

HEALTH, CAPABILITY, AND JUSTICE: TOWARD A NEW PARADIGM OF HEALTH ETHICS, POLICY AND LAW

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INTRODUCTION

Paradoxically, the American health-care system produces both therapeutic gains and major discrepancies in access to quality care. Medical advances have improved patients' lives dramatically, yet stark inequalities in access, quality, financial burdens, and resource priorities undermine the impact of technological and scientific progress. The cost of

health care is also on the rise.¹ Although providers, lawyers, ethicists, and health-policy experts have addressed these issues many times, few proposals for reform have succeeded. The failure of the Clinton Administration's 1993-94 health reform efforts illustrates the problem's complexity. Currently, physicians increasingly face the ethical dilemma of restricting access to necessary medical care when health insurers, state governments, and managed care organizations make, or require them to make, rationing decisions. Moreover, the effect of a 2004 Supreme Court ruling is that patients have little recourse in suing their health maintenance organizations (HMOs) for denial of care.² There is little consensus about how to ensure equal access, allocate scarce resources, or define a benefits package.

Health ethics, policy and law offer numerous approaches to address these issues, which have generally, though not exhaustively, fallen into five categories. The first proposes welfare economic and utilitarian schemes that rely on cost-effectiveness, cost-utility, or cost-benefit analyses to aggregate costs and benefits and thus maximize social welfare.³ Libertarian theories comprise the second category. They emphasize access to rights and typically promote free-market solutions⁴ or quasi-market-based approaches such as ex ante choices and advance contracting for health plans with specific rationing protocols.⁵ The third group includes theories that adhere to principles and practices that have evolved through community traditions and therefore vary in different localities.⁶

¹ Jon Gabel et al., *Health Benefits in 2003: Premiums Reach Thirteen-Year High as Employers Adopt New Forms of Cost-Sharing*, HEALTH AFF., Sept.-Oct. 2003, at 117, 117-119.

² *Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004) (holding that ERISA preempted plaintiffs' causes of action against their HMOs).

³ Alan M. Garber & Charles E. Phelps, *Economic Foundations of Cost-Effectiveness Analysis*, 16 J. HEALTH ECON. 1, 1-13 (1997); Milton C. Weinstein & William B. Stason, *Foundations of Cost Effectiveness Analysis for Health and Medical Practices*, 296 NEW ENG. J. MED. 716, 716-21 (1977) [hereinafter *Medical Practices*].

⁴ ROBERT NOZICK, *ANARCHY, STATE, AND UTOPIA* (1974) [hereinafter *ANARCHY*]; Loren E. Lomasky, *Medical Progress and National Health Care*, 10 PHIL. & PUB. AFF. 65, 86-88 (1981) [hereinafter *Medical Progress*] (arguing for a medical marketplace where consumers can purchase health care); H. TRISTRAM ENGELHARDT, *THE FOUNDATION OF BIOETHICS* 336-69 (2d ed. 1996); Charles Fried, *Equality and Rights in Medical Care*, HASTINGS CENTER REP. Feb. 1976, at 29, 29-34 (asserting that there is no right to equal access to health care) [hereinafter *Equality and Rights*].

⁵ CLARK C. HAVIGHURST, *HEALTH CARE CHOICES: PRIVATE CONTRACTS AS INSTRUMENTS OF HEALTH REFORM* (1995) [hereinafter *HEALTH CARE CHOICES*]. See generally MARK HALL, *MAKING MEDICAL SPENDING DECISIONS: THE LAW, ETHICS, AND ECONOMICS OF RATIONING MECHANISMS* (1997) [hereinafter *RATIONING MECHANISMS*]; PAUL T. MENZEL, *STRONG MEDICINE: THE ETHICAL RATIONING OF HEALTH CARE* (1990) 3-21, 97-115, 116-31, 199-201 [hereinafter *STRONG MEDICINE*].

⁶ See generally LIBERALISM AND ITS CRITICS (Michael J. Sandel ed., 1984) [hereinafter *LIBERALISM*]; MICHAEL J. SANDEL, *LIBERALISM AND THE LIMITS OF JUSTICE* (1982) [hereinafter *LIMITS OF JUSTICE*]; Michael Walzer, *The Communitarian Critique of Liberalism*, 18(1) POLIT-

The fourth offers procedural or democratic approaches,⁷ some of which “retreat to procedural justice”⁸ to characterize the right procedures or use open-ended or random processes to prioritize health care.⁹ Finally, egalitarian theories that stress equal access to certain goods.¹⁰ These theories have begun to form a collection of approaches to health ethics, policy and law, each having advantages and limitations when applied to the problems health-care systems face.

In this Article I offer an alternative theoretical framework for health ethics, policy and law, integrating both substantive criteria and procedural mechanisms – a joint scientific and deliberative approach – to guide health-system reform and allocation of scarce health resources. It appeals to a particular vision of the good life rooted in the capability approach¹¹ and Aristotelian political philosophy.¹² I build on and integrate these perspectives to develop a theoretical framework of health ethics, policy and law, and to elucidate public policy implications of such a theory. On this view, the ethical principle of “human flourishing”¹³ un-

ICAL THEORY 6-23 (1990) [hereinafter *Communitarian Critique*]; ALASDAIR MACINTYRE, *WHOSE JUSTICE? WHICH RATIONALITY?* (1988) [hereinafter *WHOSE JUSTICE*].

⁷ Leonard M. Fleck, *Just Health Care Rationing: A Democratic Decisionmaking Approach*, 140 U. PA. L. REV. 1597, 1617 (1992) [hereinafter *Health Care Rationing*]; Norman Daniels, *Four Unsolved Rationing Problems: A Challenge*, HASTINGS CENTER REP. July–Aug. 1994, at 27, 27-29 [hereinafter *A Challenge*].

⁸ NORMAN DANIELS & JAMES E. SABIN, *SETTING LIMITS FAIRLY: CAN WE LEARN TO SHARE MEDICAL RESOURCES?* (2002) [hereinafter *SETTING LIMITS FAIRLY*].

⁹ David Orentlicher, *Rationing and the Americans with Disabilities Act*, 271 J. AM. MED. ASS’N 308, 308-14 (1994) [hereinafter *Disabilities Act*]; John M. Taurek, *Should the Numbers Count?*, 6 PHIL. & PUB. AFF. 293, 314-316 (1977) [hereinafter *Numbers*].

¹⁰ Robert M. Veatch, *What is ‘Just’ Health Care Delivery*, in *CONTEMPORARY ISSUES IN BIOETHICS* (Thomas L. Beauchamp & Le Roy Walters eds., 1978) [hereinafter *ISSUES IN BIOETHICS*]; Gerald A. Cohen, *Equality of What? On Welfare, Goods, and Capabilities*, in *THE QUALITY OF LIFE* 9, 28 (Martha Nussbaum & Amartya K. Sen eds., 1993) [hereinafter *Equality of What*]; ERIC RAKOWSKI, *EQUAL JUSTICE* 304-05 (1991) [hereinafter *EQUAL JUSTICE*]; Richard J. Arneson, *Equality and Equal Opportunity for Welfare*, 56 PHIL. STUDIES 77-93 (1989) [hereinafter *Equal Opportunity*].

¹¹ Martha Nussbaum and Amartya Sen provide different versions of the capability approach, this Article draws on both perspectives, although more heavily on Sen in developing theory. See generally AMARTYA K. SEN, *INEQUALITY REEXAMINED* (1992) [hereinafter *INEQUALITY*]; AMARTYA K. SEN, *COMMODITIES AND CAPABILITIES* (1999) [hereinafter *COMMODITIES*]. For more on the differences between Nussbaum’s and Sen’s versions of the capability approach see generally, Martha Nussbaum, *WOMEN AND HUMAN DEVELOPMENT* (2000).

¹² See ARISTOTLE, *THE NICOMACHEAN ETHICS* (Terrence Irwin trans., 1999) [hereinafter *NICOMACHEAN ETHICS*]; ARISTOTLE, *THE POLITICS* (Cames Lord trans., 1984) [hereinafter *THE POLITICS*]; Martha C. Nussbaum, *Nature, Function, and Capability: Aristotle on Political Distribution*, in *ARISTOTLE’S POLITIK* 152 (Herausgegeben von Günther Patzig ed., 1990) [hereinafter *Political Distribution*]; Martha C. Nussbaum, *Human Functioning and Social Justice: In Defense of Aristotelian Essentialism*, 20(2) POL. THEORY 202 (1992) [hereinafter *Human Functioning*]; Martha C. Nussbaum, *The Good As Discipline, the Good As Freedom*, in *ETHICS OF CONSUMPTION: THE GOOD LIFE, JUSTICE, AND GLOBAL STEWARDSHIP* 312 (David A. Crocker & Toby Linden eds., 1998) [hereinafter *Good As Discipline*].

¹³ See generally *Political Distribution*, *supra* note 12; *THE POLITICS*, *supra* note 12.

derlies society's obligation to maintain and improve health. This principle holds that society should enable human beings to live flourishing lives.¹⁴ Flourishing and health are inherent to the human condition. Certain aspects of health, in particular, maintain other aspects of human flourishing. Because without life itself, no other human functionings, including "agency," are possible. Therefore, public policy should focus on individuals' ability to function, and health policy should aim to support individuals' capability for health functioning by enabling individuals to meet health needs and by creating conditions for health agency.¹⁵

The capability approach purports that expanding freedom is both the primary end and principle means of public policy; consequently, public policy should focus on removing barriers to freedom that leave people with little choice or opportunity to exercise their reasoned agency. Freedom entails both processes of action and decision and actual opportunities available to people, given their personal and social circumstances.¹⁶ In what follows, I will argue that both the process and opportunity aspects of freedom are essential to developing a just health care system. Public policy should also be efficient, requiring the "wasteless, productive promotion of objectives."¹⁷ The primary goal for health systems, this Article argues, is the reduction in disparities in health capabilities using the fewest resources. Therefore, some limits must be set in allocating resources, and individuals and experts must decide how to make these trade-offs.

This theoretical framework offers several key principles for health ethics, policy and law.

First, this theory is rooted in a particular view of the good life: human flourishing, which values health intrinsically and more highly than non-intrinsic or solely instrumental social goods, such as income. This view gives special moral importance to what I have called health capability. Health capability constitutes a person's ability to be healthy; it includes health functioning and health agency.¹⁸ It also suggests that certain aspects of health are prerequisites for other types of functioning, including one's agency, or the ability to lead a life one has reason to value. This view contrasts with the equality of opportunity view that

¹⁴ See generally *Political Distribution*, *supra* note 12; *THE POLITICS*, *supra* note 12.

¹⁵ Jennifer Prah Ruger, *Aristotelian Justice and Health Policy: Capability and Incompletely Theorized Agreements* (1998) (unpublished Ph.D. dissertation, Harvard University) (on file with the Harvard University Library) [hereinafter *ARISTOTELIAN JUSTICE*]; Jennifer Prah Ruger, *Health and Social Justice*, 364 *LANCET* 1075 [hereinafter *Social Justice*]; Jennifer Prah Ruger, Lecture entitled *Social Justice and Health Policy* (Health Policy Doctoral Seminar Series, Harvard University) (1997) [hereinafter *Justice and Health Policy*].

¹⁶ AMARTYA SEN, *DEVELOPMENT AS FREEDOM* 17 (1999) [hereinafter *FREEDOM*].

¹⁷ *INEQUALITY*, *supra* note 11, at 140.

¹⁸ *ARISTOTELIAN JUSTICE*, *supra* note 15; *Social Justice*, *supra* note 15; *Justice and Health Policy*, *supra* note 15.

health care is “special because of its impact on opportunity,”¹⁹ and the utilitarian view that health care is important for maximizing social welfare. These distinctions arise from the different ends of justice these theories espouse. Capability describes what individuals are able to do and be, offering a realistic sense of their real freedom to pursue the lives they have reason to value. In contrast, equality of opportunity results from “[a] time or condition [favorable] for a particular action or aim,”²⁰ as when individuals have equal access to employment opportunities,²¹ and utility encompasses desire or pleasure.

Second, this theory argues for valuing “basic” or “central” health capabilities above those that are secondary. The former include: (a) the capability to avoid premature death, and (b) the capability to avoid escapable morbidity. Agreement on the importance of providing such core health capabilities offers guidance in prioritizing health services.²² This approach can help determine whether a particular medical intervention or technology merits societal resources.

Third, this paradigm sketches a *joint scientific and deliberative approach* to judge the value of a health care intervention. It employs a public scientific process that combines the evidence base of medicine and public health with the expert opinions of physicians and public health experts with input from individuals. Ideally, physicians and public health experts and individuals would have authority in substantive deliberations about allocation decisions. This is because health policy affects individuals directly and physicians, by virtue of their medical expertise and allegiance to the Hippocratic oath, can and must act in their patients’ best interest. Thus, this view argues for supporting individuals’ health agency as well as their health.²³ At the policy level, democratically derived public policy for “human flourishing and evaluating interventions aimed at improving human functioning must depend on “reasoned consensus.”²⁴ Individuals are “active agents of change, rather than . . . passive recipients of dispensed benefits,”²⁵ and thus, are essential in

¹⁹ Norman Daniels, *Justice, Health, and Healthcare*, 1 AM. J. BIOETHICS 2, 2-16 n. 2 (2001) at 2 [hereinafter *Health, and Healthcare*]. See generally NORMAN DANIELS, *JUST HEALTH CARE* 7-8 (1985) [hereinafter *JUST HEALTH CARE*].

²⁰ THE NEW SHORTER OXFORD ENGLISH DICTIONARY ON HISTORICAL PRINCIPLES, VOL. 2 N-Z, 2009 (Lesley Brown ed., 4th ed. 1993).

²¹ See JOHN RAWLS, A THEORY OF JUSTICE 65-67, 83-84 (1971) [hereinafter *THEORY OF JUSTICE*].

²² ARISTOTELIAN JUSTICE, *supra* note 15; *Social Justice*, *supra* note 15; Jennifer Prah Ruger, *Toward a Theory of a Right to Health: Capability and Incompletely Theorized Agreements* 18 Yale J. Law & Human. 273 (2006) [hereinafter *Right to Health*].

²³ ARISTOTELIAN JUSTICE, *supra* note 15; *Social Justice*, *supra* note 15; Jennifer Prah Ruger, *Rethinking Equal Access: Agency, Quality and Norms*, 2 J. GLOBAL PUB. HEALTH, (in press). [hereinafter *Agency and Quality*].

²⁴ See FREEDOM, *supra* note 16, at 78.

²⁵ FREEDOM, *supra* note 16, at xiii.

determining social choice. Individuals must therefore have the capability to participate in such deliberations and decision-making and know the risks, benefits and costs of health prevention and treatment and various health policy options.

Fourth, under this paradigm, decisions are made by appealing to a shared concept of capability for health functioning and, when disagreements occur, practical models of agreement or consensus facilitate workable solutions. The resolutions that flow from these deliberations offer guidance in standardizing prevention and treatment decisions and developing health policies and health laws.²⁶

This view contrasts with paradigms in which consumers alone, physicians or public health experts alone, strict algorithms or cost-benefit calculations, shared decision making within an informed consent model, fair procedures, or third parties, such as insurers, make health care decisions.²⁷ While it endorses many of the principles of the shared decision making approach to individual medical treatment decisions, it focuses differently on what I call *shared health governance*, a paradigm in which individuals, providers, and institutions work together to empower individuals and create an enabling environment for all to be healthy.²⁸ Shared decision making, by contrast, focuses on individual decisions in isolation, as opposed to a shared health governance model which incorporates individuals' decisions for themselves and *for their society at large*. This approach also differs from efforts to develop a decision-making process "to set fair limits to health care."²⁹ The paradigm offered here promotes consensus on substantive principles and procedures of distribution; offers a method for achieving that consensus (incompletely theorized agreements or ITAs);³⁰ places importance on the results of health policies and laws (costs and effectiveness) in judging them; and promotes deliberation through collaborative problem solving. Thus, the framework integrates both consequential (substantive) and procedural (democratic) elements of justice and it focuses on both health functioning and on health agency. Both decision making processes and achieved outcomes are important for evaluating justice. Procedural rules alone are inadequate for justice, due to the need to account for the consequences of

²⁶ ARISTOTELIAN JUSTICE, *supra* note 15, *Right to Health*, *supra* note 22.

²⁷ See RATIONING MECHANISMS, *supra* note 5, at 8-11.

²⁸ ARISTOTELIAN JUSTICE, *supra* note 15; *Social Justice*, *supra* note 15; Jennifer Prah Ruger, *Ethics and Governance of Global Health Inequalities*, 60 J. EPIDEMIOLOGY & COMMUNITY HEALTH, (in press 2006) [hereinafter *Ethics and Governance*].

²⁹ SETTING LIMITS FAIRLY, *supra* note 8 at 2.

³⁰ See generally ARISTOTELIAN JUSTICE, *supra* note 15; *Social Justice*, *supra* note 15; *Justice and Health Policy* *supra* note 15; Jennifer Prah Ruger, *Health, Health Care, and Incompletely Theorized Agreements*, (mimeographed, Harvard University) (1995) [hereinafter *Theorized Agreements*].

such entitlements. Consequences alone are inadequate for justice, due to the need to include individuals in decisions that affect them. Since these recommendations form the basis for defining a universal benefits package, making allocation decisions, and constructing guidelines, the collective reasoning should be made public.

Shared health governance extends beyond the individual patient-doctor relationship to the institutions that oversee the health sector. For example, patients must be protected from physicians who have financial incentives to provide inappropriate and costly care, or who unfairly deny, or fail to recommend, appropriate medical care; or who practice bedside rationing. In the former case, peer review should motivate physicians to conform to established standards. In the latter, appeals procedures should protect individuals from unfair denial of care. An independent and impartial governing board should periodically review coverage and quality decisions, hear and rule on patient and physician appeals, and require guidelines to be adjusted. The board should also oversee and critically review quality of care and other information, including physician credentials and abilities. Many states currently have consumer grievance and appeal procedures, while Medicare has a federal external review system.

This shared health governance model in health ethics, policy and law can potentially improve individuals' health and health agency and decrease costs. Researchers have found, for example, that patients knowledgeable about treatment risks and benefits might actually choose treatment less often than those who spoke only briefly to their physicians about the procedure; in one case, 30% fewer patients chose surgery for severe back pain caused by a ruptured disc.³¹ Ensuring individuals' health agency for health care decision making depends critically on providing patients with the most up-to-date information on possible risks and benefits and providing them the circumstances under which they have the freedom to make such decisions.

Fifth, a shared health governance model takes a different tack on the issue of equal access.³² First, equal access should mean equal access to high-quality care, not a "decent minimum," "adequate care," or "tiered health care." Second, it is not enough to provide health care without efforts to expand individuals' health agency – their ability to engage with and navigate the health care system to prevent mortality and morbidity

³¹ See Richard A. Deyo et al., *Involving Patients in Clinical Decisions: Impact of An Interactive Video Program on Use of Back Surgery*, 38 MEDICAL CARE 959, 965 n. 9 (2000) (discussing a study in which patients who had received videodisk information about herniated disks were less likely to undergo back surgery than those who had only received a booklet).

³² *Agency and Quality*, supra note 23.

and to meet health needs.³³ Third, shared health governance means shared responsibility – that individuals, providers, and institutions have respective roles and responsibilities in achieving health goals. A major emphasis of this theory is that institutions and providers are morally obligated to provide high quality health care to all individuals.³⁴ While a focus on high quality in this paradigm intersects with recent US policy to improve health care quality, the primary motivation espoused here is one of ensuring fairness: that it is unfair to deny any one, or group of individuals, access to quality care if doing so could substantially decrease their chance of a significantly improved health outcome. In policy terms, reaching this goal would require continuous efforts to standardize medicine, reduce medical errors, and move toward a gold standard of care.³⁵ High-quality care is necessary from a moral point of view for helping people to function best, given their circumstances and for maximal capacity for functioning. Such a view would not condone the significant disparities in health care quality that exist in the U.S. and in many developing countries, for example. Moreover, universal health insurance that is community-rated and progressively financed is critical because equal access cannot be separated from equity in health care financing.³⁶ Medical appropriateness and medical necessity and not ability to pay must determine resource allocation.

Sixth, evaluation of health policies, laws, and technologies must consider costs because we live in a world of scarce resources. Moreover, every resource has an alternative use, so its expenditure corresponds with an opportunity cost. Therefore, some limits are necessary and individuals and society, through shared health governance, must use these resources parsimoniously by evaluating efficiency. Efficiency measures espoused here include cost minimization analysis and economic incentives for high quality care. Cost-effectiveness analysis (CEA) can also aid in comparing interventions for a single population, such as AIDS patients, by weighing the marginal benefits and marginal costs of two alternate interventions. For example, evaluating the cost effectiveness of combination antiretroviral therapy for HIV infection,³⁷ or of preventing AIDS

³³ *Social Justice*, *supra* note 15; *Agency and Quality*, *supra* note 23.

³⁴ *Agency and Quality*, *supra* note 23.

³⁵ See COMMITTEE ON THE QUALITY OF HEALTHCARE IN AMERICA, INSTITUTE OF MEDICINE, *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* (2001).

³⁶ See *EQUITY IN THE FINANCE AND DELIVERY OF HEALTHCARE: AN INTERNATIONAL PERSPECTIVE* (Eddie Van Doorslaer et al. eds., 1993) [hereinafter *INTERNATIONAL PERSPECTIVE*]; Jennifer Prah Ruger, *Catastrophic Health Expenditure*, 362 *LANCET* 996, 997 (2003) [hereinafter *Catastrophic Health*] (discussing the importance of health insurance).

³⁷ See Kenneth A. Freedberg, et al., *The Cost Effectiveness of Combination Antiretroviral Therapy for HIV Disease*, 344 *NEW ENG. J. MED.* 824 n. 11 (2001).

related opportunistic infections,³⁸ or simulation modeling of lifetime costs and life expectancy to inform clinical guidelines for the treatment of HIV-related *Pneumocystis carinii* pneumonia (PCP)³⁹ can help identify the additional costs society must pay for the additional benefits of each intervention.

The consideration of costs under this theory resembles a utilitarian welfare economic perspective in that costs and outcomes are both valued. However, it contrasts with the utilitarian aggregation methodology and recommends the use of cost-minimization analysis (CMA) and cost-effectiveness analysis (CEA) in combination with equity-oriented allocations (as opposed to incorporating equity weights into CEA.) It takes a step-wise approach to resource allocation whereby economic considerations follow and complement clinical input, not vice versa. In addition to helping physicians and patients judge whether a particular medical intervention or technology merits investment, CMA and CEA can reveal financial reasons for basic health care inequalities. For example, some American oncologists profit by purchasing chemotherapy agents and dispensing them at a much higher price, which leads to inefficiency through higher pricing and over-use, particularly at the end of life.⁴⁰ This practice also compromises a physician's duty to act in a patient's best interest.

This paradigm also differs from efforts to assign measures and weights to individuals' disabilities, health conditions or efforts⁴¹ in order to specify how much weight to give to severely disabled individuals. The view espoused here does not move in that direction, but suggests that it is more useful to base these types of judgments on joint patient-physician decision making (at the policy and individual levels) on medical necessity, medical appropriateness, and medical futility (as defined by individuals' agency), rather than attempting to estimate specific weights for severely disabled individuals. Thus, this framework aims to provide guidance on protecting disabled people from discrimination while limiting exorbitantly costly care that would deprive others of health resources. Moreover, a general principle of "reasonable accom-

³⁸ See Kenneth A. Freedberg, et al., *The Cost Effectiveness of Preventing AIDS-Related Opportunistic Infections*, 279 JAMA 130, 130-136 n. 2 (1998).

³⁹ See Sue Goldie et al., *Prophylaxis for Human Immunodeficiency Virus-Related Pneumocystis carinii Pneumonia: Using Simulation Modeling to Inform Clinical Guidelines*, 162 ARCHIVES OF INTERNAL MED. 921 n. 8 (2002).

⁴⁰ See Ezekiel J. Emanuel et al., *Chemotherapy Use Among Medicare Beneficiaries at the End of Life*, 138 ANNALS INTERNAL MED. 639, 639-643 n. 8 (2003) (discussing a study that showed chemotherapy was used frequently in the last three months of life by patients who died of cancer).

⁴¹ Erik Nord et al., *Incorporating Societal Concerns for Fairness in Numerical Valuations of Health Programmes*, 8 HEALTH ECON. 25, 25-39 (1999) [hereinafter HEALTH ECONOMICS].

modation” could help identify reasonable adjustments and constraints because this paradigm argues for proportional prioritization; allocating resource proportional to health needs, but recognizes that reasonable limits should apply.

By arguing for an alternative paradigm of health ethics, policy and law with roots in Aristotle’s political philosophy and Amartya Sen’s capability approach, this Article undoubtedly raises more questions than it answers. An ongoing debate that develops the more practical implications of this theory will evolve in the future. And although the Article often highlights the differences between this view and other approaches, it also acknowledges their many common features. As one ethicist has noted, the “family of views of justice”⁴² will more likely converge rather than diverge as the field progresses.

I. HEALTH ETHICS, POLICY AND LAW: THE CURRENT SET OF FRAMEWORKS

Inequality in access to health insurance and health care, exacerbated by cost constraints, has spawned many frameworks of health ethics, policy and law. These fall into a number of categories, including: (1) welfare economic and utilitarian schemes that rely on cost-effectiveness, cost-utility, or cost-benefit analyses to aggregate costs and benefits and maximize overall social welfare; (2) theories that adhere to principles developed through community traditions; (3) egalitarian perspectives that focus on equal opportunity, equal welfare, and equal resources; (4) libertarian theories that emphasize individual rights and typically promote freemarket solutions or quasi-market approaches such as ex ante choices and advance contracting; and (5) procedural or democratic approaches, which characterize the right procedures or random processes to prioritize care. This section discusses some of the advantages and shortcomings of several of these frameworks, and concludes that there is significant opportunity for an alternative paradigm.

A. WELFARE ECONOMIC AND UTILITARIAN APPROACHES

One of the leading frameworks for health ethics, policy and law is utilitarianism, which arguably serves as the standard framework for health policy analysis⁴³ and was endorsed by the Panel on Cost-Effectiveness in Health and Medicine. The United States Public Health Service created the panel in 1993 to review the state of the field and develop

⁴² See generally *Health, and Healthcare*, *supra* note 19.

⁴³ Milton C. Weinstein, *Principles of Cost-Effective Resource Allocation in Health Care Organizations*, 6(1), INTERNATIONAL JOURNAL OF TECHNOLOGY ASSESSMENT IN HEALTH CARE, 93-103 (1990) at 93-94 (applying cost-effectiveness analysis from the viewpoint of a national health care system); See *Medical Practices*, *supra* note 3, at 716-21.

guidelines for standardizing cost-effectiveness analyses in health and medicine.⁴⁴ It was comprised of thirteen nonfederal scientists and scholars with experience in cost-effectiveness analysis (CEA), medical ethics, health law, and health outcomes measurement.⁴⁵ The panel recommended a system that captures individual preferences for different states of health, and recommended Quality-Adjusted-Life-Years (QALYs) as the metric for ranking health interventions.⁴⁶

Utilitarian frameworks require allocations that maximize social utility. However, rights have an “indefinite and tenuous foundation”⁴⁷ because they rely upon overall utility maximization. Thus, only improved net social utility would justify a right to health care.⁴⁸ Cost-utility analysis (CUA) is the primary method for evaluating health policy under a utilitarian ethic. CUA values health status in terms of health preferences, desires, or utilities; the QALY index combines preferences for length of life with those for quality of life. Like most utility measures, QALYs are based on the premise that utilities of different individuals and health conditions can compare on a single quantitative scale.

Other welfare economic techniques use different outcome metrics and include CEA and cost-benefit analysis (CBA) as well as CUA. CBA translates all benefits into monetary units through various techniques such as Cost of Illness (COI) studies, which value health outcomes by direct (medical and non-medical expenses) and indirect (lost productivity costs measures) costing methods.⁴⁹ Willingness-to-Pay (WTP) and Willingness-to-Accept (WTA) methodologies use questionnaires to assess individuals’ willingness to pay for risk reduction or accept additional risk.⁵⁰ CBA analysts also assess individuals’ preferences for changes in

⁴⁴ See REPORT TO THE U.S. PUBLIC HEALTH SERVICE BY THE PANEL ON COST-EFFECTIVENESS IN HEALTH AND MEDICINE, COST-EFFECTIVENESS IN HEALTH AND MEDICINE 13 (Marthe R. Gold et al., eds., 1996) [hereinafter PANEL REPORT] (endorsing cost-effectiveness analysis as crucial in decision making, but not as the sole decision making procedure).

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ See TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 335 (1994) [hereinafter BIOMEDICAL ETHICS].

⁴⁸ See Allen E. Buchanan, *The Right to a Decent Minimum of Health Care*, 13 PHILOSOPHY & PUBLIC AFFAIRS 55-78 (1984) [hereinafter *Minimum of Health Care*]; (“Thus Utilitarianism may require that, even for the most basic services, what is guaranteed for one individual may not be available to another, even though their needs are equal and both would benefit greatly from the service.”).

⁴⁹ See DOROTHY P. RICE & ELLEN J. MACKENZIE, COST OF INJURY IN THE UNITED STATES: A REPORT TO CONGRESS 70 (1989) (measuring the economic burden on society of injury-related illness and premature death).

⁵⁰ See VALUING HEALTH FOR POLICY: AN ECONOMIC APPROACH 6, 24, 74 (George Tolley et al. eds., 1994) [hereinafter ECONOMIC APPROACH]. See also EZRA J. MISHAN, COST-BENEFIT ANALYSIS 162 (1976) (arguing that when more “objective” sources of information do not exist, questionnaires are an important way to measure costs and benefits).

risk, based on their purchasing decisions;⁵¹ and they ask people to assign a monetary value to various health states and associated risks, using Contingent Valuation (CV) surveys.⁵²

The various welfare economic techniques are not without their weaknesses, however. One common concern about CBA is that respondents' income levels skew monetary valuations. Critics have faulted COI for not including pain and suffering in its calculations. WTA and WTP have raised objections because extrapolations from market transactions and individuals' hypothetical assessments might not accurately reflect individuals' valuations of health benefits and risks. Risk and survival are difficult to quantify. Moreover, the cost-per-QALY methodology also does not recognize that health care evaluation must assess both the severity of a patient's initial state *and* the effect of treatment.⁵³ To account for the tradeoff between severity and treatment effect, Nord proposes a mathematical model and index (cost per SAVE).⁵⁴ However, these methods of health valuation yield widely disparate estimates of the "value of life," and it is unclear which method best applies the principles of welfare economics.

The application of welfare economic and utilitarian principles to health ethics, policy and law raises several concerns. First, accounting for only aggregate welfare without considering the distribution of benefits and burdens in society is problematic. CUA, CBA, and CEA tolerate significant inequalities in order to increase total or average social utility. In response to this concern, there have been attempts to incorporate a distributional ethic into the utilitarian approach.⁵⁵ Kantian and libertarian ethicists, however, would be concerned about the attempt to aggregate across persons. Such an attempt conflicts with the principle that each individual is an end in herself and cannot be used instrumentally to assist other individuals.⁵⁶

⁵¹ See W. KIP VISCUSI, *FATAL TRADEOFFS: PUBLIC AND PRIVATE RESPONSIBILITIES FOR RISK* (1992).

⁵² See *Id.* at 50.

⁵³ See Erik Nord, *The Trade-Off Between Severity of Illness and Treatment Effect in Cost-Value Analysis of Health Care*, 24 *HEALTH POLICY* 227 (1993).

⁵⁴ *Id.*

⁵⁵ See generally HEALTH ECONOMICS, *supra* note 41 (arguing for "cost-value analysis" utilizing equity weights as an approach that supplements utilitarian analysis with distributive concerns).

⁵⁶ See ANARCHY, *supra* note 4, at 228 ("People will differ in how they view regarding natural talents as a common asset. [A]nd they will wonder whether any reconstruction of Kant that treats people's abilities and talents as resources for others can be adequate."); THEORY OF JUSTICE, *supra* note 21, at 521-522 (describing the concept of private society, in which individuals or associations make individualized assessments of social arrangements as means to their own private aims, which are "either competing or independent, but not in any case complimentary." [sic]); Christine Korsgaard, *The Reasons We Can Share: An Attack of the Distinction Between Agent-relative and Agent-neutral Values*, 10 *SOCIAL PHIL. & POL'Y* 24-51 (1993)

The Oregon Medicaid experiment illustrates the problems that can result from strict application of utilitarianism and cost-utility analysis. The experiment's algorithm counterintuitively ranked tooth-capping ahead of surgery for ectopic pregnancy.⁵⁷ This "aggregation problem" results from weighing a small benefit for many individuals against a large benefit for a few.⁵⁸ Moreover, strict CUA discriminates against disabled people by assigning less weight to their health benefits than to those of non-disabled individuals.⁵⁹ This strategy relates to the "priorities problem" in health-care rationing, or determining how much weight to give to society's most needy members.⁶⁰

Using utility measures to the exclusion of other measures also raises concerns. Sen has identified three main limitations of the utilitarian framework: (1) it omits freedom and focuses on achievements; (2) it omits certain achievements that are not reflected in the utility measure; and (3) it fails to measure accurately situations of persistent deprivation and adversity, in which people with significantly reduced functioning may not appear to be so deprived because they have adapted to their adverse environment.⁶¹

Entrenched inequalities highlight the difficulty of comparing interpersonal utility and comparing different utilities on a single quantitative scale. Commensurate measures of utility cannot assess well-being in functional terms. It is also difficult to compare diverse health conditions. For example, individuals associate completely different health values with the conditions of infertility, HIV/AIDS, and hearing loss. In addition, CEA, CBA, and CUA assume that saving life and extending life are commensurable with changes in health status or quality of life. For example, Hadorn discusses the "Rule of Rescue" and the symbolic value of saving "identifiable lives," noting the need to incorporate this altruistic value into any health-related assessment.⁶² Hadorn argues for guidelines that would balance quality-of-life-based benefits with the value of saving

(disagreeing with the proposition that "the value of persons [is] a metaphysical reality. . . [that suggests] that people are a good thing, and therefore that many people are better than a few") [hereinafter *We Can Share*].

⁵⁷ Dan W. Brock, *Justice and the ADA: Does Prioritizing and Rationing Healthcare Discriminate Against the Disabled?*, 12(2) SOCIAL PHIL. & POL'Y 159, 161 (1995) [hereinafter *Prioritizing and Rationing*]; David C. Hadorn, *Setting Health Care Priorities in Oregon. Cost-effectiveness Meets the Rule of Rescue*, 265 JAMA 2218, 2219 (1991) [hereinafter *Care Priorities*].

⁵⁸ See *A Challenge*, *supra* note 7, at 28.

⁵⁹ See Brock, *Prioritizing and Rationing*, *supra* note 57, at 173.

⁶⁰ See Norman Daniels, *Rationing Medical Care: A Philosopher's Perspective on Outcomes and Process*, 14 ECON. & PHIL. 27, 37 (1998) [hereinafter *Rationing Medical Care*].

⁶¹ AMARTYA SEN, ON ETHICS AND ECONOMICS 49 (John M. Letiche ed., 1987). See also SEN ET AL., THE STANDARD OF LIVING (Geoffrey Hawthorne ed., 1987).

⁶² *Care Priorities*, *supra* note 57, at 2221–22; See ECONOMIC APPROACH, *supra* note 50, at 23–4a.

identifiable lives.⁶³ However, life-saving interventions have drawbacks when expensive technology keeps people alive temporarily, or even for extended periods of time,⁶⁴ regardless of the resulting quality of life. The challenge, then, is to respect the unique value of saving lives while recognizing the need to assess treatment efficacy.

Other critics of CUA argue that QALYs disfavor individuals with a diminished capacity to benefit,⁶⁵ older individuals with fewer years to live,⁶⁶ and, as noted above, people with disabilities.⁶⁷ Still, many defend the maximization principle behind CEA⁶⁸ and the *ex ante* rationale that accepts tradeoffs.⁶⁹ Some argue that cost-value analysis, which incorporates social values, should replace CUA altogether.⁷⁰ Cost-value analysis proponents propose that the public's preference for interpersonal tradeoffs should guide resource allocation rather than an aggregation of individuals' preferences for health states.⁷¹ Indeed, empirical research reveals that most people favor a system of resource allocation that prioritizes severely ill individuals, even if their capacity to benefit is limited and the cost of treating them is relatively high.⁷² From this perspective, CUA elicits the wrong type of preferences when it prioritizes individual preferences for health states. There are, however, critics of the cost-

⁶³ See *Care Priorities*, *supra* note 57, at 2223–24.

⁶⁴ See generally *SCHIAVO EX REL. SCHINDLER V. SCHIAVO*, 403 F.3d 1289 (11th Cir. 2005).

⁶⁵ See Madison Powers & Ruth Faden, *Inequalities in Health, Inequalities in Health Care: Four Generations of Discussion About Justice Cost-Effectiveness*, 10 *KENNEDY INST. OF ETHICS J.* 109, 113 (2000) [hereinafter *Inequalities in Health*].

⁶⁶ See JOHN R. HARRIS, *THE VALUE OF LIFE ANALYSIS* 89–90 (1985).

⁶⁷ See *Inequalities in Health*, *supra* note 65, at 113.

⁶⁸ See David M. Eddy, *Clinical Decision Making: From Theory to Practice Cost-Effectiveness Analysis: A Conversation With My Father*, 267 *J. OF THE AM. MED. ASS'N* 1669, 1675 n.12 (1992) (“We who do cost-effectiveness analyses aren’t coldhearted accountants who take pleasure in depriving people of health care. . . . We think that we are responding to a national call for help.”)

⁶⁹ Madison Powers, *Hypothetical Choice Approaches to Health Care Allocation*, in *ALLOCATING HEALTH CARE RESOURCES* 147, 159 (James Humber & Robert Almeder eds., 1995) (outlining the “*ex ante* Pareto approach” espoused by the Comparative Benefits Modeling Project).

⁷⁰ See ERIK NORD, *COST-VALUE ANALYSIS IN HEALTHCARE: MAKING SENSE OUT OF QALY'S* 123–27 (Douglas Maclean, ed., Cambridge University Press) (1999) [hereinafter *COST-VALUE ANALYSIS*] (“Such a model could formally be identical to the conventional QALY model. But its basic measurement concept would be societal value rather than individual utility.”).

⁷¹ See *id.* at 115–18 (“What ultimately is needed in resource allocation decisions is not utilities for health states *per se*, but rather societal values for different health improvements relative to each other.”); Paul Menzel, *How Should What Economists Call “Social Values” Be Measured?*, 3 *J. OF ETHICS* 249, 251–59 (1999) [hereinafter *Social Values*] (“CEA needs to incorporate a broader set of values—social or societal values—than the individual utilities incorporated by the conventional . . . form of CEA.”)

⁷² See *COST-VALUE ANALYSIS*, *supra* note 70, at 30–37 (reviewing a range of studies in which respondents placed more value on severity of injury than on utility maximization).

value paradigm who question whether so-called societal preferences actually represent the majority view.⁷³ They wonder how one can know whether such judgments are “sufficiently reflective or sufficiently informed”⁷⁴ and how to reflect political and moral disagreement about social values in a public and transparent manner. Critics also argue that the cost-value paradigm fails to account for the significance of a patient’s history and life circumstances.⁷⁵

The Disability Adjusted Life Years (DALYs) approach attempts to address some of these concerns. It advocates a process for establishing group preferences, on disability weights, which are aggregated, using DALYs, to measure the health of different population groups.⁷⁶ While the effort is laudable, concerns remain regarding the use of such data for policy purposes due to the bias towards the able-bodied over disabled persons⁷⁷ and the limited ability to incorporate additional moral criteria into decision-making.⁷⁸

B. COMMUNITARIANISM AND LIBERAL COMMUNITARIANISM

Communitarian theories of justice argue that the provision of health care is an expression of community values, and therefore, the justification for health care varies by community.⁷⁹ Under communitarian theory, each society constructs its own principles as it evolves politically; morality is a cultural rather than abstract concept.⁸⁰ Taken to the extreme, this viewpoint could threaten the sense of common humanity that is a basis for morality, and it could also undermine political and social cooperation in societies that respect individual liberties and diversity.⁸¹

⁷³ See *Inequalities in Health*, *supra* note 65, at 118.

⁷⁴ *Id.*

⁷⁵ See *id.* at 118–19.

⁷⁶ See generally Christopher Murray & Arnab Acharya, *Understanding DALYs*, 16 J. HEALTH ECON. 703 (1997) (“We do not take into account health satisfaction of individuals at all; the task is to isolate health conditions and limit the relevant non-health contingences to determine the impact of health conditions on individuals.”).

⁷⁷ See Sudhir Anand & Kara Hanson, *Disability-Adjusted Life Years: A Critical Review*, 16 J. HEALTH ECON. 685, 701–02 (1997).

⁷⁸ See *Inequalities in Health*, *supra* note 65, at 120–21.

⁷⁹ See generally *Welfare, Membership and Need*, in LIBERALISM AND ITS CRITICS (Michael A. Sandel, ed., 1984), *supra* note 6. See also ALASDAIR MACINTYRE, *AFTER VIRTUE: A STUDY IN MORAL THEORY* (Am. ed., 1981); *LIMITS OF JUSTICE*, *supra* note 6; *WHOSE JUSTICE*, *supra* note 6; *Communitarian Critique*, *supra* note 6.

⁸⁰ See generally *Communitarian Critique*, *supra* note 6.

⁸¹ See ALLEN BUCHANAN ET AL., *FROM CHANCE TO CHOICE: GENETICS AND JUSTICE* 378 (2000) [hereinafter *FROM CHANCE*] (arguing for a liberal moral theory that addressed principles as well as virtues, acknowledging that “reliance on the judgment of virtuous individuals . . . is no substitute for principled public debate about the ethical character of our common institutions”).

Ezekiel Emanuel proposes a communitarian approach that incorporates aspects of libertarianism.⁸² In an ideal system, he proposes, deliberative, democratic communities could develop shared conceptions of justice and the good life.⁸³ However, Emanuel is critical of noncommunitarian democratic political procedures, arguing that it is difficult to agree on a substantive conception of distributive justice in a liberal polity.⁸⁴ He would also designate the current level of federal health spending as the national health care budget and give patients vouchers so they could choose among community health programs (CHPs) offering different levels of resources.⁸⁵ He rejects cost-benefit, cost-utility, or cost-effectiveness methodologies because they bypass the need for collective reflection on values.⁸⁶ His proposal has been criticized on impracticality and moral grounds because CHPs might be tempted to select benefit structures that favor some citizens over others.⁸⁷

C. EGALITARIAN THEORIES: EQUAL OPPORTUNITY AND EQUAL WELFARE

Egalitarian theories, a third framework, focus on the equal distribution of certain societal goods, one of which is health care. They do not support “equal sharing of all possible social benefits.”⁸⁸ The most noteworthy egalitarian theory of justice is John Rawls’s view that justice requires the fair distribution of “primary goods.”⁸⁹ According to Rawls, rational agents behind a “veil of ignorance”⁹⁰ about their personal circumstances would choose principles of justice that maximize the minimum level of primary goods. While Rawls did not directly apply his theory to health care,⁹¹ others have done so.

⁸² See EZEKIEL J. EMANUEL, *THE ENDS OF HUMAN LIFE: MEDICAL ETHICS IN A LIBERAL POLITY* (1991) at 135 [hereinafter *HUMAN LIFE*]a

⁸³ *Id.* at 156-57.

⁸⁴ *See id.* at 149-50.

⁸⁵ *Id.* at 184-87.

⁸⁶ *See id.* at 156 (rejecting utilitarianism as a framework in which to analyze medical ethics issues).

⁸⁷ *See BIOMEDICAL ETHICS*, *supra* note 47.

⁸⁸ *Id.* at 339.

⁸⁹ *THEORY OF JUSTICE*, *supra* note 21, at 62 (“As a first step, suppose that the basic structure of society distributes certain primary goods, that is, things that every rational man is presumed to want.”).

⁹⁰ *Id.* at 12. (“The principles of justice are chosen behind a veil of ignorance. This ensures that no one is advantaged or disadvantaged in the choice of principles by the outcome of natural chance or the contingency of social circumstances.”).

⁹¹ He did include health care in later works. See John Rawls, *THE LAW OF PEOPLES* (1997).

Those who have analyzed Rawls's approach in the context of health care, particularly Rakowski, have concluded that hypothetical choosers would prioritize resources randomly.⁹²

Norman Daniels and colleagues also apply Rawls's theory of justice to health care and argue that health care is a right because it provides "equality of opportunity;"⁹³ the Fair Equality of Opportunity (FEO) account. Gerald Cohen has also drawn on Rawls's theory and expanded the Rawlsian view through an "equal opportunity for welfare or advantage" approach which supports rights for those disadvantaged by poor talents and skills as well as by disease or disability.⁹⁴ Daniels⁹⁵ counters that this interpretation places too little emphasis on choice or responsibility and raises problems for public policy⁹⁶ including access to interventions that go beyond ameliorating disease.⁹⁷ He supports the "level playing field conception of equal opportunity",⁹⁸ which requires efforts "to eliminate or ameliorate . . . social factors that limit opportunity over and above discrimination."⁹⁹

Drawing on Rawls, Daniels adopts the "veil of ignorance" concept,¹⁰⁰ which suggests that individuals should attempt to formulate hypothetical allocation standards for a "potential future self," without knowledge of their current or future health status. Under these conditions, people would choose allocations that would enable them to achieve an age-relative normal opportunity range at each stage of life.¹⁰¹

The FEO account does not discriminate among the different types of health care that society should provide its citizens under the "equality of opportunity" principle. Moreover, this theory does not consider the tradeoffs between health care and other social goods and adequately consider the costs of health insurance, goods, and services. Moreover, Daniels and others later extended the FEO approach to social determinants of

⁹² See generally EQUAL JUSTICE, *supra* note 10.

⁹³ See JUST HEALTH CARE, *supra* note 19.

⁹⁴ EQUAL OPPORTUNITY, *supra* note 10; Gerald A. Cohen, *On the Currency of Egalitarian Justice*, 99 ETHICS 906, 906-44 n. 4 (1989); and *Equality of What*, *supra* note 10, at 9-29.

⁹⁵ *Health, and Healthcare*, *supra* note 19.

⁹⁶ See generally James E. Sabin & Norman Daniels, *Determining 'Medical Necessity' in Mental Health Practice*, 24 HASTINGS CENTER REP. 5, 5-13 n. 6 (1994) (discussing the difficulties in rationing mental health care)[hereinafter *Medical Necessity*].

⁹⁷ See FROM CHANCE, *supra* note 81.

⁹⁸ See FROM CHANCE, *supra* note 81 at 65. See also generally John Roemer, *Equality and Responsibility*, 20 BOSTON REVIEW 3, 3-7 (1995); See also JOHN ROEMER, THEORIES OF DISTRIBUTIVE JUSTICE (1996).

⁹⁹ FROM CHANCE, *supra* note 81 at 16.

¹⁰⁰ THEORY OF JUSTICE, *supra* note 21.

¹⁰¹ See JUST HEALTH CARE, *supra* note 19.

health, claiming that health results largely from social conditions.¹⁰² Many have criticized this expansion, asserting, in particular, that the reduction of socio-economic inequalities might not necessarily diminish health inequalities.¹⁰³ To solve rationing problems in the realm of health care, Daniels and his colleagues argue for “fair procedures” that solve rationing problems reasonably,¹⁰⁴ although they have paid less attention to how individuals make rationing decisions and how to evaluate the outcomes such procedures generate.

The critiques of FEO tend to cluster around a few themes. First, FEO relies too heavily on statistical averages,¹⁰⁵ which fluctuate with changes in the distribution of health and disease. Second, it does not include the alleviation of pain and suffering as a goal of health care.¹⁰⁶ Third, it appears to exclude “nonproductive” or “socially isolated” individuals.¹⁰⁷ Fourth, it fails to clarify the concept of “fair equality of opportunity” and its link with health care. Fifth, indeterminacy and subjective valuation are implicit in the FEO account. A sixth area of criticism focuses on Daniels’ absence of guidance on weighing health care against other types of resources.¹⁰⁸ A seventh points to insufficient consideration of “hard cases,” such as patients with intractable and exorbitantly costly disabilities, who might receive unlimited medical services.¹⁰⁹ Eighth, some critics argue that Daniels’ notion of “adequate care” is too vague to be effectively implemented.¹¹⁰ Finally, FEO is criticized as being too circuitous because the opportunity range is endoge-

¹⁰² See *Health, and Healthcare*, *supra* note 19, at 6; NORMAN DANIELS ET AL., IS INEQUALITY BAD FOR OUR HEALTH? (Joshua Cohen and Joel Rogers eds., Beacon Press) (2000) [hereinafter *OUR HEALTH*].

¹⁰³ See generally Michael Marmot, *Do Inequalities Matter?*, in *OUR HEALTH*, *supra* note 102, at 37-41 (arguing that flattening social hierarchies altogether may not lead to a reduction in health inequalities).

¹⁰⁴ See Setting Limits Fairly, *supra* note 8.

¹⁰⁵ See Lawrence Stern, *Opportunity and Health Care: Criticisms and Suggestions*, 8 J. MED. & PHIL. 345 (1983) [hereinafter *Opportunity and Health*].

¹⁰⁶ See Sherman T. Folland, *A Critique of Pure Need: An Analysis of Norman Daniels’ Concept of Health Care Need*, 17 INT’L J. SOCIAL ECON. 40 (1990) [hereinafter *Pure Need*]; *Opportunity and Health*, *supra* note 108, at 345-49; Frances Kamm, *Health and Equality of Opportunity*, 1 AM. J. BIOETHICS 17-19 (2001) [hereinafter *Health and Equality*].

¹⁰⁷ See Ronald M. Green, *Access to Healthcare: Going Beyond Fair Equality of Opportunity*, 1 AM. J. BIOETHICS 22-23 (2001) [hereinafter *Access to Healthcare*]; See *Health and Equality*, *supra* note 106. Both articles challenge a Rawlsian understanding of FEO and argue that Daniels’ notion of species-typical normal functioning is a vague concept that may not justify the right of beneficial healthcare to nonproductive or socially isolated individuals.

¹⁰⁸ See Arti K. Rai, *Rationing Through Choice: A New Approach to Cost-Effectiveness Analysis in Health Care*, 72 IND. L.J. 1023-24 (1997) [hereinafter *Rationing Through Choice*]

¹⁰⁹ See HUMAN LIFE, *supra* note 82, at 135.

¹¹⁰ See Einer Elhauge, *Allocating Health Care Morally*, 82 CAL. L. REV. 1449-544 (1994) [hereinafter *Allocating Health*]; HUMAN LIFE, *supra* note 82; and *Rationing Through Choice*, *supra* note 108.

nous to the process of determining social investments in health care and other sectors.¹¹¹

Responding to these concerns, Daniels acknowledges that both his approach and those of his critics fail to meet many of these challenges. He identifies four unsolved rationing problems: (i) the fair chances/best outcomes problem (how to balance best outcomes with chances for a given benefit); (ii) the priorities problem (how much priority to give to the most disadvantaged); (iii) the aggregation problem (how to weigh small benefits for many against large benefits for a few); and (iv) the democracy problem (when to use fair processes that rank democratic preferences over substantive principles).¹¹² Later, Daniels also concedes that his approach does not provide assistance in choosing which opportunities to protect when it is impossible to protect every opportunity.¹¹³

A number of scholars have worked on these issues.¹¹⁴ Kamm, for example, has studied the aggregation and priorities problems, using hypothetical case studies to develop agreement on mid-level principles.¹¹⁵ Daniels believes that, even with this method, broad moral disagreements will prevent consensus on principles.¹¹⁶ Nord has proposed an empirical approach based on person-tradeoff questions in order to reveal moral principles in a given population.¹¹⁷ Others have argued for random allocation of health care to those with equal “capacity to benefit.”¹¹⁸ Despite these laudable efforts, Daniels notes that broad moral disagreements will prevent consensus on principles, and we must retreat to a process upon

¹¹¹ See *Minimum of Health Care*, *supra* note 48 at 60; *Pure Need*, *supra* note 106.

¹¹² See *A Challenge*, *supra* note 7 at 27 (acknowledging that “my ‘fair equality of opportunity’ account of just healthcare. . . fail[ed] to yield specific solutions to these rationing problems,” and further stating that there will unlikely be consensus about distributive justice and rationing problems).

¹¹³ See *Health, and Healthcare*, *supra* note 19.

¹¹⁴ See Mary Ann Baily, *The Democracy Problem*, 24 HASTINGS CENTER REP. 39-42 (1994); John Broome, *Fairness Versus Doing the Most Good*, 24 HASTINGS CENTER REP. 36-39 (1994); See JOSEPH RAZ, *THE MORALITY OF FREEDOM* 339 (1986) [hereinafter *MORALITY*]; Frances Kamm, *To Whom?*, 24 HASTINGS CENTER REP. 29-32 (1994) [hereinafter *To Whom*]; Erik Nord, *The Person-trade-off Approach to Valuing Health Care Programs*, 15 MEDICAL DECISION MAKING 201-208 (1995) [hereinafter *Person-trade-off*]; COST-VALUE ANALYSIS, *supra* note 70; Eric Rakowski, *The Aggregation Problem*, 24 HASTINGS CENTER REP. 33-36 (1994).

¹¹⁵ See generally *To Whom*, *supra* note 114; *Health and Equality*, *supra* note 106.

¹¹⁶ See *Health, and Healthcare*, *supra* note 19, at 2, 10 (reasoning that the middle-level principles supplement theories of distributive justice, which are highly contested).

¹¹⁷ See e.g., *Person-trade-off*, *supra* note 114, at 201 (“The person-trade-off technique is a way of estimating the social values of different health care interventions.”). See also COST-VALUE ANALYSIS, *supra* note 70, at 13-17, 30-31 (explaining the person-trade-off analysis of welfare economics and discussing its potential as a guideline for decision makers).

¹¹⁸ *Disabilities Act*, *supra* note 9 (interpreting the Americans With Disabilities Act as a safeguard against the discriminatory effects of rationing in health care); *Numbers*, *supra* note 9 (arguing against considering “the relative numbers of people involved as something in itself of significance” in determining a course of action in certain tradeoff situations).

which all can agree is a fair way to resolve disputes.¹⁶⁹ Below, I review a number of approaches that favor procedural mechanisms of justice and democratic deliberations for resolving such disputes.

Ronald Green has applied Rawls's theory to health care differently from the FEO account.¹²⁰ Instead of deliberative decision-making, Green envisions an income-adjusted price system that enables consumers to establish their priorities for health care.¹²¹ Finally, a major concern with the Rawlsian approach is that it focuses on means (resources) rather than ends and fails to specifically address human diversity.¹²²

Some theories of justice that focus on equal welfare attempt to address the concern with equal resource accounts. In the context of health care, Robert Veatch advocates consideration of ends into his resource-based distributive theory via a "capacity to benefit" principle of distribution.¹²³ Some critics of Veatch's theory argue that the capacity to benefit is difficult to define, both in theory and practice,¹²⁴ while others maintain that it would be quite similar to a QALY methodology.¹²⁵ Veatch emphasizes autonomy, cautioning society to "permit only certain consequences to be balanced against autonomy," such as helping the disadvantaged or promoting equality.¹²⁶ Similar equal welfare accounts employ principles of comparable opportunities¹²⁷ and argue for equal opportunity for welfare.

D. LIBERTARIAN AND MARKET-BASED APPROACHES

Proponents of the fourth framework argue that a market mechanism is the ideal way to distribute health care. This approach generally stems from an overarching libertarian philosophy¹²⁸ in which individual freedom and autonomy are the predominant societal values, and in which the

¹¹⁹ *Health, and Healthcare*, *supra* note 19, at 10.

¹²⁰ *See Access to Healthcare*, *supra* note 107, with *supra* text accompanying notes 48–62.

¹²¹ *See id.* at 23 ("[A] major role should be given to the price system, which permits citizens to establish individual priorities for healthcare services.").

¹²² *See INEQUALITY*, *supra* note 11.

¹²³ *See ISSUES IN BIOETHICS*, *supra* note 10, at 410–417.

¹²⁴ *See generally* JOHN F. KILNER, WHO LIVES? WHO DIES?: ETHICAL CRITERIA IN PATIENT SELECTION 115–60 (1990) [hereinafter PATIENT SELECTION] (presenting the justifications for and weaknesses of considerations of medical benefits, likelihood of benefit, length of benefit, and quality of benefit).

¹²⁵ *See Rationing Through Choice*, *supra* note 108, at 1065–70 (arguing that QALY maximization can be reconciled with commensurability of benefits).

¹²⁶ Robert M. Veatch, *Which Grounds for Overriding Autonomy are Legitimate?*, 26 HASTINGS CENTER REP. NOV.–DEC. 1996, at 42, 43 (1996) [hereinafter *Overriding Autonomy*].

¹²⁷ *See generally Equal Opportunity*, *supra* note 10, at 85–87 ("When persons enjoy equal opportunity for welfare in the extended sense, any actual inequality of welfare in the positions they reach is due to factors that lie within each individual's control.").

¹²⁸ *See ANARCHY*, *supra* note 4, at 167–74 (explaining how distributive justice facilitates a shift from classical liberal self-ownership to infringement of individual rights); *Medical Progress*, *supra* note 4, at 69 ("[T]here is a wide gulf between medical care being an important

government's role is to protect individual rights – especially property rights. This framework does not support a right to health care because efforts to guarantee such a right could infringe on individual liberties, by requiring people to pay taxes, for example.¹²⁹ Individuals are autonomous agents who may freely choose to purchase or forego health insurance or health care.¹³⁰ Thus, a strict market-based approach would allow the more affluent and those with strong preferences for certain goods and services to receive more and better health care, regardless of need or capability.

Havighurst argues for a market-oriented approach that would allow consumers to choose among different plans according to the benefit level they desire.¹³¹ Lomasky would give consumers the opportunity to “make informed purchases in a genuine medical marketplace.”¹³² Whereas strict libertarian views deny that society has a moral obligation to provide health resources to its citizens, more moderate adaptations support some form of income transfer. Lomasky and Engelhardt, for example, favor cash vouchers for health insurance¹³³ while Fried sanctions income transfer for health care.¹³⁴ These more moderate libertarian views recognize a very limited role for the state in improving welfare while maintaining their primary focus on individual autonomy. Engelhardt, for example, has emphasized medicine's role as a secular profession in a pluralistic society in which people disagree on a common substantive morality.¹³⁵ He focuses on the peaceful settling of moral differences, with respect for personal autonomy as the utmost societal value.¹³⁶ Engelhardt is critical of hypothetical choice procedures, arguing that they result in decisions that reflect a thin theory of the good based on antece-

human *interest* or *need* and its being a *right*.”). See generally H. TRISTRAM ENGELHARDT, JR., *THE FOUNDATIONS OF CHRISTIAN BIOETHICS* (2000) [hereinafter *CHRISTIAN BIOETHICS*].

¹²⁹ See *ANARCHY*, *supra* note 4, at 170 (“[I]f it would be illegitimate for a tax system to seize some of a man's leisure (forced labor) for the purpose of serving the needy, how can it be legitimate for a tax system to seize some of a man's goods for that purpose?”).

¹³⁰ See *Medical Progress*, *supra* note 4, at 87 (“Those who place a premium on present consumption should be free to devote only a minimal amount of income to health care coverage.”).

¹³¹ See *HEALTH CARE CHOICES*, *supra* note 5 at 3 (“This study argues that consumer choices are of limited consequence today precisely because all health plans must meet essentially the same legal standards and requirements. If consumer choice is to serve consumers and the economy well, competing health plans must be free to establish alternative standards and requirements by contract.”).

¹³² *Medical Progress*, *supra* note 4, at 88.

¹³³ See *Medical Progress*, *supra* note 4, at 86 (“I suggest . . . a cash grant or voucher program.”); See generally *CHRISTIAN BIOETHICS*, *supra* note 128.

¹³⁴ See *Equality and Rights*, *supra* note 4, at 33 (“What if . . . each person were assured a certain amount of money to purchase medical services as he chose?”).

¹³⁵ See generally *CHRISTIAN BIOETHICS*, *supra* note 128.

¹³⁶ See *id.*

dent choice.¹³⁷ Veatch cautions us to be selective in what we choose to balance against autonomy.¹³⁸

More recently, market-based approaches, such as managed care, have become more prevalent in the United States. This model attempts to allocate health services through capitated payments to physicians, financial incentives based on quantity, gate-keeping, and longer waiting periods. Although managed care may lower health-care costs in certain contexts,¹³⁹ many argue that financial incentives have put doctors in an unethical position,¹⁴⁰ by encouraging them to avoid diagnostic tests, hospitalizations, and expensive referrals that might benefit their patients. Such financial incentives erode patients' trust.¹⁴¹ There are also concerns about other quasi market-based reforms, such as ex ante contracting for insurance plans with rationing protocols that leave patients insufficiently insured for interventions they might need. In the United States, for example, the Emergency Medical Treatment and Labor Act (EMTALA) requires emergency room personnel to treat even uninsured or underinsured individuals in medical emergencies, including people who would have contracted to forgo treatment for certain conditions.¹⁴² The unpredictable nature of many adverse health events and society's obligation to address medical needs can make contractual approaches impractical and unethical.

One of the main concerns with the libertarian perspective is that the conditions for efficient market allocation based on supply and demand do not exist in the health-care or health-insurance markets.¹⁴³ Although individuals have the right to make their own treatment decisions in many settings, they often defer to providers and insurance companies because of information asymmetry, uncertain health risks, and limits on benefits. Moreover, consumers do not necessarily pay the full cost of health care or receive the full value of the goods and services they choose to

¹³⁷ See generally H. TRISTRAM ENGLEHARDT, JR., *THE FOUNDATIONS OF BIOETHICS* (1st ed. 1986).

¹³⁸ See *Overriding Autonomy*, *supra* note 126, at 43.

¹³⁹ See generally David M. Cutler et al., *How Does Managed Care Do It?*, 31 *RAND J. ECON.* 526 (2000) (studying how managed care impacts the quality of treatment for heart disease and the cost of illness).

¹⁴⁰ See Council on Ethical and Judicial Affairs, Am. Med. Ass'n, *Ethical Issues in Managed Care* 273 *JAMA* 330, 333 (1995) ("[Managed care] incentives are not inherently unethical, but they can be depending on their design and intensity.").

¹⁴¹ See *id.* at 331 ("The foundation of the patient-physician relationship is the trust that physicians are dedicated first and foremost to serving the needs of their patients.")

¹⁴² Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd (2005).

¹⁴³ See Kenneth J. Arrow, *Uncertainty and the Economics of Medical Care*, 53 *AM. ECON. REV.* 941, 948–54 (1963) (examining certain characteristics of medical care that make it unique as a commodity) [hereinafter *Uncertainty*].

purchase.⁴⁴ Also, market failures – such as the public goods aspects of medical knowledge, the externality effects of communicable diseases, the failure to serve vulnerable populations, uncertainty, asymmetric information, moral hazard, adverse selection, and equity concerns – provide a rationale for public intervention in financing (and sometimes provision of) health care.

Another approach based on the free-market view is “rationing through choice,” which claims to “[accommodate] diverse individual health and allocational preferences, and thus respects autonomy.”⁴⁵ In this model, individuals ration health care at the micro-allocational level through ex ante choices among various health plans.⁴⁶ The rationing-through-choice system, designed to use existing market mechanisms for health-care delivery, requires all individuals to contribute to a publicly funded health-care system, which would fund health plans or provide vouchers for purchasing private or public plans.⁴⁷ Plans that exceeded a certain government-allocated amount per capita would be more expensive to purchase.⁴⁸

This allocation model is similar to a “prudential insurer” system, in which initial resources are equal,⁴⁹ information on costs, benefits, and risks is widely accessible, and health-care and insurance markets function freely. Thus, individuals’ choices would define the fair and final allocation of health resources. Dworkin, in particular, has focused on this approach, drawing on Rawls’s “veil of ignorance” concept. Dworkin argues that the needs of a “representative individual” should shape the health-care budget and distribution of health-care resources.⁵⁰ The “representative individual” has an average income, full knowledge of the costs and benefits of health interventions, and the prevalence and incidence of disease, but no knowledge of his or her own genetic or medical disposition. Rakowski applies a hypothetical choice mechanism for individuals to make ex ante resource allocation choices and consent to certain rationing principles, such as life maximization.⁵¹ Elhauge argues,

¹⁴⁴ See Robert H. Blank, *Regulatory Rationing: A Solution to Health Care Resource Allocation*, 140 U. PA. L. REV. 1573, 1578-80 (1992). [hereinafter *Regulatory Rationing*].

¹⁴⁵ *Rationing Through Choice*, *supra* note 108, at 1032.

¹⁴⁶ *See id.* at 1031.

¹⁴⁷ *See id.* at 1036.

¹⁴⁸ *See id.*

¹⁴⁹ See Ronald Dworkin, *What is Equality? Part II: Equality of Resources*, 10(4) PHILOSOPHY AND PUBLIC AFFAIRS at 288 (1981) [hereinafter *Part II*]; See also Ronald Dworkin, *What is Equality? Part I: Equality of Welfare*, 10(3) PHILOSOPHY AND PUBLIC AFFAIRS 185 (1981) [hereinafter *Part I*].

¹⁵⁰ *See Part I supra* note 149; *Part II supra* note 149.

¹⁵¹ *See generally* EQUAL JUSTICE, *supra* note 10; Eric Rakowski, *Taking and Saving Lives*, 93 COLUM. L. REV. 1063 (1993).

however, that consensual theories “cannot offer a complete moral justification for health care allocations.”¹⁵²

In opposition to the free-market view, one finds the widely discussed bureaucratic, technocratic or legislative protocol approach to allocating resources.¹⁵³ This category of views are sometimes called “controlled” or “regulatory rationing” because legislators take primary control of allocating resources and weighing social costs and benefits in order to set priorities.¹⁵⁴ Conceptually, regulatory approaches to rationing merge with technocratic models. Technocratic allocation is managed by a group of experts and is authoritatively designed. The main criticism of the technocratic approach is that it is too centralized and does not involve enough public input or fair procedures. Democratic approaches ensure widespread public input and open local and national dialogue in distributing health services and goods.

E. DELIBERATIVE DEMOCRATIC PROCEDURES

Given the persistent disagreement about principles governing resource allocation, some argue that we must retreat to fair deliberative processes.¹⁵⁵ This approach abandons “direct appeals to theories of justice,” using instead “a finely honed understanding of the democratic process . . . to reach decisions about priorities.”¹⁵⁶ Fleck supports the use of democratic political procedures to make micro-allocational decisions by reaching a “reasoned agreement” on a “collective standard.”¹⁵⁷ Daniels and Sabin advocate publicly accessible decision-making for managed care decisions,¹⁵⁸ while Amy Gutmann and Dennis Thompson have identified certain procedural and substantive principles to ensure fair deliberative processes.¹⁵⁹ These proposals have been criticized for providing little guidance on the “rightness of the rationales put forward . . . e[or] any assurance of substantively just outcomes.”¹⁶⁰

In some democratic approaches to allocating resources, citizens, as payers of insurance and consumers of health-care, are involved in democratic deliberation and allocation decisions.¹⁶¹ Such approaches are con-

¹⁵² *Allocating Health*, *supra* note 110, at 1456.

¹⁵³ See, e.g., *Health Care Rationing*, *supra* note 7.

¹⁵⁴ See *Regulatory Rationing*, *supra* note 144.

¹⁵⁵ See, e.g., *Health, and Healthcare*, *supra* note 19.

¹⁵⁶ TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* (fifth edition 2001) at 258 [hereinafter *BIOMEDICAL ETHICS* 2].

¹⁵⁷ *Health Care Rationing*, *supra* note 7, at 1601.

¹⁵⁸ *SETTING LIMITS FAIRLY*, *supra* note 8.

¹⁵⁹ See generally AMY GUTMANN & DENNIS THOMPSON, *DEMOCRACY AND DISAGREEMENT* (1996).

¹⁶⁰ *Inequalities in Health*, *supra* note 65, at 115.

¹⁶¹ See, e.g., *SETTING LIMITS FAIRLY*, *supra* note 8.; *HUMAN LIFE*, *supra* note 82; *Health Care Rationing*, *supra* note 7; Howard M. Leichter, *Political Accountability in Health Care*

sidered fair because they are determined by patient choice. Anderson, for example, argues that individual autonomy is realized on a collective scale through democratic institutions.¹⁶²

One democratic decision-making model is the “informed democratic consensus model,”¹⁶³ which proposes a district health council composed of about fifty citizens. Each council would elect one person to serve as its representative to a national health congress, which would oversee a single comprehensive health plan. The national legislature would set the overall budget for the plan, and the national health congress would establish priorities and rationing protocols.

All of these prototypes espouse the principles of autonomy, political equality, deliberation, and explicit public processes. Fleck also proposes “constitutional principles of healthcare justice”¹⁶⁴ that would “avoid . . . giving political legitimacy to results of the deliberative process that are seriously unjust.”¹⁶⁵ Patients have the most stake in health allocation decisions, Fleck argues, because they are the recipients of care as well as the payers of health care, in taxes, insurance premiums, co-pays, deductibles, user fees, and other charges. The endpoint would be a set of rationing protocols, such as a list of services covered to which all would have to adhere.¹⁶⁶

A number of criticisms of democratic procedures have emerged in the literature. Some argue, for example, that neither Daniels’ approach nor other theories of just processes are ever entirely culture-free, abstract, or universal.¹⁶⁷ Others criticize Daniels’ account of the conditions of procedural fairness on the grounds that the “relevance condition” is too normative.¹⁶⁸ Since accepted reasons in a democratic process may be “theory-laden, or embedded in particular conceptions of justice,”¹⁶⁹ it might be difficult for participants to choose among competing principles

Rationing: In Search of a New Jerusalem, 140 U. PA. L. REV. 1939 (1992); James A. Morone, *The Bias of American Politics: Rationing Health Care in a Weak State*, 140 U. PA. L. REV. 1923 (1992); Jack H. Nagel, *Combining Deliberation and Fair Representation in Community Health Decisions*, 140 U. PA. L. REV. 1965 (1992).

¹⁶² ELIZABETH ANDERSON, *VALUE IN ETHICS AND ECONOMICS* (1993) [hereinafter *VALUE IN ETHICS*].

¹⁶³ *Health Care Rationing*, *supra* note 7, at 1617.

¹⁶⁴ Leonard Fleck, *Healthcare Justice and Rational Democratic Deliberation*, 1(2) *AM. J. BIOETHICS* 20 (2001).

¹⁶⁵ *Id.* at 20.

¹⁶⁶ Sarah Rosenbaum, *Mothers and Children Last: The Oregon Medicaid Experiment*, 18 *AM. J. L. & Med.* 97 (1992).

¹⁶⁷ See Mark H. Waymack, *Daniels on Justice and Healthcare: Laudable Goals - Questionable Method*, 1(2) *AM. J. BIOETHICS* 28 (2001); *WHOSE JUSTICE*, *supra* note 6.

¹⁶⁸ See Samuel Gorovitz, *Justice in Healthcare and Dimpled Chads*, 1(2) *AM. J. BIOETHICS* 29 (2001).

¹⁶⁹ *Inequalities in Health*, *supra* note 65, at 115.

of justice “in a particular distributive context.”¹⁷⁰ Emanuel argues that Daniels use of democratic political procedures as a “last resort” to “resolve all remaining problems” when defining policy is based on a conception of democratic political procedure that is practical, not philosophical. Currently, these frameworks have provided little guidance on *how* to agree on principles of justice or what the *content* of those principles should entail. They also provide little guidance on the evaluation of the outcomes of such procedures. As a result, deliberative democratic approaches raise objections about indeterminacy,¹⁷¹ given the “risk that no solution will emerge from the deliberation because the depth of moral disagreement is so great.”¹⁷²

Still others argue that using democratic procedures at the micro-allocational level to ration health care affords less respect for autonomy than does *ex ante* choice.¹⁷³ Emanuel criticizes collective political procedures for not permitting an agreed-upon, substantive conception of the “good life.”¹⁷⁴ For Beauchamp and Childress, it is “relatively unclear about what makes democratic procedures fair, how to protect against unfair outcomes, whether citizen deliberators could ever satisfy the demands of true deliberative democracy, and how much real agreement they could reach.”¹⁷⁵ Additionally, Hadorn has noted that deliberative democratic decisions tend to be most difficult to implement, given the tendency to “rescue” suffering patients, even if their condition is not covered.¹⁷⁶ Moreover, such deliberations would have to consider the costs and benefits of thousands of treatment options for thousands of diseases, a task too onerous to produce fair rationing policies. Another criticism is that “majority preferences, no matter how well informed and fair, will sometimes eventuate in unjust outcomes.”¹⁷⁷ Therefore, a purely, or even primarily, procedural mechanism could “return us to the same failures of justice that we have already encountered in health care.”¹⁷⁸

While all of these approaches strive for a just distribution of health-care resources, one medical ethicist notes that “discordant positions, irresolution, and an exhausted uncertainty seem the only conclusive products of three decades of discussion on medical ethics.”¹⁷⁹

¹⁷⁰ *Id.* at 116.

¹⁷¹ HUMAN LIFE, *supra* note 82, at 32-34.

¹⁷² *Inequalities in Health*, *supra* note 65, at 115.

¹⁷³ See, e.g., *Rationing Through Choice*, *supra* note 108, at 1096.

¹⁷⁴ HUMAN LIFE, *supra* note 82, at 144.

¹⁷⁵ See BIOMEDICAL ETHICS 2, *supra* note 158, at 258.

¹⁷⁶ *Care Priorities*, *supra* note 57.

¹⁷⁷ See BIOMEDICAL ETHICS 2, *supra* note 158, at 258.

¹⁷⁸ *Id.*

¹⁷⁹ HUMAN LIFE, *supra* note 82, at 6.

F. SUMMARY OF PROBLEMS WITH THE CURRENT SET OF FRAMEWORKS

This section has examined a number of critical issues pertaining to the current set of frameworks in health ethics, policy and law. In the process, some major themes have emerged.

First, existing frameworks, even those that include health assessment, have typically justified *health care* as a special social good. Universal concerns of social justice with respect to *health* itself have received less attention. More work must focus on the question of why *health*, as opposed to *health care*, has special moral importance.¹⁸⁰ The traditional bias seems to stem from at least one assumption: that health is not an appropriate focal variable for assessing social justice, whereas utilities, community values, liberties, opportunities, resources and primary goods are. As Daniels argues, “health is an inappropriate object, but health care, action which promotes health, is appropriate.”¹⁸¹ He and others emphasize that, “a right claim to equal *health* is best construed as a demand for equality of access or entitlement to health *services*.”¹⁸² Such reasoning illustrates a bias against health as a focal variable in current frameworks. However, the focus on health care has led one to believe that the major inequity in health policy is differential access to care, not differences in health.¹⁸³ This emphasis has left a void on the philosophical foundations of health and its distribution.¹⁸⁴

Second, efforts to establish fair procedures for allocating resources claims more attention than the development of substantive and procedural principles for prioritizing health-related goods and services. This imbalance stems, in part, from the way in which medical ethics. Establishing a right to health care has been central for decades and has thrust the field into a plethora of efforts to determine the content of a right to health care.¹⁸⁵ Despite the emphasis on fair procedures, moreover, there is little agreement on how and whether to specify such a right.¹⁸⁶ However, the focus on democratic procedures as a way of dis-

¹⁸⁰ See generally *Justice and Health Policy*, *supra* note 15; ARISTOTELIAN JUSTICE *supra* note 15; Jennifer Prah Ruger, *Health and Development*, 362 LANCET 678 (2003) [hereinafter *Health and Development*].

¹⁸¹ JUST HEALTH CARE, *supra* note 19, at 6.

¹⁸² *Id.* at 7.

¹⁸³ See Dan Brock, *Broadening the Bioethics Agenda*, 10 KENNEDY INST. ETHICS JOURNAL 21 (2000) [hereinafter *Bioethics Agenda*]; TIMOTHY EVANS ET AL., *Introduction to CHALLENGING INEQUITIES IN HEALTH: FROM ETHICS TO ACTION*, 48 (Timothy Evans et al. eds., 2001).

¹⁸⁴ See *Right to Health*, *supra* note 22, for a philosophical justification of health and its distribution.

¹⁸⁵ See, e.g., *Minimum of Health Care*, *supra* note 48; JUST HEALTH CARE, *supra* note 19; *Right to Health*, *supra* note 22.

¹⁸⁶ See *Inequalities in Health*, *supra* note 65, at 111; *Agency and Quality*, *supra* note 23.

tributing health care leaves scholars without a moral theory of prioritization and resource allocation and neglects the importance of individual and social agency. It also leaves the field without a principled approach to the problem of giving priority to the most disadvantaged and improving the overall health of the population.¹⁸⁷

Third, there is a need for workable frameworks to guide collective choices about valuable social ends and their tradeoffs. It is clear that purely procedural strategies are limited in their application to health ethics, policy and law. However, it is less clear which methodology might best elicit individual preferences for health states and incorporate them into a collective choice,¹⁸⁸ or whether this is the route to pursue at all. CEA, CUA and CBA have encountered criticism on a number of grounds, including their indifference to distributional effects and the plight of the worse off.¹⁸⁹ Although there have been efforts to quantify equity concerns and include them in cost-utility models,¹⁹⁰ such approaches still lack a deliberative component that enables groups to reach “reflective considered judgments.”¹⁹¹

A fourth theme involves the question of whether individual, or social, preferences and values should prioritize social goals and interventions aimed at reaching those goals. While preferences based on societal values should be included in CEA as the public’s distributive preferences,¹⁹² it is unclear what role these preferences might play in the development of public policy.¹⁹³

Fifth, public reasoning should receive more emphasis than formal quantitative, aggregative or purely procedural methods for making health policy. Thus, there has been more focus on “accountability for reasonableness” than on understanding how individuals and groups value different aspects of health and agree upon decisions. Eliciting an acceptable public response about resource allocation requires greater clarity about shared moral values. The field of health ethics, policy and law has much to learn from work in the fields of social choice and public choice theory.

¹⁸⁷ See *Bioethics Agenda*, *supra* note 183, at 28-29.

¹⁸⁸ See *Social Values*, *supra* note 71.

¹⁸⁹ See *Bioethics Agenda*, *supra* note 183.

¹⁹⁰ See, *eg.*, COST-VALUE ANALYSIS, *supra* note 70; PETER UBEL, *PRICING LIFE* (2000).

¹⁹¹ *Bioethics Agenda*, *supra* note 183, at 29.

¹⁹² See COST-VALUE ANALYSIS, *supra* note 70, at 89-90 (discussing whom to ask about health-related quality of life in order to assess distributive preferences); *Social Values*, *supra* note 71, at 258-59.

¹⁹³ See *Inequalities in Health*, *supra* note 65, at 114-19 (discussing three approaches to creating empirical guides for setting health-care priorities and policies).

Sixth, existing frameworks fail to ensure justice in rationing because they are indeterminate and do not solve the four rationing problems noted above.¹⁹⁴ Related to these issues are more specific concerns:

- (1) Using maximum benefit, utilities, or best outcomes as a basis for resource allocation confers lower priority to those who might benefit less from the use of a limited resource;¹⁹⁵
- (2) A strong focus on helping those in greatest need must reconcile the trend towards avoidance of the so-called “bottomless pit problem;”¹⁹⁶
- (3) Summation techniques fail to respect individuality;¹⁹⁷
- (4) Incommensurability: that all benefits are not equal and therefore cannot be assessed according to a single metric (money in CBA, and utilities in CUA);¹⁹⁸

¹⁹⁴ See *A Challenge*, *supra* note 7, at 27–29. See Norman Daniels, *Justice, Fair Procedures, and the Goals of Medicine*, 26 HASTINGS CENTER REP. 10 (1996); and Norman Daniels, *Liberalism and Medical Ethics*, 22 HASTINGS CENTER REP. 41 (1992) [hereinafter *Medical Ethics*].

¹⁹⁵ See Erik Nord, *The Relevance of Health State after Treatment in Prioritising Between Different Patients*, 19 J. MED. ETHICS 37, 37–39 (1993) [hereinafter *Health State*]. In an empirical study of Norwegian subjects, Nord found that individuals “tended to emphasise [sic] equality in value of life and in entitlement to treatment rather than level of health after treatment” when asked about their ethical preferences in prioritizing among health programs.

¹⁹⁶ See Erik Nord, *The QALY – A Measure of Social Value Rather than Individual Utility?*, 3 HEALTH ECON. 89 (1994) [hereinafter *The QALY*]; *Health State*, *supra* note 195, at 39–41; Erik Nord et al., *Maximizing Health Benefits vs. Egalitarianism: An Australian Survey of Health Issues*, 41 SOC. SCI. & MED. 1429, 1433–34 (1995) [hereinafter *Health Benefits*]; HEALTH ECONOMICS, *supra* note 41, at 27–29. In their empirical studies of ethical preferences, Nord et al., are increasingly finding that individuals are reluctant to deny benefits to patients who have less potential for health than others.

¹⁹⁷ The utilitarian notion of maximizing collective or social benefit disregards the separateness of persons. By measuring utility on a single quantitative scale, it posits global population utility as being experienced by one individual. Korsgaard in particular argues that one cannot apply a principle of “moral addition” by combining the respective assessments of happiness of two different individuals. See *We Can Share*, *supra* note 56, at 29. Rai, however, argues that these criticisms about utilitarianism are ungrounded because:

The[y]. . . are based on two faulty assumptions: first, that benefit or utility maximization would be an ex post calculation; and second, that such maximization would be imposed on individuals by an external decisionmaker. By contrast, the central issue for just distribution of scarce health care resources must be what distribution scheme individuals choose ex ante.

Rationing Through Choice, *supra* note 108, at 1061.

¹⁹⁸ See Cass Sunstein, *Incommensurability and Valuation in Law*, 92 MICH. L. REV. 779, 796 (1994) [hereinafter *Valuation in Law*] (“incommensurability occurs when the relevant goods cannot be aligned along a single metric without doing violence to our considered judgments about how these goods are best characterized.”) In terms of health, this means that different health conditions, such as deafness, blindness, cardiovascular disease, diabetes, depression, cystic fibrosis, autism, and loss of limb cannot be compared because differing values cannot be reduced to a unitary quantitative scale. Critics of commensurability differ in the degree to which different values can be compared. Sunstein, for example, does not rule out the ordinal or qualitative ranking of values, though he sees no ethical foundation in their cardinal comparison. Sunstein also believes, as do Anderson and I, that individual and collective

- (5) A lack of a reasonableness threshold: aggregation techniques can produce results that defy clinical judgment by, for example, ranking life-saving treatments below¹⁹⁹ those that improve quality of life;²⁰⁰

rational choices can be made among incommensurate alternatives. *Id.* at 809, n.108 (discussing Anderson); VALUE IN ETHICS, *supra* note 162, at 59–64. See generally ARISTOTELIAN JUSTICE *supra* note 15; *Right to Health*, *supra* note 22. For more on incomplete theorization, see Cass Sunstein, *Incompletely Theorized Agreements*, 108 HARV. L. REV. 1733 (1995) [hereinafter *Agreements*]. Raz holds a slightly different view—that rational choices cannot be made among incommensurable or incomparable alternatives. See MORALITY, *supra* note 114, at 339 (discussing that choices made between incommensurate options appear rational because the actor has made a comparative value between the options). For more on this, see generally Martha C. Nussbaum, *Plato on Commensurability and Desire*, in LOVE'S KNOWLEDGE: ESSAYS ON PHILOSOPHY AND LITERATURE (Martha C. Nussbaum ed., 1990).

¹⁹⁹ An extension of the commensurability problem occurs when one compares improvements in health status with saving or extending life. For example, in employing QALY maximization, 2 years of additional life with a 0.5 quality adjustment is deemed equivalent to one year of additional life with no quality adjustment (e.g., a fully healthy life). In addition, saving the life of 25 people for one year is deemed equivalent to saving the life of five people for five years or one person for twenty-five years. Kamm argues that individuals' judgments regarding aggregation differ when saving lives are at issue because any other change in health status (increase or decrease) cannot compete with life saving as a health outcome. See generally MORALITY, *supra* note 114. See *Rationing Through Choice*, *supra* note 108, at 1067 (discussing why these concerns about incommensurability do not “invalidate QALY maximization as an ex ante rationing choice.”). Rai claims that even incommensurabilists would “find QALY maximization to be the ex ante decision principle that most accurately reflected the trade-offs they would make between cost and various types of health benefit.” *Id.* at 1068.

²⁰⁰ See *Care Priorities*, *supra* note 57, at 2219–220 (invoking the “rule of rescue” value, whereby individuals and the public at large value saving identifiable lives as a higher-order value); *The QALY*, *supra* note 196, at 92 (noting the QALY concept does not “work in comparisons of life saving interventions with interventions that improve health or increase life expectancy.”). There are two issues here: one is whether there is a real and significant higher-order value in saving “identifiable lives” over both saving “statistical lives” and providing other health benefits. The second is whether there is a real and significant higher-order value in saving all lives (both identifiable and statistical) over providing other health benefits. Hadorn (*Care Priorities*, *supra* note 57), Tolley, Kenkel, and Fabian (*ECONOMIC APPROACH*, *supra* note 50), and Eddy (David M. Eddy, *The Individual vs. Society: Is There Conflict?*, 265 JAMA 1446-50 (1991) [hereinafter *Individual vs. Society*]; David M. Eddy, *Oregon's Methods: Did Cost-Effectiveness Fail?*, 266 JAMA 2135, 2140 (1991) [hereinafter *Oregon's Method*]) all note that saving identifiable lives has “symbolic” or “altruistic” value or even “vicarious utility” that providing other health benefits does not. Gibbard argues that although these values are irrational and will not maximize life due to the higher-order ranking of “identifiable lives” over “statistical lives,” symbolic or expressive values embody “compassion” and strengthen the “social fabric” of a society. *Interpersonal Comparisons: Preference, Good, and the Intrinsic Reward of a Life*, in THE FOUNDATIONS OF SOCIAL CHOICE THEORY 165–193 (J. Elster and A. Hylland, eds., 1986). Hadorn, however, argues that saving identifiable lives should not be traded for other health benefits. See *Care Priorities*, *supra* note 57, at 22a9-2225. See also John Harris, *QALYfing the Value of Life*, 13 J. MED. ETHICS 117 (1987) (stating that identifiable lives should have lexical and higher-order priority). My view aligns closely with those of Pildes and Anderson (see generally Richard H. Pildes & Elizabeth S. Anderson, *Slinging Arrows at Democracy: Social Choice Theory, Value Pluralism, and Democratic Politics*, 90 COLUM. L. REV. 2121, 2145-61 (1990)) and Sunstein (See generally *Valuation in Law*, *supra* note 200), who support higher-order values but do not endorse lexical ordering that protects certain values against all trade-offs. See ARISTOTELIAN JUSTICE, *supra*

- (6) Indeterminacy: The indeterminacy of distributive principles for guiding resource allocation is especially problematic in pluralistic environments where participants cannot agree about moral constraints on rationing;
- (7) Adaptive preferences: if preferences are used to allocate resources, there is some disagreement as to whose preferences should take priority²⁰¹ (e.g., those of citizens,²⁰² medical experts, patients, payers, regulators, etc.). Those with particular health conditions and disabilities have been found to modify their preferences to cope with their conditions; different preferences can result in underestimating or overestimating treatment benefits;²⁰³
- (8) Methods for eliciting preferences, costs and benefits differ and produce different results (e.g. WTP, WTA, CV, standard gamble, rating scale.) In the Oregon experiment, some argue concerns over the accuracy of measured costs and benefits discredited the cost-utility methodology;²⁰⁴
- (9) Decisions about benefits packages are unresolved: whether to guarantee and/or mandate a benefits package, which services to include and exclude, whether to provide a floor and/or a ceiling for benefits, whether to guarantee a decent minimum, a basic benefits package, or a comprehensive benefits package;

note 15; *Right to Health*, *supra* note 22; *Justice and Health Policy*, *supra* note 15. This view is concordant with the culture and ethics of the health profession. For a discussion on physician obligations of beneficence, see *BIOMEDICAL ETHICS*, *supra* note 47.

²⁰¹ See Jeff Richardson & Erik Nord, *The Importance of Perspective in the Measurement of Quality-Adjusted Life Years*, 17 *MED. DECISION MAKING* 33, 41 (1997). Nord and Jeff Richardson found that perspectives (e.g., personal or impersonal) for eliciting preference can significantly alter the values incorporated into QALY analysis. See *The QALY*, *supra* note 196, at 92.

²⁰² See Joanna Coast, *Citizens, Their Agents and Health Care Rationing: An Exploratory Study Using Qualitative Methods*, 10 *HEALTH ECON.* 159, 159 (200d). In the context of incorporating patient preferences into resource allocation decisions, a U.K. study found that “citizens vary considerably in the extent to which they want to be directly involved in making rationing decisions.” This variation related to “knowledge and experience, objectivity and the potential distress that denying care may cause.”

²⁰³ Norman Daniels, *Rationing Fairly; Programmatic Considerations*, 7(2-3) *BIOETHICS* 224-33 (1993).

²⁰⁴ The counterargument is that completely accurate measurement of costs and benefits is impossible to achieve, especially when multiple benefits and harms are involved. See generally *Individual vs. Society*, *supra* note 202 (arguing that benefits to certain individuals are sometimes achieved only at a cost to overall societal health), and *Oregon's Method*, *supra* note 202 (arguing that allocating state Medicaid on a cost-effectiveness basis failed because it measured medical benefits by outcomes provided to individuals rather than services provided to society). The Panel on Cost-Effectiveness was convened in part to answer some of these questions and standardize CEA in health and medicine, see generally *PANEL REPORT*, *supra* note 44.

- (10) Differences in view on what information to include in resource allocation:²⁰⁵ (e.g. prevalence, incidence, effectiveness in terms of quality-of-life, life-extending, life-saving effects, overall economic impact on society, medical necessity, costs, and some measure of economic efficiency measure such as CEA, CUA or CBA);
- (11) Unjust outcomes: if open and democratic processes determine resource allocation, then the decisions might or might not be just or consistent with clinical judgment; should they be accepted as a matter of procedural justice or be evaluated for substantive content; and
- (12) Costs and Efficiency: some liberal theories (e.g. equality of opportunity) do not adequately address scarcity and efficiency, set limits, or incorporate costs into their frameworks.

This critical review demonstrates that the academic area of health ethics, policy and law is at a crossroads; oscillating between two dichotomous paradigmatic positions: consequentialism and proceduralism – which adherents often present as mutually exclusive. Consequentialists argue that we should assess health policies and laws by their consequences; proceduralists believe that fair processes will yield fair decisions. Thus far, neither end of the philosophical spectrum has promised or delivered a plausible solution, and attempts to incorporate both positions have been unsatisfactory. As a result, the field is at a standstill. Any movement forward involves elements of both the consequentialist and proceduralist frameworks. Bearing both frameworks in mind, this Article proposes a capability and health account which focuses on the ability of health systems to provide the conditions under which individuals have the capability for health.

II. AN ALTERNATIVE PARADIGM: CAPABILITY AND HEALTH ACCOUNT²⁰⁶

A capability and health account, building on and integrating Amartya Sen's capability approach and Aristotle's political philosophy, contrasts with traditional health ethics, policy and law in arguing that health capability, as opposed to health care, has special moral importance

²⁰⁵ An analysis in the United Kingdom discusses the issues that arise in presenting "complex [medical] information" to patients and supports patients' ability to "take part in the rationing debate." See S. McIver, *Information for Public Choice*, 51 BRIT. MED. BULL. 900, 91a (1995).

²⁰⁶ See ARISTOTELIAN JUSTICE, *supra* note 15 and *Right to Health*, *supra* note 22, for key elements of a theoretical framework embodying an account of capability and health that builds on and integrates Aristotle's political theory, Sen's capability approach and a social choice paradigm known as incompletely theorized agreements. This section summarizes only a few major aspects of this theoretical framework and draws from *Social Justice*, *supra* note 15.

because of its status as an end of political and societal activity.²⁰⁷ This view draws on Aristotle's contention that society is obligated to promote "human flourishing,"²⁰⁸ the ability to live a flourishing life. Flourishing is critical to the human condition and health sustains other aspects of human flourishing because, without being alive, no other human functionings are possible, including agency, the ability to lead a life one has reason to value.²⁰⁹ Public policy should therefore focus on the ability to function, and health policy should aim to maintain and improve this ability by meeting health needs and ensuring the conditions for health agency.²¹⁰ This view values health intrinsically and more directly than solely "instrumental" social goods such as income or health care. It gives special moral importance to what I call health capability; an individual's ability to achieve good health and thus avoid preventable morbidity and premature death.²¹¹ A capability and health account also considers human agency. Permitting people to exercise their agency enables them to value and prioritize health domains (e.g. to trade-off quality and quantity of life) and health services.²¹²

A. AN AGENCY-ORIENTED VIEW

As discussed above, the capability approach is an agency-oriented view. Agency is important for public policy because it supports individuals' direct participation in "economic, social and political actions" and enables individuals to make decisions "as active agents of change."²¹³ This approach contrasts with the view that individuals are passive recipients of medical care, medical expenditure decisions, or other public policies. Thus, the agency-centered view promotes individuals' ability to understand and "shape their own destiny and help each other."²¹⁴ From a capability perspective, exercising personal freedom and participating in social choice should shape and influence policy and institutions.²¹⁵ And "[p]olitical and civil rights, especially those related to the guaranteeing of open discussion, debate, criticism, and dissent, are central to the

²⁰⁷ See generally ARISTOTELIAN JUSTICE, *supra* note 15; *Health and Development*, *supra* note 180, at 678; *Social Justice*, *supra* note 15, at 1075.

²⁰⁸ NICOMACHEAN ETHICS, *supra* note 12; THE POLITICS, *supra* note 12; *Human Functioning*, *supra* note 12, at 202-46; *Good as Discipline*, *supra* note 12, at 312-41; *Political Distribution*, *supra* note 12, at 152-86. Both Sen and Nussbaum have advanced versions of the capability approach, while I draw on both to develop theory, I build to a greater extent on Sen's version.

²⁰⁹ See generally COMMODITIES, *supra* note 11; FREEDOM, *supra* note 16; and INEQUALITY, *supra* note 11.

²¹⁰ *Social Justice*, *supra* note 15, at 1075; ARISTOTELIAN JUSTICE, *supra* note 15.

²¹¹ See *Social Justice*, *supra* note 15, at 1076.

²¹² *Id.*

²¹³ FREEDOM, *supra* note 16, at xiii.

²¹⁴ *Id.* at 11.

²¹⁵ *Id.* at 5.

processes of generating informed and reflected choices.”²¹⁶ Under this view, public policy is a process that expands individual freedom.

Another implication of an agency-oriented view is the interrelationship between health and agency.²¹⁷ Good health enables individuals to affect public policy and to participate in individual, political and social decision-making, both inside and outside the health sector. The opportunity to exercise one’s agency might also relate to an individual’s health because impaired agency through, for example, overt or insidious oppression, can reduce mental and physical functioning.

B. POLICY IMPLICATIONS

A capability and health account has several implications for public policy. First, such a view is important for assessing social inequalities and evaluating the effects of social policy on broader health determinants.²¹⁸ Unlike Daniels and his colleagues, who advocate policies “aimed at equalizing individual life opportunities, such as investment in basic education, affordable housing, income security, and other forms of antipoverty policy,”²¹⁹ a capability and health account emphasizes the need to evaluate both health and health policy in a larger policy context, which requires a broader understanding of social justice. From a capability point of view, it is argued, health and its determinants must be weighed in relation to other social ends in an inclusive and democratic discussion about the ends and means of public policy, and specifically health policy.²²⁰

This approach to health also argues, however, that health care is important and special. Due to its influence on health, society must guarantee healthcare so that health improves overall and health inequalities attributable to health care diminish.

This account does not provide a detailed list or specification of which type of health care should be guaranteed or to what level. Rather, although it can help identify the parameters of a comprehensive benefits package, it recognizes the need for further specification through a process that combines both substantive and procedural principles: a joint scientific and deliberative approach (discussed below). Substantively, Sen’s notion of “basic capabilities” provides guidance. This Article ex-

²¹⁶ *Id.* at 153.

²¹⁷ *Social Justice*, *supra* note 15; *Health and Development*, *supra* note 180; Jennifer Prah Ruger, *Combating HIV/AIDS in Developing Countries*, 329 *BRIT. MED. J.* 121, 121 (2004) [hereinafter *Combating HIV/AIDS*].

²¹⁸ Jennifer Prah Ruger, *Ethics of the Social Determinants of Health*, 364 *LANCET* 1092, 1092-97 (2004) [hereinafter *Social Determinants*].

²¹⁹ *OUR HEALTH*, *supra* note 102, at 25.

²²⁰ *Social Justice*, *supra* note 15, at 1076; *See generally Social Determinants*, *supra* note 218.

tends this formulation to health and generally argues for societal efforts to bring each individual's functioning as close as possible to, or above, a certain threshold functioning level (insofar as an individual's circumstances permit). "Basic capabilities" include the ability to avoid escapable morbidity and premature death. Regarding how much priority to give to society's worst-off individuals, this account promotes the use of "public reasoning" to forge a compromise between strict maximization and prioritization²²¹ (discussed below).

This "process aspect" of freedom in the capability approach has implications for health-related policy formulation. It emphasizes an individual's ability to participate in broad public policy decision-making (e.g. in prioritizing military versus health care programs) and health policy decision-making (e.g. in prioritizing domains of health and health care for resource allocation).

A joint scientific and deliberative approach can help define a comprehensive benefits package to which all should have equal access, and help prioritize different types of health care in order to maintain and improve health with the fewest possible resources. Such a process is not merely instrumental, however, this approach values individuals' role in decision-making that affects them. It also insists that valid and reliable information on benefits, risks and costs should inform the decision-making process.

This account does not divorce the equity implications of access to health care from the equity implications of its financing. Rather, it stipulates that resources be allocated on the basis of medical necessity and medical appropriateness (discussed below), rather than ability to pay.²²² From this perspective, "protective security,"²²³ through health insurance, is a necessary safety net.²²⁴ And all should share the economic burden of health care by redistributing funds from the rich to the poor and the well to the ill through community rating and progressive financing.²²⁵

An ethical framework that intrinsically values health necessitates the conceptualization and measurement of health and inequalities in its many domains.²²⁶ Even within this perspective, one must determine the most appropriate set of inequality measures for a given exercise. Else-

²²¹ *Social Justice*, *supra* note 15, at 1076; *See generally Social Determinants*, *supra* note 218.

²²² *See Social Justice*, *supra* note 15, at 1077.

²²³ FREEDOM, *supra* note 16, at 45.

²²⁴ *Social Justice*, *supra* note 15, at 1077. *See also Catastrophic Health*, *supra* note 36.

²²⁵ *Social Justice*, *supra* note 15, at 1077.

²²⁶ *See* Sudhir Anand et al., *Measuring Disparities in Health*, in CHALLENGING INEQUALITIES IN HEALTH 48, 50 (Timothy Evans et al. eds., 2001).

where, I have argued for using “shortfall equality” as a measure for evaluating deprivations in health capabilities.²²⁷

C. INCOMPLETELY THEORIZED AGREEMENTS

Incomplete theorization is usefully applied to health ethics, policy and law because it provides a model for understanding collective decision-making on human goods that are plural and fuzzy, such as health and inequality.²²⁸ It also enables people to take different paths to common, often partial, agreements. Incomplete theorization describes how people with divergent, even opposing, views on health, equity, health policy and law might agree in specific situations, and thus, generate decisions that are legitimate, stable and mutually respectful.²²⁹

An *incompletely theorized agreement (ITA)*, as developed by Cass Sunstein, is not uniformly theorized at all levels, and ranges from high-level justifications to low-level particulars.²³⁰ I employ ITA to extend and operationalize the capability approach at three different levels.²³¹ The first level is the conceptual level, which specifies the valuable functionings that constitute human flourishing and health. The second level is the policy level, which specifies policies and laws. The third level is the intervention level, which specifies actions in particular cases and decisions about medical treatments, public health interventions or social services.²³² Three types of ITA constitute the model: incompletely specified agreements, incompletely specified and generalized agreements, and incompletely theorized agreements on particular outcomes.

Incompletely specified agreements occur when there is agreement on a general principle but sharp disagreement about particular cases. For

²²⁷ ARISTOTELIAN JUSTICE *supra* note 15; *Justice and Health Policy supra* note 15; *Right to Health, supra* note 22; Jennifer Prah Ruger and Hak-Ju Kim, *Global Inequalities: An International Comparison*, 60 J. EPIDEMIOLOGY & COMMUNITY HEALTH, (in press 2006); Jennifer Prah Ruger, *Measuring Disparities in Health Care*, BRIT. MED. J., 333, 274 (2006) [hereinafter *Healthcare Disparities*].

²²⁸ See ARISTOTELIAN JUSTICE, *supra* note 15. See also, *Justice and Health Policy, supra* note 15, *Theorized Agreements, supra* note 30.

²²⁹ See *Social Justice, supra* note 15, at 1077.

²³⁰ See *Agreements, supra* note 198 at 1739.

²³¹ It is important to note, before moving on, that the ITA framework is applied here *only* to one aspect of the Aristotelian and capability points of view—that of the social choice exercise of coming to agreement — thus the use of ITA in this framework is one aspect of the theory, which complements, rather than substitutes, for the capability or Aristotelian viewpoint.

²³² See generally ARISTOTELIAN JUSTICE, *supra* note 15; *Justice and Health Policy, supra* note 15. On obtaining collective agreement on the selection and weighting of health capabilities, see *Right to Health, supra* note 22. For an analysis of U.S. health reform from the perspective of value-based arguments of different levels of generality, see generally Jennifer Prah Ruger, *Health, Health Care and Incompletely Theorized Agreements: A Normative Theory of Health Policy Decision-Making*, 32 J. HEALTH, POLITICS, POLICY & LAW (in press 2007) [hereinafter *Normative Theory*].

example, in the health policy and law context, citizens might agree that the high-level principle utilitarianism is the underlying ethical principle of health policy and law. Despite their focus on the greatest social good, they might also agree that beta-interferon, a drug that helps some individuals with multiple sclerosis (MS), should be provided to MS patients even though its cost per QALY ranges from \$35,000 to \$20 million. Or they may agree that kidney dialysis ought to be provided despite its very expensive cost for relatively small improvements in health-related quality-of-life.²³³

Incompletely specified and generalized agreements occur when people agree on a mid-level principle but disagree about both the more high-level theory that accounts for it and the outcomes generated by particular controversies. In the health policy and law context, for example, citizens might agree that all should have access to life saving interventions, but disagree on the underlying philosophical justification for this view and on whether all life saving interventions at all ages should be made available.²³⁴

Incompletely theorized agreements based on particular outcomes describe how people agree on particular policy options and legal decisions. In this model, parties agree on low-level principles that are not necessarily derived from a particular high-level theory of the right or the good. People might agree, for instance, that governments should eradicate malaria, prevent famine and prohibit genital mutilation, but they might not know exactly why they hold such beliefs.²³⁵ This aspect of the framework complements the capability approach's emphasis on partial agreements and workable solutions, which can be "based on the contingent acceptance of particular provisions, without demanding complete social unanimity."²³⁶

For these reasons and those articulated elsewhere, the ITA framework is useful in developing a capability and health account. If we are to develop a new paradigm of health ethics, policy and law, we must construct a framework that permits us to prioritize health goods and services amidst widespread disagreement. Policy evaluation poses these difficulties in particular contexts. The combination of the capability and ITA approaches enables reasoned agreement on particular health interventions without resolving all the incompleteness of such choices.

²³³ See *Social Justice*, *supra* note 15, at 1078; *ARISTOTELIAN JUSTICE*, *supra* note 15.

²³⁴ See *Social Justice*, *supra* note 15, at 1078a

²³⁵ See *id.*

²³⁶ See *FREEDOM*, *supra* note 16, at 253.

III. APPLICATIONS

A. EQUITABLE ACCESS TO HIGH-QUALITY HEALTH CARE²³⁷

1. *A Capability and Health Account of Equal Access*²³⁸

The paradigm presented here evaluates the impact of healthcare on individuals' capability to function.²³⁹ It assesses what I call health capability by examining health needs,²⁴⁰ health agency,²⁴¹ and health norms.²⁴²

This approach to equal access rests on Aristotle's principle of just distribution, or proportional justice, that like cases should be treated similarly and unlike cases differently,²⁴³ in proportion to their difference. This account is primarily needs-based and cases are considered alike if they have the same health need and unlike if they have different health needs. Below I take this line of inquiry a step further, arguing that healthcare must be medically necessary and medically appropriate. This theory supports the allocation of resources to those with health needs in efforts to bring them as close as possible to a threshold level of functioning as their circumstances permit. Thus, the *quality* of health care provided to all should be measured by its ability to address the functional impairment arising from injury or illness.

For health care, this paradigm implies that the government should make efforts to bring each individual's health functioning as close to a certain threshold level of functioning as possible, insofar as an individual's circumstances permit, but that these efforts not sacrifice the health functioning of others below the threshold functioning range. There is considerable discussion about how much priority to give society's disadvantaged. Elsewhere I argue for use of shortfall equality as a measure and standard for compromise between strict maximization and prioritiza-

²³⁷ See generally *Agency and Quality*, *supra* note 23 for a more extensive analysis and justification for rethinking equal access in terms of alternative ethical aims. This section draws on *Agency and Quality*, *supra* note 23.

²³⁸ See *Agency and Quality*, *supra* note 23 for an argument for rethinking equal access such that society examines injustices not just by healthcare resources, but by the: (1) quality of those resources and their capacity to enable effective health functioning; (2) extent to which society supports what I call health agency so that individuals can convert healthcare resources into health functioning; and (3) nature of health norms, which affect individuals' efforts to achieve functioning. This section addresses only one component of this view of equal access and draws on *Agency and Quality*, *supra* note 23 in doing so.

²³⁹ ARISTOTELIAN JUSTICE, *supra* note 15 and *Social Justice*, *supra* note 15.

²⁴⁰ *Id.*

²⁴¹ See, e.g., ARISTOTELIAN JUSTICE, *supra* note 15 and *Agency and Quality*, *supra* note 23.

²⁴² See *Combating HIV/AIDS*, *supra* note 217, *Agency and Quality* *supra* note 23, and Jennifer Prah Ruger, *Democracy and Health*, Q. J. MED. 98, 299-304 (2005) [hereinafter *Democracy and Health*].

²⁴³ See NICOMACHEAN ETHICS, *supra* note 12, at 151.

tion in implementing an equal access principle, and below I advance reasonable accommodation as a conceptual tool in hard cases²⁴⁴ and the principle of proportional justice to guide resource distribution.

In order to determine *which* health care goods and services should be guaranteed to individuals, this account of equal access must be supplemented with a framework that combines both procedural and substantive principles and integrates clinical and economic considerations. It can help prioritize the different types of health care to maintain and improve health with the fewest possible resources. It is not merely instrumental, however. Its justification lies in the concept of the good life that the capability approach espouses: that individuals should have the ability to participate in decision-making that affects them, such as decision-making about the goods and services society should guarantee them. This is discussed in Section C below.

2. *Results, Achievements and the Capability to Achieve*

This account raises two important questions: Does equal access guarantee equal results? Must individuals with the same condition always receive the same amount of care?

It is difficult to assess the link between health care and health outcomes, but the account presented here does not guarantee equal results or equal achievements among recipients. However, the principle of equal access implies that society must attempt to reduce inequalities in individuals' capability to achieve health functionings and to prevent, ameliorate, or eliminate deprivations in their capability for health functioning.

True to Aristotle's principle of proportionality, this approach does not seek equal amounts of health care for individuals or groups with very different shortfalls from a given threshold state of health functioning. This approach supports the idea that a progressive health-care delivery system provides goods and services to those with health needs, justifying unequal amounts of care for patients with different conditions. However, individuals with similar needs should receive the same level of care. A potential problem arises when different people require different amounts of goods and services to meet the same health need, as when cases differ in severity or in the conversion of resources into improved health. Under this account, every individual should be entitled to medically necessary and medically appropriate resources needed to reach a medically determined level of health functioning.

²⁴⁴ ARISTOTELIAN JUSTICE, *supra* note 15; *Health and Social Justice*, *supra* note 15; *Right to Health*, *supra* note 22; *Healthcare Disparities*, *supra* note 227.

3. *Rationale for High-Quality Care*

The argument for a decent minimum or adequate level of health care typically asserts “a government obligation to meet the basic health needs of all citizens, at least an obligation to function as a last resort.”²⁴⁵ The result is generally *two tiers* of health care, one involving “enforced social coverage for basic and catastrophic health needs”²⁴⁶ and the other permitting “voluntary private coverage for other health needs and desires.”²⁴⁷ The decent minimum concept is analogous to a general safety net. It appeals to several different philosophical perspectives such as utilitarianism, communitarianism, and egalitarianism.²⁴⁸ Operationalization is challenging, and regional, temporal, and socio-economic variations can result in differences in quality.²⁴⁹ We must therefore ask why disparities in *healthcare quality* should concern us and why efforts to reduce them are justified.

Within this paradigm, unnecessarily reduced *healthcare quality*, such as medical errors, is unjust because it undermines individuals’ capability for health functioning. For example, giving the wrong type of blood during organ transplantation, as happened in the United States, is morally troubling, not because it threatens the patient’s employment or happiness, or provides less than a decent minimum or adequate level of health care per se. The moral problem is the diminishment of the patient’s capability to function or even survive. Differences in *healthcare quality* that contradict evidenced-based standards,²⁵⁰ such as differences in effectiveness and efficacy, are therefore unjust. The quality of health care should therefore be measured in terms of its effect on functional impairment.^{25a}

Two people with the same health condition will experience very different health outcomes if one has access to high-quality medical care and the other does not. Medical evidence demonstrates that children with asthma need daily drug therapy to prevent airway swelling, but many do not receive that standard of care.²⁵² And although tight control of blood sugar levels in type 1 diabetes reduces the risk of kidney disease

²⁴⁵ BIOMEDICAL ETHICS, *supra* note 47, at 356.

²⁴⁶ *Id.*

²⁴⁷ *Id.*

²⁴⁸ *Id.*

²⁴⁹ Mark A. Schuster, Elizabeth A. McGlynn, Robert H. Brook, *How Good is the Quality of Health Care in the United States?*, 76 MILBANK QUARTERLY 517 (1998).

²⁵⁰ Steven M. Asch et al., *Who Is at Greatest Risk for Receiving Poor-Quality Health Care?*, 354 NEW ENG. J. MED. 1147-1156 (2006).

^{25a} See Leighton E. Cluff, *Chronic Disease, Function and the Quality of Care*, 34 J. CHRONIC DISEASE 299-304 (1981).

²⁵² Agency for Healthcare Research and Quality, *Research on Caring for Children with Asthma*, AHRQ Publication No. 00-P025 (2000).

by two thirds and halves the risk of eye disease,²⁵³ 40% of Americans with type 1 diabetes do not receive a routine glucose monitoring.²⁵⁴ Interventions that are known to maintain or improve health, and even lower costs, are often unavailable to those in need.²⁵⁵ From this perspective, such deficits are morally troubling because they reduce individuals' capability for health functioning.

"To err is human" and no perfect health-care system exists, but an important health-system goal is equal access to *high quality* care. Each person should receive those necessary and appropriate preventive measures and treatments that are available to others with similar needs. Achieving this objective entails a continuous effort to standardize medicine, reduce medical errors, and move toward a gold standard of care.²⁵⁶

There are at least two potential objections to the high-quality standard for equal access. The first is that it gives more priority to equality than efficiency (expressing concern over draining resources and impoverishing even adequate care efforts). The second is that a two-tier system might be more politically and administratively feasible. In response, health systems accountable only for low quality could result in sub-optimal care and inefficiencies in the long run, and thus efforts to increase political support are critical- and yet not impossible as demonstrated by calls for action in the U.S. and U.K.

4. *High-Quality Care and A Two Tiered System*

Equal access to high-quality care and a two-tiered system are not compatible. Unfortunately, universal access to high-quality health care is not always available, even in wealthy countries like the United States, where health care quality differentials are widespread. For example, the National Committee for Quality Assurance found that 50% of diabetics enrolled in managed care plans in New England received annual eye exams compared with only 33% in plans in the South Central U.S. region.²⁵⁷ Another study found in some locales twice as many diabetics

²⁵³ AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, PUBL'N NO. 00-P018, RESEARCH ON DIABETES CARE (2000), available at <http://www.ahrq.gov/research/tripdiab.htm>.

²⁵⁴ *Id.*

²⁵⁵ Elizabeth A. McGlynn et al., *The Quality of Health Care Delivered to Adults in the United States*, 348 NEW ENG. J. MED. 2635-2645 (2003).

²⁵⁶ See generally TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (Linda T. Kohn et al. eds., 2000); COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY (2001).

²⁵⁷ National Committee of Quality Assurance, *The State of Managed Care Quality* (1997), available at <http://www.ncqa.org/pages/communications/news/somcqrel.html>.

get routine care (glycosylated hemoglobin measurement, eye exams, and total cholesterol measurement) as in others across three US states.²⁵⁸

In every society, various factors impede access to high-quality health care including (1) economic barriers (lack of insurance, underinsurance, poverty); (2) supply and distributional barriers (goods and services are inappropriate, not of sufficient quality, or not nearby); (3) socio-cultural and ethnic barriers (misunderstandings between providers and clients of different backgrounds);²⁵⁹ and (4) ignorance, misinformation and misunderstanding. In many societies, eliminating financial barriers to care solves many access problems, although other impediments to access persist.

Geographic impediments are particularly problematic. Patients in remote rural areas, for example, are more likely to receive lower quality care than those in more urban, populated areas. One study found that HIV-infected patients living in rural areas were less likely to be taking anti-HIV drug cocktails and receiving medication to prevent pneumonia than those living in urban areas.²⁶⁰ Rural HIV patients were also more likely to have doctors significantly less experienced in dealing with HIV patients.²⁶¹ One study of heart bypass surgery in the United States found that privately insured HMO patients in one part of the country received higher quality care than their counterparts in other regions.²⁶²

Similarly, socio-cultural barriers to access can result in misunderstandings (in some cases, hostility) between providers and patients, maltreatment or lack of treatment, and wasted resources. Ethnic and sociolinguistic barriers to care have been problematic in the United States. One study that controlled for differences in health insurance and socioeconomic status found that Hispanic children whose parents did not speak English experienced difficulty accessing health care.²⁶³ In a 2001 Robert Wood Johnson Foundation survey,²⁶⁴ 19% of Latinos reported that language problems kept them from seeking medical care. A differ-

²⁵⁸ See Wiener et al., *Variation in Office-Based Quality: A Claims-Based Profile of Care Provided to Medicare Patients With Diabetes*, 273 JAMA 1503, 1505 (1995).

²⁵⁹ See CENTER FOR HEALTH ECONOMICS RESEARCH FOR THE ROBERT WOOD JOHNSON FOUNDATION, *ACCESS TO HEALTH CARE: KEY INDICATORS FOR POLICY* (1993) [hereinafter *KEY INDICATORS FOR POLICY*].

²⁶⁰ See S. E. Cohn et al., *The Care of HIV-Infected Adults in Rural Areas of the United States*, 28(4) J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES 385-92 (2001).

²⁶¹ See *id.*

²⁶² See José J. Escarce et al., *Health Maintenance Organizations and Hospital Quality for Coronary Artery Bypass Surgery*, 56(3) MED. CARE RESEARCH & REV. 340-62 (1999).

²⁶³ See Robin M. Weinick & Nancy A. Krass, *Racial and Ethnic Differences in Children's Access to Care*, 90(11) AM. J. PUB. HEALTH 1771-4 (2000).

²⁶⁴ See generally *KEY INDICATORS FOR POLICY*, *supra* note 259.

ent study found that Asians and Pacific Islanders on the West Coast²⁶⁵ had less access to health care than any other ethnic group, including African Americans, Hispanics, Native Americans or whites. Asians and Pacific Islanders had the worst overall scores for ability to obtain treatment when needed, as measured in length of waiting time before seeing a specialist or service approval, with a few exceptions.²⁶⁶ The many measures that could reduce or even eliminate such impediments include outreach, transportation, translation, interpretive services, health information, respecting human dignity, and communication campaigns in multiple languages. Health communication strategies that are socially, linguistically, and culturally appropriate are especially effective in reducing gaps in health education and knowledge regarding treatment options.

Shortages of high-quality health goods and services, including health personnel, equipment, medicines, and facilities, erect significant barriers to access on the supply side. In the past, some countries have addressed these issues, although more effort is needed. For example, the United States Public Health Service Commissioned Corps has provided scholarships and loan repayments to health professionals who practice in underserved communities in the United States. In the United Kingdom, physicians earn roughly 70% more to provide health services in underserved communities. Another problem is the mismatch between health resources and the health needs of the population.

Some of the most important impediments to equal access are economic. Different payment methodologies and financial arrangements within the health sector can affect both health-care quality and access. In the U.S. health-insurance status influences both access to services *and* the quality of care received. Health-insurance coverage also bears on individual health. People without health insurance have repeatedly been shown to utilize less healthcare than insured individuals.²⁶⁷

Lack of health insurance may also prevent people from seeking care. One national U.S. study found that adults who were uninsured during a one-year period were two to four times more likely to have access problems than those who were insured throughout the entire year. These access problems included: not filling a prescription, not seeing a specialist when needed, skipping a medical test, treatment, or follow-up, or not seeing a doctor when sick.²⁶⁸

²⁶⁵ Rani E. Snyder et al., *Access to Medical Care Reported by Asians and Pacific Islanders in a West Coast Physician Group Association*, 57(2) MEDICAL CARE RESEARCH AND REVIEW 196-215 (2000).

²⁶⁶ *Id.* at 203.

²⁶⁷ See generally Katherine Swartz, *The Medically Uninsured; Special Focus on Workers*, NATIONAL HEALTH POLICY FORUM (1998).

²⁶⁸ See generally The Commonwealth Fund, *Security Matters: How Instability in Health Insurance Puts U.S. Workers at Work* (2001).

Uninsured patients are also up to four times as likely as insured patients to require both hospitalization and emergency hospital care. When hospitalized, those without health insurance receive less care and are more likely to die during their stay than patients who are insured.²⁶⁹

And the United States does not compare favorably to other industrialized countries in terms of equal access to high quality care. For example, a study of ten countries belonging to the Organization for Economic Cooperation and Development (United States, United Kingdom, Switzerland, Spain, Portugal, Netherlands, Italy, Ireland, France, and Denmark) found inequalities in health-care delivery that favored the rich, especially in Spain, the United States, and the United Kingdom.²⁷⁰

5. *Voluntary Risk Compared with Involuntary Risk*

A final matter that must be addressed in any paradigm of health ethics, policy and law is how to handle the issue of voluntary versus involuntary risk, and whether a principle of equal access to high-quality health care would differ by the voluntary or involuntary nature of risk.

At first glance it appears that some people are not voluntarily risk adverse to health consequences, such as when they smoke despite their awareness of the risk of lung cancer. Some commentators think it is worthy to make people who knowingly take risks with their health pay additional sums of money or be solely responsible for paying for health insurance and health care. Such a system, it is argued, would: (1) help raise additional financing for services caused by bad health habits, and (2) help mitigate the moral hazards of such situations by giving people incentives to change their habits.²⁷¹

However, this theory suffers from several shortcomings. First, there is some evidence that certain bad health habits, such as smoking and heavy drinking, actually contribute more financially to society than they cost. For example, society saves money when smokers fail to collect social security payments because they die before becoming eligible.²⁷² Premature death from smoking could also avoid long-term care costs incurred by older patients. Second, many poor health habits, such as tobacco use, are highly addictive or heavily influenced by social factors and it is not clear that they are solely voluntary. Third, even if these

²⁶⁹ See generally Katherine Swartz, *Dynamics of People Without Health Insurance: Don't Let the Numbers Fool You*, 271(1) JAMA 64-66 (1994); Robert J. Blendon, *What Should Be Done About the Uninsured Poor?*, 260(21) JAMA 3176-7 (1988); and Jack Hadley et al., *Comparison of Uninsured and Privately Insured Hospital Patients: Condition on Admission, Resource Use, and Outcome*, 265(3) JAMA 374-9 (1991).

²⁷⁰ See generally INTERNATIONAL PERSPECTIVE, *supra* note 36.

^{271a} See generally EQUAL JUSTICE, *supra* note 10.

²⁷² See generally Willard G. Manning et al., *The Taxes of Sin: Do Smokers and Drinkers Pay Their Way?*, 261(11) JAMA 1604 (1989).

voluntary behaviors were responsible for significant additional health-care costs, financial disincentives in the form of higher health-insurance premiums might not change those behaviors.

Discussions by Gerald Dworkin²⁷³ and Elliott Sober²⁷⁴ are instructive here. On the question of financial liability, Dworkin argues that three conditions must be met before individuals should be held financially responsible for health risks. First, society must be able to understand the respective causal determinants of voluntary versus involuntary contributors to health risks. Second, it must determine the difference between involuntary and voluntary behavior. Third, society must be able to differentiate between genetic and non-genetic predisposition to disease. Sober's analysis focuses on interactions between biological and environmental factors. Like Dworkin, he notes that several conditions must be met in order to determine causation. He also notes that illness typically results from the interaction between genes and environmental factors such as lifestyle and diet. For example, the relative contributions of alcohol abuse, genes, and environmental factors to the onset and severity of chronic pancreatitis are difficult to disentangle. It is also difficult to understand why some who do not abuse alcohol develop pancreatitis whereas others who drink heavily escape it. Moreover, socio-cultural factors, such as poverty, also associate with poor health habits because disadvantaged people are less equipped to bear the potential costs of mitigating the risks of such habits and paying for the resulting health effects of their behavior. For all of these reasons, it is unjust to always blame individuals for their health problems, although individual responsibility and health agency are essential in achieving optimal health outcomes.

B. EQUITABLE AND EFFICIENT HEALTH FINANCING AND INSURANCE

1. *A Capability and Health Account of Equitable and Efficient Health Financing*

Universal health insurance coverage is important to this paradigm for several reasons.²⁷⁵

First, one of the primary economic barriers to high quality health care is lack of health insurance. Second, resource allocation in this para-

²⁷³ See Gerald Dworkin, *Taking Risk, Assessing Responsibility*, 11 (5) HASTINGS CENTER REP. 26 (1981).

²⁷⁴ See Elliott Sober, *Appendix One: The Meaning of Genetic Causation*, in FROM CHANCE TO CHOICE 347 (Allen Buchanan et al. eds., 2000).

²⁷⁵ See Jennifer Prah Ruger, *Moral Foundations of Health Insurance*, QUARTERLY JOURNAL OF MEDICINE (forthcoming) ([hereinafter *Moral Foundations*] for an ethical argument justifying universal health insurance coverage on the moral grounds of protecting individuals from vulnerability and insecurity. This section draws on *Moral Foundations*, although it does not address in depth philosophical components of this view of health insurance.

digm is based on medical necessity and medical appropriateness, not ability to pay. Third, the costs of health care can affect health directly by reducing demand for necessary care or increasing consumption of unnecessary care. Fourth, the uncertainty of health need, the catastrophic costs of medical care, individuals' riskaverse nature, and the need to redistribute resources from well to ill and rich to poor, place risk pooling at the center of health-care financing.

The paradigm presented here requires that health system financing, organization, and delivery ensure access to medically necessary and medically appropriate care and protect individuals from health-related financial burdens that could substantially erode their freedom to flourish.

This means that health policy should provide *continuous* universal health insurance so that gaps in coverage do not handicap health functioning. This arrangement should include all individuals at all times, regardless of changes in income, employment, or marital or health status.

This account argues for financing health care according to ability to pay (adjusting contributions to health-care costs by income level) and delivering it according to medical necessity and medical appropriateness (discussed below). Thus, society distributes health-care resources according to individuals' capability for health functioning, not according to their ethnicity, how much money they have, where they live, whether they are married, or what they do for a living.

An equitable health system requires financial protection of all individuals, especially the poor and most disadvantaged, against the monetary burdens associated with health risks. Pooling risks and collecting prepayments unrelated to health status or use secures this protection. Thus, provision of health-care rests on community rating and not on individuals' health status.

Maximizing the amount of resources available for health care improves the ability to meet individuals' health needs. At the same time, health-care financing must be efficient in any country adopting universal coverage because limited resources must be used wisely and wasted resources prevent important health needs from being met. To achieve both administrative and technical efficiency,²⁷⁶ the costs of collecting and distributing revenue should be minimized, as should loss of funds to corruption and fraud as discussed below.

²⁷⁶ For a useful discussion of administrative and technical efficiency, see Anne J. Mills & M. Kent Ranson, *The Design of Health Systems*, in INTERNATIONAL PUBLIC HEALTH: DISEASES, PROGRAMS, SYSTEMS, AND POLICIES (Michael H. Merson et al. eds., 2001).

2. *Gains in Well-Being from Risk Pooling and Health Insurance*

A critical area of equitable and efficient health-system financing is the extent of gains in well-being that can accrue from risk pooling. Health risks and the financial costs associated with them are difficult to predict, and even predictable ones are difficult for individuals to plan for and cover financially. Efforts to predict future health care use patterns and costs have found that between 50% and 85% of individual healthcare use is unpredictable, even given a complete set of predictive variables.²⁷⁷ People without health insurance might not have the financial resources to pay for treatment.

Collective arrangements for funding health care, such as health insurance, can protect individuals from financial loss when adverse health events occur. Individual risk is reduced by pooling a large number of people. The larger the risk pool, the more precisely insurers can predict the probability of financial loss due to illness; therefore, insurers can plan for and spread risk. Health financing mechanisms differ in their effects on equity and efficiency.

3. *Empirical Evidence on the Equity of Health Financing Models*

With the exception of the United States, nearly all higher-income market-oriented economies have institutionalized universal healthcare coverage for their populations. However, the equity of financing these schemes differs by country. In a study of ten OECD countries (United States, United Kingdom, Switzerland, Spain, Portugal, Netherlands, Italy, Ireland, France, and Denmark), researchers analyzed the percentage of funding from four general types of healthcare funding: taxation, social insurance, private insurance, and out-of-pocket payments.²⁷⁸ Using this information to compare the overall progressivity of a country's financing system, they found that countries that publicly finance the majority of their healthcare expenditures with either tax-financed systems (Denmark, Ireland, Portugal, and the United Kingdom) or social insurance funds (France, the Netherlands, and Spain), and that raise most of their funds through progressive taxation were typically more progressive. Percentages of funding from direct taxes were: Denmark, 49.4%; United Kingdom, 38.3%; Ireland, 28.5%; Portugal, 20.4%. General revenue taxation

²⁷⁷ See Dana G. Safran, *Adjusting Capitation Rates Under Managed Competition*, Prepared for the U.S. Senate Committee on Labor and Human Resources (1993) (citing results from the RAND Health Insurance Experiment (HIE) and the RAND/New England Medical Center Medical Outcomes Study (MOS)). Independent variables include disease profiles, functional status, prior utilization patterns in addition to age, income, education, race, and gender.

²⁷⁸ See generally INTERNATIONAL PERSPECTIVE, *supra* note 36.

was found to be a progressive means of raising revenue, although the degree of equity depended on the progressivity and mix of taxes in a given system. Denmark's relatively high percentage of indirect taxes (35.8%) made it slightly less progressive overall than the other three countries. Italy, with 42.3% of taxed-based funding, 37.7% of social insurance-based funding, and 20% of out-of-pocket payments, was slightly less progressive overall than Denmark, and the next two countries, the Netherlands, and Spain, due in part to its relatively high percentage of out-of-pocket expenditures.²⁷⁹

The study also found that social insurance was a more regressive method of raising health-care revenue when contributions are capped, as happens with U.S. Medicare payments, where marginal rates of contribution decline as income increases. France, the Netherlands, and Spain have a high proportion of healthcare financing through social insurance: 75.5%, 65.7%, and 61.7% respectively. Each country also uses a low percentage of total taxes for funding: 2.3%, 6.6%, and 14.0%, respectively. One progressive aspect of social insurance schemes is that they typically exempt certain groups, such as the elderly and very poor.

The study found private insurance and out-of-pocket payments even more regressive than social insurance because the former are not necessarily based on earnings. Out-of-pocket payments are even more regressive because they are not typically income-adjusted and because the poor typically have greater rates of illness than the more affluent. Among OECD countries, the United States and Switzerland have the highest percentages of payments from private sources, at 55.9% and 59.5%, respectively. Switzerland has a slightly higher percentage of payments from direct taxes (31.6%) and a slightly lower percentage of out-of-pocket payments (18.6%) than the United States, which gets 23.1% of funding from direct taxes and roughly 29.6% from out-of-pocket expenditures. A study in South Korea found that out-of-pocket payments were disproportionately shouldered by those in the lowest socioeconomic groups and those with the most severe chronic conditions.²⁸⁰

When out-of-pocket expenditures, low levels of prepayment, and regressively financed prepayments coexist, the poor suffer the most because their share of prepayments *and* their out-of-pocket expenditures are disproportionately high. In a health system, like the United States', that fails to protect everyone, some families and individuals will slide into poverty because they must purchase necessary health care without assistance or forgo medical care they cannot afford.

²⁷⁹ *Id.*

²⁸⁰ Jennifer Prah Ruger and Hak-Ju Kim, *Out-of-Pocket Health-Care Spending by the Poor and Chronically Ill in the Republic of Korea*, AMERICAN J. PUB. HEALTH (in press).

4. *Market Failures, Public Goods, and the Role of the Public Sector*

Health-care financing, delivery, and organization can involve either private or public entities or a mix of the two. On this view, society must compare the advantages and disadvantages of the free market with those of the government and other political and social institutions. This view differs from efforts to herald a foremost role for either capitalist or socialist tenets.²⁸¹ In the case of information technology, for example, the public sector created the Internet as a military communication tool, but the free market increased productivity and made the technology accessible to consumers. In the health-care sector, numerous market failures have created a rationale for public sector involvement.

Externalities are one of the most common causes of health care market failure.²⁸² When social benefits accruing from a given activity exceed individual benefits, insufficient investment or consumption by individuals results. Immunization and treatment for communicable diseases are two examples. In these cases, public financing and public-based delivery are likely necessary to achieve socially desirable ends. Public goods—those whose benefits should obtain for everyone and whose consumption by one person does not preclude consumption by another—also require public financing, because private markets typically will not produce goods they cannot sell exclusively to one person. Such goods include clean air and water, sanitation systems, medical research and knowledge, environmental health, epidemiology, health information, communication and promotion activities. There are also mixed goods that benefit specific individuals but have societal benefits as well. Rehabilitation services, for example, improve patients' physical functioning but also enhance economic progress through better labor productivity.

Another market failure in health care is information asymmetry, when health providers or insurers have significantly more information about a patient's condition than the patient does or vice versa. Although providers typically make decisions that are in their patients' best interests, self-interest sometimes plays a role. In recent years especially, economic incentives offered by managed-care companies have challenged physicians' ability to act on their patients' behalf. And even if the interests of patients and doctors are perfectly aligned, asymmetric information

²⁸¹ See generally Solomon R. Benatar, Abdullah S. Daar, Peter A. Singer, *Global Health Challenges: The Need for an Expanded Discourse on Bioethics*, R. PLOS Medicine 143 (2005); Thomas Pogge, *WORLD POVERTY AND HUMAN RIGHTS* (2002); Jennifer Prah Ruger, *Fatal Indifference: The G8 Africa and Global Health* 26 J. PUBLIC HEALTH POL. 377-382 (2005).

²⁸² See Paul A. Samuelson, *The Pure Theory of Public Expenditure*, 36 REV. ECON. & STAT. 387, 389 (1954).

denies patients the ability to make decisions entirely independently. Indeed, information symmetry might never be possible, given that doctors have many years of medical training and patients do not. Buying a medical consultation is hardly equivalent to the purchase of other marketable products such as clothing, cars, or furniture.

The uncertain nature of health care²⁸³ — the unpredictability of illness, and the impact and cost of treatment — makes risk-reduction measures such as health insurance appealing. However, insurance market failures, credit shortages, and information insufficiencies can undermine the economic benefits insurance should provide.

Finally, market failures such as adverse selection and moral hazard inhibit the efficient functioning of private health-insurance markets. Moral hazards occur when individuals who are insured and therefore do not pay the full cost of medical care have less financial incentive to avoid either poor health or high-cost services. Therefore, insulating people from the true costs of medical care through insurance might actually increase risky behavior and the probability of an insurance-covered health event. An obvious counterargument is that the risk of ill health itself is the most important deterrent to risky behavior. Efforts to mitigate the effects of moral hazard have included economic measures that sensitize patients to the real costs of medical care. However, they have had limited success.

Adverse selection can also create market failures. In both private and social insurance systems, adverse selection means sicker-than-average individuals self-select into insurance plans that offer superior health benefits. This raises the average cost of premiums, causing healthier patients to leave the plan and obtain less expensive coverage elsewhere. Private insurers attempt to reduce adverse selection by excluding preexisting conditions that will be costly at some future date, requiring medical exams, excluding high-risk individuals, and instituting waiting periods for insured care.²⁸⁴ These measures typically increase the profits of private insurers but increase societal risk-pooling problems.

Moral hazard and adverse selection require public action such as regulation of private insurers and mandatory public insurance with risk pools that include both healthy and sick and both wealthy and poor contributors.

²⁸³ *Uncertainty*, *supra* note 143.

²⁸⁴ A 1995 study found that on average HMOs enrolled younger (and thus healthier) members than traditional fee-for-service (FFS) plans. The study also found a lower percentage of enrollees with chronic diseases such as cancer, diabetes, and cardiovascular disease among HMOs as compared to FFS plans. See Annette K. Taylor et al., *Who Belongs to HMOs: A Comparison of Fee-for-Service versus HMO Enrollees*, 52(3) MEDICAL CARE RESEARCH AND REVIEW 389 (1995).

In summary, every type of health system has its advantages and disadvantages in terms of efficiency and equity. The drawbacks of an entirely public health sector or an entirely private health sector suggest that mixed public-private systems might be optimal. Market failure types suggest a greater role for public financing and private provision through nonprofit institutions. This blended approach is espoused by a capability and health account due to its emphasis on an integrated and multifaceted system, in which different types of institutions, namely the free market and the government, reinforce each other to improve health capability.²⁸⁵ To create and maintain equitable and efficient health systems, governments must offer significant direction, regulation, financing, and, in some cases, provision of care. In many settings, however, the private sector provides goods and services in conjunction with a supportive and regulatory public sector. Health sector market failures suggest a strong and continued role for public intervention. In virtually every area of the health sector, especially in generating medical knowledge, techniques, goods, and services, public-private collaboration and investment are critical.

C. ALLOCATING RESOURCES: A JOINT SCIENTIFIC AND DELIBERATIVE APPROACH

This Article now turns to the question of determining priorities for competing needs when resources are scarce. It begins with the broader societal perspective because fair decisions must balance spending on health with spending elsewhere. It then works inward to prioritize competing claims within the health budget.

1. *Reasoned Consensus Through Scientific and Deliberative Processes*

The ethic proposed here involves a joint scientific and deliberative process, integrating substantive and procedural principles, as a resource allocation framework. This public process combines the evidence base of medicine and public health with input from individuals and physician and public health experts to assess the value of treatments, medications and other health care and public health interventions. Under this view, health care and public health are special (and therefore socially guaranteed) because they play a dominant role among determinants of health capability. Consequently, it is important to assess both the *necessity* and the *appropriateness* of a health intervention.

²⁸⁵ Jennifer Prah Ruger, *Global Tobacco Control: An Integrated Approach to Global Health Policy*, 48(2) DEVELOPMENT 65, 65-69 (2005).

Although individuals have primary authority for healthcare decisions that affect them directly, physicians can help determine “medical appropriateness” and “medical necessity.” Thus, individuals employ their health agency and physicians, by virtue of their medical expertise and allegiance to the Hippocratic oath, seek their patients’ best interest. In this framework, physician-experts share expert knowledge and resources (e.g. benefits, risks, costs) with each other and with patients to achieve ethical rationality and practical reasonableness; balancing technical (or engineering) rationality with ethical rationality in collective choice.

This process emphasizes deliberately derived public policy for human flourishing and reasoned consensus to evaluate arrangements for improving human functioning. Aristotle emphasized the need for deliberative decision-making based on prudence and practical wisdom about how to insure the good of human life.²⁸⁶ Indeed, he purported that medicine was an appropriate object of deliberation and he also recognized the need for both ethical and engineering forms of reasoning.²⁸⁷ A more expansive account of rationality incorporates both.

Such deliberations help guide the allocation of health resources and facilitate the development of health policy and health laws through what is here called shared health governance. This view contrasts with the notion that consumers alone, physicians alone, public health experts alone, strict algorithms, cost-benefit calculations, fair procedures, government officials or technocrats, shared decision making within an informed consent model, or third parties such as insurers should make health spending decisions. While it endorses many of the principles of the shared decision making approach to individual medical treatment decisions, it focuses differently on shared health governance, a paradigm in which individuals, providers and institutions work together to empower individuals and create an enabling environment for all to be healthy. It also contrasts with both a strictly technocratic or engineering approach and a strictly procedural approach to collective choice. It differs from efforts to develop a decision-making process “to set fair limits to health care”²⁸⁸ as it promotes consensus on substantive—especially scientific—principles of distribution. It also offers a method for achieving consensus (incompletely theorized agreements or ITA) that differs from aggregative tools such as a strict majority vote. It empowers individuals through health agency. And its judgments place special importance on the results and scientific-basis of health policies (costs and effectiveness).

²⁸⁶ NICOMACHEAN ETHICS, *supra* note 12, at 89.

²⁸⁷ *Id.* at 35.

²⁸⁸ SETTING LIMITS FAIRLY, *supra* note 8, at 2.

Finally, it promotes public deliberation through a “collaborative comprehension of problems and remedies”²⁸⁹ among physician and public health experts and citizens. These formulations focus especially on reasoning – whether at higher levels of abstraction or lower levels of particulars – and on mutual respect among citizens and experts. This framework integrates both consequential and procedural elements of justice. Allocation theories resting on procedural justice alone view rationing decisions as “just” or “right” if such “decisions are the results of fair procedures.”²⁹⁰

This approach stresses that participatory decision-making is instrumentally important for forming values and setting priorities when policy choices are difficult.²⁹¹ Sen observes that “informed and unregimented formation of our values requires openness of communication and arguments,”²⁹² and that “we cannot, in general, take preferences as given independently of public discussion.”²⁹³ In addition, participatory decision-making has a constructive role because a critical understanding of health and social needs requires “discussion and exchange.”²⁹⁴ This approach is particularly “concerned with the agency role of the individual as a member of the public . . .”²⁹⁵ Agency is important for public policy because it gives members of the public a role in political, social and economic choice. Participation and open dialogue are especially important for the health-politics nexus.²⁹⁶

When policies and law require even greater specification, further iterations of public discussions could be necessary to make difficult choices about which health services merit societal investment. Public policy cannot result from narrow technical blueprints. Rather, this paradigm purports that it should emerge from a stepwise process that reviews scientific evidence of the consequences of policies on health. If evidence is incomplete or inconsistent, recommendations should reflect the judgment of individuals and experts. The deliberative process should also update its recommendations continually to account for changes in medical knowledge, technology, and costs when determining what probability of success would make an intervention worthwhile. Ethical rules should then be modified in the presence of new circumstance. Because these recommendations form the basis for defining a benefits package, making

²⁸⁹ See FREEDOM, *supra* note 16, at 31.

²⁹⁰ *Health, and Healthcare*, *supra* note 19, at 13.

²⁹¹ See FREEDOM, *supra* note 16, at 152.

²⁹² *Id.* at 152.

²⁹³ *Id.* at 153.

²⁹⁴ *Id.*

²⁹⁵ *Id.* at 19.

²⁹⁶ Jennifer Prah Ruger, *Disease and Democracy: The Industrialized World Faces AIDS*, BRIT. MED. J. 331 (2005); *Democracy and Health*, *supra* note 242.

resource allocation decisions, and constructing general guidelines, the underlying reasoning should be explicit and public. An appeals mechanism for reevaluating decisions is also important.

Public policy should promote objectives as efficiently as possible. Therefore, some limits must apply when allocating resources and evaluating medical technologies, and allocation decisions must consider cost. For efficiency evaluation, cost-minimization analysis (CMA) is an invaluable tool for decision-making. Cost-effectiveness analysis (CEA) can also play a role by comparing the marginal benefits and marginal costs of two or more interventions for a single condition or population, such as AIDS patients. It contrasts with utilitarian aggregation methodology and the use of utilities. Instead, it recommends the use of CMA and CEA in a stepwise manner in which economic considerations follow clinical input, not vice versa. It contrasts with methodologies to incorporate equity or deliberatively determined weights *into* CEA.

2. *Frameworks for Combining Technical and Ethical Rationality for Collective Choice*

Aristotle and Sen provide little guidance on how technical and ethical rationalities might be combined in a collective choice framework. Indeed the precise combination will vary depending on the scope and nature of the social choice exercise. For example, broader decision making at the national level requires participation by popularly representative groups (e.g. legislatures or councils) and entails trade-offs between health and other social policies, while decision making about a benefits package focuses more on broad categories of health care and public health to meet individuals' health needs. By contrast, more specific treatment decisions engage patients and providers at the local level. This Article's scope does not extend to specifying procedures for various circumstances; however, the following sections will emphasize certain substantive and procedural aspects of the process and discuss how they are combined. This approach emphasizes including *both* clinical and economic analysis for evidenced-based decision making. These key scientific components of a framework are outlined below. Deliberative components to the process build on existing literature, but move beyond that work by integrating deliberation with technical rationality and augmenting it with efforts toward incomplete theorization and partial ordering in order to come to consensus amidst pluralism and wide disagreement.

3. *Allocations within the Broader Social Budget*

In a broader resource allocation exercise, health capabilities compare with other capabilities. The capability approach offers the entire

capability set as the focal variable for decisions about macro resource allocation. Although a thorough analysis of partitioning is beyond this Article's scope, it is important to note that macro-level decisions belong within the context of a political unit. Under this approach, the decision-making process would be an open, deliberative, and democratic process²⁹⁷ that divides the overall budget and legislation into allocations for the health sector as well as other sectors of society, such as education, housing, culture, defense, etc. In the United States, the federal government achieves this budget through an interactive process between the legislative and executive branches,²⁹⁸ but this process is typically extended and contentious; indeed, the government has been known to shut down on occasion because it could not agree on a budget. Reform efforts around specific legislation, universal coverage for example, exemplify lawmaking efforts in this regard.²⁹⁹

Empirical evidence on national budgets reveals that countries tend to devote more resources and increasing shares of their national income to the health sector as their income increases.³⁰⁰ Lower-income countries on average spend less per capita on health in terms of both percentage of GDP and actual dollars.³⁰¹ In the late 1990's, for example, low-income countries spent an average of US \$21 per capita on health, compared with US \$116 for middle-income countries and US \$2,736 for high-income countries.³⁰² In the poorest countries, per capita health spending can be as low as US \$2 or \$3 per capita, with most funds coming from private sources. In terms of percentage of GDP, low-income countries spend roughly 4.3% on health, middle-income countries 5.9%, and high-income countries 10.2%.³⁰³ The public share of health expenditures, as a percentage of total health spending in 1999, was 62% (or 6.9% of GDP) in high-income countries, 52% (or 4.3% of GDP) in middle-income countries, and 27% (or 1.5% of GDP) in low-income countries. One study found that the public portion of health expenditures will increase by 1.96% for every 1% increase in per capita income in middle-

²⁹⁷ The specific details of such a deliberative political process are not critical for the current proposal.

²⁹⁸ See generally Tammy O. Tengs et al., *Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness*, 15 RISK ANALYSIS 369, 369-90 (1995) (arguing for the use of techniques such as cost-per-life saved or cost-per-QALY gained when setting budget priorities among different public measures in different policy domains). See also STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* (1993) (advocating for the use of a cost-per-life saved methodology to analyze government regulations).

²⁹⁹ See generally *Normative Theory*, *supra* note 232.

³⁰⁰ Jennifer Prah Ruger et al., *Health and the Economy*, in INTERNATIONAL PUBLIC HEALTH: DISEASES, PROGRAMS, SYSTEMS, AND POLICIES 617 (Michael H. Merson et al. eds., 2001) [hereinafter *Health and the Economy*].

³⁰¹ WORLD BANK, *WORLD DEVELOPMENT INDICATORS*, 92 (2000).

³⁰² *Id.*

³⁰³ *Id.*

and high-income countries and by 1.08% for every 1% increase in per capita income in lower-income countries.³⁰⁴

Health-system efficiency determines the extent to which better health is achieved with a given level of resources. While it is critical to allocate more national resources to the health sector,³⁰⁵ efficient allocation of these resources *within* the health system is critical as well. Efficient allocation avoids excessive administrative costs, unnecessary procedures, and allocative and technical inefficiencies. It effectively realizes the economic benefits of risk sharing. Efficient allocation also requires generating resources to finance health systems efficiently and equitably (discussed above). Thus, incentives or disincentives associated with taxation, financing, and insurance policies need close scrutiny.³⁰⁶

4. *Allocating Within the Health Policy Budget: Benefits Package: Types of Goods and Services Guaranteed*

What health goods and services should constitute a standard benefits package guaranteed to all? A major ethical issue in health resource allocation involves guidance about our social obligation to provide access to a standard benefits package of goods and services.

I have already argued that all covered goods and services must be of high quality. This principle addresses the significant inequities that occur when individuals might have equal claim to particular goods and services but in practice receive care of significantly different quality.

Second, a high quality allocation scheme guarantees equitable access to both prevention and treatment. Third, as discussed above, it guarantees equitably financed health insurance that covers this guaranteed benefits package. A final aspect of this approach leaves open the ability to define the benefits package more broadly through a public process and allows individuals to purchase additional health care on the free market. However, the government would regulate the emergence, development, and functioning of private health insurance and health care.

Under this approach, goods and services that are “medically appropriate” (a term that encompasses medical necessity)³⁰⁷ to ensure central health capabilities would form the basis of a guaranteed benefits package. Elsewhere, I analyze an incompletely theorized agreement on core dimensions of health for use in resource allocation.³⁰⁸ Society could

³⁰⁴ See generally George Schieber & Akiko Maeda, *A curmudgeon's guide to financing health care in developing countries*, in G. Schieber (Ed.) *Innovations in health care financing*. Proceedings from a World Bank Conference, March 10-11, 1997.

³⁰⁵ A major theme of The World Health Organization's Macroeconomics and Health Commission.

³⁰⁶ See generally *Health and the Economy*, *supra* note 300.

³⁰⁷ Concerns with the concept of “medical necessity” are discussed below.

³⁰⁸ See *Right to Health*, *supra* note 22; *ARISTOTELIAN JUSTICE* *supra* note 15.

then expand the package through reasoned consensus on an iterative basis if so desired. Thus, the government-guaranteed benefits package would cover appropriate and necessary care to prevent, diagnose, or treat illness, disease, injury, disability, or other medical conditions associated with escapable morbidity or premature mortality.

A major difference between this account compared to other views, is the requirement that goods and services be “medically appropriate” as well as medically necessary. They would have to be consistent with high quality standards of good medical practice in the relevant country.³⁰⁹ Adding medical appropriateness and established evidence-based clinical practice guidelines to the medical necessity standard introduces another level of prioritization grounded in scientifically based, publicly accepted methods of medicine, public health and health policy. This account gives authority back to physicians and patients, allowing them to make informed judgments about resource allocation on a category-by-category and case-by-case basis. Where medicine is more art than science, clinical judgment is critical to decision making. However, utilization reviews, appeal procedures, and evidence-based guidelines should inform the decision-making process continuously and help hold physicians accountable for their decisions.³¹⁰

Applying these additional standards to the prioritization process improves the prospect of acceptable outcomes that are both substantive and legitimized by a fair and evidence-based procedure. By contrast, attempts to agree on abstract moral principles alone are likely to fail.³¹¹ In practice, individuals often make medical decisions quickly, and members of society frequently reach agreement on a particular course of action, whether or not they agree on the underlying justification.³¹²

5. *Medical Appropriateness and Clinical Practice Guidelines*

Not all health care is medically necessary and medically appropriate. A lot of what health care has to offer, particularly in the modern day of advanced medical technology, is only marginally effective (e.g. extending life for a few weeks or months or a very low probability (<5%-

³⁰⁹ This excludes goods and services that are for the personal comfort, convenience or custodial care of the patient, family or provider.

³¹⁰ It is also important to have safeguards in place to counter, ameliorate, or suppress physician behavior due, for example, to immediate financial gain (e.g., when compensation associates with degree of utilization) or defensive medicine (e.g., to avoid personal malpractice lawsuits and thus higher insurance premiums).

³¹¹ The problem of moral disagreement on resource allocation issues is widely discussed. See *Rationing Medical Care*, *supra* note 60, and *HUMAN LIFE*, *supra* note 82.

³¹² See generally *ARISTOTELIAN JUSTICE*, *supra* note 15, individuals rarely are able to completely theorize a decision when plural and ambiguous concepts and values are involved. This difficulty is exacerbated on a collective level; people rarely agree on all aspects and at all theoretical levels of a particular solution.

10%) of success). Moreover, while millions of people in the world have received high-quality health care, many others experience underuse, overuse, misuse, or variations in health care. Some have estimated that up to 30% of all health care in the United States is wasted and could be reduced through greater efficiency in clinical practice.³¹³ Although economic approaches have been implemented to address this problem, studies demonstrate that these non-clinical solutions *alter the distribution of both necessary and unnecessary medical care*, creating additional health problems. Well-established, evidenced-based clinical guidelines can be helpful³¹⁴ because they systematically bring together experience and evidence on various conditions and provide recommendations for treatment. They are continually updated and improved based on new medical information.

The process of developing clinical guidelines is quite involved.³¹⁵ Guideline architects search, review, and synthesize extensive amounts of literature to evaluate empirical evidence and significant outcomes. Peer and field reviewers subsequently evaluate the validity, reliability, and utility of the guidelines, and solicit input from practitioners and patients. When evidence is incomplete or inconsistent, reviewers seek the professional judgment of an expert panel.³¹⁶ In practice, however, these guideline recommendations may not be appropriate for *all* circumstances.³¹⁷

While effective in recommending evidence-based care, however, clinical guidelines alone cannot reduce differences in health care quality, nor can they evaluate medical technologies, they must be embedded in broader efforts involving physicians and patients in shared governance through the assessment of medically appropriate and medically necessary

³¹³ Robert H. Brook & Kathleen N. Lohr, *Will We Need to Ration Effective Health Care?*, 3 ISSUES SCI. & TECH. 68, 68-77 (1986) [hereinafter *Effective Health Care*].

³¹⁴ One study of the use of cervical spine x-rays in patients with blunt trauma found that physicians could reduce unnecessary x-rays by using five clinical criteria. See Jerome R. Hoffman et al., *Validity of a Set of Clinical Criteria to Rule Out Injury to the Cervical Spine in Patients with Blunt Trauma*, 343(2) NEW ENG. J. MED. 94, 94-99 (2000).

³¹⁵ A number of medical subspecialties have established evidence-based clinical guidelines from extensive meta-analysis of existing studies. See, e.g., U.S. DEP'T OF HEALTH AND HUMAN SERVICES, CLINICAL PRACTICE GUIDELINE: TREATING TOBACCO USE AND DEPENDENCE (2000), available at http://www.surgeongeneral.gov/tobacco/treating_tobacco_use.pdf.

³¹⁶ For example, see guidelines for: (1) screening for pre-eclampsia; (2) vaginal birth after cesarean (VBAC); (3) immunizations and chemoprophylaxis; and hundreds more from the National Guideline Clearinghouse available at <http://www.guideline.gov/>.

³¹⁷ Clinical guidelines must be continuously tested and updated. A review of guidelines for obtaining histopathologic diagnosis on tonsillectomy and/or adenoidectomy specimens found new evidence suggesting that this diagnosis may not be necessary in this sub-population of children. See Ramzi T. Younis et al., *Evaluation of the Utility and Cost-Effectiveness of Obtaining Histopathologic Diagnosis on All Routine Tonsillectomy Specimens*, 111 LARYNGOSCOPE 2166-69 (2001).

care.³¹⁸ At least one model of such a system exists: the RAND/UCLA appropriateness method.³¹⁹

This method combines expert judgment with scientific evidence to develop procedures for measuring the appropriateness of medical care. Patients have input after physicians assess an intervention's clinical effectiveness. Its purpose is to improve health status by reducing overuse and underuse of care. The method is transparent, scientific, and deliberative and it requires medical specialists to agree on medical guidelines, with input from patients. Once courses of action are established, advanced medical information systems help physicians, patients, insurers, and health planners improve medical decision making at the point of health-care delivery and for policy.

Since 1986, more than thirty studies in the United States have used the RAND/UCLA appropriateness method to rate the appropriateness of clinical procedures such as coronary angiography, coronary artery bypass surgery, coronary angioplasty, carotid endarterectomy, colonoscopy, upper gastrointestinal endoscopy, cataract surgery, hysterectomy, cholecystectomy and other procedures. The resulting literature suggests that the percentage of inappropriate use across procedures ranges from 2.4% to 75%, while the percentage of appropriate care ranges from 35% to 91%,

³¹⁸ There is considerable data on clinical outcomes of health interventions. The Federal Agency for Healthcare Research and Quality (AHRQ), for example, focuses on research on clinical effectiveness and has created practice guidelines that offer standardized treatment protocols for certain conditions. The American Medical Association and the American College of Cardiology have also endorsed the practice guidelines approach. Some individuals have promoted the idea of combining clinical outcomes with health status evaluations and costs (in CEA) for rationing purposes. See, e.g., *Rationing Through Choice*, *supra* note 108; *Medical Practices*, *supra* note 3. See generally HEALTH CARE CHOICES, *supra* note 5.

³¹⁹ The method involves a diversity of factors and 9 stages: (1) procedure selection; (2) literature search; (3) creation of indication lists; (4) panel selection; (5) rating; (6) measurement scale development; (7) data analysis of appropriateness; (8) necessity assessment; and (9) reliability and validity tests. In the initial stages, the research team uses three selection criteria: the procedures must be (a) frequently used; (b) associated with much morbidity and/or mortality (risks and benefits, likelihood of success, quantity and quality of life improvements); and (c) found to consume considerable resources. Some examples of procedures that meet these criteria include: coronary angiography, coronary artery bypass surgery, coronary angioplasty, carotid endarterectomy, colonoscopy, upper gastrointestinal endoscopy, cataract surgery, hysterectomy, and cholecystectomy. Once the procedures are selected, the research team assembles a multispecialty panel and conducts a literature search to collect data on the efficacy, utilization, complications, cost, and stated indications for the procedure of interest. These data are used to develop a list of indications that categorize patients by symptoms, past medical history, and results of previous diagnostic tests. These clinically homogeneous groupings are used to triage patients who present symptoms. The multispecialty panel rates the indications' appropriateness on a scale from 1 to 9 (9-very appropriate to 1-very inappropriate). By definition, an indication is deemed medically appropriate if the expected medical benefit to the patient, in terms of life expectancy and health-related quality of life, exceeds the expected health risks. The procedure's cost is not incorporated in the appropriateness ranking. See Robert H. Brook, *The Rand/UCLA Appropriateness Method*, in CLINICAL PRACTICE GUIDELINE DEVELOPMENT (Kathleen A. McCormick et al. eds., 1994).

and the percentage of equivocal use ranges from 7% to 32%. For example, a study of carotid endarterectomy performed on 1,302 Medicare patients in three geographic areas of the United States found that roughly 35% were appropriate, 32% were equivocal, and 32% were inappropriate. This procedure was found to be used unnecessarily in one out of three cases.³²⁰ A study of non-emergency, non-oncological hysterectomies performed in seven managed care organizations over a one-year period deemed roughly 16% of the procedures inappropriate.³²¹ A 1990 study of 1,338 patients undergoing isolated coronary artery bypass graft surgery in fifteen different New York State hospitals judged only 2.4% inappropriate, 91% appropriate, and 7% equivocal.³²² Finally, a study of the appropriateness of tympanostomy tube surgery for recurrent acute otitis media and/or otitis media with effusion found that 41% of 6,611 cases were appropriate while 32% were equivocal and 27% were inappropriate.³²³ This sample demonstrates that the percentage of inappropriate care varies by type of procedure, geographic location, health-care volume, hospital, and other factors. There has been less work on the costs and determinants of inappropriate care. One study that examined the overall magnitude of inappropriate use in U.S. health-care suggested that, for policy purposes, roughly 30% of the procedures studied were inappropriate.³²⁴

Studies of medical care appropriateness can provide some of the evidence base combined with clinical practice guidelines for assessing health interventions.³²⁵ Combining these efforts on a category-by-category basis, in an iterative fashion, reveals areas of improvement for processes integrating science-based methodologies, expert clinical judgment, and patient input. Both the medical appropriateness and medically necessary ratings, along with efforts to develop clinical guidelines combined with patient input offer opportunities for reasoned consensus on categories of health interventions. Patient input is especially critical for

³²⁰ Christine M. Winslow et al., *The Appropriateness of Performing Coronary Artery Bypass Surgery*, 260(4) JAMA 505, 505-9 (1988). See Christine M. Winslow et al., *The Appropriateness of Carotid Endarterectomy*, 318(12) NEW ENGLAND JOURNAL OF MEDICINE 721-7 (1988) (for a study of the appropriateness of coronary artery bypass surgery).

³²¹ Steven J. Bernstein et al., *The Appropriateness of Hysterectomy: A Comparison of Care in Seven Health Plans*, 269(18) JAMA 2398, 2398-402 (1993).

³²² Lucian L. Leape et al., *The Appropriateness of Use of Coronary Artery Bypass Graft Surgery in New York State*, 269(5) JAMA 753, 753-60 (1993).

³²³ Lawrence C. Kleinman et al., *The Medical Appropriateness of Tympanostomy Tubes Proposed for Children Younger than 16 years in the United States*, 271(16) JAMA 1250, 1250-5 (1994).

³²⁴ *Effective Health Care*, supra note 313.

³²⁵ Work examining rates of surgery in Canada demonstrates the potential of population-based data both to develop clinical guidelines and to influence physician practice. See Charlyn Black et al., *Using Population-Based Data to Enhance Clinical Practice Guideline Development*, 37(6 Suppl.) MED. CARE JS254-63 (1999).

valuing effectiveness criteria in this process as citizens through deliberation and value formation help guide policymakers on the value especially of marginally effective technologies (where increases in longevity or the odds of survival are low). Moreover, incomplete theorization allows individuals to make decisions among disagreement, for example to deny some interventions that may extend life by a few weeks or months, while at the same time guarantee interventions that extend life for years. It allows for agreement where agreement is possible without requiring a full solution to the tradeoff between small gains for many compared with large gains for few. This process encompassing reasoned consensus in conjunction with substantive values of health capabilities can help evaluate the effectiveness of medical care and form deliberative decisions on guaranteed health care for all. Not all effective medical care will be included, but this process combines technical and ethical rationality to guide policy choice. Over time, these methods will evolve and become a more accepted part of health care.

At the individual level, however, clinicians must ultimately use their professional judgment, with input from their patients and with reference to guidelines, when recommending a course of treatment for specific patients. Peer review of their behavior will provide clinicians an incentive to act in accordance with established standards of medicine. For example, a study evaluating computerized guidelines for prescribing the presently overprescribed and costly antibiotic, vancomycin, found that physicians who followed the vancomycin guidelines reduced their overall vancomycin use by 30% compared with physicians who did not have access to the guidelines.³²⁶ Researchers surmised that these modifications in physician behavior would decrease costs and increase the appropriateness of medical care.³²⁷

Before moving on, let me address an obvious concern about the “medical necessity” concept – that it is subject to bias, error, or uncertainty. It is clear from the literature that both the concept and operationalization of medical necessity varies. While some argue that this variation represents deeper philosophical differences about the goals of medicine,³²⁸ others believe that the concept is unclear at a more practical level,³²⁹ and still others attribute the divergence to insurance companies’

³²⁶ Kaveh G. Shojania et al., *Reducing Vancomycin Use Utilizing a Computer Guideline: Results of a Randomized Controlled Trial*, 5 J. AM. MED. INFORMATICS ASS'N 554, 560 (1998).

³²⁷ *See id.*

³²⁸ *Id.*

³²⁹ For example, see *Rationing Through Choice*, *supra* note 108; *HUMAN LIFE*, *supra* note 82; *Allocating Health*, *supra* note 110.

efforts to reduce costs or control resources.³³⁰ Despite these issues,^{33a} I argue that health resource allocation models are unworkable *unless they consider the necessity and appropriateness of medical care*. Thus, we should work towards greater uniformity in clinical diagnosis and treatment. To address these concerns, I propose using the principle of medical appropriateness *and* evidence-based clinical practice guidelines *along with* the principle of medical necessity.³³² These scientifically based, publicly accepted methods, combined with clinicians' judgment and patients' input will help draw the line between what is and is not medically necessary.

6. *Medical Futility*³³³ *and Setting Limits*

Determining the appropriateness of medical care will also help limit treatment. It will help illuminate specific cases of medical futility, when

³³⁰ Linda A. Bergthold, *Medical Necessity: Do We Need It?*, 14(4) HEALTH AFFAIRS 180, 180-90 (1995) [hereinafter *Do We Need It?*]; Am. Med. Ass'n, *Consortium for Citizens with Disabilities (CCD)*, (2001), available at <http://www.c-c-d.org/>.

³³¹ See Mark V. Pauly, *What is Unnecessary Surgery?*, 57(1) MILBANK MEMORIAL FUND Q., 95, 95-117 (1979) (providing clarification of the terms); Mark A. Hall & Gerard F. Anderson, *Health Insurers' Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637, 1637-1712 (1992); *Do We Need It*, *supra* note 330.

³³² The model of medical necessity developed by Stanford University researchers is a good starting point, but requires additional work. The definition states that "an intervention is medically necessary if, as recommended by the treating physician and determined by the health plan's medical director or physician designee, it is (all of the following): (1) a health intervention for the purpose of treating a medical condition; (2) the most appropriate supply or level of service, considering potential benefits and harms to patient; (3) known to be effective in improving health outcomes. . .; (4) cost-effective for this condition compared to alternative interventions, including no intervention." See Stanford University Center for Health Policy, *Model Contractual Language for Medical Necessity*, at <http://www.ihc.org/mnppmld.htm> (last visited May 9, 2006). A problem with this definition is the health plan's involvement in medical necessity determinations. In this paradigm, the model used in the RAND/UCLA appropriateness method provides useful insight.

³³³ For more on this, see Simon Atkinson et al., *Identification of Futility in Intensive Care*, 344 LANCET 1203-6 (1994); Baruch A. Brody & Amir Halevy, *Is Futility a Futile Concept?*, 20 J. MED. & PHIL. 123-44 (1995); J. Randall Curtis et al., *Use of the Medical Futility Rationale in Do-Not-Attempt-Resuscitation Orders*, 273 JAMA 124-28 (1995); Council on Ethical and Judicial Affairs, *Guidelines for the Appropriate Use of Do-Not-Resuscitate Orders*, 265 JAMA 1868-71 (1991); Bernard Lo, *Unanswered Questions About DNR Orders*, 265 JAMA 1874-75 (1991); Laura Esserman et al., *Potentially Ineffective Care: A New Outcome to Assess the Limits of Critical Care*, 274 JAMA 1544-51 (1995); H. Tristram Engelhardt & George Khushf, *Futile Care for the Critically Ill Patient*, 1 CURRENT OPINION IN CRITICAL CARE 329-33 (1995); Amir Halevy et al., *The Low Frequency of Futility in an Adult Intensive Care Unit Setting*, 156 ARCHIVES INTERNAL MED. 100-4 (1996); Amir Halevy & Baruch A. Brody, *A Multi-Institution Collaborative Policy on Medical Futility*, 276 JAMA 571-74 (1996); Edmund G. Howe, *Discussing Futility*, 5 J. CLINICAL ETHICS 91-99 (1994); Nancy S. Jecker & Lawrence J. Schneiderman, *When Families Request that 'Everything Possible' be Done*, 20 J. MED. & PHIL. 145-63 (1995); Daniel Callahan, *Medical Futility, Medical Necessity*, 21 HASTINGS CENTER REP. 30-35 (1991); Marcia Angell, *The Case of Wanglie: A New Kind of 'Right to Die' Case*, 325 NEW ENG. J. MED. 511-12 (1991); Steven H. Miles, *Informed Demand for 'Nonbeneficial' Medical Treatment*, 325 NEW ENG. J. MED. 512-

withholding or withdrawing interventions might be most appropriate, because it attempts to determine when possible treatments are beyond social and medical obligations. While the issue of medical futility is implicit in methods on medical appropriateness and necessity, it is worth emphasizing again here. Much has been written on the medical futility concept,³³⁴ but in brief, a legitimate process for determining medical care appropriateness should help physicians, patients, and families determine when medical care is futile. For example, the Society of Critical Care Medicine Ethics Task Force (SCCMETF) has come to some consensus on dealing with treatment issues for critically ill patients. SCCMETF notes that terminally ill patients may be excluded from an Intensive Care Unit (ICU) when they have one of three conditions: (1) severe irreversible brain damage; (2) multiorgan failure; (3) metastatic cancer unresponsive to chemotherapy or radiation therapy. SCCMETF also notes exclusion of patients who are in a persistent vegetative or permanently unconscious state. If patients or their families have previously specified that patients wish to avoid futile care, their wishes should be met (e.g. through advance directives, Do Not Resuscitate orders, futile care withdrawal and hospice care orders).³³⁵

7. *Universal Benefits Package*

If we define a universal benefits package that includes goods and services that are medically necessary and medically appropriate for addressing central health capabilities,³³⁶ the goods and services provided would include public health, health care and health-related social services. While this Article *does not* aim to provide a specific list of goods and services, some examples of *categories* of healthcare that are subject to medical necessity and medical appropriateness assessments include:

- Medical goods and services provided by physicians and other health professionals (e.g., imaging, lab, X-ray, and other diagnos-

15 (1991); Society of Critical Care Medicine Ethics Committee (SCCMEC), *Consensus Statement on the Triage of Critically Ill Patients*, 271 JAMA 1200-3 (1994) [hereinafter *Consensus Statement*]; Tom Tomlinson & Howard Brody, *Futility and the Ethics of Resuscitation*, 264 JAMA 1276-80 (1990); H. Tristram Engelhardt Jr., *Rethinking Concepts of Futility in Critical Care*, Center for Medical Ethics and Health Policy, Baylor College of Medicine (October 1996), available at <http://www.mediscene.com/medpub/futile.html>.

³³⁴ See, Paul R. Ward, *Health Care Rationing: Can We Afford to Ignore Euthanasia?*, HEALTH SERVICES MANAGEMENT RESEARCH 32 (Feb. 1997) (discussing the potential cost savings in the United Kingdom of advance directives, do not resuscitate orders, futile care withdrawal, and hospice care). See also Stephen Horton, *Persistent Vegetative State: What Decides the Cut-Off Point?*, INTENSIVE & CRITICAL CARE NURSING, 12, 40 (1996).

³³⁵ See *Consensus Statement*, *supra* note 333. See American Thoracic Society, *Withholding and Withdrawing Life-Sustaining Therapy*, 144 AM. REV. RESPIRATORY DISEASES 726, 726-28 (1991).

³³⁶ See *Right to Health*, *supra* note 22, for the analysis of an ITA on core dimensions of health.

tic tests; preventive care for both adults and children, including periodic physical exams and office visits; immunizations and flu shots; screenings; family planning, and maternity care; therapeutic treatments (including physical medicine, occupational, and speech therapy); rehabilitative therapies; hearing and vision services including testing, treatment, and supplies; orthopedic and prosthetic devices; durable medical equipment; medical supplies; home health services; and educational classes and programs; surgical and anesthetic goods and services provided by physicians and other health-care professionals;

- Services provided by hospitals, ambulatory surgery centers, clinics, nursing care facilities, home health-care agencies;
- Services for medical emergencies and injuries; ambulance service;
- Parity with other benefits for mental health and substance abuse services provided by licensed psychiatrists, psychologists, clinical social workers, or psychiatric nurses; inpatient visits and intensive outpatient treatment; and diagnostic tests;
- Prescription drug benefits (e.g., drugs, vitamins and minerals, nutritional supplements, contraceptive drugs and devices);³³⁷
- Dental benefits (e.g., clinical oral evaluations, radiographs, tests and laboratory exams, preventive care and restorations, extractions).

Doctors and patients should specify goods and services in particular cases.

A comparison of elements of a guaranteed benefits package under this approach with those advocated by other accounts highlights several important distinctions. First, libertarian and market-based approaches do not guarantee individuals any health care. Second, fair equality of opportunity accounts have been vague in determining a benefits package and could conceivably include all beneficial health care.³³⁸ The FEO account also provides little guidance on efficiency or on the question of which goods and services are medically appropriate. Third, approaches that rely on a “prudential insurer” to choose a benefits package might or

³³⁷ This is also a matter of gender equity. One U.S. study found that women have, on average, 68% more out-of-pocket health-care expenditures than men, primarily because they have to pay for contraceptive drugs and devices. WOMEN’S RESEARCH AND EDUCATION INSTITUTE (WREI), *WOMEN’S HEALTH CARE COSTS AND EXPERIENCES 2* (1994).

³³⁸ See JUST HEALTH CARE, *supra* note 19 (asserting that *all* health care should be an isolated social good of special moral importance due to its role in protecting equality of opportunity). By insulating health care from other social goods, Daniels’ account implies that all forms of health care (even health care that may not be medically appropriate) should be isolated from trade-offs with other social goods. *But see* HUMAN LIFE, *supra* note 82, at 123, for a critical view of Daniels offering “most of what modern medicine has to offer.”

might not provide goods and services that individuals need. Much of the demand for health care is unpredictable due to the uncertainty of health need. The account presented here, on the other hand, would guarantee medically appropriate and necessary health care to reduce shortfall inequalities in individuals' central health capabilities; the process would eliminate the need for ex ante decisions about coverage. However, this account gives individuals the freedom to reject benefits or interventions and applies the cost minimization principle (below) and CEA in specific situations to achieve given health objectives with the fewest resources.

This account also differs from other perspectives in the way in which it regards specific categories of goods and services. For example, it may be more horizontally, although not necessarily more vertically,³³⁹ expansive than some views, as demonstrated, for example, by several pivotal categories of coverage. First, it would cover nutritional supplements, such as vitamins and minerals for individuals who are or are at risk of being malnourished because nutritional deficiencies undermine physical and cognitive capabilities. Prenatal iodine deficiency, for example, can cause permanent mental retardation, and chronic iodine deficiency can lead to mild mental impairment among school-aged children and adults.³⁴⁰ Micronutrient supplementation for children can especially alleviate childhood health problems and prevent diseases later in life.³⁴¹ Providing iodine and iron to micronutrient-deficient girls can help restore their cognitive functions to normal levels.³⁴² Similarly, neurological and physical impairment, mental retardation, and death can be prevented by providing low-protein formula (excluding leucine, isoleucine, and valine) to infants unable to digest certain amino acids because they have Maple Syrup Urine Disease.³⁴³

Nutritional supplementation during pregnancy benefits fetal development. Dietary supplementation of folic acid (vitamin B 9) during the first trimester of pregnancy significantly reduces the incidence of spina bifida and other neural tube defects. Thus, folic acid and regular vitamin

³³⁹ The account may be more horizontally expansive in the sense that the benefits package might cover high-quality goods and services for some conditions that other approaches might not cover. It is not necessarily vertically expansive because it provides limitations on resources in areas where other approaches may not.

³⁴⁰ Joanne Leslie & Dean T. Jamison, *Health and Nutrition Considerations in Education Planning. Educational Consequences of Health Problems Among School Age Children*, 12(3) FOOD AND NUTRITION BULLETIN 198 (1990).

³⁴¹ Alok Bhargava, *Modelling the Health of Filipino Children*, 157(3) J. ROYAL STAT. SOC'Y, SERIES A (1994).

³⁴² *Id.*

³⁴³ See Maple Syrup Urine Disease Support Group, available at <http://www.MSUD-support.org>; Dawn Falik, *A Swab Saves Lives: Doctor Develops Genetic Test to Solve Decades-Old Mystery Surrounding Death of Mennonite Babies; Maple Syrup Urine Disease*, ST. LOUIS POST-DISPATCH, Jan. 6, 2002, at A1.

supplements for pregnant women should be included in the benefits package as should vitamin supplements and/or formula for children.

Dental health benefits also distinguish this benefits package. Dental health is unduly influenced by some acute and chronic conditions. For example, children with hypohidrotic ectodermal dysplasia (HED) lose or totally lack teeth,³⁴⁴ often requiring tooth replacement or false teeth to restore their capability for oral functioning. However, U.S. insurance companies often refuse to cover dental health. Under this approach, these and other children and adults would be guaranteed dental health benefits to ensure their ability for oral functioning.

Third, the account would also cover mental health and substance abuse services, which would gain parity with other benefits. The main objective would be to ensure individuals' ability for mental health functioning. The package would cover both episodic and chronic conditions if they were diagnosed by DSM-IV criteria and treated with scientifically accepted methods of care.³⁴⁵ Goods and services recommendations would be determined by principles of medical appropriateness and medical necessity. For example, a patient presenting with acute depression would receive antidepressant and/or cognitive therapy, depending upon the extent and severity of his condition.³⁴⁶

Fourth, the account would cover family planning, contraceptive and fertility related goods and services. Other approaches would likely exclude such care, arguing that reproductive capability is beyond the scope of our obligation. These are but a few examples of elements of this account that would differ from other approaches.

This account differs from previous interpretations of the capability approach. Sabin and Daniels, for example, argued that the capability model would advocate insurance coverage for all personal attributes, such as shyness or lack of confidence, resilience, and sociability, that put individuals at a relative disadvantage. They claim that the central purpose of health care under their interpretation of a capability model is to "use health care to help people become *equal* competitors, free from disadvantageous lack of capabilities regardless of etiology."³⁴⁷ Thus, they argue, erroneously, that the capability model fails to make a "moral distinction between treatment of illness and enhancement of disadvantageous personal capabilities."³⁴⁸ By contrast, the capability and health

³⁴⁴ See generally The Sarah Moody Foundation, available at <http://www.Sarahmoodyfoundation.org/>.

³⁴⁵ See generally American Association of Community Psychiatrists (AACCP), available at <http://www.communitypsychiatry.org/>.

³⁴⁶ Mental health functioning is also linked to health agency as discussed in *Agency and Quality*, *supra* note 23.

³⁴⁷ *Medical Necessity*, *supra* note 96, at 10.

³⁴⁸ *Id.*

account presented here, defines the central purpose of health care as addressing shortfall inequalities in *health capabilities*, rather than all personal traits, talents, skills, or capabilities unrelated to health.

8. *Hard Cases: The “Bottomless Pit Objection” and “Reasonable Accommodation”*

Critics have argued that some ethical theories give insufficient guidance about providing exorbitantly costly services to individuals with intractable illnesses or injuries.³⁴⁹ A particularly difficult problem is what some have called the “bottomless pit objection,”³⁵⁰ whereby one or a few individuals with seemingly infinite needs use significant resources without improving health functioning.³⁵¹ Rawls’s maximin or difference principle³⁵² and the FEO account³⁵³ have encountered particular criticism³⁵⁴ for these problems.³⁵⁵ On the other hand, consequentialist approaches that favor allocations that produce the greatest net social benefit are criticized for discriminating against those most in need, especially the disabled, and for ignoring individuality.³⁵⁶ These failings, liberal theo-

³⁴⁹ See Norman Daniels, *Health-Care Needs and Distributive Justice*, 10 PHIL. & PUB. AFF. 146, 168 (1981) [hereinafter *Distributive Justice*]; *Decent Minimum*, *supra* note 248; Ronald Dworkin, *Justice in the Distribution of Health Care*, 38 MCGILL L.J. 883, 885-87 (1993).

³⁵⁰ See ISSUES IN BIOETHICS, *supra* note 10 (addressing attempts to limit the claims of the medical needy based on “capacity to benefit”). See also PATIENT SELECTION, *supra* note 124, at 192-207, on concerns with this concept and with randomly selecting those who might benefit from a given treatment.

³⁵¹ See Kenneth J. Arrow, *Some Ordinalist-Utilitarian Notes on Rawls’s Theory of Justice*, 70 J. PHIL. 245, 251 (1973) (criticizing Rawls’s theory of justice and noting that some health-care procedures “serve to keep people barely alive but with little satisfaction and which are yet so expensive as to reduce the rest of the population to poverty.”).

³⁵² Rawls does not apply this principle specifically to health care. See generally THEORY OF JUSTICE, *supra* note 21. Others who have applied the principle to health care, however, note that it could lead to the bottomless pit problem.

³⁵³ See *Rationing Through Choice*, *supra* note 108, at 1023-24.

³⁵⁴ See *id.* at 1024 (noting Daniels’ emphasis on priority for those diseases and disabilities that

“involve a greater curtailment of an individual’s share of the normal opportunity range . . . could . . . give rise to the ‘bottomless pit’ problem of patients whose health care costs are so high, and whose disabilities are so intractable, that promoting the normal opportunity range of these patients precludes spending to promote the normal opportunity range of all other individuals.”).

See also *Health, and Healthcare*, *supra* note 19, at 2. See generally INEQUALITY, *supra* note 11.

³⁵⁵ See *Medical Ethics*, *supra* note 194, at 42 (noting that the Daniels approach “does not tell us which opportunities to protect when scarcity prevents us from equally protecting everyone’s.”); *Distributive Justice*, *supra* note 349, at 171 (observing that the Daniels “approach provides little . . . [guidance on] hard . . . resource allocation decisions in which we must choose between services which remove serious impairments of opportunity for a few people and those which remove significant but less serious impairments for many.”).

³⁵⁶ See David C. Hadorn, *The Problem of Discrimination in Health Care Priority Setting*, 268 JAMA 1454, 1454-59 (1992); Dan W. Brock, *Priority to the Worse Off in Health Care*

rists argue, violate the Kantian principle of respect for individuals as moral agents who cannot be used solely to assist other individuals.³⁵⁷ This account also espouses this principle.

So how does society prioritize goods and services to the neediest but also set limits in order not to jeopardize a society's overall health achievements?³⁵⁸ This account addresses these competing claims in several stages. First, by prioritizing central health capabilities above non-central ones and leaving open the selection and valuation of the latter, the account explicitly prioritizes health care associated with core dimensions of health and limits others. Second, by using medical necessity, medical appropriateness and evidence-based clinical guidelines as criteria, the account further prioritizes those health goods and services deemed medically appropriate over inappropriate or futile ones. Third, within the medically appropriate care associated with central health capabilities, the account prioritizes those goods and services that reduce shortfall inequalities in central health capabilities over those that do not.³⁵⁹ Fourth, in medically appropriate health care that reduces these shortfall inequalities, the account applies the low-level principle of "reasonable accommodation" and the related "reasonable adjustments" to illuminate our obligations.³⁶⁰ This principle emerged when the United States government had to interpret the scope of its obligations to individuals with disabilities

Resource Prioritization, in *MEDICINE AND SOCIAL JUSTICE* 362, 362-72 (Rosamond Rhodes et al. eds., 2002); See generally *Prioritizing and Rationing*, *supra* note 57; Paul T. Menzel, *Oregon's Denial: Disabilities and Quality of Life*, *HASTINGS CENTER REP.*, Nov.-Dec. 1992, at 21, 21-25; See generally *Disabilities Act*, *supra* note 9; David Orentlicher, *Deconstructing Disability: Rationing of Health Care and Unfair Discrimination Against the Sick*, 31 *HARV. C.R.-C.L. L. REV.* 49, 49-87 (1996) [hereinafter *Deconstructing Disability*] (arguing that the quality adjusted life year (QALY) discriminates against the disabled); Mary A. Crossley, *Of Diagnoses and Discrimination: Discriminatory Nontreatment of Infants with HIV Infection*, 93 *COLUM. L. REV.* 1581, 1581-667 (1993) (pointing out that disabilities should not be considered if they do not have a "medical effect" on the proposed treatment). See also United States Congress, Office of Technology Assessment (OTA), *Evaluation of the Oregon Medicaid Proposal 2* (1992) [hereinafter *Medicaid Proposal*]. (noting that the Bush administration rejected Oregon's waiver application, partly on the grounds that its use of quality-of-life measures violated the Americans with Disabilities Act (ADA). *But see generally Rationing Through Choice*, *supra* note 108.

³⁵⁷ See *Allocating Health*, *supra* note 110.

³⁵⁸ Some advocate "random selection" (typically implemented by lottery) as a way to decide who gets which health resources. See generally *BIOMEDICAL ETHICS*, *supra* note 47; See generally *Disabilities Act*, *supra* note 9; See generally *PATIENT SELECTION*, *supra* note 124 (recognizing the potential use of "modified random selection" to allocate scarce treatments among those who demonstrate a certain ability to benefit (thus excluding those who have not met that threshold)); See generally *Deconstructing Disabilities*, *supra* note 356 (arguing that this threshold should be used only when the difference between those who are likely to benefit and those who are not is "large" and "certain.")). See generally *Rationing Medical Care*, *supra* note 60, for an analysis of the "fair chances vs. best outcomes" rationing problem.

³⁵⁹ See *ARISTOTELIAN JUSTICE*, *supra* note 15; *Right to Health*, *supra* note 22.

³⁶⁰ I thank Theodore W. Ruger for useful discussions on this topic.

under the Rehabilitation Act³⁶¹ and the Americans with Disabilities Act (ADA).³⁶² The Acts require programs to make “reasonable accommodations” or “modifications” so that disabled persons can meet the program’s “essential eligibility requirements.”³⁶³ In general, “reasonable accommodations or modifications” are those that are not “fundamental” or will not cause “undue hardship” to the program in question. The Rehabilitation Act and the ADA stop short of accommodations that could cause “undue hardship,” determined by the particular accommodation’s nature and cost and the financial and organizational capacity of the institution in question.³⁶⁴ In the U.K. related legislation in the Disability Discrimination Acts of 1995 and 2005 require “reasonable adjustments” to remove barriers from disabled individuals’ participation.

This account considers absolute harm to others in terms of their capability for functioning, not a cost-benefit analysis. Several commentators have criticized the application of a rigid cost-benefit analysis to interventions on disabled individuals’ behalf, on the grounds that such an allocative principle would discriminate against the disabled, who might receive less benefit relative to costs than non-disabled individuals.³⁶⁵

This account recognizes this critique’s value and rejects weighing cost considerations against the precise benefit of an intervention (for example, through CBA). It advocates directing resources to those who experience shortfall inequalities in the central health capabilities in proportion to their deprivations and the use of medical care necessity and appropriateness (and medical futility) as a standard for evaluating health care interventions. In operationalizing these normative principles and allocating health resources across society as a whole, however, considering the absolute costs of certain treatment protocols and their effects on total health system resources is appropriate (as discussed below) and must be evaluated in the context of a model of shared health governance between individuals, physicians and institutions that govern health.

Both the ADA statute itself and the Equal Employment Opportunity Commission (EEOC) regulations endorse an approach of considering absolute costs of accommodation as a relevant factor while *not* engaging in a direct *cost-benefit* analysis. The ADA defines undue hardship as “an

³⁶¹ 29 U.S.C. §§ 701–797(b) (1994).

³⁶² 42 U.S.C. §§ 12101–12213 (1994).

³⁶³ 29 U.S.C. § 795 (1994); 42 U.S.C.S. §§ 12111–12113 (1994).

³⁶⁴ 42 U.S.C. § 12111(10) (1994).

³⁶⁵ See, e.g., David Orentlicher, *Utility, Equality, and Health Care Needs in Persons With Disabilities*, in *AMERICANS WITH DISABILITIES: EXPLORING IMPLICATIONS OF THE LAW FOR INDIVIDUALS AND INSTITUTIONS* 241 (Leslie P. Francis & Anita Silvers eds., 2000). “Primary reliance on measures of outcome such as increases in length of life . . . will disfavor persons with disabilities. We should not prefer one patient over another just because the first patient will realize more benefit from the care.”

action requiring significant difficulty or *expense*.”³⁶⁶ The EEOC regulations assess hardship by considering the “nature and cost” of the accommodation and the impact on the “overall financial resources” of the organization involved.³⁶⁷ But the EEOC guidelines explain that “neither the statute [the ADA] nor the legislative history supports a cost-benefit analysis to determine . . . undue hardship.”³⁶⁸

Even economically minded federal jurists are hesitant to apply strict cost-benefit analysis to the question of undue hardship in particular cases. In *Vande Zande v. Wisconsin Department of Administration*,³⁶⁹ Judge Richard Posner states that the costs of accommodation are important for determining reasonableness and undue hardship, but that “it would not follow” from this “that the costs and benefits . . . always have to be quantified, or even that an accommodation would have to be deemed unreasonable if the cost exceeded the benefit however slightly.”³⁷⁰ Elsewhere in the opinion, however, Posner seems more predisposed to cost-benefit analysis, stating that an accommodation causes undue hardship, and thus is not “reasonable,” only if an institution must “expend enormous sums in order to bring about a trivial improvement in the life of a disabled employee,” or where “the costs are excessive in relation to . . . the employer’s financial survival or health.”³⁷¹ Extending this argument to the question of intractable conditions and health resource allocation, two factors would be relevant in defining the social obligation. The first is medical appropriateness and medical futility; the second is the point beyond which the allocation sacrifices, unduly reduces, or otherwise impacts the central health capabilities of others. Ultimately, the obligation to address intractable needs does not extend beyond the point where others might suffer harm to their central health capabilities. At the societal level, resource allocation should focus on all deprivations in health capabilities below the agreed-upon threshold level of health functioning. Combining the “reasonable accommodation” standard with “medical appropriateness” and “medical necessity” principles could help society clarify its obligations and in a way that obviates the need to employ concepts such as the “bottomless pit” problem. Existing case law could reveal the reasoning behind and the application of such a standard. Eventually, however, a body of case law and policy case stud-

³⁶⁶ 42 U.S.C. § 12111(10) (1994) (emphasis added).

³⁶⁷ 29 C.F.R. § 1630.2 (2004).

³⁶⁸ EQUAL EMPLOYMENT OPPORTUNITY COMM’N, ENFORCEMENT GUIDANCE: REASONABLE ACCOMMODATION AND UNDUE HARDSHIP UNDER THE AMERICANS WITH DISABILITIES ACT (2002).

³⁶⁹ *Vande Zande v. Wisc. Dep’t of Admin.*, 44 F.3d 538 (7th Cir. 1995).

³⁷⁰ *Id.* at 542.

³⁷¹ *See id.* at 542-43.

ies in health resource allocation could develop to offer guidance on decision making in this area.³⁷²

Fifth, as to advance directives and do not resuscitate orders the account supports efforts to ensure that end-of-life treatment complies with patients' values. Such compliance should be encouraged because it respects patient autonomy *and* holds the potential as well to reduce costs and medically futile care.³⁷³ Studies have shown that patients' end-of-life treatment preferences are often ignored,³⁷⁴ resulting in family members being two to three times more likely to err by over-treating as by under-treating.³⁷⁵ Without the use of advance directives, studies have found that physicians, like family members, are likely to over-treat their patients in efforts to do anything possible to preserve life.³⁷⁶ An analysis of hospice care found that increased use of advance directives could potentially save between 25% and 40% of health-care costs during the last month of life, and between 10% and 17% of health-care costs during the last six months of life.³⁷⁷

Sixth, this account applies "cost minimization" analysis and, in certain micro-level comparisons, cost-effectiveness analysis in order to promote shortfall equality in individuals' capabilities for health with the fewest resources possible. Cost-minimization studies assume a given objective and search for the least expensive way to achieve it. At the micro-level, cost-effectiveness compares the incremental health benefits and incremental costs of two or more interventions.

9. *Joint Clinical and Economic Solutions: Incorporating Efficiency*

Meeting the dual social obligations of equality and efficiency in health resource allocation will require both clinical and economic solutions, *but clinical and medical input must drive the process*. This ap-

³⁷² Employing the "reasonable accommodation" principle would involve using an incomplete eligibility criterion of medical appropriateness to avoid the "bottomless pit" problem, and must be done on a case-by-case basis. See, e.g., *School Bd. v. Arline*, 480 U.S. 273, 274 (1987) (stating that the court "must conduct an individualized inquiry and make appropriate findings of fact, based on reasonable medical judgments"); see also *Strathie v. Dep't of Transp.*, 716 F.2d 227 (3d Cir. 1983), as cited in *Rationing Through Choice*, *supra* note 108, at 1094–95 (noting that the determination of whether an individual with a disability poses a safety threat to others in the workplace must be made on a case-by-case basis).

³⁷³ See Ezekiel J. Emanuel, *Cost Savings at the End of Life. What do the Data Show?*, 275(24) JAMA 1907–14 (1996) [hereinafter *End of Life*].

³⁷⁴ See Peter H. Ditto et al., *Advance Directives as Acts of Communication: A Randomized Controlled Trial*, 161(3) ARCHIVES INTERNAL MED. 421, 421 (2001).

³⁷⁵ See Kristen M. Coppola et al., *Accuracy of Primary Care and Hospital-Based Physicians' Predictions of Elderly Outpatients' Treatment Preferences With and Without Advance Directives*, 161(3) ARCHIVES INTERNAL MED. 431, 435–36 (2001).

³⁷⁶ *Id.*

³⁷⁷ See generally *End of Life*, *supra* note 373.

proach ensures that physician judgment (at the bedside and *a priori* through clinical guidelines and medical appropriateness assessments) and patient input are the primary determinants of care. Yet, successful implementation of effective clinical protocols requires economic incentives. Empirical evidence suggests that economic tools can influence the behavior of patients, physicians, and planners.

Several measures have been implemented to encourage cost consciousness and improve efficiency. In the United States, for example, high and rising health-care costs have produced various economic incentives on both the supply and demand sides to reduce health-care use and expenditures. On the demand side, instruments such as co-payment schemes and health insurance deductibles require patients to pay either a percentage, or a fixed portion, of the price of a given medical procedure or health premium. The economic rationale behind co-pays and deductibles is that they sensitize consumers' to the price of health care and thus serve as a deterrent to consumption.³⁷⁸

On the supply side, price, budgetary, and salary incentives (prospective and capitated payment schemes, global budgets, competition,³⁷⁹ and utilization and management review systems) are all efforts to reduce utilization costs.³⁸⁰ In theory, these incentives force physicians and hospitals to internalize costs and to provide only the most cost-effective care. In some cases, they actually shift the financial risk of health expenditures from health insurers to health providers. The increased use of payment mechanisms (such as Diagnostic-Related Groups) and health financing and delivery institutions such as managed care organizations (HMOs)

³⁷⁸ Some free-market proponents would completely alter the incentive structure in the health-care marketplace. To increase the cost consciousness of consumers, some have proposed making families, rather than employers, responsible for purchasing health insurance through mandates and tax credits. See A NATIONAL HEALTH SYSTEM FOR AMERICA (Stuart M. Butler & Edmund F. Haislmaier eds., 1989) 58–67; See also Alain Enthoven & R. Kronick, *A Consumer-Choice Health Plan for the 1990s: A Universal Health Insurance in a System Designed to Promote Quality and Economy*, 320 NEW ENG. J. MED. 94–101 (1989) (suggesting that employees should pay the difference between what their employers paid, e.g., 80% of the cost of the average premium, and their choice of plan). This would maintain the current employer-related health insurance system while attempting to increase consumers' cost-consciousness).

³⁷⁹ In the United Kingdom, National Health Service reforms in the 1990s proposed increasing competition through "internal markets." A review of these reforms, concluded there was "little evidence from the UK or elsewhere that competition in health care produces efficiency or improvements in resource allocation." See Alan Maynard & Karen Bloor, *Universal Coverage and Cost Control: The United Kingdom National Health Service*, 20(4) J. HEALTH AND HUM. SERVICES ADMIN. 423–438 (1998).

³⁸⁰ Another method used to ration health-care goods and services is the utilization review, where health insurance companies, including managed care companies, employ panels of experts to deny approval of physician's treatment decisions. The rationale for this process is rarely made explicit, but some work suggests that decisions are made on the basis of cost.

have resulted from these efforts.³⁸¹ However, it is unclear whether these measures have actually reduced expenditures or maintained or improved effectiveness.³⁸² For example, DRGs have shifted costs from one system to another instead of achieving real savings.³⁸³ In the private U.S. health insurance market, managed care organizations proliferated for some time. They aim to control costs through pre-approval requirements, co-payments, and negotiated fees with providers and to cut back on marginal value services through use review, pre-certification, and profiling.

While such strategies may reduce the volume of health-care provided, they are devoid of clinical input and therefore often reduce *both inappropriate and appropriate care*. Thus, they can have deleterious health consequences and can be inegalitarian,³⁸⁴ particularly affecting the poor and medically indigent, who often have the greatest health-care needs and respond most sensitively to economic incentives to reduce consumption.³⁸⁵ Therefore, attempts to reduce shortfall inequalities in individuals' capabilities for health with the fewest resources possible will require a *joint clinical and economic solution*.

³⁸¹ In the United States in 2000, the HMO penetration rate (including both traditional HMOs and point-of-service [POS] plans) was roughly 30%, with 20 states having an HMO penetration rate of 30% or more. In addition, thirty of fifty states gave financial incentives to providers for withholding covered health care in 2000. See Kaiser Family Foundation, *State Health Facts Online* (2001), available at <http://statehealthfacts.kff.org> (follow "50 State Comparisons"; then follow "Managed Health Care and & Health Insurance"; then follow "HMO Penetration Rate").

³⁸² Both supply- and demand-side approaches to cost containment have advantages and disadvantages, which can be assessed by whether they: (a) reduce health-care expenditures; (b) maintain and improve health; and (c) are medically feasible. One of the perceived benefits of both approaches is a reduction in health-care utilization. In a randomly controlled health insurance experiment, for example, researchers found that increasing co-payments on health insurance reduced demand for health-care services by as much as 40%. See generally JOSEPH P. NEWHOUSE, *FREE FOR ALL? LESSONS FROM THE RAND HEALTH INSURANCE EXPERIMENT* (1993), at 31–180. But the same study found that co-payments did not differentiate between appropriate and inappropriate care. See John T. Lohr et al., *Use of Medical Care in the RAND Health Insurance Experiment: Diagnosis and Service-Specific Analysis in a Randomized Controlled Trial*, 24(9) *MED. CARE* S1, S31–38 (1986). Additionally, cross-cultural comparisons of national health systems provide evidence of the effectiveness of capitation and global budgeting in reducing health care utilization. The U. K. has lower usage rates of various diagnostic and treatment options than the United States. One study found that rates of coronary artery bypass surgery were less than one-fifth as prevalent in the United Kingdom than in the United States.

See HENRY J. AARON & WILLIAM B. SCHWARTZ, *THE PAINFUL PRESCRIPTION: RATIONING HOSPITAL CARE* 28 (1984).

³⁸³ See generally DANIEL CALLAHAN, *WHAT KIND OF LIFE: THE LIMITS OF MEDICAL PROGRESS* (1990).

³⁸⁴ See Paul T. Menzel, *Economic Competition in Health Care: A Moral Assessment*, 12(1) *J. MED. AND PHIL.* 73–77 (1987) (describing the equity implications of economic competition, particularly in the form of increased patient cost-sharing and "cream skimming").

³⁸⁵ See David Mechanic, *Socioeconomic Status and Health*, in *PATHWAYS TO HEALTH: THE ROLE OF SOCIAL FACTORS* 13 (John P. Bunker et al. eds., 1989).

Under this account, economic solutions should *follow* and *complement* clinical progress, *not vice versa*. As the evidence on the magnitude and determinants of inappropriate care accumulates, economists and health policy analysts can create policy instruments to encourage physicians, patients, and planners towards productive care. Particular attention should be paid to incentivizing and training physicians by rewarding appropriate care and penalizing inappropriate care.³⁸⁶ This paradigm uses an iterative approach, first addressing equity by using clinical input to analyze deficits in individuals' ability for health functioning below a given threshold. It then addresses efficiency, using measures of medical care appropriateness, cost-minimization, and, in specific cases, cost-effectiveness analysis.

Cost-minimization analysis is an appropriate evaluation to be used when the case for intervention has been established,³⁸⁷ and it is increasingly becoming a mainstay of efficiency analysis in public health and medicine. In obstetrics and gynecology,³⁸⁸ for example, researchers compared the costs of three alternative hysterectomy methods — abdominal hysterectomy (AH), vaginal hysterectomy (VH), and laparoscopically assisted vaginal hysterectomy (LAVH) — which have been judged equally effective.³⁸⁹ However, the study found that LAVH (at \$6,116) was more costly than either AH (at \$5,084) or VH (at \$4,221).³⁹⁰ A study of pregnancy management beyond 41 weeks also compared the costs of three strategies: expectant management (EM), immediate induction of labor using prostaglandin gel (PGE₂), and elective induction (EI).³⁹¹ All three strategies were determined to be acceptable approaches to prolonged pregnancy, but the PGE₂ treatment (at \$3,312) was approximately 33% more costly than EM and EI, which were equivalent in cost.³⁹²

Cost-minimization studies have also been applied to cancer therapy. Multiple studies compared the costs of peripheral blood progenitor cell (PBPC) transplantation with those for autologous bone marrow transplantation (ABMT) in patients with Hodgkin's or non-Hodgkin's lym-

³⁸⁶ Incentives should be meritorious and can be either financial or non-financial.

³⁸⁷ See Ray Robinson, *Cost-Minimization Analysis*, 307 BRIT. MED. J. 686-89, 726 (1993).

³⁸⁸ See Michael Gardner, *Cost Analysis in Obstetrics and Gynecology*, 41 CLINICAL OBSTETRICS AND GYNECOLOGY 296 (1998) (discussing different cost analysis used in obstetrics and gynecology).

³⁸⁹ See James H. Dorsey et al., *Costs and Charges Associated with Three Alternative Techniques of Hysterectomy*, 335 NEW ENG. J. MED. 476 (1996).

³⁹⁰ *Id.* at 476.

³⁹¹ Gardner, *supra* note 388, at 298.

³⁹² *Id.*

phoma.³⁹³ While studies found both treatments equally effective,³⁹⁴ two studies found that ABMT cost roughly \$13,600 more than the PBPC in terms of overall service rates.³⁹⁵ In another cost-minimization study of cancer therapy, researchers in the United Kingdom compared the combination chemotherapy known as CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone), fludarabine, and rituximab for treating relapsed indolent B cell non-Hodgkin's lymphoma.³⁹⁶ Similar clinical outcomes resulted from all three treatments.³⁹⁷ However, the per patient cost associated with fludarabine (£10,022) was considerably higher than that of either CHOP (£7,210) or rituximab (£6,080).³⁹⁸

Another area in which cost-minimization has been utilized is ambulatory anesthesia. One study compared four protocols: methohexital-desflurane, methohexital-sevoflurane, propofol-desflurane, and propofol-sevoflurane.³⁹⁹ Results showed that when the outcome was induction of anesthesia, methohexital costs less than propofol.⁴⁰⁰ Another study compared two rehabilitation programs for stroke patients: namely, early hospital discharge and home-based rehabilitation with conventional in-hospital rehabilitation and community care for stroke rehabilitation.⁴⁰¹ The average cost per patient was lower for early hospital discharge and home-based rehabilitation, although the difference in cost was not statis-

³⁹³ See generally T.J. Smith et al., *Economic Analysis of a Randomized Clinical Trial to Compare Filgrastim-Mobilized Peripheral-Blood Progenitor-Cell Transplantation and Autologous Bone Marrow Transplantation in Patients With Hodgkin's and Non-Hodgkin's Lymphoma*, 15 J. CLINICAL ONCOLOGY 5, (1997) (finding that overall resources used and costs were lower for PBPC than for ABMT); N. Schmitz et al., *Randomised Trial of Filgrastim-Mobilised Peripheral Blood Progenitor Cell Transplantation Versus Autologous Bone-Marrow Transplantation in Lymphoma Patients*, 347 LANCET 353 (1996).

³⁹⁴ See Smith et al., *supra* note 393, at 356 (noting that, although not specifically addressed in the study, there was no obvious difference in the overall survival and disease-free survival rates of patients receiving PBPC versus AMBT transplantations); Olivier Hartmann et al., *Peripheral Blood Stem Cell and Bone Marrow Transplantation for Solid Tumors and Lymphomas: Hematologic Recovery and Costs. A Randomized, Controlled Trial.*, 126 ANNALS INTERNAL MED. 600, 606 (1997) (noting that although death and carcinologic events were not end points, rates of relapse have been similar in both groups).

³⁹⁵ Smith et al., *supra* note 393, at 8-9; Schmitz et al., *supra* note 393, at 357.

³⁹⁶ John Sweetenham et al., *Cost-Minimization Analysis of CHOP, Fludarabine and Rituximab for the Treatment of Relapsed Indolent B-cell Non-Hodgkin's Lymphoma in the U.K.*, 106 BRIT. J. HAEMATOLOGY 47, 48 (1994).

³⁹⁷ See *id.* at 52 (noting that the response rates of relapsed patients to the three drugs has been comparable).

³⁹⁸ *Id.* at 51.

³⁹⁹ See Rui Sun et al., *A Cost Comparison of Methohexital and Propofol for Ambulatory Anesthesia*, 89 ANESTHESIA & ANALGESIA 311, 312 (1999).

⁴⁰⁰ See *id.* at 314-15a

⁴⁰¹ See Craig Anderson et al., *Home or Hospital for Stroke Rehabilitation? Results of a Randomized Controlled Trial II: Cost Minimization Analysis at 6 Months*, 31 STROKE 1032 (2000).

tically significant.⁴⁰² The study did incorporate indirect costs incurred by home-based caregivers.⁴⁰³

Cost-minimization analysis has also highlighted potential cost savings in pharmaceuticals. A 2002 study of the use of prescription drugs by Medicare patients in the United States estimated that increasing the use of generic medications would save Medicare's 40 million beneficiaries roughly \$14 billion in 2003 and more than \$250 billion over a ten-year period.⁴⁰⁴ The study concluded that the biggest savings would be achieved by prescribing generic medications for conditions for which treatments are the most costly, such as ulcers and arthritis.⁴⁰⁵ Moreover, increased use of generic drugs would save an individual Medicare patient 16.3% or roughly \$270 per Medicare patient.⁴⁰⁶ Given the significant increased drug spending by Medicare patients as compared to younger adults,⁴⁰⁷ such measures could substantially reduce the cost of a Medicare prescription drug benefit.⁴⁰⁸

More recently, cost-minimization studies have been conducted cross-nationally. For example, in a study of antiepileptic drugs for newly diagnosed epilepsy, researchers found that while all four frequently prescribed antiepileptic drugs — lamotrigine (LTG), carbamazepine (CBZ), phenytoin (PHT), and valproate (VPA) — were equally able to achieve freedom from seizures, LTG was two to three times more expensive than the other three drugs in each country.⁴⁰⁹ An earlier U.K.-based cost-minimization study concluded that LTG costs more than the three other drugs.⁴¹⁰

Lastly, cost-minimization has also been used in studies pertaining to the treatment of HIV. A pilot study by the National Institute of Allergy and Infectious Diseases (NIAID) found that cycling antiretroviral treat-

⁴⁰² *Id.* at 1035.

⁴⁰³ *Id.* at 1033-34.

⁴⁰⁴ Grant A. Ritter et al., *Greater Use of Generics: A Prescription for Drug Cost Savings* 2 (Aug. 2001) (unpublished manuscript) (on file with The Schneider Institute for Health Policy, Brandeis University).

⁴⁰⁵ *See id.* at 11; Cindy Parks Thomas et al., *Growth In Prescription Drug Spending Among Insured Elders*, 20 *HEALTH AFF.* 265, 275 (200a).

⁴⁰⁶ Ritter et al., *supra* note 404, at 2.

⁴⁰⁷ *See id.*, at 3 (noting the elderly, who consume roughly three times as many prescriptions as do the younger population, incurred an 18.5 percent increase in drug costs between 1997 and 2000, while younger enrollees only experienced a 16 percent increase); *See* Cindy Parks Thomas et al., *Growth In Prescription Drug Spending Among Insured Elders*, 20 *HEALTH CARE ANALYSIS* 265, 268-70 (2001).

⁴⁰⁸ Ritter et al., *supra* note 404, at 13.

⁴⁰⁹ *See* D.C. Heaney et al., *Cost Minimization Analysis of Antiepileptic Drugs in Newly Diagnosed Epilepsy in 12 European Countries*, 41 *EPILEPSIA* S37, S43 (2000).

⁴¹⁰ *See* Dominic C. Heaney et al., *An Economic Appraisal of Carbamazepine, Lamotrigine, Phenytoin and Valproate as Initial Treatment in Adults with Newly Diagnosed Epilepsy*, 39 *EPILEPSIA* S19, S24 (1998).

ment rather than administering a continuous dose might be as effective, have fewer side effects and be significantly less expensive.⁴¹¹

This brief summary demonstrates the enormous potential of cost-minimization studies for reducing costs and inefficiencies in health policy while avoiding some of the objectionable problems associated with other economic methodologies. The paradigm presented here differs from other efforts⁴¹² to address the efficiency-equity tradeoff.⁴¹³ It uses an iterative approach and various methodological techniques for assessing the competing claims of equality and efficiency.⁴¹⁴ Neither the benefit maximization approach, which values saving life and improving/extending life equally, nor the strict lexical prioritization of life-saving and life-extending over all other health benefits is a workable solution to this problem. For example, the Oregon Health Services Commission (HSC) abandoned the cost-utility methodology and ranking of condition/treatment pairs, which had favored relatively minor but inexpensive interventions over more expensive interventions that saved lives.⁴¹⁵ The

⁴¹¹ See National Institute of Allergy and Infections Diseases, *7-Day-On, 7-Day-Off Regimen Could Reduce Cost, Toxicities of HIV Therapy*, available at <http://www3.niaid.nih.gov/news/newsreleases/2001/dayon.htm>.

⁴¹² For example, Menzel argues that individual consent to cost-effectiveness analysis should be used as a rationing option. See generally STRONG MEDICINE, *supra* note 5. Rakowski, however, argues for using hypothetical choice constructs, such as the “veil of ignorance” when allocating resources because hypothetical consent to rules of distributive justice is similar to actual consent. See generally EQUAL JUSTICE, *supra* note 10. This line of reasoning sounds similar to that used by those working in the areas of contingent valuation and revealed preference through hedonic measures. Rakowski also notes that individuals making hypothetical choices about rationing would likely not choose utilitarian approaches to rationing, but would instead choose random selection, but with a caveat for considering age and prognosis. See *id.*

⁴¹³ On the ethical implications of QALYs, Williams in particular has argued that QALYs can “accommodate a wide variety of health dimensions and sources of valuation,” as well as “the differential weighting of benefits according to who gets them, so they do not commit their users to any particular notion of distributive justice.” Alan Williams, *QALYs and Ethics: A Health Economist’s Perspective*, 43 SOC. SCI. & MED. 1795, 1795 (1996). Menzel, however, argues that the QALY model requires considerable work in meeting moral concerns. See Paul T. Menzel, *QALYs: Maximisation, Distribution and Consent. A Response to Alan Williams*, 3 HEALTH CARE ANALYSIS 226, 228-29 (1995). For equity-efficiency tradeoffs in HIV prevention see Edward H. Kaplan & Michael H. Merson, *Allocating HIV-Prevention Resources: Balancing Efficiency and Equity*, 92 AM. J. PUB. HEALTH 1905, 1905-07 n. 12 (2002).

⁴¹⁴ Nord *et al.* are finding that individuals tend to emphasize “equality in value of life and in entitlement to treatment rather than level of health after treatment.” *Health State*, *supra* note 195, at 37; see *The QALY*, *supra* note 196, at 92; *Health Benefits*, *supra* note 196, at 1435-36. Thus, people are reluctant to deny treatment to individuals based on benefit maximization. See *Health Benefits*, *supra* note 196, at 1435. Nord and others propose an approach called “cost-value analysis,” which uses equity weights to incorporate concerns for both severity and potential health in QALY calculations. See HEALTH ECONOMICS, *supra* note 41.

⁴¹⁵ See Medicaid Proposal, *supra* note 356, at 6-7.

Oregonian public found it unacceptable.⁴¹⁶ The HSC commissioners then ranked seventeen categories of medical interventions according to community health-care values,⁴¹⁷ without including costs. This approach gave the highest ranking to interventions that would save lives and permit a full recovery.⁴¹⁸ Maternity and newborn services ranked second, saving lives without a full recovery ranked third, and interventions for fatal or nonfatal conditions that have little effect on quality of life ranked last.⁴¹⁹ The HSC Commissioners then modified the rankings slightly by introducing costs, although they continued to give priority to life-saving treatments, despite exorbitant costs in many cases.⁴²⁰

Although the HSC's approach to revising its rankings is consistent with the paradigm presented here, it differs in many ways. This approach proposes that physicians and patients should play a larger role in determining medical appropriateness *and* in using evidence-based input to assess the net effectiveness of health interventions. The problem with lexical prioritization of life-saving or life-prolonging interventions is that it is inflexible when assessing the net benefits and costs of specific interventions on a case-by-base basis.

CONCLUSION

This Article has proposed an alternative paradigm for addressing the dual social obligations of equality and efficiency in health ethics, policy and law. It has offered a resource allocation framework that relies on a joint scientific and deliberative approach incorporating both clinical and economic solutions. It recommends that economic solutions follow clinical input, not vice versa. The result is not a simple formula for answering complex questions but several key substantive and procedural principles for guiding decision-making. No framework can satisfy all ethical requirements. This theory aims to provide more equitable policies and laws that would distribute the benefits, burdens, and costs of equal access; ensure universal, comprehensive coverage; and allocate resources equitably and efficiently within the health sector.

⁴¹⁶ See *Care Priorities*, *supra* note 57, at 2220 (noting that public criticism of Oregon's original health care priority list based on cost-effectiveness analysis contributed to the decision to adopt a different method of prioritizing health services).

⁴¹⁷ See Medicaid Proposal, *supra* note 356, at 7; *Care Priorities*, *supra* note 57, at 2220. The HSC criteria for ranking involved the category's perceived value to the individual and to society and the necessity of the types of interventions in a given category. See *Medicaid Proposal*, *supra* note 356, at 7-9. For an interesting analysis that compares CEA with Oregon's prioritization list, see Tammy O. Tengs et al., *Oregon's Medicaid Ranking and Cost-Effectiveness: Is There any Relationship?*, 16 *MED. DECISION MAKING* 99 (1996).

⁴¹⁸ Medicaid Proposal, *supra* note 356, at 8; *Care Priorities*, *supra* note 57, at 2221.

⁴¹⁹ Medicaid Proposal, *supra* note 356, at 8; *Care Priorities*, *supra* note 57, at 2221.

⁴²⁰ See Medicaid Proposal, *supra* note 356, at 7-9.

Developing this framework into a policy tool will be challenging. However, many elements of it, such as determinations of medical appropriateness and medical necessity, cost-minimization analysis, and deliberative fora for reasoned judgement and patient input are already available in certain forms.

Reasonable objections to this paradigm will arise. Some critics will argue that society is unable to afford such a generous plan and will want more assurance of cost savings or containment. Although the paradigm seeks to use health resources more efficiently, it will not produce a flawlessly efficient healthcare system, given the number of organizational, institutional, and political obstacles that will likely impede its implementation. If greater health-system efficiency is achieved but healthcare costs continue to rise, the American public must decide whether it is willing to spend more on health care. Most health economists find this stage of decision-making straightforward because they believe individuals should be free to spend as much as they like on goods they value highly, provided that waste is eliminated. Recent studies suggest that Americans' willingness to pay for health care exceeds current and even projected costs of medical goods and services.⁴²¹

Another objection might come from some physicians who regard clinical guidelines as "cookbook medicine," even though such guidelines are designed to assist policy-making and not to replace clinical judgment. But guidelines, combined with input from patients coupled with information systems, help standardize health care while enabling physicians to use their clinical judgment for patients with unique circumstances. Working with such guidelines might be necessary for physicians to regain decision-making authority and prevent micromanagement of patients by others, especially third party payers. Despite these objections, the paradigm outlined above has many advantages and the potential to replace the current unjust, wasteful, and costly system with more equitable, efficient and compassionate health care.

⁴²¹ David M. Cutler & Mark McClellan, *Is Technological Change In Medicine Worth It? When Costs and Benefits are Weighed Together, Technological Advances Have Proved to be Worth Far More than their Costs*, 20 *HEALTH AFFAIRS* 11 (2001).