

GOVERNING HEALTH

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Responding to Eugene Volokh, Essay, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV L. REV. 1813 (2007).

INTRODUCTION

In his thought-provoking Essay,¹ Professor Volokh argues for a constitutional right to “medical self-defense” for two purposes: first, to allow terminally ill patients to purchase, at their own expense, drugs that have not completed the Food and Drug Administration’s (FDA) approval process and, second, to allow all individuals access to transplanted organs for which there are current bans on payment.² His claim, in essence, is that we should allow markets for experimental drugs and human organs and that prohibition of such markets is unconstitutional. He grounds this “constitutional right” to “medical self-defense” in the common law justification of lethal self-defense, and sees this principle as analogously justifying abortion jurisprudence and therefore a relevant justificatory claim for other domains of health care.³

Taking the controversial *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*⁴ case as his point of departure, Professor Volokh’s reasoning adroitly connects the dots in a web of libertarian thought that takes, as its basis, negative rights of freedom from interference. More specifically, he uses the concepts of ordered liberty and justice to make his claim. Some have already argued that this line of argument is not sufficiently justified on either common law or constitutional grounds.⁵ I will take a different approach and focus

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¹ Eugene Volokh, Essay, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV L. REV. 1813 (2007).

² See *id.* at 1835.

³ See *id.* at 1824.

⁴ 495 F.3d 695 (D.C. Cir. 2007).

⁵ See, e.g., O. Carter Snead, *Unenumerated Rights and the Limits of Analogy: A Critique of the Right to Medical Self-Defense*, 121 HARV. L. REV. F. 1 (2007), available at <http://www.harvardlawreview.org/forum/issues/120/may07/snead.pdf>.

more on the theoretical concerns with Professor Volokh's position, which, I will argue, lacks sufficient philosophical and theoretical justification as it pertains specifically to libertarian philosophical discourse.

Moreover, I will present an alternative theoretical approach to the question of rights to health and health care. I will argue that a right to health care need not, indeed cannot, be framed in an absolute libertarian framework of wholly individualistic rights against the State. My alternative is to theoretically ground a right to health in the more positive conceptualization of freedom — human flourishing — arguing for treating the right to health as an ethical demand for equity in health. Unlike the legalistic, yet theoretically ungrounded, guarantee of a “right to medical self-defense,” a right to health so conceived purports that the regulation of self and society necessitate not just justiciable and enforceable legal rights or instruments, but also individuals and a collective with internalized public moral norms that inform the choices they make for themselves and their society to ensure capabilities to be healthy for all people,⁶ including the terminally ill.

A critical component of such a theory is understanding the corresponding duties and obligations of individuals, the State, and non-state actors, providing a framework for reforming the State, where necessary, to ensure its effectiveness in creating the collective goods required for progressive realization of such a right.⁷ Drawing on the Aristotelian notion of combining ethical and technical rationality, through a scientific and deliberative process I shall argue that the State is obligated to generate public goods through scientific evaluation that are required for consumption by individual agents, as a critical component of a framework to effectuate a right to health. The FDA and other State supported entities have not only a legislative claim, but also a moral duty to draw on the collective scientific resources a society has to offer in providing the rigorous and scientifically grounded evidence base needed to give *all individuals* the opportunity to be healthy. Efforts to undermine and delegitimize this role rob all individuals (present and future) of the necessary conditions for their optimal health functioning and health agency.⁸

⁶ Jennifer Prah Ruger, *Health and Social Justice*, 364 LANCET 1075, 1075–76 (2004).

⁷ See J P Ruger, *Ethics and Governance of Global Health Inequalities*, 60 J. EPIDEMIOLOGY & COMMUNITY HEALTH 998, 1001–02 (2006).

⁸ J. P. Ruger, *Rethinking Equal Access: Agency, Quality, and Norms*, 2 GLOBAL PUB. HEALTH 78, 85 (2007).

I. LIBERTARIAN AND MARKET-BASED APPROACHES TO HEALTH AND HEALTH CARE

The nature of health and health care does not lend itself well to libertarian doctrinal thinking, which has achieved limited success in health and health care. Libertarian theories of justice, as advocated by Robert Nozick⁹ and others, would deny altogether any societal obligation to provide medical care or health insurance to all. Libertarianism takes the principle of liberty as absolute and does not give health or health care special standing. Thus, consequentialist health concerns, such as delimiting the special status of terminally ill patients or patients requiring organ donation, are not part of the libertarian theoretical framework. The libertarian approach in rights scholarship pertaining to health generally endorses the fulfillment of negative rights (civil and political rights), but fails to endorse the fulfillment of positive rights.¹⁰ This perspective rejects social, economic, and cultural rights.

Proponents of a libertarian framework argue that a market mechanism is the ideal way to distribute health and health care. This approach generally stems from an overarching libertarian philosophy¹¹ in which individual freedom and autonomy are the predominant societal values, and in which the 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, even for regulation or medical research, for example).¹² Autonomous individuals may freely choose to purchase or forego health care or health insurance.¹³ Thus, a strict libertarian or 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.

There are more modified versions of a strict libertarian approach to health and health care. Clark Havighurst argues for a market-oriented

⁹ See generally ROBERT NOZICK, *ANARCHY, STATE, AND UTOPIA* (1974).

¹⁰ Tony Evans, *A Human Right to Health?*, 23 *THIRD WORLD Q.* 197, 199–203 (2002).

¹¹ See NOZICK, *supra* note 9, at 172 (explaining how distributive justice facilitates “a shift from the classical liberals’ notion of self-ownership” to infringement of individual rights); *id.* at 167–174; Loren E. Lomasky, *Medical Progress and National Health Care*, 10 *PHIL. & PUB. AFF.* 65, 69 (1981) (“[T]here is a wide gulf between medical care being an important human *interest* or *need* and its being a *right*.”). See generally H. TRISTRAM ENGELHARDT, JR., *THE FOUNDATIONS OF CHRISTIAN BIOETHICS* (2000).

¹² See NOZICK, *supra* note 9, 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?”).

¹³ See Lomasky, *supra* note 11, 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.”).

approach that would allow consumers to choose among different health plans according to the benefit level they desire.¹⁴ Loren Lomasky would give consumers the opportunity to “make informed purchases in a genuine medical marketplace.”¹⁵ Whereas strict libertarian views deny a societal moral obligation to provide health resources to its citizens, more moderate adaptations support some form of income transfer. Lomasky and H. Tristram Engelhardt, for example, favor cash vouchers for health insurance while Charles Fried sanctions income transfer for health care.¹⁶ 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, focuses on the peaceful settling of moral differences, with respect for personal autonomy as the utmost societal value.¹⁷ Engelhardt is critical of hypothetical choice procedures, such as the Rawlsian “veil of ignorance,” arguing that they result in decisions that reflect a thin theory of the good based on antecedent choice.¹⁸

Over the past several years, modified 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,¹⁹ many argue that financial incentives have put doctors in an unethical position by encouraging them to avoid diagnostic tests, hospitalizations, and expensive referrals that might benefit their patients.²⁰ Such financial incentives erode patients’ trust in the medical system.²¹

There are also concerns about other quasi market-based reforms, such as ex ante contracting for insurance plans that leave patients insufficiently insured for interventions they might need. In the United States, for example, the Emergency Medical Treatment and Labor Act²² requires emergency room personnel to treat even uninsured or

¹⁴ See CLARK C. HAVIGHURST, *HEALTH CARE CHOICES: PRIVATE CONTRACTS AS INSTRUMENTS OF HEALTH REFORM* 3 (1995).

¹⁵ Lomasky, *supra* note 11, at 88.

¹⁶ See Charles Fried, *Equality and Rights in Medical Care*, HASTINGS CENTER REP., Feb. 1976, at 29, 33.

¹⁷ See generally ENGELHARDT, *supra* note 11.

¹⁸ See generally H. TRISTRAM ENGELHARDT, JR., *THE FOUNDATIONS OF BIOETHICS* (1st ed. 1986).

¹⁹ See generally David M. Cutler et al., *How Does Managed Care Do It?*, 31 RAND J. ECON. 526 (2000).

²⁰ See Council on Ethical and Judicial Affairs, Am. Med. Ass’n, *Ethical Issues in Managed Care*, 273 JAMA 330, 333 (1995).

²¹ See *id.* at 331.

²² 42 U.S.C. § 1395dd (2005).

underinsured individuals in medical emergencies, including people who would have contracted to forgo treatment for certain conditions. The unpredictable nature of many adverse health events and society's inherent obligation to address medical needs can make contractual approaches impractical and unethical.

One of the main concerns with the libertarian and free-market perspectives is that the conditions for efficient market allocation based on supply and demand do not exist in either the health care or the health insurance markets,²³ including the pharmaceutical market and any organ market that would be legalized. 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, due to the important role of health insurance in the health care market, consumers do not necessarily pay the full cost of health care or receive the full value of the goods and services they choose to purchase. Also, market failures — such as the public goods aspects of scientific and medical knowledge, the externality effects of communicable diseases, uncertainty, asymmetric information, moral hazard, adverse selection, equity concerns and the failure to serve vulnerable populations — provide a rationale for public intervention in regulation, financing, and often provision of health care and other medical goods.

Another approach based on the quasi-libertarian or free-market view is rationing through choice, which claims to “accommodate[] diverse individual health and allocational preferences and thus respect[] autonomy.”²⁴ This model builds on existing market mechanisms, whereby individuals ration health care at the micro-allocational level through ex ante choices among various health plans. All individuals are required to contribute to a publicly funded health-care system, which would fund health plans or provide vouchers for purchasing either private or public plans.

This allocation model is similar to a prudential insurer system, in which initial resources are equal,²⁵ information on costs, benefits, and risks is accessible, and health care and insurance markets function freely. Individuals' choices define the fair and final allocation of health resources. Ronald Dworkin, in particular, has focused on this approach, drawing on John Rawls's “veil of ignorance” concept.

²³ See Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 948–54 (1963).

²⁴ See Arti Kaur Rai, *Rationing Through Choice: A New Approach to Cost-Effectiveness Analysis in Health Care*, 72 IND. L.J. 1015, 1032 (1997) (footnote omitted).

²⁵ See Ronald Dworkin, *What is Equality? Part 2: Equality of Resources*, 10 PHIL. & PUB. AFF. 283 (1981) [hereinafter Dworkin, *Part 2*]; see also Ronald Dworkin, *What is Equality? Part 1: Equality of Welfare*, 10 PHIL. & PUB. AFF. 185 (1981) [hereinafter Dworkin, *Part 1*].

Dworkin argues that the needs of a representative individual should shape the health-care budget and distribution of health-care resources.²⁶ 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. However, this approach would not accommodate special cases such as the terminally ill or individuals requiring organ transplantation to survive. Eric 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.²⁷ Einer Elhauge argues, however, that “consensual theories cannot offer a complete moral justification for health care allocations.”²⁸ And again, ex ante choices such as these leave patients insufficiently insured or contracted for interventions they might need; the State and its citizens ultimately end up picking up the tab for health care in these situations. Limitations of even these more moderate libertarian applications empirically support sick individuals’ de facto right to health care claims in a liberal democracy.

II. A RIGHT TO HEALTH: EQUALITY AS THE STANDARD

In opposition to the libertarian or free-market view, I have argued for a right to health grounded in the Aristotelian principle of human flourishing, offering a philosophical justification for a right to health and arguing for treatment of the right to health as an ethical demand for equity in health. Rather than focus on whether the right to health is justiciable and enforceable in national and international law, I focus on explicating societal obligations, both State and non-state, for progressive realization of this right. Sustaining the effort to realize a right to health requires individual and societal commitments to what I call *public moral norms*. This ethical demand may involve legal instruments for enforcement, but more likely will require individuals, States, and non-state actors to internalize *public ethical norms* to enhance implementation and compliance with a right to health in national and international policy and law.

This theory focuses on an ethical paradigm that emphasizes a particular type of norm — a *public moral norm* — as the basis of an individual and societal commitment to a right to health, and its focus on internalizing this public moral norm at *both* the collective (as through groups and institutions) and individual levels. The regulation of self

²⁶ See Dworkin, *Part 1*, *supra* note 25; Dworkin, *Part 2*, *supra* note 25.

²⁷ See generally ERIC RAKOWSKI, EQUAL JUSTICE 304–05 (1991); Eric Rakowski, *Taking and Saving Lives*, 93 COLUM. L. REV. 1063 (1993).

²⁸ Einer Elhauge, *Allocating Health Care Morally*, 82 CAL. L. REV. 1449, 1456 (1994).

and society, I argue, requires not just legal instruments, but also individuals and groups with internalized public moral norms — as part of their own internal value systems — that inform the choices they make for themselves and their society to ensure capabilities to be healthy for all people. Such internalization in turn leads to the greater efficacy of, and greater compliance with, domestic policy and legal instruments, which I argue are as important — if not more so — than international instruments (and institutions) for progressive realization of a right to health. Such realization is more likely to occur, I argue, when individuals within a given society take ownership of the public moral norm as a guiding principle for their individual and collective efforts, as evidenced by their domestic social, political, and economic activity.²⁹

In contrast to the very narrow right to health care — the right to be free from government interference in choosing health care — my vision of a right to health and health care is grounded in the principle of equity in health. Volokh's right to "medical self-defense," if adopted, would likely lead to substantial inequities in healthcare. For example, the rich could pay for new organs and transplantation, and drug testing would be limited to the lower and middle classes, since the rich would buy experimental drugs rather than risk being randomized to a placebo in a double-blinded clinical trial. My theory takes an expansive view, providing insights into the broader questions of health and health care and the more comprehensive ethical, policy, and legal context in which any legal right to health care might prevail.

III. DUTIES AND OBLIGATIONS UNDER A RIGHT TO HEALTH

The goal and purpose of the State under a theory of a right to health grounded in human flourishing thus differs from those informed by libertarian perspectives. Rather than viewing the State as the culprit in suppressing individuals' rights of liberty, this approach views the State and its entities (e.g., the FDA and the National Institutes of Health (NIH)) as not only having a legislative claim, but also a moral duty to draw on the collective scientific resources society has to offer in providing the rigorous and scientifically grounded evidence base that is necessary for providing all individuals with the opportunity to be healthy. Efforts to undermine and delegitimize this role and responsi-

²⁹ Elsewhere, I argue for widespread internalization of the public moral norm of willingness to pay taxes for others' health insurance to achieve domestic health care reform on universal health insurance in the United States. See Jennifer Prah Ruger, *Health, Health Care, and Incompletely Theorized Agreements: A Normative Theory of Health Policy Decision-Making*, 32 J. HEALTH POLITICS, POL'Y & L. 51 (2007).

bility rob all individuals and future selves of the necessary conditions for their optimal health functioning and health agency.

Continuing with this critique of strict and even modified libertarian and market-based approaches to health and health care, my theoretical approach recognizes the need for the creation and dissemination of public goods that construct the conditions that enable the right to health to be within reach for all individuals. Furthermore, it recognizes the need to create and disseminate public goods at the collective level, transcending any one individual or interest group. Generating and disseminating scientific research on the efficacy of pharmaceuticals is, after all, a problem of the “commons,” as delineated in Garrett Hardin’s 1968 article on the tragedy of the commons.³⁰ From this perspective, individual decisions based on property rights are deemed irrelevant because resource use, medical knowledge and scientific evidence cannot be consumed exclusively by a single individual or interest group. The primary solution to the problem of the commons in this realm is the creation and dissemination of collective public goods and the regulation of positive and negative externalities resulting from the scientific process (e.g. clinical trials). Without efforts at the collective level, individuals themselves would not have the capacity, in financial or human resources, to invest in the creation and development of scientific evidence and medical knowledge. Pharmaceutical research and development is a critical public good and standards are essential for its use at the societal level. Promoting this public good requires financial and human resources mobilized through institutions like the FDA and NIH.

While the State has the legislative and moral claim to advance the collective good and protect the lives of all persons through entities like the FDA and the NIH, this claim does not mean that individuals’ autonomy should not be respected. And while the FDA is unlikely to revert to allowing terminally ill patients access to experimental drugs (due to prior episodes where many such drugs turned out to be more harmful than beneficial), it would not be out of the question to modify the process to allow greater input from individuals through better deliberation and participation. Indeed, feedback from patients and doctors to the scientific process enables further progress to be made and errors reduced.

IV. SHARED HEALTH GOVERNANCE: COMBINING TECHNICAL AND ETHICAL RATIONALITY FOR COLLECTIVE CHOICE

A joint scientific and deliberative process, integrating substantive and procedural principles, is desirable to combine the evidence base of

³⁰ Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243 (1968).

medicine and public health with input from individuals, physicians, and public health experts to assess the value of treatments, medications, and other health care interventions. Consequently, it is important to assess both the necessity and the appropriateness of a pharmaceutical or health intervention. 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 ensure the good of human life and the need for both ethical and engineering rationality.³¹ 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 I have called “shared health governance.”³² This view contrasts with the notion that individuals alone, physicians alone, public health experts alone, strict algorithms, cost-benefit calculations, fair procedures, government officials or technocrats, shared decisionmaking within an informed consent model, or insurers should make health care decisions. While it endorses many of the principles of the shared decisionmaking 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 empowers individuals through health agency. And its judgments place special importance on the results and scientific-basis of health policies (effectiveness and costs).

Finally, it promotes public deliberation through a “collaborative comprehension of problems and remedies”³³ among scientists, physicians, public health experts, and individuals. These formulations focus especially on reasoning and on mutual respect among citizens and experts. This framework integrates both consequential and procedural elements of justice.

³¹ 6 ARISTOTLE, NICOMACHEAN ETHICS 1140a–b.

³² Ruger, *Paradigm*, supra note *, at 409.

³³ See AMARTYA SEN, DEVELOPMENT AS FREEDOM 31 (1999).

Rather than creating a negative right of medical self-defense, this theory operationalizes a right to health through the justification of medically necessary and medically appropriate health care. Not all health care is medically necessary or medically appropriate. A lot of what health care has to offer, particularly in the modern day of advanced medical technology, including experimental drugs or transplant operations, is only marginally effective (e.g. extending life for a few weeks or months or a very low probability (<5%–10%) of success).

Well-established, evidenced-based clinical guidelines are one mechanism that can be helpful in assessing these interventions 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.³⁴ 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 physicians and patients. When evidence is incomplete or inconsistent, reviewers seek the professional judgment of an expert panel.³⁵ In practice, however, these guideline recommendations may not be appropriate for *all* circumstances.³⁶

While effective in recommending evidence-based care, however, clinical guidelines alone cannot reduce differences in health care access and quality, nor can they evaluate medical technologies, drugs, and treatments. As a result, they must be embedded in broader efforts involving physicians and patients in shared governance through the assessment of medically appropriate and medically necessary care. One model that provides specific components for such a system is the RAND/UCLA appropriateness method.³⁷

³⁴ A number of medical subspecialties have established evidence-based clinical guidelines from extensive meta-analysis of existing studies. See, e.g., PUB. HEALTH SERV., 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.

³⁵ For example, see guidelines for screening for pre-eclampsia, vaginal birth after cesarean, immunizations, chemoprophylaxis, and hundreds more. See National Guideline Clearinghouse, <http://www.guideline.gov> (last visited Apr. 14, 2008).

³⁶ 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 (2001).

³⁷ See Robert H. Brook, *The Rand/UCLA Appropriateness Method*, in CLINICAL PRACTICE GUIDELINE DEVELOPMENT (Kathleen A. McCormick et al. eds., 1994).

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. The method is transparent, scientific, and deliberative; 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 decisionmaking at the point of health care delivery and policy.

Studies of medical care appropriateness provide a partial evidence base which can be put together with clinical practice guidelines for assessing health interventions. 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 medical necessity 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 assessing effectiveness criteria in this process as citizens, through deliberation and value formation, help guide policymakers on the value of marginally effective technologies (where increases in longevity or the odds of survival are low). This process encompassing reasoned consensus in conjunction with substantive values of health 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.

Needless to say, experimental drugs that have not passed Phase II and Phase III of the FDA drug approval process and thus have not been proven efficacious or effective would not be deemed medically necessary or medically appropriate. While experimental drugs may offer hope, the odds are that they will not be deemed efficacious and even fewer will be deemed medically necessary and medically appropriate (only a small percentage of potential drugs make it to human trials).³⁸ Moreover, without further scientific evidence, it is unknown whether such drugs may cause more harm than good to patients.

Guaranteeing constitutional “rights to medical self defense,” by allowing terminally ill patients to buy experimental drugs that have not completed the FDA approval process, would run counter to my approach. In my approach, drugs that are not yet proven efficacious or

³⁸ Carrie Conaway, *The Pros and Cons of Pharmaceutical Patents*, REGIONAL REV., Q1 2003, at 10, 12.

effective would not be available for purchase, nor would they be made available through government sponsored programs such as Medicare and Medicaid. Rather than having individual rights against State interference determine policy, my approach would seek to bolster the scientific process and standards, applying safety, efficacy, medical necessity, and medical appropriateness to the assessment of an experimental drug to determine whether it should be made publicly available. Furthermore, allowing negative rights to trump the scientific process undermines the theoretical and policy justifications offered above involving the moral duty to draw on a society's collective scientific resources and medical knowledge to provide *all individuals* with the opportunity to be healthy. Moreover, addressing concerns that the FDA process is too slow and cumbersome to churn out potentially life saving experimental drugs in a timely manner, requires reform of the FDA process itself, not using claims of violations of individual rights to bypass or undercut that process for certain privileged social groups.

Similarly, my framework would take a different approach on the problem of organ scarcity. Rather than frame the problem as one of the suppression of individual rights by the State, my approach would frame the problem of organ scarcity in supply and demand terms that do not violate concerns about body part commodification and exploitation of the poor and vulnerable by the wealthy and well-connected. Rather than open this very serious individual and public health problem to potential exploitation of some groups in society (and potentially threatening their agency) by others due to desperation, my approach involves addressing this problem through application of scientific principles and policy prescriptions. For example, in terms of the application of scientific principles, investments in promising lines of research known as regenerative medicine, artificial and biohybrid organs and tissues, and stem and adult cell therapy offer hope for enabling those in need of organ and tissue transplantation to use their own body and lab-developed tissue and organs, not those of others, as a source of the embryonic elements of the solution to optimal organ or tissue transplantation. On the policy side, investments in efforts to encourage voluntary organ and tissue donation through living wills, advance directives, drivers licenses, presumed consent, public education, and counseling, thereby reducing the gap between public preferences and organ donation (roughly ninety-five percent of Americans support organ donation but only fifty-three percent are consented donors),³⁹ show increasing success and should be supported. These applications

³⁹ GALLUP ORG., 2005 NATIONAL SURVEY OF ORGAN AND TISSUE DONATION ATTITUDES AND BEHAVIORS 5, 9 (2005).

aim to increase the supply of organs while obviating the potential to cause harm to others.

Finally, another critical component of a theory of a right to health is a robust concept of opportunity costs. Efficiency concerns should temper the goals of equality. While consistent with welfare economics in its focus on efficiency, the view presented here differs by allowing efficiency principles to be applied to equity goals. 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.

Attempts to achieve optimal levels of health and reduce inequalities in individuals' abilities to be healthy with the fewest resources will require a joint clinical and economic solution. The approach espoused here argues for weighing risks, benefits, and costs on at least two levels. At the societal level, citizens, physicians, and public health experts delineate a package of goods and services to which all individuals are entitled. 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. This approach 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 deliberately determined weights *into* CEA.

Cost-minimization and cost-effectiveness analyses⁴⁰ provide economic input in the decisionmaking process. In this framework, a stepwise approach first addresses equity, using clinical input to promote equality in individuals' ability to be healthy; then it addresses efficiency by using cost-minimization analysis and, in specific cases, cost-effectiveness analysis. This process differs from other efforts⁴¹ to address the efficiency-equity trade-off in health policy because it is iterative and uses a variety of methodologies to address the competing social obligations of equality and efficiency.⁴²

⁴⁰ See generally Karen M. Kuntz et al., *Expert Panel vs Decision-Analysis Recommendations for Postdischarge Coronary Angiography After Myocardial Infarction*, 282 JAMA 2246 (1999).

⁴¹ On the ethical implications of Quality-Adjusted-Life-Years (QALYs), see Paul T. Menzel, *QALYs: Maximisation, Distribution and Consent. A Response to Alan Williams*, 3 HEALTH CARE ANALYSIS 226 (1995); Alan Williams, *QALYs and Ethics: A Health Economist's Perspective*, 43 SOC. SCI. & MED. 1795 (1996). Quality-Adjusted-Life-Years (QALYs) is an indicator of disease burden that incorporates both the quantity and quality of life.

⁴² See Erik Nord et al., *Incorporating Societal Concerns for Fairness in Numerical Valuations of Health Programmes*, 8 HEALTH ECON. 25 (1999); Erik Nord, *The Relevance of Health State After Treatment in Prioritising Between Different Patients*, 19 J. MED. ETHICS 37 (1993); Erik

CONCLUSION

A right to health care need not, indeed cannot, be framed in an absolute libertarian framework of wholly individualistic rights against the State. Rather, I've argued for an alternative theoretical framework grounding a right to health in the more positive conceptualization of freedom — human flourishing — arguing for treating the right to health as an ethical demand for equity in health. Unlike the legalistic, yet theoretically unjustified, guarantee of a constitutional “right to medical self-defense,” a right to health, so conceived, purports that the regulation of self and society require not just justiciable and enforceable legal rights or instruments, but also individuals and the collective with internalized public moral norms that inform the choices they make for themselves and their society to ensure capabilities to be healthy for all people, including the terminally ill.