the public, technology manufacturers, and other stakeholders. Public representatives were concerned that cost considerations would bar approval for technology that would have been approved in the past, which would leave Medicare’s elderly and often poor beneficiaries unable themselves to pay for needed services.<sup>120</sup> Health care providers complained that cost-effectiveness was simply a means of rationing needed care.<sup>121</sup> Medical device companies were concerned that their technology would be denied coverage absent proof of cost-effectiveness, and that conducting the necessary pre-market clinical trials would impose an additional financial burden, and delay diffusion of the

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115. *Id.* at 4308-09 (stating that the requirement that a covered service be reasonable “encompasses the authority to consider cost as a factor in making Medicare coverage determinations”).

116. *See id.* at 4305.

117. *Id.* at 4309. HCFA defined cost-effectiveness analysis as “an analytic tool that seeks to compare the incremental cost with the additional effectiveness of the procedure or technology.” *Id.* Cost-effectiveness is more specifically defined as an analysis that considers “the marginal cost of a new procedure for each quality-adjusted year of life that a patient gains.” Muriel R. Gillick, *Medicare Coverage for Technological Innovations—Time for New Criteria?*, 350 NEW ENG. J. MED., 2199, 2201 (2004).

118. Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology, 54 Fed. Reg. at 4308-09.

119. *Id.* at 4308. Other criteria regarding device coverage include whether the service is accepted in the medical community as safe and effective (described by HCFA as the most important criteria), the status of the device as experimental or investigational, and whether the service is appropriately furnished in an acceptable setting and by qualified personnel. *Id.* at 4306-08.

120. *See* Robert Pear, *Medicare To Weigh Cost As a Factor In Reimbursement*, N.Y. TIMES, Apr. 21, 1991, at A1 (reviewing public comments and draft of final rule).

121. *Id.* (noting that providers believe the policy “lays a foundation for the rationing of medical technology”).

technology.<sup>122</sup>

The cost-effectiveness backlash effectively halted publication of a final rule, and ten years later, in 1999, HCFA flatly announced that it had decided not to adopt its controversial 1989 proposed rule.<sup>123</sup> HCFA continued to implement coverage criteria informally, internally, and without input from concerned stakeholders. Instead of using cost-effectiveness criteria, however, HCFA adopted new terminology, focusing on whether the new technology was “comparable” to already-existing technology, or whether it had “demonstrated medical effectiveness.”<sup>124</sup>

Industry confusion over the role of cost in the decision-making process may have been fueled by inconsistent policy statements publicly made by HCFA top officials. For example, in an ABC News *Nightline* broadcast in December 1996, an HCFA administrator denied that cost was an important consideration in making coverage decisions, stating that money is “truly not an issue for us. We are obligated by law to pay for all services that are necessary and appropriate for Medicare beneficiaries.”<sup>125</sup> Yet, to the contrary, HCFA’s chief medical officer confirmed at a 1998 public town hall meeting that Medicare could not continue to pay for all beneficial new technology or surgical procedures, particularly when benefits may be marginal as compared to currently covered technology.<sup>126</sup>

In 1999, HCFA published its process for national coverage decision-making, promising to publish final coverage criteria, followed by sector-specific guidance.<sup>127</sup> In 2000, HCFA again published a Notice of Proposed Rulemaking indicating two criteria it would apply in making its national coverage decisions.<sup>128</sup> First, an item or service would be reasonable and necessary if

122. *Id.*

123. Medicare Program; Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22,619, 22,620 (Apr. 27, 1999).

124. See Foote, *supra* note 94, at 716-17 (noting that some questioned whether the new terminology was merely a substitute for cost-effectiveness).

125. Micheal M. Gaba, *Developing Integrated Product Approval and Reimbursement Strategies in the Absence of Clear Rules*, MEDICAL DEVICE LINK, SEPT. 1999, <http://www.devicelink.com/mddi/archive/99/09/009.html> (quoting statement of HCFA administrator, Bruce Vladeck, from *Nightline: High-Priced Miracles* (ABC television broadcast Dec. 27, 1996)).

126. *Id.* (describing statements of Jeffrey Kang, HCFA’s chief medical officer).

127. Medicare Program; Procedures for Making National Coverage Decisions, 64 Fed. Reg. at 22,619. The 1999 Notice did announce that CMS would publish its coverage policy on the internet—a step that did much to address stakeholder criticisms that CMS decisions were made in secret, without opportunity for public input. Eleanor D. Kinney, *Medicare Coverage Decision-Making and Appeal Procedures: Can Process Meet the Challenge of New Medical Technology?*, 60 WASH. & LEE L. REV. 1461, 1478-79 (2003).

128. Medicare Program; Criteria for Making Coverage Decisions, 65 Fed. Reg. 31,124 (May 16, 2000).

objective scientific evidence showed that it had “medical benefit” for a defined population.<sup>129</sup> Second, the item or service must provide “added value,” which essentially meant that the service would be covered if no substantially more beneficial alternative that was currently covered was available.<sup>130</sup> The cost of an item, however, would be considered if the new item and the currently covered item were of equivalent benefit. In that case, the new item would be covered only if it cost less.<sup>131</sup> Again, stakeholders were largely opposed to using cost as coverage criteria, even though it would be applied in only a limited number of cases. Some believed that added value was simply new terminology for cost-effectiveness.<sup>132</sup> Opponents were concerned that in an effort to save money, new technologies would be compared to currently covered items or services that were not truly comparable, and that the proposal would ultimately limit treatment options.<sup>133</sup>

Finally, in 2003, CMS officially threw up its hands and declared that, due to “competing interests about the coverage criteria” it would not develop a proposed rule based on the May 2000 Notice of Intent, and would not pursue rule-making with respect to its coverage criteria; rather, it would continue to make coverage decisions as it had for over thirty-five years, interpreting internally what was reasonable and necessary.<sup>134</sup>

#### *4. National Decision-Making Gains Prominence and Congress Presses CMS To Publish Its “Reasonable and Necessary” Criteria*

Although local decisions continue to vastly outnumber decisions made on the national level, national decision-making has taken on greater significance, partly due to concern over local inconsistency among carriers as well as the increasing complexity of the Medicare program. As early as 2001, the Medicare Payment Advisory Commission, in a report to Congress, recommended elimination of the local coverage process.<sup>135</sup> Two years later, a General

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129. *Id.* at 31,127.

130. *Id.*

131. *Id.*

132. See Foote, *supra* note 94, at 719 (“The added value criterion was particularly problematic because it implied economic evaluation, like cost-effectiveness or comparability, in a new form.”).

133. See Judith Lorette et al., *The Perspective of the Centers for Medicare and Medicaid Services*, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS, *supra* note 30, at 149, 158.

134. Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55,634, 55,635 (Sept. 26, 2003) (“Given that there are substantial competing interests about the coverage criteria, we believe it best not to pursue rulemaking. In the meantime, as we have done in the past 35 years, we would continue to need to make coverage decisions and interpret what is ‘reasonable and necessary.’”).

135. MEDICARE PAYMENT ADVISORY COMM’N, REPORT TO THE CONGRESS, REDUCING MEDICARE COMPLEXITY AND REGULATORY BURDEN 22 (2001), *available at* [http://www.medpac.gov/publications/congressional\\_reports/dec2001RegBurden.pdf](http://www.medpac.gov/publications/congressional_reports/dec2001RegBurden.pdf) (In an effort to

Accounting Office (GAO) report recommended that CMS eliminate the development of new local coverage policies.<sup>136</sup> At the same time, the GAO report expressed concern that the national coverage process was slow, that CMS did not publish its draft national coverage policies for public comment, and that CMS did not consistently consult with outside experts in developing coverage policies.<sup>137</sup>

Stakeholders, particularly medical device manufacturers, were concerned that increased emphasis on what they perceived as cumbersome national decision-making would be used by CMS as a means to cut costs by slowing down the influx of expensive, but vital, new technology to the nation's elderly and disabled, no doubt slowing industry profits as well.<sup>138</sup> National decision-making is troublesome to manufacturers of expensive new health care technology because it threatens to eliminate the flexibility they have had in the local process.<sup>139</sup> Often, manufacturers will pursue coverage at the local level in several regions before seeking a national coverage decision.<sup>140</sup> Local coverage is more desirable to manufacturers because local carriers may allow coverage even when experience and data on a particular device would be insufficient for an NCD.<sup>141</sup>

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reduce complexity, inconsistency, and uncertainty in the Medicare program, MPAC recommended that "CMS should move to a standard nationwide system of claims processing and eliminate local descriptions of policy and regulation").

136. GENERAL ACCOUNTING OFFICE, MEDICARE: DIVIDED AUTHORITY FOR POLICIES ON COVERAGE OF PROCEDURES AND DEVICES RESULTS IN INEQUITIES 5 (2003). The GAO report concluded that coverage authority at both the national and local level has resulted in coverage inequities for Medicare beneficiaries with similar medical conditions based on the location of their treatment, and has created administrative inefficiencies. *Id.* at 4. The GAO recommends that "CMS eliminate claims administration contractors' development of new local coverage policies for procedures and devices that have established codes" and that "CMS establish a new process for making national coverage policy." *Id.* at 5.

137. *Id.*

138. See Grinstead, *supra* note 110, at 5. In regard to allowing CMS more control over coverage of new technology, Grinstead notes, "[d]epending upon one's viewpoint, this process has either developed into an effective means of preventing the entry of charlatans and opportunists into the program, or it has stood in the way of making vital, new health care technologies available for the nation's elderly and disabled." *Id.*

139. See Susan Bartlett Foote, *Focus on Locus: Evolution of Medicare's Local Coverage Policy*, 22 HEALTH AFF. 137, 138 (2003), available at <http://content.healthaffairs.org/cgi/content/full/22/4/137>. Unlike the "all-or-nothing national decisions made by a large federal bureaucracy," a favorable local decision allows the device industry multiple points of entry into the market, allowing the manufacturer of the new technology to begin to market the product as it pursues coverage in other geographic areas. *Id.* at 144.

140. *Id.* at 138.

141. Thompson & Dahl, *supra* note 31, at 144. See also GENERAL ACCOUNTING OFFICE, *supra* note 136, at 45 (2003) (HHS reply comment) ("[A]llowing contractors to develop local coverage policies gives Medicare the opportunity to test new, experimental treatments before enough clinical evidence is available to warrant national coverage" and allows the Medicare program "the flexibility to address needs that are not national in scope.").

Local coverage also provides manufacturers with an opportunity to obtain clinical data needed to identify limited subsets of patients who have better outcomes.<sup>142</sup> With respect to the national process, stakeholders had for some time lobbied legislators to require CMS to allow input from interested parties, and to make its coverage process more open and transparent. Device manufacturers, in particular, had become increasingly frustrated with their inability to more wisely allocate their resources in planning investment strategies, to better focus their research and development efforts, and to develop strategies for marketing and diffusing clinical information.<sup>143</sup> Thus, interested stakeholders continued to press CMS for sector-specific guidance as to the level and character of evidence required in order to meet the reasonable and necessary requirement.<sup>144</sup>

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142. Thompson & Dahl, *supra* note 31, at 144.

143. See Procedure for Producing Guidance Documents Describing Medicare's Coverage Process, 69 Fed. Reg. 57,325, 57,326 (Sept. 24, 2004) ("Guidances may be useful in certain cases to help plan investment strategies, research and development efforts, and marketing and clinical diffusion strategies.").

144. See Bagley, *supra* note 41, at 23 (noting that sector-specific guidance is important because different technologies require different evidentiary approaches, and that the "level and character of evidence needed are issues of major controversy that remain to be addressed"). For example, Bagley explains that diagnostic techniques for medical devices undergo a different clinical trial process than do drug therapies, principally because it is not practical to use the double-blind randomized trials for devices that are commonly used for drugs. *Id.* at 37. One long-running point of contention was whether HCFA (now CMS) was required to engage in the rule-making and public comment procedures required by the Administrative Procedures Act. This statute requires administrative agencies to publish in the Federal Register general notice of proposed rule-making, and to engage in a period of public comment before promulgating final rules. 5 U.S.C. § 553(c) (2000). An exception exists, however, when the rules are not substantive, but instead are "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(A) (2000). Whether Medicare rules are substantive or interpretive is not always clear. A coverage policy that describes several examples of items or procedures that may or may not be reasonable and necessary is interpretive in the sense that it illuminates agency thinking on the subject. On the other hand, a beneficiary may be substantially impacted by a policy that restricts an item or service that one would reasonably believe ought to be "reasonable and necessary." A good argument may be made in this instance that the policy is substantive, and subject to notice and comment procedures. See Eleanor D. Kinney, *National Coverage Policy Under the Medicare Program: Problems and Proposals for Change*, 32 ST. LOUIS U. L.J. 869, 943 (1988). HCFA consistently took the position that its coverage criteria was a matter of internal procedure and practice that did not involve substantive, legislative decision-making; thus, it was not legally required to engage in the notice and comment procedure, even though it had attempted to do so on several occasions. See Medicare Program; Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22,619, 22,620-21 (Apr. 27, 1999). A good argument exists, however, that in order to implement the Congressional directive to pay for reasonable and necessary care, Congress has delegated to CMS the authority to create substantive rules that may change an existing law or policy, which would require CMS to comply with the Administrative Procedures Act. See *Linoz v. Heckler*, 800 F.2d 871, 876-77 (9th Cir. 1986) (holding that a national coverage policy that excluded payment to ambulance service to another hospital "solely to obtain the services . . . of a physician in a specific specialty" was invalid because it was a substantive rule, and the Secretary had failed to conform with the administrative notice and comment procedures) (footnote omitted).



Congress addressed several stakeholder concerns in a head-on manner in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).<sup>145</sup> Although Congress did not eliminate the local coverage process, the MMA directed CMS to develop a plan to achieve greater consistency among local coverage determinations, and to consider which local decisions should be adopted nationally.<sup>146</sup> Furthermore, the MMA spoke to the concerns of interested stakeholders by establishing an expedited time frame for making national coverage determinations,<sup>147</sup> requiring opportunity for public comment on draft decisions,<sup>148</sup> and requiring consultation with outside experts on national coverage determinations not referred to MCAC.<sup>149</sup> Most importantly for purposes of this Article, the MMA also required CMS to develop and make available to the public guidance documents explaining the factors CMS considers in determining whether an item or service is reasonable and necessary.<sup>150</sup>

This statutory mandate places CMS in a challenging position. Its 1989 attempt at rule-making—designating cost-effectiveness as an explicit coverage criterion—was soundly opposed, and ultimately abandoned. Yet, CMS has been able to control the cost of expensive new technology, at least implicitly, either by claiming some other reason for limiting beneficial new technology, as it did in the case of heart transplantation, or by opening an NCD and designating the technology for external technology assessment, thereby slowing the coverage process. Given the lack of statutory and popular support for considering cost-effectiveness in its decision-making, CMS surely cannot again openly designate cost, or cost-effectiveness, as a factor.

On April 11, 2006, in response to the mandates of the Medicare Modernization Act, CMS published two guidance documents that illustrate CMS's desire, yet its inability, to consider cost in making coverage determinations. In the first document, "Factors CMS Considers in Opening a National Coverage Determination," CMS avows that, even though it may choose for NCD consideration technology that is "likely to have a significant programmatic impact," which would include a significant financial impact, it would not consider the cost-effectiveness of the particular technology in

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145. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (to be codified in scattered sections of 42 U.S.C.).

146. 42 U.S.C.A. § 1395y(l)(5)(A) (West Supp. 2006).

147. 42 U.S.C.A. § 1395y(l)(2) (West Supp. 2006).

148. 42 U.S.C.A. § 1395y(l)(3) (West Supp. 2006).

149. 42 U.S.C.A. § 1395y(l)(4) (West Supp. 2006).

150. 42 U.S.C.A. § 1395y(l)(1) (West Supp. 2006) ("The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary shall develop guidance documents to carry out this paragraph . . .").

determining whether it should be covered through an NCD.<sup>151</sup> The process by which CMS internally generates an NCD is not transparent, however, and may itself be the equivalent of considering cost-effectiveness outright. Similarly, in “Factors CMS Considers in Commissioning External Technology Assessments,” CMS is less than clear with respect to whether cost considerations will be part of the “reasonable and necessary” inquiry.<sup>152</sup> In that document, CMS admits that “economic considerations may be a factor discussed in a technology assessment,” but that “cost is not a factor in our review or decision to cover a particular technology.”<sup>153</sup>

Technologies that have a significant financial impact on the Medicare program, as well as technologies that may require an external technology assessment, are just the types of interventions that may be designated for Coverage with Study Participation.<sup>154</sup> A CSP designation would effectively control costs by delaying NCD consideration indefinitely, likely for years, until clinical trials could be established and completed, and the research analyzed and published. Quite possibly, CMS could send technology it is considering for an NCD first to outside technology assessment and, following that, to CSP for clinical trials, thereby pushing a possible NCD even further into the future.

Assuming that one could prove that Coverage with Study Participation was a means of implicit cost control, CMS may not fare well in the event of a court challenge to its authority to consider cost in making coverage decisions. The Supreme Court’s opinion in *FDA v. Brown & Williamson Tobacco Corp.*<sup>155</sup> provides insight as to how a reviewing court might analyze whether CMS has the administrative authority, under the administrative deference doctrine, to consider cost in making coverage decisions. In determining the limits of agency authority, the Court stated that the first inquiry is whether Congress has directly addressed the scope of the agency’s authority.<sup>156</sup> If not, a court should consider whether Congress has subsequently taken actions regarding the specific topic at hand, thereby indicating its intent to control the area.<sup>157</sup> The final inquiry is whether the

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151. See CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 42, at pt. IV.C.

152. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 46.

153. *Id.* at pt. III.

154. Examples of the type of technology likely to have significant financial impact on Medicare policy may include the use of FDG-PET scans for suspected dementia, and the use of implantable cardioverter defibrillators for certain indications. See Tunis & Pearson, *supra* note 9, at 1222-23. CMS, after initial resistance, agreed to cover these interventions subject to beneficiary participation in prospective clinical trials or registries. *Id.* at 1222-24.

155. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). The issue in *Brown & Williamson* was whether the FDA had authority to regulate tobacco products under its authority to regulate drugs and devices, under the theory that cigarettes and smokeless tobacco were “combination products” that delivered nicotine to the body. *Id.* at 125.

156. *Id.* at 132.

157. *Id.* at 133 (“[T]he meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand.”). In *Brown & Williamson*, the Court reviewed numerous instances where Congress had acted to regulate the

topic involves a “policy decision of such economic and political magnitude” that Congress would not likely have delegated the area to an administrative agency.<sup>158</sup>

Since Congress has not specifically stated whether CMS can consider cost in making coverage decisions, the analysis turns on the latter two inquiries. First, Congress has, on several occasions, indicated its intent to control Medicare program costs. The most striking example of congressional intervention to address and restrain rising program costs is the enactment in 1983 of the prospective hospital payment legislation, followed in 1989 with a new fee schedule for physicians, the Resource-Based Relative Value Scale.<sup>159</sup> One reason for congressional action was to keep disputes over cost control out of the political process.<sup>160</sup> Interesting to note is the proximity in time of the 1989 physician fee schedule legislation to Medicare’s 1989 failed attempt to use the administrative rule-making process to institute cost-effectiveness analysis into its coverage criteria.<sup>161</sup> Clearly, congressional implementation of the prospective payment system and physician fee schedule indicates that Congress, not CMS, is the proper vehicle for addressing rising health care costs.

The second inquiry necessary to determine whether Congress intended CMS to consider cost in its coverage criteria is whether the topic involves a “policy decision of such economic and political magnitude” that Congress would not likely have delegated the area to an administrative agency.<sup>162</sup>

Congress has given CMS the authority to consider the cost of new services and technologies when it sets payment rates, which is accomplished in a process that is separate and apart from the coverage process.<sup>163</sup> Congress’s explicit grant of permission to consider costs in the payment process, and the lack of any such permission respecting the coverage process, indicates that Congress intended to keep that authority for itself.

Moreover, cost control in the coverage process is synonymous with rationing

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tobacco industry, noting that these actions by Congress precluded the FDA from claiming jurisdiction to regulate tobacco products. *Id.* at 143-55.

158. *Id.* at 133.

159. MARMOR, *supra* note 81, at 108 (describing the prospective hospital payment legislation and the physicians fee schedule as “effective in achieving the overarching goal of restraining the growth of Medicare expenditures”).

160. *Id.* at 109.

161. See discussion *supra* at Subsection III.B.3.

162. *Brown & Williamson*, 529 U.S. at 133.

163. See 42 U.S.C.A. § 1395ww(d)(5)(K)(i)-(ii) (2003) (“[T]he Secretary shall establish a mechanism to recognize the costs of new medical services and technologies under the payment system . . . . The mechanism . . . shall . . . apply to a new medical service or technology if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG [diagnosis-related group] prospective payment rate otherwise applicable to such discharges under this subsection is inadequate . . .”).

care. The term “health care rationing” is itself politically charged, raising issues of economic and political magnitude. The Court in *Pegram v. Herdrich* made it clear that health care rationing is an area that Congress would not likely delegate to an agency. In that case, the Court noted that Congress is better equipped than the courts to make health care rationing decisions, given the comprehensive investigations and social value judgments that would be required to balance optimal treatment levels against health care expenditures.<sup>164</sup> Certainly, Congress would not likely delegate health care rationing decisions to an administrative agency.

Implicit rationing, however, is less noticeable and far more politically acceptable than explicit rationing. Perhaps CMS, facing the inability to overtly use cost in its decision-making, yet possessed of the practical reality that not all beneficial technology can be paid for indefinitely, has devised a means of implicit rationing by slowing down the coverage process, perhaps for years, through Coverage with Study Participation.

### III. PROBLEMS WITH INCLUDING MEDICARE BENEFICIARIES IN CLINICAL TRIALS

Coverage with Study Participation (CSP) restricts payment for the items and services provided in a study to those Medicare qualified patients who are subjects in the study.<sup>165</sup> Several concerns surface with respect to the difficulty of achieving “qualified trial” status to meet CMS’s stated goals, the challenges of including elderly and disabled persons in clinical trials, and the troubling issue of obtaining the voluntary consent of research subjects in the CSP context.

#### *A. Meeting CMS Goals and the “Qualifying Trial” Standard*

Providers have expressed concern over the increasing weight CMS is giving to randomized, double-blinded, peer-reviewed clinical trials in making coverage decisions for the Medicare population, some claiming that proof in the scientific literature of the effectiveness of the vast majority of Medicare-covered procedures can not be found.<sup>166</sup> The primary purpose of a CSP clinical trial is to

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164. See *Pegram v. Herdrich*, 530 U.S. 211, 221 (2000) (stating that “such a debatable social judgment [is] not wisely required of courts unless for some reason resort cannot be had to the legislative process, with its preferable forum for comprehensive investigations and judgments of social value, such as optimum treatment levels and health care expenditure”); see also Fox, *supra* note 81, at 624.

165. CMS, CED GUIDANCE DOCUMENT, *supra* note 6, at pt. VI.B.

166. Letter from E. Ratcliffe Anderson Jr., on behalf of the American Medical Association, to Hugh M. Hill, Acting Director, Coverage and Analysis Group, Health Care Financing Administration (May 9, 2000), available at <http://www.incontinet.com/ama2mcac.doc>. In opposing MCAC’s alleged over-reliance on peer-reviewed scientific journals to determine the effectiveness of a medical intervention, to the exclusion of clinical guidelines that reflect the standard of care, Mr. Anderson stated that “[t]he effectiveness of the vast majority of procedures that are covered by

test whether the intervention potentially improves the participants' health outcomes.<sup>167</sup> Yet providers are concerned that, although clinical trials can provide valuable information, they often do not produce data regarding health outcomes.<sup>168</sup> Moreover, given that a large percentage of Medicare beneficiaries have poor health, and for other reasons that will be discussed later in this Part, they typically are not recruited for randomized, double-blinded clinical trials.<sup>169</sup> In order to limit variability within a trial, only those Medicare patients with limited co-morbidities would likely be recruited, and the trial results would be skewed toward this limited subset of patients.<sup>170</sup> Studying outcomes data is often prohibitive in such size-limited studies.<sup>171</sup> Thus, CMS may have difficulty meeting its goals of generating sufficient outcome data to support a national coverage determination through its CSP initiative.

Moreover, CMS will only provide payment for clinical research that meets the standards of a qualified trial. These standards are outlined in its Clinical Trial Policy, which CMS is revising to encompass CED. One of the requirements of a CSP qualified trial will be that the trial should include a representative sample of Medicare beneficiaries with the health condition being researched.<sup>172</sup> CMS engages in circular reasoning here. Trial data cannot be generalized to the Medicare population unless a significant number of Medicare beneficiaries with the condition are enrolled in the trial. Yet the trial will not be covered unless it ultimately recruits the requisite number of Medicare beneficiaries. How likely is it that a Medicare beneficiary will enroll in a clinical trial unless coverage is assured? Not very.

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Medicare today for its aged and disabled beneficiaries has not been demonstrated in peer-reviewed scientific literature.” *Id.*

167. CMS, CED GUIDANCE DOCUMENT, *supra* note 6, at pt. VI.B.

168. Rachel F. Ochs-Ross & Thomas A. Connaughton, *The Perspective of Providers*, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS, *supra* note 30, at 105, 115 (“While many experts agree that the standard of controlled randomized clinical trials generally provides valuable information, data from these trials that include health outcomes often do not exist, either for most of the therapies currently in use or for new treatments.”).

169. See HENRY J. KAISER FAMILY FOUND., MEDICARE CHART BOOK 2, 5 (3d ed. 2005), available at <http://www.kff.org/medicare/upload/Medicare-Chart-Book-3rd-Edition-Summer-2005-Report.pdf> (reporting that 90% of Medicare beneficiaries have one or more chronic illnesses; 60% have hypertension; 58% have arthritis, and 25% have a cognitive or mental impairment).

170. Ochs-Ross & Connaughton, *supra* note 168, at 115 (“Results from clinical trials, by necessity, are limited to the patient base studied in the trial and, because of the need to limit variability within a clinical trial, skewed to patients with limited co-morbidities.”).

171. *Id.* (“[S]ize limitations often make the study of outcomes data prohibitive, not just because of cost, but because of recruitment difficulties and the long time periods often required to adequately assess large numbers of patients.”).

172. CMS, CED GUIDANCE DOCUMENT, *supra* note 6, at pt. VI.B (“The sample of study subjects in the trial should include individuals representative of the Medicare population with the condition described in the NCD.”).

Although the elderly are the chief consumers of medical services, they are typically under-represented in clinical trials. The standard Phase I drug trial consists of subjects aged between eighteen and forty-five,<sup>173</sup> despite federal guidelines for clinical trials that require new drugs to be studied in all age groups, including the geriatric group if they are the group who will most benefit from the drug.<sup>174</sup> Nevertheless, most clinical trials seek healthy, younger subjects, and typically exclude subjects over sixty-five. For example, according to the National Institute on Aging, most tumors are diagnosed in persons ages seventy to seventy-four, and information on the safety and effectiveness of treatments is badly needed for this elderly population.<sup>175</sup> Patients in this age group, however, seldom meet the eligibility criteria for clinical trials, and so tend not to be referred to these trials. To the contrary, clinical researchers typically recruit younger individuals who represent the minority of persons with the particular disease. The unfortunate result is data that cannot be generalized to the over-sixty-five (i.e. Medicare) population as a whole.<sup>176</sup>

### *B. The Difficulty of Including Medicare Beneficiaries in Clinical Trials*

Many reasons exist for the lack of Medicare beneficiary participation in clinical trials. Although Medicare beneficiaries include many under-sixty-five disabled persons, most of the literature pertains to the significant majority of beneficiaries who are elderly. Thus, this Section focuses on the difficulty of including the elderly in clinical trials, although many of the basic principles apply to other beneficiaries as well. The aging process leads to changes in physical, mental, hormonal and metabolic conditions that may cause many elderly persons to be excluded from trials.<sup>177</sup> Elderly persons may have decreased bone mass, muscle strength, and immune response to infection. They may be more susceptible to heat and cold, and have increased sensitivity to medications.<sup>178</sup> Elderly persons may be excluded from trials because the researcher is concerned that these conditions may interfere with trial objectives.

To a significant extent, the hesitation of the elderly to enroll in clinical trials is due to their perceived, as well as actual, health condition. Medicare beneficiaries total 41.8 million persons, with 35.4 million age sixty-five or over,

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173. Daniela Kosling, *Elderly in Clinical Trials—Requirement or Risk?*, THE IMFORMER (NEWSL. FROM IMFORMER GMBH, DARMSTADT, GERMANY), Apr. 2003.

174. See Guidelines on Studies in Support of Special Populations: Geriatrics, 59 Fed. Reg. 39,398 (Aug. 2, 1994); Guidelines for the Study of Drugs Likely To Be Used in the Elderly, 55 Fed. Reg. 7777 (Mar. 5, 1990).

175. Nat'l Inst. on Aging, Working Group 2: Treatment Efficacy and Tolerance, <http://www.nia.nih.gov/ResearchInformation/ConferencesAndMeetings/WorkshopReport/WorkingGroupReports/WorkingGroup2.htm> (last visited May 3, 2007).

176. *Id.*

177. See Kosling, *supra* note 173.

178. *Id.*

and 6.3 million under sixty-five with permanent disabilities.<sup>179</sup> When non-institutionalized beneficiaries were asked to self-report their general health condition, 28% reported being in fair or poor health, with a considerably higher proportion of poor beneficiaries reporting being in poor health than their wealthier counterparts.<sup>180</sup> Over half of non-institutionalized Medicare beneficiaries report living with chronic conditions such as hypertension and arthritis.<sup>181</sup> In addition, functional impairment resulting in difficulty with bathing, eating, and other activities of daily living affects one third of all beneficiaries.<sup>182</sup> Aside from health concerns, many elderly persons may have difficulty participating in clinical trials due to lack of social support, difficulty in obtaining transportation to and from the trial site, or lack of caregiver assistance.<sup>183</sup> Some may simply be unwilling to participate because the trial is perceived as too much effort, or because they are afraid of possible risks.<sup>184</sup>

Another concern is the ability of some elderly persons to give truly informed consent to participate in a clinical trial. An older person may not completely understand the implications of a research protocol, and the quality of informed consent forms varies from institution to institution. Although the federal regulations that protect human subjects in clinical trials provide special protections for “vulnerable populations” such as children, prisoners, persons with mental disabilities, pregnant women and the economically or educationally disadvantaged, they provide no additional protections for elderly subjects who participate in clinical trials.<sup>185</sup> Vulnerability, however, is sensitive to situational context, and elderly persons may be vulnerable in one situation, but not in another.<sup>186</sup> For example, some elderly persons may regularly put aside their own concerns to defer to the wishes of their adult children.<sup>187</sup> Others may feel

179. HENRY J. KAISER FAMILY FOUND., *supra* note 169, at 3 (figures based on 2004 research). While most beneficiaries are between ages 65 and 74, 12% are age 85 and above. *Id.* at 3.

180. *Id.* at 2. (noting that 43% of those with incomes less than 100% of the federal poverty guideline reported their health to be fair or poor, but only 17% with incomes at 300% or above the poverty line report their health as fair or poor).

181. *Id.* at 2 (noting that 60% reported living with hypertension and 58% reported living with arthritis).

182. *Id.* at 5.

183. Nat'l Inst. on Aging, *supra* note 175.

184. See Kosling, *supra* note 173.

185. See 45 C.F.R. § 46.111(3) (describing “vulnerable populations” as children, prisoners, pregnant women, mentally disabled persons, or the economically or educationally disadvantaged).

186. See NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS 85 (2001), available at [http://bioethicsprint.bioethics.gov/reports/past\\_commissions/nbac\\_human\\_part.pdf](http://bioethicsprint.bioethics.gov/reports/past_commissions/nbac_human_part.pdf) (“[V]ulnerability, in the context of research, should be understood to be a condition, either intrinsic or situational, of some individuals that puts them at greater risk of being used in ethically inappropriate ways in research.”).

187. *Id.* at 89.

pressured to defer to their physicians' suggestion that they enroll in a clinical trial, and they wish not to disappoint their physicians, or they may be concerned that their refusal may negatively affect their care.<sup>188</sup>

*C. CSP May Violate HHS Protection of Human Subject Regulations*

Perhaps the most serious objection to CSP is that it runs afoul of federal regulations designed to protect human subjects who participate in medical research.<sup>189</sup> Without question, federal regulations would apply to the research contemplated by the CSP arm of CED, since regulations broadly define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."<sup>190</sup> Research conducted or supported by a federal department or agency must comply with federal regulations outlining basic policy for the protection of human subjects.<sup>191</sup>

At the heart of human subject protection is the principle of informed consent.<sup>192</sup> Human beings may be used as research subjects only if they are

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188. *Id.*

189. The term "subject" is used to describe persons who participate in medical research in order to distinguish them from patients who are receiving medical treatment or therapy, even though an individual may be both a patient and a research subject. Medical ethicist Jay Katz notes that it is "imperative to view clinical research as a distinct category, sharply delineated from clinical practice." Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7, 17 (1993). Research subjects may or may not benefit from the particular research intervention, but the purpose of research is to resolve genuine medical uncertainties for the benefit of future patients, and not for the research subjects. This is unlike the typical therapeutic encounter, where the physician acts solely in the best interests of her patient. To the contrary, in clinical research, patient-subjects are objectified to the extent that they are being used to promote scientific ends. *Id.* at 15-17. Thus, the term "subject" is used in the research context.

190. 45 C.F.R. § 46.102(d) (2006).

191. Research involving human subjects conducted by the Department of Health and Human Services (HHS) is governed by 45 C.F.R. Part 46, and research conducted by the Food and Drug Administration (FDA) involving drugs and devices regulated by the FDA is governed by 21 C.F.R. Parts 50 and 56. 45 C.F.R. § 46.101(a) (2006) provides that federal policy "applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency which takes appropriate administrative action to make the policy applicable to such research." The regulations further provide that "[r]esearch that is conducted or supported by a federal department or agency . . . must comply with all sections of this policy." 45 C.F.R. § 46.101(a)(1) (2006).

192. The principle of informed consent developed in response to the atrocities committed by Nazi doctors and scientists under the guise of medical research during World War II and the subsequent 1946 Nuremberg Military Tribunal, which brought these war criminals to justice. See generally, *THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION* (George J. Annas & Michael A. Grodin eds., 1992). Part of the Tribunal's decision included what has become known as the Nuremberg Code. The first principle of the Nuremberg Code is "[t]he voluntary consent of the human subject is absolutely essential." *Nuremberg Code*, in 2 *Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council No. 10*, 181-82 (U.S. Gov't Printing Office 1949) [hereinafter *Nuremberg Code*],



legally competent to consent to participate, and only after the details of the research have been explained, including the purpose of the research and any potential risks or benefits involved in the research.<sup>193</sup>

Most pertinent to CSP, however, is the principle that the subject's informed consent must be voluntary.<sup>194</sup> The Nuremberg Code, which provides the historical basis for federal regulations requiring the informed consent of research participants, described voluntary consent as being "without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form

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available at <http://ohsr.od.nih.gov/guidelines/nuremberg.html>. This principle was modified in 1964 by the Declaration of Helsinki, which allows a legally authorized representative to consent for legally incompetent persons who are physically or mentally incapable of giving consent. WORLD MED. ASS'N, DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (adopted 1964, amended 1975, 1983, 1989, 1996, and 2000), available at <http://www.wma.net/e/policy/b3.htm>. Medical research practice in the United States was surprisingly unchanged by the Nuremberg Trials and the ensuing world attention on the use of humans in medical research. It was not until 1966, when a highly controversial article by Dr. Henry K. Beecher provided twenty-two examples of unethical research, that the federal government focused on the need to regulate medical research. The FDA and the National Institutes of Health (NIH) developed internal guidelines providing rudimentary subject protections that were codified as federal regulations in 1974. See Harold Y. Vanderpool, *Introduction and Overview*, in THE ETHICS OF RESEARCH INVOLVING HUMAN SUBJECTS FACING THE 21ST CENTURY 1, 10 (Harold Y. Vanderpool ed., 1996). Also in 1974, the newly formed National Commission for the Protection of Human Subjects of Biomedical Research and Behavioral Research (National Commission) was given the task of identifying the ethical principles underlying biomedical research involving human subjects and instructed to develop federal guidelines. See William J. Winslade & Todd L. Krause, *The Nuremberg Code Turns Fifty*, in ETHICS CODES IN MEDICINE 150 (Ulrich Trohler & Stella Reiter-Theil eds., 1996). Among the seventeen reports produced by the National Commission was the Belmont Report, which served as the basis for our current federal regulations. The Belmont report provided a framework for solving the ethical problems that arise in human subject research, and sheds light on the application of ethical principles in the clinical setting. See Nat'l Comm'n for the Prot. of Human Subjects of Biomedical & Behavioral Research, *The Belmont Report: Ethical Principles & Guidelines for Research Involving Human Subjects*, 44 Fed. Reg. 23,192 (Apr. 18, 1979), available at <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm> [hereinafter Belmont Report]. The Belmont Report identified and enumerated three fundamental ethical principles necessary for the protection of human subjects in medical experimentation: respect for persons; beneficence; and justice. *Id.*

193. See 45 C.F.R. § 46.116(a)(1)-(8) (2006). The basic elements of informed consent include an explanation of the purpose of the research, the duration of the subject's participation, an explanation of each step of the research procedure, a description of the risks, discomforts, or benefits that might reasonably be expected from the research, alternatives available should the subject choose not to participate in the research, a description of how records will be kept confidential, and other protections. *Id.*

194. See *Nuremberg Code*, *supra* note 192 ("The voluntary consent of the human subject is absolutely essential."). The Nuremberg Code was drafted during the Nuremberg War Crime Tribunals as a set of principles, or standards, for judging those physicians and scientists who had conducted medical experimentation on concentration camp prisoners during World War II.

of constraint or coercion . . . .”<sup>195</sup> Similarly, the Belmont Report, which provides a framework for solving the ethical problems that arise in medical research on human subjects, explains that in order for consent to be truly voluntary, it must be “free of coercion and undue influence.”<sup>196</sup> Coercion occurs when the potential research subject is threatened with harm in order to obtain compliance with the research protocol.<sup>197</sup> Undue influence occurs when an excessive reward or incentive is offered to gain subject participation, or when an inducement is offered to a potential subject who is particularly vulnerable.<sup>198</sup> These basic ethical principles are also embodied in HHS and FDA regulations, which require that investigators seek the consent of potential subjects only under circumstances that “minimize the possibility of coercion or undue influence.”<sup>199</sup>

If a particular intervention is approved for payment under Coverage with Study Participation, only Medicare beneficiaries who agree to participate in the research will have access to the service. Payment for the items and services provided in the clinical trial is restricted to those services provided to Medicare beneficiaries who are enrolled in the study.<sup>200</sup> Thus, the cost to the patient of choosing not to participate in research is that the service would be prohibitively expensive. A decision to participate in medical research cannot be truly voluntary, however, when participation is the only way to receive the service. This is particularly troublesome in light of the fact that the particular intervention has likely already been FDA-approved as safe and effective, deemed appropriate

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195. *Id.*

196. Belmont Report, *supra* note 192. The Belmont Report analyzes the consent process as containing three elements: information (disclosure of all aspects of the research); comprehension (the information must be conveyed in a manner that is understandable to the subject, given the subject’s intelligence, maturity, and language comprehension); and voluntariness (consent to participate in research must be free from coercion, undue influence). *Id.*

197. The Belmont Report defines coercion as occurring “when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance.” *Id.*

198. The Belmont Report defines undue influence as occurring “through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance.” *Id.* The report adds that “inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.” *Id.*

199. 45 C.F.R. § 46.116 (2006) (“An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.”). The FDA regulations governing research on human subjects involving drugs or devices contain identical language. *See* 21 C.F.R. § 50.20 (2006). HHS regulations regarding informed consent and other subject protections are found in Subpart A of 45 C.F.R. Part 46. Subpart A is typically referred to as the Common Rule because it incorporates the Federal Policy for the Protection of Human Research Subjects. This Federal Policy is also reflected in the regulations for an additional fourteen government departments that conduct research using human subjects. *See, e.g.,* Protection of Human Subjects, 45 C.F.R. Part 46 (2006) (regulating research of HHS); Protection of Human Subjects, 7 C.F.R. § 1c (2006) (regulating research of Department of Agriculture); Protection of Human Subjects, 10 C.F.R. § 745 (2006) (regulating research of Department of Energy).

200. CMS, CED GUIDANCE DOCUMENT, *supra* note 6, at pt. VI.B.

for the patient by the patient's treating physician, and considered by CMS to be sufficiently reasonable and necessary to be approved for Medicare beneficiaries, but only so long as they agree to participate in research. CMS may be engaging in coercion or undue influence in violation of federal regulations in the sense that coverage of the service is essentially the patient's reward for enrolling in the trial.

Theoretically, a Medicare beneficiary could bypass CSP and privately pay for the intervention, receiving it through a provider who has opted out of the Medicare program.<sup>201</sup> For the most part, CSP will involve new technology that has been FDA-approved as safe and effective, and may well be publicly available outside the Medicare program. The practical reality, however, is that the cost would be prohibitive for a significant majority of Medicare beneficiaries. Most Medicare beneficiaries rely on their Social Security checks for living expenses and non-covered health care services. A Kaiser Family Foundation study reveals that in 2003, 10% of Medicare beneficiaries over sixty-five had incomes below \$8825.<sup>202</sup> In 2004, nearly four in ten elderly Medicare beneficiaries had incomes below \$18,120 for individuals and \$22,836 for couples.<sup>203</sup> Similarly, most Medicare beneficiaries have minimal assets. In 2002, the most recent year for which data is available, more than half of non-institutionalized Medicare beneficiaries had assets of \$20,000 or less.<sup>204</sup> Given the high cost of new health care technology, no realistic possibility of private purchase exists.<sup>205</sup> The effect

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201. See 42 U.S.C.A. § 1395a(b) (West Supp. 2006) (allowing a physician to enter into a private contract with a Medicare beneficiary, provided no claim for payment is submitted and no reimbursement is received from Medicare); 42 U.S.C.A. § 1395a(b)(2) (West Supp. 2006) (requiring physician's private written contract with beneficiary to state that the physician's charges are not limited by the Medicare rules, and that the beneficiary may not submit any claim for reimbursement to Medicare); 42 U.S.C.A. § 1395a(b)(3)(B) (West Supp. 2006) (requiring the physician to file an affidavit with the Secretary affirming the physician will not submit any claim for any service provided to any Medicare beneficiary, or receive reimbursement for any service for a two year period).

202. HENRY J. KAISER FAMILY FOUND., *supra* note 169, at 6.

203. *Id.* at i.

204. *Id.* at 2.

205. After publication of CMS's CED Draft Guidance, many stakeholders questioned whether a national coverage determination designating a service for CED (now CSP) would preclude them from seeking a local coverage determination. CMS responded to this and other concerns in a follow-up fact sheet. See CTRS. OF MEDICARE & MEDICAID SERVS., FACT SHEET: CMS RESPONDS TO STAKEHOLDER FEEDBACK REGARDING COVERAGE WITH EVIDENCE DEVELOPMENT (2005), *available at* <http://www.cms.hhs.gov/coverage/download/guidfactsheet.pdf>. CMS indicated that, although an NCD supersedes any inconsistent local decision, the local carriers could "continue to make independent medical decisions while CMS is considering a new NCD." *Id.* at 2. Under these circumstances, however, local coverage for subjects who are unable or unwilling to participate in CED research is not likely to happen. Carriers are typically unwilling to cover a new item or service once CMS has indicated its intention to subject it to a national coverage decision. See, e.g., Letter from Laura Thevenot, Executive Director, American Society for Therapeutic Radiology & Oncology, to Steve Phurrough, Director, CMS Coverage and Analysis Group, (June 6, 2005) (on

of non-coverage outside of CSP is that patients unable or unwilling to enroll in research will not have access to the service.

#### IV. RECOMMENDATIONS

Medicare began as a politically acceptable compromise for its architects, who had expected it to be the first step toward universal national health insurance.<sup>206</sup> The expectation was that Medicare patients would receive the same level of care as was enjoyed by other paying or insured patients,<sup>207</sup> and that hospitals and physicians would be paid their full costs.<sup>208</sup> What soon became apparent, however, was that after-the-fact reimbursement for hospital costs and physician services was flawed, creating considerable incentive for over-utilization, and that government intervention would be required to rein in costs that were rapidly approaching crisis proportions.<sup>209</sup> To address rising hospital costs, in 1982 Congress implemented a prospective payment system based on diagnostic related groups for hospitals, followed in 1989 by similar cost-saving measures for Part B physician services.

Today, it is commonly accepted that changes in medical technology account for a significant portion of health care costs, which are again approaching crisis levels.<sup>210</sup> Not only is it costly to bring new technology through the extensive

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file with author) (public comment on CED policy, stating that many carriers are unwilling to cover a new item or service once CMS is considering it for NCD). Moreover, in CMS's subsequent CED Guidance Document, CMS has apparently backed off its earlier response, since the new document does not mention local coverage. In any event, a local carrier would not likely cover an item or service designated for CSP, since CMS has indicated that those interventions are not (yet) "reasonable and necessary."

206. See Ball, *supra* note 80, at 62-72. Ball, who served as commissioner of Social Security under Presidents Kennedy, Johnson, and Nixon, explained that the Medicare bill likely would never have passed had the architects created a more prominent role for the government. *Id.* at 67.

207. *Id.* at 67. Ball writes that "the aged, who were mostly poor, were usually treated in hospital wards where their care was often left to interns and medical students." *Id.* at 68. To be treated the same as paying patients meant being treated in a two-bed, semi private room, with respect, and without discrimination on the basis of race. *Id.*; see also Marian Gornick et al., *Twenty Years of Medicare and Medicaid: Covered Populations, Use of Benefits, and Program Expenditures*, 6 HEALTH CARE FIN. REV. 13, 14 (Supp. 1985) (indicating that in 1963, only about half of the over-sixty-five population had hospital insurance, in contrast to about three-fourths of the under-sixty-five population).

208. Ball, *supra* note 80, at 68. That the government was originally slated for a hands-off role is reflected in the first section of the Medicare Act, which provides a "prohibition against any federal interference . . . [or the] exercise [of] supervision or control over the practice of medicine . . . [or over] any such institution, agency or person" providing health services. 42 U.S.C. § 1395 (2000).

209. See FURROW ET AL., *supra* note 45, at 373 (noting that between 1967 and 1983, hospital expenditures increased eleven times, from \$3 billion to \$33 billion).

210. See David M. Cutler & Mark McClellan, *Is Technological Change in Medicine Worth It?*, HEALTH AFF., Sept.-Oct. 2001, at 11 ("It is widely accepted that technological change has accounted for the bulk of medical care cost increases over time."); see also CITIZENS' HEALTHCARE WORKING GROUP, THE HEALTH REPORT TO THE AMERICAN PEOPLE 7 (Mar. 31, 2006), available at

FDA approval process, but costs multiply when the technology leads to many more people being treated for diseases that, for better or worse, were not treatable on the same level prior to the advent of the new technology.<sup>211</sup> The prospective payment system is of limited utility in addressing the cost of new technology because a reimbursement rate set too low not only discourages innovation, but essentially is a de facto non-coverage decision.

It appears that CMS is using Coverage with Study Participation as a cost-cutting initiative, achieved by tying up expensive technology in clinical trials for which financing is uncertain and recruiting is slow, and thereby delaying diffusion of the technology into the marketplace for an indefinite period of time. CMS predicts, without commitment, that at some undetermined point down the road it will analyze the data to determine whether the technology merits a national coverage decision.<sup>212</sup> Meanwhile, CMS contends that CSP is a means of enhancing access to promising new medical technology that otherwise would not be covered. That such services would be non-covered seems disingenuous, however, since CMS *is* covering the service for those Medicare beneficiaries enrolled in trials.

The more likely explanation is that the evidence *is* sufficient to support a national coverage determination, but the financial impact on the program would be too great if the service was implemented nationally. This rationale is supported by CMS's original Draft Guidance position that it could cover certain technology linked to clinical trials because the available evidence indicated that the technology *was* "reasonable and necessary."<sup>213</sup> Only when doubt arose as to

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<http://www.citizenshealthcare.gov/healthreport/healthreport.php> (reporting total health care spending will increase to \$4 trillion by 2015, with Medicare spending becoming an increasingly large percentage of overall spending). According to CMS 2005 statistics, the United States spent \$6697 per person on health care, totaling \$2 trillion. Although the rate of increase was somewhat less than in previous years, health care spending overall grew to 16% of the gross domestic product in 2005. CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURE DATA, <http://cms.hhs.gov/nationalhealthexpenddata/Downloads/highlights.pdf> (last visited May 3, 2007). The Medicare program is the dominant source of public spending, with \$342 billion spent in 2005. In 2005 alone, Medicare spending rose 7.8%, due primarily to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which increased payments for capitated health plans and rural providers, and home health and physician services. *Id.* This growth represents a 2% rise over 2003 spending. *Id.*

211. See Cutler & McClellan, *supra* note 210, at 12 (describing the "treatment expansion effect" as a "major factor in the benefits and failures of technological innovation").

212. See CMS, CED GUIDANCE DOCUMENT, *supra* note 6, at pt. V.B.

213. See CMS, DRAFT GUIDANCE, *supra* note 58, at 4. This Draft Guidance was CMS's *first* public explanation regarding a new coverage category that linked coverage decisions to the collection of additional data. CMS clearly stated that the statutory authority for this type of coverage was the "reasonable and necessary" provision. *Id.* With its July 2006 CED Guidance Document, CMS did a complete about face, announcing that this coverage category would include services that were *not* "reasonable and necessary," but that CMS had the statutory authority to

whether CMS had the statutory authority to limit coverage in this manner did it do an about face and declare that this category of coverage would actually involve services that did *not* meet the “reasonable and necessary” standard for national coverage purposes.<sup>214</sup> The inference is that CMS, under extreme pressure to contain program costs, yet aware that some expensive technology holds promise for beneficiaries, has discovered a means of slowing national availability of new technology through implicit cost-cutting maneuvers. Absent congressional direction, responsibility for controlling costs has been a burden assumed by CMS, but CMS can address cost issues only when setting payment for services, since it does not have the legislative authority to consider cost, or engage in cost-effectiveness analysis, when making coverage decisions.<sup>215</sup>

In light of stakeholder opposition, the lack of statutory support, and the political unpopularity of cost-cutting that might be construed as health care rationing, CMS has resorted to implicit cost control, most recently through its Coverage with Study Participation policy. The reality, however, is that broad national coverage of items or services designated for CSP may be delayed for a significant time, first in the technology assessment process, and later in CSP. Even after a service is designated for CSP, delay may be indefinite because at this point many details of the policy remain unclear, such as who will pay for the costs of structuring the trials. After trials have “qualified” for CSP via a process that has yet to be defined, items or services could be delayed for years, during which time Medicare beneficiaries outside of trials will be denied services that their physicians deem beneficial.<sup>216</sup> Add to this undesirable state of affairs the proposition that CMS may not have the statutory authority to restrict new technology as it proposes in CSP, coupled with the likelihood that CSP violates the federal regulations for the protection of human subjects, and it becomes clear

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cover the services in clinical trials pursuant to its authority to conduct quality control research. *See* CMS, CED GUIDANCE DOCUMENT, *supra* note 6. CMS’s original plan to link coverage with additional data collection was to apply to services that met the statutory reasonable and necessary standard, but CMS simply wanted more and better evidence before granting national coverage. Only when CMS had doubts about its statutory authority to do so did it change its position and state that services designated for trials were not reasonable and necessary. This supports the position that services designated for CSP would more likely merit a decision of coverage rather than non-coverage, and CSP is in reality a means of cutting costs by projecting into an indefinite future the point at which a national decision is made.

214. CMS, CED GUIDANCE DOCUMENT, *supra* note 6, at pt. V.B (stating that “CSP will allow coverage of certain items or services for which the evidence is not adequate to support coverage under” the reasonable and necessary provision).

215. *See* discussion *supra* Part II.

216. Although CMS has indicated that the end-point for CED research studies is predetermined in the study protocol, this does not address the fact that it may take years before a statistically significant number of Medicare beneficiaries are enrolled, given that many elderly and disabled persons may meet exclusion criteria. *See* CMS, CED GUIDANCE DOCUMENT, *supra* note 6, at pt. VIII.A (2006) (stating that the end to data collection in research studies is predetermined in the study protocol).

that CSP is not the best means of achieving CMS's goals.

To the extent that data obtained from clinical trials provides the most meaningful evidence of outcomes, one obvious solution would be to encourage more Medicare beneficiaries to participate in clinical trials on a truly voluntary basis, without linking coverage of the item or service to the trial. Although it may appear that trial enrollment incentive is lacking where the service is available outside of the trial, one recent study indicates that elderly people may be more willing than previously believed to consider participation in a clinical trial.<sup>217</sup> The study indicates that elderly patients do not actively seek clinical trials, and that they are often not informed about such trials by their physicians. Given the opportunity, however, three-quarters of the cancer patient respondents in the study indicated that they would participate in a trial to prevent or screen for cancer, just over half would enroll in a trial comparing a new drug to a standard drug, and 70% would agree to test a new drug where no standard drug was available.<sup>218</sup> Keep in mind, this research concerned the inclination of elderly cancer patients to enroll in clinical trials of cancer drugs that were not yet FDA-approved. Interventions that CMS would designate for Coverage with Study Participation, however, would be those that have already been FDA-approved and that the physician has indicated are medically necessary for the patient. Under these circumstances, the rate of voluntary participation in clinical trials should be significantly higher. With this recommendation, however, coverage of the intervention would not be linked to a clinical trial, but would be available outside of the trial context for those who require it. This would include those persons identified earlier, for whom participation in a trial is not possible due to medical conditions, transportation or logistic impediments, lack of necessary social support, or simple disinclination.<sup>219</sup>

CMS could also achieve its goal of generating additional data by enhancing its traditional relationship with the AHRQ. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 specifically directs the Secretary of Health and Human Services to use the AHRQ to conduct and support outcomes, effectiveness, and appropriateness research to improve the quality of health care for Medicare beneficiaries.<sup>220</sup> AHRQ is the lead federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care for all Americans. Its mission is to improve the quality, appropriateness, and

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217. Carol A. Townsley et al., *Understanding the Attitudes of the Elderly Towards Enrolment into Cancer Clinical Trials*, 6 BMC CANCER 34 (2006), available at <http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1382233&blobtype=pdf>.

218. *Id.*

219. See discussion *supra* Section III.B.

220. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 § 1013, 117 Stat. 2066, 2438 (to be codified at 42 U.S.C. § 1395y).

effectiveness of health services.<sup>221</sup> To that end, AHRQ conducts research regarding all aspects of health care, including research on the cost-effectiveness of health care practices, and the costs of health care.<sup>222</sup> Since 1997, AHRQ has conducted research to promote evidence-based practice through its twelve Evidence-based Practice Centers located throughout the United States and Canada.<sup>223</sup> CMS can use the services of AHRQ, as it has been doing for many years, to serve the needs of the Medicare program without restricting present coverage to Medicare beneficiaries in clinical trials.

Another organization that is ideally situated to address CMS concerns is the Centers for Education and Research on Therapeutics (CERTs) program, which is administered in cooperation with AHRQ, and in consultation with the Food and Drug Administration.<sup>224</sup> CERTs is a research and educational program aimed at improving quality in the use of therapeutics, a category that includes drugs, medical devices, and biological products.

Coverage with Appropriateness Determination (CAD) presents perhaps the best opportunity for CMS to obtain the additional data it desires, without restricting coverage to clinical trials.<sup>225</sup> CAD, as explained earlier,<sup>226</sup> is the first arm of CMS's Coverage With Evidence Development (CED) policy. CAD is designed to allow for payment of items or services that meet the statutory "reasonable and necessary" standard, but for which CMS would like to obtain additional clinical data.<sup>227</sup> Essentially, services designated for CAD would be

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221. See 42 U.S.C. § 299(b) (2000) ("The purpose of the Agency is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health system practices, including the prevention of diseases and other health conditions.").

222. See *id.*; *id.* § 299(b)(1)(B)-(D) (2000) (stating that the AHRQ shall promote health care quality improvement by conducting and supporting . . . research that develops and presents scientific evidence regarding all aspects of health care, including . . . (B) the outcomes, effectiveness, and cost-effectiveness of health care practices . . . (D) the costs and utilization of, and access to health care.").

223. See Agency for Healthcare Research & Quality, Evidence-based Practice Centers, <http://www.ahrq.gov/clinic/epc/> (last visited May 3, 2007) (stating that the EPCs conduct a "rigorous, comprehensive syntheses and analyses of the scientific literature" and produce reports for use by CMS, as well as other governmental and private entities that make health care organization and delivery decisions).

224. See AGENCY FOR HEALTHCARE RESEARCH & QUALITY, CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS: OVERVIEW (2007), available at <http://www.ahrq.gov/clinic/certsovr.htm>. CERTs has eleven research centers and a coordinating center, and CERT programs represent collaborations with other public and private organizations concerned about health care quality and safety. *Id.*

225. CMS, CED GUIDANCE DOCUMENT, *supra* note 6, at pt V.A.

226. See *id.*

227. *Id.* CMS deems items or services designated for CAD to be "reasonable and necessary," but that "additional clinical data is needed that is not routinely available on claims forms to ensure that the item or service is being provided to appropriate patients in the manner described in the NCD." *Id.*



covered so long as physicians submit additional clinical data with the claims forms used for reimbursement of the service.<sup>228</sup> Such data is to be put into a database or registry for research purposes.<sup>229</sup> Since data collection would place an additional burden on providers, CMS should consider payment to providers to secure their participation in CAD, and to assure that physicians would not hesitate to recommend CAD for their patients where appropriate. Surely any additional cost to CMS would be significantly less than what would be required in CSP, which involves clinical trials.

The solution to controlling Medicare program costs is not simple. A way for our nation to keep its promise to provide high quality health care to its elderly and disabled citizens, but at the same time protect the Medicare trust is far from obvious. Should the present rate of growth continue, Medicare Part A will be depleted by the year 2018.<sup>230</sup> And, even though Part B is funded out of the general tax, a large portion of our taxes already go toward financing a system that will become increasingly difficult to maintain as baby boomers reduce their incomes and retire from the workforce in greater numbers.<sup>231</sup>

Realistically, no one believes that Medicare can continue indefinitely to pay for all promising medical technology, no matter how high the cost. The alternative, of course, is that either cost-sharing must be increased or benefits for very expensive technology must be rationed. Some commentators would like clear authority to include cost-effectiveness analysis in coverage determinations,<sup>232</sup> even though using economic analysis in medical decision-

228. *Id.* ("The extra data supplements the information gathered routinely through claims for services rendered and is collected by providers when the service is provided."). CMS has long understood the value of using administrative or claims data in health care research. Claims data is obtained from the process of billing insurance carriers for medical care, and it allows researchers to analyze patient histories and accumulated claims for services, including diagnoses and procedures, over time. See Medical Technology & Practice Patterns Inst., *An Opportunity To Improve Quality of Care in the Medicare Program Using Enhanced Administrative Data* (2004), [http://www.mtppi.org/physio\\_symp\\_comments.asp](http://www.mtppi.org/physio_symp_comments.asp).

229. CMS, CED GUIDANCE DOCUMENT, *supra* note 6, at pt V.A ("[P]roviders will submit extra data to databases or registries specifically designed for collecting data specified in the NCD in question.").

230. BDS. OF TRS., FED. HOSP. INS. & FED. SUPPLEMENTARY MED. INS. TRUST FUNDS, 2006 ANNUAL REPORT OF THE BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS, ANNUAL REPORT 4 (2006), available at <http://www.cms.hhs.gov/ReportsTrustFunds/downloads/tr2006.pdf> (reporting that Part A Hospital Insurance fund assets are projected to be exhausted in 2018).

231. See *id.* (reporting that Part B financing, although adequately financed at present, would have to increase rapidly to meet expected future needs, and to keep assets at an appropriate level).

232. See Sean R. Tunis, *Economic Analysis in Healthcare Decisions*, 10 AM. J. MANAGED CARE 301, 304 (2004) ("A decision-making framework that explicitly includes economic analysis would enable us to adopt explicit and consistent reimbursement guidelines that link healthcare benefits to the amount paid."); see also Fox, *supra* note 81, at 632 (2005) (calling for congressional action to

making as it relates to individual patients is problematic.<sup>233</sup> Yet, it is incumbent upon Congress, after robust public debate, to address the issues of cost and cost-effectiveness, and not for CMS to implicitly ration care by restricting coverage of certain expensive technology to clinical trials, as it is doing with CSP. Rationing may well be unavoidable if we are to preserve Medicare, but Congress, not CMS, bears responsibility for bringing the issues to the forefront for public debate. Congress, and not CMS, must face the hard question of how to pay for our future.

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guide Medicare as to “how Congress expects it to grapple with extremely expensive, medically effective technology,” including the role of cost-effectiveness as well as the absolute costs of new technology in its coverage process); Alan M. Garber, *Cost-Effectiveness and Evidence Evaluation As Criteria for Coverage Policy*, HEALTH AFF., W4-284 (May 19, 2004), <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.284v1>. One expert notes that cost-effective analysis is actually a significant influence on health care policy, but in a manner characterized as “cost effectiveness once removed.” Peter J. Neumann, *Why Don't Americans Use Cost-Effectiveness Analysis?*, 10 AM. J. MANAGED CARE 308, 311 (2003) (stating that cost-effectiveness analysis is used “only at a safe distance,” and that “rationing is permitted under the radar”).

233. Tunis, *supra* note 232, at 304. Dr. Tunis explains that when applied to an individual patient, such as someone's child or other loved one, cost-effectiveness analysis is problematic because the underlying logic of a decision based on medical necessity is that the benefits for the patient will outweigh the risks, but the underlying logic of cost-effectiveness analysis is that a patient may be denied a potentially beneficial intervention because the procedure is simply too expensive. Certainly several high-cost medical procedures that today are covered by Medicare would likely not have been covered were CMS to weigh cost-effectiveness analysis in its coverage criteria. See Gillick, *supra* note 117, at 2199. In her article, Dr. Gillick looks at the actual cost of three procedures that were ultimately covered by Medicare—lung-volume-reduction surgery, implantable cardioverter-defibrillators, and left ventricular assist devices. She then applied standard cost-effectiveness analysis to each of the three procedures, concluding that under this analysis, CMS would not have approved coverage of either lung-volume-reduction surgery or implantation of the left-ventricular assist device. *Id.* at 2202.

# Bioethics, Philosophy, and Global Health

**Maria Merritt\***

## INTRODUCTION

This Article addresses the present state and future prospects of the field of bioethics. The subject is open to more than one attitude of address. Possibilities include preoccupation with the professional status of bioethics, critical scrutiny of its research programs and methodologies, and anxiety about whether some areas of bioethics have become intertwined with—and perhaps co-opted by—extra-professional, extra-academic agendas, such as those that drive profit-making enterprises (pharmaceuticals, biotechnology, HMOs) or partisan politics (debates over abortion, stem cell research, withdrawing artificial nutrition and hydration from patients like Terri Schiavo). These attitudes, whatever their merits, are all somewhat self-focused. Without denying the importance of the problems they target or the necessity of continual self-critical reflection among the practitioners and friends of bioethics, this Article assumes a more straightforward, outward-looking stance.

This stance is meant to complement the inward-looking attitudes and to affirm the values that motivate them. Those of us who work in bioethics can demonstrate the professional and academic value of our field only through the substance of the contributions we make in its name. With respect to worries about inappropriate involvement with corporate or partisan agendas, the issue is protecting the intellectual integrity we need in order to make headway on problems whose solutions cannot be left to the rough-and-tumble of the market and the political arena. We ought to set our own research agenda, rather than acquiesce in its distortion by external interests, political pressures, and popular sensations du jour.<sup>1</sup>

Hence the straightforward question: What belongs on our agenda? One item

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1. Distortion by external factors is a danger to which bioethics is exposed by its interdisciplinary orientation, which may tend to loosen the ties that anchor scholars to their home disciplines. Thanks to Dennis F. Thompson for this observation.

that certainly belongs on it is global health. This Article surveys a constellation of global health problems that exert increasing influence in bioethics today and indicate promising directions for future research.

“Global health” is an expression used to talk about issues in health policy that reach beyond or across national boundaries. The authors of a recent article in the *American Journal of Public Health* characterize its meaning partly by contrasting it with another expression used for similar purposes—“international health”:

“International health” was already a term of considerable currency in the late 19th and early 20th century, when it referred primarily to a focus on the control of epidemics across the boundaries between nations. . . . “Global health,” in general, implies consideration of the health needs of the people of the whole planet above the concerns of particular nations.<sup>2</sup>

A distinct interest in “global health” is on the rise, as measured by the frequency of its mention in the scholarly literature and its visibility in the names of academic, government, and philanthropic organizations concerned with transnational matters of public health.<sup>3</sup>

From the viewpoint of ordinary morality, the notion of global health captures several interconnected themes. First, it seems obviously wrong that poor people across the world, many of them infants and small children, should suffer the ravages of illness and death from conditions (like pneumonia, diarrhea, malaria, tuberculosis, AIDS, and even childbirth) that can be treated, prevented, or managed by methods readily available to most people in rich countries. Two further themes bring in causal interconnections related to the globalization of trade, labor, finance, transportation, communication, culture, and climate change. We all participate in the institutional systems that perpetuate or could alleviate the conditions of poverty that prove so lethal to the most vulnerable populations. Finally, we are also all embedded in—and ourselves potentially vulnerable to—the biological, social, and environmental systems through which globalization affects health, as already threatened by infectious diseases like SARS, West Nile virus, avian flu, and drug-resistant forms of tuberculosis.<sup>4</sup>

Academic bioethics is beginning to pick up these same themes, generally with greater emphasis on the first two.<sup>5</sup> In so doing, bioethics follows a pattern of

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2. Theodore M. Brown et al., *The World Health Organization and the Transition from International to Global Public Health*, 96 AM. J. PUB. HEALTH 62, 62 (2006); see also Kelley Lee & Derek Yach, *Globalization and Health*, in INTERNATIONAL PUBLIC HEALTH: DISEASES, PROGRAMS, SYSTEMS, AND POLICIES 681 (Michael H. Merson et al. eds., 2d ed. 2006) [hereinafter INTERNATIONAL PUBLIC HEALTH].

3. Brown et al., *supra* note 2, at 62; see also Susan Okie, *Global Health – The Gates-Buffett Effect*, 355 NEW ENG. J. MED. 1084 (2006).

4. Lee & Yach, *supra* note 2, at 687-89.

5. See, e.g., Gopal Sreenivasan & Solomon Benatar, *Challenges for Global Health in the 21st*

concern established by moral and political philosophy in the latter part of the twentieth century. The harms suffered by the world's very poor, together with the causal involvement of the affluent in the global systems that perpetuate these harms, invite continuing examination of a central question in moral philosophy: Who owes what to whom?<sup>6</sup> In political philosophy, a form of the same question re-emerges at the institutional level: What do affluent states, acting both on their own and through international agencies, owe to the poor in other countries? This question of global distributive justice defines one of the most active areas of current political philosophy.<sup>7</sup> At the same time, philosophers are participating in the formation of global health policy with increasing frequency.<sup>8</sup>

Responding to problems of public health that occur in both domestic and international contexts, some bioethicists have begun to urge a shift in perspective to "population-level bioethics."<sup>9</sup> "Where clinical bioethics speaks of the rights and responsibilities of patients and doctors, bioethics at the population level assesses the obligations of societies toward their members and each other and the norms governing complex relationships of individuals, groups, and the state."<sup>10</sup> Yet, even from the viewpoint of this shift in perspective, individuals do not drop

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*Century: Some Upstream Considerations*, 27 THEORETICAL MED. & BIOETHICS 3 (2006); Alex John London, *What is Social and Global Justice to Bioethics or Bioethics to Social and Global Justice?*, HASTINGS CENTER REP., July-Aug. 2006, at 3.

6. See, e.g., SAMUEL SCHEFFLER, *BOUNDARIES AND ALLEGIANCES: PROBLEMS OF JUSTICE AND RESPONSIBILITY IN LIBERAL THOUGHT* (2002); PETER UNGER, *LIVING HIGH AND LETTING DIE: OUR ILLUSION OF INNOCENCE* (1996); Peter Singer, *Famine, Affluence, and Morality*, 1 PHIL. & PUB. AFF. 229 (1972).

7. See, e.g., Joshua Cohen & Charles Sabel, *Extra Republicanam Nulla Justitia?*, 34 PHIL. & PUB. AFF. 147 (2006); Thomas Nagel, *The Problem of Global Justice*, 33 PHIL. & PUB. AFF. 113 (2005).

8. See, e.g., HEALTH, WELL-BEING, JUSTICE: ETHICAL ISSUES IN HEALTH RESOURCE ALLOCATION (Christopher J.L. Murray & Daniel Wikler eds., forthcoming 2007); Dan W. Brock, *The Separability of Health and Well-Being*, in SUMMARY MEASURES OF POPULATION HEALTH: CONCEPTS, ETHICS, MEASUREMENT AND APPLICATIONS 115 (Christopher J.L. Murray et al. eds., 2002) [hereinafter SUMMARY MEASURES]; John Broome, *Measuring the Burden of Disease by Aggregating Well-Being*, in SUMMARY MEASURES, *supra*, at 9; Norman Daniels, *Fair Process in Patient Selection for Antiretroviral Treatment in WHO's Goal of 3 by 5*, 366 LANCET 169 (2005); Frances P. Kamm, *Health and Equity*, in SUMMARY MEASURES, *supra*, at 685.

9. See Norman Daniels, *Equity and Population Health: Toward a Broader Bioethics Agenda*, HASTINGS CENTER REP., July-Aug. 2006, at 22-23 (arguing that bioethics has myopically focused on special doctor-patient or researcher-subject relationships, and sensational questions about new technologies, at the expense of "examining the broader institutional settings and policies that mediate population health"); Daniel Wikler & Dan W. Brock, *Population-Level Bioethics: Mapping a New Agenda* (unpublished manuscript, on file with author) (arguing that the population-level perspective reveals ethical problems that extend beyond health care to other determinants of health, beyond the domestic U.S. setting to the least-healthy populations worldwide, and beyond the present to the health of future generations); see also PUBLIC HEALTH, ETHICS, AND EQUITY (Sudhir Anand et al. eds., 2004) (presenting the works of scholars in philosophy, anthropology, economics, and public health to analyze ethical problems related to health inequalities among and within populations).

10. Wikler & Brock, *supra* note 9, at 1.

out of the picture altogether as subjects of moral inquiry. Rather, inquiry about what is owed *to* individuals must stem in part from their circumstances as members of populations. Likewise, inquiry about what is owed *by* individuals must stem in part from their circumstances as contributors to institutional actions. This Article focuses on the latter branch of inquiry and discusses recent and emerging scholarship that highlights the moral obligations of affluent individuals to the global poor, in two types of institutional roles. Part I develops the idea of a human right to health and considers how the duties imposed by such a right could possibly be distributed among affluent individuals in their causal role as participants in global institutional systems. Part II addresses the obligations of medical professionals, as affected by their institutional roles in two types of organizations that attempt to help the global poor: humanitarian aid organizations and not-for-profit scientific research organizations.

The unifying theme of this Article has to do with the spirit in which it makes sense to consider our obligations to the global poor. Determining the nature and extent of our obligations is an intellectual challenge worthy of the best minds in moral philosophy, but it is at most only a first step toward meeting the practical challenges of global health. Even if moral theory shows why the human rights of the very poor require the affluent to help alleviate the global health crisis, the truly hard problems begin with working out how to do so. How can proven preventive and therapeutic health interventions be delivered with all due haste to those vulnerable people who need them most urgently? How can failed health systems be transformed into functional ones that protect people from ever becoming so vulnerable in the first place? These problems occupy some of the most distinguished scholars in every discipline of public health, not to mention the world's most talented entrepreneurs and financiers. But, this Article concludes, no amount of intellectual firepower can bring about socially enduring solutions except through systematic efforts to include, consult, and empower the people who actually experience the problems.

### I. A HUMAN RIGHT TO HEALTH?

The idea of a human right to health expresses noble aspirations to promote and protect health for all persons. Critics of such a right argue that no matter how praiseworthy those aspirations may be, the attempt to act on them by insisting on a human right to health is either misconceived or, even if well-conceived in principle, incapable of delivering specific policy guidance beyond a minimal starting point of simply acknowledging the right in question. Recent philosophical advances bring fresh conceptual resources to this debate.

At the outset, we must distinguish between legal and moral conceptions of human rights. Under the legal conception of human rights, the specification of the content of such rights, the identification of those who hold them, and the identification of those who bear obligations to protect or fulfill them are determined by the actions of government entities empowered to make, enforce,

and interpret the law. Under the moral conception of human rights, the content of such rights is to be specified, and right-holders and duty-bearers are to be identified, through analysis of moral considerations, regardless of whether any government entities do in fact recognize them. This Article adopts the moral conception of human rights. It presupposes, but does not argue for, a plausible view of the relationship between the moral conception and the legal conception. In light of the seriousness of the relevant moral considerations, together with the minimal conditions for the moral legitimacy of government entities, the vindication of any human right by moral considerations constitutes a strong moral reason for government entities to recognize such a right by force of law.<sup>11</sup>

The standard idea of a human right to health, understood as a moral right, can be clarified by attending to its three component concepts: *right*, *human*, and *health*. At the core of the idea of a human right to health is the concept of a *right*. Moral philosophy contains longstanding controversies about how best to understand the function and justification of rights.<sup>12</sup> Nonetheless, there is widespread agreement on the logical structure of rights.<sup>13</sup> This provides a few anchor points for discussing the human right to health. First, if there is a human right to health, it is what rights theorists call a *claim right*. Any assignment of a claim right to one party logically entails the assignment of correlative duties to at least one other party. That is,

*A has a claim that B φ if and only if B has a duty to A to φ.*<sup>14</sup>

Thus, if I have a right to health, then at least one other party must have at least a duty not to actively harm my health, and possibly also duties to promote and protect my health. This is an instance of the second anchor point, which is that duties correlative to claim rights may be either negative or positive. In other words, “φ” in the formulation above may symbolize either refraining from some

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11. See generally THOMAS W. POGGE, *WORLD POVERTY AND HUMAN RIGHTS: COSMOPOLITAN RESPONSIBILITIES AND REFORMS* 52-70 (2002) (introducing the distinction between moral and legal conceptions of human rights and explicating the moral conception).

12. See generally Leif Wenar, *Rights*, in *STANFORD ENCYCLOPEDIA OF PHILOSOPHY* (2005), available at <http://plato.stanford.edu/entries/rights/> (outlining the main rival schools of thought on these questions). As Wenar explains, the function of rights is a matter of what they do for the right-holder; justification involves determining what rights there are and why we ought to respect them. *Id.* § 2.

13. *Id.* § 2.

14. *Id.* § 2.1.2 (summarizing the widely endorsed analytical framework developed in WESLEY NEWCOMB HOHFELD, *FUNDAMENTAL LEGAL CONCEPTIONS AS APPLIED IN JUDICIAL REASONING* (Walter Wheeler Cook ed., Yale Univ. Press 1919). Although Hohfeld, a legal theorist, developed this framework for use in thinking about legal rights and duties, it is readily transferable to moral rights and duties. See also Brenda Almond, *Rights*, in *A COMPANION TO ETHICS* 259, 262-63 (Peter Singer ed., 1991); Onora O'Neill, *The Dark Side of Human Rights*, 81 INT'L AFF. 427, 430-431 (2005) (applying the Hohfeldian logical point about the correlation between claim rights and duties to the discussion of human rights); George W. Rainbolt, *Rights Theory*, 1 PHIL. COMPASS 11, 11-13 (2006), available at <http://www.blackwell-synergy.com/doi/abs/10.1111/j.17479991.2006.00003.x>.

action (in the case of a negative duty) or performing some action (in the case of a positive duty).<sup>15</sup> Negative duties correlative to a right to health would include duties not to inflict sickness on people.<sup>16</sup> An example is the duty not to supply a population with drinking water known to contain bacteria that cause cholera.<sup>17</sup> Correlative positive duties would include the provision of health care and of other social goods, such as literacy, that significantly improve health outcomes.

Third, the bearers of duties correlative to rights may be either individual persons or other kinds of agents. With respect to the idea of a right to health, a standard assumption is that, for each right-holder, the bearer of the correlative duties is the government of the state where the individual resides. In cases of impoverished, ineffective, or failed states, perhaps the governments of other, better-functioning states should be the bearers through efforts coordinated by international agencies like the World Health Organization (WHO).<sup>18</sup>

There are two aspects of the moral duties that would be correlative to a right to health: an individual aspect and a population aspect. First, each individual's right to health would entail correlative duties to avert harms and provide services insofar as they have a causal impact on that individual. For example, a right to health would impose a correlative duty to provide timely treatment of an infection from which an individual is suffering. Second, assuming every individual member of a population has a right to health, this collective state of affairs further entails correlative duties to avert harms and provide services insofar as they make an impact on the health of the population. If increasing the rate of female literacy will significantly improve health outcomes and the equity of their distribution across the population, then the duty to promote female

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15. Wenar, *supra* note 12, § 2.1.2. *But see* NORMAN DANIELS, JUST HEALTH CARE 6 (1985) (noting that those who advocate a right to health typically regard it as entailing both positive and negative duties: "Someone who claims a right to health . . . should be understood to be claiming that certain individuals or groups (or society as a whole) are obliged to perform certain actions which promote or maintain his good health and are obliged to refrain from actions which interfere with it.").

16. Another way to think about the negative duties correlated with claim rights is to use Hohfeld's coinage "no-right," the opposite of a right. One might say that if I have a right to health, other parties have a no-right to actively harm my health. HOHFELD, *supra* note 14, at 65. *See also* Wesley Newcomb Hohfeld, *Some Fundamental Legal Conceptions as Applied in Judicial Reasoning*, 23 YALE L.J. 16, 30-33 (1913). Thanks to Natalie Ram for helpful comments on Hohfeld.

17. Cholera is an acute intestinal infection producing severe diarrhea and often vomiting. Without treatment, victims become dehydrated so rapidly that they may die within hours of the onset of symptoms. Cholera bacteria spread mainly through drinking water contaminated with human feces, as a result of poor sanitation and lack of access to clean water. WORLD HEALTH ORG., CHOLERA, FACT SHEET NO. 107 (2000), <http://www.who.int/mediacentre/factsheets/fs107/en>; *see also* Sharon LaFraniere, *In Oil-Rich Angola, Cholera Preys upon Poorest*, N.Y. TIMES, June 16, 2006, at A1; Steven Shapin, *Sick City*, NEW YORKER, Nov. 6, 2006, at 110.

18. GEORGE J. ANNAS, AMERICAN BIOETHICS: CROSSING HUMAN RIGHTS AND HEALTH LAW BOUNDARIES 21 (2005); Jonathan M. Mann et al., *Health and Human Rights*, in HEALTH AND HUMAN RIGHTS: A READER 7, 8-10 (Jonathan M. Mann et al. eds., 1999).



literacy is a duty both to the individual girls and women who could benefit directly from it and to all members of the population to which they belong, male or female.

A problem in public health ethics is that it may sometimes be necessary to make trade-offs between duties owed to individuals directly and duties owed to individuals *qua* members of the population. For example, in deciding how to ration vaccines in the event of an influenza pandemic, one might develop a rationing scheme based on asking which individuals have priority in their claim to the vaccine, a question that is itself a difficult one to answer (the most vulnerable individuals? the individuals most likely to survive? the individuals likely to reap the greatest benefits from the investment they have already made in their lives?).<sup>19</sup> But any such prior-claim scheme could be in tension with the overarching objective of minimizing transmission throughout the population (also operating for the ultimate benefit of its individual members), which would dictate that those individuals most likely to transmit the virus to others should get the vaccine first (regardless of whether they would otherwise have any prior claim).<sup>20</sup>

Turning to the next component concept, to regard a right as a *human* right is to find that each individual holds that right simply by virtue of being a person—that is, simply because morality requires that all persons be treated in a certain way. The right-holder's moral status as a person suffices as the moral ground of his or her claims against bearers of the correlative duties.<sup>21</sup> For this reason, human rights are universal. The moral status of persons is independent of institutional contingencies like citizenship or residence in one state or another. For instance, an uncontroversial human right is the right not to be enslaved.<sup>22</sup> Even where the government of a state tolerates the practice of slavery, all of its residents nonetheless have the right not to be enslaved, simply by virtue of their moral status as persons. Individual slaveholders violate a duty correlative to this right—the duty not to enslave others; states that tolerate slavery violate a correlative duty to protect all individuals from being enslaved by others. From the standpoint of morality, agents have the duties correlative to human rights and may be culpable for violations, whether or not they have voluntarily assumed

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19. See generally Ezekiel J. Emanuel & Alan Wertheimer, *Who Should Get Influenza Vaccine When Not All Can?*, 312 SCI. 854 (2006) (arguing for a version of the investment scheme).

20. Whether or not there is a human right to health, this kind of trade-off remains a problem for agencies charged with protecting and promoting the public health.

21. Different theories of what morality requires offer differing accounts of the specific ground for the moral status of persons. The main alternatives are: (1) the distinctively rich and complex capacity for well-being and suffering (based on utilitarian moral theory); and (2) the capacity for rational agency (based on Kantian moral theory). See *infra* Subsection I.A.1).

22. Unfortunately, the age-old practice of enslaving others remains alive and well in various parts of the world. Nonetheless, the right not to be enslaved is uncontroversial, in the sense that anyone who agrees that persons as such have moral status should straightforwardly accept the claim that every person thereby has the right not to be enslaved.

these duties. If there is a human right to health, any state or other party bearing the correlative duties with respect to the members of a given population will stand in violation of those duties if it willingly neglects them or adopts policies contrary to their fulfillment.

The universality of human rights means that states' breaches of them cannot be morally excused or made good by claims to political sovereignty. The recognition of any right as a *human* right thus carries grave political consequences, especially to the extent that the correlative duties lie with state governments, because it clears a space for the principled moral justification of external intervention (political or economic, if not military) in the domestic affairs of sovereign states.<sup>23</sup> This is one of the factors that perennially politicizes and polarizes international discussions of which rights are human rights. The question of a human right to health is a case in point.<sup>24</sup>

The last component concept is *health*. Given that a claim right entails correlative duties, and given the political consequences of recognizing any claim right as a human right, the conception of health as the object of a human right is bound to weigh heavily in determining precisely what the correlative duties are and who bears them. Leading proponents of a human right to health have typically drawn on a conception of health that is comparatively ambitious in several respects. The preamble to the WHO Constitution defines "health" comprehensively as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."<sup>25</sup> Even if health is understood so broadly, it may yet come in degrees, and the preamble goes on to declare that "[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being."<sup>26</sup> Furthermore, it is crucial that the object of the declared right is health, not (only) health care. A right to health encompasses far more than a right to health care, because the determinants of health reach far beyond access to care.<sup>27</sup> If there is a human right to health, its correlative duties must be duties to address a variety of socially controllable determinants of health, including levels of income and education.<sup>28</sup>

Critics of the idea of a human right to health address two different types of problems: problems of conception and problems of implementation. This Part

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23. That said, even when moral considerations about human rights count in favor of intervention, there may also be moral reasons to refrain from intervention, and in particular cases the reasons to refrain might outweigh the reasons to intervene. This form of argument is often used by those who oppose military interventions ostensibly undertaken in the name of human rights.

24. ANNAS, *supra* note 18.

25. WORLD HEALTH ORG. CONST. pmb., available at [http://www.who.int/governance/eb/who\\_constitution\\_en.pdf](http://www.who.int/governance/eb/who_constitution_en.pdf).

26. *Id.*

27. "Only a small fraction of the variance of health status among populations can reasonably be attributed to health care; health care is necessary but clearly not sufficient for health." Mann et al., *supra* note 18, at 8.

28. Daniels, *supra* note 9, at 24-25.

discusses each type in turn, together with some representative current efforts to respond on behalf of the moral aspirations that typically motivate the assertion of a human right to health.

### *A. Problems of Conception*

Onora O'Neill presents a critique of declarations of a human right to health, taking the WHO's declaration as a representative target.<sup>29</sup> Noting that a claim right entails correlative duties, she presses the point that the right itself cannot be defined unless its correlative duties are allocated to identifiable parties: "[W]here anyone is to have a right there must be identifiable others (either all others or specified others) with accurately corresponding obligations."<sup>30</sup> She accuses the "international human rights culture" of being "often muddled or vague, or both" about this duty-allocation problem.<sup>31</sup>

O'Neill observes that explicit attempts to allocate the duties correlative to human rights, as in the International Covenant on Economic, Social, and Cultural Rights (ICESCR) of 1966, have assigned them to states that are signatories to relevant Covenants.<sup>32</sup> But, as O'Neill points out, this approach to the allocation problem fails to capture the universality of *human* rights, in two ways.<sup>33</sup> First, it confines the allocation of duties to states that voluntarily assume them, contrary to the foundational understanding of human rights as claimable by all persons solely by virtue of their moral status. Human rights are supposed to be rights whose correlative duties fall to duty-bearers independently of voluntary transactions like signing a covenant. Second, the allocation of duties only to signatory states implies that the correlative rights themselves likewise derive from institutions, such as international covenants: If there were no covenant, the duties and the rights alike would be unjustifiable. In contrast, the justifiability of human rights is supposed to be pre-institutional.

A promising answer to this line of criticism proceeds in two steps. The first step is to identify precisely what is so morally troubling about how things stand in global health, such that for anyone who is paying serious attention, it can make intuitive sense to seek the global fulfillment of a human right to health. To what state of affairs are the most vigorous practical advocates of such a right responding, as they dedicate their work in medicine and public health to the Herculean task of securing a right to health worldwide? The second step is to re-examine how the conceptual resources of moral philosophy might support a

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29. O'Neill, *supra* note 14, at 429.

30. *Id.* at 431.

31. *Id.* at 428.

32. *Id.* at 431. O'Neill notes that it is this Covenant from which the WHO Constitution derives its commitment to the "highest attainable standard of physical and mental health." *Id.* at 429; see also International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), Art. 12, U.N. Doc. A/6316 (Dec. 16, 1966), available at <http://ohchr.org/english/law/pdf/cesr.pdf>.

33. O'Neill, *supra* note 14, at 431-32.

principled response to this state of affairs that is both sensitive to what is at stake and capable of resolving conceptual worries like those articulated by O'Neill.

Thomas Pogge has summed up the answer to the first question with eloquent rhetorical restraint. The catastrophic facts and figures speak for themselves.

Some eighteen million human beings die prematurely each year from medical conditions we can cure—this is equivalent to fifty thousand avoidable deaths per day, or one-third of all human deaths. Hundreds of millions more suffer grievously from these conditions. The lives of additional hundreds of millions are shattered by severe illnesses or premature deaths in their family. . . . This huge incidence of mortality and morbidity is not randomly distributed. For a variety of social reasons, females are significantly overrepresented among those suffering severe ill health. . . . Being especially vulnerable and helpless, children under the age of five are also overrepresented, accounting for about two-thirds of the death toll. . . . But the most significant causal determinant is poverty: Nearly all the avoidable mortality and morbidity occurs in the poor countries . . . particularly among their poorer inhabitants.<sup>34</sup>

How might the awareness of this state of affairs motivate the intuition that there is a human right to health? We know that ill health is the proximate cause of avoidable death for some eighteen million people per year, about ten million of whom are under five years of age.<sup>35</sup> This is what makes it seem sensible to focus on *health* as the content of the deficit that would, in a better world, be made good. But why does it seem sensible to make health the object of a *claim right*, which requires the allocation of correlative duties, and moreover to conceive of that claim right as a *human* right, which gives rise to the problems of universality exposed by O'Neill?

If we have reason to believe that the medical conditions in question are treatable and preventable at a reasonably low cost, the next intuitive step is to look for some agent or group of agents who can do something about it. A further thought is that if there is somebody who can do something about it, especially at comparatively little cost to themselves, then they ought to do something about it.<sup>36</sup> But this line of reasoning runs into an elementary problem of moral

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34. Thomas Pogge, *Human Rights and Global Health: A Research Program*, 36 METAPHILOSOPHY 182, 182-83 (2005). Pogge's text provides sources for the data cited and lists the specific medical conditions causing preventable mortality (for example, pneumonia and other respiratory infections, HIV/AIDS, perinatal conditions, diarrhea, tuberculosis, malaria, measles, maternal conditions, malnutrition, sexually transmitted diseases, meningitis, and hepatitis) and morbidity (for example, all of the above, plus dengue fever, leprosy, sleeping sickness, river blindness, leishmaniasis, lymphatic filariasis, and schistosomiasis).

35. Robert E. Black et al., *Where and Why Are 10 Million Children Dying Every Year?*, 361 LANCET 2226 (2003).

36. See Jennifer Bryce et al., *Can the World Afford To Save the Lives of 6 Million Children Each Year?*, 365 LANCET 2193 (2005); Gareth Jones et al., *How Many Child Deaths Can We Prevent This Year?*, 362 LANCET 65 (2003).

philosophy: Under what conditions do we owe a duty of assistance to others, as contrasted with the duty not to harm them?

This problem is one of a broad class of problems collected under various labels: action versus omission; killing versus letting die; doing harm versus allowing harm.<sup>37</sup> The contested issue about duty is whether to mark a morally important distinction between different types of causal role that an agent's behavior might play in the occurrence of bad consequences. Some conceptions of morality focus only on the badness of the consequences, so that what matters is simply whether an agent might have produced different consequences by behaving differently.<sup>38</sup> On this view, non-helping by omission can be as serious a wrong as active harming, provided the consequences in each case are the same.<sup>39</sup> Other conceptions of morality insist on a morally important distinction between different kinds of contribution that an agent might make to the occurrence of a harm. In one representative version, we look for the agent's "most direct contribution" to the harm and ask whether that contribution is an action or an omission (for example, "pushing the head under water or refraining from throwing a life preserver").<sup>40</sup>

A quarter-century ago, philosopher Philippa Foot expressed her version of the latter view as follows:

Most of us allow people to die of starvation in India and Africa, and there is surely something wrong with us that we do it; it would be nonsense, however, to pretend that it is only in law that we make the distinction between allowing people in the underdeveloped countries to die of starvation and sending them poisoned food. There is worked into our moral system a distinction between what we owe people in the form of aid and what we owe them in the way of non-interference.<sup>41</sup>

Let us bracket the question of whether affluent individuals only "allow" the harms suffered by the global poor or whether we are culpably implicated in active harming, not by any action so overtly hostile as sending poisoned food, but rather by other actions of routinely accepting, participating in, and benefiting from the institutions that regulate global trade, labor, finance, and other features in the background of severe chronic poverty.<sup>42</sup> Suppose it is only a matter of

37. For a helpful overview, see Frances Howard-Snyder, *Doing vs. Allowing Harm*, in STANFORD ENCYCLOPEDIA OF PHILOSOPHY (2002).

38. See, e.g., Singer, *supra* note 6, at 231 (providing a famous example).

39. *Id.* at 235.

40. Howard-Snyder, *supra* note 37 (discussing Warren Quinn, *Actions, Intentions, and Consequences: The Doctrine of Doing and Allowing*, 98 PHIL. REV. 287 (1989)).

41. PHILIPPA FOOT, VIRTUES AND VICES 26-27 (1981). For selecting this quotation and locating it in the context of the present discussion, credit is due to Kasper Lippert-Rasmussen, 3 J. MORAL PHIL. 97, 97 (2006) (reviewing POGGE, *supra* note 11).

42. Making the case for the claim that we actively harm the global poor is the aim of Pogge. POGGE, *supra* note 11. For an excellent debate on this issue, see Mathias Risse, *Do We Owe the*

allowing the global poor to suffer harm. (Figuratively, suppose that what we are doing is more like refraining from throwing life buoys, and less like pushing people's heads under water.) Are we thereby neglecting a duty to give assistance? More to the point, even if we have a duty to give assistance, is it the kind of duty that we have because it correlates with the human rights of others? (If so, "our" moral system should be revised to acknowledge it.) Finally, even if the answer to both these questions is yes, how is it possible to allocate to several billion affluent individuals the duties that correlate with the claim rights of one to two billion impoverished individuals?<sup>43</sup>

Here is where recent philosophical advances in thinking about human rights can offer at least a partial solution. Elizabeth Ashford, a philosopher, has recently proposed a novel conception of the human right to basic necessities.<sup>44</sup> While this is not the same as a human right to health, the object of a human right to basic necessities would include secure access to certain crucial determinants of health, such as clean water, sanitation, and adequate nutrition, as well as to basic health care. In addition to this overlap in content, the two rights have a similar logical structure: A human right to basic necessities would entail both negative and positive correlative duties, similar to the examples mentioned above in connection with the idea of a human right to health. Since the claim that human rights give rise to negative duties is comparatively uncontroversial, the discussion of Ashford's work that follows will focus on her arguments about positive duties.<sup>45</sup> Addressing the question of who owes how much to whom, Ashford argues that the two dominant philosophical accounts of the moral status of persons, utilitarianism and Kantianism (both to be outlined below), converge

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*Global Poor Assistance or Rectification?*, 19 ETHICS & INT'L AFF. 9 (2005), and Thomas Pogge, *Severe Poverty as a Violation of Negative Duties*, 19 ETHICS & INT'L AFF. 55 (2005). See also Mathias Risse, *How Does the Global Order Harm the Poor?*, 33 PHIL. & PUB. AFF. 349 (2005). For general analysis of relevant conceptions of personal responsibility, see Samuel Scheffler, *Individual Responsibility in a Global Age*, in SCHEFFLER, *supra* note 6.

43. "One in five people in the world—more than 1 billion people—still survive on less than \$1 a day, a level of poverty so abject that it threatens survival. Another 1.5 billion people live on \$1-2 a day. More than 40% of the world's population constitute, in effect, a global underclass, faced daily with the reality or the threat of extreme poverty." UNITED NATIONS DEV. PROGRAMME, HUMAN DEVELOPMENT REPORT 2005: INTERNATIONAL COOPERATION AT A CROSSROADS: AID, TRADE AND SECURITY IN AN UNEQUAL WORLD 24 (2005), available at [http://hdr.undp.org/reports/global/2005/pdf/HDR05\\_complete.pdf](http://hdr.undp.org/reports/global/2005/pdf/HDR05_complete.pdf). Existence in extreme poverty burdens more than 850 million of these people—"including one in three preschool children"—with chronic malnutrition; more than 1 billion of them with no access to safe water; and approximately 2.6 billion of them with no access to improved sanitation. *Id.*

44. Elizabeth Ashford, *The Duties Imposed by the Human Right to Basic Necessities*, in FREEDOM FROM POVERTY AS A HUMAN RIGHT: WHO OWES WHAT TO THE VERY POOR? (Thomas Pogge ed., forthcoming July 2007) (manuscript at 1, on file with author).

45. As Ashford articulates the distinction, negative duties are duties "to forbear from initiating a threatening causal sequence of events" (such as actively supplying the population with water known to be contaminated), whereas positive duties are duties "to actively aid someone." *Id.* (manuscript at 5).

in their implications for a human right to basic necessities—and this is so despite the fact that they represent systematically opposing conceptual frameworks in moral philosophy.<sup>46</sup> They both reasonably impose “positive duties to secure persons’ access to basic necessities,” and these positive duties are “sufficiently morally urgent to constitute human rights claims.”<sup>47</sup>

A selective reconstruction of Ashford’s argument for this position will help to explicate the idea of a human right to basic necessities and its potential for addressing the duty-allocation problem. Let us begin with an overview. As Ashford notes, the justification of any human right has two parts. The first part is to show that its object has such fundamental moral importance as to be owed to all persons simply by virtue of their moral status.<sup>48</sup> The second part is to show “that the duties generated by the right can reasonably be imposed on agents,” since a human right is a claim-right logically correlated with duties.<sup>49</sup> Moreover, the duties whose imposition on agents must be shown to be reasonable will take a particular form: they are duties of justice, in the sense that human rights *entitle* right-holders to make moral claims on duty-bearers. This is in contrast with duties of benevolence, also known as humanitarian duties or duties of charity, which do not entitle would-be recipients of aid to make moral claims on would-be benefactors.<sup>50</sup>

Finally, Ashford rejects the assumption that, in order to allocate the duties correlative to human rights, it must be possible in every instance to “match up” individual right-claimants with “specific addressees.”<sup>51</sup> Instead, in the case of a human right to basic necessities, right-holders can justifiably make moral claims not only against institutional agents such as their own governments, but also against all affluent individuals, because the condition of affluence itself puts one in a causal position to help alleviate severe chronic poverty. Moral responsibility is distributed among the affluent, in ways that make sense in light of the actions that we are typically able to perform as private individuals. This distribution of responsibility does not require anything like the manifestly impossible process of tracing actual causal links—through complex global systems of trade, labor, finance, politics, climate, and so on—between specifiable affluent individuals and specifiable individuals suffering from severe chronic poverty. Instead, the upshot is simply that each affluent individual has certain positive duties to do at least his or her fair share in supporting effective aid and pressing for institutional reform.<sup>52</sup>

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46. *Id.* (manuscript at 1).

47. *Id.* (manuscript at 6).

48. *Id.*

49. *Id.*

50. *Id.* (manuscript at 27).

51. *Id.* (manuscript at 32).

52. *Id.* (manuscript at 32-33).

*1. The Moral Status of Persons and the Importance of Basic Necessities*

Ashford's starting point is the assumption that underlies the claim that there are such things as human rights: "[T]hat each person without exception has moral status and can therefore justifiably demand not to be treated in ways that are fundamentally incompatible with that moral status."<sup>53</sup> The two dominant philosophical accounts of the moral status of persons are found in utilitarianism and Kantianism.

Utilitarianism, in its classic formulation, defines right action as the maximization of well-being (technically "utility," also known as "welfare"), as assessed from an impartial perspective that encompasses all persons and all sentient beings. The maximization of well-being requires, among other things, the alleviation of suffering. Utilitarianism has many variants emphasizing different accounts of the good(s) that ought to be maximized and, consequently, emphasizing different aspects of the moral importance of personhood. A centrally influential version of utilitarianism grounds the moral status of persons in the richness and complexity of our capacity for both well-being and suffering.<sup>54</sup> It is this version of utilitarianism that Ashford deals with in her discussion of human rights.<sup>55</sup>

The label "Kantianism" indicates an approach to moral theory rooted in the legacy of Enlightenment philosopher Immanuel Kant (1724-1804). Kantian theories ground the moral status of persons in the capacity for autonomous rational agency; roughly, the capacity to make one's own choices about what to do.<sup>56</sup> This is in contrast to being manipulated or pushed around like a mere object, whether by the actions of others or by the compulsion of one's own unmet needs (such as hunger, thirst, pain, illness). Perhaps the most culturally influential Kantian expression of the criterion of right action, and the one most closely associated with human rights discourse, is one of Kant's own formulations: "Act in such a way that you treat humanity, whether in your own person or in the person of another, always at the same time as an end and never simply as a means."<sup>57</sup> In more colloquial terms, Kantian moral theory demands that we act always according to principles that respect and support the dignity of persons (ourselves and others), in particular the capacity to choose one's own

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53. *Id.* (manuscript at 2).

54. Roger Crisp & Tim Chappell, *Utilitarianism*, in *CONCISE ROUTLEDGE ENCYCLOPEDIA OF PHILOSOPHY* 909, 909 (2000); *see also* J.S. MILL, *UTILITARIANISM* (Roger Crisp ed., 1998) (1861) (introducing a classic foundation for the philosophical tradition that informs the version of utilitarianism most relevant to this article).

55. Ashford, *supra* note 44 (manuscript at 3).

56. *See generally* Thomas E. Hill, Jr., *Kantian Normative Ethics*, in *THE OXFORD HANDBOOK OF ETHICAL THEORY* 480 (David Copp ed., 2006) (surveying Kantian moral philosophy).

57. IMMANUEL KANT, *GROUNDWORK FOR THE METAPHYSICS OF MORALS* 229-230 (Thomas E. Hill, Jr. & Arnulf Zweig trans. & eds., 2002) (1785).



actions.<sup>58</sup>

To establish that basic necessities have fundamental importance by the standards of both utilitarian and Kantian accounts of the moral status of persons, one needs to show that without secure access to basic necessities—such as sanitation, clean drinking water, adequate nourishment, and the level of medical care necessary for survival plus some decent modicum of health—people are condemned to suffering and deprived of well-being or indeed of life itself, and that they are also deprived of meaningful agency. For a clear appreciation of these points, we have only to consider the horrendous quality of existence suffered by the very poor. Ashford presents it as follows:

When people lack secure access to basic necessities their lives are drastically impoverished and stunted. Chronic poverty imposes very severe restrictions on the range of options they can pursue. It may undermine their most central goals and commitments that are absolutely integral to their ability to live out their conception of a decent life, such as their goal of raising flourishing children if, for example, they are unable to provide their children with the food or basic medical care they need for health or even survival. Malnutrition can cause chronic lethargy, which restricts persons' ability to pursue any activity. It can moreover cause brain damage and so permanently impair persons' rational autonomous faculties, and it can cause other permanent debilities. It can also cause extreme physical pain (from hunger or disease) and mental pain (through the preventable death of several close family members, for example). Lack of basic necessities can therefore preclude a minimally decent and autonomous life.<sup>59</sup>

To some extent, it is the very experience of chronic insecurity about access to necessities like water, sanitation, and food (in addition to the absence of these necessities themselves) that also precludes meaningful agency. Not only does such insecurity curtail one's most basic options for choosing what to do; it also goes hand in hand with abject humiliation. Life on the edge of survival is felt by the very poor as a constant assault on their dignity.<sup>60</sup> In sum, from the utilitarian viewpoint, secure access to basic necessities is indispensable for well-being;

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58. Hill, *supra* note 56, at 489 (offering the following gloss on Kant's formulation: "To value rational persons as ends, we must not use them for ends that, in some sense, they cannot share. . . . Kant adds that persons, conceived as members of a kingdom of ends, have a *dignity*, which is grounded in their *autonomy* of will. . . . Dignity is an 'unconditional and incomparable worth,' above all *price* and 'without equivalent.' Thus dignity is a value that is independent of a person's social status and utility."'). For a sustained discussion of Kantian moral theory and human rights, see James Griffin, *Discrepancies Between the Best Philosophical Account of Human Rights and the International Law of Human Rights*, 101 PROC. ARISTOTELIAN SOC'Y 1 (2001).

59. Ashford, *supra* note 44. (manuscript at 6-7). See generally Keith P. West, Jr. et al., *Nutrition*, in INTERNATIONAL PUBLIC HEALTH, *supra* note 2, at 187 (surveying scientific literature on food security, population spectrum of nutritional status, undernutrition, micronutrient deficiencies, diet and undernutrition, malnutrition among older persons, and more).

60. See DEEPA NARAYAN ET AL., VOICES OF THE POOR: CAN ANYONE HEAR US? (2000).

likewise, from the Kantian viewpoint, it is essential to sustaining meaningful agency.

## *2. Positive Duties Correlative to a Human Right to Basic Necessities*

The greater philosophical challenge is to make the case for the reasonableness of the positive duties that a human right to basic necessities would impose upon agents. Starting with utilitarianism, Ashford reminds us that because it is concerned with occurrences of suffering or well-being, whether or not they result from a given agent actively introducing them into the world, it makes no intrinsic distinction between that agent's allowing harm (e.g., failing to relieve famine) and causing harm (e.g., sending poisoned food), supposing the consequences are identical. If omissions may have the same consequences for suffering and well-being as would active harms, then rights should protect right-holders against omissions as much as against active harms.<sup>61</sup>

But this is not yet the whole story. Since utilitarianism defines right action from a viewpoint that is impartial across persons, a utilitarian analysis of human rights must accommodate the prospect of interpersonal trade-offs. Some states of affairs, such as secure access to basic necessities, are so important for a person's well-being that for purposes of measurement and interpersonal comparison, we should arguably register a discontinuity in the scale of value, so that "one person's human right could never be outweighed by any number of others' trivial interests."<sup>62</sup> For instance, suppose that the choices of one thousand people to eat as much beef as they want for dinner every night for a year adds up to a quantity of aggregate pleasure that would, on a strictly continuous scale, cancel out the suffering that one severely and chronically malnourished person would endure, over the same time period, as a result of agricultural policies that divert a population's grain supply to the feeding of beef cattle for export. The fact that severe chronic malnourishment undercuts one's very capacity to experience well-being at all counts in favor of stipulating a discontinuity in the scale, so that such pervasive suffering on the part of any person cannot be "cancelled out" by any quantity of trivial pleasures enjoyed by others. At the same time, utilitarian analysis must continue to register the possibility that "the basic interests protected by human rights could be outweighed by the comparably serious interests of several others."<sup>63</sup> This means that, for utilitarianism, the importance of the interests that a putative human right would protect must be weighed against the cost to others of protecting those interests. Accordingly, "[t]he question of what human rights there are will be determined by examining how much sacrifice would be required from how many for the sake of how much gain

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61. Ashford, *supra* note 44 (manuscript at 5).

62. *Id.*

63. *Id.*

for how many.”<sup>64</sup>

What it would actually take to eradicate severe chronic poverty, and what it would cost, are questions that lead beyond the scope of this Article.<sup>65</sup> The point of principle is that insofar as the cost of securing basic necessities for the poor could be distributed among the affluent without threatening any comparably significant interests of ours, it is entirely reasonable to recognize a human right (to basic necessities) whose correlative duties would impose that level of cost upon the affluent. This point of principle leaves open the question of effective and feasible means. It cannot by itself determine which solutions will work, and in particular it does not privilege simple donation or massive wealth transfer over context-sensitive programs that might include better governance, the establishment and enforcement of universal property rights under the rule of law, economic growth, market-based mechanisms like for-profit microfinance, or pricing schemes that would protect supplies of potable water better than wasteful giveaways.<sup>66</sup> The point is only that *whatever* the cost of eradicating poverty might be, through *whatever* means are effective and feasible, it is reasonable to impose that cost on the affluent insofar as it threatens no comparably significant interests of ours.

Ashford’s utilitarian argument for a human right to basic necessities is reminiscent of a principle famously articulated in 1972 by the utilitarian philosopher Peter Singer, also in the context of challenging the complacency of the affluent toward global poverty: “If it is in our power to prevent something bad from happening, without thereby sacrificing anything of comparable moral importance, we ought, morally, to do it.”<sup>67</sup> While Ashford’s analysis substantially extends and fleshes out the line of thought earlier opened by Singer, her most striking innovation is her Kantian argument for the claim that a human right to basic necessities reasonably imposes positive duties upon agents.

Ashford’s Kantian argument draws on the model of Kantian contractualism developed by T.M. Scanlon.<sup>68</sup> Contractualism is a method for the moral

64. *Id.*

65. For a recent estimate, drawing on the latest figures compiled by the United Nations and showing that the eradication of severe chronic poverty is easily within the financial reach of the world’s affluent in aggregate, see Peter Singer, *What Should a Billionaire Give—and What Should You?*, N.Y. TIMES, Dec. 17, 2006, § 6 (Magazine), at 58. For other examples of steps in this direction, see Thomas W. Pogge, *Eradicating Systematic Poverty: Brief for a Global Resources Dividend*, 2 J. HUM. DEV. 59 (2001); Gopal Sreenivasan, *International Justice and Health: A Proposal*, 16 ETHICS & INT’L AFF. 81, 83 (2002).

66. For discussion of related issues in the provision of water and sanitation, see UNITED NATIONS DEV. PROGRAMME, HUMAN DEVELOPMENT REPORT 2006: BEYOND SCARCITY: POWER, POVERTY AND THE GLOBAL WATER CRISIS (2006), available at <http://hdr.undp.org/hdr2006/pdfs/report/HDR06-complete.pdf>.

67. Singer, *supra* note 6, at 231. Singer updates the application of this principle to the present-day global situation in Singer, *supra* note 65.

68. T.M. SCANLON, WHAT WE OWE TO EACH OTHER (1998); Elizabeth Ashford, *The Demandingness of Scanlon’s Contractualism*, 113 ETHICS 273 (2003).

assessment of proposed principles to regulate individual or institutional conduct. In brief, it works by specifying a set of hypothetical conditions and asking what principles it would be reasonable for parties to accept, or what it would *not* be reasonable for them to reject, under those conditions. Kantian contractualism grounds the acceptability of principles in the requirement of equal respect for each party as a rational autonomous agent. This means that the acceptability of a proposed principle depends on whether each affected individual, from a position of equal moral standing, could reasonably agree to it. Recognizing the equal and fundamental moral importance of each individual nevertheless allows for comparison between the strengths of different individuals' reasons for accepting or rejecting a principle.<sup>69</sup>

Consider the proposed principle that *affluent agents have a duty to help the victims of severe chronic poverty to gain secure access to basic necessities, when they can do so without significant cost to themselves*. Clearly, each poor individual's reasons for accepting this principle are stronger than any reason an affluent individual might give for rejecting it. Thus, the affluent have some duty to aid the poor. The important question, Ashford argues, is "whether this duty of aid should be seen as a duty of benevolence or as a duty of basic justice to which the chronically poor are entitled as a human right."<sup>70</sup> The interestingly controversial comparison, then, is between two candidate principles for specifying the nature of the duty to give assistance. The principle specifying it as a duty of benevolence would be something like, *each affluent agent has a duty to help some chronically poor individuals some of the time*. The rival principle specifying it as a duty of basic justice would be something like, *each affluent agent has a duty to do his or her fair share to secure every chronically poor individual's access to basic necessities*.<sup>71</sup>

Consider what it would be like for affected individuals to accept the principle specifying the duty to give aid as a duty of benevolence. For any given poor individual, helping that person would be "morally optional"; no particular poor individual could claim any entitlement to basic necessities.<sup>72</sup> By contrast, the duty-of-basic-justice specification entitles every poor individual to make claims on affluent agents, at least in the aggregate, which in practice translates into claims on the governments of affluent states and the international institutions in which affluent states participate. On this specification, no poor individual's lack of secure access to basic necessities can be permissibly excluded from

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69. Ashford, *supra* note 44 (manuscript at 4).

70. *Id.* (manuscript at 26). A duty of "basic justice" here is a pre-institutional or extra-institutional duty. That is, its moral force does not require that the parties involved be related through any social institutions; to the contrary, it serves as a criterion of justice for the critical examination of social institutions. In particular, the duties correlative to human rights are duties of basic justice, in virtue of the universality that is part of the concept of a human right.

71. My formulation of the principles to be compared is meant to summarize Ashford's more detailed discussion. *See id.* (manuscript at 27).

72. *Id.*

consideration on the grounds that helping that individual is “morally optional.”<sup>73</sup> Each poor individual thus has strong reasons for rejecting the duty-of-benevolence specification in favor of the duty-of-basic-justice specification. And given what is at stake for severely impoverished individuals, as in the case of the principle that acknowledges the duty to assistance in the first place, each poor individual’s reasons are far stronger than the opposing reasons that any affluent individual could present.<sup>74</sup>

In addition, Ashford argues that affluent individuals have compelling reasons of their own to prefer that the duty to aid be specified as a duty of basic justice rather than as a duty of benevolence.<sup>75</sup> The full comparative argument between the two candidate specifications, as they would affect affluent individuals, is too complex to summarize here. The main point is that a duty of basic justice would underwrite a system of enforceable compliance, fairly distributing the burdens of giving aid across all affluent individuals, so that each individual would be required to give *no more than* his or her fair share. But even if we leave aside this strand of the argument, the prior point is that the affluent cannot reasonably reject the claims of each poor individual to being treated with respect for their agency, specifically in the form of securing their access to basic necessities—the material prerequisites of meaningful agency—where doing so would burden affluent individuals very little. This point suffices to vindicate a construal of the duty to aid as one owed by right to each individual person in severe chronic poverty.

### 3. *Duty Allocation*

We are now in a position to revisit the duty-allocation problem that troubles O’Neill in her criticism of the human right to health. The implication Ashford draws from her argument for a human right to basic necessities is that the correlative duties are shared by all affluent individuals. She acknowledges that, as a matter of fact, only entities on the order of national governments and global institutions are typically able to command the economic resources and political clout necessary to address the root causes of chronic severe poverty.<sup>76</sup> Nonetheless, even if the complex set of background conditions affecting the global poor is dominated by institutional actors, individuals remain responsible for their actions and omissions with respect to influencing how these actors operate. Affluent individuals hold positions of non-negligible power within the global order, so that their positive duties include pressing for reform of the institutions whose activities determine the background conditions so pervasively.

Exceptionally influential individuals, by collaborating with governments and

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73. *Id.*

74. *Id.* (manuscript at 28).

75. *Id.*

76. *Id.* (manuscript at 7).

global institutions to transform their *modus operandi*, can make significant progress in altering the global order on behalf of the poor. For example, in the words of a *Time* article naming the rock star Bono a 2005 Person of the Year along with Bill and Melinda Gates, “Bono charmed and bullied and morally blackmailed the leaders of the world’s richest countries into forgiving \$40 billion in debt owed by the poorest; now those countries can spend the money on health and schools rather than interest payments—and have no more excuses for not doing so.”<sup>77</sup> And since 1986, former U.S. President Jimmy Carter and his wife Rosalynn have worked with WHO and others in an effort to eradicate neglected diseases, such as Guinea worm disease, trachoma, river blindness, schistosomiasis, and lymphatic filariasis, which are suffered exclusively by hundreds of millions of the poorest and most dispossessed people in the world.<sup>78</sup>

The positive duties of ordinary individuals include contributing at least their fair share of resources to an effective aid or development agency.<sup>79</sup> In addition, if Ashford’s arguments succeed, individuals ought to supplement donations with efforts to promote institutional reform in order to sustain a morally adequate response, both to the utilitarian requirement to take responsibility for the important consequences of one’s actions and omissions and to the Kantian contractualist principle specifying the duty to give assistance (up to the point of securing access to basic necessities) as a duty of basic justice.

Even individuals who lack the public visibility of rock stars and former presidents can exert remarkable leverage in transforming global institutions. A recent success story is the development of a new market mechanism, the Advance Market Commitment (AMC). The AMC guarantees that a market will exist for new vaccines designed to avert the leading causes of child mortality among the poorest populations, who would otherwise be unable to pay for them. The goal is to encourage manufacturers to produce such vaccines sooner and more cheaply than would otherwise be feasible, and to reimburse resource-challenged national governments for distributing them to the poor. The pilot AMC project, funded at \$1.5 billion, aims eventually to vaccinate seventy million to one hundred million children against pneumococcal disease, which now causes approximately one million child deaths per year.<sup>80</sup> While it takes powerful

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77. Nancy Gibbs, *Persons of the Year*, TIME, Dec. 26, 2005, at 38.

78. Nicholas Kristof, *Torture by Worms*, N.Y. TIMES, Feb. 18, 2007, at A13. The Carter Center pursues its health programs explicitly under the banner of good health as “a basic human right.” The Carter Center, <http://www.cartercenter.org/health/index.html> (last visited May 3, 2007). See also Alan Fenwick, *Waterborne Infectious Diseases—Could They Be Consigned to History?* 25 SCI. 1077, 1078 (detailing “the joint efforts of the Carter Center and WHO” toward the eradication of Guinea worm disease).

79. Peter Singer has estimated that donating one percent of one’s annual income toward overcoming world poverty is “the minimum that one must do to lead a morally decent life.” PETER SINGER, *ONE WORLD: THE ETHICS OF GLOBALIZATION* 194 (2d ed. 2002). For a proposal about reasonable levels of donation stratified by income, see Singer, *supra* note 65.

80. Andrew Cole, *Governments Unite to Fund Vaccine for Poor Countries*, 334 BMJ 29

institutional actors to finance and execute such a project (in the case of pneumococcal vaccine, these are Italy, the U.K., Norway, Russia, Canada, and the Bill and Melinda Gates Foundation), it is only through the day-to-day efforts of individual scientists and policy analysts that such schemes actually come to exist. Far from being pop icons, the people who work behind the scenes are more like the colleagues you might routinely meet in your office corridor.<sup>81</sup>

To the extent that a human right to basic necessities does require that correlative duties be delegated to states and global institutions, much work remains to be done toward specifying the details.<sup>82</sup> But on Ashford's account, this does not have the paradoxical consequence of pairing a supposedly universal right with duties borne only by the self-selected group of institutional actors that volunteer to take them on. Rather, the universal right is paired with duties borne primarily by all affluent individuals as a non-optional matter of what morality requires and only derivatively by the institutional actors necessary to carry out those moral duties effectively. Ashford's argument can deliver this result because it confers the status of *human* right only upon object-based claim-rights that satisfy two conditions. First, the lack of the object makes even the most minimal degree of well-being and meaningful agency untenable. Second, the means to secure the object could be provided by other individuals (the affluent), regarded in aggregate, *without significant loss in well-being or meaningful agency for anyone*, so that to accept a state of affairs in which some (not to say a billion or two) individuals suffer this lack is *to deny their moral status as persons*. Secure access to basic necessities meets both of these conditions.

Arguably, those two conditions are not satisfied by the WHO Constitution's more ambitious understanding of health as the object of a human right: "a state of complete physical, mental, and social well-being" enjoyed at the "highest attainable standard."<sup>83</sup> Indeed, it proves challenging enough to argue for basic necessities (including basic health care and adequate provision of other determinants of health) as the object of a human right correlated with positive duties to give assistance.<sup>84</sup> Establishing the universality and morally well-founded enforceability of any such right—that is, giving it teeth as a *human* right—requires careful calibration in the conception of its object. Pruning back the currently expansive conception of health as the object of the right may well be the price of developing a solution to the duty-allocation problem.

At the same time, we should preserve a sharp distinction between brute

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(2007); *New Vaccines for Old Killers*, *ECONOMIST*, Feb. 17, 2007, at 62.

81. See, e.g., Orin Levine & Michael J. Klag, *Vaccines for the Vulnerable Around the World*, *BALT. SUN*, Jan. 3, 2007, at 11A (providing commentary by two public health scientists closely involved in advocacy for the pneumococcal AMC).

82. See, e.g., Allen Buchanan & Matthew DeCamp, *Responsibility for Global Health*, 27 *THEORETICAL MED. & BIOETHICS* 95 (2006).

83. WORLD HEALTH ORG. CONST. pmb1., available at [http://www.who.int/governance/eb/who\\_constitution\\_en.pdf](http://www.who.int/governance/eb/who_constitution_en.pdf).

84. See, e.g., Ashford, *supra* note 44.

political feasibility and the calibration of morally principled limits on duty-bearers' burdens.<sup>85</sup> For any putative human right, on both the utilitarian model and the Kantian contractualist model, specifying the content of the right's object O requires asking what burdens would be imposed on duty-bearers D by the protection of morally fundamental O-related benefits for right-holders R. On the utilitarian model, the theoretical limit is reached at the point where the burdens on D would threaten any of D's interests in well-being in ways that are comparable in gravity to the morally fundamental O-related aspects of R's well-being. On the Kantian model, the theoretical limit is reached at the point where the burdens on D would make it reasonable, on grounds of respect for D's agency, for D to reject any principle requiring D to assume those burdens. In real-world attempts to specify the content of health-related human rights, the application of either or both of these models leaves as an open question precisely how expansive the operative conception of "health" should be. Regarding affluent individuals and poor individuals, respectively, in global aggregate, one might think that demands on the affluent could be greatly stepped up before we would reach either the utilitarian or the Kantian theoretical limit.

Nevertheless, in the countries and cities where the global poor live, suffer, and die in greatest numbers, health systems and other determinants of health present fiendishly complex problems that either cannot be solved simply by an influx of resources or, even if they could be, must in the meantime be addressed in the absence of adequate resources.<sup>86</sup> As described below, realities that are far from ideal may affect the specific entitlements that people can claim in the name of their health-related rights.<sup>87</sup>

### *B. Problems of Implementation*

Critics who focus on problems of implementation are, for the most part, sympathetic to the spirit in which advocates of a human right to health assert such a right. Their critical concerns have to do with the daunting conceptual and political complexity of determining how to secure any such right in real-world settings.

Norman Daniels argues that so far as states bear duties to secure the health-related rights of their individual citizens, even if these rights are construed as human rights and thus as universal, the claims that individual right-holders can thereby make on their state for specific goods and services will be in practice

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85. Thanks to Chad Flanders for his illuminating comments on this issue.

86. For an exemplary overview of some key problems, see Lynn P. Freedman et al., *Transforming Health Systems To Improve the Lives of Women and Children*, 365 LANCET 997 (2005); Lant Pritchett & Michael Woolcock, *Solutions When the Solution Is the Problem: Arraying the Disarray in Development*, 32 WORLD DEV. 191 (2004).

87. John D. Arras & Elizabeth Fenton, *Bioethics and Human Rights: Curb Your Enthusiasm*, 33 (unpublished manuscript, on file with author).



relative to that state's available resources. Limited resource-availability means that states will need to set priorities in allocating resources toward the realization of health-related rights. The upshot is that regardless of whether foundational philosophical arguments can establish the universality of health-related rights, states will nevertheless, in the attempt to realize them, confront several classic "unsolved rationing problems."<sup>88</sup>

Undoubtedly, such problems are inevitable when states must set priorities for the allocation of limited resources. And a fair deliberative process, as developed for instance by Daniels in the form of "accountability for reasonableness," presents a philosophically well-grounded and practically viable approach to the problems of priority-setting.<sup>89</sup> But there is still room in this picture for differences to be made by foundational arguments for the universality of certain health-related rights.

One potential difference is in the severity of the limitation on a state's available resources that affluent global on-lookers can accept, compatible with recognizing the moral status of each individual person. If there is a human right to basic necessities, and basic health care is by definition a basic necessity, then there is a human right to basic health care. But how are we to understand "basic health care?" A powerful criterion is available in the form of Ashford's argument that the object of any universal claim-right is specified jointly by (a) the importance of what each right-holder stands to lose and (b) the reasonableness of requiring each duty-bearer to contribute their fair share to the protection of right-holders against that loss. So, if some citizens of a given state suffer levels of morbidity and mortality that (a) subvert any prospect of well-being or meaningful agency and (b) could be avoided by health care measures or public health measures (water, sanitation) deliverable at little cost, yet the state's available resources are so meager as to be unable to support delivery of even these relatively cheap measures, then affluent agents in the rest of the world have duties of basic justice to make good on the deficit.<sup>90</sup> A universal right to basic health care would thus establish a limit on the severity of priority-setting

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88. Daniels, *supra* note 9, at 23-24; see Norman Daniels, Just Health (manuscript on file with author).

89. NORMAN DANIELS & JAMES E. SABIN, SETTING LIMITS FAIRLY: CAN WE LEARN TO SHARE MEDICAL RESOURCES? 43 (2002). Because reasonable disagreement about priority-setting is to be expected, the process used to reach decisions must be one that even those who lose out can accept as legitimate. This requires that justifying reasons be both transparent and rationally defensible to all parties, whether or not they benefit from the decisions reached. Daniels and colleagues also include accountability for reasonableness in a set of "benchmarks for fairness" developed as a policy tool for health care reform. Norman Daniels et al., *An Evidence-Based Approach to Benchmarking the Fairness of Health-Sector Reform in Developing Countries*, 83 BULL. WORLD HEALTH ORG. 534 (2005); Norman Daniels et al., *Benchmarks of Fairness for Health Care Reform: A Policy Tool for Developing Countries*, 78 BULL. WORLD HEALTH ORG. 740, 745-746 (2000).

90. Elizabeth Ashford, Lecturer in Moral Philosophy, Univ. of St. Andrews, Scot., Comments on Presentation by Norman Daniels at Harvard University Conference on Equality and the New Global Order (May 13, 2006).

problems that a state should have to face.

The 2005 Montreal Statement on the Human Right to Essential Medicines provides a template for recognizing and implementing a human right to basic health care.<sup>91</sup> The Statement's first point establishes the importance of what is at stake for people who lack essential medicines—"Two billion people lack access to essential medicines. This deprivation causes immense suffering: pain, fear, loss of dignity and life. Forty-thousand people die daily as a result, the vast majority of them children under five years old."<sup>92</sup>

Points (2) and (3) make the case for the reasonableness of requiring affluent agents to protect the global poor against the deprivation of essential medicines:

Poor people lack access to essential medicines because research and development do not address their priority health needs, because health systems are inadequate, and because existing medicines are unaffordable to them. . . . Existing policies, rules, and institutions foreseeably give rise to deprivations on a massive scale. Alternative designs are feasible; reforms are urgently required. . . . At a minimum, trade agreements, intellectual property laws, loans, aid, and other international arrangements as well as national institutions, laws, and policies must be designed so as to avoid violation of this right.<sup>93</sup>

Point (4) attributes to states a "core obligation to respect, protect, and fulfill the right to essential medicines" for their own populations, an obligation that "requires immediate and effective measures and is not subject to progressive implementation."<sup>94</sup> This rules out priority-setting choices that would deprive a state's citizens of essential medicines if the state has the resources to supply them. Accordingly, "[t]he human right to essential medicines requires that national health systems guarantee at all times that the population receive all essential medicines in adequate amounts, of assured quality, at the appropriate time and in the appropriate dosage . . . at a price the individual and the community can afford."<sup>95</sup> In addition, taking a human right to essential medicines seriously commits outsiders to ensuring that states have the resources to supply them.<sup>96</sup>

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91. The Montreal Statement is the result of a workshop held in 2005 by individuals representing NGOs, governments, international agencies, and academia. See Thomas Pogge, *Montreal Statement on the Human Right to Essential Medicines*, 16 CAMBRIDGE Q. HEALTHCARE ETHICS 97, 104-07 (2007) (reprinting the Montreal Statement). Credit is due to John Arras for pointing out that essential medicines are a powerful example of how to understand "basic health care." Arras & Fenton, *supra* note 87, at 34.

92. POGGE, *supra* note 91, at 104.

93. *Id.*

94. *Id.* The Montreal Statement limits its explicit attribution of this obligation to state signatories to international human-rights treaties. But if there is a human right to basic necessities, including essential medicines, then every capable state has the same obligation.

95. *Id.* at 105.

96. Does it also commit outsiders to intervening in states that have the resources but still neglect their population's basic needs? Non-governmental aid organizations often take the liberty

The responsibility of governments for the fulfillment of human rights includes international assistance and cooperation. "Affluent countries must, therefore, ensure fairer trade and investment, eliminate crippling debt, and contribute equitably to international assistance aimed at facilitating the full realization of the right to essential medicines."<sup>97</sup>

Moreover, the Montreal Statement (Point 5) pegs its conception of "essential medicines" to the WHO's Essential Drugs List.<sup>98</sup> Which medicines count as essential is to be specified by reference to "the priority health care needs of the population, in light of their public health relevance, proven quality, efficacy and safety, and comparative cost-effectiveness."<sup>99</sup>

But not all worries about the implementation of health-related human rights can be addressed by focusing primarily on specific health care interventions like access to essential medicines. For one thing, even those efforts must be anchored in health system reform, as noted in the Montreal Statement's Point 7. In practice, the reform of national health systems must take place in a local or regional context of broadly problematic political, economic, and institutional circumstances.<sup>100</sup> In addition, the successful uptake of medical interventions that health systems might attempt to make available is often inextricable from complex cultural factors. For instance, suppose that a key risk factor in children's death from diarrhea is whether women have the effective freedom to take children to the doctor, even when a male relative is not available or willing to accompany them. More generally, preventive and therapeutic interventions based on biomedical science may compete for cultural uptake with long-entrenched belief systems that attribute illness to supernatural or other non-biomedical causes.<sup>101</sup> Simply making material resources available may be of little, if any, help. In order to make serious headway, greater availability of material resources must be supplemented with research into the operations of health systems in order to identify and study context-specific obstacles to the population-wide delivery of proven interventions.<sup>102</sup>

The global AIDS epidemic exemplifies, on a larger scale, the danger of

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of intervening in such cases. Here is one plausible view. As with civil and political rights, so too with socio-economic rights: a state's violation of human rights counts as *one* reason in favor of intervening, but this reason may in particular cases be outweighed by other reasons, including moral reasons, against intervening; or some specific forms of intervention may be ruled out by the countervailing reasons, while others may be permitted.

97. POGGE, *supra* note 91, at 106.

98. *Id.* at 105. For WHO's Essential Drugs List, see WORLD HEALTH ORG., ESSENTIAL MEDICINES: WHO MODEL LIST (14th ed. 2005), available at [http://whqlibdoc.who.int/hq/2005/a87017\\_eng.pdf](http://whqlibdoc.who.int/hq/2005/a87017_eng.pdf).

99. POGGE, *supra* note 91, at 105.

100. Phyllida Travis et al., *Overcoming Health-Systems Constraints To Achieve the Millennium Development Goals*, 364 LANCET 900, 901-02 (2004).

101. Susan C. Scrimshaw, *Culture, Behavior, and Health*, in INTERNATIONAL PUBLIC HEALTH, *supra* note 2, at 43, 47.

102. Travis et al., *supra* note 100, at 903-04.

associating health-related human rights too closely with an imperative to make treatment interventions available. Daniels points out that in the late 1990s, advocates of human rights appealed to a form of a right to health, in particular a right to health care, in order to derive a universal right specifically to antiretroviral medication for AIDS. As a result, treatment was prioritized over prevention in the global response to the HIV/AIDS crisis, even though re-directing at least some efforts toward prevention might have saved more lives at lower cost over time.<sup>103</sup>

Arguably, this was a case of misidentifying, through over-specification, the object of the relevant health-related right in the attempt at implementation. Whatever is supposed to be protected by health-related rights, prevention and treatment might both contribute comparably to protecting it for different persons. It is an error, from within the perspective of accurately recognizing the importance of what is at stake for each person, to regard the risk of becoming infected with HIV as having only secondary relevance in comparison with the burdens of being infected with HIV. The risk of infection is a risk of suffering exactly the same burdens. If people who are infected with HIV have a right not to suffer those burdens when their infection could be treated at little cost to others, people who are at risk of infection equally have a right not to be exposed to that risk when their exposure could be prevented at little cost to others. Thus, recognition of health-related human rights only brings into focus the fact that there is a problem of how to allocate resources between treatment and prevention. It cannot on its own determine the solution in favor of treatment or prevention.<sup>104</sup>

Another problem with the idea of “basic” health care is that needs which are basic in the sense of essential to survival cannot always be met by interventions that are basic in the sense of cheap and simple. For many persons, in the face of life-threatening conditions prevalent in their population, staying above even a minimal threshold of well-being and meaningful agency may require access to relatively highly-skilled medical personnel and to a broadly functional health system. One signal example in global health is maternal health and survival. Every year, an estimated 529,000 women die in pregnancy or childbirth, an estimated 9.5 million women suffer serious illness related to pregnancy, and an estimated 20 million suffer pregnancy-related disabilities.<sup>105</sup> The disabilities include a conservatively estimated 50,000 to 100,000 cases per year of obstetric fistula, a condition of total urinary and bowel incontinence that often results in

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103. See DANIELS, *supra* note 88, (manuscript at 372).

104. For a currently influential epidemiological analysis of the prevention/treatment question, see Joshua A. Salomon et al., *Integrating HIV Prevention and Treatment: From Slogans to Impact*, 2 PLoS MED. e16 (2005).

105. Veronique Filippi et al., *Maternal Health in Poor Countries: The Broader Context and a Call for Action*, 368 LANCET 1535, 1536 (2006).

humiliation and social exclusion in addition to horrible debilitation.<sup>106</sup> The distribution of these burdens between affluent and poor populations is tremendously inequitable. For instance, estimated in terms of a woman's chances of dying as a consequence of pregnancy or childbirth over her lifetime, the risk of maternal death ranges from 1 in 6 (Afghanistan and Sierra Leone) to 1 in 30,000 (Sweden).<sup>107</sup>

Maternal health and survival could be vastly improved by expanding women's access to emergency obstetric care, delivered by health professionals who are qualified and equipped to perform procedures like caesarean sections.<sup>108</sup> Yet, one of the greatest obstacles to improved maternal health for the girls and women who need it most urgently is "the dire scarcity of skilled providers and health-system infrastructure."<sup>109</sup> This state of affairs raises a problem of policy, in which the investment of different amounts of time and resources needed to train birth attendants must be traded off against rapidly expanding the extent of coverage for women who need obstetric services.<sup>110</sup> It also highlights the systemic problems that contribute to maternal morbidity and mortality in poor populations, such as the acute crisis of health-related human resources, and the fragility of the transportation and communication infrastructure.<sup>111</sup>

Indeed, some experts warn that the billions of dollars now becoming available for global health may conceivably end up doing more harm than good, due to adverse impacts on the functioning of severely strained health systems.<sup>112</sup> At the heart of the problem on the donor side is lack of coordination. Many donors, aid programs, and non-governmental organizations (NGOs) are each focused on specific diseases, to the neglect of overall health system improvement. For example, HIV/AIDS programs have reduced the prevalence of HIV-infection in Haiti from six to three percent between 2002 and 2006, but by every other indicator the health status of the population worsened during this period.<sup>113</sup> Generally, the influx of donor monies to fund disease-specific programs may create an internal brain drain, siphoning skilled health workers away from general health-care facilities.<sup>114</sup> This exacerbates the ill effects of the

106. WORLD HEALTH ORG., OBSTETRIC FISTULA: GUIDING PRINCIPLES FOR CLINICAL MANAGEMENT AND PROGRAMME DEVELOPMENT (2006), available at [http://www.who.int/reproductive-health/docs/neonatal\\_perinatal\\_mortality/text.pdf](http://www.who.int/reproductive-health/docs/neonatal_perinatal_mortality/text.pdf); Sharon LaFraniere, *Nightmare for African Women: Birthing Injury and Little Help*, N.Y. TIMES, Sept. 28, 2005, at A1.

107. Carine Ronsmans & Wendy J. Graham, *Maternal Mortality: Who, When, Where, and Why*, 368 LANCET 1189 (2006).

108. Margie Koblinksky et al., *Going to Scale with Professional Skilled Care*, 368 LANCET 1377 (2006).

109. *Id.* at 1377.

110. *Id.*

111. Richard Horton, *Healthy Motherhood: An Urgent Call to Action*, 368 LANCET 1129 (2006).

112. See, e.g., Laurie Garrett, *The Challenge of Global Health*, 86 FOREIGN AFF. 14 (2007).

113. *Id.* at 23.

114. *Id.*

external brain drain caused by wealthy countries' active recruitment of nurses and physicians from poor countries.<sup>115</sup>

One sensible proposal is that donor efforts should be coordinated not around specific diseases, but around such basic goals as increasing maternal survival and increasing overall life expectancy.<sup>116</sup> Beyond their intrinsic importance, maternal survival and overall life expectancy are excellent proxy indicators for overall health-system functioning.<sup>117</sup> In order to fulfill the human right to basic necessities to the greatest extent possible, it would seem that donors interested in global health should focus primarily on helping to build local, internally sustainable capacity to improve such indicators among the poorest and most vulnerable members of populations. An emphasis on reaching the neediest people would ideally be built into every stage of health system capacity-building: consulting stakeholders in each location to prioritize needs and identify specific constraints on health-system performance; continuously monitoring and evaluating programs introduced; and systematically collecting data to facilitate global information-sharing about factors that contribute to failure and success.<sup>118</sup>

## II. GLOBAL HEALTH AND PROFESSIONAL ETHICS

Whatever the nature of affluent individuals' duties to meet the health-related needs of the global poor, one important means of acting on them is to support the activities of health professionals whose work reaches across national borders. NGOs like Médecins Sans Frontières (MSF) offer aid in the form of medical care and other basic necessities.<sup>119</sup> Government bodies, such as the U.K. Medical Research Council (MRC) and the U.S. National Institutes of Health (NIH), and charities, such as the Bill and Melinda Gates Foundation and The Wellcome Trust, figure prominently in medical research aimed at meeting the needs of poor populations.<sup>120</sup> More broadly, global humanitarian efforts on the ambitious scale

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115. Daniels, *supra* note 8, at 30-31. Daniels argues that the external brain drain should be alleviated not by restricting migration (itself the object of certain human rights) but by measures such as contributing financial resources to help poor countries retain skilled health-care personnel by improving their working conditions.

116. Garrett, *supra* note 112, at 23.

117. *Id.*

118. See, e.g., David H. Peters et al., *Research for Future Health Systems*, 3 GLOBAL F. UPDATE ON RES. FOR HEALTH 133 (2006), available at <http://www.futurehealthsystems.org/publications/index.htm> (outlining the research program of Future Health Systems: Innovations for Equity, a consortium of researchers from Uganda, Nigeria, India, China, Bangladesh, the U.K., and the U.S., funded by the U.K. Department for International Development). For a specific working example of this approach to reviving a shattered national health system, see David H. Peters et al., *A Balanced Scorecard for Health Services in Afghanistan*, 85 BULL. WORLD HEALTH ORG. 146 (2007).

119. See DAN BORTOLOTTI, *HOPE IN HELL: INSIDE THE WORLD OF DOCTORS WITHOUT BORDERS* (2004).

120. NUFFIELD COUNCIL ON BIOETHICS, *THE ETHICS OF RESEARCH RELATED TO HEALTHCARE IN*

of the Global Fund to Fight AIDS, Tuberculosis, and Malaria ultimately depend on the work of physicians and scientists to carry out their aims.<sup>121</sup>

It is debatable whether physicians and scientists as individuals, simply by virtue of their professional qualifications, have special duties to help the global poor that others do not have.<sup>122</sup> Does every individual trained in obstetrics and gynecology have a duty to spend at least several weeks a year helping women in poor countries who suffer from obstetric fistula or helping to build local capacity in emergency obstetric care to prevent maternal death and disability?<sup>123</sup> Maybe, but that is not a problem that this Article takes up here. The point for present purposes is rather that, if all affluent individuals have some duty to help the global poor (be it a duty of benevolence or a duty of justice), then, in order to act on that duty effectively, most of us must depend on others who both hold the relevant professional qualifications and choose to employ them in the service of this cause. Physicians and scientists, acting as agents of the donors, sponsors, and organizations who fund their programs, then find themselves offering health care or conducting health-related research in locales where available resources can hardly begin to meet even the basic needs of the resident population.<sup>124</sup> The question is, what do physicians and scientists working under those circumstances owe to needy members of the host population?

This Part considers this question under two distinct headings: aid and research. What the aid *versus* research distinction tracks here is not primarily the qualifications of individual professionals, but rather the aims of the organizations for which they work. Organizational aims determine these individuals' institutional roles, thereby strongly influencing the nature of their obligations as professionals.

At this point, a brief terminological aside is in order. In this Part, "organization" and cognate terms are used to refer to particular corporate agents like MSF or specific kinds of corporate agents like NGOs and research universities. A corporate agent is an agent whose policies are typically determined, and whose actions are typically executed, through the organized activity of multiple individual persons acting in roles established by the agent

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DEVELOPING COUNTRIES 28-29 (2002); Okie, *supra* note 3.

121. Gill Walt & Kent Buse, *Global Cooperation in International Public Health*, in INTERNATIONAL PUBLIC HEALTH, *supra* note 2, at 649.

122. See John D. Arras, *Fair Benefits in International Medical Research*, HASTINGS CENTER REP., May-June 2004, at 3; Samia A. Hurst & Alex Mauron, *Allocating Resources in Humanitarian Medicine* (unpublished manuscript, on file with the author).

123. LaFraniere, *supra* note 106.

124. A professional who works with poverty-stricken populations may be either an expatriate citizen of an affluent country (e.g. a French physician working in South Africa), an expatriate citizen of another country where people suffer from poverty in large numbers (e.g. a Sudanese scientist working in Malawi), or a co-citizen with members of the local population (e.g. a Ugandan scientist working in Uganda). In any case, questions about obligations to the poor arise from professional-role ethics in the context of access to institutional resources.

itself in keeping with the specific kind of agent it is. (So, for example, a hospital is the kind of corporate agent that normally must establish roles for executives, board members, legal counsel, administrators, physicians, nurses, social workers, and so on.) “Institution” and cognate terms are used to refer to the type of social impact and consequent ethical accountability that many such corporate agents have. Somewhat like individual persons, and unlike states, institutions exercise considerable freedom to set their own policies and act accordingly. They are often not bound by any formal constitutional or contractual relationships to outside individuals whose conduct the institution will affect. Yet, more like states and less like individual persons, institutions may have an extensive, enduring, and causally traceable impact on the surrounding society through the activity of setting and executing their policies. Finally, discussion of the “institutional role” of individuals alludes to two facts: (1) their professional responsibilities are ordered and regulated to a great extent by the policies of the organizations for whom they work; and (2) in carrying out those responsibilities, individuals participate in the broader social impact that their organization is making.

In organizational and professional ethics generally, a great deal more research is needed on the problem of how institutional roles ought to shape the professional obligations of the individuals who occupy them. Dennis F. Thompson’s essay, *The Institutional Turn in Professional Ethics*, offers a helpful framework for discussion.<sup>125</sup> Thompson distinguishes two problems of institutional ethics, the *problem of representation* and the *problem of authority*:

The general point is that an institution needs to have a policy, which means that (a) the rules may require individuals in the institution to act in ways that they may not otherwise act on their own; and (b) someone has to decide what the rules are. The first is the problem of representation, and the second, the problem of authority.<sup>126</sup>

Both problems are prominent in the operation of institutions that reach across borders in the service of global health. Section A considers examples of these problems as they occur in the transnational activities of non-governmental aid organizations. Section B looks at the activities of research organizations that are based in affluent countries but study scientific questions of importance to poor populations elsewhere.

#### *A. Non-Governmental Aid Organizations*

MSF is a good example because its operations have been carefully studied by researchers using methods of social science and, in the case of at least one

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125. Dennis F. Thompson, *The Institutional Turn in Professional Ethics*, in *RESTORING RESPONSIBILITY: ETHICS IN GOVERNMENT, BUSINESS, AND HEALTHCARE* 267 (Dennis F. Thompson ed., 2005).

126. *Id.* at 269.



researcher, philosophy as well. In collaboration with Eric Goemaere, head of MSF's South African Mission, medical sociologist Renee Fox has been studying the process of "patient selection" for antiretroviral treatment (ART) in MSF's project in Khayelitsha, South Africa.<sup>127</sup> Meanwhile, philosopher Lisa Fuller has been engaged in a multi-stage collaborative study of "ethics, principles, and decision-making" in the activities of MSF-Holland.<sup>128</sup> Fuller first studied field operations through MSF-Holland's Nairobi Office and its projects in Galkayo, Somalia, and Mandera, Kenya, and then studied the organizational decision-making process at MSF-Holland's Amsterdam headquarters. While Fox's and Fuller's studies should be understood in the first instance as windows onto the particular MSF units they observed, the interpretations offered by both researchers also lend themselves to generalization, at least with respect to ethical analysis of the problems in institutional ethics and institution-related professional ethics that MSF exemplifies.

In brief, the background of MSF's Khayelitsha project is as follows. As Fox and Goemaere recount, the residents of Khayelitsha are some 500,000 extremely impoverished people, many suffering from lack of running water, electricity, and decent shelter. Rates of unemployment and violent crime, including domestic violence, are high. Prevalence of HIV/AIDS among pregnant women is approximately twenty-six percent. At the time of writing, the MSF Khayelitsha project was providing ART to roughly 2000 of the 8000 patients with HIV/AIDS who frequent the MSF clinics. With the support of the Global Fund, financing for ART is now ample, but its provision is constrained by the brain drain of physicians and nurses from South Africa to higher-income positions in other countries (mainly the United States, United Kingdom, Canada, and Australia). Thus, MSF must still practice patient selection, in effect rationing treatment.<sup>129</sup>

MSF clinicians provide the leadership and main membership of several selection committees in Khayelitsha, one committee per HIV clinic.<sup>130</sup> In order to be selected for ART, prospective patients must in principle satisfy the whole of an extensive set of criteria, including medical, social, and behavioral components.<sup>131</sup> In practice, however, as Fox and Goemaere report, "the most

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127. Renee C. Fox & Eric Goemaere, *They Call It 'Patient Selection' in Khayelitsha: The Experience of Médecins Sans Frontières—South Africa in Enrolling Patients To Receive Antiretroviral Treatment for HIV/AIDS*, 15 CAMBRIDGE Q. HEALTHCARE ETHICS 302 (2006).

128. Lisa Fuller, *Justified Commitments? Considering Resource Allocation and Fairness in Médecins Sans Frontières—Holland*, 6 DEVELOPING WORLD BIOETHICS 59, 61 (2006).

129. Fox & Goemaere, *supra* note 127, at 302-04. A cautionary note: Presumably, as in any organization, MSF procedures are open to change, and might be different by the time this Article is published. This Article discusses the procedures that Fox and Goemaere reported to be in place at the time of their 2006 publication in the *Cambridge Quarterly of Healthcare Ethics*.

130. *Id.* at 304. Although each committee also includes a patient, Fox and Goemaere focus on the feelings and deliberations reported by clinical personnel and do not report on patients' contributions or reactions to committee proceedings in their article.

131. *Id.* at 304-06. Behavioral components of the selection criteria are meant to indicate the

striking feature of [committee] deliberations is the inward pressure they feel to accept patients for treatment.”<sup>132</sup> They tend to admit even patients who do not satisfy all the criteria; indeed, they almost never reject candidates, preferring instead to categorize them as needing further preparation with respect to social and behavioral criteria.<sup>133</sup> The pressure they feel to start patients on ART intensifies “when they are confronted with patients in a very advanced, rapidly evolving stage of HIV/AIDS who have a high risk of imminent death.”<sup>134</sup> Clinicians are inclined to accept these patients ahead of up to 500 patients who also satisfy basic medical criteria (primarily, a CD4 count of less than 200/ml)—even though they know that prioritizing such desperately ill patients “will not only delay the treatment of other patient-candidates who may have been waiting longer, but may also contribute to the further deterioration of their immune function because of the extended waiting time.”<sup>135</sup>

MSF’s Khayelitsha project, as described in this scenario, exemplifies classic problems of priority-setting and public health ethics.<sup>136</sup> Ruth Macklin and Solomon Benatar have offered comments analyzing Khayelitsha in those terms.<sup>137</sup> My purpose here is to look at the same scenario from the viewpoint of institutional ethics.

Thompson’s *problem of representation* appears in the anguished attempts of MSF’s Khayelitsha clinicians to apply principled criteria in selecting patients for ART. As Thompson writes, the problem is that the rules of an institution’s policy “may require individuals in the institution to act in ways that they may not otherwise act on their own.”<sup>138</sup> He further specifies the problem as follows: “Whom does the individual professional represent when acting as an official of the institution?”<sup>139</sup> It seems that MSF clinicians in Khayelitsha feel torn between two attitudes toward treating their clinic’s patients. They feel that they should serve as advocates for each individual patient, responding most intently to the patient whose needs of the moment are most urgent. At the same time, they occupy an institutional role as committee members allocating limited resources to serve their organization’s client population, all of whom are extremely needy. If

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likelihood of adherence to treatment. Part of the rationale for emphasizing adherence is to avert the development of drug-resistant strains of HIV.

132. *Id.* at 306.

133. *Id.*

134. *Id.* at 308.

135. *Id.* at 308-09.

136. Daniels, *supra* note 9, at 23-24.

137. Solomon Benatar, *Facing Ethical Challenges in Rolling Out Antiretroviral Treatment in Resource-Poor Countries: Comment on “They Call It ‘Patient Selection’ in Khayelitsha,”* 15 CAMBRIDGE Q. HEALTHCARE ETHICS 322 (2006); Ruth Macklin, *No Shortage of Dilemmas: Comment on “They Call It ‘Patient Selection’ in Khayelitsha,”* 15 CAMBRIDGE Q. HEALTHCARE ETHICS 313 (2006).

138. Thompson, *supra* note 125, at 269.

139. *Id.* at 271.

each of these physicians were acting “on their own,” they would probably be strongly inclined toward acting on the individual-patient-advocate attitude. But the institutional role that they occupy requires, at least formally and in principle, that in their decisions as committee members they respond primarily to the needs of patients as a population.

These MSF clinicians lack certain luxuries present in situations that lie closer to the institutional ideal. Consider Thompson’s sensible prescription for the operation of hospitals: “Some division of moral labor is necessary in any complex institution. The doctor at the bedside should not have cost containment uppermost in his mind, and the CEO of the HMO (even if he is a doctor) cannot give absolute priority to the individual welfare of each patient.”<sup>140</sup> A combination of dire circumstances and organizational aims may often force practitioners of humanitarian medicine into the position of attempting to fill both kinds of roles, which may be psychologically untenable for someone who cares about professional integrity. A plausible interpretation of the MSF clinicians’ tendency to subvert their own formal patient-selection criteria is that doing so is a way to relieve this acute tension, even if only temporarily and with uncomfortable residual doubts. Their experience highlights an important point about the problem of representation, as emphasized by Thompson. It is not merely a problem facing individuals who wish to maintain professional integrity, but more deeply a problem that the institution must address in its design of the roles it will ask professionals to occupy.<sup>141</sup> An institution’s policies stand in need of revision if they regularly place professionals in the type of bind suffered by MSF clinicians in Khayelitsha.

Regarding the design of institutional policy, the *problem of authority* presses the still deeper question of who should participate in making policy and in what ways. In particular, organizations that provide services like health care need to confront the issue of how to involve, or at the very least how to consult, the populations they purport to serve.<sup>142</sup> A tremendously challenging version of this problem for aid organizations like MSF is the issue of their accountability to needy populations, including both actual and potential recipients of medical aid. This has been the subject of Lisa Fuller’s research with MSF.<sup>143</sup>

Fuller addresses MSF’s procedures for deliberating and deciding on questions of resource allocation on the largest scale. Where, and when, should MSF open, close, or restructure specific medical aid projects? MSF and other NGOs are vital in the provision of health care among extremely needy populations. Yet strikingly, in contrast with government agencies (such as Ministries of Health), which also need to decide how to allocate health care resources, the operational autonomy typical of NGOs leaves them with

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140. *Id.* at 272.

141. *Id.*

142. *See id.* at 272-73.

143. Fuller, *supra* note 128.

“complete discretionary power” over all their allocation decisions, including the most fundamental ones of where, when, for how long, with what aims, and by what measures of success or failure they should operate their programs.<sup>144</sup> Until recently, as a matter of formal organizational accountability, populations of the kind these NGOs purport to serve have not had much of a say in such decision-making.<sup>145</sup> Fuller reports that NGOs are just beginning to explore mechanisms to improve accountability to their intended beneficiaries.<sup>146</sup>

As a first step toward developing “a full theory of NGO accountability to recipients in need of medical care,” Fuller critically examines the justifications most often used in MSF’s decisions on large-scale resource allocation.<sup>147</sup> She does so with an eye to the legitimacy of these justifications from the viewpoint of those who need medical assistance. She analyzes the allocation of scarce NGO-provided medical aid as a case of decision-making that calls for justification through a deliberative process incorporating “accountability for reasonableness.”<sup>148</sup> In the case of MSF and similar NGOs, due attention to accountability for reasonableness would acknowledge “that potential recipients of aid have a vital interest in MSF’s decisions, while at the same time accommodating the fact that resources are limited and so not all suitable populations can be benefited.”<sup>149</sup>

Fuller finds that MSF medical personnel feel a strong obligation to stay and work with communities with whom they have become involved through existing projects dedicated to general health care.<sup>150</sup> In contrast, projects narrowly focused on a single short-term outcome, such as the control of a specific disease outbreak, allow for statistical measures to determine when the outcome has been achieved, providing an identifiable reason for MSF to end its relationship with the community at a particular time.<sup>151</sup> General health care projects are more problematic for personnel to close, even if they have achieved overall improvements to the point where other emergencies elsewhere clearly present greater need from an impartial perspective. Personnel feel that they have committed to a relationship with the people who live in the community, so that if no government or other system is prepared to take responsibility for meeting the

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144. *Id.* at 60.

145. *Id.*

146. *Id.* As examples, Fuller cites The Sphere Project: Humanitarian Charter and Minimum Standards in Disaster Response, <http://www.sphereproject.org/> (last visited May 3, 2007) and Alnoor Ebrahim, *Accountability in Practice: Mechanisms for NGOs*, 31 *WORLD DEV.* 813 (2003).

147. Fuller, *supra* note 128, at 60.

148. *Id.*; see also DANIELS & SABIN, *supra* note 89, at 44. Thompson, *supra* note 125, at 274, also suggests procedures modeled on deliberative democracy as a way for institutions to handle the problem of authority.

149. Fuller, *supra* note 128, at 63.

150. *Id.*

151. *Id.*

community's general health care needs, they feel obligated to stay.<sup>152</sup>

Another kind of case presents similar difficulties. MSF's policy for certain HIV-treatment programs is to demonstrate treatment feasibility in selected low-resource or politically unstable environments.<sup>153</sup> What drives the policy is the long-term goal of helping to make HIV treatment available to as many people as possible, in contrast with the alternative of making treatment available to fewer people by running permanent programs in only a few places. To this end, MSF sometimes employs a time-limited strategy, staying in any given host country no longer than roughly five years. During this period, the organization's aims are (a) to demonstrate the feasibility of HIV treatment in the local setting, and (b) to find or pressure other agencies, which may include the government of the host country, to continue care for HIV patients after the temporary MSF program closes.<sup>154</sup>

Yet MSF field staff, influenced by sensibilities of the kind Fuller has observed, say that they find it very hard to leave the host country at the appointed time, especially when they are uncertain about whether local efforts to continue therapy will be successful.<sup>155</sup> They have in some cases actually reversed organizational close-down decisions, prolonging the stay of their clinics past the designated time to leave.<sup>156</sup> This could undermine the very policies that ostensibly form the *raison d'être* for the programs they serve. For one thing, if the MSF program prolongs its stay indefinitely, it may have the unwelcome effect of actually relaxing pressure on other capable agencies: Why should they commit resources if MSF will take care of it? More important for the present discussion, another consequence of staying too long is that while the local population gains further benefits in addition to what they have already received, other needy populations elsewhere lose the opportunity to have any such benefit at all.

When attachments to communities already being served dominate decision-making at the level of headquarters as well, the organization is in effect systematically making decisions that seriously affect candidate populations elsewhere for reasons that might not be legitimately justifiable to these populations. Fuller distinguishes between a "relational" perspective more appropriate to field staff who feel the pull of existing community ties, and a "comparative" perspective more appropriate to headquarters, which in the ideal case impartially considers fairness in the feasible distribution of good outcomes for all candidate populations, whether they are current beneficiaries or

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152. *Id.*

153. Interview by Samia Hurst, Maitre assistante, Institute for Biomedical Ethics, Geneva University Medical School, with MSF personnel, June 5, 2005 (on file with author). Thanks to Samia Hurst for her explanation of this MSF policy and its underlying rationale.

154. *Id.*

155. *Id.*

156. *Id.*

prospective beneficiaries.<sup>157</sup> She suggests a number of adjustments that might facilitate due incorporation of the comparative perspective into the organization's decision-making. For instance, she proposes a constraint on the content of justifications for continuing existing projects, to rule out "[t]he mere fact that MSF-H[olland] has been engaged with a given group of people for some time."<sup>158</sup>

While Fuller is on the right track in emphasizing organizational accountability to all needy populations, her proposed adjustments include such populations in the decision-making process only by turning the minds of organizational officials in the direction of an impartial perspective. What about more directly seeking real input from the people who actually have the needs? One researcher, Stuart Rennie, has recently proposed a study of community attitudes toward ART rationing in the Democratic Republic of Congo (DRC).<sup>159</sup> As of 2004, only about two percent of people in the DRC who needed ART were receiving it. The DRC's national plan estimates that, at best, only sixty-nine percent of approximately 340,000 people who need ART can receive it by 2009, in part because of the exodus of skilled health care personnel (again, brain drain) and the country's devastating recent history of violent conflict.<sup>160</sup> Rationing ART will in all likelihood be inevitable in the DRC for some time.

Rennie asked MSF-Belgium headquarters for permission to interview its DRC field personnel in support of his inquiry. He reports his astonishment upon finding that MSF was unwilling to participate, due to what he portrays as an ideological rejection of the very idea of rationing. An editorial in *Developing World Bioethics* (the journal that published Rennie's critique of the position he attributes to MSF, alongside a response by MSF officials) accuses MSF of "taking some kind of pride in not having any kind of ethical resource allocation process in place."<sup>161</sup> The editorial's authors rest their accusation on two sources: first, Fuller's findings, which the authors interpret as evidence that MSF has no "uniform, transparent policies" for deciding when, where, and why to open, close, or modify its projects; second, the words of the responding MSF officials themselves, which characterize rationing as "a tactical acceptance of injustice."<sup>162</sup>

The worry expressed in MSF's stated position is that those who accept

157. Fuller, *supra* note 128, at 69.

158. *Id.* at 64-65.

159. Stuart Rennie, *Is It Ethical To Study What Ought Not To Happen?*, 6 DEVELOPING WORLD BIOETHICS 71 (2006).

160. *Id.* at 71 (citing WORLD HEALTH ORG., UNAIDS & DRC NAT'L AIDS CONTROL PROGRAM, PLAN NATIONAL D'EXTENSION DE L'ACCÈS AUX TRAITEMENTS ANTI-RÉTROVIRAUX EN RDC (2005-2009) (2005)); WORLD HEALTH ORG., '3 BY 5' PROGRESS REPORT (2004).

161. Willem A. Landman & Udo Schuklenk, *Médecins Sans Frontières Under the Spotlight*, 6 DEVELOPING WORLD BIOETHICS iii (2006).

162. *Id.* (quoting Rony Zachariah et al., *Do Aid Agencies Have an Ethical Duty To Comply with Researchers? A Response to Rennie*, 6 DEVELOPING WORLD BIOETHICS 78 (2006)).

rationing as inevitable may be indulging their own and others' complacency toward the shortfall of resources available to meet the needs of the poor:

We consider rationing as a tactical acceptance of injustice that aims to respond to imbalances by offering only limited assistance for a chosen few. Some may view this as a naïve starting point, but that is what principles aspiring for justice should be inspired by. MSF believes that a technical approach to political distortions will only refine injustice. When people die, a technique that allows discrimination between who will die fairly or unfairly doesn't seem the right answer.<sup>163</sup>

The MSF officials who take this stand against "rationing" also insist that MSF's explicitly endorsed "patient selection" policy (as employed, for instance, in the Khayelitsha project described above) is not equivalent to "rationing":

Within MSF's programmes, the medical and social criteria applied to determine who needs antiretroviral therapy are employed not as rationing criteria but as good medical practice and public health practice. Medical criteria (clinical staging, CD4 count, and viral load) are employed to ensure that only people who need to be treated are treated; social criteria . . . are used as public health provisions to avoid providing antiretroviral therapy to patients with a high probability of non-adherence and in doing so promoting drug resistance.<sup>164</sup>

However, based on a neutral definition of "rationing," MSF's "patient selection" policy is indeed a form of rationing. In economics, "rationing" refers to "any policy or practice that restricts consumption of goods."<sup>165</sup> The market rations goods by price. When demand exceeds supply for non-market goods like the ART dispensed by MSF, the consumption of the good is perforce restricted in some other way.<sup>166</sup> Any policy that applies criteria to restrict the consumption of a good, however the criteria may be regarded or conceived of by those who apply them, amounts to rationing in this neutral sense.

Terminology aside, there is a point of principle lodged against MSF by its critics. While, of course, every possible measure must be taken toward hastening the arrival of the day when scarce resources like ART are universally accessible to those in need, that day is not yet here. And even if, *per impossibile*, every effort in its direction were to meet with perfect success, it would still not be here for at least a few years.<sup>167</sup> In the interim the impossibility of offering ART to

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163. Rony Zachariah et al., *Do Aid Agencies Have an Ethical Duty To Comply with Researchers? A Response to Rennie*, 6 DEVELOPING WORLD BIOETHICS 80 (2006).

164. *Id.*

165. Sydney Rosen et al., *Hard Choices: Rationing Antiretroviral Therapy for HIV/AIDS in Africa*, 365 LANCET 354, 354 (2005) (citing JOSEPH E. STIGLITZ, *ECONOMICS OF THE PUBLIC SECTOR* (2d ed. 2004)).

166. *Id.*

167. See Rennie, *supra* note 159.

everyone who needs it would remain, and in the far-from-ideal actual world it will remain well into the foreseeable future. Fairness to people in need thus requires transparent, consistently applied policies for allocating ART, through processes of decision-making that offer accountability for reasonableness. The interests of people who need ART are poorly served by any organization that plays an important part in distributing ART among them, yet avoids the formulation and execution of policies for doing so fairly. Finally, learning more about the conceptions of fairness held by people in need is an elementary and crucial step toward developing any decision-making process, whether in government agencies or NGOs, that would be truly accountable to them.<sup>168</sup>

If it is correct to assert that the institutional culture of MSF, in many respects a laudable organization, is biased against formulating fair policies in a responsible manner, here is one way to diagnose its dysfunction. Fuller observes that “most people at headquarters have extensive field experience,” a background which makes them “extremely sympathetic” to the partial, relational perspective at the expense of the impartial, comparative perspective.<sup>169</sup> But any sound rationing policy would have to be grounded in the comparative perspective. Over-representation of the relational perspective in deliberations about large-scale resource allocation would tend, inappropriately, to duplicate at the level of headquarters the psychological propensity of field staff to shy away from the comparative perspective. Even if a bias toward the relational perspective helps individual professionals in the field to cope (however imperfectly) with the role conflicts engendered by the problem of representation, the institutional leadership ought to correct for that bias in its own policy-making rather than take up the bias and amplify it into a systematic evasion of the problem of authority.

MSF is not an isolated example. On the whole, shortfalls in institutional accountability appear to be common among humanitarian aid organizations. Rarely do these groups consult beneficiaries in evaluating the impact of their efforts.<sup>170</sup> In addition, another telling sign is the absence in the published literature of a significant body of evidence to assess, by any measure, the impact and cost-effectiveness of standard emergency interventions.<sup>171</sup> These standard

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168. Among the questions Rennie seeks to answer are: “What do affected community members find fair in regard to the allocation of this very scarce and vital medical resource? Do their conceptions of fairness in treatment access rationing differ from those of national or international authorities who will most likely have the greatest say in the matter?” *Id.* at 71-72.

169. Fuller, *supra* note 128, at 69.

170. Shannon Doocy et al., *The Delivery of Essential Humanitarian Services After the Tsunami in Aceh, Indonesia*, 4 J. EMERGENCY MGMT. 43, 44 (2006) (citing HUMANITARIAN POLICY GROUP, MEASURING THE IMPACT OF HUMANITARIAN AID: A REVIEW OF CURRENT PRACTICE (2004)).

171. ARABELLA DUFFIELD ET AL., REVIEW OF THE PUBLISHED LITERATURE FOR THE IMPACT AND COST-EFFECTIVENESS OF SIX NUTRITION RELATED EMERGENCY INTERVENTIONS (2004), available at <http://www.ennonline.net/docs/ENNCIDASFPREPORT.pdf> (reviewing published papers “to assess the impact and cost-effectiveness of six health-related emergency interventions”); Arabella Duffield et al., *Evidence Base for Interventions in Complex Emergencies*, 365 LANCET 842 (2005).



interventions, which consume large amounts of aid money, include nutritional supplementation, measles vaccination, vitamin A supplementation, and anti-malarial bed-nets.<sup>172</sup> Aid organizations, lacking an evidence base to assess the options for deploying possible interventions, are likely to persist in allocating their precious resources according to status quo policies around which they happened to build up their expertise and declared their organizational mandates, but which remain untested and unchallenged by systematic observation.<sup>173</sup> The authors of a recent report on this subject recommend the creation of “an independent body or institutional mechanism” responsible for amassing the necessary evidence base and using it to advocate improvements in practice.<sup>174</sup>

In sum, for any institutional program that undertakes to distribute basic necessities to the very poor, two fundamental ethical considerations are fairness and cost-effectiveness. Most humanitarian aid organizations, however admirable their motivations and however heroic their exertions in the field, seem to stand in need of marked improvement on both counts.<sup>175</sup> A necessary component of taking each consideration seriously is consultation with intended beneficiaries.<sup>176</sup>

### *B. Research Organizations*

Growing attention in bioethics focuses on a cluster of questions about the ethics of international medical research.<sup>177</sup> One way to frame these questions is to start with what we might call the “domestic” ethics of medical research with human participants and see what happens when we extend it to the context of

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For three out of six common emergency interventions, no published impact-assessment studies appeared, while the other three were the subject of nine, fifteen, and sixteen impact-assessment studies, respectively. With respect to cost-effectiveness, only one economic-evaluation study was published on each of only three interventions out of six. Duffield et al., *supra*, at 842-43.

172. Duffield et al., *supra* note 171, at 843.

173. *Id.*

174. *Id.*

175. Evidence and explanations for a prevailing lack of accountability in philanthropy, the genre of which humanitarian aid is a species, are offered in Editorial, *The Business of Giving*, *ECONOMIST*, Feb. 25, 2006, at 3-5.

176. A recent survey of Indonesian households displaced by the December 2004 tsunami exemplifies what might be accomplished by systematically studying the impact of humanitarian efforts, and in particular by including beneficiary consultation. Doocy et al., *supra* note 170. Other useful sources include the series of country-specific monographs produced by the Active Learning Network for Accountability and Performance in Humanitarian Action (ALNAP). See ACTIVE LEARNING NETWORK FOR ACCOUNTABILITY AND PERFORMANCE IN HUMANITARIAN ACTION, GLOBAL STUDY ON CONSULTATION WITH AND PARTICIPATION BY BENEFICIARIES AND AFFECTED POPULATIONS IN THE PROCESS OF PLANNING, MANAGING, MONITORING AND EVALUATING HUMANITARIAN ACTION (2002), available at <http://www.globalstudyparticipation.org/english/tor.htm>.

177. See, e.g., *ETHICAL ISSUES IN INTERNATIONAL BIOMEDICAL RESEARCH: A CASEBOOK* (James V. Lavery et al. eds., 2007); RUTH MACKLIN, *DOUBLE STANDARDS IN MEDICAL RESEARCH IN DEVELOPING COUNTRIES* (2004).

international research.<sup>178</sup> This Section addresses research sponsored by organizations in affluent countries to study scientific questions of import for poor populations, meaning that the social value of answering the questions under study lies in their relevance to the needs of the poor.

Among several core duties of any medical researcher working with human participants are duties to respect the participants and not to harm them in the course of the study. One question raised by the disparities in wealth, health, and health care that pervade the context of international research is whether researchers also owe various kinds of benefits to impoverished participants. We can think of the benefits in question as radiating outward in several directions from the uncontested core duties.

It is uncontroversial that researchers have a duty to provide basic medical care pertaining directly to the interaction between the medical condition under study and the intervention that the study is testing, at least for as long as the participant is enrolled in the study. But for impoverished participants whose society offers them little or no other source of medical care, do researchers also have a duty to treat conditions other than the one under study? If so, which ones and to what extent? This is the problem of *ancillary care*, and it calls for much further inquiry.<sup>179</sup> While ancillary care is primarily a matter of what should happen during an individual's study participation, another problem that needs further inquiry is what, if any, benefits participants should receive after the study (post-trial benefits).<sup>180</sup> Most centrally, if the evidence shows that participants who receive the intervention under study have benefited from it, do researchers have a duty to continue treatment for impoverished participants who have no way

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178. In the United States, ethical guidelines for research with human subjects are rooted in the Belmont Report. See NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979), available at <http://ohsr.od.nih.gov/guidelines/belmont.html>. For a systematic framework of ethical requirements that integrates the Belmont Report with leading international principles and guidelines, see Ezekiel J. Emanuel et al., *What Makes Clinical Research Ethical?*, 283 JAMA 2701 (2000) [hereinafter Emanuel, *Clinical Research*]. For an extension of this framework to the circumstances of research in low-resource settings, see Ezekiel J. Emanuel et al., *What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research*, 189 J. INFECTIOUS DISEASES 930 (2004) [hereinafter Emanuel, *Benchmarks*]. See also NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL AND POLICY ISSUES IN INTERNATIONAL RESEARCH: CLINICAL TRIALS IN DEVELOPING COUNTRIES (2001); Nuffield Council on Bioethics, *supra* note 120.

179. See Leah Belsky & Henry S. Richardson, *Medical Researchers' Ancillary Clinical Care Responsibilities*, 328 BMJ 1494 (2004); Neal Dickert et al., *Ancillary-Care Responsibilities in Observational Research: Two Cases, Two Issues*, 369 LANCET 874 (2007); Henry S. Richardson, *Gradations of Ancillary-Care Responsibility for HIV-AIDS in Developing Countries*, AM. J. PUB. HEALTH (forthcoming 2007); Henry S. Richardson & Leah Belsky, *The Ancillary-Care Responsibilities of Medical Researchers: An Ethical Framework for Thinking About the Clinical Care that Researchers Owe Their Subjects*, HASTINGS CTR. REP., Jan.-Feb. 2004, at 25.

180. Christine Grady, *The Challenge of Continued Post-Trial Access to Beneficial Treatment*, 5 YALE J. HEALTH POL'Y L. & ETHICS 425, 425-27 (2005).

of securing access to it when the study ends? If so, for how long?

Before we take up the question of obligations to provide such benefits, an issue that calls for some comment is “undue influence.”<sup>181</sup> For research in low-resource settings, one might worry that in the prevailing absence of adequate medical care, the offer of ancillary care or post-trial benefits could lead people to participate in research when, in the absence of such benefits and all else being equal, they would otherwise decline. However, it has been argued that the influence of such incentives is “undue” only if it actually distorts people’s judgment to the point that they make choices harmful to their interests.<sup>182</sup> Since no research protocol that poses excessive risks or burdens to participants ought to pass independent review, a properly reviewed study should already be such that a prudent person could reasonably choose to participate in it, whatever the additional benefits or lack thereof.<sup>183</sup> The general form of this point is that many safeguards ought to be in place throughout the research process—from study design, through independent review, to the monitoring of participants’ safety and well-being, to follow-up as needed after their participation—to assure that risks and burdens are not excessive. If any protective concern should be intensified by gaping disparities of wealth between prospective participants and the researchers who ask them to take part, it is the concern to minimize the risks and burdens of the research. When that concern receives the attention it is due, there should be no residual worry that benefits otherwise indicated by ethical considerations—especially benefits *owed* to participants—are somehow ethically suspect.<sup>184</sup>

Returning to the topic at hand, one way to argue for some duty to provide ancillary care or post-trial benefits might be to invoke global justice.<sup>185</sup> When medical research in severely impoverished populations is sponsored by agencies in wealthy countries, it may seem that research sponsors, if not scientists themselves, have an obligation of justice to provide such further benefits, as a gesture toward redressing the vast resource inequalities that their very presence

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181. The U.S. federal regulations governing research with human subjects address this topic under the heading of informed consent. 45 C.F.R. § 46.116 (2006) (“An investigator shall seek . . . [informed] consent only under circumstances that provide the prospective subject . . . opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.”).

182. Ezekiel J. Emanuel, *Ending Concerns About Undue Inducement*, 32 J.L. MED. & ETHICS 100, 101 (2004).

183. *Id.* at 104.

184. A kindred set of worries involves research in low-resource settings that is undertaken not for the benefit of the poor, but in order to develop treatments for people in the affluent world. There are important reasons to question the ethical legitimacy of recruiting members of medically deprived populations to participate in such research, even if risks and dangers are minimized and the actual risk/benefit profile would in itself make participation reasonable. See Jennifer S. Hawkins, *Justice and Placebo Controls*, 32 SOC. THEORY & PRAC. 467 (2006).

185. See generally Alex John London, *Justice and the Human Development Approach to International Research*, HASTINGS CENTER REP., Jan.-Feb. 2005, at 24 (arguing that global justice is the key to a comprehensive re-conception of the ethics of international research).

in the host country makes embarrassingly obvious. But appeals to global justice might just as well support a policy of curtailing further benefits: Scientifically valid clinical research on questions important to poor populations is urgently needed, and resources for conducting such research are limited (especially when a commercial profit motive is absent). Arguably, so far as global justice is concerned, scientists and research sponsors ought to focus their resources on doing research and leave social welfare to others.<sup>186</sup>

As a supplement or alternative to invoking global justice, it is illuminating to examine researchers' and sponsors' obligations to research participants through the lens of institutional ethics. To begin with, consider more closely the relationship between researchers and their institutional sponsors, and the relationship of both to research participants. Scientists who conduct medical research in low-resource settings are acting, in part, in the role of agents representing their sponsors. Producing generalizable knowledge through scientific inquiry is typically the sponsor's chief objective in funding the researcher's work. At the same time, the social value of the expected scientific results supplies part of the ethical rationale for researchers' coming into medically intimate contact with participants.<sup>187</sup> Even when sponsors and researchers intend the social value of their scientific results to accrue mainly to the poor, the way in which they expect this to come about is through the generalizability of their results to populations beyond the one immediately under study. Thus the researchers, not only in pursuing their own projects, but also by acting on behalf of their sponsors, are asking participants to take on the risks and burdens of research *in the service of other people*. It is this feature of any researcher-participant relationship that engenders the researcher's distinctive professional obligation not to disregard the participant's well-being.<sup>188</sup> Since the sponsoring institution is a party to putting the researcher (as its representative and agent) in this situation, the sponsoring institution is also, in some sense, a party to the obligations that arise from the researcher's professional relationship with participants.

In the context of research with participants in low-resource settings, due regard for their well-being raises the problem of responding to at least some aspects of their medical needs, which, in more comfortable circumstances, the researcher could simply address through referral to existing services. A case in point is the question of providing post-trial access in ART trials for impoverished study participants who have benefited from ART during the study, but cannot

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186. At most, on this view, global justice requires researchers to propose scientific questions whose answers will have value for poor populations, to conduct scientifically valid research, to publicize their results, and perhaps to press for the incorporation of their findings into equitable national and global health policy.

187. See Emanuel, *Clinical Research*, *supra* note 178; Emanuel, *Benchmarks* (2004), *supra* note 178.

188. Maria Merritt, *Moral Conflict in Clinical Trials*, 115 *ETHICS* 306, 312, 322 (2005).

afford to secure access to it afterward. Recent policy guidance from the NIH encourages sponsored researchers who foresee these circumstances to coordinate plans ahead of time with host-country agencies, so that trial participants can secure ART through local treatment sites supported by international aid programs like the Global Fund.<sup>189</sup> This policy guidance seems to be a good-faith attempt to treat the Global Fund and similar programs as “existing services,” to the end of acknowledging researchers’ professional obligation not to disregard the well-being of their participants. Researchers’ home organizations (for example, their university institutional review boards) and other sponsoring agencies might well like to encourage compliance with the NIH policy guidance on post-trial ART, as a solution to one instance of the “problem of representation.”<sup>190</sup> Such encouragement is a convenient and low-cost expression of institutional support for researchers who feel obligated to assure participants of post-trial ART. It relieves researchers of worries about incurring this professional obligation in the absence of an institutionally endorsed means of fulfilling it.

But even if the NIH policy guidance for post-trial ART does solve the problem of representation, it does so only at the cost of exacerbating the “problem of authority.”<sup>191</sup> What raises the problem of authority is a severe shortage of ART, which requires rationing among those in urgent need. This same shortage is what originally made the host country a good candidate for international aid from programs like the Global Fund.<sup>192</sup> To pursue special arrangements as encouraged by the NIH policy guidance could be, in effect, to request that ART trial participants be offered special priority for access to ART at the expense of other similarly needy compatriots.<sup>193</sup> But legitimate justifications for rationing the resources of international aid programs in low-resource settings must extend beyond special relationships like the researcher-participant relationship. As we saw above, the reasons given for the priorities set in rationing must be justifiable even to the people who lose out.<sup>194</sup> It is of questionable legitimacy to appeal to the special researcher-participant relationship to justify asking research participants’ similarly needy compatriots, who may not have had the opportunity to participate in ART trials, to postpone or give up their own chance at access to ART in deference to participants.<sup>195</sup> More generally, as a rule, no foreign research sponsor has legitimate authority to direct

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189. NAT’L INST. OF HEALTH, GUIDANCE FOR ADDRESSING THE PROVISION OF ANTIRETROVIRAL TREATMENT FOR TRIAL PARTICIPANTS FOLLOWING THEIR COMPLETION OF NIH-FUNDED HIV ANTIRETROVIRAL TREATMENT TRIALS IN DEVELOPING COUNTRIES (2005), *available at* <http://grants.nih.gov/grants/policy/antiretroviral>.

190. THOMPSON, *supra* note 125.

191. *Id.*

192. See Rosen et al., *supra* note 165.

193. See Maria Merritt & Christine Grady, *Reciprocity and Post-Trial Access for ART Trial Participants*, 20 AIDS 1791 (2006).

194. See *supra* note 89 and accompanying text.

195. Merritt & Grady, *supra* note 193.

the allocation of scarce resources within the host country.

On the other side, host-country authorities responsible for setting priorities, who are ideally supposed to represent the entire constituency of people who need ART as regarded from an impartial perspective, may be tempted by the attractions of hosting externally sponsored research to short-circuit the deliberative process unfairly. While it is possible that ART trial participants as a group might be assigned priority in ART rationing through a fair deliberative process, it can hardly be taken for granted that this would be the outcome of an actual deliberative process, and in any given setting there may be no such process or fairly decided set of priorities yet in place.

A promising alternative is to re-conceptualize any obligation to assure participants of post-trial care, such that the obligation includes off-setting the local health-system impacts of providing such care.<sup>196</sup> This would modify the content of researchers' professional obligations, and the content of their sponsors' supporting institutional policy, to register the complexities of institutional ethics for research in low-resource settings. A sponsor ought to set policy informed by the professional obligations that researchers incur while acting as its agents, but a sponsor also ought to be constrained by boundaries proper to its relationship with other institutions, such as international aid agencies and the government of the host country.<sup>197</sup>

## CONCLUSION

As population-level bioethics rightly gains currency, critical reflection on the obligations of individuals, both as ordinary persons and as the occupants of institutional roles, continues to be warranted. Considering the actions open to individuals from the standpoint of their foreseeable impact on the health of the world's poor, what emerges is the importance of consultation and partnership with intended beneficiaries, together with concern to mitigate the consequences for others who may also be affected.

The tacit assumption in the background of this discussion has been that the affluent, in aggregate, still care too little about the poor. It does not follow,

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196. This is a slight modification of a suggestion originally made by Henry S. Richardson. Richardson, *supra* note 179 (manuscript at 2) ("If those who sponsor and carry out medical research have a responsibility to provide ART to trial participants, this can be conceived as an obligation to take the steps necessary to increase the overall availability of ART and skilled personnel in the country or countries hosting the research, if only for the benefit of their trial participants. By so conceiving it, we may sidestep the difficult issues that would arise if trial participants were to be seen as competing with their co-nationals for priority in access to a fixed supply of anti-retrovirals or medical professionals.").

197. In the case of post-trial ART, one means of satisfying both demands is for the research sponsor to negotiate parallel funding mechanisms, through partnerships with private donors and NGOs. See, e.g., Jintanat Ananworanich et al., *Creation of a Drug Fund for Post-Clinical Trial Access to Antiretrovirals*, 364 LANCET 101 (2004).

however, that simply caring more would be better. Clumsy attention can be worse than none at all. An insidious impediment to making our attention properly sensitive is indulgence (even if unwitting) in fantasy that portrays the poor as passive victims awaiting rescue, where we as benefactors play the starring role. We, the affluent, will do better to consider in a spirit of self-effacement the kind and degree of assistance we owe to the poor. Ideally, the aid and scientific research that we sponsor should proceed hand-in-hand with in-country training of professionals, incentives to keep trained professionals there, and context-specific health-systems operations research, all directed toward the goal of building self-sufficient health-system capacity on a scale commensurate with the size of populations in need.<sup>198</sup> This is part of what it would take not only to meet the needs of the poor, but also to raise and hold global standards of living above poverty.

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198. NUFFIELD COUNCIL ON BIOETHICS, *supra* note 120; LYNN. P. FREEDMAN ET AL., UN MILLENNIUM PROJECT TASK FORCE ON CHILD HEALTH & MATERNAL HEALTH, WHO'S GOT THE POWER? TRANSFORMING HEALTH SYSTEMS FOR WOMEN AND CHILDREN 22 (2005); Brian W. Simpson, *If We Don't Do it, Then Who?* JOHNS HOPKINS PUB. HEALTH MAG., Spring 2006, at 24.





# A Human Rights Approach to Routine Provider-Initiated HIV Testing

Rahul Rajkumar\*

## INTRODUCTION

This Article describes the ethical, legal and public health implications of routine HIV testing—that is, testing such that individuals receive a routine offer of an HIV test whenever they come into contact with the health care system. In recent months, the consensus in favor of voluntary testing has yielded to a debate over whether efforts to curb the spread of HIV and to treat individual patients themselves would benefit from health care providers initiating testing.

This Article first describes the history of HIV testing policy in the United States and internationally. It outlines the arguments in favor of routine provider-initiated testing and responds to objections that have been raised in the literature. Finally, it describes a proposal for an ethical routine testing regime that is consistent with human rights principles as well as U.S. and international statutes and case law on testing. This Article also proposes model legislation that addresses the issues of counseling, confidentiality, and informed consent in the context of routine-offer HIV testing.

HIV, the virus that causes AIDS, has spread to every region of the world.<sup>1</sup> There are now nearly forty million people living with HIV. In 2006 alone, some 4.3 million people became infected with HIV and nearly three million people died of AIDS.<sup>2</sup> AIDS is a leading cause of adult death in many developing countries.<sup>3</sup>

As a result of HIV/AIDS, average life expectancy in some African countries, which had been rising consistently over the past fifty years, has fallen by twenty years or more.<sup>4</sup> AIDS also continues to devastate the civil societies and economies of poor nations. The disease has orphaned an estimated twelve million children in sub-Saharan Africa and has decimated the ranks of teachers, health

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1. UNAIDS, 2006 AIDS EPIDEMIC UPDATE 1-2 (2006).

2. *Id.*

3. *Id.*

4. UNAIDS, 2004 REPORT ON THE GLOBAL AIDS EPIDEMIC 43 fig.13 (2004).

care workers, and civil servants.<sup>5</sup> A 2003 study by the World Bank predicts that South Africa—the nation with the largest number of AIDS cases, with a prevalence that may be as high as 26.5% of the adult population—will face “complete economic collapse” within three generations if the country does not take effective measures to combat AIDS.<sup>6</sup> By any objective measure—lives lost, children orphaned or GDP growth unrealized—the AIDS epidemic has been and continues to be a global catastrophe.

A crucial—but so far uncelebrated—strategy to curb the spread of AIDS is expanding HIV testing such that all individuals receive a routine offer of an HIV test whenever they come into contact with the health care system. This Article argues in favor of routine provider-initiated testing. Specifically, I argue that the benefits of routine provider-initiated HIV testing, both for individual patients and for the public health, weigh heavily in favor of shifting to routine testing, provided that certain conditions are met. Routine testing must be coupled with a promise of antiretroviral (ARV) treatment for those who test positive and meet the clinical criteria for treatment. Moreover, routine testing must be coupled with a guarantee of confidentiality and a rigorous standard for informed consent. If these conditions are met, it is possible to design a fair, equitable, and non-coercive testing regime that protects the human rights principles of autonomy, confidentiality, and voluntariness.

## I. BACKGROUND AND LIMITATIONS

### *A. The Consequences of Untreated HIV Infection*

HIV specifically targets CD4+ T-cells, a type of white blood cell that helps to organize and coordinate the body’s immune response against infections. HIV weakens the body’s immune system until it can no longer resist infections, leaving it vulnerable to many types of pneumonia, diarrhea, tumors, and other illnesses that would pose no threat to uninfected individuals. The opportunistic infections common among AIDS patients are known as “AIDS defining illnesses.”<sup>7</sup>

A patient’s “CD4+ count”—the number of CD4+ T-cells per unit of blood—is a useful measure of disease progression in HIV infection. A normal adult has a CD4+ count of 500 to 1500 cells per cubic millimeter of blood. AIDS is defined as a CD4+ count of less than 200, or a CD4+ count higher than 200 if the

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5. *Id.* at 61.

6. WORLD BANK, THE LONG-RUN ECONOMIC COSTS OF AIDS: THEORY AND APPLICATION TO SOUTH AFRICA 3 (C. Bell et. al. eds., 2003), available at [http://www1.worldbank.org/hiv\\_aids/docs/BeDeGe\\_BP\\_total2.pdf](http://www1.worldbank.org/hiv_aids/docs/BeDeGe_BP_total2.pdf); Press Release, Sibani Mngadi, Spokesperson, S. Afr. Minister of Health, HIV Prevalence in South Africa (July 3, 2003), available at <http://www.doh.gov.za/docs/pr/2003/pr0703.html>.

7. *Id.*

individual has an AIDS defining illness.<sup>8</sup> The length of time between infection with HIV and progression to AIDS varies considerably among individuals. However, most HIV-infected individuals will develop AIDS, and all of these individuals will die without treatment. The average life expectancy for an untreated HIV-infected patient between the age of twenty-five and thirty-four is approximately ten years.<sup>9</sup>

### *B. The Possibility of Mass-Scale Treatment*

The arrival of Highly Active ARV Therapy (HAART) in 1996 radically altered the natural progression of HIV infection in the United States and in Europe.<sup>10</sup> HAART is a combination of several ARV drugs that is used to treat HIV by inhibiting different parts of the life cycle of HIV. HAART is responsible for a decrease in the incidence of AIDS, opportunistic infections, and AIDS-related mortality by 60% to 80% in the United States.<sup>11</sup> The number of deaths attributed to AIDS in the United States decreased from 48,371 in 1995,<sup>12</sup> to 16,316 in 2005, according to a review of data from death certificates by the CDC.<sup>13</sup> Other studies have demonstrated that a patient's probability of surviving for at least twenty-four months following a clinical diagnosis of AIDS based on a CD4+ count of less than 200 cells per cubic millimeter of blood increases dramatically with HAART.<sup>14</sup> It is important to note that many of the deaths reported in these studies occurred in patients who had already developed clinical AIDS before they had access to HAART.<sup>15</sup> The weight of the clinical and

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8. Kenneth G. Castro et al., *1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults*, MORBIDITY & MORTALITY WKLY. REP., Dec. 18, 1992, at RR-17, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm>.

9. Collaborative Group on AIDS Incubation and HIV Survival, *Time from HIV-1 Seroconversion to AIDS and Death Before Widespread Use of Highly-Active ARV Therapy: A Collaborative Re-Analysis*, 355 LANCET 1131, 1134 tbl.2 (2000); see generally George W. Rutherford et al., *Course of HIV-1 Infection in a Cohort of Homosexual and Bisexual Men: An 11 Year Follow Up Study*, 301 BMJ 1183 (1990) (describing the natural history of HIV infection in an eleven-year follow up study of a cohort of homosexual and bisexual men).

10. See A. Mocroft et al., *Decline in the AIDS and Death Rates in the EuroSIDA Study: An Observational Study*, 362 LANCET 22, 24-27 (2003).

11. John G. Bartlett, *The Stages and Natural History of HIV Infection*, [Version 15.1] UpToDate ¶ 4 (Aug. 11, 2006).

12. Ctrs. for Disease Control & Prevention, 9 HIV-AIDS SURVEILLANCE REP. 1, 20 (1997), available at <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/pdf/hivsur92.pdf>.

13. Ctrs. for Disease Control & Prevention, 17 HIV-AIDS SURVEILLANCE REP. 1 (2005), available at <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/2005report/pdf/2005SurveillanceReport.pdf>.

14. See, e.g., Matthias Egger et al., *Prognosis of HIV-1 Infected Patients Starting HAART: A Collaborative Analysis of Prospective Studies*, 360 LANCET 119 (2002) (summarizing data on improved survival with the advent of HAART).

15. *Id.*

scientific evidence suggests that clinical AIDS can be averted altogether in HIV-infected individuals if they begin ARV treatment early and are followed closely enough.<sup>16</sup>

Until recently, it appeared that the citizens of resource-poor countries in Africa, Asia, and Latin America would not see the benefits of ARV therapy. During the early stages of the treatment era, many international donors and public health authorities constructed a dichotomy between prevention and treatment, and withheld treatment from poorer populations in favor of prevention-only strategies to combat the AIDS epidemic. Particular notions about Africans and other inhabitants of less developed countries, their perceived inability to comply with complicated treatment regimens, and the literature on cost-effectiveness all fueled this approach to confronting the epidemic. The weight of criticism from treatment activists and the governments of poor countries during the late 1990s largely eroded this dichotomy between prevention and treatment in the public discourse on the AIDS pandemic.

While the provision of adequate treatment for millions of HIV-positive individuals in poor countries is still far from reality, there now appears to be a greater political commitment to treat HIV in resource-poor countries. This political commitment has been justified in both moral and economic terms. There is an overwhelming need to prolong millions of productive lives in developing countries so as to prevent economic collapse, keep families intact, and prevent millions of children from being orphaned. ARV agents both lower viral load, which reduces HIV transmission, and reduce maternal-to-child transmission of HIV. Expanded access to treatment will improve the morale and performance of health care workers. Treatment will lessen AIDS-related stigma and mobilize communities to develop more effective AIDS policies.

Western governments have committed significant resources to attempt to treat HIV in the developing world. In 2003, the World Health Organization (WHO) publicly declared that it would pursue an approach to AIDS control that combines treatment and prevention, and committed to treating three million people in developing nations with ARV therapy by the end of 2005.<sup>17</sup> In January

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16. See generally Felipe Garcia et al., *Long-Term CD4+ T-Cell Response to Highly Active ARV Therapy According to Baseline CD4+ T-Cell Count*, 36 J. ACQUIRED IMMUNE DEFICIENCY SYNDROME 702 (2004) (describing the results of an observational study of the long term CD4+ cell response to HAART); Roy M. Gulick et al., *Six-Year Follow-Up of HIV-1-Infected Adults in a Clinical Trial of ARV Therapy with Indinavir, Zidovudine, and Lamivudine*, 17 AIDS 2345 (2003) (reporting the results of a randomized trial finding that ARV therapy with indinavir, zidovudine, and lamivudine suppressed HIV viremia and produced continued CD4 cell increases in a majority of subjects for six years); Gilbert R. Kaufmann et al., *CD4 T-Lymphocyte Recovery in Individuals with Advanced HIV-1 Infection Receiving Potent ARV Therapy for 4 Years: The Swiss HIV Cohort Study*, 163 ARCHIVES INTERNAL MED. 2187 (2003) (reporting the results of a longitudinal cohort study of CD4+ counts in Swiss subjects receiving HAART).

17. Lawrence K. Altman, *W.H.O. Declaring Crisis, Plans a Big Push With AIDS Drugs*, N.Y. TIMES, Sept. 22, 2003, at A5.

of 2003, the United States signaled a major shift in its thinking on the global AIDS pandemic when President Bush pledged to spend \$15 billion over five years to treat HIV in the most afflicted nations of Africa and the Caribbean.<sup>18</sup> Whatever the reasoning behind them, these massive treatment initiatives all depend on identifying HIV-positive individuals, and therefore they depend on an equally massive effort to expand access to testing for HIV.

### *C. HIV Testing and Treatment*

During the early days of the global AIDS epidemic, there was a broad international consensus that all HIV testing should be not only confidential, accompanied by counseling, and based on informed consent, but also that health care providers should only test individuals on a voluntary basis.<sup>19</sup> This consensus emerged during a period when there was no treatment for HIV. Recognizing that HIV-positive individuals faced considerable stigma and discrimination, it was reasoned that the potential costs of a positive test result for an individual might outweigh the benefit to the individual.

ARV therapy for HIV has fundamentally changed this calculus, as some public health authorities now view the lack of widespread HIV testing in the general population as a barrier to treatment. Twenty-five percent of the nearly one million HIV-positive individuals in the United States are thought to be unaware of their status.<sup>20</sup> As a result, the consensus behind the strict commitment to voluntary testing has steadily eroded. According to one author writing in a prominent medical journal, "Increasingly, the challenge for the health care community is not how to prevent progression of HIV disease in a person with known infection, but, rather, is how to identify persons who are unknowingly infected with HIV."<sup>21</sup> At the same time, there has been significant opposition to routine provider-initiated testing from the human rights community. Some have argued that routine-offer testing compromises human rights principles and is potentially coercive and paternalistic—and, rather than expanding testing programs, we should instead aim to create a "climate in which people *want* to know their HIV status and *trust* health care providers to provide them both that information and concomitant support."<sup>22</sup>

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18. George W. Bush, Pres. of the U.S., 2003 State of the Union Address (Jan. 28, 2003).

19. Renslow D. Sherer, *Physician Use of the HIV Antibody Test: The Need for Consent, Counseling, Confidentiality, and Caution*, 259 JAMA 264, 264-65 (1988).

20. Patricia L. Fleming et al., Abstract, HIV Prevalence in the United States, 2000, Program and Abstracts of the 9th Conference on Retroviruses and Opportunistic Infections (Feb. 25, 2002), available at <http://www.retroconference.org/2002/abstract/13996.htm>.

21. Curt G. Beckwith et al., *It Is Time To Implement Routine, Not Risk-Based, HIV Testing*, 40 CLINICAL INFECTIOUS DISEASES 1037, 1039 (2005).

22. Mary Crewe & Frans Viljoen, *Routine HIV Testing: A Challenge to Human Rights* 17 (Feb. 14, 2005) (unpublished manuscript, on file with author).

This Article argues in favor of a policy of routine provider-initiated testing—coupled with the promise of ARV treatment for those who test positive and meet clinical criteria for treatment. Specifically, I argue that we should not think of legal and ethical concerns as barriers to expanded testing. Rather, these considerations will assist us in creating a fair, equitable, and non-coercive testing regime that will more fully realize the end goal of testing itself: bringing more individuals into treatment programs. The legal and ethical considerations of informed consent, confidentiality, and voluntariness can all work to reinforce public health goals, as people who understand testing and who are given a sense of agency over their own health care are more likely to act on a positive HIV test result.

#### *D. Limitations of This Article*

This Article is limited in at least two significant ways. As I have described, in the early years of the AIDS epidemic, policy makers constructed a dichotomy between rich countries and poor countries. As a result, treatment was available for those who were fortunate enough to live in Europe or North America, but denied to those who were unfortunate enough to live in Africa or South Asia. This Article deliberately avoids creating a new dichotomy between settings where routine testing may be “culturally feasible” and settings in which it may be “culturally infeasible.” Rather, it attempts to develop an argument for routine testing, based on certain conditions that must be met, that can be generalized across settings. Given that the impact of HIV/AIDS promises to be so profoundly catastrophic in resource-poor settings such as Africa and South Asia, it is especially important that these regions move toward routine provider-initiated testing coupled with treatment. However, there are relatively few studies of the uptake, impact, and consequences of routine testing in resource-poor settings. This Article relies mainly on data from the United States to substantiate most of its empirical claims.

Second, while cultural considerations should not impact the decision to implement routine testing—just as they should not impact the decision to provide ARV treatment—such considerations may significantly impact the manner in which routine testing is implemented. To the extent that culture is relevant, other technical considerations are relevant too. For example, how often should tests be offered and what specific type of HIV test should be used? These questions are beyond the scope of this Article. My purpose is only to set out the case for routine testing, to address the arguments against routine testing and, finally, to describe the requirements for a testing regime that is consistent with human rights principles.

## II. A BRIEF HISTORY OF HIV TESTING POLICY

Before discussing the history of HIV testing policy, it is useful to clarify the

terminology used in this Article, as this is a source of considerable confusion in both the medical and legal literature. Voluntary counseling and testing (VCT), the dominant testing paradigm in both the United States and in most resource-poor settings, describes a system in which health care providers make testing available but do not offer an HIV test to patients routinely.<sup>23</sup> Rather, individuals must consciously seek out an HIV test. This mode of testing is also referred to as patient-initiated or opt-in testing.

At the other extreme, mandatory testing describes a type of screening, either for certain groups of patients or for patients in the general population, in which the patients themselves are required to submit to testing either by law or as a condition for receiving health care services. Examples of mandatory testing programs include those initiated by the Government of Zambia for all new military recruits in that country as a condition for military service,<sup>24</sup> or those implemented in New York and Connecticut for all newborn children whose mothers were not tested for HIV during pregnancy.<sup>25</sup>

Routine testing differs from both of the above models in that health care providers themselves may initiate a discussion on HIV testing with individuals who come into contact with the health care system. Under this model, the health care provider offers the patient a choice between proceeding with an HIV test and opting out of a test. This mode of testing, also referred to as provider-initiated, opt-out, or routine voluntary testing, is the norm for several subgroups in the United States: pregnant women, patients presenting at sexually-transmitted disease clinics, and other patients in high HIV prevalence areas.<sup>26</sup> Routine testing is “voluntary” in the sense that individuals must give informed consent before being tested; they are protected by guarantees of confidentiality and counseling; and they remain free to refuse testing. So as to avoid confusion, this paper will use the term “routine provider-initiated testing” or “routine testing” to refer to this mode of testing.<sup>27</sup>

23. PHILLIP NIEBURG ET AL., CTR. FOR STRATEGIC & INT’L STUDIES, EXPANDED HIV TESTING 5-6 (2005) [hereinafter CSIS REPORT], available at <http://usinfo.state.gov/gi/img/assets/5096/expandedhivtesting.pdf>.

24. Zarina Geloo, *Zambia in a Quagmire over AIDS Testing*, MAIL & GUARDIAN (Johannesburg), Sept. 16, 2004.

25. Ctrs. for Disease Control & Prevention, *HIV Testing Among Pregnant Women—United States and Canada, 1998-2001*, 51 MORBIDITY & MORTALITY WKLY. REP. 1013, 1014-15 (2002).

26. Beckwith et al., *supra* note 21, at 1038.

27. Yet another testing modality, distinct from the routine testing proposal presented in this Article, would be required routine testing, which is similar to the “required request” laws that are in place in at least forty-two U.S. states and require hospitals to have procedures to tell families about organ donation. American Heart Association, Organ Donation, <http://www.americanheart.org/presenter.jhtml?identifier=4697> (last visited May 3, 2007). Currently, HIV testing strategy is implemented through guidelines promulgated by “expert” bodies such as the CDC and the WHO. Because there is still much to understand about the practical aspects of routine testing for HIV, I opt in this Article against recommending required routine testing. Rather, routine testing should be coupled with a program for systematic data gathering—

It is important to note that many authors conflate the terms mandatory and routine provider-initiated testing. Consider, for example, this excerpt from a 1989 article in the *Villanova Law Review*: “This article argues that routine testing of patients entering a health care institution is of little benefit in protecting health care workers. Furthermore, testing of blood without the consent of the patient greatly compromises the patient’s rights and is neither legally nor morally defensible.”<sup>28</sup> The author uses the term routine testing but directs his argument against mandatory testing. Routine testing does not mean testing without a patient’s consent—it only means that the health care provider, rather than the patient, may initiate a conversation on testing.

Lastly, all of the above testing modalities—voluntary, mandatory, and routine provider-initiated—describe HIV screening strategies either for the general population or for certain subgroups of individuals. This is distinct from diagnostic HIV testing, which describes a situation in which a patient presents to a health care facility with symptoms of HIV infection. In such cases, it is widely expected that HIV testing can and should become a routine part of a patient’s diagnostic evaluation. Diagnostic HIV testing is not at issue in this Article.

Because all of the testing modalities described above permit diagnostic testing for individuals who exhibit the symptoms of HIV infection, any shift to routine testing will have implications primarily for asymptomatic individuals. This Article recommends a policy shift toward routine testing for asymptomatic individuals in the general population whenever they come into contact with the health care system. This includes but is not limited to routine clinic visits, prenatal care, visitations to hospital emergency departments, and hospital admissions.

#### *A. HIV Testing During the Early Years of the Epidemic*

In June 1987, then Vice President George H.W. Bush delivered a speech in which he discussed making HIV testing routine.<sup>29</sup> He was booed during the speech, which was felt by many AIDS activists and civil rights groups to reflect an insensitive response to the epidemic.<sup>30</sup> The Reagan-Bush administration scuttled the idea and, soon thereafter, state and local governments passed laws that recognized the special nature of HIV testing. These laws required patients to sign separate and extraordinarily detailed informed consent documents before they could be tested for HIV.<sup>31</sup>

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and the testing policy must remain agile enough to respond to the results of this information.

28. Barry R. Furrow, *AIDS and the Health care Provider: The Argument for Voluntary HIV Testing*, 34 VILL. L. REV. 823, 828 (1989).

29. Marlene Cimon & Harry Nelson, *Bush Is Booed As He Defends AIDS Proposals*, L.A. TIMES, June 2, 1987, at 1.

30. Mark D. Wagner, *Back to Basics: Making HIV Testing Routine*, 9 IAPAC MONTHLY 187, 187 (2003).

31. *Id.*



The rationale behind voluntary HIV testing with detailed informed consent was rooted in the idea that a diagnosis of HIV infection is somehow exceptional. Unlike a diagnosis for diabetes or hypertension, a diagnosis of HIV was surrounded by an aura of stigma, discrimination, and fear. During the early years of the AIDS epidemic, a positive test result could result not only in psychological and emotional hardship, but financial, occupational, and legal hardship as well—and there were few available treatment options.<sup>32</sup> Further, it was thought that routine—and potentially coercive—testing without the possibility of treatment would not aid prevention efforts in that it would only drive HIV-positive individuals away from the health care system. It is useful to consider a few examples that reflect the enormous potential cost of HIV testing to individuals.

As Ronald Bayer describes in *Private Acts, Social Consequences: AIDS and the Politics of Public Health*, HIV-positive individuals and AIDS patients suffered from overt discrimination in employment, housing, obtaining health insurance, and accessing health care services.<sup>33</sup> A representative for National Gay Rights Advocates explained his fears to a *Los Angeles Times* reporter in 1987: “All those who test positive are going to get their insurance canceled and go on Medicaid, possibly lose their jobs, their apartment.”<sup>34</sup>

One 1988 survey reported that between one in four and one in five people in the United States “believe that those with AIDS should be excluded from working with them, attending school with their children, and living in their neighborhoods.”<sup>35</sup> Internationally, many countries officially outlawed people with HIV or members of high-risk social groups like commercial sex workers and homosexuals.<sup>36</sup> As Barry Furrow suggests in his article, the U.S. public merged its fears of the AIDS epidemic with negative attitudes toward high-risk groups such as homosexuals.<sup>37</sup> Violence against homosexuals in the United States escalated from 4946 incidents in 1986, to 7008 incidents in 1987.<sup>38</sup>

This report by a physician, excerpted from an article published in 1988 in the *Journal of the American Medical Association*, describes some of these effects:

In 1985, I was the primary physician for a young man whose life was ruined by the inappropriate disclosure of a positive human immunodeficiency virus (HIV)-antibody test. A physician ordered the test without consent and notified

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32. See David J. Casarett & John D. Lantos, *Have We Treated AIDS Too Well? Rationing and the Future of AIDS Exceptionalism*, 128 ANNALS INTERNAL MED. 756, 756-59 (1998).

33. RONALD BAYER, *PRIVATE ACTS, SOCIAL CONSEQUENCES: AIDS AND THE POLITICS OF PUBLIC HEALTH* 101-36 (1989).

34. Lynn Simross, *AIDS, Politics: Seeking a Safe Stand*, L.A. TIMES, June 3, 1987, at 1.

35. Robert J. Blendon & Karen Donelan, *Discrimination Against People With AIDS: The Public's Perspective*, 19 NEW ENG. J. MED. 1022, 1026 (1988); see also Furrow, *supra* note 28, at 830 (describing the reasons that policy makers initially favored a policy of voluntary testing for HIV).

36. LAURIE GARRETT, *THE COMING PLAGUE* 457-77 (1994).

37. Furrow, *supra* note 28, at 830.

38. Blendon & Donelan, *supra* note 35, at 1023.

the local health department of the positive result. The health department notified the individual's employer and he was promptly fired. These events became common knowledge at his workplace and in his rural Midwestern town and he was shunned. His landlord asked him to move. Ten days after testing, the life he had known for the past ten years was permanently ruined and he left town. With the loss of his job came loss of health insurance and insurability; he has been unable to obtain health or life insurance since then.<sup>39</sup>

Moreover, during the early years of the epidemic, some physicians and health care workers themselves reinforced these fears by calling for mandatory HIV testing of patients as a condition for receiving medical services. While these calls were soundly rejected by policy makers, there is evidence that at least some hospitals implemented de facto mandatory testing programs. One study published in the *Journal of the American Medical Association* in 1988 concluded that about 80% of HIV tests carried out in a hospital in Minnesota were performed without justification or patient consent.<sup>40</sup>

A full accounting of the sufferings of HIV-positive individuals during the early years of the AIDS epidemic is beyond the scope of this Article. It should suffice to say that HIV-positive individuals held a well-founded fear of discrimination, prejudice, and violence—and it was in the context of this social environment that policy makers chose to emphasize voluntary counseling and testing for HIV.

### *B. A Shifting Paradigm*

In a 1993 article in the *South African Journal on Human Rights*, Australian High Court Judge Michael Kirby described the “AIDS paradox,” which encapsulates the basic rationale for voluntary testing:

[O]ne of the most effective laws we can offer to combat the spread of HIV . . . is the protection of persons living with AIDS, and those about them, from discrimination. This is a paradox because the community expects laws to protect the uninfected from the infected. Yet, at least at this stage of this epidemic, we must protect the infected too.<sup>41</sup>

According to this view, voluntary testing is necessary not only because it protects HIV-positive individuals, but also because protecting HIV-positive individuals itself is the most effective strategy to combat the AIDS epidemic.

This is not an uncontroversial assertion. The traditional public health approach to combating an epidemic necessarily involves widespread routine

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39. Sherer, *supra* note 19, at 264.

40. Keith Henry et al., *Analysis of the Use of HIV Antibody Testing in a Minnesota Hospital*, 259 JAMA 229, 231 tbl.5 (1988).

41. Michael Kirby, *AIDS and the Law*, 9 S. AFR. J. ON HUM. RTS. 1, 3-4 (1993).

testing to protect the uninfected from the infected.<sup>42</sup> In the case of HIV testing policy, these two goals—protecting HIV-positive individuals and protecting HIV-negative individuals—can be in tension with one another. Those concerned with protecting HIV-positive individuals focus on the costs of HIV testing to individuals and adopt the defensive model of voluntary testing. In contrast, the impulse of many public health experts to prioritize protecting HIV-negative individuals may lead them to favor a more standard public health approach of routine provider-initiated testing, even if this means accepting the dangers attendant with this approach. Because the proponents of voluntary testing have thus far prevailed in policy debates over HIV testing, the goal of protecting HIV-negative individuals through expanded testing and counseling has, in the view of some public health experts, been subordinated to the goal of protecting HIV-positive individuals.

However, even in these early debates, some proponents of voluntary testing recognized that, if a treatment or a vaccine for HIV were developed, the balance between these two priorities might shift in favor of expanded routine provider-initiated testing.<sup>43</sup> With the availability of ARV treatment for HIV, this now appears to be happening. The most recent UNAIDS/WHO guidelines on HIV testing published in June 2004 nominally support voluntary testing.<sup>44</sup> This has unfortunately contributed greatly to the confusion between voluntary and routine-provider initiated testing, as these guidelines also call for an expansion of routine testing for patients in sexually transmitted disease clinics, pregnant women, and in clinical settings where HIV is prevalent and ARV therapy is available.<sup>45</sup> The last part of this statement essentially calls for a shift to routine provider-initiated testing for individuals in the general population, provided that testing is coupled with treatment.

These changes mirror statements that the WHO has published more recently. For example, the 2004 guidelines themselves include the following introductory statement:

In many low and middle income countries, the primary model for HIV testing has been the provision of client-initiated voluntary counselling and testing services. Increasingly, provider-initiated approaches in clinical settings are being promoted, i.e. health care providers routinely initiating an offer of HIV testing in a context in which the provision of, or referral to, effective prevention and treatment services is assured. To reach people in need of treatment, tens of millions of tests will have to be conducted among those who may have been

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42. See Chandler Burr, *The AIDS Exception: Privacy vs. Public Health*, ATLANTIC MONTHLY, June 1997, at 57-67 (arguing that a new public health approach to HIV/AIDS is required).

43. See, e.g., David Miller et al., *HTLV-III: Should Testing Ever be Routine?*, 292 BMJ 941, 943 (1986).

44. UNAIDS/WHO Policy Statement on HIV Testing 1, June 2004, [hereinafter UNAIDS/WHO] available at [http://data.unaids.org/una-docs/hivtestingpolicy\\_en.pdf](http://data.unaids.org/una-docs/hivtestingpolicy_en.pdf).

45. *Id.*

exposed to HIV.<sup>46</sup>

Another unpublished WHO policy document describes a positive HIV test as “a sick patient’s gateway to health” as opposed to something to be feared.<sup>47</sup> Most recently, Kevin De Cock, Director of the WHO Department of HIV/AIDS, made the following statement at the Sixteenth International AIDS Conference in Toronto:

Only ten percent of people living with HIV in the world are aware of their HIV status. That’s appalling. We have to scale up the traditional ways of knowledge, in other words voluntary counseling and testing . . . we need innovative ways of doing it. We will talk about provider-initiated testing and counseling.<sup>48</sup>

On the same day, the WHO and UNAIDS Secretariat released a joint statement on HIV testing and counseling—as of this writing, the most current WHO/UNAIDS public statement on HIV testing. The statement notes that uptake from voluntary counseling and testing has been inadequate and calls for a “more diverse range of approaches” to increase knowledge of HIV status—including both “client-initiated” and “provider-initiated” testing, depending on the prevalence of HIV in a particular setting and other local conditions.<sup>49</sup> Further, in June 2006, the WHO and UNAIDS Secretariat initiated a consultative process to develop guidance on provider-initiated HIV testing and counseling in health care settings. This process included an international meeting of experts, government representatives, and non-governmental organizations.<sup>50</sup> As of February 2007, the WHO has circulated draft guidelines for comment. It is unclear when the WHO will issue formal guidelines in final form.

Other international organizations involved in HIV care such as the Global HIV Prevention Working Group<sup>51</sup> and the Global Business Coalition on HIV/AIDS<sup>52</sup> are also encouraging a shift toward expanded testing. In parallel, several countries have begun to revise their laws and guidelines on HIV testing in favor of expanded testing. In 2004, Botswana introduced a routine provider-initiated testing program in which all patients are tested for HIV during doctors’

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46. *Id.* (emphasis omitted).

47. David Miller et al., World Health Org., *The Gateway to Treatment: An Increased Role for Provider-Initiated Testing and Counseling in Resource-Poor Settings* 4 (Oct. 2004) (unpublished manuscript, on file with author).

48. Isabel Parenthoen, WHO Calls for Massive Increase in Global AIDS Tests, *AGENCE FRANCE-PRESSE*, Aug. 15, 2006.

49. Joint Statement, WHO and UNAIDS Secretariat Statement on HIV Testing and Counselling, Aug. 14, 2006, *available at* [http://www.who.int/hiv/toronto2006/WHO-UNAIDS\\_statement\\_TC\\_081406\\_dh.pdf](http://www.who.int/hiv/toronto2006/WHO-UNAIDS_statement_TC_081406_dh.pdf).

50. *Id.*

51. GLOBAL HIV PREVENTION WORKING GROUP, *HIV PREVENTION IN THE ERA OF EXPANDED TREATMENT ACCESS* (2004), *available at* <http://www.kff.org/hivaids/upload/HIV-Prevention-in-the-Era-of-Expanded-Treatment-Access.pdf>.

52. Richard Holbrooke & Richard Furman, Op-Ed., *A Global Battle’s Missing Weapon*, N.Y. TIMES, Feb. 10, 2004, at A25.

visits unless they opt out.<sup>53</sup> This policy was adopted in recognition of the fact that uptake of voluntary testing in sub-Saharan Africa is troublingly low, and it aims to reduce HIV-related stigma by administering the HIV test like any other routine medical test. In November 2005, Lesotho launched a program with a goal of informing every person in the country of his or her HIV status. The program calls for door-to-door “confidential and voluntary HIV testing and counseling with an aim to reach all households in Lesotho by the end of 2007.”<sup>54</sup> Similar initiatives are being considered in Malawi and Zambia, to name just two countries.<sup>55</sup>

Perhaps most significantly, in September 2006, the CDC released revised guidelines on HIV testing that called for routine HIV testing for the general U.S. population:

In all health-care settings, screening for HIV infection should be performed routinely for all patients aged 13–64 years. Health-care providers should initiate screening unless prevalence of undiagnosed HIV infection in their patients has been documented to be <0.1%. In the absence of existing data for HIV prevalence, health-care providers should initiate voluntary HIV screening until they establish that the diagnostic yield is <1 per 1,000 patients screened, at which point such screening is no longer warranted.<sup>56</sup>

The earlier guidelines, published in 2001, recommended routine testing only where the prevalence of HIV infection is greater than 1% of the adult population as well as for individuals with increased behavioral and clinical risks for HIV infection, regardless of the prevalence of HIV.<sup>57</sup> The revised 2006 guidelines also differ from the prior recommendations in the following respects: 1) A patient may be screened for HIV after being notified, unless he or she specifically declines; 2) Specific signed consent for HIV testing is not required (a general consent to medical care suffices); 3) Individuals at high risk for HIV should be screened annually; 4) Prevention counseling is not required as a part of HIV screening programs in all health-care settings—though, it is encouraged for persons at high risk for HIV in settings such as STD clinics.

These policy statements represent the beginning—not the end—of a policy debate that has already begun to take place in state legislatures and ministries of

53. Sheri D. Weiser et al., *Routine HIV Testing in Botswana*, 3 PLOS MED e261 (2006).

54. World Health Org., Lesotho Launches Groundbreaking HIV Campaign on World AIDS Day, Nov. 30, 2005, <http://www.who.int/mediacentre/news/releases/2005/pr64/en/index.html>.

55. CSIS REPORT, *supra* note 23, at 4.

56. Ctrs. for Disease Control & Prevention, *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings*, 55 MORBIDITY & MORTALITY WKLY. REP. 1, 7 (2006).

57. *Id.*; see also Judith A. Aberg et al., *Primary Care Guidelines for the Management of Persons Infected with Human Immunodeficiency Virus*, 39 CLINICAL INFECTIOUS DISEASE 609 (2004) (describing similar guidelines promulgated by the Infectious Diseases Society of America that call for routine testing in areas where the prevalence of HIV infection is greater than 1%).

health around the world. A number of human rights advocates have swiftly criticized this move toward routine provider-initiated testing. In response to Kevin De Cock's comments at the 2006 AIDS Conference, Mary Robinson, former president of Ireland and patron of the International Community of Women Living with HIV/AIDS, had this to say: "Scaling up HIV testing isn't a simple matter, and especially for women, and HIV-positive women know this very well."<sup>58</sup> Similarly, Joe Amon, director of HIV-AIDS programs at Human Rights Watch, voiced concern:

The testing creates a moment when there can either be trust and a relationship with health-care provision or it can be a moment when people are turned away or they don't want to come back. And that's why it's critical that there be counseling and there be an opportunity to build a relationship for chronic disease care over the long term.<sup>59</sup>

At the same time, several U.S. states are now debating proposals to align their laws on HIV testing with the CDC's revised recommendations. The New York State Assembly is currently considering a proposal by Dr. Thomas Freiden, the Health Commissioner of New York City, to change a 1988 state law that requires physicians to obtain specific written consent for an HIV test and conduct lengthy pre-test counseling. Freiden's proposal would give doctors the option of obtaining oral consent, simplify pre-test counseling, and strengthen post-test counseling.<sup>60</sup> The New York Civil Liberties Union and several physician activists have criticized this proposal.<sup>61</sup>

Despite this debate, there is clearly a new momentum toward routine provider-initiated testing. One interpretation of these events is that science is finally winning over politics. According to this view "activists and civil libertarians" have tied the hands of public health experts for years with misplaced concerns over privacy rights and discrimination.<sup>62</sup> Now that treatment for HIV has fundamentally changed the cost-benefit calculus for individuals, it is possible to shift to a more standard public health approach to combating the spread of HIV.<sup>63</sup> This Article does not share this view, though it does argue in favor of routine provider-initiated testing. The history of the AIDS epidemic demonstrates that the concerns of the activists and civil libertarians are neither misplaced nor merely political. They were well founded. The challenge now is to craft a public

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58. Sheryl Ubelacker, *HIV Testing can have Severe Consequences, Especially for Women: Robinson*, CANADIAN PRESS, Aug. 16, 2006, available at <http://www.cbc.ca/cp/health/060816/x081624.html> (internal quotation marks omitted).

59. *Id.*

60. Sewell Chan, *Rifts Emerge on Push To End Written Consent for H.I.V. Tests*, N.Y. TIMES, Dec. 25, 2006, at B1.

61. *Id.*

62. Wagner, *supra* note 30, at 2.

63. *Id.*

health approach to fighting AIDS, one that includes routine provider-initiated testing, but also safeguards the rights of individual patients.

### III. THE CASE FOR ROUTINE PROVIDER-INITIATED HIV TESTING

There are at least six broad arguments in favor of routine provider-initiated HIV testing. First, whereas during the early days of the AIDS pandemic testing exposed individuals to potential stigma while offering them scant benefit, the availability of life-saving treatment for HIV infection has fundamentally altered this balance. Where treatment is available, individual patients now stand to benefit from routine testing. Second, at the national and international levels, the slow uptake of voluntary testing is inhibiting the roll-out of HIV treatment programs. Third, the slow uptake of voluntary testing is impeding HIV prevention efforts. Individuals need to “know their status” in order to take steps to prevent spreading the virus. Fourth, routine-offer testing is the norm for most other treatable diseases for which there are straightforward tests. Promoting “AIDS exceptionalism” actually perpetuates the stigma, denial, and fear associated with HIV. Fifth, a recent series of studies have demonstrated that routine HIV testing is cost-effective. Testing is not only better for individuals and for combating the AIDS pandemic, but it is also a comparatively good value for society. Sixth, while opponents of expanded testing often cite human rights principles for support,<sup>64</sup> one can argue that principles of international human rights law, such as the right to health, actually favor routine provider-initiated testing. That is, we should not take extraordinary measures to safeguard autonomy at the expense of patients’ health or well-being. I will address each of these arguments in turn.

#### *A. Individual patients now stand to benefit from routine testing*

##### *1. Treatment for HIV*

A positive HIV test result in the pre-treatment era conferred little benefit to patients. The only rationale that those in favor of routine testing could offer was that it represented the most effective prevention strategy. According to this argument, which was eventually rejected by guideline-writing authorities, the benefit of these prevention efforts to society outweighed the imposition on the individual.

With the advent of treatment, the potential benefit of an HIV test to an individual patient has increased relative to the potential harm. ARV therapy can result in improvements in CD4+ counts and HIV viral loads that have been

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64. Crewe & Viljoen, *supra* note 22, at 1.

sustained over four to five years in observational studies.<sup>65</sup> Though long-term clinical data is not yet available, it appears possible that individuals can maintain their health on ARV therapy indefinitely. In the United States alone, the use of ARV therapy has resulted in a decrease in HIV mortality rates from 20 to 30 deaths per 100 person-years to 8.4 to 8.8 deaths per 100 person-years.<sup>66</sup>

In this context, testing is important because health care providers often do not recognize infected individuals during the quiescent phase of HIV infection.<sup>67</sup> HIV positive individuals are more commonly identified when they present with opportunistic infections or other clinical symptoms. As one study in the *Archives of Internal Medicine* described, the years during which individuals unknowingly carry HIV “represent therapeutic opportunities lost.”<sup>68</sup> Routine provider-initiated testing is likely to identify substantial numbers of asymptomatic individuals who would qualify for treatment under current guidelines—as many as 740 for every 10,000 individuals tested, according to one study.<sup>69</sup>

A number of observational studies suggest that starting ARV therapy early diminishes the incidence of opportunistic infections and allows individuals to sustain normal CD4+ levels—sparing them the morbidity and mortality associated with such infections.<sup>70</sup> It is important to note that these observational studies are not definitive. The case for routine testing would be greatly strengthened by evidence from a randomized prospective trial showing that identifying HIV-positive patients at an earlier stage of infection, who might not qualify for treatment under current clinical guidelines, nonetheless confers a benefit in the form of increased survival.

The results of the ongoing Strategies for Management of Anti-Retroviral

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65. Garcia et al., *supra* note 16, at 704-08.

66. Richard D. Moore & Richard E. Chaisson, *Natural History of HIV Infection in the Era of Combination Antiretroviral Therapy*, 13 AIDS 1933, 1936-37 (1999); see also Frank J. Palella Jr. et al., *Declining Morbidity and Mortality Among Patients with Advanced Human Immunodeficiency Virus Infection*, 338 NEW ENG. J. MED. 853 (1998) (describing the decline in mortality attributable to AIDS after the advent of ARV).

67. Cf. Jeffrey H. Samet et al., *Trillion Virion Delay: Time from Testing Positive for HIV to Presentation for Primary Care*, 158 ARCHIVES INTERNAL MED. 734 (1998) (concluding that “patients with positive HIV test results often delay for more than a year before establishing primary medical care”); Barbara J. Turner et al., *Delayed Medical Care after Diagnosis in a US National Probability Sample of Persons Infected with Human Immunodeficiency Virus*, 160 ARCHIVES INTERNAL MED. 2614 (2000) (identifying health care and patient factors that are associated with delayed medical care for HIV).

68. Rochelle Walensky et al., *Identifying Undiagnosed Human Immunodeficiency Virus*, 162 ARCHIVES INTERNAL MED. 887, 890 (2002).

69. This figure varies depending on the population prevalence of HIV. Seven hundred and forty represents the upper limit of an estimate based on a population prevalence of 15%. Roger Chou et al., *Screening for HIV: A Review of the Evidence for the U.S. Preventive Services Task Force*, 143 ANNALS INTERNAL MED. 55, 62 (2005).

70. See, e.g., Bruno Ledergerber et al., *AIDS-Related Opportunistic Illnesses Occurring After Initiation of Potent Antiretroviral Therapy: The Swiss HIV Cohort Study*, 282 JAMA 2220, 2221-24 (1999).



Therapy (SMART) trial may resolve this issue. The trial was designed to analyze whether it is better to use ARV medicines continuously to maintain the viral load as low as possible or to delay therapy until the CD4+ count is higher.<sup>71</sup> Participants in the trial were assigned at random to viral suppression therapy, in which ARV therapy was taken on an ongoing basis to suppress viral load, or drug conservation therapy, in which ARV therapy was started only after the participant's CD4+ count dropped below 250 cells per milliliter of blood.<sup>72</sup> However, enrollment in the trial was stopped on January 11, 2006, after a periodic interim analysis of the trial data showed that participants receiving drug conservation therapy had twice the risk of disease progression (defined as the development of clinical AIDS or death). Moreover, participants in the drug conservation arm were also found to have a higher rate of major complications such as cardiovascular, kidney, and liver disease.<sup>73</sup> These results, when combined with those from observational studies, strongly suggest that individual patients can improve their own chance of survival by learning that they are infected sooner rather than later and by initiating ARV therapy earlier.

By extension, routine testing is also likely to produce substantial reductions in HIV-related mortality at the population level. A recent systematic review of the empirical evidence on HIV testing for the U.S. Preventive Services Task Force considered outcomes of counseling and one-time screening for HIV infection after three years in a hypothetical cohort of 10,000 asymptomatic adults. Where the population prevalence of HIV is one percent, routine testing was projected to prevent between two and twenty-eight cases of clinical progression or death over three years. Where the population prevalence of HIV is between 5% and 15%—as it is in some sub-Saharan African nations—routine testing was projected to prevent between 24 and 410 cases of clinical progression or death over three years, assuming that treatment is available.<sup>74</sup>

## *2. Other Developments That May Mitigate the Harm to Individuals of HIV Testing*

As I have already described, HIV testing has been associated in the past with a number of harms. However, since the early days of the epidemic, there have been a number of developments in addition to the clear benefits of treatment that may mitigate some of these harms.

First, some opponents of testing point out that false-positive test results may

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71. Press Release, Nat'l Inst. of Health, A Large International HIV/AIDS Study Comparing Two Strategies for Management of Anti-Retroviral Therapy (The SMART Study) (Jan. 18, 2006), available at <http://www3.niaid.nih.gov/news/newsreleases/2006/smartqa06.htm>.

72. *Id.*

73. Press Release, Nat'l Inst. of Health, International HIV/AIDS Trial Finds Continuous Antiretroviral Therapy Superior to Episodic Therapy (Jan. 18, 2006), available at <http://www.nih.gov/news/pr/jan2006/niad-18.htm>.

74. Chou et al., *supra* note 69, at 57-58, 62.

produce unnecessary anxiety and emotional distress.<sup>75</sup> False negative results could provide false reassurance if individuals take such results as a license to engage in high-risk behavior.<sup>76</sup> Advances in the science of HIV testing now make both false-positive and false-negative test results extremely rare. The current HIV testing protocol of an enzyme-linked immunosorbent assay (EIA) followed by a confirmatory Western Blot analysis has a sensitivity (the proportion of people with disease who have a positive test result) and specificity (the proportion of people without disease who have a negative test result) that approaches 100%.<sup>77</sup> Newly developed rapid test kits can deliver final negative results and preliminary positive results within one hour of testing.

Second, opponents of testing argue that true-positive test results are associated with even more serious harms. These include fears of rejection or abandonment by partners, verbal abuse, physical assault, loss of a job, social ostracization, emotional and psychological distress, and an increased risk of suicide.<sup>78</sup> However, evolving legal norms may mitigate many of these harms, further altering the harm-benefit equation for individuals. Since the 1980s, a number of U.S. states have enacted anti-discrimination laws to protect HIV-positive individuals and marginalized groups.<sup>79</sup> HIV-positive individuals in the United States qualify for protection under certain provisions of the Americans with Disabilities Act.<sup>80</sup> Internationally, the WHO convened some 150 nations to sign a document that calls for a "human rights approach" to HIV/AIDS and for compassion and solidarity with people living with HIV.<sup>81</sup> These nations recognize that the protection of human rights is a necessary element of a worldwide public-health response to the AIDS pandemic. In theory, at least, this should force public accountability on the part of governments and international organizations for their actions toward HIV-positive individuals.

Evolving social norms, which are more nebulous and therefore more difficult to describe, also appear to be shifting. One marker of these evolving social norms is the U.S. Supreme Court's 2003 decision in *Lawrence v. Texas*,<sup>82</sup> which struck down a Texas anti-sodomy law. The Court struck down its earlier

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75. *Id.* at 57-58.

76. *Id.*

77. Beckwith et al., *supra* note 21, at 1039.

78. Chou et al., *supra* note 69, at 57-58.

79. See generally Paul Barron et al., *State Statutes Dealing With HIV and AIDS: A Comprehensive State-by-State Summary (2004 Edition)*, 13 L. & SEXUALITY 1 (2004).

80. George J. Annas, *Protecting Patients from Discrimination: The Americans with Disabilities Act and HIV Infection*, 339 NEW ENG. J. MED. 1255, 1255-56 (1998).

81. World Health Org., World Health Assembly, Avoidance of Discrimination Against HIV-Infected Persons and Persons with AIDS, pmbl., Resolution WHA 41.24 (May 13, 1988); World Health Org., World Health Assembly, Global Strategy for the Prevention and Control of AIDS, Resolution WHA 40.26 (May 15, 1987).

82. *Lawrence v. Texas*, 539 U.S. 558 (2003).

1986 decision, *Bowers v. Hardwick*,<sup>83</sup> which had upheld a state law banning homosexual sex. Justice Sandra Day O'Connor, who cast a critical vote in *Lawrence* remarked in a recent collection of essays, "rare indeed is the legal victory—in the court or legislature—that is not the careful byproduct of an emerging social consensus."<sup>84</sup> Pamela Karlan, a law professor at Stanford University who filed an amicus curiae brief in the case, notes that during the seventeen years between *Bowers* and *Lawrence*, the justices' were influenced by a growing familiarity with gays.<sup>85</sup> That is, being "gay" became relatively normalized and, therefore, discriminatory laws based on the nonconforming behavior of a minority—though "normal"—group became untenable.

It is difficult to state quantitatively how this legal and social evolution will impact individuals who receive a routine offer for an HIV test—and there will be vast differences depending on where the person lives. Still, according to a 1999 study published in the *American Journal of Public Health* based on a telephone survey of 1300 U.S. adults, negative feelings toward people living with AIDS among respondents decreased by at least 8% annually between 1991 and 1999.<sup>86</sup> Similarly, the proportion of respondents who said that they would avoid a coworker with AIDS, and that they would have their own children avoid a schoolmate with AIDS, declined significantly between 1991 and 1999.<sup>87</sup> In 1991, 45% of respondents said that they would avoid shopping at a grocery store whose owner had AIDS. By 1999, this proportion had dropped to approximately 29%.<sup>88</sup> Another study published in 2000 by the CDC, also based on a telephone survey, concluded that most U.S. adults—approximately 80%—do not hold stigmatizing views about persons with HIV infection or AIDS. Moreover, stigmatizing attitudes about HIV were associated with misinformation about HIV transmission—suggesting that increased education about HIV may result in lower levels of stigmatizing beliefs about HIV-positive individuals.<sup>89</sup>

More recent population studies in the United States have found that HIV-negative and HIV-positive individuals appear to have similar rates of intimate partner violence when controlled for other high-risk behaviors.<sup>90</sup> At least two

83. *Bowers v. Hardwick*. 478 U.S. 186 (1986).

84. Linda Greenhouse, *The Supreme Court: The Justices; Context and the Court*, N.Y. TIMES, June 25, 2003, at A1.

85. Wagner, *supra* note 30, at 6.

86. Gregory M. Herek et al., *HIV-Related Stigma and Knowledge in the United States: Prevalence and Trends, 1991-1999*, 92 AM. J. PUB. HEALTH 371, 371 (2002).

87. *Id.* at 373.

88. *Id.*

89. Ctrs. for Disease Control & Prevention, *HIV-Related Knowledge and Stigma-U.S., 2000*, 49 MORBIDITY & MORTALITY WKLY. REP. 1062, 1062-64 (2000).

90. Chou et al., *supra* note 69, at 58; see Linda J. Koenig & Jan Moore, *Women, Violence, and HIV: A Critical Evaluation with Implications for HIV Services*, 4 MATERNAL CHILD HEALTH J. 103 (2000) (concluding, based on a literature review, that violence is not statistically increased among HIV-infected women compared to demographically and behaviorally similar uninfected women); David Vlahov et al., *Violence Among Women with or at Risk for HIV Infection*, 2 AIDS & BEHAV.

observational studies have shown that HIV-positive individuals had a rate of partnership dissolution that was no higher than that of HIV-negative individuals.<sup>91</sup>

Unfortunately, most questions related to the harms associated with a positive HIV-test result—including the risk of suicide,<sup>92</sup> the incidence of individual cases of discrimination, and emotional distress—have not been studied systematically since the beginning of the treatment era. Nevertheless, while there is not enough evidence to state this quantitatively, and while there is undoubtedly still much progress to be made, the situation for HIV-positive individuals is not what it was twenty years ago. Further, as I will argue later, routine provider-initiated testing may actually work to de-stigmatize HIV infection. When coupled with the potentially lifesaving benefit of treatment, which can be stated quantitatively and would in and of itself support an argument for routine testing, these evolving legal and social norms bolster the case for routine provider-initiated testing.

*B. The Slow Uptake of Voluntary Testing Is an Obstacle to National and International HIV Treatment Programs*

Closely related to the argument that individual patients now stand to benefit from routine testing is the argument that certain disadvantaged groups, especially poor minorities and women, and indeed whole societies will also benefit from expanded routine testing. While there is an emerging political commitment to treat HIV positive individuals in both rich and poor countries, the slow uptake of voluntary counseling and testing is inhibiting the roll-out of treatment programs. Zimbabwe, for example, missed the WHO's "3 by 5" target of providing 120,000 HIV/AIDS patients with treatment by the end of 2005. While the exact number of individuals receiving treatment is not yet known, only 17,500 people were receiving treatment for HIV as of August 2005. According to Owen Mugurungi, head of the tuberculosis and AIDS unit in Zimbabwe's Ministry of Health and Child Welfare, insufficient uptake in Zimbabwe's voluntary HIV testing program was one of many factors that contributed to the country missing its treatment target.<sup>93</sup> It now appears likely that most of the countries targeted by the WHO

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53 (1998) (finding that both physical abuse and sexual abuse were similarly common among both HIV-seropositive (66.4%, 45.7%) and HIV-seronegative women (69.2%, 48.8%), respectively); see also Mardge Cohen et al., *Domestic Violence and Childhood Sexual Abuse in HIV-Infected Women and Women at Risk for HIV*, 90 AM. J. PUBLIC HEALTH 560, 560 (2000) (finding that HIV-positive and HIV-negative individuals have similar rates of intimate partner violence).

91. Tamara Hoxworth et al., *Changes in Partnerships and HIV Risk Behaviors after Partner Notification*, 30 SEXUALLY TRANSMITTED DISEASES 83, 86 (2003); Patricia J. Kissinger et al., *Partner Notification for HIV and Syphilis: Effects on Sexual Behaviors and Relationship Stability*, 30 SEXUALLY TRANSMITTED DISEASES 75, 78-79 (2003).

92. Chou et al., *supra* note 69, at 58.

93. *Zimbabwe Has Missed World Health Organization "3 by 5" Target*, LIFE SCI. WKLY., Jan. 3, 2006, at 801.

have missed their treatment targets.<sup>94</sup> In short, voluntary counseling and testing does not work at the population level because it does not allow public health authorities to identify cases of HIV with enough frequency and reliability to administer a viable large-scale treatment program.

*1. Routine Testing Results in an Increased Uptake in Testing and in Fewer Missed Diagnoses*

Botswana's experience with voluntary counseling and testing provides a vivid example of the need to rethink testing strategy at the population level. Botswana, despite having the highest per capita GNP in sub-Saharan Africa and a relatively impressive health infrastructure, has an estimated HIV prevalence of 35%. As a result, life expectancy at birth in this small nation of 1.7 million people has fallen from sixty-five years in 1990-1995 to thirty-nine years in 2004—a decline so severe that it threatens Botswana with complete economic collapse.<sup>95</sup> The government of Botswana, led by President Festus Mogae, has responded to this national crisis with one of the most assertive AIDS campaigns in Africa. Botswana budgeted \$198 million dollars for AIDS treatment and prevention in 2004-2005, including \$60 million of its own money. This program undertook to treat some 20% of the country's HIV-positive individuals, possibly as much as 4% of the total population of Botswana, with ARV therapy.<sup>96</sup>

Since only a small percent of the population of Botswana had been tested for HIV as of 2002, the first major obstacle the government faced was identifying which 4% of the population required treatment.<sup>97</sup> Individuals in this 4% would qualify for treatment under current clinical guidelines but would otherwise be indistinguishable from uninfected individuals even based on a thorough medical exam. Facing this enormous challenge, the Government of Botswana increased the number of voluntary testing centers. However, by early 2003, only 28% of the country's citizens in the most populous districts knew their HIV status and only 10,000 people were receiving treatment. This was far below the government's target.<sup>98</sup>

In late 2003, the Government of Botswana sponsored a public discussion on its HIV testing strategy and held a consultative meeting with experts from UNAIDS and the CDC. The outcome of this discussion was a decision to shift course by adopting a country-wide program of routine provider-initiated HIV testing. Under this program, patients in Botswana are offered an HIV test whenever they have contact with their health care system. Though individuals

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94. WHO Likely To Miss "3 by 5" AIDS Drug Target, REUTERS, June 29, 2005.

95. UNITED NATIONS, THE IMPACT OF AIDS 17 (2004), available at [http://www.un.org/esa/population/publications/AIDSimpact/5\\_CHAP\\_II.pdf](http://www.un.org/esa/population/publications/AIDSimpact/5_CHAP_II.pdf).

96. CSIS REPORT, *supra* note 23, at 8.

97. Weiser et al., *supra* note 53.

98. CSIS REPORT, *supra* note 23, at 9.

remain free to opt out of testing, the default position has changed such that all individuals are tested unless they specifically decline to be tested.<sup>99</sup>

There is insufficient data to evaluate Botswana's routine testing program since it was put into place in January 2004. However, some 28,000 people are now receiving ARV treatment in Botswana<sup>100</sup> and the percentage of women receiving an HIV test in antenatal clinics in one city for which data is available has risen from 75% to 90%.<sup>101</sup> As of this writing, few adverse consequences of this program have been publicly reported in the medical or legal literature or in the English-language press—and those reports that have been published have been limited to describing confusion among health care workers as to when to offer an HIV test, increased stress on the country's health infrastructure, and bottlenecks in laboratory logistics.<sup>102</sup>

Data from four U.S. studies in settings with an HIV prevalence of greater than one percent support these basic conclusions from Botswana. All four studies demonstrated an increased yield in testing and two retrospective studies indicated a lower rate of missed diagnosis after the implementation of routine provider-initiated testing.<sup>103</sup> The most recent of these studies implemented a routine testing program for admitted patients at a Boston teaching hospital and compared the results of this program with a fifteen-month historical control period. The study found that patients admitted during the study program period were 3.4 times more likely to undergo HIV testing. Patients who would not have undergone testing had the program not been implemented had an HIV prevalence of 3.8%. This would mean that routine testing could detect 19 undiagnosed cases of HIV in a hospital with 500 medical admissions per month—this as compared with a detection rate of 1.3 undiagnosed cases for targeted testing.<sup>104</sup>

Similarly, a 2003 study in the United Kingdom published in the *British Medical Journal*, also found that switching from voluntary to routine provider-initiated testing resulted in an increased uptake in HIV testing from 35% of patients to 65% of patients examined in the clinical center.<sup>105</sup> These findings are further verified by data from the antenatal testing context, where routine testing is the norm in most countries. The CDC published a study in 2002 which found that antenatal testing rates for pregnant women are much higher in states that use an opt-out approach as opposed to an opt-in approach.<sup>106</sup>

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99. *Id.*

100. *Id.*

101. Khumo Seipone et al., *Introduction of Routine HIV Testing in Prenatal Care*, 53 MORBIDITY & MORTALITY WKLY. REP. 1083, 1083-84 (2004).

102. CSIS REPORT, *supra* note 23, at 9-10

103. See Chou et al., *supra* note 69, at 57.

104. Rochelle P. Wallensky et al., *Identifying Undiagnosed HIV: The Yield of Routine, Voluntary Inpatient Testing*, 162 ARCHIVES INTERNAL MED. 887, 889-91 (2002).

105. Belinda Stanley, *Uptake of HIV Screening in Genitourinary Medicine After Change to "Opt-Out" Consent*, 326 BMJ 1174, 1174 (2003).

106. Ctrs. for Disease Control & Prevention, *HIV Testing Among Pregnant Women—United*

## *2. The Disparate Impact of Voluntary Testing on the Poor and Uneducated*

While there is a relative lack of data on the population level impact of voluntary versus routine HIV testing in poor countries, data from the United States, which is available, supports the contention that national voluntary testing programs are insufficiently sensitive to patterns and trends in HIV prevalence. One 2002 study, which used data from the 1998 National Health Interview Survey, found that 66% of the 32,440 U.S. adults surveyed had not been tested for HIV.<sup>107</sup> More alarmingly, however, the study found that potential barriers to seeking HIV testing included age, ethnicity, educational level, marital status, gender, and region of residence.<sup>108</sup> Certain subpopulations are more likely to seek testing than others. Perhaps unsurprisingly, those without insurance and those without higher education are less likely to seek testing.<sup>109</sup>

If these findings can be generalized, they would necessarily mean that the poor and less educated will have a lower testing rate, and therefore less access to potentially life-saving treatment, even though the policy of voluntary testing was ostensibly developed to protect the poor and less educated. It is not a coincidence that AIDS afflicts certain populations, namely poorer populations, more than others.<sup>110</sup> The shortcomings of voluntary testing, which track other traditional indices of access to information such as poverty and illiteracy, are more likely to shortchange the very people that voluntary testing was meant to protect.

## *3. Targeting High-Risk Groups Is Not a Viable Testing Strategy*

Some countries have adopted so called “risk-based” HIV testing, a blend of voluntary testing and routine testing for the general population. Risk-based testing is essentially routine provider-initiated testing for certain subgroups that are thought to be at high risk for HIV infection—or in clinical settings that are thought to have a high HIV prevalence. Voluntary testing remains the norm for the rest of the general population. This Article argues that risk-based testing, the status quo testing policy in the United States, is no more viable than voluntary testing as a testing strategy because it too prevents the identification of a large number of cases of HIV.

There are at least three reasons that risk-based HIV testing fails in practice in

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*States and Canada, 1998-2001*, 51 MORBIDITY & MORTALITY WKLY. REP. 1013, 1013-16 (2002).

107. Joseph N. Inungu, *Potential Barriers to Seeking HIV Testing Among Adults in the U.S.: Data from the 1998 National Health Interview Survey*, 16 AIDS PATIENT CARE & STDs 293, 297 (2002).

108. *Id.*

109. There are some exceptions to this general finding. Some poor subpopulations are more likely to be tested. One example would be injection drug users, who have higher testing rates, as they are often targeting by HIV prevention programs. Robert Heimer et al., *Assessment of HIV Testing of Urban Injection Drug Users*, 97 AM. J. PUB. HEALTH 110 (2007).

110. *Id.*

the United States, the country for which the best data is available. First, while a substantial percentage of Americans report high-risk behaviors,<sup>111</sup> high-risk behaviors often remain undetected in health care settings.<sup>112</sup> Second, even when detected, high-risk behaviors often fail to lead to testing.<sup>113</sup> Third, a large number of HIV-infected individuals report no risk factors for infection. According to one U.S. study of 1.2 million individuals identified at federally funded testing sites, between 20% and 26% of HIV-positive individuals reported no risk factors for infection.<sup>114</sup> Other smaller studies have placed this figure between 7% and 51%.<sup>115</sup>

In short, strategies that are based on risk, or based on the prevalence of HIV in a certain subpopulation, are impractical because they rely on risk assessment either by health care providers or by patients themselves, both of which are inherently inaccurate.<sup>116</sup> Multiple studies in the United States have attempted to devise risk-based or prevalence-based criteria for HIV testing. These studies report a rate of missed diagnosis of HIV that ranges from 7% to 74%.<sup>117</sup> Even 7% is an unacceptably high number for a fatal illness that is otherwise treatable.

Moreover, even if epidemiologic science could devise criteria for risk-based testing that could eliminate missed diagnoses altogether, most of the legal and ethical issues associated with routine provider-initiated testing would still remain. Risk-based testing only shifts the negative burden of widespread HIV testing from the general population to a more specific subpopulation.

### *C. The Low Testing Rate Associated with Voluntary Testing Is an Obstacle to HIV Prevention*

The slow uptake and low testing rates associated with voluntary testing does not just impede treatment, but also impedes efforts to prevent the spread of HIV. This is an argument advanced most visibly and forcefully by Richard Holbrooke, former U.S. Ambassador to the United Nations and the President of the Global Business Coalition on HIV/AIDS. Holbrooke noted in an op-ed essay that the number of people infected with HIV has increased every day since the first

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111. For example, one telephone survey of 33,913 U.S. residents found that 11% of respondents reported having multiple sexual partners within the past year. P. Owens et al., *Prevalence of Risk Behaviors for HIV Infection Among Adults*, 50 MORBIDITY & MORTALITY WKLY. REP. 262, 262 (2001).

112. Daniel Klein et al., *Review of Medical Encounters 5 Years Before a Diagnosis of HIV-1 Infection*, 32 J. ACQUIRED IMMUNE DEFICIENCY SYNDROME 143, 143 (2002).

113. Rebecca V. Liddicoat et al., *Assessing Missed Opportunities for HIV Testing in Medical Settings*, 19 J. GEN. INTERNAL MED. 349, 352-53 (2004).

114. Thomas A. Peterman et al., *Opportunities for Targeting Publicly Funded Human Immunodeficiency Virus Counseling and Testing*, 12 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES & RETROVIROLOGY 69 (1996).

115. Chou et al., *supra* note 69, at 57.

116. Beckwith et al., *supra* note 21, at 1038.

117. Chou et al., *supra* note 69, at 57.



World AIDS Day.<sup>118</sup> While action on many fronts is necessary to combat the spread of AIDS, the world community has been silent on testing and detection. Holbrooke writes,

Because of legitimate concerns about confidentiality and the risk of stigmatization, testing has always been voluntary, and it has been systematically played down as an important component of the effort . . . [this] means that 90 percent of the roughly 12,000 people around the world who will be infected today—just today!—will not know it until roughly 2013. That's plenty of time for them to spread it further, infecting others, who will also spread it, and so on. No wonder we are losing the war against AIDS: In no other epidemic in modern history has detection been so downgraded.<sup>119</sup>

Holbrooke further argues that more people must be made aware of their HIV status, as this knowledge changes people's behavior. That is, many who learn that they are HIV-positive act on the information they receive from HIV testing to behave more carefully, preventing the further spread of the virus.

Holbrooke preempts the charge of medical paternalism by casting his argument as one for empowering patients by providing them with more information. Routine provider-initiated testing is part of a larger package of information dissemination that strengthens the ability of individuals to take measures to protect themselves and their families. I will address each of Holbrooke's arguments in turn.

### *1. The Relationship Between Access to Information and Testing Rates*

I have already reviewed the evidence that routine provider-initiated testing leads to a greater uptake of testing in the general population. A related finding is that individuals in high-risk groups—individuals with multiple sexual partners and homosexual men—are more likely to be tested for HIV than individuals in the general population.<sup>120</sup> As the authors of one such study note, this suggests that increased HIV testing in high-risk populations results from a reasoned decision making process on the part of individuals and their health care providers.<sup>121</sup> That is, high-risk groups are the subjects of targeted information and education campaigns, and increased information leads to testing. This finding, when joined with the studies from the above Section on the impact of provider-initiated testing and the disparate negative impact of voluntary testing on the poor and less educated, suggests that a lack of access explains—at least in part—the low testing rates associated with voluntary testing. This would support

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118. Richard Holbrooke, *AIDS: The Strategy Is Wrong*, WASH. POST, Nov. 29, 2005, at A21.

119. *Id.*

120. See, e.g., Christine McGarrigle et al., *Investigating the Relationship Between HIV Testing and Risk Behaviour in Britain*, 19 AIDS 77, 83 (2005).

121. *Id.* at 83.

Holbrooke's argument that a lack of information or knowledge regarding HIV explains the low percentage of individuals who know their HIV status.

## *2. The Relationship Between Expanded Testing and Reduced HIV Transmission*

While Holbrooke claims that knowledge of one's HIV status leads to changes in high-risk behavior, the reality appears to be somewhat more complicated. Because all studies must involve, as a matter of research ethics, interventions such as counseling or treatment, no studies have examined whether simply learning of one's HIV status leads to a change in behavior. However, it is possible to examine the effects of treatment and counseling on high-risk behavior.

One recent meta-analysis of twenty-five studies published in the *Journal of the American Medical Association* found that there was neither an association between receiving ARV therapy and having unprotected sex, nor an association between having an undetectable viral load and having unprotected sex.<sup>122</sup> However, among both HIV-positive and HIV-negative individuals, the study found that having unprotected sex was associated with having optimistic beliefs about HIV treatment.<sup>123</sup> This suggests that treatment in and of itself does not lead to an increase or decrease in high-risk behavior—rather, changes in behavior appear to be mediated through counseling and education.<sup>124</sup>

The data on the effects of testing and counseling on sexual risk behavior gives some reason for cautious optimism about the power of testing to aid prevention efforts. Three systematic reviews of the literature found that testing, together with counseling, was effective in reducing sexual risk behavior among those who tested positive for HIV and among serodiscordant heterosexual couples (couples with one HIV-infected partner).<sup>125</sup> While the counseling methods used vary significantly across these studies, some of the studies included in these analyses found that more intensive counseling was associated with greater reductions in risky behavior. However, while testing positive for HIV appears to lead to reductions in risky behavior, it also appears that testing negative for HIV either has no effect on risky behavior or may actually increase risky behavior.<sup>126</sup>

Independent of its effect on sexual risk behavior, expanded testing may reduce transmission through mechanisms that are more difficult to study. The example of Botswana, discussed above, suggests that stimulating a public

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122. Nicole Crepaz et al., *Highly Active Antiretroviral Therapy and Sexual Risk Behavior*, 292 JAMA 224, 231-34 (2004).

123. *Id.*

124. *Id.*

125. Chou et al., *supra* note 69, at 59.

126. *Id.* at 59-60.

dialogue on testing may itself lead to greater social awareness and decreased transmission of HIV. Botswana's efforts to increase testing are only one part of the country's larger campaign to implement a community-based educational program.<sup>127</sup> Also, when coupled with treatment, HIV testing will decrease the viral load in the general population.<sup>128</sup> This will aid prevention efforts as it will decrease overall transmission rates.

The lack of studies that analyze how all of these factors—risk behavior, counseling, and viral load—fit together to impact overall HIV transmission rates represents a major gap in the public health literature. Only one study has followed the effect of a national testing and treatment campaign on the evolution of an HIV epidemic. This study, conducted in Taiwan between 1997 and 2002, analyzed national HIV surveillance data and estimated the HIV transmission rate by using a statistical projection. The study found that expanded testing, coupled with providing free ARV therapy to all HIV-infected citizens, was associated with a 53% decrease in the HIV transmission rate.<sup>129</sup> While this is certainly an area for further study, there is at least reason to be hopeful that routine provider-initiated testing can help to slow the spread of HIV.

*D. Routine Testing May Work To Reduce the Stigma and  
Fear Associated with HIV*

Because routine testing is the norm for most other treatable diseases for which there are straightforward tests, creating a system of rules and procedures for AIDS—that is, promoting “AIDS exceptionalism”—may actually perpetuate the stigma, denial, and fear associated with HIV. This is a controversial argument; and, indeed, some opponents of routine testing have argued that expanded testing will not necessarily reduce HIV-related stigma.<sup>130</sup> At best, the argument that routine testing will lessen stigma represents an optimistic hope, not an assertion that is well established by existing evidence.

However, there are at least a few reasons to be optimistic that expanded testing may dilute stigma. First, as I have already noted, testing rates have risen dramatically in settings where routine testing has been attempted. It is important to note that even in situations where testing is routine, testing is still voluntary. That is, individuals can still decline to be tested. This suggests that an increasing number of individuals are at least willing to accept HIV testing. The alternative explanation, that this dramatic rise in testing rates can be explained by

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127. Weiser et al., *supra* note 53.

128. See Thomas C. Quinn, *Viral Load and Heterosexual Transmission of Human Immunodeficiency Virus Type 1*, 342 NEW ENG. J. MED. 921, 923-26 (2000).

129. Chi-Tai Fang et al., *Decreased HIV Transmission After a Policy of Providing Free Access to Highly Active Antiretroviral Therapy in Taiwan*, 190 J. INFECTIOUS DISEASES 879, 881-83 (2004).

130. Crewe & Viljoen, *supra* note 22, at 10.

widespread coercion, is unlikely. Some studies suggest that patients are generally accepting of routine testing and may even prefer routine testing.<sup>131</sup>

Second, the example of Botswana suggests that downgrading HIV to a “manageable disease” has contributed to changes in deeply rooted perceptions of the moral stature of AIDS patients. Botswana’s routine testing program has resulted in a dramatic uptake in testing at the same time as it has stimulated a public dialogue on HIV and the possibility of treatment. Though the effects of this program are still being studied, there have been no reports of adverse consequences. Indeed, the President of Botswana had his blood drawn for an HIV test and admitted publicly that he was concerned that he could be infected.<sup>132</sup>

Third, the principle of voluntary testing, though developed in response to HIV-associated stigma, does nothing by itself to preempt such stigma. Because nearly everyone with HIV who does not receive will develop clinical AIDS with its attendant body marks—skin lesions and wasting, to name two—the best that can be said of a policy that leaves most individuals ignorant of their HIV status is that it merely postpones stigma. Testing coupled with treatment, on the other hand, has the power to prevent individuals from developing the physically distinguishing characteristics of HIV infection.

Despite these reasons for optimism, subjecting individuals to HIV-associated stigma remains a very real concern for any routine testing program. For this reason, it is essential that even under a routine testing paradigm individuals retain control over the time and place of HIV testing and, as I will argue, over any subsequent disclosure of test results to others. As this Article argues, it is possible to advance the goal of expanded access to testing and treatment while at the same time advancing the goal of protecting individual rights. In fact, as I will argue in the final section of this paper, these twin goals can be mutually reinforcing.

#### *E. Routine Provider-Initiated HIV Testing Is Cost-Effective*

Until recently there have been few studies that have examined the cost-effectiveness of routine testing for HIV in the era of ARV treatment. In 2005, however, several papers were published that examined this issue for specific target populations. One study of pregnant women in Chicago found that universal screening for this population would both decrease the number of HIV-infected newborns and save money when compared to a voluntary testing strategy, where population prevalence of HIV was .21% or higher.<sup>133</sup> Another modeling study

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131. Angela B. Hutchinson et al., *Understanding the Patient’s Perspective on Rapid and Routine HIV Testing in an Inner-City Urgent Care Center*, 16 AIDS EDUC. & PREVENTION 101 (2004).

132. CSIS REPORT, *supra* note 23, at 10.

133. Lilly Cheng Immergluck et al., *Cost Effectiveness of Universal Compared With Voluntary Screening for Human Immunodeficiency Virus Among Pregnant Women in Chicago*, PEDIATRICS

applied to inpatients at U.S. hospitals found that screening is cost-effective assuming a prevalence of 1% (the threshold, according to the recommendations of the CDC, for routine testing). As a point of reference, the prevalence of HIV in the U.S. general population is approximately 0.10%.<sup>134</sup> Although this is less than the minimum prevalence for which these studies found that routine testing would be cost-effective, they support the argument that routine testing is desirable in high-prevalence areas.

Most notably, the authors of two landmark papers in the *New England Journal of Medicine* conducted a modeling analysis to estimate the cost of one-time screening in the U.S. general population. These two papers found the cost to be \$38,000 and \$41,736 respectively per quality-adjusted life-year gained—estimates calculated using a prevalence of 1%.<sup>135</sup> Both of these estimates are lower than the commonly cited \$50,000 threshold for cost-effective care—a threshold that is derived from the per capita GDP of the United States.

One of these studies also estimated that routine one-time screening would reduce the annual HIV transmission rate by more than 20%. When this consideration is included in the analysis, the cost of screening in a population with a prevalence of 1% fell to \$15,078 per quality-adjusted life year. Moreover, the study found that when decreased transmission was included in the analysis, the cost of routine screening does not cross the \$50,000 threshold until the prevalence of HIV falls below 0.05%.<sup>136</sup>

These studies did not include in their analysis several of the secondary benefits of routine testing—for example, averting the productivity loss caused by HIV infection and the effect of expanded testing on combating other sexually transmitted diseases. As the accompanying editorial in the *New England Journal of Medicine* notes, the most provocative implication of these studies is that expanded testing could, if combined with a partially effective vaccine, reduce the person-to-person transmissibility below the threshold of one new infection per infected person. If achieved, this would lead to the end the AIDS epidemic.<sup>137</sup> All of these secondary benefits could potentially lower the cost of HIV testing below the figures put forth by these two studies.

It should be noted that these two studies do have some moderate limitations. The estimates for the costs associated with counseling and testing may exceed those assumed, as different settings may have different operational difficulties.

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April 2000, at E54.

134. Samuel A. Bozzette, *Routine Screening for HIV Infection—Timely and Cost-Effective*, 352 NEW ENG. J. MED. 620, 620 (2005).

135. A. David Paltiel et al., *Expanded Screening for HIV in the United States—An Analysis of Cost-Effectiveness*, 352 NEW ENG. J. MED. 586, 586 (2005); Gillian D. Sanders et al., *Cost-Effectiveness of Screening for HIV in the Era of Highly Active Antiretroviral Therapy*, 352 NEW ENG. J. MED. 570, 570 (2005).

136. Sanders et al., *supra* note 135, at 577.

137. Bozzette, *supra* note 134, at 586-87.

The increased need for pre-test and post-test counseling may divert health care workers from other activities, further increasing costs. Lastly, these modeling studies used variables that are specific to the United States.<sup>138</sup> It is unclear what these findings would mean for testing in resource-poor settings. However, given that treatment and testing are cheaper, and that prevalence is higher, in these settings—and that these are essentially the two main determinants of cost-effectiveness—it may be even more cost-effective to begin routine screening in poor countries.

Despite their limitations, these studies present solid evidence that routine provider-initiated testing is cost-effective in the U.S. context. They suggest that routine testing is likely cost-effective in resource poor settings as well. As I have argued, routine testing benefits individuals by giving them an opportunity to receive life-saving treatment and society at large by offering a powerful tool for combating the AIDS epidemic. While the finding that routine testing is cost-effective may not carry the moral force of these arguments, it does demonstrate that routine testing represents a comparatively good value for society.

#### *F. Routine Provider-Initiated Testing Is Consistent with Human Rights Principles*

##### *1. Social and Economic Rights: The Right to Health*

Perhaps the strongest charge leveled against routine testing proposals is that they are inconsistent with the principle of autonomy, the idea that individuals have a right to make choices free from coercion based on their own values and beliefs.<sup>139</sup> The principle of autonomy has at least two sources in U.S. law. Courts in almost all U.S. jurisdictions have recognized the existence of a common law right to be free from nonconsensual bodily invasion. Further, in *Cruzan v. Missouri*, the U.S. Supreme Court affirmed that there is a constitutional Substantive Due Process right to make decisions of critical importance to one's own destiny.<sup>140</sup>

The autonomy principle is also strongly rooted in international law. Both Articles 1 and 3 of the Universal Declaration of Human Rights as well as Article 10 of the International Covenant on Civil and Political Rights recognize the "inherent dignity of the human person."<sup>141</sup> Article 17 recognizes that "No one

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138. *Id.*

139. Crewe & Viljoen, *supra* note 22, at 9.

140. The Court also held that Missouri could limit the exercise of this right for persons found to be incompetent. *See Cruzan v. Director, Mo. Dept. of Health*, 497 U.S. 261 (1990).

141. International Covenant on Civil and Political Rights, pmbl., art. 10, adopted Dec. 16, 1966, 999 U.N.T.S. 171 (entered into force Mar. 23, 1976) [hereinafter ICCPR]; *see* Universal Declaration of Human Rights, arts. 1, 3, G.A. Res. 217A(III), at 71, U.N. Doc A/810 (Dec. 12, 1948) [hereinafter UDHR].

shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honour and reputation.”<sup>142</sup> This foundational idea—that individuals should have control over what is done to their own bodies—protects patients in at least two ways. In many countries, including the United States, it gives patients a cause of action if they have suffered a harm due to an unwanted bodily invasion.<sup>143</sup> More importantly, this idea has developed into the legal doctrine of informed consent, which allows patients to prevent unwanted bodily invasions by refusing care.

Critics of routine testing argue that routine testing contravenes the principle of autonomy and use human rights principles to justify a policy of voluntary testing. However, this Article argues that one can use human rights principles to justify routine provider-initiated testing.

First, the autonomy principle contains more than the simple right to decline medical care. Respect for autonomy involves not only refraining from coercion, but it also involves ensuring the necessary conditions for exercising free choice. Especially as it is expressed in the doctrine of informed consent, autonomy also includes a right to a certain package of information. This is, after all, what separates *informed* consent from mere consent. Indeed, the main issue of contention in many judicial opinions on informed consent is the issue of materiality, or what information is material to a patient’s decision to undergo a given therapy or procedure.<sup>144</sup> The argument for routine-offer testing is essentially an argument for giving patients more information. By giving patients more information to make informed decisions about their health, routine testing may potentially enhance individual autonomy.

Second, even independent of the autonomy principle, the letter and the substance of international human rights law can be interpreted to support routine provider-initiated HIV testing. Simply put, the principle of autonomy and the right to be free from coercion must be supplemented and augmented by other equally important human rights principles. One such principle is the right to health, which is expressed in several international human rights documents, including Article 25 of the Universal Declaration of Human Rights,<sup>145</sup> Article 12 of the International Covenant on Economic, Social and Cultural Rights,<sup>146</sup> Article

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142. *Id.*

143. *See, e.g.,* *Canterbury v. Spence*, 464 F.2d 772, 787 (D.C. Cir. 1972) (defining the physician’s duty to disclose as including information that is material to a patient’s decision if “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 [information] in deciding whether or not to forgo the proposed therapy”).

144. 464 F.2d 772, 787; *see also* *Culbertson v. Mernitz*, 602 N.E.2d 98, 102-04 (Ind. 1992) (holding that expert testimony from a physician is required to establish the professional standard of care in an action for negligence based on physician’s failure to obtain informed consent).

145. UDHR, *supra* note 141, art. 25.

146. International Covenant on Economic, Social and Cultural Rights, art. 12, adopted Dec. 16, 1966, 993 U.N.T.S. 3 (entered into force Jan. 3, 1976).

24 of the Convention on the Rights of the Child,<sup>147</sup> and Article 16 of the African Charter on Human and Peoples' Rights.<sup>148</sup> Several national constitutions also recognize the right to health, including Article 47 of the Constitutional Law of the Republic of Angola,<sup>149</sup> Section 27 of the Constitution of the Republic of South Africa,<sup>150</sup> Article 30 of the Republic of Malawi,<sup>151</sup> and Article 21 of the Republic of India.<sup>152</sup>

As David Patterson of the Canadian HIV/AIDS Legal Network notes, historically human rights discourse in Western countries has tended to privilege civil and political rights over social and economic rights.<sup>153</sup> This is most apparent in the human rights community's focus on discrimination against people living with HIV/AIDS, which reflects the concern with individual rights that is characteristic of American civil libertarianism. However, this narrow formulation of "human rights," which has drawn criticism from some practitioners in developing countries,<sup>154</sup> fails to address the human rights imperative to ensure the right to health of HIV positive individuals by giving them access to treatment.<sup>155</sup>

Few issues other than HIV testing better illustrate the tension that can exist between civil and political rights, and social and economic rights. One could imagine a regime justifying mandatory testing by invoking social and economic human rights principles—that is, by arguing that the public health imperative presented by HIV/AIDS overrides the autonomy principle.<sup>156</sup> On the other hand, the current policy of voluntary testing privileges civil and political rights at great expense in terms of public health and the right to health of individuals. As this paper has already argued, expanded testing coupled with treatment comes with potentially enormous benefits both for individuals and for society. To the extent that the autonomy principle may be in tension with the right to health, HIV testing policies should not take extraordinary measures to safeguard autonomy at

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147. Convention on the Rights of the Child, art. 24, G.A. Res. 25, 44th Sess., Annex, Agenda Item 108, at 170, U.N. Doc. A/RES/44/25 (1989).

148. African Charter on Human and Peoples' Rights, art. 16, adopted June 27, 1981, 1520 U.N.T.S. 217 (entered into force Oct. 21, 1986).

149. CONST. ANGL. part 2, art. 47 (1992).

150. S. AFR. CONST. 1996, sec. 27.

151. CONST. OF THE REP. OF MALAWI chap. 4, art. 30 (1994).

152. INDIA CONST. arts. 21 and 14. Article 21 provides for the "right to life." Article 14 provides for the "right to equality." The Indian Supreme Court has interpreted these two provisions as guaranteeing a right to health.

153. David Patterson & Leslie London, *International Law, Human Rights and HIV/AIDS*, 80 BULLETIN WORLD HEALTH ORG. 964, 965 (2002).

154. Kevin De Cock et al., *Shadow on the Continent: Public Health and HIV/AIDS in Africa in the 21st Century*, 360 LANCET 67, 67 (2002).

155. Patterson & London, *supra* note 153, at 966.

156. One example of this would be Cuba's mandatory quarantine policy for people with HIV infection. Ronald Bayer & Cheryl Heaton, *Controlling AIDS in Cuba: The Logic of Quarantine*, 320 NEW ENG. J. MED. 1022 (1989).



the expense of the health or well-being of the public.

## *2. The Human Rights Consequences of a Policy of Voluntary Testing*

While it is possible that a routine testing may erode individual autonomy—a possibility that I will consider in the following Subsection—it is also possible that the failure to make HIV testing routine may itself lead to a non-recognition of the right of individuals to know their HIV status. As a result, individuals who *voluntarily* seek an HIV test may be denied a test.

Few courts have actually considered the issue of whether individuals have a right to an HIV test. In the United States, this question has been considered only in the context of whether prisoners have a right to HIV testing on demand. The U.S. Supreme Court's Eighth Amendment jurisprudence requires prison officials to provide prisoners with adequate medical care. Under the analysis provided by the Court in *Estelle v. Gamble*, "adequate" is defined according to a community standard.<sup>157</sup> To demonstrate that the denial of a particular form of medical care violates the Eighth Amendment, *Estelle* requires evidence that (1) there was deliberate indifference on the part of prison officials and (2) that the prisoner's medical needs were serious.<sup>158</sup>

Only one case has applied *Estelle* to a situation where an HIV test was denied. In *Doe v. Wigginton*, the Sixth Circuit considered the case of an inmate in the Kentucky State Reformatory in 1989, who requested an HIV test. His request was denied by a nurse because he did not meet the testing criteria established by Kentucky's medical regulations for correctional facilities. These regulations specifically stated that no routine testing would be performed, but that a physician could order a test if an inmate has physical symptoms of HIV infection or a presumptive history of exposure.<sup>159</sup> The inmate in question was transferred to another facility two years later, where he was tested for HIV and found to be positive. By the time of his diagnosis, his immune function had already declined.<sup>160</sup> The Sixth Circuit held that the prison officials were not deliberately indifferent to the possibility that the inmate had been infected with the HIV virus.<sup>161</sup> In its reasoning, the court relied heavily on the fact that HIV testing was not routine in the community and that Kentucky's regulations on HIV testing, therefore, were reasonable.<sup>162</sup> If routine testing had been the norm in the community, this likely would have satisfied the constitutional standard for an Eighth Amendment violation. In essence, the court treated HIV testing, because it was not routine in the community, as if it was unnecessary or extraordinary

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157. *Estelle v. Gamble*, 429 U.S. 97, 103 (1976).

158. *Id.* at 104.

159. *Doe v. Wigginton*, 21 F.3d 733, 733-35 (6th Cir. 1994).

160. *Id.*

161. *Id.* at 738.

162. *Id.*

medical care.

Even in countries that recognize a right to health, courts are hesitant to recognize a self-standing and independent positive right for individuals to claim some basic minimum package of medical care, often preferring instead to review government actions for reasonableness. The South African Constitutional Court, for example, has twice been asked to enforce the right to health under Article 27 of the South African Constitution. In the first case, *Soobramoney v. Minister of Health*, the court considered whether a forty-one-year-old man with chronic renal failure, who required lifelong dialysis to survive but did not qualify for dialysis at his local medical facility, could require the health department to provide a sufficient number of machines to offer dialysis to everyone whose life could be saved through such treatment. The court noted that the right to health is limited by “available resources” and that the courts should not interfere with decisions that are rational and made “in good faith by the political organs and medical authorities whose responsibility it is to deal with such matters.”<sup>163</sup> In *TAC v. Minister of Health*, the court considered whether the government’s refusal to allow doctors to use the ARV drug nevirapine, which was freely available in South Africa, was reasonable in light of the drug’s ability to reduce the risk of mother to child transmission of HIV—and whether the South African government’s delay in introducing a comprehensive plan to reduce mother to child transmission of HIV was reasonable. The court ruled that the government’s actions were unreasonable, but implied that individuals had no self-standing right to claim a minimum package of medical care.<sup>164</sup>

It is not so difficult to imagine governments or public health authorities denying HIV testing to individuals by citing resource constraints. If HIV testing remains a voluntary medical test as opposed to a routine medical test, courts may interpret the denial of an HIV test on demand as reasonable—just as the Sixth Circuit did in *Wigginton*. This could potentially mean that many individuals seeking an HIV test would be denied access to a test by their health care system.

### 3. *Balancing Individual Autonomy and the “Right to Know”*

In truth, one can use human rights principles to justify either a voluntary or a routine-offer testing policy. It simply depends on whether one chooses to emphasize civil and political rights or social and economic rights. This Article takes the view that it is inconsistent with the right to health not to offer individuals a test for a treatable disease—that, if there is a right to health, it follows as a corollary that there must also be a right to comprehensive HIV care, of which HIV testing is a necessary component. By offering an HIV test to an individual, a health care worker helps that individual realize this right.

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163. *Soobramoney v Minister of Health (KwaZulu-Natal)* 1997 (12) BCLR 1696 (CC) 1706 (S. Afr.).

164. *TAC v Minister of Health* 2001 (4) BCLR 356 (T), 2001 SACLR LEXIS 123 (S. Afr.).

However, the right to health in the context of HIV testing, if taken to its extreme, can easily become an argument for paternalism. As some proponents of mandatory testing argue, avoiding the greatest human rights violation of all, premature and avoidable death, requires abandoning the autonomy principle. Kevin De Cock has asserted that the “failure to prevent HIV transmission constitutes an infringement of human rights that hampers Africa’s human and social development.”<sup>165</sup> De Cock creates a dichotomy between the human rights principles of autonomy and the right to health. In his view, human rights advocates deter HIV testing by demanding specialized informed consent and confidentiality procedures. Because this Article argues in favor of coupling expanded testing with expanded protection for individual rights, it argues for a balance between individual autonomy and the right to health implicated by HIV testing.

Equally problematic is the way in which the WHO has chosen to frame this issue—that is, in terms of the individual’s “right to know” their HIV status. Consider this excerpt from a 2003 WHO policy paper: “People have a right to know their HIV status, and testing and counseling should be widely accessible through innovative, ethical and practical models of delivery.”<sup>166</sup> Another 2004 policy paper described “the right to seek, receive and impart information . . . as a fundamental human right.”<sup>167</sup>

While this paper agrees with the claim that people have a right to know their HIV status, this formulation taken alone is potentially problematic given the current politics of HIV testing. Richard Holbrooke, for example, chose to weigh the autonomy principle against the “right to know”: “[Knowledge of HIV status] changes people’s behavior; many who learn that they are HIV positive behave more carefully, and they can act on the information to save themselves and their family members. Isn’t this the most important human right of all?”<sup>168</sup> This statement implies that the civil and political rights of individuals, as expressed in the autonomy principle, are somehow less important than the “right to know.” Segolame Ramothlwa, operations manager for Botswana’s national treatment program, expressed this idea more directly while responding to concerns that Botswana’s decision to start routine testing would compromise patients’ rights: “I think the first right of a human being is to be alive. All other rights are secondary.”<sup>169</sup> One need only traverse a short logical distance from this statement to construe the “right to know” as implying that the state has a duty to inform individuals of their HIV status, even if they do not want to be informed of it.

165. De Cock et al., *supra* note 154, at 71.

166. WORLD HEALTH ORG., THE RIGHT TO KNOW: NEW APPROACHES TO HIV TESTING AND COUNSELING (2003).

167. Miller et al., *supra* note 47, at 3; UDHR, *supra* note 141, art. 19; ICCPR, *supra* note 141, art. 19.2; Convention on the Rights of the Child, *supra* note 147, arts. 13, 17, 24.

168. Holbrooke, *supra* note 118.

169. *Botswana’s AIDS Program Confronts Stigma, Fear*, ASSOCIATED PRESS, Jan. 5, 2005.

It is important, while recognizing the “right to know” or the right to have a test offered by a health care worker, to clarify the accompanying responsibilities of governments, public health authorities, and health care workers. Asserting a “right to know,” disconnected from a duty to protect individual rights, invites violations of individual autonomy in the name of social and economic rights. This is both inadvisable and unnecessary. More preferable would be a strategy of expanded routine provider-initiated testing that includes expanded protection for autonomy and confidentiality. This strategy, which unifies principles of civil and political rights with principles of social and economic rights, is discussed further in the proposal for expanded protections for individual rights in the final Part of this Article.

#### IV. THE CASE AGAINST ROUTINE PROVIDER-INITIATED HIV TESTING

The case against routine testing can be summarized as follows: routine-offer testing is potentially coercive and paternalistic and compromises important human rights principles. According to this argument, national health care systems should instead aim to create a climate in which people want to know their HIV status and trust health care providers to provide them with information and support. Opponents of routine testing have raised at least six specific objections to routine testing proposals. While I will discuss each in turn, these objections can be grouped into three categories. The first two reflect a fundamental misunderstanding of proposals for routine-offer testing: that routine testing will be packaged with a streamlining of informed consent procedure; and that those who test positive under routine testing may not receive treatment. The second two arguments challenge proposals for routine-offer testing on the basis of currently available evidence: that routine testing may hamper prevention efforts and that routine testing is not necessary for rational patient management. Finally, two of the objections raised by opponents of routine testing—that routine testing will result in mandatory testing via a slippery slope and that routine testing will lead to a greater number of involuntary disclosures of HIV status—are serious concerns that require a more thoughtful response.

##### *A. The Danger of Streamlined Informed Consent*

Opponents of routine testing, who fear that patient consent is unlikely to be fully informed in routine testing situations, make two claims. First, proposals for routine testing are often packaged with proposals that call for a streamlining of counseling and informed consent protocols.<sup>170</sup> Second, as a result of this streamlining of informed consent, patients will receive less information.<sup>171</sup>

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170. See Can. HIV/AIDS Legal Network, *Human Rights and HIV/AIDS in the Context of 3 by 5: Time for New Directions?*, 9 CAN. HIV/AIDS POL’Y & L. REV., August 2004, at 10.

171. Crewe & Viljoen, *supra* note 22, at 6.

The second claim is simply untrue. Routine testing would mean that the *average* patient would receive more information about HIV testing than under voluntary testing, because under voluntary testing patients who do not seek an HIV test receive no information. Even if the first claim were entirely true—that routine testing will be packaged with a relaxation of informed consent requirements—only a small percentage of individuals would receive less information than they would in a voluntary testing regime, because so few individuals actually volunteer to be tested.

In any case, the first claim is only partially true. A 1999 Institute of Medicine panel issued a report that recommended routine prenatal HIV testing and also concluded that pre-test counseling and specific written consent requirements deterred providers from offering HIV testing to pregnant women. According to the panel, many health care providers reported that they lacked sufficient time to offer testing and counseling.<sup>172</sup> Michigan, which required routine testing for pregnant women, found that only 55% of women actually received an offer of an HIV test.<sup>173</sup> Other than the Institute of Medicine, few routine testing proposals promulgated by major public health agencies actually call for a streamlining of informed consent procedure. The 2004 guidelines on HIV testing published jointly by the WHO and UNAIDS discuss improved protections for individual rights quite prominently in the first section of a three page document:

[T]he cornerstones of HIV testing scale-up must include improved protection from stigma and discrimination as well as assured access to integrated prevention, treatment and care services. The conditions under which people undergo HIV testing must be anchored in a human rights approach which protects their human rights and pays due respect to ethical principles.<sup>174</sup>

Similarly, the CDC guidelines for HIV testing include specific and stringent procedures for confidentiality and for obtaining informed consent before an HIV test.<sup>175</sup>

Some individual authors have called for a streamlining of informed consent requirements for HIV testing. Richard Holbrooke, as noted earlier, has done this indirectly in suggesting that the rights to life and health outweigh the principles of autonomy and privacy. Though he has made no direct statement on this issue, his earlier position favoring mandatory testing for individuals participating in U.N. peacekeeping forces suggests that he might be amenable to relaxing informed consent requirements in the context of routine testing.<sup>176</sup>

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172. REDUCING THE ODDS: PREVENTING PERINATAL TRANSMISSION OF HIV IN THE U.S. 85 (Michael A. Stoto & Marie C. McCormick eds., 1999).

173. *Id.* at 78-79.

174. UNAIDS/WHO, *supra* note 44, at 1.

175. See Ctrs. for Disease Control & Prevention, *supra* note 56, at 7.

176. See UN-AIDS: UNAIDS Says HIV Testing Must Be Voluntary for UN Troops, AGENCE

Kevin De Cock published two widely cited papers in *The Lancet* in which he called for routine testing as well as for a “serostatus approach” to HIV—that is, an approach based on widespread routine testing in which individuals learn their status, disclose it to their partners and seek medical care.<sup>177</sup> However, De Cock also argues that routine testing should not require specific consent or pre-test counseling: “Awareness of HIV/AIDS is now high in Africa, and evidence that more extensive pre-test counseling is necessary for HIV than for other diseases is lacking.”<sup>178</sup>

De Cock is essentially arguing for a default policy of testing without pre-test counseling, unless an individual specifically elects to decline testing, with post-test counseling for those infected with HIV. This Article agrees with the idea that HIV should be treated more like other diseases only in the limited sense that health care providers should make a routine offer of a test to their patients. However, rather than relax informed consent requirements for HIV testing, this Article instead proposes specialized informed consent, confidentiality, and counseling procedures for HIV.

The apparent differences among the positions of De Cock, the WHO, the CDC, and this Article mirror a larger controversy in informed consent. As Peter Schuck has written, there is an informed consent gap between the ideal of informed consent represented in legal doctrine, and the actual practice of informed consent by physicians.<sup>179</sup> At the poles of this gap are idealists, mostly judges and legal ethicists who want an expansive and subjective conception of a physician’s duty to disclose, and realists, primarily physicians who question whether patients want exhaustive information and whether fully informed consent is worth its costs.

One might describe De Cock as a realist who believes that the idealized form of consent required for HIV testing is overly burdensome in that it has a detrimental effect on health care delivery. Both De Cock and the Institute of Medicine (in the specific context of prenatal testing) suggest that extensive and specialized pre-test counseling may not be necessary. While this Article argues otherwise, it is important not to overstate the scope of this disagreement. Everyone agrees that patients should receive some information before testing and should be free to decline testing. The real debate is about how much information they should receive—not whether to jettison informed consent altogether. To the extent that there is disagreement, the major public health agencies have favored a specific and rigorous informed consent requirement for HIV testing.

This Article agrees with this majority position. A shift from voluntary to

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FRANCE-PRESSE, July 17, 2000, available at <http://www.aegis.com/news/afp/2000/AF0007E2.html>.

177. Kevin M. De Cock et al., *A Serostatus-Based Approach to HIV/AIDS Prevention and Care in Africa*, 362 LANCET 1847, 1847 (2003).

178. De Cock, *supra* note 154, at 69.

179. Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899 (1994).

routine testing need not mark a broader systemic shift in the culture of our approach to the HIV/AIDS pandemic, nor a move away from prevention strategies based on education and behavior change toward strategies that emphasize testing exclusively. Routine provider-initiated testing does not imply that we must abandon the key principles of autonomy, confidentiality, and informed consent. Quite the contrary, human rights aims and public health aims can be mutually reinforcing. In order to further public health aims, patients must become engaged in preventive and treatment programs. This requires voluntary long-term cooperation.

*B. Individuals Who Test Positive May Not Receive Treatment*

Some critics of routine testing have pointed out that there is no guarantee that those who are tested and are found to require ARV treatment will receive treatment. Treatment remains unavailable for most HIV-positive individuals in the world. Therefore, one cannot assume that the proposed tradeoff—"universal treatment in exchange for a reduction in individual rights—even exists."<sup>180</sup> Notwithstanding the contention that routine testing does not necessarily result in a reduction in individual rights, this statement is entirely true. As one critic has accurately described, treatment programs in most developing countries are site-based, not universal. Especially in rural areas, some individuals may have no conceivable access to treatment.<sup>181</sup>

Without access to treatment, the strongest arguments for testing, which are rooted in the benefit to the individual being tested, do not hold up. What is left of the case for routine testing depends on the idea that it may aid prevention efforts: that individuals need to "know their status" in order to take steps to prevent spreading the virus, as Richard Holbrooke has argued.<sup>182</sup> This is essentially similar to the situation that existed before the ARV era, during which governments and public health agencies made testing strictly voluntary.

Because testing without treatment may yield more harm than benefit for individuals, this Article takes the stand that routine testing should be strictly coupled with a promise of access to treatment. Where treatment is not a possibility, the status quo policy of voluntary testing should be maintained. This is the same position adopted by the WHO and UNAIDS in their 2004 guidelines on HIV testing.<sup>183</sup>

*C. Routine Testing May Impede Prevention Efforts*

While I have suggested that routine testing is likely to aid prevention efforts,

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180. Crewe & Viljoen, *supra* note 22, at 11.

181. *Id.*

182. Holbrooke & Furman, *supra* note 52, at A25.

183. UNAIDS/WHO, *supra* note 44, at 2.

some critics argue that routine testing may actually impede prevention. According to this argument, routine testing may lead to some individuals being tested against their will. Some number of individuals, out of fear and distrust engendered by this forced medical treatment, may avoid medical care altogether.<sup>184</sup> As a corollary to this argument, critics also suggest that people who are at risk for HIV, and who are therefore more likely to fear HIV-associated stigma, may make the decision to opt out of testing while those at lower risk may submit to testing unnecessarily.

While there is a dearth of empirical evidence on this issue, the little evidence that is available suggests that routine testing does not adversely impact overall health care utilization. Botswana, one of the few countries for which data is available, implemented routine testing for pregnant women in 2004. The CDC Global AIDS Program conducted a study of four selected clinics in Francistown, Botswana's second largest city. Data on prenatal care-attendance, HIV test acceptance, and receipt of test results were collected for four months before the implementation of routine testing and then for four months afterward. A median of 114 women per month began prenatal care during the initial four months; a median of 130 women per month began prenatal care during the three months after the implementation of routine testing. The study concluded that routine testing did not lead to reductions in the number of women attending prenatal care. Moreover, approximately 90% of women opted to have an HIV test—a finding that suggests that testing not only had no impact on health care utilization but also that testing was well accepted by patients.<sup>185</sup> Botswana has since extended routine testing to individuals in the general population. While comprehensive national data is not yet available, no adverse consequences of this program have been reported to date.<sup>186</sup>

It also appears unlikely that those who are at high risk of becoming infected with HIV are more likely to decline testing and thereby thwart much of the purpose of routine testing. Several studies have found that higher acceptance rates for HIV testing are associated with the individual's perception of HIV risk and acknowledgement of risk behaviors. Conversely, low prevalence settings are associated with lower acceptance rates for testing.<sup>187</sup>

As I have already described, it is at least a very real possibility that routine testing will bolster HIV prevention efforts. Testing may bring about reductions in sexual risk behavior, though the evidence on this issue remains equivocal. Expanded testing is also likely to reduce transmission through other mechanisms: by stimulating a greater social awareness of HIV and, when coupled with

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184. Bozzette, *supra* note 134, at 621; Crewe & Viljoen, *supra* note 22, at 11.

185. Ctrs. for Disease Control & Prevention, *Introduction of Routine HIV Testing in Prenatal Care—Botswana, 2004*, 53 MORBIDITY & MORTALITY WKLY. REP. 1083 (2004), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5346a2.htm>.

186. CSIS REPORT, *supra* note 23, at 9.

187. Chou et al., *supra* note 69, at 58.



treatment, by decreasing viral loads and transmissibility.<sup>188</sup>

*D. Routine Testing Is Not Necessary for Rational Patient Management*

Opponents of routine testing argue that diagnosing HIV is not necessary to ensure rational patient management where treatment is not available.<sup>189</sup> This paper concedes that for individuals who have no access to ARV treatment the harms associated with routine testing may outweigh the benefits. However, where treatment is available, this statement is simply untrue.

A recent review article found that between 12% and 43% of patients already had full-blown AIDS—that is, a CD4+ count of less than 200 cells per cubic millimeter of blood—at the time they were diagnosed with HIV infection.<sup>190</sup> Even 12%, which represents the lower end of this range, is alarmingly high. Two studies in particular, conducted in Boston and in San Francisco, found that on initial presentation for HIV-related medical care, 37% and 29% of patients respectively had a CD4+ count of less than 200 cells per cubic millimeter of blood.<sup>191</sup> According to a 2001 report by the CDC, 39% of individuals who received a diagnosis of HIV infection in the United States developed AIDS within a year of receiving their diagnosis.<sup>192</sup> As high as the rate of late presentations is in the United States, one could reasonably expect it to be even higher in resource-poor settings, where the number of individuals who know their status is far lower.<sup>193</sup>

As I have described earlier, a number of observational studies show that starting treatment early diminishes the incidence of opportunistic infections and allows individuals to sustain normal CD4+ levels, sparing them the morbidity and mortality associated with such infections.<sup>194</sup> Initiating therapy earlier leads to a higher likelihood of suppressing viral replication, improving immunity, and reducing drug-related adverse events.<sup>195</sup> Conversely, it appears that interventions are less effective in persons with advanced immune deficiency.<sup>196</sup>

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188. See *supra* Section III.C.

189. Crewe & Viljoen, *supra* note 22, at 17.

190. Chou et al., *supra* note 69, at 58.

191. Mitchell H. Katz et al., *CD4 Lymphocyte Count As an Indicator of Delay in Seeking Human Immunodeficiency Virus-Related Treatment*, 152 ARCHIVES INTERNAL MED. 1501, 1501 (1992) (describing San Francisco study); Samet et al., *supra* note 67, at 737 tbl.2 (describing Boston study).

192. CTRS. FOR DISEASE CONTROL & PREVENTION, HIV/AIDS SURVEILLANCE REPORT (2002).

193. Miller et al., *supra* note 47, at 2.

194. Ledergerber et al., *supra* note 70, at 2220.

195. Scott D. Holmberg et al., *The Case for Earlier Treatment of HIV Infection*, 39 CLINICAL INFECTIOUS DISEASES 1699, 1700 (2004).

196. Egger et al., *supra* note 14, at 119.

*E. Routine Testing Will Lead to Mandatory Testing via a Slippery Slope*

Perhaps the core argument offered against routine testing is that it is inherently coercive. As one critic describes, it is unrealistic to expect already overburdened health care workers to provide meaningful counseling and consent. Once these safeguards are “diluted,” individuals will be coerced into testing.<sup>197</sup> That is, routine-offer testing will necessarily lead to mandatory testing for the general population, which is universally rejected by public health experts and multilateral bodies and would be tantamount to outing HIV-positive individuals.<sup>198</sup>

Indeed, some articles in the medical literature suggest that doctors should re-offer tests to those who initially refuse. One 2005 study published in *AIDS Patient Care & STDs*, for example, concluded from a survey of prenatal care providers that the percent of providers reporting universal testing among their patients was associated with the degree to which they encouraged testing.<sup>199</sup> The authors implicitly recommend that health care providers strongly encourage testing and persist in offering testing to women who have initially refused.<sup>200</sup> This language, which stops short of suggesting coercion, nevertheless suggests that a fine line separates coercion from persuasion.

The same critic of routine testing quoted above echoes this idea: “Part of the problem with most health services is that they are disempowering, paternalistic and authoritarian. They tend to infantilise people by reducing their power and claiming to know what is best for them.”<sup>201</sup> Notwithstanding the sweeping generalization about patient-provider interaction it contains, this statement does convey a valid criticism in that it is representative of the way that many critics feel about the practice of informed consent in health care. This Article offers three interrelated arguments in response.

First, to the extent that there is slippage between routine testing with informed consent and coercion, I have already argued that a utilitarian end justifies this risk. The potential benefits to the individual and to society are high and, if routine testing is part of a package of protections for individual rights, the risk of coercion can be minimized. Moreover, the risk of slippage between voluntary consent and coercion exists throughout medicine. The real question

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197. Crewe & Viljoen, *supra* note 22, at 18.

198. Mandatory testing is a much closer question in limited cases involving select populations—pregnant women, public employees—and has survived constitutional scrutiny in the United States in cases that are specific to these groups. See Dorian L. Eden, *Is It Constitutional and Will It Be Effective? An Analysis of Mandatory HIV Testing of Pregnant Women*, 11 HEALTH MATRIX 659 (2001); Kellie E. Lagitch, *Mandatory HIV Testing: An Orwellian Proposition*, 72 ST. JOHN’S L. REV. 103 (1998).

199. John E. Anderson et al., *Achieving Universal HIV Screening in Prenatal Care in the United States: Provider Persistence Pays Off*, 19 AIDS PATIENT CARE & STDs 247, 251 (2005).

200. *Id.*

201. Crewe & Viljoen, *supra* note 22, at 18.

raised by the danger of coercion is whether there is any rational reason for treating HIV testing differently from any other type of diagnostic testing. With all other types of diagnostic testing, it is assumed that a utilitarian end justifies the risk of coercion. That is, while ordinary people lack sufficient knowledge to seek out diagnostic tests that may improve their longevity on their own, they can decide on the basis of information presented to them whether or not to undergo a particular diagnostic test. Hence, all other diagnostic testing in medicine is initiated by health care providers or “routinely offered.” This Article has argued that the twin possibilities of HIV treatment and prevention lead to a utilitarian calculus for HIV testing that resembles that which is used to justify all other types of diagnostic testing.

Second, even the current voluntary approach to HIV testing concedes some risk—albeit a lower risk—of slippage into coercion. For example, the WHO, the International Labor Organization (ILO) and several countries have actively promoted a “Know Your Status” campaign whose main goal is to persuade more individuals to seek an HIV test.<sup>202</sup> As part of this campaign, the WHO and the ILO created a pamphlet, presumably for dissemination by health care providers, entitled “Know Your Status. HIV Testing and Counseling: The Gateway to Wellness.”<sup>203</sup> Inherent in these persuasive materials is a claim that public health authorities know what is best for certain individuals. The main difference between this form of persuasion and that in routine testing is that in the latter setting a health care provider would actually verbalize an offer of a test, as opposed to merely offering a patient literature about a test.

Third, slippage between routine testing with informed consent and coercion is not inevitable. Because the danger of coercion—and the fact that many patients feel overborne by their doctors—is not itself a justification for making all medical care patient-initiated, it is more useful to ask whether there are other remedies for this danger than denying medical care altogether. One such remedy, which I will describe in more detail in the final Part of this Article, is to create a more robust standard for informed consent in routine HIV testing that unites the goals of expanding access to testing and protecting individual rights.

#### *F. Routine Testing Will Lead to Involuntary Disclosures of HIV Status*

The right to privacy is closely related to concerns about autonomy and informed consent, and is the other core human rights issue implicated by routine testing. Critics of routine testing argue that routine testing is disempowering because it may lead to a greater number of involuntary disclosures of HIV

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202. Press Release, World Health Org., ILO and WHO Co-developing Guidelines on Workplaces and HIV/AIDS (Mar. 14, 2005), available at <http://www.who.int/3by5/news44/en/>.

203. Int'l Labor Org., Know Your Status: HIV Testing and Counseling: The Gateway to Wellness (Mar. 14, 2005), available at <http://www.ilo.org/public/english/protection/trav/aids/publ/kys-en.pdf>.

status.<sup>204</sup> Involuntary disclosure—whether due to mandatory partner notification laws or other breaches of confidentiality—will put some people at risk of social stigmatization and even of physical danger. This, in turn, amplifies the danger associated with the possibility of routine testing slipping into coercion.

Moreover, women are more likely to face the dangers associated with involuntary disclosures of HIV status, since they are more likely to have contact with the health care system, mostly notably through antenatal care.<sup>205</sup> Women also often face spousal abuse when they are known or are suspected to be HIV positive.<sup>206</sup> Moreover, as has been widely documented, cultural norms and laws on property, inheritance, and divorce in many countries provide a foundation of inequality on which this violence thrives. This inequality limits the choices that women have and prevents them from leaving abusive relationships.<sup>207</sup> One study of 245 women in Tanzania, who were followed for three months after HIV testing, found that younger (less than thirty years old) women who were HIV-positive were ten times more likely than younger HIV-negative women to report partner violence.<sup>208</sup> Another qualitative study of women in the Dominican Republic by Human Rights Watch found that,

regardless of the actual source of the infection, many women who test positive for HIV are subject to ostracism, violence, or abandonment by spouses, long-term partners, or families. In the Dominican Republic, moreover, cultural norms dictate that women—but not necessarily men—should be faithful and that a woman is ultimately responsible even for her spouse's infidelity.<sup>209</sup>

In the United States, there have been reports of women being physically and verbally abused after revealing their HIV status.<sup>210</sup>

204. Crewe & Viljoen, *supra* note 22, at 16.

205. *Id.*

206. HUMAN RIGHTS WATCH, JUST DIE QUIETLY: DOMESTIC VIOLENCE AND WOMEN'S VULNERABILITY TO HIV IN UGANDA 28-29 (2003).

207. See HUMAN RIGHTS WATCH, DOUBLE STANDARDS: WOMEN'S PROPERTY RIGHTS VIOLATIONS IN KENYA 30 (2003).

208. Suzanne Maman et al., *HIV-Positive Women Report More Lifetime Partner Violence: Findings from a Voluntary Counseling and Testing Clinic in Dar es Salaam, Tanzania*, 92 AM. J. PUB. HEALTH 1331 (2002). The women in this study reported violence over their entire lifetimes—that is, both before and after their HIV tests. As a result, this study does not directly support the contention that a positive diagnosis of HIV results in partner violence. Rather, the study identifies violence as a risk factor for HIV infection.

209. HUMAN RIGHTS WATCH, A TEST OF INEQUALITY: DISCRIMINATION AGAINST WOMEN LIVING WITH HIV IN THE DOMINICAN REPUBLIC 2 (2004), available at <http://hrw.org/reports/2004/dr0704/>.

210. See, e.g., Richard L. North & Karen H. Rothenberg, *Partner Notification and the Threat of Domestic Violence Against Women with HIV Infection*, 329 NEW ENG. J. MED. 1194 (1993); Karen H. Rothenberg et al., *Domestic Violence and Partner Notification: Implications for Treatment and Counseling of Women with HIV*, 50 J. AM. MED. WOMEN'S ASS'N 87 (2005); Karen H. Rothenberg & Stephen J. Paskey, *The Risk of Domestic Violence and Women with HIV Infection: Implications for Partner Notification, Public Policy, and the Law*, 85 AM. J. PUB. HEALTH 1569 (1995); Leslie E. Wolf et al., *Legal Barriers to Implementing Recommendations for Universal, Routine Prenatal HIV*

### 1. A Guarantee of Confidentiality

In light of these findings, this Article argues that routine testing must be linked to a guarantee of confidentiality. This position echoes the strong presumption in international human rights law in favor of policies that respect the right to privacy through confidentiality and informed consent. The right to privacy is protected by Article 17 of the International Covenant on Civil and Political Rights, Article 11 of the American Convention on Human Rights, Article 8 of the European Convention on Human Rights, and Article 16 of the U.N. Convention on the Rights of the Child.<sup>211</sup> State laws in the United States by and large reflect this presumption in favor of privacy for HIV test results. Thirty-two states have adopted laws that specifically protect the confidentiality of HIV test results. Of these states, only six permit disclosure to a test subject's spouse without consent. Three additional states permit disclosure to a spouse, a sexual partner, or needle-sharing partners, with two of these three requiring that the test subject be notified first.<sup>212</sup> Some scholars have argued that certain personal information—presumably including such sensitive information as the results of an HIV test—is constitutionally protected, subject to a balancing test regarding the individual's privacy right against the interests of the state.<sup>213</sup>

It is important to note that this guarantee of confidentiality would not preclude systematic voluntary partner notification, provided that such notification is based on the same rigorous standard of informed consent that I propose in the final section of this paper. Both the CDC and UNAIDS have published guidelines that support providing voluntary partner notification services to those who test positive for HIV.<sup>214</sup> The UNAIDS guidelines also support creating provisions for exceptional cases where voluntary partner notification is not possible. Suggested provisions include establishing a panel of experts to provide advice to health care providers on the ethics of partner notification, or requiring health care providers to consult with another professional before notifying an HIV-positive patient's sexual partners. The guidelines emphasize that health care

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Testing, 32 J. L. MED. & ETHICS 137, 138 (2004); Sally Zierler et al., *Violence Victimization After HIV Infection in a US Probability Sample of Adult Patients in Primary Care*, 90 AM. J. PUB. HEALTH 208, 208 (2000).

211. See Ctr. for Reproductive Rights, *Safe and Legal Abortion Is a Woman's Human Right* 5 (2004), available at [http://www.crlp.org/pdf/pub\\_bp\\_safeandlegal.pdf](http://www.crlp.org/pdf/pub_bp_safeandlegal.pdf).

212. Wolf et al., *supra* note 210, at 142.

213. See generally Roger Doughty, Comment, *The Confidentiality of HIV-Related Information: Responding to the Resurgence of Public Health Interventions in the AIDS Epidemic*, 82 CAL. L. REV. 111, 148-154 (1994) (reviewing the constitutional status of HIV-related personal information).

214. UNAIDS/WHO, *supra* note 44, at 1; UNAIDS, HANDBOOK FOR LEGISLATORS ON HIV/AIDS, LAW AND HUMAN RIGHTS 45 (1999); Ctrs. for Disease Control & Prevention, *Advancing HIV Prevention: New Strategies for a Changing Epidemic—United States 2003*, 52 MORBIDITY & MORTALITY WKLY. REP. 329, 329-30 (2003).

professionals should not be required to notify patients' sexual partners.<sup>215</sup> Moreover, the American Civil Liberties Union (ACLU), which has taken a strong stand against mandatory partner notification, endorses public health programs that help people with HIV notify their partners, provided that these services are voluntary, non-coercive, and confidential.<sup>216</sup>

The remaining question is whether third-party notification is ever permissible without an individual's consent. International codes of medical ethics generally require that physicians maintain complete loyalty to their patients. The World Medical Association Declaration of Geneva calls on physicians to pledge that "the health of [their] patient[s] shall be [their] first consideration."<sup>217</sup> The World Medical Association International Code of Medical Ethics states that "a physician shall owe his/her patients complete loyalty and all the scientific resources available to him/her."<sup>218</sup> In reality, physicians are often called upon to maintain a "dual loyalty"—a simultaneous obligation to a patient and to a third party (an individual, an organization, or the state)—in many of the tasks they perform or preside over: forensic psychiatry, vaccination, organ donation, employment evaluation, and, in the context of the "war on terror," participating in the interrogation of prisoners.<sup>219</sup> In the case of partner notification for HIV, the question is whether physicians have a simultaneous duty to warn third parties of the danger of HIV infection and to take action that may prevent the spread of HIV. I have already argued that a utilitarian calculus justifies the danger that some individuals may be tested without their consent; a similar utilitarian argument could be used to justify partner notification.

There are at least two reasons to recommend a policy that forbids partner notification without consent. First, as I have already argued, there is a strong presumption in both U.S. law as well as in international human rights law in favor of privacy. Second, as a matter of public health policy, the utilitarian calculus probably cuts against partner notification without consent. Prevention strategies based on testing in the general population require widespread cooperation—and there are several reasons to believe that this cooperation is dependent upon the promise of confidentiality. Many patients fear partner notification because they believe it will lead to domestic violence.<sup>220</sup> As I have already described, involuntary partner notification can put individuals in physical danger. Moreover, some means of transmitting HIV implicate activity that is illegal in many jurisdictions. Injection drug use is a felony in all fifty U.S. states,

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215. UNAIDS, *supra* note 214, at 45.

216. AM. CIVIL LIBERTIES UNION, HIV PARTNER NOTIFICATION: WHY COERCION WON'T WORK 6 (1998).

217. WORLD MED. ASS'N, INTERNATIONAL CODE OF MEDICAL ETHICS: DECLARATION OF GENEVA (1949), available at <http://www.wma.net/e/policy/c8.htm>.

218. WORLD MED. ASS'N, INTERNATIONAL CODE OF MEDICAL ETHICS: DUTIES OF PHYSICIANS TO PATIENTS (1949), available at <http://www.wma.net/e/policy/c8.htm>.

219. PHYSICIANS FOR HUMAN RIGHTS, DUAL LOYALTY AND HUMAN RIGHTS 1 (2003).

220. AM. CIVIL LIBERTIES UNION, *supra* note 216, at 7.

and homosexual intercourse remains illegal in many countries.<sup>221</sup> Without a strict promise of confidentiality, HIV testing may result in a de facto admission of criminal activity.<sup>222</sup>

Moreover, there is some evidence in the public health literature that involuntary partner notification is ineffective as a public health strategy for controlling the spread of sexually transmitted diseases when there is a considerable delay before sexual partners can be contacted.<sup>223</sup> This is a hallmark characteristic of HIV infection. Most importantly, there are no community-based comparison studies that demonstrate a reduction in the incidence or prevalence of a sexually transmitted disease based on an intervention strategy including involuntary partner notification.<sup>224</sup>

This is quite different from voluntary partner notification programs, which have been studied to a limited extent. According to the results of one program reported by the San Francisco Department of Public Health in the *San Francisco Chronicle*, a voluntary partner notification program was able to notify 112 partners of 136 clients newly diagnosed with HIV. The program detected ten new cases of HIV.<sup>225</sup>

As a practical matter, part of the reason to favor a policy of voluntary partner notification is that in addition to the need to ensure cooperation in order for a testing strategy to work, health care providers would be hard pressed to enforce a notification policy without the cooperation of the individuals involved, regardless of what the law holds. An individual can simply choose to withhold information about his or her sexual or needle-sharing partners. Few health care providers would be in a position to question the accuracy of these information disclosures.<sup>226</sup> For example, one study reported the results of a partner notification program in North Carolina, a state where the failure of an HIV-positive individual to notify his or her sexual partners is a misdemeanor punishable by incarceration and a fine. The study found that only 7% of study participants succeeded initially in notifying their partners of their HIV status. Even after the participants were given assistance, 66% of partners could not be found.<sup>227</sup>

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221. *Id.*

222. *Id.*

223. *Id.* at 5.

224. *Id.* See generally Ronald Bayer & Kathleen E. Toomey, *HIV Prevention and the Two Faces of Partner Notification*, 82 AM. J. PUB. HEALTH 1158, 1158-63 (1992); Frances M. Cohen et al., *The Role and Effectiveness of Partner Notification in STD Control: A Review*, 72 GENITOURINARY MED. 247, 247-52 (1996).

225. Sabin Russell, *Dreaded Call Becomes Words To Live By—Notifying Partners of HIV-Positive People: An Important Weapon in the Fight Against AIDS*, S.F. CHRON., Jan. 9, 2006, at A1.

226. See Bayer & Toomey, *supra* note 224 (describing the practical difficulties involved in enforcing a mandatory partner notification policy for HIV).

227. Suzanne E. Landis et al., *Results of a Randomized Trial of Partner Notification in Cases of*

Moreover, partner notification is an extremely sensitive task that requires the skill of highly trained social workers and health care providers. As one social worker in San Francisco put it, "it takes a special kind of person to do this job."<sup>228</sup> Partner notification must involve extensive counseling, and different strategies will be appropriate for different situations. For example, interventions to prevent domestic violence may be necessary in many cases. Mandatory notification threatens to create a blanket policy that will not be able to accommodate the range of situations that health care providers may encounter.

The fact that so few people are offered voluntary partner notification services suggests that any discussion of involuntary partner notification is simply premature. If voluntary partner notification proves to be a viable public health strategy, and if the voluntariness principle is actually found to be limiting, then it may be necessary to revisit the possibility of creating limited exceptions for extreme cases where voluntary notification is not possible. As I have already discussed, the human rights guidelines published by UNAIDS already favor creating such exceptions.

## *2. Other Interventions To Mitigate the Danger of Involuntary Disclosure*

In addition to a legally enforceable guarantee of confidentiality, a policy of routine testing should be coupled with other "structural" interventions to prevent involuntary disclosures and to protect HIV-positive individuals from abuse. One such change might be to implement anonymous testing, wherein health care providers would not be able to associate any particular set of test results with any individual patient.<sup>229</sup> Forty-five U.S. states offer anonymous testing as an option, and several studies have demonstrated that anonymous testing results in increased testing rates.<sup>230</sup> However, anonymous testing places the burden for follow up on the individual patient and therefore comes with several drawbacks: more patients may be lost in follow up; some may not receive referrals for treatment and care; and many will likely not receive post-test counseling. Much of the benefit of expanded testing—in terms of guiding individuals into treatment programs and stemming the spread of HIV through behavior modification—may be lost as a result. Other structural interventions to reduce the risk of involuntary

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*HIV Infection in North Carolina*, 326 NEW ENG. J. MED. 101 (1992).

228. Russell, *supra* note 225.

229. This is different from confidential testing, in which the health care provider can identify a test result with a particular patient.

230. KAISER FAMILY FOUND., HIV/AIDS POLICY FACT SHEET (2005), available at <http://www.kff.org/hiv/aids/upload/updated-fact-sheet-HIV-Testing-in-the-United-States.pdf>; Laura J. Fehrs et al., *Trial of Anonymous Versus Confidential HIV Testing*, 1988, 2 LANCET 379, 380-81 (1998); Iruce Hertz-Picciotto, *HIV Test-Seeking Before and After the Restriction of Anonymous Testing in North Carolina*, 86 AM. J. PUB. HEALTH 1446, 1448-49 (1996); Douglas Hirano et al., *Anonymous HIV Testing: The Impact of Availability on Demand in Arizona*, 84 AM. J. PUB. HEALTH 2008, 2009-10 (1994).



disclosures could include requiring training in confidential testing procedures for health care workers, similar to HIPAA training in the United States, or creating a cause of action for individuals whose right of privacy has been violated. Other interventions may mitigate the dangers of involuntary disclosures after they have occurred. These include, but are not limited to creating emergency help lines for patients, providing safe shelters for battered women, and training law enforcement and social workers in handling AIDS-related violence.<sup>231</sup> Longer-term structural interventions, which are beyond the scope of this Article, but critical nonetheless, might include school and community-based awareness programs and reform of inequitable laws on property, inheritance, and divorce.

Routine testing must be implemented as a part of a larger package of interventions that address HIV-related stigma and empower individuals. The human rights approach to testing that this paper proposes would expand testing at the same time as it implements this larger package of interventions and, as I describe in the final Part, safeguards both autonomy and confidentiality.

#### V. A PROPOSED FRAMEWORK FOR AN ETHICAL ROUTINE TESTING PROGRAM

I have already argued that any shift toward routine testing must be linked to a guarantee of confidentiality, informed consent and, should the individual meet the appropriate clinical criteria, ARV treatment. States must not prioritize routine-offer testing above their obligation to protect those who test positive from discrimination and violence. More than this, policies that promote informed decisions and that protect individual patients will benefit the public's health, as all of the positive benefits of expanded testing, including treatment and the possibility of behavior modification, depend on the cooperation of individuals.<sup>232</sup> More specifically, what are the components of an ethical HIV testing program? I will use the last Part of this Article to present one particular legislative model for addressing the issues of informed consent, counseling, and confidentiality in the context of routine-offer HIV testing. The model legislation to which I refer appears as Appendix 1 and was prepared by myself in cooperation with the Human Rights and Democratization in Africa Programme at the University of Pretoria and the Allard K. Lowenstein International Human Rights Clinic at Yale Law School. I will describe each section of this model legislation in turn.

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231. Joanne Csete et al., Letter, *Opt-Out Testing for HIV in Africa: A Caution*, 363 LANCET, 493, 494 (2004).

232. Wolf et al., *supra* note 210, at 144.

*A. Informed Consent**1. The Scope of the Informed Consent Disclosure*

With the exception of some inherited genetic disorders, the test for HIV is the only diagnostic test in the United States that requires specific consent, as opposed to general consent to medical care. A majority of U.S. states and territories require specific consent for HIV testing.<sup>233</sup> The Model Legislation on Testing and Counseling for HIV/AIDS does not disturb this majority rule. It requires specific consent for HIV testing. Sixteen states require written consent, though nearly all of these states permit oral consent if written consent is not possible.<sup>234</sup> This model legislation requires written consent, unless written consent is not possible.

In order for a patient's consent to be meaningful, the health care provider must give the patient all information that would be material to her decision about whether to be tested before the test is administered. This is, not coincidentally, the main question debated among jurists and medical ethicists with regard to informed consent. That is, how much information does a health care provider have to disclose in order to make consent "informed consent?" Different institutions and jurisdictions have interpreted the materiality requirement in different ways. This model legislation provides a non-exhaustive list of information and considerations that must be discussed with the patient before the patient's consent can be considered informed and voluntary. This list is based on guidelines promulgated by the WHO,<sup>235</sup> the South African *Department of Health Draft National Policy on Testing for HIV*,<sup>236</sup> the United Kingdom General Medical Council statement on informed consent,<sup>237</sup> as well as a survey of case law and statutes from the U.S. states.

The June 2004 guidelines published jointly by UNAIDS and WHO outline the information that must be disclosed to the patient in order to obtain his or her informed consent prior to testing for HIV. At a minimum, the guidelines require that the informed consent disclosure must include information on the clinical benefit and the prevention benefits of testing; the right to refuse; the follow-up services that will be offered in the event of a positive test result; and the importance of anticipating the need to inform anyone at ongoing risk who would otherwise not suspect they were being exposed to HIV infection.<sup>238</sup> It is

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233. See also, Barron et al., *supra* note 80; Wolf et al., *supra* note 210, at 141-42.

234. Wolf et al., *supra* note 210, at 141.

235. UNAIDS/WHO, *supra* note 44, at 3.

236. S. AFR. DEP'T. OF HEALTH, DRAFT NATIONAL POLICY ON TESTING FOR HIV (1990), available at <http://www.doh.gov.za/aids/docs/policy.html>.

237. U.K. GEN. MED. COUNCIL, SEEKING PATIENTS' CONSENT: THE ETHICAL CONSIDERATIONS (1998), available at <http://www.gmc-uk.org/guidance/current/library/consent.asp>.

238. UNAIDS/WHO, *supra* note 44, at 3.

important to emphasize that these guidelines describe a *minimum* requirement. In the context of HIV, even the expansive informed consent disclosure they describe may not adequately safeguard the interests of an individual patient.

Rather than rely on an ambiguous legal standard, this model legislation clearly and specifically defines the required scope of the health care provider's informed consent disclosure. However, the listed points of information are not meant to be exhaustive—courts and national health authorities would remain free to expand the scope of the informed consent disclosure even further as our understanding of HIV/AIDS evolves.

The 2002 South African *Draft National Policy on Testing for HIV*, though not formally enacted into law, provides a useful benchmark for defining the scope of the informed consent disclosure: "In the context of HIV/AIDS, testing with informed consent implies that the individual understands what the test is, why it is necessary and the benefits, risks, alternatives and possible social implications of the outcome."<sup>239</sup>

According to the South African Department of Health, the patient should also be given the following specific information:

- What an HIV test is, the purpose of the test;
- The meaning of both a positive and negative result, including the practical implications such as medical treatment and care, sexual relations, psycho-social implications, etc;
- Assessment of personal risk of HIV infection;
- Safer sex and strategies to reduce risk;
- Coping with a positive test result, including whom to tell and identifying needs and support services; and
- An opportunity for decision making about taking the HIV test.<sup>240</sup>

Other national authorities have set out even more specific guidelines for defining the scope of the informed consent disclosure. The United Kingdom General Medical Council offered the following detailed advice to physicians in a 1998 statement on informed consent:

The information which patients want or ought to know, before deciding whether to consent to treatment or an investigation, may include:

- details of the diagnosis, and prognosis, and the likely prognosis if the condition is left untreated;
- uncertainties about the diagnosis including options for further investigation prior to treatment;
- options for treatment or management of the condition, including the option not to treat;
- the purpose of a proposed investigation or treatment; details of the procedures or therapies involved, including subsidiary treatment such

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239. S. AFR. DEP'T. OF HEALTH, *supra* note 236, at 3.

240. *Id.*

as methods of pain relief; how the patient should prepare for the procedure; and details of what the patient might experience during or after the procedure including common and serious side effects;

- for each option, explanations of the likely benefits and the probabilities of success; and discussion of any serious or frequently occurring risks, and of any lifestyle changes which may be caused by, or necessitated by, the treatment;
- advice about whether a proposed treatment is experimental;
- how and when the patient's condition and any side effects will be monitored or re-assessed;
- the name of the doctor who will have overall responsibility for the treatment and, where appropriate, names of the senior members of his or her team;
- whether doctors in training will be involved, and the extent to which students may be involved in an investigation or treatment;
- a reminder that patients can change their minds about a decision at any time;
- a reminder that patients have a right to seek a second opinion;
- where applicable, details of costs or charges which the patient may have to meet.<sup>241</sup>

In the United States, two competing standards for interpreting the materiality requirement exist. The "patient centered" standard for defining the physician's duty to disclose maintains that information is material to a patient's decision if "a reasonable person, in what the physician knows or should know to be the patient's position, would likely attach significance to the [information] in deciding whether or not to forgo the proposed therapy."<sup>242</sup> The majority of U.S. jurisdictions apply the "physician centered" standard, which requires health care providers to disclose information based on the prevailing practice among similarly situated professionals.<sup>243</sup> This standard is somewhat ambiguous, as it is open to interpretation by courts and professional associations. This model legislation opts instead to define the scope of the informed consent disclosure more specifically.

Additionally, I have also incorporated the most expansive set of specific information as defined by HIV testing-specific state statutes in the United States. Twenty-two U.S. states specify information that must be conveyed to patients during pre-test counseling as part of the informed consent process. This information includes: how test results may be used; the risks and benefits of testing; the nature of HIV/AIDS; information on prevention measures; the voluntary nature of the test; the right to refuse testing; the requirement of written consent; information on the confidentiality of test results; circumstances, if any,

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241. U.K. GEN. MED. COUNCIL, *supra* note 237, at 2.

242. *Canterbury v. Spence*, 464 F.2d 772, 787 (D.C. Cir. 1972).

243. *See, e.g., Culbertson v. Mernitz*, 602 N.E.2d 98, 102-04 (Ind. 1992).

under which confidentiality may be overridden; the availability of treatment; and the effect of testing on the patient's ability to receive further services.<sup>244</sup>

*2. Limited Situations in Which Individuals May Be Tested Without Their Consent*

This model legislation defines four specific situations in which HIV testing may be permissible without a patient's informed consent. These circumstances are the only exceptions, and they are meant to be strictly construed.

The provision allowing for anonymous research testing will allow for important fact-gathering about the spread of HIV and AIDS. In order to ensure the privacy of the donors, all identifying information about the donors must be separated from the sample. Such research testing must be in accordance with national legal and ethical guidelines regarding research testing.<sup>245</sup> The language for this provision draws primarily from the South African *Draft National Policy on Testing for HIV*.

Another provision allows for testing without consent when a health care worker has experienced an occupational exposure. In these cases, HIV testing of the source patient may be necessary so that, in the event that the source patient is HIV positive, the health care worker can take steps to lower her risk of infection by taking HIV prophylaxis. This provision is borrowed with slight modification from the South African *Draft National Policy on Testing for HIV*, which allows testing without informed consent after an occupational exposure, but only after informing the source patient that the result may be disclosed, and only if the source person has declined to give her informed consent or is unable to do so.<sup>246</sup> The *American Medical Association Code of Ethics* similarly provides that "when a health care provider is at risk for HIV infection because of the occurrence of puncture injury or mucosal contact with potentially infected bodily fluids, it is acceptable to test the patient for HIV infection even if the patient refuses consent."<sup>247</sup>

The model legislation also provides an exception to informed consent for life-threatening situations and emergencies. In a recent commentary in the *Journal of the American Medical Association*, bioethicist Scott Halpern outlined three reasons why HIV testing should be permitted without consent for critically ill patients. First, such testing may improve the quality of their care. Prompt ARV therapy may effectively treat such conditions as HIV dementia, progressive multifocal leukoencephalopathy, respiratory failure, and fever of unknown origin. Second, because most patients in one of these situations would likely

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244. Wolf et al., *supra* note 210, at 141.

245. S. AFR. DEP'T OF HEALTH, *supra* note 236.

246. *Id.*

247. AM. MED. ASS'N, AMA CODE OF ETHICS E-2.23 (1994), available at <http://www.ama-assn.org/ama/pub/category/print/8463.html>.

choose to be tested if they were competent, allowing testing may respect the autonomy of those who cannot voice their preferences. Finally, closely tracking the arguments I have laid out in this Article, Halpern argues that HIV should no longer be treated as an exceptional disease—policies on HIV testing should be brought into line with general medical practice.<sup>248</sup>

Among U.S. states, twenty-six states do not specify any exceptions to informed consent laws for HIV testing. Thirteen states permit testing without the patient's specific consent whenever a physician expects that the test result would improve the patient's immediate medical care, provided that the patient has already provided general consent to care. Both the American Medical Association and the British General Medical Council endorse this position.<sup>249</sup> Six states permit such testing only in emergency or life-threatening situations. Eight states permit testing if the patient's legal guardian or next-of-kin provides surrogate consent.<sup>250</sup> This model legislation takes the view that allowing an exception to specific informed consent based on the medical opinion of a physician is too permissive a standard. Instead, it permits an exception for life-threatening and emergency situations and, for other situations, the possibility of proxy consent whenever a physician expects that the test result would improve the patient's immediate medical care. The person giving proxy consent must be legally permitted to give consent for the patient in question. In accordance with common law and statutory provisions, this may include, but is not limited to, a parent or guardian of a child below the age of consent, individuals designated by law to consent for individuals with mental illness, or an individual designated by the patient to exercise durable power of attorney for the patient.<sup>251</sup>

### *B. Counseling*

There is little evidence to suggest that simply supplying patients with information about a specific test, therapy or procedure actually helps patients to understand this information unless this disclosure is accompanied by interactive counseling by the health care provider.<sup>252</sup> A number of empirical studies have

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248. Scott D. Halpern, *HIV Testing Without Consent in Critically Ill Patients*, 294 JAMA 734, 736 (2005).

249. AM. MED. ASS'N, HIV TESTING, H-20.920 (2005); GEN. MED. COUNCIL, SERIOUS COMMUNICABLE DISEASES (1997).

250. Halpern, *supra* note 248, at 735.

251. See Dom W. Brock, *Children's Competence for Health care Decision-making*, in CHILDREN AND HEALTH CARE: MORAL AND SOCIAL ISSUES 181-212 (Loretta M. Kopelman & John C. Moskop eds., 1989); Nancy M.P. King & Alan W. Cross, *Children As Decision Makers: Guidelines for Pediatricians*, 115 J. PEDIATRICS 10 (1989).

252. A number of studies have demonstrated that written informed consent forms often contain unreadable jargon. A 2003 study in *The American Journal of Medicine* surveyed Institutional Review Board (IRB) forms used for consent in human research at sixty-one U.S. medical schools. The study found that the average Flesch-Kincaid score for these forms was 10.6 (the Flesch-Kincaid scale assigns a score based on the minimum grade level required to understand a particular

presented alarming findings on the gap between informed consent disclosures and patient understanding, and these studies suggest that health care providers must work harder to ensure that patients understand the risks involved with medical tests, therapies or procedures.<sup>253</sup> However, there is strong evidence that interactive counseling and spending more time with patients are both independently effective ways of improving patients' understanding of informed consent disclosures.<sup>254</sup> Informed consent should be an interactive process—not simply a signature on a pre-prepared form.

Counseling is especially important in the context of HIV testing because a positive result involves a serious medical condition and may result in severe social stigmatization, discrimination, and emotional and psychological stress. In the 1996 South African case of *C v. Minister of Correctional Services*, the court emphasized the need for counseling:

It is axiomatic that there can only be consent if the person appreciates and understands what the object and purpose of the test is, what an HIV positive test is, what an HIV positive result entails and what the probability of AIDS occurring thereafter is. Evidence was led in this case on the need for informed consent before the HIV test is performed. . . . Because of the devastation which a positive result entails, the norm so developed contains as a requirement counseling both pre- and post-testing, the latter in the event of a positive result.<sup>255</sup>

As the court recognized, the issue of informed consent is closely related to the issue of counseling. Most medical tests, therapies, and procedures are accompanied by pre-test counseling, if for no other reason, to obtain informed consent. However, because of the unique social implications associated with a positive HIV test result, as well as the physical devastation which HIV may cause if left untreated, counseling assumes an added importance. In the context of HIV, both pre-test and post-test support and services are crucial.

This model legislation implements the guidelines for HIV pre-test

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text). This exceeded the average of the published standards of these IRBs by 2.8 grade levels. Michael K. Paasche-Orlow & Frederick L. Brancati, *Assessment of Medical School Institutional Review Board Policies Regarding Compensation of Subjects for Research-Related Injury*, 118 AM. J. MED. 175, 175(2005).

253. One analysis of a cross-section of patients receiving experimental therapies in cancer trials showed that 30% of participants believed they were receiving a treatment that had already been proven to be the best treatment for their cancer. Steven Joffe et al., *Quality of Informed Consent in Cancer Clinical Trials*, 358 LANCET 1772, 1772 (2001). In another study assessing the use of beta-blocker drugs to prolong the lives of people who have suffered from a heart attack, 43% of research participants did not know that they were being assigned randomly to receive beta-blocker treatment or a placebo. John M. Howard et al., *How Informed is Informed Consent?*, 2 CONTROLLED CLINICAL TRIALS 287, 292 (1981).

254. See James Flory & Ezekiel Emanuel, *Interventions To Improve Research Participants' Understanding in Informed Consent for Research*, 292 JAMA 1593, 1599 (2004).

255. *C v Minister of Correctional Services* 1996 (4) SA 292 (T) at 301 (S. Afr.).

counseling published by the CDC. All patients who request or are offered an HIV test should receive the following information in addition to the informed consent disclosure, even if they decline to be tested:

- Information regarding the HIV test and its benefits and consequences;
- Risks for transmission and how HIV can be prevented, including but not limited to: a) descriptions or demonstrations of how to use condoms correctly; b) information regarding risk-free and safer sex options; c) descriptions regarding the effectiveness of using clean needles, syringes, cotton, water, and other drug paraphernalia;
- The importance of obtaining test results and explicit procedures for doing so;
- The meaning of the test results in explicit, understandable language;
- Where to obtain further information or, if applicable, HIV prevention counseling;
- Where to obtain other services;
- Information regarding other sexually transmitted and bloodborne diseases;
- Where applicable, information regarding drug treatment.<sup>256</sup>

In addition to obtaining informed consent during pre-test counseling, the health care provider should offer HIV prevention counseling. That is, the health care provider should help the patient identify specific behaviors that put her at risk for acquiring or transmitting HIV and should help her understand how to reduce this risk.<sup>257</sup> A number of empirical studies have demonstrated that ongoing counseling and testing is negatively associated with high-risk sexual behavior.<sup>258</sup> This underscores the need to recognize pre-test counseling as more than simply an opportunity to obtain informed consent. Pre-test counseling can also be an effective public health intervention. Because women are at particular risk for domestic violence, and because they are more likely to be tested, this model legislation also requires a domestic violence screening and referral to appropriate counseling as part of pre-test counseling.

This legislation also draws on the detailed post-test counseling guidelines described in the South African *Department of Health Draft National Policy on Testing for HIV*<sup>259</sup> and the *World Health Organization Testing and Counseling Toolkit*.<sup>260</sup> Post-test counseling should provide appropriate information about the

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256. CTRS. FOR DISEASE CONTROL & PREVENTION, REVISED GUIDELINES FOR HIV COUNSELING, TESTING, AND REFERRAL AND REVISED RECOMMENDATIONS FOR HIV SCREENING OF PREGNANT WOMEN 13-14 (2001).

257. *Id.*

258. See, e.g., P. Sangani et al., *Population-Based Interventions for Reducing Sexually Transmitted Infections, Including HIV Infection*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS CD001220 (2001).

259. See S. AFR. DEP'T OF HEALTH, *supra* note 236.

260. See WORLD HEALTH ORG., TESTING AND COUNSELING TOOLKIT (2004), available at



test result and its implications, referral to care, support, and treatment.<sup>261</sup>

State law among U.S. states is not as useful in guiding counseling requirements, as most of these laws appear to fall short of the guidelines published by the above authorities. Only eleven states address counseling in their HIV testing statutes: Georgia, Hawaii, Illinois, Maine, Maryland, Michigan, Montana, New York, North Carolina, Pennsylvania, and Rhode Island. Seven of these states require pre-test counseling, whereas four only require physicians to make an offer of pre-test counseling. Two states, Maine and Maryland, require that counseling be face-to-face. Two states, North Carolina and Rhode Island, imply that counseling must be oral.<sup>262</sup>

### C. Confidentiality

I have already argued that, because an assurance of confidentiality is necessary to encourage persons at high risk of contracting HIV to undergo testing, consent to disseminate information about the HIV status of individuals should be required in all cases. HIV-positive individuals, especially women, who are more likely to be tested for HIV, face a well-founded fear of partner abuse, stigma and discrimination. Therefore, though health care workers should counsel patients to inform their partners of their HIV status, health care workers are specifically prohibited from informing a partner, employer, family member, or any other third party of a patient's HIV status unless the patient explicitly authorizes it. Similarly, children should be allowed to obtain confidential HIV/AIDS testing and treatment without parental consent. This model legislation defines a limited and specific exception to this rule for emergencies.

However, courts have recognized that in certain situations the health care worker's duty to maintain confidentiality may conflict with their duty to protect third parties from imminent danger. In the United States, for example, state courts have held that a doctor has a duty to warn third parties of the foreseeable dangerous conduct of her patient.<sup>263</sup> The case most often cited in support of this proposition is *Tarasoff v. Regents of the University of California*, in which a therapist whose patient threatened to kill a woman with whom he had been romantically involved neglected to warn that woman that she was in any danger. The court held that the therapist had a duty to use reasonable care to protect the intended victim against the danger threatened by the patient.<sup>264</sup> Other nations have also held that the doctor-patient relationship imposes on a doctor the duty to use reasonable care to protect other individuals from danger that might result

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<http://who.arvkit.net/tc/en/contentdetail.jsp>.

261. *Id.*

262. Wolf et al., *supra* note 210, at 140.

263. See, e.g., *Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334 (Cal. 1976).

264. *Id.* at 339-41.

from a patient's illness.<sup>265</sup> However, it is unclear whether courts are willing to extend this line of cases to include a doctor's duty to warn an HIV-positive individual's sexual partner that he or she may be in danger of being infected with HIV. The hypothetical situation evoked by a routine HIV test would be strictly analogous to that in *Tarasoff* if an individual announced his intention to purposefully infect his sexual partner with HIV through unprotected intercourse. This is obviously an unlikely scenario. In reality, HIV-positive individuals may or may not disclose her sexual contacts; they may take precautions on their own; and even unprotected sex may or may not result in the transmission of HIV.

There is also another line of state court cases in the United States that holds that a physician has a duty to exercise reasonable care to warn members of a patient's family if the patient has a contagious disease and if they are likely to have contact with the patient.<sup>266</sup> However, these cases, which concern diseases like typhoid, smallpox, and tuberculosis, predate much of the understanding about disease prevention gleaned from the modern science of public health. The public health interest in maintaining confidentiality, so that more people will submit to testing, is high. Moreover, it is unclear that mandatory partner notification is necessary or even useful. For these reasons, and because of the importance of protecting confidentiality, this model legislation does not impose a "duty to warn" on health care workers. Instead, it takes the position that the health care workers have a duty to counsel their patients on the advantages and consequences of disclosing his or her HIV status to their partners.

### CONCLUSION

Not all of the necessary elements of an ethical testing program can be encapsulated in a piece of model legislation. It is necessary to distinguish between substantive protections that such a program might include and the process through which it should be enacted. The process of enacting a routine testing program should include representation by civil society—including groups of people living with AIDS; women, who are more likely to be tested for HIV; and disenfranchised minorities, who may view a program of routine testing more suspiciously. This will allow policy makers to include input from the communities most at risk into their decision-making process on testing policies. This will also allow policy makers to adapt the general human rights principles discussed in this paper to the cultural context in which they operate. For example, the Government of Botswana sponsored an extensive public discussion as well as

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265. See, e.g., *Jansen van Vuuren & Another NNO v Kruger* 1993 (4) SA 842 (A) (S. Afr.); J.S. Talbot, *The Conflict Between a Doctor's Duty To Warn a Patient's Sexual Partner that the Patient has AIDS and a Doctor's Duty To Maintain Patient Confidentiality*, 45 WASH. & LEE L. REV. 355, (1988).

266. *Davis v. Rodman*, 227 S.W. 612 (Ark. 1921); *Hoffman v. Blackmon*, 241 So. 2d 752 (Fla. Dist. Ct. App. 1970); *Jones v. Stanko*, 160 N.E. 456 (Ohio 1928).

a series of consultative meetings with civil society groups and international experts before unveiling its routine testing program in 2003.<sup>267</sup> This consultative process likely had some role in the widespread acceptance of routine testing in Botswana.<sup>268</sup>

Further, any shift to routine testing should also be accompanied by a commitment to operational research and systematic data gathering to understand better the impact of routine testing on treatment, stigma, and prevention efforts. Many unanswered questions about routine testing remain. What is the precise impact of routine-offer testing on testing rates? How much information must be conveyed—and in what format—for consent to be truly informed? Do patients experience routine-offer testing as coercion? How much and what type of counseling is required to affect risk behavior for HIV? Do the answers to these questions vary across different cultures and settings? These are just a few of the questions that we should ask in defining a research agenda to inform future policy debates about HIV testing.

I have argued that access to HIV treatment—and the benefits to the individual and to the public health that come with the promise of treatment—require us to rethink our approach to HIV testing. Where treatment is available, a human rights approach to HIV requires that health care providers routinely offer HIV tests to their patients. This proposed shift in policy need not signify a broader shift in the culture of our approach to the HIV/AIDS pandemic away from education and toward coercion. I have argued that HIV testing should be brought into line with general medical practice only in the sense that testing should be offered to individuals. However, a human rights approach to routine testing also requires that health care providers not abandon the principles of autonomy and privacy. To this end, I have argued that routine testing should be accompanied by a commitment to use specialized informed consent, counseling, and confidentiality procedures.

This commitment to scale up HIV testing in conjunction with a scaling up of protections for individual rights will require a significant expenditure of resources, most notably in the form of the time that health care workers will have to spend training in and complying with these procedures. This is a potentially significant issue—and one that is beyond the scope of this paper. However cost alone should not dissuade policy makers from adopting a human rights approach to routine testing for HIV. Those who insist that expanding HIV testing will require a curtailment of protections for individuals insist on a false dichotomy between protecting civil and political rights and guaranteeing the right to health.

Only a few years ago, few thought that mass-scale treatment for HIV was possible in poor countries—ARV drug prices were too high; health systems in

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267. CSIS REPORT, *supra* note 23, at 9.

268. Seipone et al., *supra* note 101, at 1083.

poor countries lacked sufficient manpower to administer complicated drug regimens; and it was thought that individuals in poor countries would not be able to adhere to complicated dosing regimens. Treatment activists prevailed in changing the world's thinking on HIV treatment because they worked to change every constraint that their critics believed to be binding. As a result, prices have been lowered, health care workers are being trained, and several studies have shown that individuals in poor countries do adhere to dosing regimens for ARV treatment, perhaps better than their counterparts in rich countries.<sup>269</sup> Similarly, shifting to routine testing in a way that preserves and enhances protections on individual rights will require new thinking, new understanding, and new resources.

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269. D. Coetzee et al., *Promoting Adherence to ARV Therapy: The Experience from a Primary Care Setting in Khayelitsha, South Africa*, 18 AIDS S27, S30-31 (2004); S. Koenig et al., *Scaling-Up HIV Treatment Programmes in Resource-Limited Settings: The Rural Haiti Experience*, 18 AIDS S21, S25 (2004); I. Lanièce et al., *Adherence to HAART and Its Principal Determinants in a Cohort of Senegalese Adults*, 17 AIDS S103, S107 (2003); M. Nemes et al., *ARV Therapy Adherence in Brazil*, 18 AIDS S15, S12 (2004).

APPENDIX 1

*Model Legislation on Testing Counseling for HIV/AIDS*

*Preamble*

*Recognizing* that testing for human immunodeficiency virus (HIV) infection implicates serious medical, legal, ethical, economic, social, and psychological issues;

*Recognizing* that HIV infection is life-threatening;

*Recognizing* that HIV causes AIDS;

*Recognizing* that HIV is treatable;

*Recognizing* that individuals have a right to health, which includes a right to know their HIV status;

*Understanding* that individuals may face significant discrimination and social stigmatization based on their HIV status;

*Respecting* the right to life, the guarantees of freedom and security of the person, and the right to privacy and dignity, as protected by the International Covenant on Civil and Political Rights;<sup>270</sup>

*Recognizing* the goals of expanding testing, decreasing HIV-related stigma, increasing the reach of treatment programs and empowering people living with HIV to improve their health;

The following provisions of legislation are hereby proposed:

*Definitions*

*Acquired Immunodeficiency Syndrome (AIDS)*: The advanced stage of HIV disease during which the patient displays the signs and symptoms of severe immune deficiency, and the patient's body loses its ability to resist infections. Defined by the presence of an AIDS-defining opportunist infection or a CD4 T-lymphocyte count of less than 200/micro-liter.<sup>271</sup>

*Epidemiology*: The study of the distribution of diseases in society, and the application of this information for the prevention and control of disease.

*Epidemiological Purposes*: The testing for HIV in order to obtain information

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270. ICCPR, *supra* note 141, arts. 6, 9, 10, 17.

271. Castro et al., *supra* note 8.

regarding the distribution of HIV infection within society.

*Full Informed Consent Disclosure:* Disclosure of material information prior to obtaining patient's consent to testing, as provided for in Article 1.

*Human Immunodeficiency Virus (HIV):* The virus that causes AIDS.

*HIV Testing:* The obtaining of a bodily sample for the specific purpose of performing a medical test or a number of medical tests to determine the HIV status of a person.

*Proxy Consent:* Consent by a person legally permitted to give consent for another individual. This may include, but is not limited to: a parent or guardian of a child below the age of consent; individuals designated by law to consent for individuals with mental illness; and an individual exercising durable power of attorney for a patient.

*Occupational Exposure:* An exposure to HIV that carries the risk of infection and that occurs during the course of an individual's occupational activities (an accident such as a needle-stick injury, in which a health care worker has been exposed to a patient's blood.)

#### *Article 1:*

##### *Right To Refuse Testing And The Right To Informed Consent*

(a) Except for the limited provisions contained in Article 4:

(1) All individuals have a right to refuse to be tested.

(2) All individuals have a right to informed consent.

(b) Informed consent requires that the individual voluntarily agrees to be tested. Informed consent also requires that the individual giving consent does so without any element of coercion and that the individual is equally free to grant or withhold consent. Testing with informed consent means that the individual understands information related to the test. This information must be disclosed by the health care provider prior to testing and should include, at minimum, the following non-exhaustive points of information:

(1) The patient's right to refuse testing;

(2) A reminder that patients can change their minds about a decision at any time;

(3) A reminder that patients have a right to seek a second opinion;

(4) Confidentiality procedures;

(5) What the test is;

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- (6) Why the test is necessary;
- (7) Risks of testing;
- (8) Benefits of testing;
- (9) Alternatives to testing;
- (10) Possible social implications of a positive test result;
- (11) Follow up services that will be offered;
- (12) The availability of treatment for HIV in that particular location and the likelihood of receiving treatment if the test result is positive;
- (13) Options for treatment or management of the condition - including the option not to treat;
- (14) For each treatment option – including the option to forgo all treatment – explanations of the likely benefits and the probabilities of success, and a discussion of any serious or frequently occurring risks, and of any lifestyle changes which may be caused by or necessitated by the treatment;
- (15) The name of the health care provider who will have overall responsibility for follow up care;
- (16) Details of costs or charges which the patient may have to meet; and
- (17) The importance of informing anyone at ongoing risk of infection if the test result is positive.

### *Article 2:*

#### *Requirements for Ensuring Testing Occurs with a Patient's Voluntary and Informed Consent*

- (a) HIV testing must always be conducted with the informed consent of the individual being tested, except in the limited set of circumstances outlined in Article 4.
- (b) The patient's consent must be obtained by the health care provider in writing except where this is impossible.
- (c) Where applicable, a patient's refusal to be tested should be documented in writing.
- (d) HIV testing must always be accompanied by pre-test counseling and post-test counseling. Counseling should include, at a minimum, the information included in Article 1.

### *Article 3:*

#### *Circumstances Under Which HIV Testing May Be Conducted with Informed Consent*

- (a) Subject to the provisions of this Statute, HIV testing may only be conducted under the following circumstances and with the informed consent of the patient:
  - (1) Upon individual request;
  - (2) Upon the recommendation of a health care provider; and

(3) As part of the screening protocol for blood products or organ donations, provided that such testing is conducted in accordance with the statutory provisions on blood donations.

(b) Where a patient presents to a health care provider with recognizable symptoms that are specific to HIV/AIDS, but no facilities exist for HIV testing, the health care provider must provide pre-test counseling and then refer the patient to a facility that offers HIV testing.

*Article 4:*

*Limited Circumstances Under Which HIV Testing May Be Conducted Without Informed Consent*

(a) Notwithstanding the provisions in Article 1, testing for HIV without informed consent may be conducted under the following strictly limited circumstances:

(1) When an existing blood or tissue sample is being used in an anonymous testing protocol for epidemiological purposes. Further, such testing must be conducted in accordance with national legal and ethical guidelines regarding research testing, unless such national guidelines are contrary to the provisions of this legislation. The identity of the donor will be kept anonymous and will not be included in any records involving the sample.

(2) When a health care worker has experienced an occupational exposure, HIV testing of the source patient may be conducted without informed consent, but only after informing the source patient that the result may be disclosed to relevant medical personnel and the exposed health care worker, and only if: 1) the source person has declined to give his/her informed consent; or 2) the source person is unable to give informed consent and no proxy consent is available. In all such cases, the source patient must receive an offer of pre-test and post-test counseling.

(3) When an individual is unable to consent to an HIV test due to their incapacity or age, and a physician expects that the test result would improve the patient's immediate medical care, another person with legal guardianship of the incapacitated individual may offer proxy consent.

(4) In emergency or life-threatening situations.

(b) These circumstances are the only exceptions to the requirement of informed consent and shall be strictly and narrowly construed.

*Article 5:*

*Right To Pre-Test And Post-Test Counseling*

*Pre-Test Counseling*

(a) All individuals have a right to pre-test counseling before receiving an HIV test. Pre-test counseling shall be offered to an individual before an HIV test by a suitably trained person (a doctor, nurse, trained social worker, psychologist, or



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trained HIV counselor) with the purpose of offering information, gaining consent and ensuring that the individual has sufficient information to make an informed decision about having an HIV test. This session must include a full informed consent disclosure, as defined by Article 1 of this statute. During the pre-test counseling session the individual patient should be given an opportunity to make a decision, free from any element of pressure or coercion, as to whether or not he/she wishes to be tested for HIV.

Regardless of whether the individual refuses testing, pre-test counseling should also include discussions on the following:

- (1) An assessment of personal risk of HIV infection;
- (2) Safer sex and strategies to reduce risk.
- (3) A domestic violence screening with referral to appropriate counseling, if necessary;
- (4) This list shall not be construed as limiting or exhaustive.

### *Post-Test Counseling*

(b) All individuals have a right to post-test counseling after receiving an HIV test. Post-test counseling shall be provided by a suitably trained person (a doctor, nurse, trained social worker, psychologist or trained HIV counselor) to a patient when he/she receives his/her HIV test result. Post-test counseling must involve two or more sessions. These sessions should include:

- (1) An opportunity for the patient to provide feedback;
- (2) Interpretation of the test results;

If the result is negative:

- (3) Counseling on strategies for risk reduction; and
- (4) Counseling on the possibility that the patient may be in the “window period,” during which HIV antibodies are not yet detectable, but during which the patient may still be infectious.

If the result is positive:

- (5) Immediate emotional counseling, as necessary;
- (6) Counseling on the personal, family and social implications;
- (7) Reasonable assistance in coping with difficulties that the patient may foresee;
- (8) Counseling on the patient’s responsibilities to sexual partners;
- (9) An assessment of immediate needs and social support identification;
- (10) A schedule for follow up supportive counseling; and
- (11) Arrangements for follow-up medical care.
- (12) This list shall not be construed as limiting or exhaustive.

*Article 6:  
Confidentiality*

- (a) No health care provider shall disclose any information concerning the result of an HIV test or any related assessment of a patient to any other person except with the written consent of that patient.
- (b) Where the written consent of a patient cannot be procured for the purposes of section (a) in an emergency, the consent of the following persons shall suffice:
  - (1) If the patient is a minor, the written consent of a parent or legal guardian of that child; or
  - (2) If the patient is unable to give written consent, with the oral consent of the patient or with the written consent of the person with the power of attorney for that patient.
- (c) Any consent for disclosure required under section A above must be accompanied by pre-consent and post-consent counseling, which must, at a minimum, facilitate an understanding of the nature and purpose of the consent to disclose, the advantages and disadvantages of the consent, and the effect of the consent upon the patient.
- (d) A person's HIV test result may be disclosed without their consent only if the information is used for statistical or other purposes that could not reasonably be expected to lead to the identification of the person to whom it relates.
- (e) The results of an HIV test shall not be discoverable in any civil, criminal, or administrative proceeding, except with the written consent of the patient involved.
- (f) A medical practitioner has a duty to encourage the patient to disclose his or her HIV status to his or her sexual partner(s) and counsel the patient on issues and consequences related to such disclosure.

*Article 7:  
Interpretation*

- (a) In all instances, this statute shall be interpreted to ensure respect for rights to privacy, dignity, bodily integrity, and autonomy.

*Article 8:  
Enforcement*

- (a) This statute shall not be construed as interfering with an individual's rights as guaranteed by any other statute, constitutional provision, or international legal instrument.
- (b) Under this legislation, individuals possess a private right of action for the violation of their rights as specified above, by any individual, acting within the scope of his or her professional capacity.

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- (c) All requirements and provisions specified in this legislation are subject to review by national courts.
- (d) In addressing alleged violations of the provisions of this legislation, national courts have the authority to grant remedies in the form of injunctive relief, damages, attorney's fees, and any further awards deemed appropriate by the court.



## NOTE

### Health Courts: An Extreme Makeover of Medical Malpractice with Potentially Fatal Complications

Emily Chow\*

#### INTRODUCTION

United States citizens spent \$5267 per capita on health care in 2002, nearly \$2000 more than any other country,<sup>1</sup> with annual spending reaching \$1.6 trillion.<sup>2</sup> Yet quality and availability of medical care continue to be concerns, and medical malpractice litigation is frequently blamed for rising consumer costs and skyrocketing physicians' malpractice premiums.<sup>3</sup> With physicians abandoning medical specialties with high malpractice premiums like neurosurgery,<sup>4</sup> and obstetrics-gynecology residencies reaching only 65% capacity for the medical school class of 2004,<sup>5</sup> there is a growing consensus within the medical

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\* J.D., University of Wisconsin, 2007; B.A., Johns Hopkins University, 2004. I must thank my parents for their many years of support and sacrifice; my sister, Lilly, for her inspirational brilliance and amusing palaver; and Jonathan Packer for his unending patience and constant encouragement. I would also like to thank Alexander Park for introducing me to this topic, Katie Mason and Nic Eichenseer for their insightful comments on earlier drafts, and the 2006-07 senior board of the *Wisconsin Law Review* for indulging me during the production of this Note.

1. Gerard F. Anderson et al., *Health Spending in the United States and the Rest of the Industrialized World*, 24 HEALTH AFF. 903, 904 (2005).

2. Katharine Levit et al., *Health Spending Rebound Continues in 2002*, 23 HEALTH AFF. 147, 148 (2004).

3. Ceci Connolly, *Malpractice Situation Not Dire, Study Finds*, WASH. POST, Mar. 10, 2005, at A8 (reporting that President George W. Bush, the American Medical Association, and some scholars believe lawsuits and large jury awards "have forced malpractice premiums to historically high levels"); Mark Moran, *Malpractice Liability Cap Fails in Senate*, PSYCHIATRIC NEWS, Aug. 1, 2003, at 1.

4. Joe Fahy, *Neurosurgeons Flee High Insurance Costs*, PITTSBURGH POST-GAZETTE, Mar. 26, 2006, at A13.

5. Press Release, Nat'l Resident Matching Program, Record Number of Applicants Matched to Residency Programs (Mar. 18, 2004), <http://www.aamc.org/newsroom/pressrel/2004/040318>

community that current efforts to resolve the “medical malpractice crisis” are failing.<sup>6</sup> The debate has spawned a variety of actions, including implementing noneconomic damage caps,<sup>7</sup> physician walkouts,<sup>8</sup> and the firing of a hospital staff member whose spouse’s law firm had a malpractice group.<sup>9</sup> A surgeon from South Carolina has even attempted to obtain the American Medical Association’s (AMA) support for his grassroots approach of refusing treatment to malpractice lawyers, their families, and their employees: “[it is] analogous to hitting the lawyers with a 2-by-4. Now we have their attention. Now maybe we can make some progress.”<sup>10</sup>

In fact, there has not been much progress in medical malpractice reform, especially as compared to the technological advancements in medicine over the last thirty years.<sup>11</sup> Malpractice became “medicine’s most serious crisis” for the first time in 1975, when many commercial insurers struggled to provide adequate coverage for physicians.<sup>12</sup> Despite the cyclical onset of several of these crises,<sup>13</sup> the traditional tort system remains the primary tool for victims of malpractice seeking compensation.<sup>14</sup>

The AMA has designated seventeen states as being in a full-blown medical

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.htm (noting that, despite a 5.3% increase in participation from 2003 levels, only 65.1% of the obstetrics-gynecology residency positions were filled). Since then, the interest in obstetrics-gynecology has increased: “[Ninety-eight] percent of these positions were filled [in 2006], 72 percent by U.S. medical school seniors.” Press Release, Nat’l Resident Matching Program, More U.S. Medical School Seniors Choose Residencies in Competitive and “Lifestyle” Specialties (Mar. 16, 2006), <http://www.aamc.org/newsroom/pressrel/2006/060316.htm>.

6. See Michelle M. Mello et al., *The New Medical Malpractice Crisis*, 348 NEW ENG. J. MED. 2281, 2284 (2003) (“[M]ost expect the malpractice crisis to deepen and spread even in the face of aggressive tort-reform efforts at the state and federal levels.”); Common Good, *An Urgent Call for Special Health Courts: America Needs a Reliable System of Medical Justice* (2005), <http://cgood.org/assets/attachments/130.pdf>.

7. See, e.g., Press Release, Wis. Office of the Governor, Governor Doyle Signs Assembly Bill 1073 (Mar. 22, 2006), [http://www.wisgov.state.wi.us/journal\\_media\\_detail.asp?locid=19&prid=1842](http://www.wisgov.state.wi.us/journal_media_detail.asp?locid=19&prid=1842) (reporting the implementation of a new higher noneconomic-damage cap in Wisconsin).

8. *AMA Chief, Professor Square Off on Blame for Malpractice Crisis*, 33 MOD. HEALTHCARE 52 (2003) (reporting the reactions of AMA president-elect Donald Palmisano and Professor Jonathan Turley to a physician walkout in West Virginia). Turley accused the doctors of “medical terrorism.” *Id.* According to Turley, “These latest walkouts are nothing short of hostagetaking: demanding huge benefits in exchange for basic medical care for captive patients.” *Id.*

9. Laura Parker, *Medical-Malpractice Battle Gets Personal*, USA TODAY, June 14, 2004, at 1A.

10. *Id.*

11. William M. Sage, *Medical Malpractice Insurance and the Emperor’s Clothes*, 54 DEPAUL L. REV. 463, 463 (2005).

12. *Id.* at 469.

13. *Id.* at 469-70.

14. See James C. Mohr, *American Medical Malpractice Litigation in Historical Perspective*, 283 JAMA 1731, 1736 (2000) (“[N]otwithstanding some movement in recent decades toward special judicial panels . . . the nation’s commitment to the ultimate mechanism of the ordinary jury is . . . likely to remain unshakably in place.”).

liability crisis because “the nation’s out-of-control legal system is forcing physicians . . . to retire early, relocate or give up performing high-risk medical procedures,” effectively preventing patient access to medical care.<sup>15</sup> Numerous studies link physicians’ fear of litigation and higher insurance premiums to their practice of “defensive medicine”<sup>16</sup> and the avoidance of high-risk specialties to qualify for less expensive liability insurance.<sup>17</sup> Some commentators worry that the rising malpractice costs will force physicians to stop practicing altogether, jeopardizing the availability of health care in some areas of the country.<sup>18</sup> Despite endorsement from the AMA, over fifty other physician, insurance, and patient organizations, as well as President George W. Bush, legislation proposing to limit malpractice liability has consistently failed to pass through Congress.<sup>19</sup>

In an early 2005 speech advocating for the cap, President Bush stated that

[w]hat’s happening all across this country is that lawyers are filing baseless suits against hospitals and doctors . . . . So doctors end up paying tens of thousands, or even hundreds of thousands, of dollars to settle claims, out of court, even when they know they have done nothing wrong. When insurance premiums rise, doctors have no choice but to pass some of the costs on to their patients . . . . If you’re a patient, it means you’re paying a higher cost to go see your doctor.<sup>20</sup>

Meanwhile, researchers studying the alleged medical malpractice crisis in the

15. Am. Med. Ass’n, AMA (Policy) Medical Liability Crisis Map, <http://www.ama-assn.org/ama/noindex/category/11871.html> (last visited May 3, 2007).

16. “Defensive medicine is a deviation from sound medical practice that is induced primarily by a threat of liability. . . . [by] supplement[ing] care . . . , replac[ing] care . . . , or reduc[ing] care . . . .” David M. Studdert et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 JAMA 2609, 2609 (2005). Although the prevalence of defensive medicine is difficult to quantify, *id.*, Common Good claims that doctors order “billions of dollars of unnecessary tests and procedures each year” in order to protect themselves from malpractice liability. Common Good, *supra* note 6, at 2.

17. See, e.g., Katherine Baicker & Amitabh Chandra, *Defensive Medicine and Disappearing Doctors?*, REG., Fall 2005, at 24, 30; Studdert et al., *supra* note 16, at 2616.

18. See Common Good, *supra* note 6, at 8 (“Unreliable justice is driving good ob-gyns out of practice, scaring medical students away from obstetrics and gynecology, and leaving women across the nation without prenatal and delivery care.” (quoting Vivian M. Dickerson, President, Am. Coll. of Obstetricians & Gynecologists)); Charles Hurt, *Edwards’ Malpractice Suits Leave Bitter Taste*, WASH. TIMES, Aug. 16, 2004, at A1 (“As a result of [malpractice] cases, insurance rates have skyrocketed—putting some out of business and driving others away, especially from rural areas.”). But see CONG. BUDGET OFFICE, LIMITING TORT LIABILITY FOR MEDICAL MALPRACTICE 1 (2004); Baicker & Chandra, *supra* note 17, at 29 (concluding that “there is little evidence of a mass exodus of physicians in response to increases in malpractice liability” upon analysis of empirical data). The General Accounting Office substantiated reduced access to emergency surgery and newborn delivery “in scattered, often rural, areas where providers identified other long-standing factors that affect the availability of services,” but it determined that high malpractice premiums “did not widely affect access to health care.” CONG. BUDGET OFFICE, *supra*, at 7.

19. See, e.g., Moran, *supra* note 3, at 1.

20. Connolly, *supra* note 3.

President's home state of Texas, one of the AMA's crisis states, found a sea of calm and reported that "at least in Texas, the tort system can't be the cause of spikes in malpractice premiums."<sup>21</sup>

Despite Bush's characterization of the malpractice crisis, the upward trend of litigation and damage awards does not directly correlate to the steady rise in malpractice premiums.<sup>22</sup> In July 2005, the Wisconsin Supreme Court found a ten-year-old noneconomic damage cap of \$350,000 to be unconstitutional, "unreasonable and arbitrary because it [was] not rationally related to the legislative objective of lowering medical malpractice insurance premiums."<sup>23</sup> In overturning the cap, the court cited various Wisconsin Office of the Commissioner of Insurance Reports on the statute, which "indicate[d] that a number of factors affect malpractice premium insurance rates, and that . . . 'no direct correlation [could] be drawn between the caps enacted in 1995 and current rate changes taking place in the primary market today.'"<sup>24</sup> Amidst the ongoing controversy over the effectiveness—and even constitutionality—of inconsistent reforms among different states, some advocates are now seeking a long-term solution through structural alteration of the traditional medical malpractice system in the form of health courts to hear malpractice cases.<sup>25</sup>

Like other courts in areas such as tax and bankruptcy, health courts would take the decision-making process away from juries and instead leave determinations up to a panel of expert judges.<sup>26</sup> According to Philip K. Howard, Chair of Common Good—a nonpartisan tort reform organization seeking to implement health courts—"the goal is to have deliberate rulings . . . so that doctors know where they stand because standards of care will be judged by people with expertise in the medical field."<sup>27</sup> To regulate the distribution of compensation under the health court model, Common Good has proposed the use of a rate schedule to normalize the amount of damages awarded for various

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21. *Id.* (quoting one of the study's co-authors, Professor David A Hyman). After analyzing about fifteen years worth of medical malpractice claims from Texas, researchers determined that "[n]o sudden rise in claim frequency, payments, defense costs, or jury verdicts preceded or accompanied the premium spike that occurred in Texas after 1998." Bernard Black et al., *Stability, Not Crisis: Medical Malpractice Claim Outcomes in Texas, 1988-2002*, 2 J. EMPIRICAL LEGAL STUD. 207, 255 (2005). See Am. Med. Ass'n, *supra* note 15 (citing Texas as a "great example" of a state enacting significant reforms and improving its "liability climate").

22. Sage, *supra* note 11, at 470.

23. *Ferdon ex rel. Petrucelli v. Wis. Patients Comp. Fund*, 701 N.W.2d 440, 468 (Wis. 2005). Following *Ferdon*, Wisconsin passed a new noneconomic damage cap of \$750,000. Wis. Office of the Governor, *supra* note 7.

24. *Ferdon*, 701 N.W.2d at 470-71 (quoting the Wisconsin Office of the Commissioner of Insurance report on the impact of the 1995 cap).

25. Michael Romano, *Trial and Error: Medical Courts, Arbitration Systems Are Among the Ideas Gaining Attention As Answers to the Malpractice Liability Crisis*, 33 MOD. HEALTHCARE 26, 26 (2003).

26. *Id.*

27. *Id.*



injuries and a 20% cap on trial-lawyer contingency fees to ensure that the victim is the one who is actually compensated.<sup>28</sup> Without the expenses of educating a lay jury and the threat of multimillion-dollar damages, the health court model would in theory lower the cost of litigating a malpractice claim, and its proponents assume that lower litigation costs translate to lower liability insurance premiums and health care costs.<sup>29</sup>

Proponents also believe that health courts would be more equitable for injured patients by preventing trial lawyer screening for “jackpot justice” (that is, the practice of only accepting sympathetic cases with the promise of large payouts).<sup>30</sup> Without this financially driven filter, so the argument goes, more victims with less severe injuries could gain access to the courtroom. Health courts could also benefit physicians by taming the soaring cost of malpractice insurance often attributed to the unpredictable application of medical standards by overly compassionate juries.<sup>31</sup>

There are, however, many unanswered concerns associated with such an extreme makeover of the traditional tort scheme. Critics claim that health courts would deprive injured victims of the right to be heard by fellow citizens considered so sacrosanct by the founding fathers.<sup>32</sup> Employing these specialized tribunals to discipline negligent doctors undercuts the notion of community standards by charging a select group of similarly trained individuals with the task of compensating malpractice victims.<sup>33</sup> Moreover, there exists a high risk of politicization of the health court’s bench, given the financial stakes that insurance companies, defendant physicians, trial lawyers, and plaintiff victims all have in medical malpractice litigation.<sup>34</sup> Most significantly, while the use of health courts may lower the transactional costs of each individual claim, the net effect of lowering the transactional costs is the invitation of more claims that victims would otherwise not file under the high transactional costs of the current system. It is unclear how a limited number of health courts would be able to handle this increased burden and how the malpractice insurers would respond.

28. Common Good, *supra* note 6.

29. *Id.* (“Fear of lawsuits makes it almost impossible even to talk about containing costs.”).

30. Philip K. Howard, Chair, Common Good, Address at the Annual Meeting of the American Medical Association’s House of Delegates (June 17, 2003), *available at* <http://cgood.org/healthcare-reading-cgpubs-speeches-8.html>.

31. Romano, *supra* note 25, at 26.

32. *Id.*

33. Kristin Eliasberg, *Malpractice Fix: Everyone Wants To Untangle the Medical Malpractice Mess—But Balancing Justice and Medicine May Be a Risky Procedure*, BOSTON GLOBE, Aug. 21, 2005, at E1 (“[Relying on a jury in medical malpractice cases] seems better than relying on an elite group who all have similar training and biases that go along with that training—whether in law school or medical school.”) (quoting Professor Nancy Marder, Chicago-Kent College of Law).

34. Catherine T. Struve, *Improving the Medical Malpractice Litigation Process*, 23 HEALTH AFF. 33, 37 (2004) (comparing the issue of politicization in health courts to the diffusion of political pressures in the conventional tort system due to a large number of judges hearing a variety of cases).

Despite protests from trial lawyers across the country,<sup>35</sup> the idea of health courts surfaced in Washington in the form of pending legislation, the Fair and Reliable Medical Justice Act of 2005.<sup>36</sup> Introduced for the second time by Senator Michael Enzi of Wyoming on June 29, 2005 (and cosponsored by Senator Max Baucus of Montana), the Act provides up to ten federal grants to interested states for “the development, implementation, and evaluation of alternatives to current tort litigation” in medical malpractice.<sup>37</sup> Each state pursuing a federal grant under the Act would be required to demonstrate how its alternative “(A) makes the medical liability system more reliable through prompt and fair resolution of disputes; (B) encourages the early disclosure of health care errors; (C) enhances patient safety; and (D) maintains access to liability insurance.”<sup>38</sup> The Act expressly suggests a “special health care court model,” as one of three enumerated possible alternatives.<sup>39</sup> The courts would give “judges with health care expertise” the authority “to make binding rulings on causation, compensation, standards of care, and related issues with reliance on independent expert witnesses commissioned by the court.”<sup>40</sup> The Act’s funding of these pilot programs is limited by “such sums as may be necessary. . . . [These funds] shall remain available until expended.”<sup>41</sup>

The bill has already garnered support across party lines and from both the medical and legal communities.<sup>42</sup> On June 22, 2006, the Senate Committee on Health, Education, Labor and Pensions held hearings on medical-liability proposals, including the Fair and Reliable Medical Justice Act.<sup>43</sup> *Congressional Quarterly HealthBeat* reported that health courts “attracted much attention . . . [with witnesses] divided on their merits.”<sup>44</sup> Howard was the third witness to testify at the committee hearing:

A court that writes opinions based on accepted medical standards not only holds the promise of overcoming the debilitating distrust [towards the current tort system], but can provide affirmative guidelines for improving care . . . . By

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35. See Eliasberg, *supra* note 33; Romano, *supra* note 25, at 26-27.

36. Fair and Reliable Medical Justice Act, S. 1337, 109th Cong. (2005).

37. *Id.* § 3(a)-(b).

38. *Id.* § 3(c)(2).

39. *Id.* § 3(d)(2)-(4).

40. *Id.* The bill itself does not define “health care expertise”; it only requires that health court judges “meet applicable State standards for judges and . . . agree to preside over such court voluntarily.” *Id.*

41. *Id.* § 3(k).

42. See Press Release, Common Good, Bipartisan Legislation to Create Special Health Courts Is Introduced in U.S. Senate (June 30, 2005), <http://cgood.org/healthcare-newscommentary-inthenews-241.html>.

43. See U.S. Senate Comm. on Health, Educ., Labor & Pensions, Hearings and Executive Sessions, [http://help.senate.gov/Hearings/2006\\_06\\_22/2006\\_06\\_22.html](http://help.senate.gov/Hearings/2006_06_22/2006_06_22.html) (last visited May 3, 2007).

44. Enzi Casts Wider Net for Solutions to Malpractice Compensation Woes, CQ HEALTHBEAT, June 22, 2006, available at [http://www.cmfw.org/healthpolicyweek/healthpolicyweek\\_show.htm?doc\\_id=378750](http://www.cmfw.org/healthpolicyweek/healthpolicyweek_show.htm?doc_id=378750).

restoring reliability to healthcare disputes, special health courts hold the promise of bringing order and good sense to the vital decisions needed for effective, safe and affordable healthcare in America.<sup>45</sup>

Despite the superficial appeal of health courts, however, these specialized tribunals may have detrimental effects on the cost of providing and obtaining health care, the efficiency of trials, and the equity of judgments. This Note compares the concept of health courts with the traditional tort regime to determine whether health courts could actually serve as a superior alternative in alleviating the malpractice crisis.<sup>46</sup>

Part I of this Note presents an overview of the Fair and Reliable Medical Justice Act of 2005 and the health court model as it has been marketed to the medical community. Part II compares the proposed model to the current malpractice litigation system in terms of equity of judgments, per trial and net transactional costs, efficiency of dispute resolution and victim compensation, liability insurance premiums, and health care costs. Part III examines the potential effects of employing health courts through case studies of nontraditional tort programs, including California's Medical Injury Compensation Reform Act arbitration provision, Wisconsin's medical mediation panels, and New Jersey's special mass tort courts.

This Note concludes that the risks associated with the implementation of health courts outweigh the few benefits they may provide over the traditional tort system. While health courts may increase courtroom access to more victims of medical malpractice and establish a uniform standard of care for physicians, they would also likely impose an immense net transactional cost, delay victim compensation, and drive up malpractice premiums without ensuring more equitable results or lowering the cost of health care. Employing a health court system would thus only aggravate the nation's health care problems. And in light of the curative effect of some existing reforms,<sup>47</sup> replacing the tort system with a specialized administrative court with uncertain consequences appears

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45. *Medical Liability: New Ideals for Making the System Work Better for Patients: Hearing Before the S. Comm. on Health, Education, Labor & Pensions*, 109th Cong. 11-12 (2006) (statement of Philip K. Howard, Chair of Common Good), available at [http://help.senate.gov/Hearings/2006\\_06\\_22/howard.pdf](http://help.senate.gov/Hearings/2006_06_22/howard.pdf).

46. This Note uses the term "malpractice crisis" to describe the subset of problems associated with the availability and affordability of liability insurance. See Mello et al., *supra* note 6, 2281-82.

47. CONG. BUDGET OFFICE, *supra* note 18, at 5. See, e.g., OFFICE OF TECH. ASSESSMENT, U.S. CONG., *IMPACT OF LEGAL REFORMS ON MEDICAL MALPRACTICE COSTS* 65 (1993) (summarizing the findings of six studies on total damage and noneconomic damage caps and concluding that damage caps generally reduced the size of malpractice claims and premiums); Kenneth E. Thorpe, *The Medical Malpractice 'Crisis': Recent Trends and the Impact of State Tort Reforms*, HEALTH AFF., W4-20, W4-26-27 (Jan. 21 2004), <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.20v1.pdf> (finding, in a comparison between states, that damage caps reduce malpractice premiums by 17.1% on average). See also *infra* text accompanying notes 312-26 (discussing potential methods of reforming the current system).

unwarranted and unnecessary.

## I. OVERVIEW OF HEALTH COURTS AS A RESPONSE TO THE MEDICAL MALPRACTICE CRISIS

The Fair and Reliable Medical Justice Act of 2005 embodies the frustration of physicians and health care consumers with the current state of medical malpractice and the intent of legislatures to respond with nontraditional alternatives.<sup>48</sup> Although the Act's section endorsing state experimentation with special health courts leaves much to the imagination, the legal reform organization, Common Good, has been lobbying for its own health court model,<sup>49</sup> which fits comfortably within the Act's loose framework.<sup>50</sup> The proposal materialized as a reaction to the medical malpractice crisis in the United States, and its proponents believe that it is a desirable alternative to the current litigation scheme.<sup>51</sup>

### A. *The Fair and Reliable Medical Justice Act of 2005*<sup>52</sup>

In 1932, Justice Louis Brandeis stated in a dissenting opinion that "[i]t is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."<sup>53</sup> With pending legislation and the potential availability of federal grant money, states may soon be able to act as laboratories for an alternative to the current medical malpractice tort regime. Building upon a 2002 Institute of Medicine report advocating the use of state experiments in medical liability reform,<sup>54</sup> the Fair and Reliable Medical Justice Act of 2005 proposes to fund state experiments in tort reform to find a long-term solution to the medical malpractice crisis.<sup>55</sup>

In introducing the Act to Congress, Senator Enzi cited the 1991 Harvard Medical Practice Study, which found that less than 2% of those injured by

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48. See 151 CONG. REC. S7636-37 (daily ed. June 29, 2005) (statement of Sen. Enzi)

Clearly, the American people and their elected representatives have identified the need to reform our current medical litigation system. . . . [W]e ought to lend a hand to States that are working to change their current medical litigation systems and to develop creative alternatives that could work much better for patients and providers.

49. Common Good, *supra* note 6; see also Michelle M. Mello et al., "Health Courts" and Accountability for Patient Safety, 84 MILBANK Q. 459, 460-61 (2006).

50. See S. 1337, 109th Cong. § 3(d)(4) (2005).

51. See Common Good, *supra* note 6, at 4.

52. S. 1337.

53. *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

54. Press Release, Max Baucus, Baucus Bill Seeks to Streamline Medical Malpractice Claims (June 29, 2005), <http://baucus.senate.gov/newsroom/details.cfm?id=252923>.

55. See S. 1337.

medical negligence actually brought a case to court, meaning that most cases of actual medical negligence were not litigated at all:

We like to say that justice is blind. With respect to our medical litigation system, I would say that justice is absent and nowhere to be found . . . No one questions the need to restore reliability to our medical justice system. But how do we begin the process? One way is to foster innovation by encouraging States to develop more rational and predictable methods for resolving healthcare injury claims. And that is what the Fair and Reliable Medical Justice Act aims to do. After all, the unfairness and unreliability of the current tort system seem to be supported by the fact that over ninety-eight percent of malpractice victims do not have their day in court.<sup>56</sup>

Although the Act would help finance any state program that “demonstrate[s] how the proposed alternative . . . makes the medical liability system more reliable through prompt and fair resolution of disputes; encourages the early disclosure of health care errors; enhances patient safety; and maintains access to liability insurance,” it explicitly approves the three models described in its text,<sup>57</sup> including the “early disclosure and compensation model,”<sup>58</sup> the “administrative determination of compensation model,”<sup>59</sup> and the “special health care court model.”<sup>60</sup>

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56. 151 CONG. REC. S7635 (daily ed. June 29, 2005) (statement of Sen. Enzi); *see also* A.Russell Localio et al., *Relation Between Malpractice Claims and Adverse Events Due to Negligence. Results of the Harvard Medical Practice Study III*, 325 NEW ENG. J. MED. 245, 247, 250 (1991) (concluding through the use of empirical data that “the civil-justice system only infrequency compensates injured patients and rarely identifies and holds health care providers accountable for substandard medical care”). The Harvard Medical Practice Study “identified patients who had filed claims against physicians and hospitals” in New York State in 1984 and compared those results to “the incidence of injuries to patients caused by medical management.” *Id.* at 245.

57. S. 1337, 109th Cong. § 3 (2005).

58. *Id.* § 3(d)(2). The Act’s “early disclosure and compensation model” requires health care providers to disclose incidents of medical negligence resulting in severe injury to the patient and provides those providers with the opportunity to offer good faith compensation of economic damages, noneconomic damages, and reasonable attorney fees for a limited time without subjecting them to tort liability. *Id.* § 3(d)(2)(A)–(D). This model expressly preserves “the right of an injured patient to seek redress through the State tort system if a health care provider does not enter into a compensation agreement with the patient.” *Id.* § 3(d)(2)(E).

59. *Id.* § 3(d)(3). The Act’s “administrative determination of compensation model” calls for a board to establish classes of avoidable injuries and for the state to modify tort liability to bar negligence claims in court against health care providers for those classes of avoidable injuries except in cases of fraud or criminal conduct. *Id.* § 3(d)(3)(A)(i). The board would resolve liability claims for the classes of avoidable injuries and determine compensation through the use of a schedule, which would consider economic damages, noneconomic damages, and reasonable attorney fees. *Id.* § 3(d)(3)(A)(ii). The model permits states to choose between three types of appellate review: de novo review, review with deference, or opportunity for the victim to reject the board’s determinations and seek civil action. *Id.* § 3(d)(3)(B).

60. *Id.* § 3(d)(4).

Far less developed than the other two suggested options, the Act's "special health care court model" only consists of five brief paragraphs.<sup>61</sup> The brevity is perhaps intentional, insofar as it permits various experimental spin-offs. The section requires interested states to "ensure that such court is presided over by judges with health care expertise who meet applicable State standards for judges and who agree to preside over such court voluntarily."<sup>62</sup> States must also allow the judges to make binding decisions on "causation, compensation, standards of care, and related issues with reliance on independent expert witnesses commissioned by the court."<sup>63</sup> The Act also instructs interested states to provide for an appeals process, but it does not offer any further guidance in ensuring adequate appellate review.<sup>64</sup> Additionally, the bill suggests optional use of an "administrative entity" comprised of state-licensing boards, patient-advocacy groups, health care providers, and trial attorneys—all of whom would act to oversee the special court.<sup>65</sup>

The Act's flexible structure would easily permit Common Good's health court model. In fact, Senator Enzi ostensibly borrowed the organization's stated mission of providing a more reliable system of medical justice for all Americans when he introduced the bill to Congress in 2005. Aimed at combating the "random justice" of inconsistent jury verdicts in medical malpractice cases and the high costs of health care in America, Common Good's health court concept boasts support from nearly ninety medical school deans and professors, university presidents, and politicians.<sup>66</sup> Even the *Economist* has agreed that Common Good's health court proposal appears to be a "sensible idea" to fight defensive medicine, restore access to health care for Americans, and compensate actual victims of medical negligence.<sup>67</sup> By selectively combining several reforms into one model, Common Good has created a superficially appealing solution to the problems associated with the current tort system—however, it is a solution that offers only limited improvements with significant setbacks.

### *B. Proposed Logistics of the Common Good's Health Court Model*

Phillip Howard has said that "[m]edical courts are a better system, there's no question about it."<sup>68</sup> The most developed and well-known plan for health courts

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61. *See id.*

62. *Id.* § 3(d)(4)(B).

63. *Id.* § 3(d)(4)(C).

64. *Id.* § 3(d)(4)(D). Common Good's proposal states that "[t]o assure uniformity and predictability, each ruling could be appealed to a new Medical Appellate Court." Common Good, *supra* note 6, at 4.

65. S. 1337, 109th Cong. § 3(d)(4)(E) (2005).

66. *See* Common Good, *supra* note 6.

67. *Scalpel, Scissors, Lawyer: Litigation and Health Care*, *ECONOMIST*, Dec. 17, 2005, at 51 [hereinafter *Scalpel, Scissors, Lawyer*].

68. Romano, *supra* note 25, at 26.

is Common Good's model, which replaces juries with a tribunal of judges with medical expertise gained through education or experience to establish a uniform standard of care.<sup>69</sup> The proposal circumvents the "dueling experts" phenomenon by soliciting testimony from a neutral expert selected by the health court judges. It also attempts to cut the cost of trial by imposing a 20% cap on attorney contingency fees.<sup>70</sup> The model includes a predetermined injury-specific rate schedule to normalize the distribution of noneconomic damages for any given injury from verdict to verdict.<sup>71</sup> While these four logistical elements may accomplish their express goals, their implementation would also threaten to aggravate the current malpractice crisis.<sup>72</sup>

### *1. Expert Judges Instead of Juries*

Howard has stated that one of the principal problems with the current tort system is that juries make particularized decisions about the standard of care, leading to inconsistent application from jury to jury.<sup>73</sup> Compounding the problem is that juries can award damages reaching tens of millions of dollars based on shaky merits.<sup>74</sup> In order to develop a uniform standard of care for physicians, the health court model abolishes the use of juries in medical malpractice cases and instead calls for review by full time judges who are "dedicated solely to addressing healthcare cases . . . [and] appointed through a nonpartisan screening commission."<sup>75</sup> These judges would have relevant background or gain expertise through handling medical malpractice cases exclusively.<sup>76</sup> Proponents argue that these judges would become more expert in the overlap of the medical and legal arenas and could establish precedents to guide doctors and patients on the proper standard of care.<sup>77</sup> Written rulings setting forth standard of care precedents would promote consistency across fact patterns.<sup>78</sup> To maintain the uniformity of

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69. *Id.*

70. Common Good, *supra* note 6; Mello et al., *supra* note 49, at 463 fig.1.

71. Common Good, *supra* note 6.

72. *See infra* Part II.

73. Philip K. Howard, Op-Ed., *Strong Medicine*, WALL ST. J., Jan. 6, 2007, at A6 ("[T]he civil jury was never supposed to decide standards of care as a matter of law . . ."). *See also* Eliasberg, *supra* note 33.

74. *See, e.g.*, Alastair MacLennan et al., *Who Will Deliver Our Grandchildren? Implications of Cerebral Palsy Litigation*, 294 JAMA 1688, 1689 (2005); Stephanie Reitz, *Hospital, Doctor Faulted: Boy Suffered Brain Damage During Birth*, HARTFORD COURANT, Nov. 29, 2005, at A1.

75. Common Good, *supra* note 6.

76. *See* Romano, *supra* note 25, at 26 ("Health court judges would be nominated by a board of qualifications, whose members would be appointed by the state. . . . The composition and appointment procedures for the board of qualifications are matters for state policymakers to decide but should be designed to ensure fairness and a balanced representation of stakeholders' interests."); Mello et al., *supra* note 49, at 464.

77. Mello et al., *supra* note 49, at 464.

78. Common Good, *supra* note 6.

judgments, any appeals would be reviewed by a new medical appellate court.<sup>79</sup>

This carving out of medical malpractice for adjudication by a specialized tribunal draws its legitimacy from the success of specialized administrative courts in other legal areas, like bankruptcy<sup>80</sup> and tax.<sup>81</sup> Certainly, the complexity of medical standards, procedures, and terminology is not unlike the complexity encountered in bankruptcy and tax proceedings, but the notion of removing the decision-making process from a jury has constitutional and equitable implications if done federally.<sup>82</sup> Currently pending health court legislation avoids involving the Seventh Amendment right to trial by jury guaranteed in federal courts by seeking implementation on a state level.<sup>83</sup> With the limited number of health court judges, however, even state health courts do not escape the inevitable politicization of the health court bench.<sup>84</sup> In such a highly polarized environment, the selection of judges—even if by “a nonpartisan screening commission”<sup>85</sup> or a “board of qualifications”<sup>86</sup>—could taint the fairness of trials. The judges would be the sole determiners of liability and hand-pick “neutral” experts from a predetermined pool selected by the same commission or board that appoints the judges.<sup>87</sup>

## 2. “Neutral” Experts

Called upon to educate the jury and the legal community on the appropriate

79. *Id.*

80. Although Article I of the Constitution expressly gives Congress the authority to create uniform laws on bankruptcy, U.S. CONST. art. I, § 8, cl. 4, the bankruptcy jurisdiction of federal courts is a relatively recent development. See Bankruptcy Reform Act of 1978, Pub. L. No. 95-598, 92 Stat. 2549 (1978), amended by Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1984, Pub. L. No. 98-166, 97 Stat. 1071 (1984). The Bankruptcy Reform Act granted original bankruptcy jurisdiction to the district courts and instituted a bankruptcy court in every judicial district. *Id.*

81. Created by the Tax Reform Act of 1969 under Article I of the Constitution, U.S. Tax Courts only hear federal tax cases and issue regular and memorandum decisions. See Tax Reform Act of 1969, Pub. L. No. 91-172, 83 Stat. 730.

82. See *Duncan v. Louisiana*, 391 U.S. 145, 156-57 (1968) (“We are aware of the long debate, especially in this century, [as] to the wisdom of permitting untrained laymen to determine the facts in civil and criminal proceedings. [Most] of the controversy has centered on the jury in civil cases.”).

83. “Our recent work, conducted in partnership with . . . Common Good . . . , has led to a number of refinements of the proposal: most notably, the proposition that reform should begin with small-scale policy experiments.” Mello et al., *supra* note 49, at 460. See also Romano, *supra* note 25, at 26.

84. See *infra* Subsection II.B.2.

85. Common Good, *supra* note 6.

86. Mello et al., *supra* note 49, at 465.

87. *Id.* The board would make its selection “after soliciting applications from the medical community.” *Id.* To qualify as an expert in a given case, the witness “would have to be qualified in the same profession as the defendant . . . and in a clinical specialty relevant to the nature of the claim and to certify that he or she had no conflict of interest with respect to the case.” *Id.*



application of the standard of care in various situations, medical experts serve to clarify and reinforce the standard by testifying about matters in their sphere of medical expertise, exposing noncompliant physicians and protecting patients from harmful practitioners.<sup>88</sup> As such, expert testimony is the foundation of any medical malpractice case. Traditionally, each party has relied on their own medical expert to support its legal arguments, thus creating the perception that “dueling ‘hired gun’ experts . . . confuse and prolong disputes . . . .”<sup>89</sup> Although expert testimony is often necessary to explain the intricacies of medical procedures and treatment to juries, the phenomenon of dueling experts tends to undermine efficiency and accountability by lengthening trials and encouraging the jury to believe that medical knowledge and practice support both parties.<sup>90</sup>

The AMA’s Code of Medical Ethics requires that testifying medical experts “have recent and substantive experience in the area in which they testify and should limit testimony to their sphere of medical expertise . . . [without] becom[ing] an advocate or a partisan in the legal proceeding.”<sup>91</sup> Medical experts, however, are well compensated for their testimony,<sup>92</sup> and testifying for the winning party increases an expert’s marketability as a witness. While bad-faith testimony from medical experts may be rare,<sup>93</sup> an expert’s financial interest in

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88. See AM. MED. ASS’N, E-9.07 MEDICAL TESTIMONY, in AMA CODE OF MEDICAL ETHICS, available at <http://www.ama-assn.org/ama/pub/category/8539.html>.

89. Common Good, *supra* note 6, at 6. See also J.H. Beuscher, *The Use of Experts by the Courts*, 54 HARV. L. REV. 1105, 1105-06, (1941) (arguing that the use of “partisan experts . . . frequently operates to confuse the . . . jury rather than to inform”); Scott E. Sundby, *The Jury as Critic: An Empirical Look at How Capital Juries Perceive Expert and Lay Testimony*, 83 VA. L. REV. 1109, 1129-30 (1997) (“Interviews of jurors in . . . medical malpractice litigation . . . found jurors skeptical of the economic, medical, and actuarial experts who had testified.”).

90. See Sundby, *supra* note 89.

91. AM. MED. ASS’N, *supra* note 88. The AMA’s Council on Ethical and Judicial Affairs relies on findings of unethical conduct made by state medical societies and national specialty societies “to acquit, admonish, censure, or place on probation the accused physician or suspend or expel him or her from AMA membership . . . . However, the AMA is not in a position to take action against a physician’s license to practice medicine.” Am. Med. Ass’n, *Frequently Asked Questions in Ethics*, [http://www.ama-assn.org/ama/pub/category/5105.html#what\\_can\\_ama\\_do](http://www.ama-assn.org/ama/pub/category/5105.html#what_can_ama_do) (last visited May 3, 2007). State medical societies and licensing boards can begin professional reviews of physicians who violate the AMA’s Code of Medical Ethics. Am. Med. Ass’n, *AMA (Ethics) Reporting Ethical Violations*, <http://www.ama-assn.org/ama/pub/category/2509.html> (last visited May 3, 2007). State licensing boards can initiate legal action on the physician’s fitness to practice medicine. *Id.*

92. *Kirby v. Ahmad*, 635 N.E.2d 98, 99 (Ohio Com. Pl. 1994) (noting that “the Hippocratic Oath has been supplanted by opportunism and greed by those who participate as medical expert witnesses” and charge 500 to 750 dollars per hour); GERRY SPENCE, *WITH JUSTICE FOR NONE* 270 (1989) (“Some medical school professors . . . make several times their annual salary by selling testimony to anyone who will retain them.”); Douglas R. Richmond, *Expert Witness Conflicts and Compensation*, 67 TENN. L. REV. 909, 934 (2000) (“Treating physicians may charge expert witness fees much higher than regular patient rates, a practice criticized by reviewing courts.”).

93. Alexis Wood, *Professional Oversight of Expert Testimony*: Austin v. American Association of Neurological Surgeons, AM. MED. ASS’N J. ETHICS, Apr. 2005, available at <http://www.ama-assn.org/ama/pub/category/14859.html> (“While compensation will not buy bad

the outcome of the case can conflict with the obligation to advocate for the well-being of patients.<sup>94</sup> Ultimately, the cost in terms of time, money, and reliability associated with the use of dueling experts appears to undercut the accountability of the justice system in medical malpractice cases. Health courts resolve this issue by authorizing judges to select “neutral experts” in the relevant area of medicine, rather than listen to dueling experts hired by the two parties.<sup>95</sup> Still, in certain controversial areas of medicine, “neutral” experts may not exist, and the current adversarial nature of expert witness testimony may be desirable.<sup>96</sup> It is unclear how the health court judges would then decide which expert’s opinion to adopt as the standard of care. Despite these uncertainties, by abolishing the use of dueling experts, Common Good claims that health courts would be able to resolve most cases “within months” and “reduc[e] current costs by almost half.”<sup>97</sup>

### 3. A 20% Cap on Attorney Fees

Common Good’s proposal also seeks to maximize victim compensation by limiting attorney’s fees to 20%.<sup>98</sup> Malpractice attorneys typically operate on contingent fees, such that they are only paid upon settlement or victory in court.<sup>99</sup> These fees usually constitute one-third of any award, but malpractice contingency fees “are higher because [malpractice cases] are much riskier and require the investment of substantial[ly] more money and time than the average personal injury case.”<sup>100</sup> Because most malpractice attorneys operate on a contingent-fee basis (charging at least forty percent),<sup>101</sup> they maintain financial incentives to screen malpractice cases before providing representation, so as to turn the highest possible yield: “Pursuing litigation is costly for lawyers. They won’t lay out a bet unless they think they’ll win.”<sup>102</sup> Thus, cases with expected damages of less than \$200,000 are frequently turned down, leaving victims with less severe injuries uncompensated.<sup>103</sup>

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faith testimony from most physicians, having a financial interest in the outcome of the case can conflict with a physician’s obligation to put the well-being of patients foremost at all times.”).

94. AM. MED. ASS’N, *supra* note 88.

95. Romano, *supra* note 25, at 26.

96. See, e.g., *infra* Subsection II.B.1 (describing the lack of consensus within the medical community regarding the merits of electronic fetal monitoring in cerebral-palsy malpractice cases against obstetrician-gynecologists).

97. Common Good, *supra* note 6.

98. *Id.*

99. Alexander Tabarrok, *Give the Lawyer His Cut*, FORBES, Oct. 3, 2005, at 42.

100. The Cochran Firm, The Attorney’s Fee Contingency Fee, [http://www.cochranfirm.com/resource\\_detail.asp?id=4&resource=17&detail=70](http://www.cochranfirm.com/resource_detail.asp?id=4&resource=17&detail=70) (last visited May 3, 2007).

101. Romano, *supra* note 25, at 27.

102. Tabarrok, *supra* note 99.

103. Romano, *supra* note 25, at 26.

Common Good's proposal attempts to encourage the litigation of claims seeking lesser damages, by effectively lowering the litigation bar of \$200,000 through the lower cost per trial, and to put an extra 20% of damage awards in the victim's pocket, by capping contingent fees in malpractice cases at 20%.<sup>104</sup> This fee restriction would lead attorneys to modify client payment to maximize profits, causing a shift to an hourly rate or a significant increase in claims to make up for the reduced return in contingent fees.<sup>105</sup> Thus, the potential unintended effects of reducing the economic barrier to litigation could be the discrimination against those who cannot afford to pay upfront fees and the straining of the health court docket.<sup>106</sup> It remains uncertain whether the limited venues will be able to deal with the influx of claims that the current system weeds out, especially given the proposed shift from a compensation standard of negligence to one of avoidability.<sup>107</sup>

#### *4. An Avoidability Standard for Compensation and a Predetermined Noneconomic Damages Schedule*

In response to the inability of the current tort system to compensate patients who have suffered avoidable injuries, health court advocates have proposed relaxing the standard for compensation from negligence to avoidability.<sup>108</sup> "Avoidable adverse events are injuries that are (1) caused by treatment (or the omission of treatment) and (2) should rarely . . . occur when care is provided according to best practice."<sup>109</sup> By switching to an avoidability standard, the pool of potential claims would expand to include patients who suffered avoidable injuries not due to negligence.<sup>110</sup> Researchers have estimated the avoidability standard to allow twice as many potential litigants as the negligence standard.<sup>111</sup>

Damages awarded to successful plaintiffs in health courts would include economic damages (for medical costs and lost income)<sup>112</sup> and a predetermined

104. See Common Good, *supra* note 6.

105. See *infra* Section II.C. It is possible that, despite the lower transactional cost per trial, attorneys may not be able to profit from litigating health court claims with the 20% contingent-fee cap; if this were the case, taking on more cases would not adequately sustain their income stream. Without the financial incentives that the current litigation system offers, attorneys may lose interest in litigating malpractice claims altogether, perhaps facilitating a more administrative version of health courts with pro se litigants. For purposes of discussion, however, this Note assumes that the twenty-percent cap on contingency fees will not force attorneys out of the malpractice equation.

106. See *id.*

107. See *id.*; *infra* Section III.B.

108. See Mello et al., *supra* note 49, at 466 (characterizing the avoidability standard as "occup[ying] a middle ground between the standards of strict liability . . . and negligence"); Howard, *supra* note 75.

109. Mello et al., *supra* note 49, at 466.

110. *Id.*

111. *Id.* at 467.

112. *Id.* Surprisingly, Professor Michelle Mello qualifies the full compensation of economic

sum to cover noneconomic damages for the particular injury, set by another panel of experts.<sup>113</sup> Because jury compositions and determinations vary by case, there is little consistency among awards of noneconomic and even economic damages.<sup>114</sup> A team of researchers from Common Good and the Harvard School of Public Health plans to propose a schedule for automatic compensation of noneconomic damages on an injury-specific basis to reimburse victims<sup>115</sup> “based on decision-science research about how the public values various utility losses and public deliberation about reasonable compensation.”<sup>116</sup> By removing the shaky calculus of jury negligence and award determinations, the intended consequence of this no-fault compensation would be twofold: quicker and more predictable victim compensation and prevention of medical errors for patient safety.

According to proponents of the rate schedule, “[health care providers would] be able to say, ‘If this happens, we pay, no matter what,’” thus providing quicker payouts to injured patients,<sup>117</sup> especially those with less severe injuries who are left uncompensated due to the trial lawyer screening process.<sup>118</sup> Moreover, by not focusing on negligence, the rate schedule supports disclosure of medical errors and improvement in the health care system.<sup>119</sup> Nevertheless, the combination of expert judges and rate schedule causes some consumer advocates to characterize the health court proposal as “not only depriv[ing] plaintiffs of the right to a trial by jury but also . . . establish[ing] caps on noneconomic damages . . . . This is totally an attempt to give HMOs, hospitals and doctors a private tribunal where there’s little justice but a lot of predictability for defendants.”<sup>120</sup> During the June 2006 Senate committee hearings, the American Bar Association (ABA) testified to the inherent unfairness of the rate schedule: “Would it be fair to award a prefixed award for negligence that resulted in a paralyzed hand for a surgeon, lost or impaired vision for an artist, or lost or impaired hearing for a musician?”<sup>121</sup>

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damages by suggesting “some kind of eligibility threshold . . . to control the number and costs of claims brought.” *Id.* The implementation of such a threshold seems reminiscent of the current system’s litigation bar, and contrary to her efforts in addressing “the undercompensation problem.”

113. Common Good, *supra* note 6.

114. Eliasberg, *supra* note 33. Recognizing the lack of consistency in jury awards, researchers submitted the same fact pattern to 120 mock six person juries and found a standard deviation of \$344,566 in the noneconomic damage awards. Shari Seidman Diamond et al., *Juror Judgments about Liability and Damages: Sources of Variability and Ways To Increase Consistency*, 48 DEPAUL L. REV. 301, 305, 314 & tbl.3 (1998).

115. Eliasberg, *supra* note 33.

116. Mello et al., *supra* note 49, at 468.

117. Eliasberg, *supra* note 33 (quoting Professor Troyen Brennan, who helped develop the Common Good model).

118. See Mello et al., *supra* note 49, at 464.

119. *Id.* at 473.

120. Romano, *supra* note 25, at 26 (quoting Jamie Court, Executive Dir., Found. for Taxpayer & Consumer Rights).

121. ABA Network, Tort Law: Health Courts, <http://www.abanet.org/poladv/priorities/>

Essentially, proponents intend for health courts to promote predictability and the compensation of victims via the implementation of four logistical elements: determination of physician negligence by expert judges, solicitation of testimony from neutral experts, restriction of attorney profits, and distribution of noneconomic damage awards through the use of the rate schedule. The risks related to the implementation of health courts, however, outweigh the limited benefit they may offer over the current litigation scheme. Given the drastic nature of the proposed changes, it is important to compare the two models before committing to a complete overhaul of medical malpractice litigation.

## *II. Comparing Health Courts to the Traditional Tort System*

In Pennsylvania—one of the AMA’s crisis states<sup>122</sup> and a likely grant candidate under the Fair and Reliable Medical Justice Act—the Project on Medical Liability independently explored litigation alternatives, including the feasibility of the implementation of special health courts, such as those proposed by Common Good.<sup>123</sup> Funded by the Pew Charitable Trusts, the Project’s mission was to serve as an independent, impartial voice on medical liability, and malpractice issues and provide decision-makers with objective information about the ways in which medical, legal, and insurance-related issues affect the medical liability system and malpractice reforms.<sup>124</sup> Ultimately, despite the model’s endorsement by the president of the Pennsylvania Medical Society,<sup>125</sup> the Project characterized the health court model as “unpromising,” and concluded that “[a]n examination of the court proposed for Pennsylvania . . . reveals serious risks of increased politicization [of the bench], narrowed judicial perspective, and greater costs to litigants.”<sup>126</sup> The Project found that Common Good’s goals could be accomplished without a complete overhaul of the traditional litigation system.<sup>127</sup> After exploring the birth and evolution of medical malpractice in the United

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healthcourts.html (last visited May 3, 2007).

122. See Am. Med. Ass’n, *supra* note 15.

123. Press Release, The Pew Charitable Trusts, Pew Trusts Invest \$3.2 Million to Research Medical Liability in Pennsylvania and Identify Possible Reforms (Mar. 15, 2002), [http://www.pewtrusts.com/ideas/ideas\\_item.cfm?content\\_item\\_id=986&content\\_type\\_id=16&issue\\_name=Medical%20liability&issue=32&page=16&name=Pew%20Press%20Releases](http://www.pewtrusts.com/ideas/ideas_item.cfm?content_item_id=986&content_type_id=16&issue_name=Medical%20liability&issue=32&page=16&name=Pew%20Press%20Releases); see also CATHERINE T. STRUVE, PROJECT ON MED. LIAB. IN PA., EXPERTISE IN MEDICAL MALPRACTICE LITIGATION: SPECIAL COURTS, SCREENING PANELS, & OTHER OPTIONS 2-3 (2003).

124. See Project on Medical Liability in Pennsylvania, <http://www.pewtrusts.org/ideas/indx.cfm?issue=32> (last visited May 3, 2007).

125. William W. Lander, *Malpractice—A Medical Crisis: It’s Time for Special Health Courts in Pennsylvania*, TRIB.-DEMOCRAT, Oct. 14, 2005, available at [http://www.tribune-democrat.com/siteSearch/apstorysection/local\\_story\\_287100437.html](http://www.tribune-democrat.com/siteSearch/apstorysection/local_story_287100437.html).

126. STRUVE, *supra* note 123, at 4-5.

127. *Id.* at 80-81. “[P]rocedural reform should focus . . . on supporting the efforts of judges and juries to assess scientific and medical questions and on providing guidance for the award and review of noneconomic damages.” *Id.* at 91.

States, this Part compares Common Good's health court model with the traditional tort system in terms of equity of judgments, transactional costs, efficiency of dispute resolution and compensation, liability insurance premiums, and the cost of health care.

*A. The History of American Medical Malpractice Litigation*

Written in the 1760s, Blackstone's *Commentaries on the Laws of England* introduced the American colonies to the concept of medical malpractice as "[i]njuries . . . by the neglect or unskilful [sic] management of [a person's] physician, surgeon, or apothecary . . . because it breaks the trust which the party had placed in his physician, and tends to the patient's destruction."<sup>128</sup> The first actions against negligent physicians, however, did not begin to surface in the United States until the middle of the 1800s with the onset of "marketplace professionalism."<sup>129</sup> Because the states avoided regulating professions like medicine and law, herbal healers competed with European-trained surgeons for the business of health care consumers.<sup>130</sup> The lack of regulation and a uniform standard of care forced victims of malpractice to seek recourse by holding individual practitioners to whatever standard the victim or the victim's lawyer wanted to impose.<sup>131</sup> Courts aided the growth of the budding legal field by easing requirements for initiating tort claims, leading to an "explosion of medical malpractice suits" and a 950% increase in appellate review from 1840 to 1860.<sup>132</sup>

Although most physicians initially embraced the idea of weeding out their negligent peers, by 1850,

the nation's best-educated and most professionally minded physicians observed with a sort of defensive incredulity and disbelieving horror that many, if not most, of the burgeoning numbers of malpractice suits were being lodged not against charlatans and amateur hacks, but against others like themselves, the best-educated and most successful physicians.<sup>133</sup>

As patients increasingly sued the more wealthy physicians instead of the herbal healers who had fewer assets, physicians in the 1850s largely "regarded the spread of malpractice litigation as a quasi-revolutionary assault,"<sup>134</sup> with one famously stating that malpractice lawyers "follow us as the shark does the emigrant ship."<sup>135</sup>

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128. WILLIAM BLACKSTONE, 3 COMMENTARIES \*122.

129. Mohr, *supra* note 14, at 1732.

130. *Id.*

131. *Id.*

132. *Id.*

133. *Id.* at 1732-33.

134. *Id.*

135. *Id.* at 1733-34.

The advent of liability insurance at the end of the nineteenth century solved the liability problem for individual physicians and thus rendered tort actions the main vehicle for victim compensation.<sup>136</sup> Despite the medical advancements achieved over the last 150 years, medical malpractice litigation and the polarization of the medical and legal communities that began in the mid-1800s still exist today.<sup>137</sup> Only now, doctors are fleeing states with the highest liability insurance premiums, and some commentators worry that this exodus will limit the availability of care in some areas of the country.<sup>138</sup> Though most can agree that change is needed, it is crucial to ensure that the proposed alternative will in fact solve the problems associated with the traditional litigation system.

### *B. Equity of Judgments*

Proponents of Common Good's health court model seek to prevent the inequities of the current system—namely, the under-compensation of actual malpractice victims, the unfair compensation of meritless claims, and disparate damage awards across fact patterns.<sup>139</sup> A 1984 study of medical malpractice in New York hospitals estimated that about 27,179 cases of negligence occurred in the state, but only 415 (1.5%) resulted in legal action, suggesting an overwhelming number of uncompensated patients.<sup>140</sup> A 1999 Institute of Medicine report approximated that 98,000 patients may die of preventable medical mistakes annually.<sup>141</sup> Ultimately, “[t]oo few claims are asserted, in that many of those injured by medical negligence never bring a claim; yet too many claims are asserted, in that some suits turn out to lack merit.”<sup>142</sup> These statistics—coupled with the fact that defendants win about 75% to 80% of malpractice cases<sup>143</sup>—suggest that plaintiffs often file meritless claims and try to convince juries to award unfair compensation payments. The variability of noneconomic damage awards across juries further compounds the compensation problem.<sup>144</sup> Common Good's health court proposal builds on these assumptions

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136. *Id.* at 1735.

137. *Id.* at 1731-37.

138. *Scalpel, Scissors, Lawyer*, *supra* note 69, at 51 (“Pennsylvania lost a third of its general surgeons between 1995 and 2002.”).

139. See Mello et al., *supra* note 49, at 465-66.

140. Localio et al., *supra* note 56, at 248 fig.1.

141. INST. OF MED., NAT’L ACAD. OF SCIS., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM I (1999).

142. Struve, *supra* note 34, at 34. *But see* Romano, *supra* note 25, at 26 (“The percentage of [medical malpractice] cases that go to trial . . . is typically lower than most other tort claims.”) (quoting Professor Catherine Struve, Univ. of Penn. Law School).

143. See BUREAU OF JUSTICE STATISTICS, U.S. DEP’T OF JUSTICE, MEDICAL MALPRACTICE TRIALS AND VERDICTS IN LARGE COUNTIES, 2001 (2004) (reporting that “[t]he overall win rate for medical malpractice plaintiffs (27%) was about half of that found among plaintiffs in all tort trials (52%)”), available at <http://www.ojp.usdoj.gov/bjs/pub/pdf/mmtv1c01.pdf>; Eliasberg, *supra* note 33.

144. Diamond et al., *supra* note 114, at 318 & tbl.3 (noting a high variability in noneconomic

to push for adjudication by expert judges as a way to achieve equity and accuracy.<sup>145</sup>

### *1. Processing Expert Testimony: The Jury Versus Expert Judges*

Perhaps the most radical component of the health court model is the substitution of expert judges for the civil jury—the poster scapegoat for the malpractice crisis.<sup>146</sup> A staple in the traditional tort regime, the jury “by definition [is] an . . . experience in the conduct of serious human affairs that, virtually from its inception, has been the subject of deep controversy.”<sup>147</sup> Juries in medical malpractice trials must discern whether a defendant physician’s conduct was reasonable given the medical custom standard set forth by expert testimony.<sup>148</sup> “When the jury is working well, it represents a fair cross-section of the community . . . [which] seems better than relying on an elite group who all have similar training and biases that go along with that training—whether in law school or medical school.”<sup>149</sup> This ignorance, however, necessitates education on the appropriate standard of care by “hired gun” experts, which perpetuates inconsistent verdicts across juries.

By replacing lay juries with judges with medical expertise, health courts offer increased consistency in the determination of standards of care. Instead of listening to experts hired by the parties, judges would have the authority to consult neutral experts in each area of medicine,<sup>150</sup> thus eliminating adversarial testimony: “The point is not to shield bad doctors from legal consequences but to ensure that judgments are based on sound science rather than on compelling theatrics.”<sup>151</sup> Intuitively, the jury’s unfamiliarity with complex medical terminology and procedures, combined with the presentation of sympathetic fact patterns, suggests a bias that might unfairly favor a victim plaintiff.

In reality, defendants win most malpractice verdicts.<sup>152</sup> A Bureau of Justice Statistics study on medical malpractice trials and verdicts in the country’s

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damage awards in a study of 120 mock juries).

145. See Common Good, *supra* note 6.

146. See, e.g., Howard, *supra* note 73 (“Fear of erratic jury decisions in medical malpractice cases has spawned a culture of fear, causing inefficiencies that infect every level of medicine.”).

147. HARRY KALVEN, JR. & HANS ZEISEL, *THE AMERICAN JURY* 3-4 (1966).

148. Jay Alexander Gold, *Wiser Than the Laws? The Legal Accountability of the Medical Profession*, 7 AM. J.L. & MED. 145, 179 (1981).

149. Eliasberg, *supra* note 33 (quoting Professor Nancy Marder). See also Nancy S. Marder, *The Myth of the Nullifying Jury*, 93 NW. U. L. REV. 877, 932 (1999) (“At the heart of the jury system . . . is a belief that jurors will bring to the task of judging their sense of justice. . . . [T]he jury often has been described as representing the ‘conscience of the community.’”).

150. Common Good, *supra* note 6.

151. MacLennan et al., *supra* note 74, at 1689.

152. Eliasberg, *supra* note 33. But see Localio et al., *supra* note 56, at 248 tbl.3 (“Of the 280 patients who had adverse events caused by medical negligence as defined by the study protocol, eight filed malpractice claims.”).



seventy-five largest counties in 2001 found that “[t]he overall win rate for medical malpractice plaintiffs . . . was [27%, which was] about half of that found among plaintiffs in all tort trials [52%].”<sup>153</sup> Plus, courts later reduce nearly half of jury verdicts,<sup>154</sup> indicating judicial review of the more outlying awards. The media fuels the perception of plaintiff-friendly juries awarding frequent windfall payments by reporting cases with verdicts between four and thirty-four times greater than the average case.<sup>155</sup>

For example, in November 2005, the media reported that a six-member Connecticut jury awarded a record \$36.5 million<sup>156</sup> to the family of a six-year-old Nicholas Cowles, who was blind and brain-damaged and suffered from cerebral palsy (CP) due to injuries sustained during delivery by a surrogate mother.<sup>157</sup> Nicholas was present at trial, and jury foreman Julia Torres commented that “we all wanted to reach out and hug him.”<sup>158</sup> The jury found that the obstetrician failed to properly interpret data from an electronic fetal monitoring (EFM) device, which should have indicated that the fetus was in distress.<sup>159</sup> The length of the difficult delivery was so long that it caused the fetus to suffer from a dangerous increase in blood acidity, and jurors concluded that Nicholas should have been delivered via Caesarean section long before he actually was.<sup>160</sup> Torres said “[h]ad the Caesarean been performed even [thirty] minutes earlier, Nicholas would be fine today. It was just tragic that it happened that way.”<sup>161</sup>

Jurors in the Cowles trial found the appropriate standard of care to include use of the data from the monitoring strips in determining the necessity of a C-section.<sup>162</sup> As average American citizens with limited medical backgrounds, they undoubtedly reached their decision by weighing the testimony of dueling experts.<sup>163</sup> This reliance on expert testimony is a necessary component of a lay jury’s decision-making process and propagates the perception of arbitrary decisions. Health courts could potentially remedy this through judicial selection

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153. BUREAU OF JUSTICE STATISTICS, *supra* note 143.

154. Joseph T. Hallinan, *In Malpractice Trials, Juries Rarely Have the Last Word*, WALL ST. J., Nov. 30, 2004, at A1.

155. Deborah L. Rhode, *Frivolous Litigation and Civil Justice Reform: Miscasting the Problem, Recasting the Solution*, 54 DUKE L.J. 447, 463 (2004).

156. The \$36.5 million Cowles award is nearly sixteen times greater than the median award for malpractice in childbirth cases of \$2.3 million, MacLennan et al., *supra* note 74, at 1688, and eighty-six times the average malpractice award of \$320,000, CONG. BUDGET OFFICE, *supra* note 18, at 4.

157. Reitz, *supra* note 74.

158. *Id.*

159. *Id.*

160. *Id.*

161. *Id.*

162. *Id.*

163. See Gold, *supra* note 148, at 179.

of a “neutral expert,”<sup>164</sup> but it is unclear what characteristics a “neutral expert” might possess or whether neutral experts even exist in such a controversial area of medicine.

In fact, most clinicians do not believe that babies acquire CP from the failure of the obstetrician to deliver them by C-section.<sup>165</sup> Studies conducted on the efficacy of EFM patterns, like those presented in the Cowles trial, have demonstrated that the use of EFM “has not led to a decreased rate of [CP].”<sup>166</sup> Still, the fear of litigation pushes some doctors to perform unnecessary C-sections, exposing mothers to increased risks of hemorrhage, infection, and postpartum complications.<sup>167</sup> A 2006 study examined characteristics of repeat expert witnesses in 827 neurologic birth injury cases and identified 71 physicians who participated in 738 (or 89%) of the selected cases.<sup>168</sup>

If the EFM read-outs that acted as the foundation for the Cowles case are not an effective method for determining fetal distress, then these hired medical experts should cease perpetuating those beliefs. Even members of the medical community have suggested that professional schools should “train, register, and audit those offering medicolegal opinion,” such that “any expert asserting that a CP outcome was preventable . . . should have to produce evidence of good medical quality that the advocated policy has reduced rates of CP.”<sup>169</sup> Thus, if the medical community desires a uniform standard of care, it should police medical experts and their testimony to reflect accepted standards of the medical profession. Implementing measures to ensure the accountability of these experts would significantly minimize the effect of dueling experts on lay juries without depriving malpractice victims of a jury trial.

Furthermore, taking malpractice cases away from juries may be unwarranted. A 2006 study conducted at the Harvard School of Public Health challenges the common view among tort reformers that the traditional tort scheme entertains and cultivates frivolous claims.<sup>170</sup> Out of a random sample of 1452 completed malpractice claims from five insurers, 3% did not involve medical injuries and 37% did not involve medical errors;<sup>171</sup> in other words, the Harvard researchers agreed with the verdicts of a majority of lay juries. According to lead researcher Professor David Studdert, “We found the system did reasonably well in sorting the good claims from the bad ones, but there were

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164. Common Good, *supra* note 6.

165. MacLennan et al., *supra* note 74, at 1688; *Scalpel, Scissors, Lawyer*, *supra* note 67, at 52.

166. MacLennan et al., *supra* note 74, at 1689.

167. *Id.*

168. Aaron S. Kesselheim & David M. Studdert, *Characteristics of Physicians Who Frequently Act As Expert Witnesses in Neurologic Birth Injury Litigation*, 108 OBSTETRICS & GYNECOLOGY 273, 275 (2006). The judgments for the 827 cases totaled \$2.9 billion. *Id.*

169. MacLennan et al., *supra* note 74, at 1689.

170. See David M. Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 NEW ENG. J. MED. 2024 (2006).

171. *Id.* at 2026, 2028 fig.1.

problems.”<sup>172</sup> Still, these problems do not seem to warrant an overhaul of the entire system, especially with the availability of modest but effective supplemental reforms.<sup>173</sup>

## 2. Preventing the Practice of Defensive Medicine and Establishing a Standard of Care

Howard has explained that, “[a] reliable system of medical justice could take many forms, but . . . the key element must be expert judges ruling on standards of care.”<sup>174</sup> The veritable lack of a uniform standard of care has led to the practice of defensive medicine—defined as “a deviation from sound medical practice that is induced primarily by a threat of liability.”<sup>175</sup> Although the phenomenon is well documented,<sup>176</sup> researchers do not agree on the amount spent on defensive medicine, and the topic remains highly controversial, because it is difficult to isolate what services are solely defensive.

A recent study supported by the Project on Medical Liability in Pennsylvania found that nine out of ten physicians in six especially high-risk specialties practice defensive medicine ranging from ordering extra tests to avoiding patients perceived to pose a litigation risk.<sup>177</sup> The Office of Technology Assessment, however, found that “a relatively small proportion of all diagnostic procedures—certainly less than 8 percent overall—is performed *primarily* due to conscious concern about malpractice liability risk.”<sup>178</sup> The Congressional Budget Office (CBO) determined “[o]n the basis of existing studies and its own research . . . that savings from reducing defensive medicine would be very small,” with no statistically significant discrepancy in health care spending per capita between states with restrictive limits on malpractice claims and states without them.<sup>179</sup> Still, the reduction of unnecessary and potentially harmful invasive procedures like biopsies is needed and may come with the development of uniform clinical standards of care.<sup>180</sup>

The written decisions by the expert judges presiding over health courts

172. Alicia Chang, *Study Asserts Many Medical Malpractice Suits Groundless*, HOUSTON CHRON., May 11, 2006, at A11.

173. Diamond et al., *supra* note 114, at 318.

174. Philip K. Howard, Op-Ed., *The Best Course of Treatment*, N.Y. TIMES, July 21, 2003, at A15.

175. Studdert et al., *supra* note 16, at 2616.

176. See *id.*; OFFICE OF TECH. ASSESSMENT, U.S. CONG., DEFENSIVE MEDICINE AND MEDICAL MALPRACTICE (1994); P.C. Coyte et al., *Medical Malpractice: The Canadian Experience*, 324 NEW ENG. J. MED. 89 (1991); N. Summerton, *Positive and Negative Factors in Defensive Medicine: A Questionnaire Study of General Practitioners*, 310 BRITISH MED. J. 27 (1995).

177. Studdert et al., *supra* note 16, at 2616.

178. OFFICE OF TECH. ASSESSMENT, *supra* note 176, at 74 (emphasis added).

179. CONG. BUDGET OFFICE, *supra* note 18, at 6.

180. Studdert et al., *supra* note 16, at 2617.

would serve to establish uniform precedents and guidelines for patient care.<sup>181</sup> Appointed by a nonpartisan screening committee, the judges would adjudicate only health care matters.<sup>182</sup> Unlike generalist judges and lay juries, expert medical judges could rely upon their familiarity with medical custom to more accurately apply the appropriate standard of care and to achieve consistency across the state.

Some jurisdictions, however, are moving towards a “reasonable physician” standard of care instead of the traditional medical custom standard, thus minimizing the desirability of expert judges skilled at hearing the traditional standard.<sup>183</sup> Generalist judges may be better equipped to determine the reasonable care standard by drawing upon their familiarity with other tort areas. Along with specialization in a particular field of law comes de-familiarization with other legal doctrines, such that “the specialists’ field may diverge from the larger body of law and may also lose the benefit of experience in other fields.”<sup>184</sup>

Moreover, because health courts cover such a narrow and highly contentious area of law, there is an extremely high risk of politicization of the health court bench.<sup>185</sup> The ABA’s Commission on the Twenty-First Century Judiciary found that recent state judicial election campaigns have been politicized due to the participation of “interest groups that formed to promote a specific political issue.”<sup>186</sup> Given the highly polarized atmosphere of the malpractice issue, neither the appointment nor the election of medical judges could be expected to escape intense lobbying by consumer groups, trial attorneys, physicians, and insurance providers.<sup>187</sup>

In the current litigation system, the incentives to lobby for a sympathetic judge are muted by the fact that malpractice cases are distributed among a number of judges, each of whom hears only a small portion of the total claims in any given state. In other words, the threat of politicization is spread out over many judges hearing many kinds of cases. With fewer venues and fewer judges, the political pressures applied from all sides of the malpractice debate would inevitably pervade the health court bench, jeopardizing the goal of providing “a reliable system of medical justice.”<sup>188</sup>

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181. Common Good, *supra* note 6.

182. *Id.*

183. Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 164 (2000).

184. STRUVE, *supra* note 123, at 75.

185. *Id.*

186. AM. BAR ASS’N, COMM’N ON THE 21ST CENTURY JUDICIARY, JUSTICE IN JEOPARDY 22 (2003).

187. See STRUVE, *supra* note 123, at 74.

188. *Id.* at 69.

### C. Per Trial and Net Transactional Costs

Perhaps the greatest inequities of the current system are the inaccessibility of the courtroom to malpractice victims with lesser damages and the under-compensation of successful victim plaintiffs.<sup>189</sup> Both of these sources of inequity are related to the transactional costs of the traditional tort system: “Those patients with small claims often cannot find a lawyer to represent them, while those who win find their lawyers have swallowed half the payout from the doctors.”<sup>190</sup> Research has revealed that sixty cents of every dollar paid in malpractice premiums go to legal fees, court costs, and other administrative expenses, leaving only forty cents per dollar to compensate victims of medical negligence.<sup>191</sup> In 2002, the average malpractice claim payment had increased to \$320,000.<sup>192</sup> Thus, after paying off all litigation-related expenses, the average victim receives only \$128,000 to cover damages.

Common Good’s health court proposal seeks to make litigation more affordable to those injured by negligence through adjudication by an expert tribunal, education of the tribunal by neutral experts, and a 20% cap on contingency fees.<sup>193</sup> Without the expenses of assembling a jury, compensating dueling experts, or relinquishing 20% of damages to trial attorneys, the cost of litigating in health courts is estimated by Common Good to be half of what it is now.<sup>194</sup> Because health court cases would be less expensive to litigate per trial, fewer claimants would choose to settle,<sup>195</sup> and more victims with less severe injuries would gain access to the courts. Nevertheless, attorneys make the ultimate decision of whether a claim should be litigated; if their contingent fees are halved, they would theoretically need to seek claims with larger payouts or litigate more claims to maintain their profit.<sup>196</sup>

Currently, sixteen states restrict contingent fees in medical malpractice or

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189. See Mello et al., *supra* note 49, at 465-66 (“A major shortcoming of the current tort liability system is that the negligence standard leaves many patients with preventable injuries ineligible for compensation. Because only about one in four injuries related to hospital treatment can be attributed to negligence, the majority of injured patients cannot access the current compensation system.” (citations omitted)).

190. *Scalpel, Scissors, Lawyer*, *supra* note 67.

191. 151 CONG. REC. 7635 (daily ed. June 29, 2005) (statement of Sen. Enzi).

192. CONG. BUDGET OFFICE, *supra* note 18, at 3-4. The average malpractice claim payment in 1986 totaled \$95,000. *Id.*

193. Common Good, *supra* note 6.

194. *Id.*

195. *But see* STRUVE, *supra* note 123, at 77 (finding that the decreased convenience—particularly for malpractice plaintiffs—might lead to an increase in dropped and settled claims, despite the potential availability of more experienced counsel concentrated near the court locales).

196. Without the expenses associated with hiring expert witnesses, the malpractice attorney may determine that a 20% contingent fee is an attractive return for some cases. See *supra* notes 98-107 and accompanying text.

personal injury cases.<sup>197</sup> When states limit fees to less than the usual 33% for personal injury cases, attorneys have less economic incentive to screen each case carefully for the likelihood of a large payout.<sup>198</sup> Therefore, capping contingent fees leads to one of two potential outcomes: abandonment of the contingent fee for an hourly rate or a significant increase in claims filed by trial attorneys to compensate for the reduced return in contingent fees.<sup>199</sup> Either result threatens to undo the proposed benefits of health courts.

Contingency fees improve access to courts for low-income plaintiffs because lawyers are paid from the settlement or judgment and not the client's pocket.<sup>200</sup> An hourly rate prevents less wealthy litigants from bringing claims, as it requires paying attorney fees prior to and regardless of any recovery. The use of an hourly rate, instead of contingent fees, would shift the burden of under-compensation from victims with the least severe injuries to victims with the least financial resources. This hardly seems to be the right result because, arguably, the most impoverished victims need compensation from damages the most. Payment of attorneys' fees by the hour also discourages efficiency and settlement, such that a plaintiff may pay high hourly rates without ever receiving any compensation for the malpractice injury.<sup>201</sup>

On the other hand, capping contingent fees might push malpractice attorneys to relax the practice of screening malpractice claims, potentially causing an influx of claims into the court system that are currently not considered worth litigating. This enhanced access to the courtroom for malpractice victims with less severe injuries is certainly one of the health court model's major selling points; however, increased courtroom access directly translates to increased litigation. As health courts would necessarily operate in regular sessions in limited venues, a boost in the number of claims could clog the circuits. For example, a proposed model for health courts in Pennsylvania provided for six circuit level courts to replace the sixty judicial districts available to hear

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197. See ALEXANDER TABARROK & ERIC HELLAND, TWO CHEERS FOR CONTINGENT FEES 16-17 tbl.1 (2005). For a fifty-state survey of restrictions on attorneys' fees, see NAT'L CONFERENCE OF STATE LEGISLATURES, STATE MEDICAL LIABILITY LAWS TABLE (2002), available at <http://www.ncsl.org/programs/insur/medliability.pdf>. In 2005, twelve states considered legislation that would restrict contingent fees. Nat'l Conference of State Legislatures, State Medical Malpractice Reform: 2005 Numbers at a Glance, <http://www.ncsl.org/standcomm/sclaw/medmalataglace.htm> (last visited May 3, 2007).

198. See TABARROK & HELLAND, *supra* note 197, at 18 tbl.2. A 2005 study conducted by Professors Alexander Tabarrok and Eric Helland found that, in states with restrictions on contingent fees, 18% of cases dropped before trial without settlement, and that, in states without restrictions, only 5% of cases dropped. *Id.* The researchers concluded that the data demonstrated the connection between contingent fees and trial-lawyer screening. *Id.* at 15.

199. See *id.* at 10-11.

200. G.M. Filisko, *Fee Caps Won't Solve Liability Crisis, Study Says*, ABA J., Sept. 23, 2005.

201. See Tabarrok, *supra* note 99 (reporting that "the time to settlement in medical malpractice cases is 22% longer in states that restrict contingent fees" and that, in the year following the enactment of Florida's contingent-fee restrictions in 1985, "settlement time increased by 13%").

malpractice claims under the current system.<sup>202</sup> Health courts may mean quicker trials,<sup>203</sup> but, with a limited number of courts and a flood of claims, it is unclear how the courts would handle such an overwhelming caseload.

While the cost of each health court trial might be markedly less, the total cost of compensating more litigated claims could drive up the net transactional cost of the health court system, perhaps surpassing the estimated \$6.5 billion spent on defending malpractice claims (including plaintiff awards, legal costs, and underwriting costs) in 2001.<sup>204</sup> Thus, although it would theoretically provide increased accessibility to the courtroom, the health court model would also impose increased stress on the system, perhaps diluting the benefits of lowering the litigation bar. Even Professor Troyen A. Brennan, a member of the Common Good project, concedes that “[a]n increase in the number of medical errors reported, and compensated, could drive overall malpractice costs up as much as fourfold.”<sup>205</sup> In other words, decreasing the cost per malpractice trial makes litigation an attractive option for more plaintiffs, leading to more trials, more compensation, and a higher net transactional cost.<sup>206</sup>

In contrast, there is some certainty in the current litigation system. Despite the obvious injustice of a \$200,000 bar to litigation,<sup>207</sup> the prelitigation screening of malpractice claims by trial attorneys has kept the number of malpractice claims filed each year remarkably stable.<sup>208</sup> Statistics released from the National Center for State Courts disclosed that malpractice claims per 100,000 people actually decreased by 1% from 1992 to 2001.<sup>209</sup> In general, the total number of federal and state lawsuits filed each year climaxed in the mid-1980s and has drastically decreased ever since.<sup>210</sup> Thus, practically speaking, it seems more productive to focus on the reform of a stable system with a constant number of lawsuits, than to implement a new scheme with uncertain and potentially devastating consequences.

#### *D. Efficiency in Dispute Resolution and Compensation*

Closely tied to increasing access to the courtroom is the efficiency in dispute resolution and compensation. Data collected by the National Practitioner Data Bank showed that the national average time from injury to payout in malpractice cases in 2004 was 4.61 years—one week longer than the 2003 average.<sup>211</sup> This

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202. STRUVE, *supra* note 123, at 77.

203. Common Good, *supra* note 6.

204. Anderson et al., *supra* note 1, at 910.

205. Eliasberg, *supra* note 33.

206. *See infra* Section III.B.

207. *See Romano, supra* note 25, at 26.

208. CONG. BUDGET OFFICE, *supra* note 18, at 4.

209. Romano, *supra* note 25, at 26.

210. Rhode, *supra* note 155, at 456-57.

211. NAT'L PRACTITIONER DATA BANK, U.S. DEP'T OF HEALTH & HUMAN SERVS., 2004 ANNUAL

“payment delay” ranged from 2.81 years in South Dakota to 6.69 years in Rhode Island. Unlike the current tort system, Common Good’s health court model separates the determinations of liability (and economic damages) and compensation for noneconomic damages: expert judges establish whether malpractice occurred and the amount of economic losses, while a predetermined rate schedule sets noneconomic damages for various injuries.<sup>212</sup> Without the need to educate a jury, Common Good claims that its procedure will significantly increase efficiency in terms of dispute resolution and compensation such that “[m]ost cases would be resolved within months.”<sup>213</sup> Though it seems that each health court trial will take less time from injury to compensation, the net effect of increased litigation could be a clogged docket, causing even longer payment delays than those found in the current system.

In 2004, Pennsylvania’s average payment delay was 5.58 years<sup>214</sup>—nearly a year longer than the national average.<sup>215</sup> The health court model proposed there would have three-judge panels sitting in six venues across the state.<sup>216</sup> Because health courts would have original jurisdiction for all medical malpractice claims, these six courts would hear all of Pennsylvania’s malpractice claims, which are now dispersed through sixty judicial districts.<sup>217</sup> Siphoning out malpractice claims would likely make the judicial system as a whole more efficient, but with an influx of more litigation due to the decreased cost per trial, the health court docket could quickly become overwhelmed.<sup>218</sup> Moreover, “courts need not be specialized in order to implement strategies to reduce delay, such as active case management and the imposition of deadlines on discovery and dispositive motions.”<sup>219</sup>

### *E. Liability Insurance Premiums*

One of the driving forces behind the search for litigation alternatives is the ever-rising cost of liability insurance for physicians, especially in high-risk specialties like obstetrics-gynecology, surgery, anesthesiology, emergency medicine, and radiology.<sup>220</sup> In 2004, Rick Miller, a neurosurgeon in New Hampshire, refused to treat the president of the New Hampshire Trial Lawyers

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REPORT 31, 72 tbl.13 (2004), available at [http://www.npdb-hipdb.hrsa.gov/pubs/stats/2004\\_NPDB\\_Annual\\_Report.pdf](http://www.npdb-hipdb.hrsa.gov/pubs/stats/2004_NPDB_Annual_Report.pdf).

212. See Common Good, *supra* note 6; Mello et al., *supra* note 49, at 467-68.

213. Common Good, *supra* note 6.

214. NAT’L PRACTITIONER DATA BANK, *supra* note 211, at 72 tbl.13.

215. *Id.* at 31.

216. STRUVE, *supra* note 123, at 71.

217. *Id.*

218. See *supra* Section II.C.

219. STRUVE, *supra* note 123, at 72.

220. Daniel P. Kessler et al., *Impact of Malpractice Reforms on the Supply of Physician Services*, 293 JAMA 2618, 2619 (2005).



Association because of the latter's lobbying efforts against limits on malpractice suits.<sup>221</sup> Considered the best neurosurgeon on the Sea Coast, Miller paid \$84,151 a year for liability insurance, leaving him with only \$64,000 after business costs and taxes.<sup>222</sup>

That's less than my malpractice premium. This puts in perspective how desperate the situation is. Attorneys who choose to speak out and try to derail efforts at meaningful tort reform do so at some risk—that they will not be able to come to the best neurosurgeon in New Hampshire. They'll have to go elsewhere, the same way that patients will have to go elsewhere if neurosurgery is no longer available on the Sea Coast.<sup>223</sup>

Though most doctors have not bought into the refuse-to-treat tactic, they undoubtedly share Miller's concern for their own survival and for the availability of health care; after all, "[i]f physicians in [high-risk] specialties find coverage unaffordable and limit or abandon their practices, the entire health care system potentially fails."<sup>224</sup>

In marketing health courts to the medical community, Common Good implies that its model can counter "[s]tunning increases in medical malpractice premiums," thus encouraging the practice of medicine and enhancing availability of health care.<sup>225</sup> Apparently, the organization's claim that insurers will lower malpractice premiums relies on the normalization and subsequent predictability of damages.<sup>226</sup> By implementing a rate schedule to determine damages specific to a victim's injuries and abolishing the use of lay juries, health courts effectively rule out the possibility of capricious awards for noneconomic damages, which Common Good claims collectively drive up malpractice premiums.<sup>227</sup> Whether the model can live up to its proposed goal of protecting physicians from the cost of growing premiums remains uncertain.

Although malpractice litigation is frequently blamed for the current malpractice crisis, researchers have observed that there is no clear-cut correlation between trends in lawsuits and awards and trends in premiums or insurance availability.<sup>228</sup> Insurance providers rely on the influx of premium payments and investment capital to fund claim payments and other administrative costs.<sup>229</sup>

221. Parker, *supra* note 9.

222. *Id.*

223. *Id.*

224. Sage, *supra* note 11, at 473.

225. Common Good, *supra* note 6.

226. See Mello et al., *supra* note 49, at 470 ("[A] health court system presents greater possibility for cost control than the tort system does. . . . Whether malpractice litigation costs currently exceed the socially optimal level is controversial, but the desirability of being able to control the system's costs should not be.") (citation omitted).

227. See Common Good, *supra* note 6.

228. Sage, *supra* note 11, at 470.

229. *Id.*

Premiums for malpractice insurance are set so that, over time, insurers' income from those premiums equals their total costs—including a competitive return to their investors—less any excess funds in reserve.<sup>230</sup> This insurance underwriting reflects everything from the potential risks of medical advances to the public perception of medical error.<sup>231</sup>

Malpractice premiums are a poor reflection of current litigation trends, “[b]ecause liability insurers hold premium dollars for many years before paying them out to claimants [and] the long tail also makes current pricing depend to a greater extent on investment income than is typical of other forms of insurance.”<sup>232</sup> With the average malpractice claim taking nearly five years to resolve<sup>233</sup> and some injuries being inherently latent, insurance companies must project years, and sometimes decades, into the future.<sup>234</sup> Data regarding formulas for underwriting insurance premiums has not been collected reliably on a national level, making research and studies on the topic particularly difficult.<sup>235</sup>

The first medical malpractice crisis surfaced in 1975, when many commercial insurance providers ceased or threatened to stop giving liability coverage.<sup>236</sup> During the next crisis in the mid-1980s, malpractice premiums increased significantly for a couple of years in response to a speculated increase in claims by insurance companies.<sup>237</sup> Ultimately, their speculations were too high, and insurers placed the surplus funds into reserves, which subsequently lightened the premiums for the 1990s.<sup>238</sup> From 2000 to 2002, the average malpractice premium for American physicians increased by 15%, with a 22% increase for obstetricians-gynecologists and a 33% increase for internists and general surgeons.<sup>239</sup> Given the cyclical nature of the insurance crises, it seems that malpractice crises are the result of insurance underwriting—not of periods of increased litigiousness or payouts<sup>240</sup>—and it is unclear how underwriters would respond to the uncertainties of the health court model.<sup>241</sup>

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230. CONG. BUDGET OFFICE, *supra* note 18, at 3.

231. *See* Sage, *supra* note 11, at 480.

232. *Id.*

233. NAT'L PRACTITIONER DATA BANK, *supra* note 211, at 31.

234. Sage, *supra* note 11, at 480-81.

235. U.S. GEN. ACCOUNTING OFFICE, MEDICAL MALPRACTICE: IMPLICATIONS OF RISING PREMIUMS ON ACCESS TO HEALTH CARE 40-41 (2003), available at <http://www.gao.gov/new.items/d03836.pdf>.

236. Sage, *supra* note 11, at 469.

237. *See id.* at 469-70; CONG. BUDGET OFFICE, *supra* note 18, at 4-5.

238. CONG. BUDGET OFFICE, *supra* note 18, at 4-5.

239. *Id.*

240. Sage, *supra* note 11, at 471.

241. Research suggests that even a systemic change accompanied by a sustained decrease in payouts might not deflate premiums. One study examined Texas medical malpractice claims from 1988 to 2002 and concluded that “[n]o sudden rise in claim frequency, payments, defense costs, or jury verdicts preceded or accompanied the premium spike that occurred in Texas after 1998.” Black et al., *supra* note 21, at 255.

### F. Cost of Health Care

Despite what Common Good has suggested,<sup>242</sup> reducing malpractice premiums does not appear to have a significant effect on economic efficiency or the affordability of health care for patients. In fact, research suggests that it is the cost of treatment, not malpractice litigation, which accounts for the high cost of health care in the United States.<sup>243</sup> The CBO recently found that even a 25% to 30% savings in premiums can have only a small direct impact on health care spending, because the cost of malpractice litigation accounts for less than 2% of total health care spending in America,<sup>244</sup> regardless of the type of reform used to achieve the premium reduction.

A recent Harris poll<sup>245</sup> found that 62% of American adults supported the adjudication of medical malpractice cases in health courts.<sup>246</sup> Implying a correlation between large jury payouts and the price consumers pay to see their doctors, Common Good appeals to the public by highlighting the rising cost of health care and by offering the rate schedule for damages as an alternative to the “random justice” of jury awards.<sup>247</sup> Compensation based on the schedule would award “so much for an arm . . . rather than by having jurors pluck a number out of the air.”<sup>248</sup> The schedule would normalize damage awards across fact patterns and effectively act as a set of noneconomic damage caps itemized by injury.<sup>249</sup>

Many states that initially adopted noneconomic damage caps have since repealed them on constitutional grounds, including Alabama, Illinois, Kentucky, New Hampshire, North Dakota, Oregon, and Washington.<sup>250</sup> Wisconsin recently

242. Common Good, *supra* note 6.

243. Gerard F. Anderson et al., *It's the Prices, Stupid: Why the United States Is So Different from Other Countries*, 23 HEALTH AFF. 89 (2003).

244. CONG. BUDGET OFFICE, *supra* note 18, at 6.

245. Harris Interactive is one of the largest market research firms in the country and also manages the longest running independent opinion poll. Harris Interactive, About Us, <http://www.harrisinteractive.com/about/> (last visited May 3, 2007).

246. Common Good, Senate Majority Leader Bill Frist Calls for the Creation of Special Health Courts (July 19, 2004), <http://cgood.org/healthcare-newscommentary-inthenews-140.html>.

247. Common Good, *supra* note 6.

248. *Scalpel, Scissors, Lawyer*, *supra* note 67.

249. See Eliasberg, *supra* note 33.

250. See ALA. CODE § 6-5-544 (2003), *invalidated by* Mobile Infirmary Med. Ctr. v. Hodgen, 884 So. 2d 801, 813-14 (Ala. 2003) (holding that the cap on noneconomic damages in medical malpractice cases violated the right to jury trial and the equal protection provisions of the Alabama Constitution); 735 ILL. COMP. STAT. 5/2-1115.1 (1996), *invalidated by* Best v. Taylor Mach. Works, 689 N.E.2d 1057, 1066-81 (Ill. 1997) (holding that the limitation on compensatory damages for noneconomic injury violated the Illinois Constitution); KY. REV. STAT. ANN. § 304.40-270 (West 1980), *invalidated by* McCoy v. W. Baptist Hosp., 628 S.W.2d 634, 635 (Ky. Ct. App. 1981) (finding the statutory cap unconstitutional as an invasion of the rule-making power of the courts); N.H. REV. STAT. ANN. § 507-C:7 (1980), *invalidated by* Carson v. Maurer, 424 A.2d 825, 830-31 (N.H. 1980) (holding that the cap on noneconomic damages in medical malpractice actions violated the equal protection clause of the New Hampshire Constitution); N.D. CENT. CODE § 26-40.1-11

implemented a second, significantly higher damage cap to replace the one struck down in *Ferdon ex rel. Petrucelli v. Wisconsin Patients Compensation Fund*.<sup>251</sup> In that case, the Supreme Court of Wisconsin found statistics in Wisconsin mirroring those in the CBO's report and held the state's \$350,000 noneconomic damage cap to be unconstitutional because

even if the \$350,000 cap on non-economic damages would reduce medical malpractice insurance premiums, this reduction would have no effect on a consumer's health care costs. Accordingly, there is no objectively reasonable basis to conclude that the \$350,000 justifies placing such a harsh burden on the most severely injured medical malpractice victims.<sup>252</sup>

Between the *Ferdon* decision and the passage of the new cap, the Wisconsin Hospitals Association reported that Wisconsin hospitals had difficulty recruiting physicians and that the number of malpractice claims increased.<sup>253</sup> PIC Wisconsin, the largest provider of liability insurance in the state, raised premiums by 5% in January 2006, tentatively waiting for lawmakers and the state supreme court to chart a new course.<sup>254</sup>

Prior to signing the new \$750,000 damage cap for malpractice cases,<sup>255</sup> Governor Jim Doyle vetoed an attempt by the Wisconsin Legislature to pass a \$450,000 cap because the proposal "suffer[ed] from the exact same constitutional defects" as the unconstitutional cap in *Ferdon*.<sup>256</sup> The governor reportedly felt that "[a]pproving a law that would be quickly overturned doesn't do anyone any good."<sup>257</sup> The *Ferdon* court found that the \$350,000 noneconomic damage cap "was designed by the legislature to help limit the increasing cost of health care

(1977), *invalidated by* Arneson v. Olson, 270 N.W.2d 125, 131-36 (N.D. 1978) (holding that the \$300,000 cap on medical malpractice awards was a violation of equal protection); OR. REV. STAT. § 18.650(1) (1999), *invalidated by* Lakin v. Senco Prods., Inc., 987 P.2d 463, 465-69 (Or. 1999) (holding that the noneconomic damage cap unconstitutional for abridging the right to jury trial); WASH. REV. CODE ANN. § 4.56.250 (1988), *invalidated by* Sofie v. Fibreboard Corp., 771 P.2d 711 (Wash. 1989) (holding that the noneconomic damage cap violated the Washington Constitution and the right to a jury trial).

251. Wis. Office of the Governor, *supra* note 7; *see also* WIS. STAT. § 893.55 (2005), *invalidated by* *Ferdon ex rel. Petrucelli v. Wis. Patients Comp. Fund*, 701 N.W.2d 440 (Wis. 2005) (holding that the statutory cap failed to demonstrate a rational relationship to legislative objectives).

252. 701 N.W.2d at 485. *See also* CONG. BUDGET OFFICE, *supra* note 18, at 6. The \$350,000 cap mentioned in *Ferdon* was indexed for inflation and reached \$445,775 when the Wisconsin Supreme Court struck it down in July 2005. David Wahlberg, *Medical Malpractice Caps Have Little Effect on Rates*, WIS. ST. J., Mar. 5, 2006.

253. Stacy Forster & Derrick Nunnally, *Doyle Vetoes Medical Malpractice Caps: Limits Too Similar to Those Overturned by Court, Governor Says*, MILWAUKEE J. SENTINEL, Dec. 2, 2005, available at <http://www.jsonline.com/news/state/dec05/375058.asp>.

254. *Id.*

255. Wis. Office of the Governor, *supra* note 7.

256. Forster & Nunnally, *supra* note 253.

257. *Id.*

and possible ‘diminishing . . . availability of health care in Wisconsin.’”<sup>258</sup> Ultimately, the court struck down the cap as unconstitutional because the legislature failed to demonstrate a rational relationship to the legislative objectives, finding that “the correlation between caps on noneconomic damages and the reduction of medical malpractice premiums or overall health care costs is at best indirect, weak, and remote.”<sup>259</sup> Sixty-eight percent higher than the unconstitutional cap in *Ferdon*,<sup>260</sup> Wisconsin’s legislature hopes that its new \$750,000 cap will not suffer the same fate as its predecessor and will return stability to the state’s malpractice environment.

Drawing from the concept of noneconomic damage caps, Common Good’s plan attempts to circumvent the inequity of capping all claims at the same amount by creating a rate schedule for injury-specific noneconomic damages.<sup>261</sup> Damages awarded by health courts would include economic damages (such as lost wages and hospital bills) and noneconomic damages according to the schedule.<sup>262</sup> Common Good equates this prevention of “random justice” with the ability to provide affordable health care to consumers, but given the lesson learned in *Ferdon*, it seems unlikely that providing varied injury-specific damage caps would strengthen the link between restricting damage awards and lowering the cost of health care.

In sum, health courts may lower the litigation bar to encourage victim compensation and cultivate a uniform standard of care to guide physicians. Unfortunately, they would also increase the new transactional cost of malpractice litigation, postpone victim compensation, and raise liability insurance premiums without providing significantly more equitable results<sup>263</sup> or lowering health care costs. These shortcomings of the health court model can be suggested from a piecemeal assessment of nontraditional litigation alternatives in California, Wisconsin, and New Jersey.

### III. CASE STUDIES

Outside of the unpopular refuse-to-treat tactic, the health court model is one of the most radical approaches in battling the malpractice crisis. A drastic

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258. *Ferdon ex rel. Petrucelli v. Wis. Patients Comp. Fund*, 701 N.W.2d 440, 465 (Wis. 2005).

259. *Id.* at 485.

260. Press Release, Wis. Hosp. Ass’n, Hospitals Praise Bipartisan Vote on Damage Caps: Senate Sends Bill to Gov. Doyle with Another Strong Vote (Mar. 8, 2006), <http://www.wha.org/newsCenter/pdf/nr3-8-06senateab1073.pdf>.

261. Eliasberg, *supra* note 33.

262. Common Good, *supra* note 6.

263. See, e.g., Mello et al., *supra* note 49, at 467 (conceding the realistic necessity of “cost control”); *infra* Section III.C (discussing possible inequitable consequences of the health court model). Mello suggests “some kind of eligibility threshold—a minimum . . . of [four weeks] of disability [and] a minimum amount of [\$3,000 to \$4,000 in] out-of-pocket expenses— . . . in order to control the number and costs of claims brought.” Mello et al., *supra* note 49, at 467.

departure from the current tort litigation scheme, health courts would funnel all malpractice cases to limited venues in the state judiciary for adjudication by a panel of expert judges.<sup>264</sup> As with any innovative and radical tort reform, however, integration of specialized health courts into the American judiciary system carries risks similar to other litigation alternatives: arbitration employs a pool of subject-sophisticated arbitrators to award compensation in the absence of direct consent;<sup>265</sup> medical mediation panels demonstrate the potential influx of claims into the health court system without the deterrent effect of costly litigation;<sup>266</sup> and mass tort courts are another form of specialized court experiencing an overburdened docket.<sup>267</sup> Based on this piecemeal assessment, the implementation of health courts may result in unfair compensation due to politicization of the bench and the normalization of noneconomic injuries in the rate schedule, significantly increased net transactional costs and malpractice premiums, and delayed dispute resolution and compensation.

*A. The Equity of Health Courts and California's Medical Injury Compensation Reform Act's Arbitration Provision*<sup>268</sup>

In enacting the Medical Injury Compensation Reform Act (MICRA), the California legislature acknowledged the onset of America's first medical malpractice crisis in the 1970s,<sup>269</sup> and "a potential breakdown of the health delivery system, severe hardships for the medically indigent, a denial of access for the economically marginal, and depletion of physicians such as to substantially worsen the quality of health care available to citizens of [California]."<sup>270</sup> Designed to improve the quality of health care in California, the Act includes an arbitration provision, allowing patients and their health care providers to agree that any future dispute will be adjudicated through binding arbitration.<sup>271</sup>

Although the AMA supports voluntary arbitration as a method to weed out meritless claims from litigation,<sup>272</sup> the American Arbitration Association reported that only about 60 out of the 219,000 cases it handled in one year were

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264. Mello et al., *supra* note 49, at 467.

265. *See infra* Section III.A.

266. *See infra* Section III.B.

267. *See infra* Section III.C.

268. CAL. CIV. PROC. CODE § 1295 (West 2005).

269. Sage, *supra* note 11, at 469.

270. CAL. BUS. & PROF. CODE § 6146 note (West 2003).

271. CAL. CIV. PROC. CODE § 1295. Although the Federal Arbitration Act is the primary authority on arbitration clauses in contracts governed by state law, states still have control over the substantive content of the clauses. *See* David M. Studdert & Troyen A. Brennan, *Toward a Workable Model of "No-Fault" Compensation for Medical Injury in the United States*, 27 AM. J.L. & MED. 225, 236 (2001).

272. Romano, *supra* note 25, at 29.

medical malpractice claims, which is equivalent to 0.03% of its caseload.<sup>273</sup> Given arbitration's reputation for doling out smaller awards, it is not surprising that most medical malpractice arbitrations are triggered by adhesion contracts rather than the will of the plaintiff.<sup>274</sup>

For about thirty years, one of the largest HMOs in America, Kaiser Permanente, has taken advantage of MICRA's arbitration provision by "operat[ing] a mandatory, binding arbitration scheme to judge compensation for medical injury claims arising in its facilities."<sup>275</sup> Even though Kaiser's contracts waiving the right to litigation are repeatedly challenged for the absence of informed consent,<sup>276</sup> the California Supreme Court has continually broadened the applicability of Kaiser's arbitration clause, reinforcing the state's confidence in MICRA and arbitration in medical malpractice cases: "MICRA legislation was based on an assumption that there were advantages to arbitration that would more than offset the potential lack of direct informed consent, including expedited resolution of claims, reduced costs, sophisticated decision making, and removal of disputes from the adversarial atmosphere of the courtroom."<sup>277</sup>

In fact, health courts would essentially be a mandatory and more regulated version of arbitration with far fewer arbitrators; in other words, they would have the drawbacks of MICRA without the benefits. Unlike Kaiser's contracts and the workers' compensation model (in which the "trade-off of loss of a right to bring an action in court that is counterbalanced by a 'guaranteed' award that is not fault based"),<sup>278</sup> health courts absolutely deprive would-be litigants from their right to pursue trial in the traditional system. Furthermore, without a large pool of potential judges, the health court model presents a concentrated problem of politicization, as both sides would lobby for the appointment or election of their favored judges. Moreover, the additional implementation of a rate schedule for injury-specific noneconomic damages would further limit the judges' ability to award appropriate damages.<sup>279</sup> Because health courts will not reduce the net

273. *Id.* The American Arbitration Association states that it "provides services to individuals and organizations who wish to resolve conflicts out of court." Am. Arbitration Ass'n, About Us, <http://www.adr.org/About> (last visited May 3, 2007).

274. David Zukher, Comment, *The Role of Arbitration in Resolving Medical Malpractice Disputes: Will a Well-Drafted Arbitration Agreement Help the Medicine Go Down?*, 49 SYRACUSE L. REV. 135, 141 (1998).

275. Studdert & Brennan, *supra* note 271, at 236.

276. *See Engalla v. Permanente Med. Group*, 938 P.2d 903 (Cal. 1997) (remanding for consideration of the lower court to consider whether an arbitration agreement should be unenforceable because evidence supported fraud and bad-faith delay on the part of Kaiser); *Madden v. Kaiser Found. Hosps.*, 552 P.2d 1178 (Cal. 1976) (holding that Kaiser's medical services contract was not adhesive); *Tunkl v. Regents of Univ. of Cal.*, 383 P.2d 441 (Cal. 1963) (holding that Kaiser's contract was unenforceable because the patient was not in a position to reject the agreement).

277. Studdert & Brennan, *supra* note 271, at 237-38.

278. ABA Network, *supra* note 121.

279. Common Good, *supra* note 6.

transactional cost or expedite the resolution of claims, the health court model fails to satisfy all of the California Supreme Court's justifications for upholding Kaiser's arbitration clause under MICRA. Without certain improvement of the malpractice problem, the idea of subjecting one state's residents to mandatory adjudication similar to arbitration without consent does not appear to be equitable.

*B. The Net Transactional Cost of Health Courts and Wisconsin's Medical Mediation Panels*<sup>280</sup>

Created in 1986 by the state legislature, Wisconsin's medical mediation panels provide "an informal, inexpensive and expedient means for resolving [medical malpractice] disputes without litigation."<sup>281</sup> Claimants cannot commence court action prior to filing a request for mediation unless proceedings began within fifteen days before the filing and there have not been any discovery or pretrial or trial conferences.<sup>282</sup> The mediation panel consists of three individuals (a layperson serving a two year term, a licensed Wisconsin attorney, and a health care provider), each of whom receives \$150 in compensation per day of mediation.<sup>283</sup>

As mediations are less formal proceedings, there are no records, physical examinations, subpoenas, oaths, or expert witnesses;<sup>284</sup> however, the statutes expressly permit the mediation panel to consult and reimburse any expert it feels necessary.<sup>285</sup> The panel's decision is not binding.<sup>286</sup> Annual fees charged to health care providers and to hospitals for each occupied bed fund the costs of the mediation panel.<sup>287</sup> The availability of mediation panels potentially reduces litigation costs because the panel informally assesses the strength of the plaintiff's claim and the physician's defense, which can lead to settlements or dropped claims.

Based on available statistics from 1986 to 1994, it appears that adjudication by the mediation panels keeps a significant number of cases from entering the court system.<sup>288</sup> When cases entered mediation prior to the filing of a court claim, nearly half either settled as a direct result of mediation or became inactive after the statute of limitations had expired.<sup>289</sup> Like health courts, mediation

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280. WIS. STAT. § 655.42(1) (2005).

281. Act of June 12, 1986, No. 340, § 69m, 85 WIS. ACT 1508 (1986).

282. WIS. STAT. § 655.44, .445.

283. *Id.* § 655.465.

284. *Id.* § 655.58.

285. *Id.* § 655.58(3)(b).

286. Wis. Court Sys., Medical Mediation Panels, <http://www.wicourts.gov/about/organization/offices/mmp.htm> (last visited May 3, 2007).

287. WIS. STAT. § 655.61.

288. *See id.*

289. *Id.*



panels serve as a more affordable litigation alternative, thus inviting claims of lesser damages.<sup>290</sup> In fact, pro se litigants brought nearly 15% of the claims presented to mediation panels.<sup>291</sup> Because the financial accessibility of the mediation panels mirrors the broader courtroom access proposed by health courts, studying the distribution of cases heard by mediation panels may help demonstrate the potential increase of lesser claims under the health court model.

In mediation cases seeking damages less than \$25,000, nearly half resulted in no action after mediation and about a quarter settled at or shortly after the mediation session.<sup>292</sup> Certainly, there are many variables in deciding to pursue litigation, but it is likely that claimants dropped or settled those claims due to questionable merit or the expected cost of trying the claim in court. Victims with lesser claims may not be able to recover through mediation because a mediator's determination is not binding, thus a plaintiff's damages still have to exceed litigation costs before any compensation occurs.

Currently, the limited accessibility of litigation maintains a steady rate of about fifteen court claims filed per one hundred doctors, with 30% of those claims resulting in an insurance payment.<sup>293</sup> If health courts replaced the current litigation system, it is possible that a large portion of the 73% of the mediation panel's cases under \$25,000 that were not litigated would have been, as fewer claimants would have settled out of court if binding litigation were more feasible.<sup>294</sup> Furthermore, although the statistics are unclear as to how many cases lacked merit, at least some of the cases would have been adjudicated in health court because of the smaller perceived hurdle to potential compensation. With 90% of asserted claims dropped, dismissed, or settled before reaching trial,<sup>295</sup> the effect of lowering the litigation bar could better compensate victims with less severe injuries; but the increase in litigated claims could also overwhelm the health court docket, raise net transactional costs, and cause insurance companies to hike up malpractice premiums.

### *C. The Efficiency of Health Courts and New Jersey's Special Mass Tort Courts*<sup>296</sup>

As home to many of the world's pharmaceutical companies, New Jersey has opted to channel mass torts into specialized courts to ease the stress on the

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290. *See id.*

291. *Id.*

292. *Id.* Twenty-four percent of the cases seeking less than \$25,000 settled at or shortly after the session "[a]s a direct result of mediation." *Id.* In 49% of the cases, however, there was neither a settlement nor a filing in circuit court by the time the statute of limitations had expired. *Id.*

293. CONG. BUDGET OFFICE, *supra* note 18, at 4.

294. Wis. Court Sys., *supra* note 286.

295. Romano, *supra* note 25, at 29.

296. *See generally* Editorial, *Health Courts Are Worth a Try*, STAR-LEDGER (Newark, N.J.), July 18, 2005; Press Release, N.J. Judiciary, Adoption of Rule 4:38A – "Centralized Management of Mass Torts" (Oct. 23, 2003), <http://www.judiciary.state.nj.us/notices/n031028a.htm>.

superior courts.<sup>297</sup> Conceptually, the ability to centralize numerous substantively similar claims makes the system significantly more efficient and the results more consistent. In 2003, the New Jersey legislature established specialized courts to handle certain types of mass tort cases, including those concerning Vioxx.<sup>298</sup> Any judge or attorney involved with a potential mass tort case may apply to the New Jersey Supreme Court for designation of the case as a mass tort.<sup>299</sup> If the state's supreme court determines a case to be a mass tort, the Chief Justice will assign it to one of four superior court judges designated to exclusively manage mass tort cases under the civil section of the New Jersey Superior Court in three locations across the state.<sup>300</sup> All orders handed down in mass tort courts will be "published in the legal newspapers, and will be posted in the Mass Tort Information Center on the Judiciary's Internet website."<sup>301</sup>

Like New Jersey's mass tort courts, the proposed health courts would filter malpractice cases out of the traditional state circuits for adjudication by judges exclusively hearing health care matters.<sup>302</sup> Theoretically, the advantage of these specialized courts is two-fold: promoting efficiency in the circuits and uniformity of outcomes. Since New Jersey declared Vioxx-related injuries to be a mass tort in June 2003,<sup>303</sup> thousands of claims have been filed in New Jersey against pharmaceutical giant Merck, which is headquartered in the state.<sup>304</sup> Merck pulled Vioxx from the shelves on September 30, 2004 following FDA reports that the use of the drug may have resulted in 27,000 heart attacks and sudden cardiac deaths.<sup>305</sup> After the recall, the number of claims filed in New Jersey state courts

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297. See N.J. Judiciary, *supra* note 296.

298. N.J. R. SUPER. CT., TAX CT., & SURR. CT. CIV. R. 4:38A (2005) (authorizing the New Jersey Supreme Court to designate a case or category of cases as a mass tort for centralized adjudication). Other New Jersey mass torts currently include Accutane, asbestos, Bextra/Celebrex, Ciba Geigy, diet drugs, hormone-replacement therapy (HRT), Long Branch Manufactured Gas Plant (LBMGP), lead paint, phenylpropionolamine (PPA), and tobacco. *Id.*; see also Richard J. Williams, Admin. Dir. of the Courts, Directive 11-03, Mass Torts—Guidelines and Criteria for Designation (Oct. 27, 2003), available at [http://www.judiciary.state.nj.us/directive/civil/dir\\_11\\_03.pdf](http://www.judiciary.state.nj.us/directive/civil/dir_11_03.pdf) (setting forth the mass-tort guidelines).

299. Williams, *supra* note 298. New Jersey Directive 11-03 lists fourteen non-exclusive factors considered in determining whether a case should be designated as a mass tort and provides "a procedure for interested attorneys to have input into the process." *Id.*

300. N.J. Judiciary, Mass Tort Frequently Asked Questions, <http://www.judiciary.state.nj.us/mass-tort/faq.htm> (last visited May 3, 2007). Subsequent cases that fall within the established mass tort categories transfer automatically to the appropriate mass tort judge. Williams, *supra* note 304.

301. Williams, *supra* note 298.

302. STRUVE, *supra* note 123, at 71.

303. N.J. Judiciary, Notice to the Bar, RE: Designation of Vioxx Litigation as a Mass Tort (June 6, 2007), available at <http://www.judiciary.state.nj.us/notices/n030611a.htm>.

304. John Curran, *Vioxx Cases Would Take Judge 583 Years To Hear*, TALLAHASSEE DEMOCRAT, Dec. 26, 2005, at A7.

305. John Covalleski, *Mass Tort Docket Grows in New Jersey as HRT, Vioxx Litigation Multiplies*, N.J. L.J., Oct. 15, 2004, available at <http://www.law.com/jsp/article.jsp?id=1097686249066>.

ballooned from 175 to 4333.<sup>306</sup> The state supreme court centralized all of the New Jersey Vioxx cases and assigned them to superior court Judge Carol Higbee—a former malpractice attorney chosen for her familiarity with mass torts and “largely because other vicinages handling mass torts have full caseloads.”<sup>307</sup> In the end, if the 4333 Vioxx cases in New Jersey had not been centralized, they would have clogged the dockets of the various superior courts, which in turn could compound inefficiency with inconsistent holdings.

The efficiency of the judicial system as a whole, however, does not necessarily include the efficiency of the specialized court. “If [New Jersey’s 4,333 Vioxx cases] all go to trial and take as long as a recent, seven-week case, Higbee would need 583 years to hear them all.”<sup>308</sup> At that rate, while the liability portion of the trials might be efficient, the damage calculation for individual victims could take years following the filing of a claim. Furthermore, a mass tort in New Jersey is defined by an identification of certain common case characteristics,<sup>309</sup> whereas medical malpractice claims are inherently fact-intensive. Thorough adjudication of these facts would only add to the length of trials and the amount of time victims of medical negligence would have to wait to receive compensation. Common Good has asserted that “[p]atients injured by mistakes should be compensated for their injuries without waiting years,”<sup>310</sup> but even assuming that the use of health courts would reduce the actual length of each trial, specialized courts do not guarantee more timely compensation.<sup>311</sup>

## CONCLUSION

Ultimately, Common Good’s health court model falls short of its advocates’ expectations, and its potential benefits do not sufficiently outweigh its likely costs for the United States to abandon using the traditional tort system for medical malpractice claims. Admittedly, there are problems with the current litigation scheme. Unlike the uncertainty that would come with implementing health courts, however, the problems with malpractice litigation are predictable

306. *Id.*; Curran, *supra* note 304.

307. Covalenski, *supra* note 305.

308. Curran, *supra* note 304.

309. N.J. JUDICIARY, NEW JERSEY MASS TORT (NON-ASBESTOS) RESOURCE BOOK 1 (2005), available at <http://www.judiciary.state.nj.us/mass-tort/masstortsopnonasbestos.pdf>.

310. Common Good, *supra* note 6.

311. Consider the following statistics. According to the Kaiser Family Foundation, there were 1061 paid medical malpractice claims in Pennsylvania in 2005. Kaiser Family Foundation, 50 State Comparisons: Number of Paid Medical Malpractice Claims, 2005, <http://www.statehealthfacts.org/cgi-bin/healthfacts.cgi?action=compare&category=Providers+%26+Service+Use&subcategory=Medical+Malpractice&topic=Paid+Medical+Malpractice+Claims> (last visited May 3, 2007). If one assumes a 27% plaintiff win rate, BUREAU OF JUSTICE STATISTICS, *supra* note 143, it can be estimated that Pennsylvanians litigated 3930 claims in 2005. While this crude hypothetical does not factor in the influx of lesser claims, *see supra* Section II.C, it suggests the inevitability of a clogged health court docket.

and, to some extent, controllable, in that the rate of claims filed remains stagnant from year to year.<sup>312</sup>

Despite the apparent disconnect between litigation trends and malpractice premiums,<sup>313</sup> there is evidence from over forty states with at least one statutory restriction on malpractice awards in the current tort scheme that premiums are lower with restrictions than without them.<sup>314</sup> Furthermore, a 2005 study on physician supply found “greater growth in physician supply in states that adopted reforms directly limiting liability than in states that did not.”<sup>315</sup> Tort reformers should not discount the relatively certain success that comes with reforming the traditional litigation scheme.<sup>316</sup> In contrast, the health court model limits individual liability while expanding collective liability, and its adoption would aggravate the impact of the next malpractice crisis. As such, tort reformers should focus their efforts on modifying the current system instead of spending federal dollars to experimentally implement an unproven new program.

In a 2003 report concluding that health courts were not the answer to Pennsylvania’s medical malpractice crisis, the Project on Medical Liability “suggest[ed] that procedural reform should focus instead on supporting the efforts of judges and juries to assess scientific and medical questions and on providing guidance for the award and review of noneconomic damages.”<sup>317</sup> To prevent the dueling-experts phenomenon, the report proposed imposing heightened standards for expert witnesses or encouraging judges to obtain expert testimony from neutral sources (for example, using empirical data to establish medical custom).<sup>318</sup> The report also mentioned methods for increasing consistency among noneconomic damage awards—including proposed statutory provisions that “would direct the judge to order remittitur if the judge determines that the jury’s award ‘deviates materially from what would be reasonable compensation’” and effectively lower the common “shocks the conscience” standard.<sup>319</sup> Although researchers have not yet studied the effects of these more modest reforms, their experimental implementation would cost substantially less than a health court test run.

With the Fair and Reliable Medical Justice Act sitting in committee following June 2006 hearings,<sup>320</sup> the medical malpractice reform debate has taken on new life. The potential for federal funding encourages states to tackle the malpractice crisis by implementing litigation alternatives, including health

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312. CONG. BUDGET OFFICE, *supra* note 18, at 4.

313. See *supra* notes 232-35 and accompanying text.

314. *Id.*

315. Kessler et al., *supra* note 220, at 2623.

316. See, e.g., *id.*; sources cited *supra* note 47.

317. See STRUVE, *supra* note 123, at 91.

318. *Id.* at 83-84.

319. *Id.* at 89.

320. *Medical Liability: New Ideals for Making the System Work Better for Patients: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions*, 109th Cong. (2006).

courts. According to Howard, “We need . . . to make a compelling case that, one, the current system doesn’t work very well, and two, [the health court model] has a chance of working hopefully much better, and therefore we should try it out.”<sup>321</sup> Still, America has experienced malpractice crises twice before,<sup>322</sup> and Professor William Sage, a principal researcher for the Project on Medical Liability, cautions that “[t]oday we have to think about all the aspects of this problem before jumping to any solution.”<sup>323</sup>

The foremost concerns in this crisis are the cost of obtaining and providing health care, the efficiency of dispute resolution, and the equity of judgments. The proposal of health courts ambitiously attempts to solve all of those issues by carving out malpractice claims from the traditional litigation system and creating specialized tribunals of expert judges to hear them instead. By virtue of having lesser venues and no juries, state health courts could theoretically set forth a more consistent standard of care for physicians in less time with less cost. Implementing these courts, however, could lead to inequitable judgments, drive up transactional costs and malpractice premiums, and delay the resolution and compensation of victims’ claims.

Regardless of the variables that make up the malpractice crisis, when one third of a state’s surgeons leave in the span of eight years,<sup>324</sup> there is unquestionably a need for reform, and that reform should improve upon, rather than overhaul, the litigation system.<sup>325</sup> Pending the passage of the Fair and Reliable Medical Justice Act of 2005, states could soon be able to take advantage of federally funded grants to explore malpractice litigation alternatives. Despite having been touted as “a reliable system of medical justice” by its proponents,<sup>326</sup> health courts provide a very limited solution while potentially aggravating the current malpractice climate. Tort reformers should solve the problems of the current system by modifying it, instead of instigating an extreme makeover with uncertain and undesirable consequences.

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321. Eliasberg, *supra* note 33.

322. Sage, *supra* note 11, at 469-70.

323. Romano, *supra* note 25, at 28.

324. *Scalpel, Scissors, Lawyer*, *supra* note 67.

325. In 2005, thirty-two states enacted medical malpractice legislation, ranging from expert-witness qualifications to administrative procedures for the revocation of licenses from doctors who are repeatedly found guilty of medical malpractice. Nat’l Conference of State Legislatures, Medical Malpractice Tort Reform: 2005 Enacted Legislation in the States, <http://www.ncsl.org/standcomm/sclaw/medmalenacted2005.htm> (last visited May 3, 2007). Researchers could study the indoctrination of these varied state reforms to determine the optimal combination for resolving the problems associated with the malpractice crisis.

326. Common Good, *supra* note 6.

