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The Medical Cost Pandemic: Why Limiting Access to Cost-Effective Treatments Hurts the Global Poor

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The Medical Cost Pandemic: Why Limiting Access to Cost-Effective Treatments Hurts the Global Poor

Govind Persad*

Abstract

Medical innovation in developed countries like the U.S. leads to an ever-changing medical standard of care. This innovation frequently also brings rising costs. While these costs strain even the sizeable health care budgets of developed countries, imposing them on developing countries would be much more burdensome. Yet a variety of commentators and legal actors, such as the World Health Organization and UNAIDS, have argued that the same standards of care must be provided worldwide, and have enforced mandates to that effect. Interpretations of the human right to health as a right to the “biggest attainable standard of health” similarly advance the idea of a uniform worldwide standard of care and threaten to produce excessive costs. This Article has two objectives: first, to identify, describe, and criticize the legal mandates and norms that threaten to produce increased medical costs and reduced access to cost-effective care in developing countries, and, second, to suggest how we can prevent these outcomes.

Table of Contents

I. Introduction.....	561
II. Limiting Access to Cost-Effective Treatments	563
A. Pharmaceuticals.....	563
B. Medical Donations.....	572
C. Vaccines.....	576
III. Granting Rights to Expensive Treatments	578

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A. Soobramoney.....	580
B. Treatment Action Campaign.....	581
C. Tutelas	582
IV. Can Limiting Access Be Justified?.....	585
A. Special Obligations	586
1. The duty not to harm.	586
2. The duty to rescue.....	592
3. The duty of reciprocity.....	594
B. Global Justice.....	595
C. Consequences.....	601
V. Preventing the Pandemic	603
A. Adequacy, Not Maximization	603
B. Local Variation, Not Transnational Uniformity.....	606
VI. Conclusion.....	609

I. INTRODUCTION

In 2003, Pauline Talty petitioned the Australian government to provide her a potentially lifesaving intestinal transplant.¹ No doctor in Australia had ever performed an intestinal transplant; at the University of Pittsburgh—the world center for intestinal transplants—they cost three million dollars. After initially refusing Talty’s request, the Australian government eventually acquiesced under political pressure.² In 2009, Talty left Australia for Pittsburgh, hoping to receive a transplant.³

In 1874, the *HMS Dido*, too, left Australia, bound not for Pittsburgh but for Fiji.⁴ En route to Fiji, two passengers contracted measles, a disease prevalent in Australia but unknown in Fiji.⁵ In January 1875, the *Dido* docked in Fiji, where its passengers disembarked and unknowingly spread measles to the Fijians.⁶ By June, around 40,000 Fijians were dead.⁷

What else—beyond beginning in Sydney—does Talty’s journey have in common with the *Dido*’s, and why does either matter? This Article argues that international adoption of the norms that made Talty’s journey possible threatens to produce a second pandemic. While the 1875 measles pandemic resulted from medical ignorance, what I call the “medical cost pandemic” stems not from ignorance but from good intentions. And, while the 1875 pandemic involved the developed world’s pathogens inflicting devastation on a developing country, the medical cost pandemic spreads not through viruses or bacteria, but instead through norms and mandates. Well-intentioned mandates and norms threaten to enable expensive standards of care adopted in developed countries like the U.S. and Australia—standards of care that treat surgery like Talty’s three-million-dollar intestinal transplant as an individual entitlement—to cross borders and devour the much scarcer resources of developing countries. While expensive and often cost-ineffective standards of care also imperil budgets and healthcare systems in the developed world, developing countries’ more meager resources

¹ See Nick Miller, *Intestinal Fortitude Required*, THE AGE, Nov. 14, 2009, available at <http://www.theage.com.au/national/intestinal-fortitude-required-20091113-ieta.html>.

² See *id.*

³ See Xanthe Kleinig, *Pauline Talty Wins \$3M Bowel Cancer Surgery Fight*, NEWS.COM.AU (May 15, 2009, 12:00 AM), <http://www.news.com.au/national/pauline-wins-3m-surgery-fight/story-e6frfkp9-1225712344307> (last visited Nov. 20, 2014).

⁴ See Carla Garnett, *NLM History Lecture Examines Death in the Cannibal Islands*, NIH RECORD, Nov. 16, 1999, available at http://nihrecord.od.nih.gov/newsletters/11_16_99/story01.htm.

⁵ See *id.*

⁶ See *id.*

⁷ See *id.*

will come under strain far more quickly—just as measles was burdensome in Australia but catastrophic in Fiji.

To see the catastrophe that mandating universal provision of the medical care Pauline Talty received would cause, return to Fiji, the victim of the 1875 pandemic. In 2008, its medical budget was approximately 140 million Fijian dollars (FJD), which was equivalent to 81 million U.S. dollars (USD), and Fiji's per-capita spending on health care was 165.33 FJD (96.18 USD).⁸ This means that the three million dollars Australia spent on Talty's transplant would have consumed more than three percent of Fiji's health care budget—more than would have been spent on medical care for *thirty thousand* Fijians. (In contrast, Australia's per capita spending on health care was twenty times Fiji's.⁹)

Transnationally mandating that all governments providing medical care provide their citizens the level of care Australia provided Talty would obviously be unsustainable for a nation like Fiji. Yet the international community frequently adopts legal norms that threaten to inflict the runaway costs that beset health systems in developed countries on much poorer nations in the developing world. For example, as I detail below, interpretations of the right to health as an individually assertible right to the “highest attainable standard of . . . health”¹⁰ have allowed private citizens to sue their governments for access to costly treatments. And norms that direct developing countries to provide the developed-country standard of care for other medical interventions—requirements that mandate new pacemakers instead of used ones, or the newest HIV medications rather than older, cheaper alternatives—leave developing countries with a choice between providing an unaffordable standard of care and providing nothing at all.

This Article has two objectives: (1) to identify, describe, and criticize the legal mandates and norms that threaten to produce a medical cost pandemic, and (2) to suggest how we can prevent that pandemic. Sections II and III identify two trends that threaten to produce runaway medical costs: Section II discusses proposals to mandate developed-country standards of care for specific conditions, while Section III discusses interpretations of the right to health that

⁸ See WORLD HEALTH ORGANIZATION, THE FIJI ISLANDS HEALTH SYSTEM REVIEW 45–49 (2011), available at http://www.wpro.who.int/asia_pacific_observatory/hits/series/Fiji_Islands_Health_Systems_Review.pdf. The currency conversion is based on INTERNAL REVENUE SERVICE, TREASURY REFORMING RATES OF EXCHANGE AS OF DEC. 31, 2008, <http://www.irs.gov/Businesses/Small-Businesses-&Self-Employed/Treasury-Reporting-Rates-of-Exchange-as-of-December-31-2008> (last visited Nov. 20, 2014).

⁹ See WORLD HEALTH ORGANIZATION, *supra* note 8, at fig. 3–5.

¹⁰ International Covenant on Economic, Social, and Cultural Rights, G.A. Res. 2200A (XXI), art. 12, U.N. GAOR, 21st Sess., Supp. No. 16 at 49, U.N. Doc. A/6316 (Dec. 16, 1966) [hereinafter ICESCR].

have similar effects. Section IV evaluates and criticizes arguments that have been advanced in defense of these norms and mandates, such as their refusal to harm patients with dangerous drugs, their expressive endorsement of a just global distribution of resources, and their usefulness as a lever to improve global standards of health. Section V discusses how we can reshape our medical norms to prevent the pandemic and rein in medical costs. Making these changes before unaffordable spending commitments become entrenched could give developing countries a chance to protect themselves from the problems that developed countries now face.

This project brings together two important but hitherto disconnected debates in law and global health. The debate over whether the developed world's standards of medical care should be adopted worldwide has focused on cases involving research on human subjects but has ignored questions of clinical care.¹¹ And while recent debates over universal health coverage in the U.S. have drawn attention to problems of priority-setting in health and to Americans' inability to limit health care costs,¹² these debates have focused solely on the American context. This Article will demonstrate how well-intentioned legal mandates threaten to globalize the problems that afflict health care systems in the U.S. and other developed countries.

II. LIMITING ACCESS TO COST-EFFECTIVE TREATMENTS

A. Pharmaceuticals

The pace of technical advances in treatment for HIV has been remarkable. The first effective treatment for HIV-infected patients, azidothymidine (AZT), received FDA approval in 1987.¹³ Over the next two decades, rapidly improving treatments have largely rendered HIV a chronic and manageable—though not yet curable—condition in the developed world.¹⁴

These advances have prompted efforts to ensure better outcomes for HIV-infected patients in developing countries. Some have called for revisions to the

¹¹ See, for example, David P. Fidler, "Geographical Morality" Revisited: *International Relations, International Law, and the Controversy over Placebo-Controlled HIV Clinical Trials in Developing Countries*, 42 HARV. INT'L. L.J. 299 (2001); Annette Rid & Harald Schmidt, *The 2008 Declaration of Helsinki—First Among Equals in Research Ethics?*, 38 J.L. MED. & ETHICS 143 (2010).

¹² See generally Russell Korobkin, *Comparative Effectiveness Research as Choice Architecture: The Behavioral Law and Economics Solution to the Health Care Cost Crisis*, 112 MICH. L. REV. 523 (2014); Christopher Robertson, *The Split Benefit: The Painless Way to Put Skin Back in the Health Care Game*, 98 CORNELL. L. REV. 921 (2013).

¹³ See *Weaver v. Reagen*, 886 F.2d 194, 196 (8th Cir. 1989).

¹⁴ See Sarah J. Newman, Note, *Prevention, Not Prejudice: The Role of Federal Guidelines in HIV-Criminalization Reform*, 107 NW. U. L. REV. 1403, 1410–11 (2013).

pharmaceutical patent regime to ensure better access to high-quality treatments.¹⁵ Others have called for adopting laws and regulations ensuring that patients in developing countries receive the same medications that developed countries provide. The Executive Director of the Joint United Nations Program on HIV/AIDS (UNAIDS), for example, recently noted that UNAIDS has adopted a new Outcome Framework, which advocates “ending the two-tiered system of global AIDS treatment” and “stopping the practice of using outmoded drugs for people in developing countries.”¹⁶ Kevin De Cock, director of the HIV/AIDS Department of the WHO, similarly argued in 2009 that “[t]he world cannot allow a permanently two-tiered system of global AIDS treatment with late initiation of outmoded drugs reserved for the South.”¹⁷

The WHO, like UNAIDS, has adopted regulations that reflect the commitment to avoiding two-tiered care. While the WHO, like many other international organizations, generally lacks power to enforce its regulations on external actors,¹⁸ its definitions and directives have been carried into force by national legal systems.¹⁹ They also shape private actors’ decisions when drafting contracts and internal regulations.²⁰ In 2010, the WHO’s guidelines on HIV

¹⁵ See, for example, Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1036 (2005).

¹⁶ Michel Sidibé, Exec. Dir., UNAIDS, Crisis, Opportunity and Transformation: AIDS Response at a Crossroads, Address to Program Coordinating Board, at 5 (June 23, 2009), http://www.unaids.org/en/media/unaids/contentassets/dataimport/pub/speech/2009/jc1750_opening_pcb_speech_en.pdf (last visited Nov. 20, 2014).

¹⁷ Kevin M. De Cock, Dir., HIV/AIDS Dept., WHO, Presentation at the 2009 HIV/AIDS Implementers’ Meeting (June 10, 2009), http://www.who.int/hiv/events/implementers2009_kdc/en/index.html (last visited Nov. 20, 2014).

¹⁸ See Eric A. Posner & David Weisbach, *International Pareiticism: A Defense*, 13 CHI. J. INT’L L. 347, 354 (2013) (listing the WHO among several international organizations that “do not possess formal legal authority and so cannot issue binding rules or orders”). *But see* David P. Fidler, *The Future of the World Health Organization: What Role for International Law?*, 31 VAND. J. TRANSNAT’L L. 1079, 1087–88 (1998) (noting that the WHO has the power to issue regulations that “come into force for each WHO Member State unless a Member State notifies WHO of reservations to, or rejection of, the adopted regulations within a fixed period of time,” although it has rarely used this power).

¹⁹ See, for example, *Guo Qi Wang v. Holder*, 583 F.3d 86, 91 n.3 (2d Cir. 2009) (using WHO guiding principles on organ transplantation to support a finding that black market organ sales are a serious nonpolitical crime); *Bah v. Mukasey*, 529 F.3d 99, 101–02 (2d Cir. 2008) (noting that the U.S. Department of State employs the WHO definition of female genital mutilation); *United States v. S. Mgmt. Corp.*, 955 F.2d 914, 921 (4th Cir. 1992) (referencing legislative history that relies on WHO classification of addiction as a mental disorder).

²⁰ See, for example, *Basch v. Westinghouse Elec. Corp.*, 777 F.2d 165, 168 n.2 (4th Cir. 1985) (noting that Westinghouse’s contract incorporated WHO regulations); *Drolla v. ChevronTexaco Corp.*, No. A104161, 2004 WL 2750328, at *8 (Cal. Ct. App. Dec. 2, 2004) (noting that Chevron adopted WHO definitions as part of its internal job qualifications).

treatment recommended that health care systems worldwide—including those in resource-limited settings—“take steps to progressively reduce the use of stavudine (d4T) in first-line regimens because of its well-recognized toxicities.”²¹

As Jay Purcell observes,

Stavudine exemplifies the clearest disconnect between developed- and developing-world standards of care for HIV patients. An NRTI [nucleoside reverse transcriptase inhibitor], [s]tavudine reaches over 75 percent of patients in developing countries. It does not, however, appear on the list of therapies recommended by the WHO or Department of Health and Human Services. Domestically, physicians replaced [s]tavudine years ago, when superior, safer, and more effective NRTIs entered the market.²²

But transitioning from stavudine to the WHO’s (and Purcell’s) preferred substitute, tenofovir, would increase costs dramatically. Purcell notes that “[e]xplaining the omnipresence of [s]tavudine in resource-limited settings is simple: the Clinton Foundation’s 2009 Antiretroviral [ARV] Price List records [s]tavudine, at \$0.036/unit, as the cheapest ARV on earth. Tenofovir, [s]tavudine’s domestic replacement, sells at \$0.280/unit.”²³ This represents nearly an eightfold difference in price.

HIV is not the only condition where drug recommendations in developed and developing countries have diverged due to cost considerations, and where some have called for mandating the developed-country standard of care as a universal standard. The same has been true for epilepsy treatments. A recent article in the *Bulletin of the World Health Organization* notes that researchers historically “advocated the use in developing countries of antiepileptic drugs such as phenobarbital . . . which were considered to be particularly desirable because of their low cost and the quality of the treatment they provided.”²⁴ The authors note that a variety of newer antiepileptic medications, which are less toxic and have fewer side effects, have superseded phenobarbital in developed countries.²⁵

This divergence between antiepileptic medications provided in developed and developing countries has been criticized as morally objectionable:

²¹ WORLD HEALTH ORGANIZATION, ANTIRETROVIRAL THERAPY FOR HIV INFECTION IN ADULTS AND ADOLESCENTS: RECOMMENDATIONS FOR A PUBLIC HEALTH 20 (2010), available at http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf.

²² Jay Purcell, *Adverse Clinical and Public Health Consequences of Limited Anti-Retroviral Licensing*, 25 BERKELEY TECH. L.J. 103, 119 (2010).

²³ *Id.*

²⁴ K. Nimaga et al., *Treatment With Phenobarbital and Monitoring of Epileptic Patients in Rural Mali*, 80 BULL. WORLD HEALTH ORG. 532, 535 (2002).

²⁵ *See id.*

[P]henobarbital's profile of toxicity has discouraged its use in developed countries, at least as a first choice anticonvulsant. The most important toxic effects are hyperactivity in children and sedation in adults, and it is cynical to believe that these side effects are of no importance in the less privileged developing countries. This is to put a geographic hierarchy on brain function, which is unacceptable.²⁶

Similarly, a letter to the *Lancet* argues for focusing on absolute effectiveness to the exclusion of cost considerations:

If a broad-spectrum antiepileptic is proven better as first-line treatment than phenobarbital, on the basis of clinical trials in developing countries, then it should be bought in large quantities at discount and distributed to epilepsy-treatment programmes in developing countries The epilepsy and public-health communities can do better than phenobarbital or phenytoin for the world's 34 million people with epilepsy who live in the developing world.²⁷

And, in a 2004 article in the *British Medical Journal*, physicians Rajendra Kale and Emilio Perucca similarly ask: "If people with epilepsy in Britain are not prescribed phenobarbital because of its toxicity, is it ethical to recommend its use in developing countries?"²⁸

However, others have argued that phenobarbital's exceptionally low cost ethically justifies its continuing use in developing countries. Patrick Kwan and Martin Brodie argue that "[p]erhaps the greatest advantage of PB [phenobarbital] is its unparalleled low net cost," and contrast it with later anti-epilepsy drugs that cost four or five times as much and cutting-edge drugs that cost more than a hundred times as much.²⁹ Kwan and Brodie go on to note that "[f]or developing countries with low purchasing power, cost-effectiveness is of top priority in choosing treatment [I]n poor regions, 'the choice is not between phenobarbital and a new medicament but between phenobarbital and no treatment at all.'"³⁰ Interestingly, the WHO's position here has been to endorse

²⁶ S.D. Shorvon & P.J. Farmer, *Epilepsy in Developing Countries: A Review of Epidemiological, Sociocultural, and Treatment Aspects*, 29 *EPILEPSIA* S36, S49 (1988).

²⁷ Edwin Trevathan, Marco T. Medina & Amanda Madrid, *Antiepileptic Drugs in Developing Countries*, 351 *LANCET* 1210, 1210 (1998).

²⁸ Rajendra Kale & Emilio Perucca, *Revisiting Phenobarbital for Epilepsy: Large Gaps in Knowledge Still Exist, but We May Be Underestimating Its Clinical Value*, 329 *BRIT. MED. J.* 1199, 1199 (2004).

²⁹ Patrick Kwan & Martin J. Brodie, *Phenobarbital for the Treatment of Epilepsy in the 21st Century: A Critical Review*, 45 *EPILEPSIA* 1141, 1145 (2004).

³⁰ *Id.* at 1146–47 (quoting Nimaga, *supra* note 24, at 535). See also Kale & Perucca, *supra* note 28, at 1200 ("In the developing world, when the choice is between the cheapest treatment or no treatment at all, phenobarbital should be used, particularly in adults.").

the use of phenobarbital in developing countries, in contrast to its rejection of a “two-tiered” regime of HIV medications.³¹

Bacterial meningitis represents another illness for which the WHO has permitted a disparity between developed- and developing-country treatments. Both the antibiotic ceftriaxone and a combination therapy of penicillin and chloramphenicol are effective in treating bacterial meningitis. Ceftriaxone is more effective and has fewer side effects,³² but until becoming generic was substantially more expensive than the penicillin/chloramphenicol combination. In 1997, the WHO recommended that ceftriaxone be used in developed countries but that developing countries use the lower-cost penicillin/chloramphenicol combination.³³ Once ceftriaxone became available as a lower-cost generic, the WHO recommended ceftriaxone worldwide.³⁴ The WHO’s decision to recommend the lower-cost penicillin/chloramphenicol combination in developing countries seemed to accept that high costs and scarcity of resources could justify using cheaper but less effective treatments.

International bodies like the WHO and UNAIDS are not the only ones to adopt the view that developing-country patients must receive developed-country standards of care if they are to receive care at all. Domestic law in the U.S. did the same for many years by prohibiting American firms from exporting domestically unapproved drugs, even if approved in the importing country. Between 1938 and 1986, American companies were not permitted to export medicines to other countries unless the FDA had approved those medicines for

³¹ See Kwan & Brodie, *supra* note 29, at 1141 (noting that phenobarbital “is recommended by the World Health Organization as first-line for partial and generalized tonic-clonic seizures in developing countries,” even though “its purported propensity to cause sedation and other cognitive and behavioral side effects has relegated it to second- or third-line use in many parts of the industrialized world”); see also World Health Organization [hereinafter WHO], Global Campaign Against Epilepsy, *Epilepsy in the WHO African Region: Bridging the Gap*, AFR/MNH/04.1 (2004) (“One may remember that 61 to 72.8% of the population in the poorest countries of the African region live on less than U.S. \$1.00 per day. This is a convincing fact, underlining the need to use [p]henobarbital as the first choice in public health intervention for epilepsy.”).

³² See Edilane L. Gouveia et al., *Clinical Outcome of Pneumococcal Meningitis During the Emergence of Penicillin-Resistant Streptococcus Pneumoniae: An Observational Study*, 11 BMC INFECTIOUS DISEASES, no. 323, 1–2 (2011).

³³ See WHO, *Antimicrobial and Support Therapy for Bacterial Meningitis in Children: Report of the Meeting of 18–20 June 1997 Geneva, Switzerland*, WHO/EMC/BAC/98.2 (1997), at 3, available at <http://www.who.int/csr/resources/publications/meningitis/whoemcbac982.pdf>.

³⁴ See WHO, *Standardized Treatment of Bacterial Meningitis in Africa in Epidemic and Non-Epidemic Situations*, WHO/CDS/EPR/2007.3 (2007), at 5, available at http://www.who.int/csr/resources/publications/meningitis/WHO_CDS_EPR_2007_3.pdf.

use in the U.S.³⁵ (In contrast, several countries in Europe permitted the export of drugs unapproved for domestic use.³⁶)

In 1986, Congress considered and ultimately approved the Drug Exports Amendments Act (DEAA), which relaxed restrictions on the export of unapproved drugs. The DEAA's proposal and passage prompted extensive debate, much of which focused on an ethical issue that also arose in the cases above: may different countries adopt different standards of care? As Mindy Hatton notes, "[o]ne of the most repeated criticisms of the drug export legislation was that it represented an invidious double standard by protecting American consumers from potentially unsafe drugs while leaving the rest of the world to fend for itself."³⁷ Two of the most prominent proponents of the double-standard argument were Sidney Wolfe, of the consumer advocacy group Public Citizen,³⁸ and Ohio Senator Howard Metzenbaum.³⁹ In his minority statement, Metzenbaum argued:

³⁵ See FOOD AND DRUG ADMIN., OFFICE OF INT'L PROGRAMS, GUIDANCE FOR INDUSTRY: EXPORTS UNDER THE FDA EXPORT REFORM AND ENHANCEMENT ACT OF 1996 11 (2007), available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125898.pdf>; see also Eve C. Gartner, Note, *Regulating the Export of Unapproved Drugs: An Examination of the Drug Export Amendments Act of 1986*, 19 COLUM. HUM. RTS. L. REV. 97, 98–102 (1987).

³⁶ See U.S. INT'L TRADE COMM'N, GLOBAL COMPETITIVENESS OF U.S. ADVANCED-TECHNOLOGY INDUSTRIES: PHARMACEUTICALS, 1991 WL 790123, at *59 (1991) ("France, the United Kingdom, Germany, and Switzerland reportedly do not ban the export of unapproved drugs.").

³⁷ Mindy Hatton, Note, *Exporting Unapproved New Drugs: Saving American Jobs or Imperiling Foreign Consumers?* 4 J. CONTEMP. HEALTH L. & POL'Y 429, 440 (1988). See Alan H. Kaplan, *Fifty Years of Drug Amendments Revisited: In Easy-To-Swallow Capsule Form*, 50 FOOD & DRUG L.J. 179, 193 (1995) (discussing "those who believed that it would be immoral for the United States to permit the export of drugs that could not be marketed domestically"); Gartner, *supra* note 35, at 104–05; Jeanmarie T. Sales, Note, *The Drug Export Amendment Act of 1986*, 15 RUTGERS COMPUTER & TECH. L.J. 475, 481 (1989) ("Opponents of drug export reform claimed that permitting the export of unapproved drugs to foreign markets created a double standard: a standard of proven safety and efficacy for drugs for United States consumers, and a lesser standard for exported drugs."); *Drug Price Competition and Patent Term Restoration Act of 1984, Hearing on S. 2748 before the S. Comm. on Labor & Hum. Resources*, 98th Cong. 229 [hereinafter *Hearing*] (statement of Louise Greenfield, Staff Attorney, Public Citizen's Congress Watch) ("Our most fundamental argument against the export of unapproved drugs is that it would establish a double standard. This violates our basic belief that the health and safety of international consumers is no less important than that of American consumers."); *id.* at 330 (statement of Sybil Shainwald, National Women's Health Network) ("What's not good enough for Americans cannot be good enough for the Third World.").

³⁸ See Hatton, *supra* note 37, at 440–41 ("In testimony before the Senate, Sidney M. Wolfe, M.D., Director of Public Citizen's Health Research Group, described this double standard as the most fundamental argument against the bill, and one that he believed was a compelling reason for retaining the ban, outweighing the industry's claims that lifting the export ban would lead to the creation of jobs and halt the loss of technology and capital.").

³⁹ See Gartner, *supra* note 35, at 104–05.

This legislation sets up [a] double standard—American consumers would be protected from unsafe, hazardous and ineffective drugs through the PDA approval process, while foreign consumers and Americans travelling abroad would receive inferior protection. The message S. 1848 would send to the rest of the world is clear and unambiguous: “These drugs aren't good enough for us, but they're good enough for you.” How will this nation be judged if one of these unapproved drugs causes death and injury abroad while American citizens are protected because we only allowed the drug to be produced for export? Why should we tarnish the “Made in America” label?⁴⁰

This view had earlier antecedents—the 1982 Report to the President on the Review of U.S. Hazardous Substances Export Policy stated that “materials banned at home should not, on ethical grounds, be sold to other countries.”⁴¹

In contrast, others argued that imposing the U.S. standard of care on other nations was inappropriately paternalistic, inconsistent with principles of international sovereignty, and might deny patients in developing countries beneficial treatments.⁴² We see evidence of this in the fact that religious organizations attempted to use the pre-DEAA prohibition on export to block developing countries' access to affordable contraceptives that were not approved in the U.S.⁴³ The final version of the DEAA permitted the export of drugs not approved by the FDA for use in the U.S., but only to a list of developed countries.

A particularly interesting departure from the uniform-standards view was the “tropical disease” exception, which permitted unapproved drugs to be exported to developing countries for the treatment of tropical diseases. In reviewing applications under this exception, the DEAA directed the FDA to consider not whether the drug was efficacious by U.S. standards, but rather whether it would be safe and effective by *developing-world* standards. (In contrast,

⁴⁰ S. REP. NO. 99-225, at 67 (1985) (minority views of Sen. Howard Metzenbaum), available at <http://digitalcollections.library.cmu.edu/awweb/awarchive?type=file&item=428126>.

⁴¹ American Home Products Corporation, SEC No-Action Letter, 1984 WL 45839, at *25 (Mar. 8, 1984).

⁴² See Gartner, *supra* note 35, at 105 (“The contrary argument, based on principles of sovereignty, emphasizes that each country should have the right to make its own regulatory decisions as to which drugs to import, independent of the decisions of other nations.”).

⁴³ See The Upjohn Company, SEC No-Action Letter, 1984 WL 45801, at *3–17 (Mar. 7, 1984); see also BETSY HARTMANN, REPRODUCTIVE RIGHTS AND WRONGS 182 (1995). Exporting manufacturers had to meet additional conditions: most importantly, an Investigational New Drug (IND) application had to have been made for the drug's active ingredient. See *id.* As Sales notes, the IND requirement allowed the FDA to block exports—even when approved and requested by a developing country—by making a final determination to disapprove a new drug for U.S. use or by placing the IND application on clinical hold. See Sales, *supra* note 37, at 492. However, the FDA Export Reform and Enhancement Act of 1996 removed the requirement of filing an IND application.

opponents of the DEAA had argued for a single safety and efficacy standard worldwide.⁴⁴) A commentator at the time observed that the “FDA’s administration of the tropical disease drug export provisions will be particularly interesting to watch. For the first time since there was an efficacy requirement for new drugs, FDA must now apply a second, lesser standard for efficacy for one class of drugs.”⁴⁵ However, a 1994 study found that this exception went unused between 1987 and 1992.⁴⁶

The FDA Export Reform and Enhancement Act of 1996 liberalized regulations on drug export to developing nations. It permitted exports to *any* country as long as the product exported was approved for use in a listed developed country. Rather than positioning the FDA as the sole gatekeeper, the 1996 Act in effect allowed the judgment of other developed nations’ regulatory bodies to substitute for the FDA’s. Although it also expanded the tropical disease provision to include devices, diagnostic interventions, and treatments for non-tropical diseases that are “not of significant prevalence” in the U.S.,⁴⁷ it did not explicitly permit the decisions of other developed countries’ regulatory bodies to substitute for the FDA’s judgment as to whether a drug qualified for that provision.⁴⁸

The 1996 Act also allowed the export of drugs not approved in *any* developed country if: (a) the drugs complied with the laws of the foreign country and that country had adequate ability to review their safety; or (b) the foreign country had requested the drugs’ export, and the FDA judged that the drugs were safe and effective under foreign conditions of use. However, unapproved drugs exported under this provision still needed to meet Good Manufacturing

⁴⁴ See, for example, *Hearing, supra* note 37, at 236 (statement of Louise Greenfield and Janet S. Hathaway, Staff Attorneys, Public Citizen’s Congress Watch) (“The only justifiable exception to a basic rule against exporting unapproved drugs would be to allow the American manufacture and export of drugs for diseases which occur only abroad Because U.S. approval probably would not be sought due to the lack of a U.S. market, this would not constitute a double standard [W]e would seriously question whether any drug which the FDA has affirmatively banned should be approved for export.”); *id.* at 344 (statement of Philip R. Lee, M.D., Professor, University of California, San Francisco) (“I would agree that no drug should be exported that has been banned in the United States. There should be no exception to this, including the proposal that export would be prohibited ‘unless FDA or USDA determines that it is nonetheless eligible for export because of particular diseases or health conditions abroad that do not exist in the United States.’ It is inconceivable to me that the U.S. Congress would permit the export of a drug whose use had been banned in the United States.”) (citation omitted).

⁴⁵ Sales, *supra* note 37, at 498.

⁴⁶ See Sheila R. Shulman et al., *The Drug Export Amendments Act of 1986: Is It All It Was Intended to Be?*, 49 FOOD & DRUG L.J. 367, 379 (1994).

⁴⁷ FOOD & DRUG ADMIN., *supra* note 35, at 50–51.

⁴⁸ See Dan Phair, Note, *Orphan Drug Programs, Public-Private Partnerships and Current Efforts to Develop Treatments for Diseases of Poverty*, 4 J. HEALTH & BIOMEDICAL L. 193, 224 (2008).

Practices standards.⁴⁹ These standards have been enforced in court against at least one medical device manufacturer.⁵⁰

The changes from the pre-1986 to the post-1996 regime of drug export were dramatic, and seemed to reflect a shift away from Metzenbaum and Wolfe's view—that different standards for the U.S. and developing countries were unacceptable—toward the view that “foreign nations have a right to make autonomous decisions regarding the potential risks and benefits of new pharmaceuticals,”⁵¹ and that “other countries have different needs and regulatory structures.”⁵² For example, as Eve Gartner notes with regard to the contraceptive Depo-Provera,

the risk-benefit determination in a less developed country may emphasize the dearth of inexpensive, effective, and unobtrusive methods of birth control; the high mortality rate for women in childbearing, which may warrant using riskier contraception in order to prevent childbearing; the greater need to control population growth which may also justify the use of riskier contraception; and the shorter life expectancy for women in less developed countries, which statistically decreases the possibility that a woman taking Depo-Provera will die from breast cancer.⁵³

The post-1996 regime hews much more closely to the view that “limitations on unapproved new drugs were contrary to the international law principle that sovereign nations are entitled to make their own determinations as to what they will or will not accept within their borders.”⁵⁴

However, the post-1996 regime still contains substantial deviations from a principle of deference to other nations' regulatory schemes: under the 1996 Act,

⁴⁹ See Linda Horton, *Mutual Recognition Agreements and Harmonization*, 29 SETON HALL L. REV. 692, 704–05 (1998).

⁵⁰ See generally *United States v. Undetermined Quantities of Boxes of Articles of Device*, No. 07-1769, 2007 WL 1575188 (D.N.J. May 30, 2007); Edward M. Basile et al., *Export of Pharmaceuticals and Medical Devices under the Federal Food, Drug & Cosmetic Act: FDA's Striking Change in Interpretation Post-Shelhigh*, 64 FOOD & DRUG L.J. 149 (2009).

⁵¹ Michael Traynor & Brian C. Cunningham, *Emerging Product Liability Issues in Biotechnology*, 3 HIGH TECH. L.J. 149, 190 n.142 (1988). See *Hearing*, *supra* note 37, at 8 (statement of Mark Novitch, M.D., Acting Comm'r of Food and Drugs, Food and Drug Administration) (“We believe that the governments of other nations are the proper authorities to address their own health needs, the diseases and health-related characteristics of their populations, the nature of their health care delivery systems, the availability of treatment alternatives, and all of the many other factors that go into these risk/benefit decisions.”).

⁵² Marc J. Scheineson, *Legal Overview of Likely FDA Regulation of Internet Promotion*, 51 FOOD & DRUG L.J. 697, 715 (1996).

⁵³ Gartner, *supra* note 35, at 107. See generally Susan D. Goland, Note, *Export of Pharmaceutical Products Under the Federal Food, Drug, and Cosmetic Act*, 13 CORNELL INT'L L.J. 125 (1980) (making similar arguments).

⁵⁴ Kaplan, *supra* note 37, at 193.

the FDA may still ban exports if it perceives an imminent danger to public health in the importing country, regardless of whether the importing country perceives such a danger.⁵⁵ David Fidler notes that such bans “show federal law moving beyond deference to local laws toward independent health-based review of U.S. exports.”⁵⁶ Advocates for exporters have objected to this non-deferential aspect of the Good Manufacturing Practices requirement, stating that “it should be evident that the intent of Congress in the Act was to avoid the needless destruction of potentially valuable drug products that meet the needs and standards of other countries, if not those of our own,” and criticizing legal standards under which “bulk drugs manufactured for export, under conditions which do not meet current good manufacturing practice requirements, would be adulterated and subject to seizure and destruction the instant they are manufactured, without regard to whether they could readily and legally be sold abroad.”⁵⁷

B. Medical Donations

The WHO’s guidelines on medical donation represent another medical norm that imposes First World standards on the Third World. These guidelines, adopted in 2000, regulate donations of medical equipment between countries. They specify that “there should be no double standard in quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.”⁵⁸ These standards have been incorporated by some non-governmental organizations (NGOs) that work in the area of medical equipment reuse: the Medical Surplus Recovery Organization’s Code of Conduct, for instance, incorporates the “no double standard” language from the WHO’s guidelines.⁵⁹ Legal commentators have also endorsed the guidelines.⁶⁰

⁵⁵ See Ansis M. Helmanis, *The FDA Export Reform and Enhancement Act of 1996: The FDA’s New Extraterritorial Authority over Labeling and Promotional Practices*, 51 FOOD & DRUG L.J. 631, 632 (1996).

⁵⁶ David P. Fidler, *A Globalized Theory of Public Health Law*, 30 J.L. MED. & ETHICS 150, 154 (2002).

⁵⁷ Brief of Appellant, *United States v. Kanasco*, 123 F.3d 209 (4th Cir. 1997) (No. 96-1996), 1996 WL 33453853, at *8–9.

⁵⁸ WHO, *Guidelines for Health Care Equipment Donations*, at 9, WHO/ARA/97.3 (March 2000), available at http://www.who.int/medical_devices/publications/en/Donation_Guidelines.pdf.

⁵⁹ CATHOLIC HEALTH ASS’N OF THE U.S., MEDICAL SURPLUS CODE OF CONDUCT 9 (2012), available at <http://www.chausa.org/docs/default-source/international-outreach/medical-surplus-code-of-conduct.pdf>. See generally THE ROYAL AUSTRALIAN AND NEW ZEALAND COLLEGE OF RADIOLOGISTS, POSITION STATEMENT ON INT’L DEVELOPMENT ACTIVITIES IN RADIOLOGY AND RADIATION ONCOLOGY 5 (2013), available at http://www.ranzcr.edu.au/component/docman/doc_download/2866-international-development-activities-position-statement; K.D. Bustamante et al., *Medical Equipment Conditions for Underserved Rural Hospitals in Chihuahua, Mexico*, paper presented at the 7th International Conference on Appropriate Healthcare Technologies for

The WHO's requirement that donated items meet First World standards has the desirable effect of preventing the donation of ineffective or dangerous medical equipment. But it sweeps much more broadly than that, also restricting access to items that could benefit patients but do not meet the high standards imposed by First World regulators. In so doing, the WHO's directive limits access to equipment that could save individuals, particularly individuals in the developing world, from disease and death.

Among the most prominent limiting effects of the WHO's guidelines is their inconsistency concerning reuse of implantable devices. Heart arrhythmias cause substantial mortality and morbidity in both developed and developing countries.⁶¹ Pacemakers could improve length and quality of life for many of these patients.⁶² However, new pacemakers are very expensive, often costing more than one year of income for the average citizen of a developing country.⁶³ This high cost means that, in many developing countries, new implantable pacemakers are available only to a small fraction of the richest citizens, and are almost never available to average-income patients.⁶⁴ In an effort to help arrhythmia patients in developing countries, NGOs have implemented programs to reuse pacemakers from cadavers in developed countries.⁶⁵ These are then shipped to developing countries for implantation in patients. Reused pacemakers perform nearly as well as new ones,⁶⁶ and these efforts to reclaim medical devices in developed countries and reuse them in developing countries have garnered broad support.⁶⁷ However, the U.S. and European Union prohibit the domestic reuse of pacemakers.⁶⁸ Following the WHO guidelines, therefore, blocks developing country patients from receiving beneficial medical interventions by limiting the donated devices they receive.

The WHO guidelines would also block the cost-effective reuse of single-use items (SUIs) where such items are not reused in developed countries. Such

Developing Countries, Sept. 18–19, 2012, available at <http://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=6458813>.

⁶⁰ See, for example, Roger Colinvaux, *Charitable Contributions of Property: A Broken System Reimagined*, 50 HARV. J. ON LEGIS. 263, 316 (2013) (praising the WHO regulations as “sensible”).

⁶¹ See Jamie VanArtsdalen et al., *Pacemaker Reuse for Patients in Resource Poor Countries: Is Something Always Better than Nothing?*, 55 PROGRESS CARDIOVASCULAR DIS. 300, 300–01 (2012).

⁶² See *id.* at 301.

⁶³ See Krishna Aragam et al., *The Ethics of Pacemaker Reuse: Might the Best Be the Enemy of the Good?*, 97 HEART 2005, 2005 (2011).

⁶⁴ See VanArtsdalen et al., *supra* note 61, at 301.

⁶⁵ See *id.*

⁶⁶ See Aragam et al., *supra* note 63, at 2005.

⁶⁷ See *id.*

⁶⁸ See VanArtsdalen et al., *supra* note 61, at 302.

reuse could prevent developed countries from being held “financial hostage to manufacturers” and free resources for allocation “to other sectors of healthcare that are currently lacking.”⁶⁹ Examples include the reuse of anesthesia equipment⁷⁰ as well as neurosurgery equipment.⁷¹

As well as inhibiting reuse of medical devices, the WHO’s prohibition serves to block developing-country citizens from receiving supplies of expired but otherwise unobjectionable medications that could be beneficial. Many developed countries set conservative expiration dates for their medications. Yet there is compelling evidence that most medications are effective long after their printed expiration dates. Ophthalmologist John Sandford-Smith describes several of his experiences with effective outdated medications:

When we had more surgery to do than we had anticipated I have used lignocaine at least 10 years out of date, stored away in a hospital pharmacy in the middle of the country, without any apparent loss of its effect. I have found that even biologically active drugs such as freeze dried hyaluronidase seem to retain their potency even years after an expiry date. When unable to sleep because of jet lag, I have benefited from very outdated temazepam.⁷²

The most exhaustive study comes from the U.S. Department of Defense’s Shelf Life Extension Program (SLEP), initiated to evaluate whether drug stockpiles would need to be discarded, and which studied the biological activity of numerous drugs after their expiration date. SLEP found that most drugs would be effective and safe for several years after their expiration date, with only marginal declines in effectiveness.⁷³ Other studies support their research.⁷⁴

As with pacemakers, developed countries have so far largely been able to absorb the high costs of conservative expiration dates. (However, recent lawsuits alleged that drug companies profited unjustly from excessively conservative

⁶⁹ A. Moszczyński, *Is Once Always Enough? Revisiting the Single Use Item*, 35 J. MED. ETHICS 87, 88 (2009).

⁷⁰ See A.R. Gatrad et al., *Equipment Donation to Developing Countries*, 62 ANAESTHESIA 90, 91 (2007) (“The donation of date-expired equipment also represents an ethical dilemma, particularly the accusation of double standards—if a piece of equipment is deemed unacceptable in the donor country, then it should be viewed in the same way in the recipient country. However, in the face of impoverished anaesthesia systems, should armoured tubes that are out of date be disposed of, or could good use be made of them in an environment where tracheal tubes are routinely re-used many times?”).

⁷¹ See Joong-Uhn Choi, *The Promotion of Pediatric Neurosurgery Throughout the World*, 23 CHILD. NERVOUS SYST. 929, 929 (2007) (“[W]e must consider donating medical equipment and instruments to developing countries, which [sic] are no longer used in developed countries.”).

⁷² John Sandford-Smith, Letter, *Outdated Drugs May Be Useful*, 326 BRIT. MED. J. 51, 51 (2003).

⁷³ See generally Jay M. Pomerantz, *Recycling Expensive Medication: Why Not?*, 6 MEDSCAPE GEN. MED. 4 (2004).

⁷⁴ See *id.* (collecting studies).

expiration dates,⁷⁵ and the Association of State and Territorial Health Officials suggested relaxing expiration dates to remedy drug shortages.⁷⁶) In contrast, imposing these expiration dates on developing countries less able to bear high costs means that many individuals could go without beneficial medicines. As Sandford-Smith points out in a letter to the *British Medical Journal*, the alternative to an outdated medication donation no longer acceptable in the donor country is not a brand-new medication. Rather, the alternative “to outdated medicine is no medicine at all,” while outdated medications can frequently be effective.⁷⁷ Where outdated medication provides a greater benefit than the likely alternatives, prohibiting it can produce a substantial medical burden.

The main justifications offered for mandating the same standard of care in developed and developing countries appeal to the disrespect that different standards of care might show. Sandford-Smith observes:

This issue of drugs—or even of sterile wrapped equipment, such as intraocular lenses—that are past their expiry date is unfortunately an extremely sensitive one with customs officials and the like in developing countries. I understand the point of view of someone without any scientific training who sees a label stating that something has expired on a certain date and feels it is his or her responsibility to destroy or confiscate it to protect the country from the condescending benevolence of the rich Western world.⁷⁸

Alice Moszczynski suggests a similar concern about what the donation of single-use items expresses:

It is common practice to donate unused SUIs [single-use items] to medical missions for use in majority world countries. We must pause here and ask two material questions. First, if these items can indeed be reprocessed for reuse, why are we not using these items in our country and demonstrating fiscal soundness? Second, if these items are not acceptable for use in our workplace, how are they acceptable for use in a needy country? While the responsibility and risk rests with the medical mission to decide what is used or discarded, we must be very careful and consider what message is sent to the global community at large when donating SUIs.⁷⁹

Even if such donations produce a medical benefit, the argument goes, they may express a disrespectful message. In contrast, prohibiting the reuse of medical

⁷⁵ See, for example, *Raskas v. Johnson & Johnson*, 719 F.3d 884, 886 (8th Cir. 2013) (describing three lawsuits of this kind).

⁷⁶ See ASS'N OF STATE AND TERRITORIAL HEALTH OFFICIALS, *COPING WITH AND MITIGATING THE EFFECTS OF SHORTAGES OF EMERGENCY MEDICATIONS* 18–20 (2012), available at http://www.ems.gov/pdf/2013/ASTHO_Shortages_of_Emergency_Meds.pdf.

⁷⁷ Sandford-Smith, *supra* note 72, at 51.

⁷⁸ *Id.*

⁷⁹ Moszczynski, *supra* note 69, at 89.

items might appear to demonstrate appropriate respect for the inestimable value of health: as Moszczynski observes, “it is argued that single use only practices are fiscally sound, for each patient is treated the same in receiving a new item, and what cost can be put on a person’s health?”⁸⁰

However, where scarcity exists, both of Moszczynski’s last two claims are misleading. While every patient who receives *something* is “treated the same in receiving a new item,”⁸¹ those patients who receive nothing—but perhaps could have received a beneficial reused item were one available—are treated very differently, and end up worse off than they could have been. And where scarcity exists, as I argue in Section IV, refusing to compare costs against health benefits can undermine public health and divert resources from other worthwhile goals.

C. Vaccines

Currently, different vaccines are used for the same conditions in the developed and developing world. For example, although whole-cell vaccine is effective at preventing the dangerous communicable disease pertussis (also known as “whooping cough”), it occasionally causes serious side effects.⁸² These side effects led to lawsuits in the U.S.⁸³ and, eventually, to its withdrawal from the market.⁸⁴ However, the whole-cell vaccine is still used in developing countries, because it is inexpensive, effective, and substantially safer than going unvaccinated.⁸⁵ The WHO, interestingly, recommends whole-cell pertussis

⁸⁰ *Id.* at 86.

⁸¹ *Id.* at 88.

⁸² See *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 236 (3d Cir. 2009), *aff’d sub nom.* *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011) (“Although the whole-cell vaccine effectively reduced pertussis infections and deaths associated with these infections, it was also linked to a variety of adverse events.”).

⁸³ See, for example, *Bruesewitz*, 561 F.3d 233; *Jones by Jones v. Lederle Labs*, 982 F.2d 63 (2d Cir. 1992).

⁸⁴ See *Valico v. Sec’y of Health & Human Servs.*, No. 00-662V, 2002 WL 508344, at *3 n.4 (Fed. Cl. Mar. 11, 2002) (“In the last several years, a new type of ‘acellular’ pertussis vaccine has become available, and is now being substituted for the whole-cell pertussis vaccine in most diphtheria-pertussis-tetanus inoculations in this country.”); Elizabeth A. Breen, Note, *A One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM. & MARY L. REV. 309, 313 n.35 (1999) (stating that “the more dangerous whole-cell pertussis vaccine has all but completely yielded to the newer acellular pertussis vaccination”).

⁸⁵ See, for example, Hitt Sharma et al., *A Phase III, Randomized Controlled Study to Assess the Safety and Immunogenicity of a Semi-Synthetic Diphtheria, Tetanus and Whole-Cell Pertussis Vaccine in Indian Infants*, 30 VACCINE 6157, 6160 (2012) (“Due to reactogenicity temporally associated with whole-cell component of the DTwP vaccines, several developed countries have started using acellular pertussis (DTaP) vaccines in their routine immunization programme. However, the development cost of the acellular vaccine is higher, the production more complex and the efficacy is not better in comparison to whole-cell pertussis vaccines. Further, in developing countries, the DTwP

vaccine as acceptable in developing countries, largely because “there is insufficient marginal benefit to consider changing from wP [whole-cell vaccines]” to more expensive acellular ones.⁸⁶ This recommendation parallels the WHO’s recommendation for meningitis and epilepsy, which permitted different standards in developed and developing countries for cost reasons, and diverges from its recommendations for HIV and medical donations. The use of whole-cell vaccines in other countries, in fact, motivated at least one call in the U.S. for permitting the export of unapproved drugs.⁸⁷

Another context where vaccine recommendations have diverged involves the human papilloma virus (HPV) vaccine. While HPV vaccination has become commonplace in the U.S., its costs remain high. A recent law review article notes the potential conflict between providing HPV vaccine and pursuing other medical priorities in developing countries:

[T]he current high cost of HPV vaccination is an enormous obstacle for developing countries. However, efforts are being made to develop mechanisms to make HPV vaccines more affordable, especially for public sector programs in low- and middle-income countries [B]oth Merck and GSK have promised to offer their vaccines to the public sectors of developing countries at prices tiered to country income. Even with concerted efforts to reduce HPV vaccine costs, however, developing countries will likely face difficult decisions regarding whether to allocate their limited financial resources to HPV immunization programs.⁸⁸

The author then goes on to propose that international funding, such as that provided by the Bill & Melinda Gates Foundation to non-profit HPV immunization initiatives, could ease the difficult choices the HPV vaccine poses for developing countries.⁸⁹ But even where international funding is available for HPV vaccination, the developing country’s citizens might prefer—reasonably—to use that same funding to pursue other health care priorities, as a recent letter to the *Lancet* argues:

First, although the burden of cervical cancer in low-income and middle-income countries is substantial (3.8 million disability-adjusted life-years [DALYs]), it ranks well behind that of other vaccine- preventable diseases

reactogenicity issue is not generally seen as a major problem. Therefore, in such countries with limited resources, whole-cell pertussis remains the vaccine of choice.”).

⁸⁶ *Pertussis Vaccines: WHO Position Paper—Recommendations*, 29 *VACCINE* 2355, 2355–56 (2011).

⁸⁷ See *Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review*, 70 Fed. Reg. 75018, 75020 (Dec. 19, 2005) (“The comment noted that medical practices in other countries may differ from those in the United States and that in some countries Pertussis Immune Globulin (Human) plays an important role in the augmentation of therapy with antibiotics in young, very ill infants with pertussis.”).

⁸⁸ Gregory D. Zimet, *Potential Barriers to HPV Immunization: From Public Health to Personal Choice*, 35 *AM. J.L. & MED.* 389, 395 (2009).

⁸⁹ See *id.*

such as tetanus (8.3 million DALYs) and measles (23 million DALYs). Second, the effectiveness of the HPV vaccine against cervical cancer is still unknown. This uncertainty concerns African populations in particular, with their high HIV prevalence. Third, to remain cost-effective in GAVI-eligible [Global Alliance for Vaccines and Immunization-eligible] countries, the costs for a vaccinated individual should not exceed US\$10 for the three doses. This cost contrasts unfavourably with the arguably lowest price negotiated so far—\$16.95 per dose.⁹⁰

Policymakers in developing countries may also worry that once initial funding for HPV vaccination dries up, the developing country may end up worse off than if it had never taken the funding, because the vaccination program will be difficult to terminate.⁹¹

III. GRANTING RIGHTS TO EXPENSIVE TREATMENTS

While the debates above focus on particular interventions and conditions, debates over the right to health take a more general perspective. The International Covenant on Social, Economic, and Cultural Rights (ICESCR) defines this right as “the right to the enjoyment of the highest attainable standard of physical and mental health.”⁹² The ICESCR’s conception of the right to health as a right to maximum health parallels the WHO’s similar definition.⁹³ Other influential human rights documents have adopted similar conceptions of the right to health as a right to maximal health.⁹⁴ So, too, have human rights

⁹⁰ Nobila Ouedraogo et al., Letter, *Human Papillomavirus Vaccination in Africa*, 378 LANCET 315, 315–16 (2011).

⁹¹ See *id.* at 316 (“When the donations are drained off, GAVI will be in a difficult position: terminating this highly publicised programme will be unpopular It would be a tragedy if funds were shifted from proven, cost-effective vaccines and the strengthening of health systems to new but costly vaccines of unknown effectiveness.”).

⁹² ICESCR, *supra* note 10, art. 12.

⁹³ See Puneet K. Sandhu, Comment, *A Legal Right to Health Care: What Can the United States Learn from Foreign Models of Health Rights Jurisprudence?*, 95 CAL. L. REV. 1151, 1158 (2007) (“The World Health Organization (WHO) Constitution names ‘[t]he enjoyment of the highest attainable standard of health’ as a ‘fundamental right[] of every human being.’”) (quoting CONSTITUTION OF THE WORLD HEALTH ORGANIZATION (1946), available at http://www.who.int/governance/eb/who_constitution_en.pdf).

⁹⁴ See, for example, European Social Charter art. 11, Oct. 18, 1961, 529 U.N.T.S. 89, rev’d May 3, 1996, available at http://www.coe.int/t/dghl/monitoring/socialcharter/Presentation/ESCCollectedTexts_en.pdf (“Everyone has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable.”); African Charter on Human and Peoples’ Rights (“Banjul Charter”) art. 16, June 27, 1981, CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), available at <http://www.achpr.org/instruments/achpr> (“Every individual shall have the right to enjoy the best attainable state of physical and mental health.”).

documents dedicated to the protection of particular vulnerable groups.⁹⁵ Activists, policymakers, and scholars have praised this conception.⁹⁶

The ICESCR defines only the right to health in maximal terms.⁹⁷ In contrast, it defines the right to food in adequacy terms, and does the same for the right to shelter.⁹⁸ Likewise, the right to work entitles workers to “just and favourable conditions of work” which provide “a decent living for themselves and their families,” not to maximal pay or minimal hours.⁹⁹ Other rights, like the rights to education, social insurance, and cultural participation, as well as the right to benefit from science, are left open-ended.¹⁰⁰ Further, the right to health generates a negative duty “to refrain from interfering directly or indirectly with

⁹⁵ See, for example, Convention on the Rights of the Child art. 24, Nov. 20, 1989, 1577 U.N.T.S. 3, available at <http://www.ohchr.org/en/professionalinterest/pages/crc.aspx> (“States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health.”); Convention on the Rights of Persons with Disabilities art. 25, Dec. 13, 2006, 2515 U.N.T.S. 3, available at <http://www.un.org/disabilities/convention/conventionfull.shtml> (“States Parties recognize that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability.”); United Nations Declaration on the Rights of Indigenous Peoples, G.A. Res. 61/295, U.N. Doc. A/RES/61/295, 46 I.L.M. 1013 ((Sept. 13, 2007), art. 24, available at http://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf (“Indigenous individuals have an equal right to the enjoyment of the highest attainable standard of physical and mental health.”). See generally Virginia A. Leary, *The Right to Health in International Human Rights Law*, 1 HEALTH & HUM. RTS. 24, 32–33 (1994) (discussing various statements of the right to health).

⁹⁶ See, for example, Lawrence O. Gostin, *The Human Right to Health: A Right to The “Highest Attainable Standard of Health,”* 31 HASTINGS CFR. REP. 29, 29–30 (2001) (praising the ICESCR definition); Matti Hayry & Heta Hayry, *Health Care As a Right, Fairness and Medical Resources*, 4 BIOETHICS 1, 21 (1990) (arguing in favor of realizing the right to the highest attainable standard of health by shifting resources from nonmedical “purposes which are, on reflection, far less important than the prolongation of life and the improvement of health”).

⁹⁷ See Amir Attaran, *Human Rights and Biomedical Research Funding for the Developing World: Discovering State Obligations under the Right to Health*, 4 HEALTH & HUM. RTS. 26, 31 (1999) (“The Article 12 right is tremendously ambitious in scope. It provides that the right to health inures to ‘everyone’ and that everyone should enjoy the ‘highest attainable standard’ of well-being. No other right in the ICESCR is framed in such superlative language.”)

⁹⁸ See ICESCR, *supra* note 10, art. 11 (“The States Parties to the present Covenant recognize the right of everyone to an adequate standard of living for himself and his family, including adequate food, clothing and housing, and to the continuous improvement of living conditions.”) (emphasis added).

⁹⁹ *Id.* art. 6.

¹⁰⁰ See *id.* arts. 9 (“The States Parties to the present Covenant recognize the right of everyone to social security, including social insurance.”), 13 (“The States Parties to the present Covenant recognize the right of everyone to education.”), 15 (“The States Parties to the present Covenant recognize the right of everyone: (a) To take part in cultural life; (b) To enjoy the benefits of scientific progress and its applications.”).

the right to health” (the “obligation to respect”) as well as a positive duty to promote health (the “obligation to fulfill”).¹⁰¹

In the next three subsections, I discuss three areas of case law where low- and middle-income countries have faced the challenge of balancing this maximalist right to health against cost considerations.

A. Soobramoney

In 1997, the Constitutional Court of South Africa decided its first case concerning the right-to-health provisions of the South African Constitution. The appellant, Thiagraj Soobramoney, sought access to renal dialysis for which a state hospital had found him ineligible due to his poor prognosis and the limited resources available. Soobramoney alleged that the hospital’s decision violated his rights under Section 27(3) of the South African Constitution, which provides that “[n]o one may be refused emergency medical treatment,” and Section 11, which stipulates a right to life.¹⁰² The Court found that Soobramoney’s needs were not emergency needs, but rather needs for the treatment of an ongoing, chronic illness. As such, the Court decided that his claims instead fell under the provisions of Sections 27(1) and 27(2), which obligate the government to take reasonable measures “within its available resources” to enable everyone to access health care services. After analyzing the reasons the government offered (which had prevailed in the lower court), the Court concluded that the government had made a rational decision not to treat Soobramoney, and that ordering the government to treat him would be contrary to the needs of other people whom the government also had a duty to assist.¹⁰³

The *Soobramoney* decision was controversial among activists and academics, many of whom argued that the Court could and should have done more for Soobramoney. Human rights lawyers and the public pointed to the extremity of Soobramoney’s plight;¹⁰⁴ academics called *Soobramoney* “a rather timid approach to social and economic rights”¹⁰⁵ and charged that “[i]n acknowledging that a

¹⁰¹ OFFICE OF THE UNITED NATIONS HIGH COMM’R FOR HUM. RTS., *THE RIGHT TO HEALTH* 25 (2008).

¹⁰² *Soobramoney v. Minister of Health, Kwa-Zulu-Natal*, 1997 (12) BCLR 1696 (CC) (S. Afr.).

¹⁰³ *Id.* ¶¶ 11, 36.

¹⁰⁴ *See, for example*, Richard J. Goldstone, *A South African Perspective on Social and Economic Rights*, 13 HUM. RTS. BRIEF 4, 5 (2005) (“The Court was criticized by much of the media for effectively sentencing Soobramoney to death.”); Emily Bazelon, *After the Revolution*, LEGAL AFF. (Jan./Feb. 2003), available at http://www.legalaffairs.org/issues/January-February-2003/feature_bazelon_janfeb2003.msp (suggesting that “most human rights lawyers read the majority opinion [in *Soobramoney*] as a major disappointment”).

¹⁰⁵ Dennis M. Davis, *Socioeconomic Rights: Do They Deliver the Goods?*, 6 ICON 687, 692 (2008).

person's wealth determined whether he would live or die, yet failing to interpret the constitutional rights to life and health to avoid this outcome, the Court missed an important opportunity to give meaning to the new social contract."¹⁰⁶

B. Treatment Action Campaign

Rather than representing a break with an under-ambitious first attempt in *Soobramoney*, as some have argued,¹⁰⁷ the South African *Treatment Action Campaign (TAC)* case represented a continuation of the same universalization norm applied to a different policy. And, as often happens, a different policy produced a different result.

In *TAC*, the Constitutional Court considered whether to require the government to make nevirapine, a highly-active antiretroviral drug, available widely to mothers in order to combat mother-to-child HIV transmission.¹⁰⁸ The *TAC* suit responded to the government's policy of making the drug only available in a very few pilot sites. The government's arguments focused on the desirability of providing nevirapine in the context of an integrated HIV treatment strategy (which would be possible at the pilot sites),¹⁰⁹ whereas the plaintiffs contended that there was no point in preventing patients who would not be able to access the drug at the pilot sites from accessing the drug altogether.¹¹⁰ The Court ultimately concluded that the government had an obligation to expand access to nevirapine beyond the pilot sites.¹¹¹

What differences between the situations in *TAC* and *Soobramoney* produced this very different outcome? I believe there were two primary factors. First, the *TAC* suit was brought by a group, rather than a single individual. If the plaintiffs prevailed, a large group of similarly situated and poorly-off people would be helped. It has been suggested that the *TAC* decision "saved tens of thousands of lives,"¹¹² whereas even if the plaintiff in *Soobramoney* had prevailed, only his own life would have been (temporarily) saved. Second, the *TAC* case did not require the government to bear all the costs of the requested intervention. Instead, the private sector also stepped up to bear some of the costs: as the South African

¹⁰⁶ Jeanne M. Woods, *Justiciable Social Rights as a Critique of the Liberal Paradigm*, 38 TEX. INT'L L.J. 763, 783 (2003).

¹⁰⁷ See, for example, *id.* at 786.

¹⁰⁸ See *Minister of Health v. Treatment Action Campaign 2002* (10) BCLR 1033 (CC) (S. Afr.), ¶ 19 [hereinafter *TAC*].

¹⁰⁹ See *id.* ¶ 16.

¹¹⁰ See *id.* ¶ 18.

¹¹¹ See *id.* ¶ 68.

¹¹² *Minister of Health v. Treatment Action Campaign (TAC) (2002) 5 SA 721 (CC)*, ESCR-NET, available at <http://www.eschr-net.org/docs/i/403050>.

Constitutional Court noted, “the manufacturers of [n]evirapine offered to make it available to the South African government free of charge for a period of five years.”¹¹³

C. Tutelas

What might have happened if the South African Constitutional Court had found in Soobramoney’s favor? Many Latin American courts have taken an approach of this kind when addressing the right to health, and we might learn from their experience. I will argue that the Latin American cases—despite some praise from human rights commentators—ultimately illustrate that recognizing claims like Soobramoney’s would have inevitably proven so costly and time-consuming as to be unworkable, and would have actually worked to undermine the rights of the worst-off in society.

One such example is that of Colombian *tutelas*—legal proceedings by which Colombian citizens can enjoin the national government to pay for lifesaving medical care. Colombia’s experience is a microcosm of the problems Latin American nations have faced when permitting individual citizens to bring right-to-health suits against the government. In the mid-1990s—just as the South African Constitutional Court was working out its approach to the right to health—the Colombian Constitutional Court elected to permit *tutelas*.

As might be expected from the South African reaction to *Soobramoney*, the *tutela* system’s willingness to cater to the needs of identifiable and seriously unwell individuals attracted public praise.¹¹⁴ However, as we might equally expect, the system has proven exceptionally expensive.¹¹⁵ In Colombia, the

¹¹³ *TAC*, *supra* note 108, ¶ 19.

¹¹⁴ *See, for example*, Rodrigo Uprimny, *Should Courts Enforce Social Rights? The Experience of the Colombian Constitutional Court*, in *COURTS AND SOCIAL TRANSFORMATION IN NEW DEMOCRACIES* 127, 141 (Roberto Gargarella et al. eds., 2006) (“Others, however, as beneficiaries of these rulings, find in the Court’s progressivism a means for satisfying a basic need of such magnitude as health, and for improving their life quality in an important way.”) (summarizing Salomón Kalmanovitz, *Las consecuencias económicas de los fallos de la Corte Constitucional*, 276 *Economía Colombiana* 124 (1999)); Everaldo Lamprea & Tatiana Andia, *Local Maladies, Global Remedies: Rethinking Right to Health Duties* (unpublished manuscript presented to the Linda Randall Meier Global Justice Workshop, Stanford University, May 21, 2010), at 2, *available at* http://iis-db.stanford.edu/evnts/6170/Global_Justice_May_21_2010.pdf (“Paying for this type of expensive life-saving pharmaceuticals is, in itself, a remarkable achievement for a government of a developing country. Unlike millions of other cases around the developing and developed world, Colombians afflicted by excruciating and highly onerous medical conditions have, in the last resort, a judicial action that may allow them to have access to such expensive, life-saving goods.”).

¹¹⁵ *See* Uprimny, *supra* note 114, at 142 (arguing that the *tutela* system undermines public health interventions like childhood immunization in order to treat high-profile cases); *see also* Maria Paula Saffon, *Can Constitutional Courts Be Counterhegemonic Powers vis-a-vis Neoliberalism? The Case of the*

system more than tripled health care expenditures in a single year—between 1998 and 1999.¹¹⁶ This rise in health care costs continued over time: as Everaldo Lamprea and Tatiana Andia’s research shows, “the cost of health litigation climbed from U.S. \$1.48 million in 2001 up to U.S. \$344 million in 2008.”¹¹⁷ Not only did health care expenditures rise staggeringly, but the court system also became overburdened: “[I]n 2004 . . . 1 of every 597 Colombian citizens used the basic rights injunction for the protection of basic rights (*Tutela*) in order to obtain health-related goods and services,”¹¹⁸ and by 2008, there had been more than 650,000 right to health actions brought.¹¹⁹ Some have argued that the *tutela* system is a valuable counteractive to neoliberal policies that spend money on military might and corporate tax breaks rather than directly on the worst-off.¹²⁰ But the greater resources that flow to the individuals winning *tutela* judgments have frequently—as many feared would have happened in South Africa had the *Soobramoney* court not ruled as it did—come not from increased tax revenue or cuts in other sectors, but from cannibalizing less visible but crucial parts of the health sector, like childhood immunizations,¹²¹ and have flowed to the middle class rather than to the working class and the poor.¹²² Similar problems have occurred in Argentina, Costa Rica, and Brazil.¹²³

Colombian Constitutional Court, 5 SEATTLE J. SOC. JUST. 533, 547–48 (2007) (noting that the *tutela* system more than tripled health care expenditures between 1998 and 1999, that the system is unsustainable because of lack of state resources, and that many have criticized *tutelas* for inefficiently directing money to high-cost interventions; nonetheless praising the *tutela* system because it has concretely helped some citizens). See generally Alicia Ely Yamin & Oscar Parra-Vera, *Judicial Protection of the Right to Health in Colombia: From Social Demands to Individual Claims to Public Debate*, 33 HASTINGS INT’L & COMP. L. REV. 431 (2010) (describing the evolution of the *tutela* system in Colombia).

¹¹⁶ See Saffon, *supra* note 115, at 547–48.

¹¹⁷ Lamprea & Andia, *supra* note 114, at 6 (noting also that “the cost of treatments and medications that are not included in the Basic Health Plan paid to private HMOs by the tax-financed fund FOSYGA escalated from U.S.\$ 2.8 million [sic] in 2001 to U.S.\$ 605.3 million [sic] in 2008”).

¹¹⁸ *Id.* at 4.

¹¹⁹ *Id.* at 4–5.

¹²⁰ See, for example, Saffon, *supra* note 115, at 547–48.

¹²¹ See sources cited *supra* note 115.

¹²² See David Landau, *The Reality of Social Rights Enforcement*, 53 HARV. INT’L L.J. 189, 215 (2012).

¹²³ See generally Fabiola Sulpino Vieira, *Right to Health Litigations: A Discussion on the Observance of the Principles of Brazil’s Health System*, 42 REV. SAUDIE PUBLICA 365 (2008) (criticizing the Brazilian Supreme Court for issuing rulings guaranteeing access to medicines that ignored resource scarcity and cost-effectiveness); see Alicia Ely Yamin & Oscar Parra-Vera, *How Do Courts Set Health Policy? The Case of the Colombian Constitutional Court*, 6 PLOS MED. 147, 149 (2009), available at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000032> (observing that “[i]n Brazil, thousands of court cases have been brought since 1992 relating to access to medications—many of which are highly costly and not included in Brazil’s national

Noah Novogrodsky effectively summarizes the difference between the group focus of a case like *TAC* and the individual focus of the *tutela* cases:

One characteristic of this shift has been the emphasis on demands for treatment as an individual rather than a collective right. Rightly or wrongly, the interest in ARVs [antiretroviral medications] has focused attention on individual, biomedical needs rather than public health requirements. Where “[p]ublic health is what we, as a society, do collectively to assure the conditions of people to be healthy,” treatment is essentially an atomized, clinical exercise. While many theorists insist that the right to health is better understood as a society-level collective right focused on the underlying determinants of health, not specific case-by-case interventions, the treatment cases use the provision of ARVs to enforce individual claims to dignity and sustainable treatment.¹²⁴

Among the cases that Novogrodsky cites as examples of this individual-focused view are *tutela* cases. What I want to suggest is that Novogrodsky is far too optimistic in thinking that individual-focused cases like the *tutela* cases could be able to realize “sustainable treatment.”¹²⁵ As we see above, they instead have led to runaway costs and an overburdened legal system.

Another crucial difference between *TAC* and the *tutela* cases is the source of the resources being given to the worst-off. Novogrodsky mistakenly reads *TAC* as holding that “states parties must make ‘every effort’ using ‘all’ available resources to ensure fulfillment of [the right to health.]”¹²⁶ But in *TAC*, pharmaceutical companies made nevirapine available to the government *for free*. It is by no means clear from the *TAC* decision that the South African Constitutional Court would have directed the government to *buy* nevirapine at the market price for all mothers with HIV/AIDS.

In contrast, in the *tutela* cases, the private sector (rather than the state) was not asked to contribute anything to ease the plight of the worst off. Instead, as Lamprea and Andia observe, Colombia acquiesced in extraordinarily high pharmaceutical prices:

Colombia is a country with some of the most expensive pharmaceuticals in the region. Two [WHO] and Health Action International (HAI) studies confirm this fact. The first study compared Colombia’s essential medicine prices with those of Bolivia, Perú, Ecuador, Venezuela and Nicaragua, and concluded that Colombia has the highest prices of brand name

health plan—resulting in distortions of the health budget,” and noting similar practices in Argentina and Costa Rica).

¹²⁴ Noah Novogrodsky, *The Duty of Treatment: Human Rights and the HIV/AIDS Pandemic*, 12 YALE HUM. RTS. & DEV. L.J. 1, 41 (2009) (quoting Benjamin Mason Meier & Larisa M. Mori, *The Highest Attainable Standard: Advancing a Collective Human Right to Public Health*, 37 COLUM. HUM. RTS. L. REV. 101, 121 n.78 (2005)).

¹²⁵ *Id.*

¹²⁶ *Id.* at 34.

pharmaceuticals in the Region. The second study, an international price “snapshot” of Ciprofloxacin (a commonly used off-patent antibiotic) in 93 countries concluded that “Colombia showed the largest brand premium, with the originator brand priced at 60 times the lowest priced generic. Colombia also had the highest treatment cost for originator brand ciprofloxacin in the private sector.”

This overpricing of pharmaceuticals due to deregulation proved to be toxic when the wave of health-related litigation forced the government to use taxpayer money to pay for high-cost exclusive pharmaceuticals produced by Big Pharma companies [I]n 2008 the cost of the Top Ten Bestseller high-cost pharmaceuticals in Colombia—many of which were obtained by patients through health-litigation and were paid by the tax-financed fund Fosyga—reached US\$ 210 million [sic]. Moreover, nine of these ten products are sold in Colombia at prices that are between 200% and 540% higher than the ones paid in Argentina, Brasil, Chile, Ecuador, México, Panamá, Perú and Venezuela.¹²⁷

Andia and Lamprea’s research suggests that Colombia’s strategy was the polar opposite of South Africa’s. Rather than strictly limiting individual right-to-health claims, Colombia welcomed them; rather than having the private sector contribute to the costs of essential medicines, the government absorbed the entire cost of each individual rights claim granted.¹²⁸

IV. CAN LIMITING ACCESS BE JUSTIFIED?

States and international legal actors can prevent access to less expensive, less effective treatments directly through bans or indirectly by emptying government coffers to pay for individually demanded expensive treatments. Nonetheless, where a less expensive and effective intervention, like stavudine treatment for HIV or a used pacemaker, is more cost-effective—it can treat more people and provide a larger net medical benefit for a given sum of money—the moral case in its favor is simple and compelling. Making it possible for *more* people to live longer, or allowing more people to experience a higher quality of life, better respects the value of each person’s life than would helping *fewer* people with the same resources. Choosing a medically less effective but more cost-effective intervention often makes a better outcome possible. As one of stavudine’s proponents put it, “[a] minister of health or donor faced with the decision to treat two people with a moderately toxic drug or one with a relatively safe regimen, with the other person definitely dying of AIDS, faces very little choice.”¹²⁹

¹²⁷ Lamprea & Andia, *supra* note 114, at 15.

¹²⁸ *See id.*

¹²⁹ W.D. Francois Venter et al., *Low-Dose Stavudine Trials: A Public Health Priority for Developing Countries*, 13 S. AFR. J. HIV MED. 20, 21 (2012).

This section will focus on three types of responses to this simple argument against limiting access to less expensive, less effective treatments. These responses appeal to special obligations that physicians owe patients, to the value of expressing disapproval of an unjust situation, and to the potentially good long-term consequences of mandating the same treatments in developing countries as are provided in developed ones.

A. Special Obligations

Choices about whether to help specific individuals (like Thiagraj Soobramoney or Pauline Talty) vindicate their right to the highest attainable standard of health, or to help individuals in developing countries secure the same medications that are provided in developed countries, frequently involve appeals to the importance of special obligations owed those in need. The physician-activist Paul Farmer makes this point eloquently:

Over the past decade and against a steady current of naysaying, we have channeled significant resources to the destitute sick in Haiti, Peru, Mexico, and Boston. We didn't argue that it was "cost-effective," nor did we promise that such efforts would be replicable. We argued that it was the right thing to do. It was the human rights thing to do.¹³⁰

Were helping these patients costless, there would be little reason to resist Farmer's claim that helping them was the right thing to do. But helping them is not costless. In the cases I detail, the money, time, and medical resources spent in order to provide specific individuals with the highest attainable standard of health, or secure the highest-quality treatments, could almost certainly have saved more lives if instead used to provide less effective (or more toxic) treatments to more people.

Farmer's claim, however, could still be true if a special moral obligation were to override the aforementioned justifications for helping more people. In this subsection, I consider three potential sources of such an obligation: (1) the duty not to harm; (2) the duty to rescue the sick; and (3) the duty of reciprocity.

1. The duty not to harm.

Many second-best treatments, such as stavudine, have more burdensome side effects than more expensive alternatives. If these side effects were to constitute harms, then aiding more people by providing them with stavudine may also entail harming more people. And cases where aiding more people requires causing harm seem more morally complex than those where aiding some people requires failing to aid other people. In such cases, medical

¹³⁰ Paul Farmer & Nicole Gastineau, *Rethinking Health and Human Rights: Time for a Paradigm Shift*, 30 J. L. MED. & ETHICS 655, 664 (2002).

professionals' duty not to harm might potentially bar them from providing aid.¹³¹ Many arguments against the export of unapproved drugs appeal to the claim that providing these drugs would risk harming some of the patients who received them.¹³²

Whether side effects constitute harms depends on how we define harm. Within what legal scholar Seana Shiffrin calls *comparative* models of harm, someone suffers a harm when she is made worse off than she would have been in some alternative scenario.¹³³ In comparative terms, stavudine does not harm those who receive it even when they experience side effects, so long as these side effects are less bad than the effects of untreated HIV. Since receiving stavudine—despite its side effects—is better than suffering from untreated HIV, stavudine benefits those who receive it rather than harming them. While advocates of the comparative model might say that stavudine's side effects are—considered on their own—*harmful*, they would deny that stavudine, all things considered, *harms* patients with HIV. Similarly, they would deny that a successful rescuer who injures the person she rescues harms that person. As Joel Feinberg points out, “the rescuer-defendant did not cause a condition that was harmful on balance, offset as it was by the overriding benefit of rescue [H]e cannot be said, therefore, to have harmed the [rescued person] (in the relevant full sense) at all.”¹³⁴

Shiffrin herself endorses a noncomparative model of harm, rather than a comparative model. On Shiffrin's view,

harm involves the imposition of a state or condition that directly or indirectly obstructs, prevents, frustrates, or undoes an agent's cognizant interaction with her circumstances and her efforts to fashion a life within them that is distinctively and authentically hers—as more than merely that which must be watched, marked, endured or undergone.¹³⁵

The injuring rescuer clearly causes harm on Shiffrin's view, although he also prevents harm. However, Shiffrin denies that causing a lesser harm to someone in order to save her from a more serious harm generates a special obligation to

¹³¹ See, for example, N.J. Stat. Ann. § 45:1-54 (West 2013) (mentioning “the medical dictum to first, do no harm”); *Finucan v. Md. State Bd. of Physician Quality Assur.*, 827 A.2d 176, 187 n.7 (Md. App. 2003), *aff'd sub nom. Finucan v. Md. Bd. of Physician Quality Assur.*, 846 A.2d 377 (Md. 2004) (collecting cases discussing the “first, do no harm” maxim).

¹³² See, for example, Hatton, *supra* note 37, at 443 (noting that “the United States may find itself the butt of international criticism if an exported unapproved new drug, unavailable to American consumers, causes illness or deaths abroad”).

¹³³ See Seana Valentine Shiffrin, *Wrongful Life, Procreative Responsibility, and the Significance of Harm*, 5 LEGAL THEORY 117, 121 (1999).

¹³⁴ *Id.* at 120 (quoting Joel Feinberg, *Wrongful Life and the Counterfactual Element in Harming*, in FREEDOM AND FULFILLMENT 3, 27 (1992) (emphasis omitted)).

¹³⁵ *Id.* at 123–24.

rectify the lesser harm. Rather, Shiffrin concludes that “when a person is unavailable for consent, it can be justified both to inflict a lesser harm upon her to avert a greater harm, and to refrain from providing compensation or apologies for one’s act.”¹³⁶ Therefore, although Shiffrin and Feinberg disagree about whether the injuring rescuer harms the rescuee, they agree that he owes no compensation, because he does not worsen the rescuee’s position. Case law adopts a similar stance.¹³⁷

Arthur Applbaum seems to disagree with Shiffrin’s conclusion, as well as that of the comparativists, and grounds his intuition in an example:

[I]n Imperial Russia, young boys were sometimes impressed into the tsar’s army for many years of harsh, cruel, and dangerous service. Some parents, to spare their sons this fate, would cut off the boys’ trigger fingers at a very young age [T]o cut off a boy’s finger under the circumstances described is to violate a right not to have one’s person violated. Let us suppose that the conditions of conscription amounted to involuntary servitude to a tyrant, and so was a greater violation of these boys’ rights [T]he parents violate a lesser right of their child to prevent a greater violation by the tsar of the rights of the same child.¹³⁸

Applbaum concludes that “[s]uch a desperate choice is ghastly to contemplate, and I cannot say with confidence that it is morally permissible.”¹³⁹ I agree with Applbaum that the choice is ghastly. But I cannot imagine why—in a case where the child is certain to suffer a far worse fate—cutting off his finger would be impermissible. Medical cases make this clear. Imagine, for instance, a child with an osteosarcoma (cancer) of the leg that will metastasize unless the leg is amputated.¹⁴⁰ It is certainly ghastly to be put in a position where one must choose between cutting a child’s leg off or their dying of cancer—though pediatric oncologists realize their choice of career will frequently put them in such a position—but, once one is inescapably in such a position, doing what is better for the patient seems clearly permissible.

¹³⁶ *Id.* at 126.

¹³⁷ *See, for example*, *Rodrigue v. United States*, 968 F.2d 1430, 1434 (1st Cir. 1992) (“Good Samaritan rule does not impose liability for mere negligent failure to confer a benefit, but only for negligently making matters worse.”); *United States v. DeVane*, 306 F.2d 182, 186 (5th Cir. 1962) (“[T]he negligence of the volunteer rescuer must worsen the position of the person in distress before liability will be imposed.”); *see also* Dov Waisman, *Negligence, Responsibility, and the Clumsy Samaritan: Is There a Fairness Rationale for the Good Samaritan Immunity?*, 29 GA. ST. U. L. REV. 609, 620 (2013) (“The injured party has traditionally been required to show that the ultimate result of the rescuer’s conduct was to place the injured party in a worse position than she would have been in had that particular rescuer never intervened.”) (emphasis omitted).

¹³⁸ Arthur Isak Applbaum, *Are Violations of Rights Ever Right?*, 108 ETHICS 340, 349 (1998).

¹³⁹ *Id.* at 349.

¹⁴⁰ For discussion of such a case, *see generally* *Turner v. Steriltek, Inc.*, No. M2006-01816-COA-R3-CV, 2007 WL 4523157 (Tenn. Ct. App. Dec. 20, 2007).

Some side effects, however, actually make patients worse off than they would have been *were they never treated*. For instance, stavudine occasionally causes fatal lactic acidosis.¹⁴¹ The patient who experiences this side effect is in a different position from the rescuee injured during her rescue or the osteosarcoma patient saved by amputation, or even the stavudine recipient whose HIV is managed at the cost of disfigurement. For the patient who dies of stavudine-induced lactic acidosis, what was *ex ante* expected to be the substitution of a lesser harm for a great harm turned out *ex post* to be the substitution of an *even* greater harm for the great harm. The same would be true in Applbaum's case if we know in advance that some boys who have their trigger fingers cut off—although we do not know *which* boys—would not have been impressed by the tsar anyway, or in the osteosarcoma case if osteosarcomas ever go into spontaneous remission.

Where we know that a treatment's side effects will prove to be more burdensome for some individuals than the condition it purports to prevent would have been, we cannot appeal to Shiffrin's justification of the treatment: that it harms people but in so doing saves them from a greater harm. However, even the most serious harms stavudine causes are the sort of harms that we are—on many views—permitted to impose in order to prevent greater harm. This is so for several reasons:

- Receiving stavudine rather than receiving nothing is *ex ante* in each recipient's interest, even though it proves not to be in some recipients' interest *ex post*.
- Recipients consented to take the risk of side effects in exchange for the prospect of medical benefit.
- Patient deaths from stavudine-related side effects are not causally upstream from the benefits to the patients stavudine saves, nor are those deaths necessary to realizing stavudine's benefits.
- Stavudine-induced deaths are foreseen rather than intended.

Some of these factors are arguably sufficient on their own to justify the potential imposition of harm. The ethicist Frances Kamm, for instance, argues that a harm being consented to and in one's *ex ante* interest can justify imposing it. Kamm motivates her view by presenting the "Disease Case," where someone can reduce their chance of dying of a deadly disease by taking a drug that will kill them if they were among the few people immune to the disease. Taking the drug

¹⁴¹ See Joel E. Gallant, *Drug Resistance after Failure of Initial Antiretroviral Therapy in Resource-Limited Countries*, 44 *CLIN. INFECTIOUS DISEASES* 453, 453 (2007).

is *ex ante* in the person's interest, though having done so may not be in their interest *ex post*.¹⁴²

Kamm also argues that it is morally appropriate to redirect a danger away from a greater number of people and toward a lesser number of people—even non-consenting people.¹⁴³ She contrasts such redirection cases with cases where someone harms a lesser number of people in order to later reach a greater number of people and save them from harm.¹⁴⁴ In the latter case, the harm we impose is causally upstream of the harm we prevent and is therefore more objectionable.¹⁴⁵ Others reach a similar conclusion, but by appealing to our intentions rather than to the causal structure of the situation. Warren Quinn, for instance, argues that the permissibility of harming the lesser number in redirection cases stems in part from the harm's being foreseen rather than intended.¹⁴⁶

For these reasons, I believe that—at least where consent exists—adopting a policy that will inevitably cause the sort of harm that second-best treatment imposes is clearly permissible, particularly where this policy could be predicted to benefit more people than it harms. Such a policy would parallel the negligence, as opposed to strict liability, structure of rescuer liability in much of Western case law. If a rescuer's actions could *ex ante* have been expected to benefit the rescuee (that is, if the rescuer was not negligent), the rescuer is not required to compensate the rescuee, even where the attempted rescue leaves the rescuee worse off *ex post*.¹⁴⁷ Indeed, many states have adopted statutes shielding

¹⁴² See FRANCES M. KAMM, *MORALITY, MORTALITY, VOL. 2: RIGHTS, DUTIES, AND STATUS* 293 (1996).

¹⁴³ See FRANCES M. KAMM, *INTRICATE ETHICS: RIGHTS, RESPONSIBILITIES, AND PERMISSIBLE HARM* 138–43 (2007) (discussing Philippa Foot, *The Problem of Abortion and the Doctrine of Double Effect*, in *ABORTION: MORAL AND LEGAL PERSPECTIVES* 177–85 (Jay Garfield & Patricia Hennessey eds., 1984)).

¹⁴⁴ See KAMM, *INTRICATE ETHICS*, *supra* note 143, at 147–48.

¹⁴⁵ See *id.*

¹⁴⁶ See Warren S. Quinn, *Actions, Intentions, and Consequences: The Doctrine of Doing and Allowing*, 98 *PHIL. REV.* 287, 287 (1989).

¹⁴⁷ See, for example, *Atkinson v. Stateline Hotel Casino & Resort*, 21 P.3d 667, 672 (Utah Ct. App. 2001) (“[O]ur construction of section 324(b) requires a plaintiff to prove . . . that the plaintiff's ending up in a worse position is due to the defendant's failure to take reasonable care given the facts the defendant knew or should have known at the time.”) (citing *RESTATEMENT (SECOND) OF TORTS* § 324(b) (1965); *RESTATEMENT (THIRD) OF TORTS: PHYSICAL & EMOTIONAL HARM* § 44 (2012) (“This Section eschews strict liability when a rescuer leaves another worse off, instead requiring that the actor exercise reasonable care not to leave the other in a worse position upon termination.”)).

rescuers from liability even when they are ordinarily negligent in attempting rescue, so long as they are not grossly negligent.¹⁴⁸

Even if it is permissible to impose the harms second-best drugs like stavudine cause, that these drugs carry an increased risk of harm might justify someone refusing, on conscientious grounds, to provide them. Refusal to be involved in harm may be defensible even where refusal to take on minor burdens would be morally monstrous. To see why, return to Applbaum's case of the tsar. If you have the option to move from Russia to Finland and have only a slight preference to stay in Russia, it would seem monstrous to ignore the fact that leaving Russia will save your son from impressment into the tsar's army. But it does not seem monstrous to refuse to cut off your son's finger in order to save him from impressment. If you cut off your son's finger, you become the proximate cause of the pain he suffers. Even though the tsar may be *morally* responsible for that harm, since he placed you in the ghastly situation you now face,¹⁴⁹ morality may not require us to take on that kind of responsibility: to, as Michael Walzer puts it, "dirty our hands" with the blood of innocents.¹⁵⁰

Such concerns, I believe, can excuse mere bystanders from otherwise obligatory rescues: I am not sure morality can require you to cut off a *stranger's* trigger finger in order to save that stranger from death at the tsar's hands. But in the case of those who already owe a professional duty of care, dirty hands concerns seem less relevant. Return, for instance, to the osteosarcoma case. Even though it may be ghastly to imagine cutting off one's own child's leg, it seems clear that a parent should authorize a physician to perform the amputation—and, indeed, were she to have the expertise and be the only one able, to perform the amputation herself.

I believe that physicians and institutional actors stand in a similar position to parents. A physician, a health care administrator, or a state may not refuse to save someone from an avoidable harm because doing so might entail doing harm. As with the osteosarcoma and vaccine cases, if providing an intervention can be *ex ante* expected to protect the patient from harm, and the patient consents to the intervention, a desire to avoid causal involvement in harm cannot justify refusing to protect someone from a far greater harm.

¹⁴⁸ See Waisman, *supra* note 137, at 611 ("By 1980, all fifty states had enacted 'Good Samaritan immunity' statutes shielding medical professionals (and, in most states, laypersons) from liability for ordinary negligence committed in the course of a voluntary, good-faith attempt to assist someone in an emergency.").

¹⁴⁹ See KAMM, *INTRICATE ETHICS*, *supra* note 143, at 309.

¹⁵⁰ See generally Michael Walzer, *Political Action: The Problem of Dirty Hands*, 73 *PHIL. & PUB. AFF.* 160 (1973); see also KAMM, *INTRICATE ETHICS*, *supra* note 143, at 325.

This point finds additional support in a claim by Thomas Nagel. Nagel argues that the distinction between harming and failing to benefit applies differently to institutions than to individuals:

The lack of a washing machine by the family next door is not even in part my doing or my responsibility just because I could have bought them one. But I believe that such restrictions on what is usually called negative responsibility do not apply in the same way to our relations to one another through our common social institutions, especially an involuntary institution such as the state, together with its economic structure. We are responsible, through the institutions which require our support, for the things they could have prevented as well as for the things they actively cause.¹⁵¹

Even if individuals enjoy a permission to refuse to aid when doing so would involve them in harm, the same is not true of institutions. Since the institutions—unlike the individuals—would bear responsibility for the deaths of those who go unaided, they have a duty to prevent those deaths even when doing so involves doing harm.

2. The duty to rescue.

Albert Jonsen describes the “Rule of Rescue” as an imperative that operates analogously to the duty not to harm and limits efforts to save the most lives:

Our moral response to the imminence of death demands that we rescue the doomed. We throw a rope to the drowning, rush into the burning buildings to snatch the entrapped, dispatch teams to search for the snowbound. This rescue morality spills over into medical care, where our ropes are artificial hearts, our rush is the mobile critical care unit, our teams the transplant services.¹⁵²

Jonsen’s claim here is that we owe a special obligation to those faced with imminent harm. Ignoring someone faced with imminent harm would wrong them, and that wrong would not be canceled out—though it might be outweighed—by saving more people from a harm that is less imminent.

There are three reasons, however, why the Rule of Rescue does not direct us to provide world-class care to a few rather than second-best care to many. First, not all these trade-offs occur in rescue situations. Second, some of these cases involve tradeoffs between different rescues—for instance, the Rule of

¹⁵¹ THOMAS NAGEL, EQUALITY AND PARTIALITY 84 (1991). See Govind C. Persad, Note, *Risk, Everyday Intuitions, and the Institutional Value of Tort Law*, 62 STAN. L. REV. 1445, 1452 (2010) (“[I]nstitutions such as governments may be so intimately involved with all causal interactions that there is no normative difference between their positive and negative responsibility for an outcome.”).

¹⁵² Albert R. Jonsen, *Bentham in a Box: Technology Assessment and Health Care Allocation*, 14 J. L. MED. & HEALTH CARE 172, 174 (1986).

Rescue may count in favor of rescuing someone using a second-best method, rather than leaving them to die. Third, and most significantly, the moral relevance of the Rule of Rescue—notwithstanding its psychological pull—is dubious in cases where rescue involves sacrificing something morally important. The clearest examples of the Rule of Rescue, like Peter Singer’s case where saving someone from a shallow pond requires merely muddying one’s shoes,¹⁵³ involve cases where rescuing someone in need does not jeopardize anything else of importance. But rescuing someone by providing them tenofovir or a new pacemaker, when doing so means that others will go without any treatment at all, does involve a serious moral tradeoff. Rescuing some with a high-cost treatment means leaving fewer resources available for others. As Nancy Jecker observes, that the duty to rescue may trump a rescuer’s trivial projects does not mean that it has purchase against the weighty though less urgent needs of third parties. In discussing Singer’s view and that of Tom Beauchamp, Jecker notes that

Both of these approaches appeal to beneficence to support RR [the Rule of Rescue] in trade-off situations where the benefits to the rescued individual are likely to be greater than the harms to that person and to the one rescuing. However, the focus of the analysis remains quite narrow, emphasizing a single individual requiring rescue. Justice . . . deals more broadly with the situation we actually face when we attempt to apply RR to a group of needy people. For example, in health care, many individuals are at risk of loss of or damage to health if they do not receive healthcare resources. Justice helps us to decide whom to rescue, and how to prioritize rescue versus other types of healthcare investments.¹⁵⁴

Others have argued that, in a situation with clear tradeoffs (that is, where health care resources are scarce), we should prioritize those who are going to be worst off *overall* over those who need help soonest.¹⁵⁵ To see why, imagine a community where people receive their monthly pay at different times. Directing all our aid to the people who are poorest at this moment ignores the fact that they may simply be poorest because they are furthest from their payday, while others will be as poor or even poorer later in the month. We should instead employ our aid to keep as many workers out of poverty as possible. The WHO seems to recognize similar considerations when making recommendations about where ambulances should be deployed:

¹⁵³ See Peter Singer, *Famine, Affluence, and Morality*, 1 PHIL. & PUB. AFF. 229, 231–33 (1972).

¹⁵⁴ Nancy S. Jecker, *The Problem with Rescue Medicine*, 38 J. MED. & PHILOS. 64, 74 (2013).

¹⁵⁵ For a survey of such views, see I. Glenn Cohen, *Rationing Legal Services*, 5 J. LEGAL ANALYSIS 221, 252 (2013); see also Govind Persad et al., *Principles for Allocation of Scarce Medical Interventions*, 373 LANCET 423, 425 (2009) (criticizing views that allocate scarce resources to those who are currently sickest).

Although a fully fitted and equipped ambulance vehicle complete with trained paramedics delivers better outcomes, ethical and equity considerations dictate that before this vehicle is made available to an elite population in the urban areas, basic transportation must be assured for all who need emergency transportation and care.¹⁵⁶

Perfectly realizing our duty to rescue in individual cases, the WHO seems to concede here, must take a back seat to ensuring that all patients have a decent chance of being helped.

3. The duty of reciprocity.

Some legal commentators have argued that developed-country researchers owe clinical trial participants in developing countries a higher standard of care than those participants would otherwise have received (and, indeed, may owe them the developed world standard of care).¹⁵⁷ Two prominent justifications for this heightened standard of care make the case that special solicitude for research participants is necessary either to avoid exploiting them¹⁵⁸ or to fulfill special obligations researchers have acquired.¹⁵⁹

This argument is controversial even in the research arena.¹⁶⁰ But it should have no purchase where medical care is concerned. Providing *patients* a lower standard of care in order to reach more patients—unlike providing *trial participants* a lower standard—does not exploit the patients who receive second-best care, nor use them as a means. Rather, each aid recipient receives the highest standard of care that is consistent with fellow aid recipients receiving similarly good care. Nor is it plausible that we owe special obligations to some patients but not others, in the way that we might owe special obligations to trial participants that exceed our obligations to their co-nationals. Each patient in a developing country stands on the same footing as every other.

¹⁵⁶ WORLD BANK, DISEASE CONTROL PRIORITIES IN DEVELOPING COUNTRIES 1268 (Dean T. Jamison et al. eds., 2d ed. 2006).

¹⁵⁷ See, for example, Alice K. Page, *Ethical Issues in International Biomedical Research: An Overview*, 37 J. HEALTH L. 629, 642 (2004); Rid & Schmidt, *supra* note 11, at 146.

¹⁵⁸ See James V. Lavery, *Putting International Research Ethics Guidelines to Work for The Benefit of Developing Countries*, 4 YALE J. HEALTH POL'Y L. & ETHICS 319, 320–22 (2004).

¹⁵⁹ See Henry S. Richardson, *Incidental Findings and Ancillary-Care Obligations*, 36 J.L. MED. & ETHICS 256, 263 (2008).

¹⁶⁰ See, for example, David Orentlicher, *Universality and Its Limits: When Research Ethics Can Reflect Local Circumstances*, 30 J.L. MED. & ETHICS 403, 403 (2002) (“It does not follow that, if a research study is unethical in the United States, it is also unethical in Kenya. Rather, one can accept the same principles of research ethics for Kenya and the United States and still conclude that those universal principles allow for different studies in different countries because of differences in local circumstances.”).

B. Global Justice

Even if failing to provide the developed-world standard of care worldwide does not violate obligations to the particular individuals who receive second-best care—as the previous subsection argued—providing second-best care might appear to violate principles of global justice. Given that all human beings are equal in some morally relevant sense, some complain that treating them with different medications fails to appropriately recognize the value of human equality.¹⁶¹ Some likewise complain that interpreting the right to health as an adequacy right will still allow the wealthy to buy health care that goes beyond the adequacy standard, such as costly but lifesaving medical procedures.¹⁶²

However, this suggestion does not hold up under inspection, even in a situation where all countries are receiving the resources to which justice entitles them. First, other goods—education and housing, for instance—serve as “social determinants of health,” which contribute to health as much as, or even more than, health care does.¹⁶³ Second, achieving decent standards in education, housing, infrastructure, and working conditions seems as important as promoting health.¹⁶⁴ Third, as Amy Gutmann argues, it can be permissible to invest resources in even nonessential goals at the expense of maximizing health:

[A]bove some less-than-maximum level in the provision of opportunity goods, it seems reasonable for people to value what, for want of a better term, one might call “quality of life” goods: cultural, recreational, noninstrumental educational goods, and even consumer amenities. A society

¹⁶¹ See, for example, sources cited *supra* note 37 and accompanying text.

¹⁶² See, for example, Woods, *supra* note 106, at 783.

¹⁶³ See Emily Whelan Parento, *Health Equity, Healthy People 2020, and Coercive Legal Mechanisms as Necessary for the Achievement of Both*, 58 *LOY. L. REV.* 655, 713 (2012) (“[N]o amount of health care can provide population health in the absence of measures to remedy disparities in the social determinants of health.”); see also *COLO. REV. STAT. ANN.* § 25-4-2202 (West 2014) (“‘Social determinants of health’ means life-enhancing resources, such as food, housing, economic and social relationships, transportation, education, and health care, whose distribution across populations effectively determines the length and quality of life.”); *WASH. REV. CODE ANN.* § 43.20.025 (West 2014) (“‘Social determinants of health’ means those elements of social structure most closely shown to affect health and illness, including at a minimum, early learning, education, socioeconomic standing, safe housing, gender, incidence of violence, convenient and affordable access to safe opportunities for physical activity, healthy diet, and appropriate health care services.”).

¹⁶⁴ See Georgia J. Maheras, *Vermont Health Reform*, 9 *J. HEALTH & BIOMEDICAL L.* 61, 66 (2013) (“The increase in health care costs limits the ability of Vermonters and the state to pay for other things such as education, transportation, and non-medical emergency services.”); Scott D. Litman, *Health Care Reform for the Twenty-First Century: The Need for a Federal and State Partnership*, 7 *CORNELL J.L. & PUB. POL’Y* 871, 879 (1998) (“[I]ncreased state expenditures on health care have decreased the amount of money that states have been able to allocate to other areas (i.e. education, infrastructure and tax relief).”).

that maximized the satisfaction of needs before it even began to provide access to “quality of life” goods would be a dismal society indeed. Most people do not want to devote their entire lives to being maximally secure and healthy. Why, then, should a society devote all of its resources to satisfying human *needs*?¹⁶⁵

Choices about these priorities may vary internationally: some nations may treat health as a paramount value, while others may place greater emphasis on education or culture. More recently, Veronique Munoz-Darde has similarly argued that it is appropriate to pursue collective goals and shared projects, such as the maintenance of museums and universities, even at the expense of maximally realizing basic needs.¹⁶⁶

In an unjust situation—where some countries lack the resources to which justice entitles them—mandating that all patients worldwide receive the developed-world standard of care if they are to receive care at all would still be inappropriate. In fact, it may be *more* inappropriate, because—in an unjust situation—mandating that all patients receive the highest standard of care is likely to prevent many people from receiving any care at all.¹⁶⁷

Some of the attraction of policies like the WHO’s ban on used pacemakers seems to stem from a belief that such policies expressively recognize the injustice of the current global distribution of resources, whereas providing used pacemakers would express endorsement of injustice.¹⁶⁸ Acting as we would act *were the distribution of resources just* might appear to express endorsement of a just distribution. On this picture, these policies are justified not because of their material consequences for patients—and, indeed, in spite of those consequences—but instead because of what they assert or express. This way of seeing policies not as a way of producing certain outcomes but instead as “a form of assertion, a mode of expression in which we purport to represent things as they really are,”¹⁶⁹ recalls the views of the eighteenth-century British rationalist

¹⁶⁵ Amy Gutmann, *For and Against Equal Access to Health Care*, 59 MILBANK Q. 542, 556 (1981) (emphasis in original).

¹⁶⁶ See Veronique Munoz-Darde, *In the Face of Austerity: The Puzzle of Museums and Universities*, 21 J. POL. PHIL. 221, 239–40 (2013) (“It is through coming together and partaking in idiosyncratic but necessarily joint enterprises that we find meaning together. It cannot, therefore, be a proper demand of justice or of morality that this should be forsaken in other than the most extreme circumstances.”).

¹⁶⁷ See John A. Siliciano, *Wealth, Equity, and the Unitary Medical Malpractice Standard*, 77 VA. L. REV. 439, 459–60 (1991) (“This choice between high-quality care for a few of the poor or lower quality care for more of the poor is unquestionably second-best. By definition, the care provided the poor under the second, binary-standard option is care that a reasonable, fully-informed, paying patient would regard as inadequate. Yet the care provided under the unitary standard, while avoiding this problem, is deficient in another respect, for it leaves more of the poor without any care at all.”).

¹⁶⁸ See, for example, Moszczynski, *supra* note 69, at 89.

¹⁶⁹ Tamar Schapiro, *Three Conceptions of Action in Moral Theory*, 35 NOÛS 93, 97 (2001).

philosopher William Wollaston, who believed “*that whoever acts as if things were so, or not so, doth by his acts declare, that they are so, or not so; as plainly as he could by words, and with more reality.*”¹⁷⁰ A Wollastonian view might undergird the WHO’s position. If everyone received what justice requires, then no one would receive used pacemakers; therefore, by ensuring that no one receives used pacemakers, we express our commitment to everyone’s receiving what justice requires.

However, this view seems untenable for several reasons. First, it is not clear that providing used pacemakers, for example, would be inappropriate even under a just economic distribution.¹⁷¹ Second, prohibiting the provision of used pacemakers does not express a *commitment* that everyone *should* receive what justice entitles them to; rather, it seems to express a mistaken belief that everyone *will* receive what justice entitles them to. Blocking the provision of used pacemakers while the distribution of resources remains grossly unjust seems analogous to another of Wollaston’s examples, in which someone uses and disposes of an object in his possession without in fact owning it. The person who treats an object as if he owned it does not thereby come to own it: rather, he simply makes a false assertion.¹⁷² Similarly, blocking the provision of used pacemakers—and thereby acting as if people had enough money to buy new ones—does not express a commitment to justice, but simply a mistaken belief that acting as if injustice did not exist will make injustice go away.¹⁷³

To see this point in greater detail, consider the philosopher Bernard Williams’s famous scenario of “Jim and the Indians,” in which the unjust Captain threatens to have his henchman Pedro kill a group of Indians unless a bystander, Jim, is willing to kill one of the Indians instead.¹⁷⁴ In a just world—one with a just Captain who makes no threats—it would be morally monstrous for Jim to kill one of the Indians, just as it would be monstrous to give someone a suboptimal treatment in a world of unbounded resources. But in Jim’s *actual* circumstances, it may be morally legitimate for him to kill one of the Indians, especially with their consent. As Christine Korsgaard argues,

Suppose the oldest Indian steps forward and says “Please go ahead, shoot me, and I forgive you in advance.” This doesn’t make things wonderful but

¹⁷⁰ *Id.* (quoting WILLIAM WOLLASTON, *THE RELIGION OF NATURE DELINEATED* (1722), *excerpted in 1 BRITISH MORALISTS: 1650–1800* 242 (D.D. Raphael ed., 1991)) (emphasis in original).

¹⁷¹ See VanArtsdalen et al., *supra* note 61, at 301 (noting that Sweden and Canada once treated pacemaker reuse as the standard of care).

¹⁷² See Schapiro, *supra* note 169, at 97.

¹⁷³ See Rae Langton, *Duty and Desolation*, 67 *PHILOSOPHY* 481, 502 (1992) (“[I]n an evil world, acting in accordance with the ideal may backfire, and make the achievement of the ideal more, and not less, remote.”).

¹⁷⁴ See J.J.C. Smart and Bernard Williams, *UTILITARIANISM: FOR AND AGAINST* 98 (1973).

it does help. Very roughly speaking, you are not treating him as a mere means if he consents to what you are doing. Of course the Indian does not in general consent to be shot, and his gesture does not mean that after all he has not been wronged. In the larger moral world he has. But if you and the Indians are forced to regard Pedro and the Captain as mere forces of nature, as in this case you are, then there is a smaller moral world within which the issue is between you and them, and in that world this Indian consents.¹⁷⁵

The Indian's consent does not require Jim to kill him. But, Korsgaard believes, it at least permits Jim to kill the consenting Indian in order to save others, particularly since that Indian will be (unjustly) killed anyway. Likewise, the agreement or consent of people in the developing world permits us to provide them a second-best treatment, particularly where the alternative for them is much worse. This is true even if the different needs of developing countries stemmed from the unjust treatment of their citizens. For instance, as the WHO has detailed, "the incidence of cervical cancer in developing countries is relatively high in comparison with the incidence of these cancers in developed countries, whereas the incidence of breast cancer is relatively low in developing countries compared with that in developed countries."¹⁷⁶ This may be the result of economic injustice that makes the lifespans of women in developing countries too short for them to suffer high rates of breast cancer. But even if the higher rates of cervical cancer in the developing world reflect economic injustice, blocking developing countries from addressing those higher rates of cervical cancer and requiring them to devote their resources to breast cancer instead would be an inappropriate way to recognize that injustice.

Third, even if refusing to provide second-best drugs expresses a commitment to justice, that expression comes at a substantial cost, one borne not by those expressing that commitment but rather by the people in need. Expressing a commitment to justice through protest or speech seems preferable to expressing that commitment through depriving the worst-off of goods that would benefit them—to do the latter is not merely to cut one's nose off to spite one's face, but to cut *someone else's* nose off in pursuit of that aim. Taking a pacemaker from the dead body of a citizen of the developed world, sterilizing it, and implanting it into the body of a developing-world citizen certainly makes the inequality between the two starkly vivid. The pacemaker is, in a very real way, a "hand-me-down." But this inequality in treatment serves to narrow the inequalities in health that global economic inequality produces. Concerns about equality would be better directed toward reducing global economic inequality upstream than toward blocking efforts to use limited resources more efficiently.

¹⁷⁵ Christine Korsgaard, *The Reasons We Can Share: An Attack on the Distinction between Agent-Relative and Agent-Neutral Values*, 10 SOC. PHIL. & POL'Y 24, 26 (1993) (emphasis omitted).

¹⁷⁶ WORLD BANK, *supra* note 156, at 582.

The most compelling case for denying second-best treatments on grounds of justice appeals to the values of solidarity and community. The economist Thomas Schelling suggests as much when he states that “[t]hose who want to risk their lives at sea and cannot afford a safe ship should perhaps not be denied the opportunity to entrust themselves to a cheaper ship without lifeboats; but if some people cannot afford the price of passage with lifeboats, and some people can, they should not travel on the same ship.”¹⁷⁷ That the rich float safely away from an accident in lifeboats while the poor perish would, in Schelling’s view, be too destructive of solidarity. Criticism of tiered health care proposals that provide different standards of care for the domestic rich than the domestic poor may reflect similar reasoning to Schelling’s.¹⁷⁸

However, others have argued in favor of tiered health care even in the domestic context, on the basis that blocking the rich from access to higher-quality care does no good for the poor, and that the domestic poor may well prefer lower-quality care to no care at all.¹⁷⁹ As John Siliciano argues,

In a very real sense, then, the poor constitute a separate nation, and their health care needs should be assessed accordingly. To blink in the face of this painful reality and judge the medical care provided to the indigent under a standard of care derived to protect the well-off makes little more sense than would a foreign aid policy insisting that the humanitarian medical care this

¹⁷⁷ THOMAS SCHELLING, CHOICE AND CONSEQUENCE 115–16 (1984).

¹⁷⁸ See, for example, *Deberry v. Sherman Hosp. Ass’n*, 775 F. Supp. 1159, 1162 (N.D. Ill. 1991) (noting that the Emergency Medical Treatment and Active Labor Act “was enacted to stop the widespread hospital practice of refusing to treat indigent patients, or providing them with a lower standard of medical care”); *Louis v. Perales*, No. 91 Civ. 4038 (LMM), 1991 WL 167978, at *1 (S.D.N.Y. Aug. 20, 1991) (reporting plaintiffs’ assertion “that the tests ordered by Dr. Louis, and those performed at the request of other physicians by Biologic, are diagnostic tools routinely ordered by private physicians for non-Medicaid patients and that the Department’s actions force health care providers to choose between fulfilling their professional responsibilities or participation as providers in the Medicaid program, and reduce the quality of care available to the Medicaid beneficiaries by insuring that only providers who will apply a double standard of care are eligible to participate in the program”); *Jeneski v. Myers*, 209 Cal. Rptr. 178, 183 (Cal. Ct. App. 1984) (reporting that a physician objecting to formulary restrictions for Medicaid patients charged that “the new system constituted a ‘clear class system of medical treatment’ and a ‘double standard of health care’”).

¹⁷⁹ See, for example, Ira Mark Ellman & Mark A. Hall, *Redefining the Terms of Health Insurance to Accommodate Varying Consumer Risk Preferences*, 20 AM. J.L. & MED. 187, 200 n.33 (1994) (“[V]arying tort standards should apply to non-treatment decisions rendered at different funding tiers.”); Richard A. Epstein, *Market and Regulatory Approaches to Medical Malpractice: The Virginia Obstetrical No-Fault Statute*, 74 VA. L. REV. 1451, 1463 (1988) (“[T]here is no reason to tie the fortunes of the poor to the tastes of the middle class. The desire for greater legal protection against medical malpractice may well reflect middle-class patients’ greater willingness and ability to pay. There seems to be no reason to assume that poor people have the same preferences, given their far lower levels of income. Hence, poor people should not be forced to enter into exactly the same kind of contracts.”).

country supplies to impoverished nations like Ethiopia or Bangladesh match that provided by Massachusetts General Hospital.¹⁸⁰

The granting of malpractice immunity to volunteer physicians who treat the domestic poor seems to reflect this view.¹⁸¹

Even if we accept Schelling's objection as a reason to reject the domestic double standards Siliciano advocates, the upshot of Schelling's view for global health is not that we should prohibit the provision of the second-best treatment. Rather, we should mandate its provision everywhere, and prohibit the best treatment: if everyone worldwide were "on the same ship" in Schelling's sense, then *no one* should receive new pacemakers unless *everyone* can. A new-pacemaker mandate that raises some patients to the best available standard but leaves more patients untreated produces not less inequality but more.¹⁸² Furthermore, as Schelling granted, different standards of safety may be appropriate for *different* ships. If different nations represent different ships—that is, if national borders matter from the point of view of justice—then it may be acceptable for different countries to provide different medications to their citizens. Even if no American should receive new pacemakers unless every American does, it may be acceptable for Americans to receive new pacemakers in America while non-Americans receive used ones.

Note that believing *national borders matter* is very different from believing *existing distributions are just*. Someone could believe both that justice requires substantial transfers from the global North to the global South and that it is acceptable for the global South to use those transfers differently from the way they are used in the North. For instance, the global South could permissibly focus more on the provision of preventive care, food, or education, and less on the provision of high-technology medical interventions—just as many believe we should do (but have not been doing) in the global North.¹⁸³ It would be bizarre

¹⁸⁰ Siliciano, *supra* note 167, at 465–66.

¹⁸¹ See, for example, Gwendolyn L. Pulido, *Immunity of Volunteer Health Care Providers in Texas: Bartering Legal Rights for Free Medical Care*, 2 SCHOLAR 323, 342 (2000); see also John L. Brown, *Statutory Immunity for Volunteer Physicians: A Vehicle for Reaffirmation of the Doctor's Beneficent Duties—Absent the Rights Talk*, 1 WIDENER L. SYMP. J. 425, 425, 460 (1996).

¹⁸² See Siliciano, *supra* note 167, at 484 (“[T]he symbolic affirmation of equality embedded in the unitary standard loses much of its force when it is preceded by tort law’s other message in this context: that absent an emergency, indigent patients have absolutely no right of access to the health care system.”).

¹⁸³ See Lance Gable, *The Patient Protection and Affordable Care Act, Public Health, and the Elusive Target of Human Rights*, 39 J.L. MED. & ETHICS 340, 342 (2011) (“The prevailing incongruity between high health care expenditures and less than impressive health outcomes in the United States likely stems from a number of sources, including . . . a preference for costly high-technology health care over more affordable preventive approaches.”); Lawrence O. Gostin et al., *Restoring Health to Health Reform: Integrating Medicine and Public Health to Advance the Population’s Well-Being*, 159 U. PA. L.

to prohibit developing nations from adopting the cost-control measures that we believe we should adopt merely because in developed countries we cannot bring ourselves to adopt them.

What if the international and developed-country decision-makers attempting to help developing countries grapple with the effects of an unjust distribution of resources are themselves, as Thomas Pogge and others argue, the cause of that unjust distribution of resources?¹⁸⁴ This may make these actors blameworthy for the initial injustice, but it still fails to justify a choice to save fewer people from being harmed by that injustice. Imagine that I—through negligence or recklessness—have caused a fire that threatens to destroy an apartment building. Turning on the sprinkler system will stop the fire but ruin many people's valuables. Yet it seems obvious that I should turn the sprinkler on: I cannot undo my past wrong, but I can partly mitigate its effects. This is true even if I could fully mitigate the effects of my wrongdoing: even if I have a fire extinguisher, but do not want to take the risk of putting out the fire myself, I should still activate the sprinkler rather than simply fleeing. Likewise, even if developed countries and international institutions bear responsibility for poverty in developed countries, and indeed even if they could provide the resources to fully undo the health effects of that poverty, they still would do better to provide second-best treatments than to do nothing at all to mitigate the wrong, or—worse—to exacerbate the wrong by promulgating an unfunded mandate that all patients receive the best available treatment.

C. Consequences

Some commentators have argued in the context of HIV treatment that mandating the provision of the best extant intervention worldwide will force down its cost and produce better long-term outcomes.¹⁸⁵ Likewise, some argue

REV. 1777, 1783 (2011) (proposing “reforms [that] involve shifting the financial and political focus away from high-cost, high-technology interventions, thereby transforming the nation’s conception of medicine, public health, and health itself”); John A. Robertson, *Law, Science, and Innovation: Introduction to the Symposium*, 38 J.L. MED. & ETHICS 175, 187 (2010) (describing legal scholar Rebecca Dresser as “questioning whether advanced societies should be so focused on expensive technologies that treat the chronic diseases of aging, such as heart disease, diabetes, and neurological disorders, when many more people would benefit from the same funds being spent on prevention and the delivery of health care”).

¹⁸⁴ See generally THOMAS POGGE, *WORLD POVERTY AND HUMAN RIGHTS* (2002); see also Ilan Benshalom, *The New Poor at Our Gates: Global Justice Implications for International Trade and Tax Law*, 85 N.Y.U. L. REV. 1, 16–17 (2010).

¹⁸⁵ See, for example, WORLD HEALTH ORGANIZATION, *PLHIV INPUT INTO THE REVISION OF THE WHO ART GUIDELINES 6* (2009), available at http://www.who.int/hiv/topics/treatment/final_report_gnphiv.pdf (“Many felt that if tenofovir were made part of first line regimens, there would be increased pressure to increase generic production and lower its price.”).

in favor of publicly adopting a definition of the right to health that is *more expansive* than may actually be justified—such as the “highest attainable standard”—in order to ensure that the right to health survives the realities of political compromise.¹⁸⁶ Evaluating this debate requires more empirical evidence than either side currently possesses, and more than I am qualified to assess. But I will note that any such empirical investigation must attend to opportunity costs. Lowering the price of tenofovir or new pacemakers over the long-term through negotiation or technical innovation could potentially coexist with continuing to provide stavudine or reused pacemakers in the short term. And even if purchase prices drop because of negotiation, the time and political capital invested in these efforts might have helped many more people if deployed elsewhere. For instance, cutting stavudine costs by \$30 per year would improve access more than would cutting tenofovir’s price in half.¹⁸⁷

This argument raises an additional ethical concern if the suffering of those who go without aid becomes a *means*, rather than a side effect, of lowering costs. Mandating the gold standard both because drug companies will cave and lower prices when faced with people suffering from lack of tenofovir, but would not cave if those people were treated with stavudine, inappropriately uses non-consenting patients who are left to suffer as hostages in an effort to pressure corporations and developed countries to lower drug prices. That developing-country patients have the right to go without second-best care in protest of injustice does not support our forcing that outcome on them, just as prisoners’ right to a hunger strike to protest inadequate conditions would not support outside activists imposing deprivation on non-consenting prisoners in order to highlight the injustice of the prison system.

Adopting a conception of the right to health more expansive than is actually warranted may likewise be inappropriate. Some have argued that it is inappropriate for prosecutors to “overcharge” arrestees—charging them with offenses that do not fit their alleged crime’s actual severity—in order to gain leverage for a plea bargain.¹⁸⁸ Likewise, it may be inappropriate to enforce a

¹⁸⁶ See, for example, Attaran, *supra* note 97, at 36 (“‘Maximum’ stands for idealism; ‘available’ stands for reality. ‘Maximum’ is the sword of human rights rhetoric; ‘available’ is the wiggle room for the state.”) (quoting R. Robertson, *Measuring State Compliance with the Obligation to Devote the “Maximum Available Resources” to Realizing Economic, Social, and Cultural Rights*, 16 HUM. RTS. Q. 693, 694 (1994)).

¹⁸⁷ Robin Wood, *The Role of Stavudine in the South African Public Sector Antiretroviral Programme: Should the Perfect Be the Enemy of the Good?*, 7 S. AFR. J. HIV MED. 5, 5 (2006).

¹⁸⁸ See, for example, Daniel S. Medwed, *Emotionally Charged: The Prosecutorial Charging Decision and the Innocence Revolution*, 31 CARDOZO L. REV. 2187, 2189–90 (2010) (“Several ethics codes . . . forbid prosecutors from ‘overcharging’ solely in the hopes of developing leverage for plea bargaining negotiations.”).

conception of the right to health one knows to be overbroad in order to exert political leverage. Additionally, selecting an overly expansive conception may be counterproductive as well as unjust: where rights claims seem unfulfillable, people may come to ignore them entirely, whereas a more modest conception of the right might have greater practical force.¹⁸⁹

V. PREVENTING THE PANDEMIC

The previous section argued that costly rights and mandates, such as requirements that developing countries provide the standard of care provided in developed countries, lack sound normative justification. In this section, I argue for rethinking rights to health and to healthcare interventions in order to place them on a sounder foundation, one that promotes health across the population and affords developing countries greater discretion.

A. Adequacy, Not Maximization

Recognizing an individual right to the highest attainable standard of health exposes emerging international institutions and developing nations to the same problem that developed nations like the U.S. and Germany now face:¹⁹⁰ the high cost of medical care, which threatens spending on other essentials. Unless we are to abandon the right to health altogether, we need an alternative, less problematic understanding of that right; I argue for understanding it as a right to *adequate* resources to maintain health, rather than to the highest attainable standard of individual health. Such a standard avoids many of the problems of the ICESCR standard, while still maintaining the idea that there is a robust and enforceable right to health.

Defining the right to health as an adequacy right has previously been recognized as tenable. The Universal Declaration of Human Rights (UDHR) chose the language of adequacy rather than the language of maximization:

¹⁸⁹ See Cass Sunstein, *Against Positive Rights*, 2 E. EUR. CONST. REV. 35, 37 (1993) (arguing that unachievable positive entitlements can reinforce “cynicism about constitutions”).

¹⁹⁰ See Klaus M. Brisch & Claudia E. Haupt, *Information Technology Meets Healthcare: The Present and Future of German and European E-Health Initiatives*, 12 DEPAUL J. HEALTH CARE L. 105, 114 (2009) (“The health care costs in Germany are among the highest in Europe and they are continuously on the rise. In fact, it has been asserted that the very concept of the social state has entered a critical phase and the currently high level of social welfare benefits cannot be financed in the long term.”); see also Maggie H. Francis, *Beyond “Safe and Effective”: The Role of the Federal Government in Supporting and Disseminating Comparative-Effectiveness Research*, 21 ANNALS HEALTH L. 329, 339 (2012) (noting that “all developed countries have struggled with cost control issues to some extent”); Douglas J. Besharov, *Creating A Marketplace for Social Welfare Services*, 16 NOTRE DAME J.L. ETHICS & PUB. POL’Y 519, 555 (2002) (“In the United States and many other OECD countries, the costs of fee-for-service health care programs are escalating rapidly.”).

“[e]veryone has the right to a standard of living *adequate* for the health and well-being of himself and of his family including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.”¹⁹¹ The UDHR conception, unlike that of the ICESCR, sees the right to health as on par and interrelated with other important social and economic rights like food, clothing, and housing. (It is particularly interesting that Paul Farmer, whom many see as radically committed to the rights of the poor, references an adequacy right rather than the seemingly more generous maximization right.¹⁹²)

An adequacy right, by permitting a variety of limitations on individual efforts to pursue maximal health, may promote population health in a variety of ways. For instance, an adequacy right would permit the government to prevent patients from accessing medications that lack clinical trial testing and approval.¹⁹³ Preventing such access could help to protect the integrity of the clinical trial system and therefore promote long-run population health.¹⁹⁴

Permitting states to limit access to certain health care services also provides a crucial tool to stem runaway costs and the diversion of resources away from essential health and non-health goals. In contrast, allowing each person to maximize her individual health without restriction may incentivize specialization in expensive procedures rather than cost-effective ones.¹⁹⁵

¹⁹¹ Universal Declaration of Human Rights, G.A. Res. 217A (III), U.N. Doc. A/810 at 71, art. 25 (1948) (emphasis added).

¹⁹² See Farmer & Gastineau, *supra* note 130, at 655. Farmer is also willing to prioritize some health goals over others. See Paul Farmer, *Never Again? Reflections on Human Values and Human Rights*, in PARTNER TO THE POOR: A PAUL FARMER READER 517 (Haun Saussy ed., 2010) (“Relativism is a part of the problem. Why is it impolitic in the groves of academe to argue that dying of never-treated AIDS in a dirt-floored hut in Africa is worse than dying of AIDS in a comfortable hospice in Boston after having failed a decade of therapy?”).

¹⁹³ This issue was raised in American courts in *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschebach*, 495 F.3d 695 (2007), *cert. denied* 128 S. Ct. 1069 (2008) (reversing panel decision supporting a fundamental right to access unapproved but potentially lifesaving drugs).

¹⁹⁴ See generally Seema Shah & Patricia Zettler, *From a Constitutional Right to a Policy of Exceptions: Abigail Alliance and the Future of Access to Experimental Therapy*, 10 YALE J. HEALTH POL’Y, L. & ETHICS 1 (2010); Jerry Menikoff, *Beyond Abigail Alliance: The Reality Behind the Right to Get Experimental Drugs*, 56 KAN. L. REV. 1045 (2008).

¹⁹⁵ See Gutmann, *supra* note 165, at 552 (“Without restricting the free market in extra health care goods, a society risks having its best medical practitioners drained into the private market sector, thereby decreasing the quality of medical care received by the majority of citizens confined to the publicly funded sector.”); see also Frank Pasquale, *Access to Medicine in an Era of Fractal Inequality*, 19 ANNALS HEALTH L. 269, 310 (2010) (“A relatively fixed supply of doctors can mean that any group that uses its buying power to purchase disproportionately time-consuming (and often unnecessary) medical attention threatens to divert care from those with less purchasing power.”).

Another advantage of defining the right to health in adequacy terms is the leeway it provides for experimentation by different nations and localities, in contrast to the transnational uniformity the maximization standard requires. Such local experimentation has been praised in other contexts.¹⁹⁶ While some suggest that the right to the highest attainable standard of health is inherently flexible,¹⁹⁷ the textual provisions they reference do not support such flexibility. “Progressive realization”¹⁹⁸ of the right to maximal health simply delays the problem of excessive cost, and even if the highest attainable standard evolves over time,¹⁹⁹ the highest attainable standard at any given time may still be extremely demanding. In contrast, an adequacy right permits greater scope for discretionary choices.

Defining the right to health as an adequacy right may sometimes allow the wealthy to buy their way to better health. But a threshold of adequacy can guarantee certain basic and essential health interventions to poor and rich alike, and it can provide many people services that will help them integrate into the population. A plausible right to adequacy will sometimes mean that we have to say “no” to someone who can genuinely benefit, as the South African Constitutional Court did in *Sooibramoney*. But such a right will also give us the financial leeway to say “yes” to another person down the road who needs an immunization, or to fund a new primary school.

Ultimately, adequacy’s willingness to countenance inequality is not a necessary feature of adequacy. Rather, inequality stems more centrally from the fact that we countenance substantial intranational and international inequalities in wealth. Given those inequalities, we are faced with the choice of either blocking exchanges that would convert wealth to health, or permitting inequalities in health. An adequacy right—unlike a maximization right—permits us, for instance, to tax cost-ineffective medical procedures as luxuries. These taxes could be reinvested in maintaining health infrastructure for the poor, or in other social aims like education. In contrast, a maximization right commits us to matching, for each individual, whatever health expenditures the wealthiest among us decide on for themselves. As we learn from the example of the *tutelas*, such a system is unsustainable: it limits care not by cost-effectiveness or clinical

¹⁹⁶ See, for example, *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) (“[A] single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.”).

¹⁹⁷ Alicia Ely Yamin, *The Right to Health Under International Law and Its Relevance to the United States*, 95 AM. J. PUB. HEALTH 1156, 1156 (2005) (“The reference to a ‘highest attainable standard’ of health . . . builds in a reasonableness standard.”).

¹⁹⁸ *Id.*

¹⁹⁹ See *id.* (“[T]he highest attainable standard will necessarily evolve over time, in response to medical inventions, as well as demographic, epidemiological, and economic shifts.”).

effectiveness, but by financial exhaustion. The ability of the wealthy to purchase expensive drugs or procedures despite the luxury tax I suggest is more properly attributed to the inequalities we countenance than to the definition of the right to health in adequacy terms.

On an adequacy view, *Soobramoney* was in fact rightly decided, and—far from being a timid decision—it was actually a courageous one. It is easy for a court to rule in favor of a sympathetic plaintiff and ignore the long-term consequences of a judgment. What the South African Constitutional Court did in *Soobramoney*, and what is admirable about that decision, was to look ahead and rule based on the long-term effects of the decision on *all* affected parties, rather than the effects on one party alone.

B. Local Variation, Not Transnational Uniformity

The WHO should move toward the model it chose for antiepileptic medications and for antibiotics, which allows for local sovereignty and variations in the standard of care, and away from its cost-blind, universal recommendations regarding medical donations and HIV medication. Countries should be empowered to make risk-benefit decisions for themselves, rather than having those decisions made in other countries. Local variations in disease prevalence, in available resources, and in societal priorities can all appropriately affect which medical treatments are available in different countries,²⁰⁰ and at what cost.

This does not imply that universal human rights should not be upheld, nor that developed countries should simply ship drugs overseas and let developing countries sort things out. But universal human rights should be upheld on the ground that they are *universal*, not on the ground that developed countries have adopted them. And developed countries would do better to focus on providing relevant guidance—such as information about the safety and efficacy of pharmaceuticals—instead of banning exports that may be cost-effective elsewhere.

Furthermore, international and foreign decision makers should attend to the judgment of *all* developing country citizens about the appropriate distribution of resources, rather than catering primarily to the demands of

²⁰⁰ See MILTON SILVERMAN, THE DRUGGING OF THE AMERICAS: HOW MULTINATIONAL DRUG COMPANIES SAY ONE THING ABOUT THEIR PRODUCTS TO PHYSICIANS IN THE UNITED STATES, AND ANOTHER THING TO PHYSICIANS IN LATIN AMERICA 131 (1976) (“[N]either the United States nor any other nation has a mandate or moral right to export its health policies to other countries, or to induce by whatever means any other country to adopt its own decisions, practices, customs, techniques or standards. The health policy decisions in each [country] must be made by those countries.”).

special-interest groups within developing countries. For this reason, I disagree in part with M. H. Kottow's argument that

[t]he acceptability of negative side effects in relation to purported benefits is not to be decided by benevolent paternalism; rather, it is for public health policies and for the affected population to evaluate, especially if the argument of lesser evil is invoked. Whether it is preferable to avoid pregnancy at the risk of getting cancer can only be decided by the women to whom quinacrine [a sterilization drug] might be offered, supported by local health care officials who must assess the rationale of this approach as compared to alternatives.²⁰¹

I agree with Kottow that no competent patient should be forced to take a drug she finds excessively dangerous. As Emilio Perucca and Rajendra Kale observe with regard to antiepileptic medications, "local doctors should not present phenobarbital to patients as the best drug but should inform them about its advantages and disadvantages (and deficiencies in knowledge) compared with alternative treatments."²⁰² But, at the policy rather than physician-patient level, stakeholders other than the potential beneficiaries of a treatment should be involved in deciding what treatments are available. Some diseases—like HIV and heart disease—are prevalent in both developed and developing countries; their broader prevalence makes possible the development of transnational patient and disease advocacy efforts.²⁰³ Others, like malaria and obstetric fistula, are concentrated in developing countries: unlike the case of HIV, there is no transnational network of malaria sufferers that includes better-resourced citizens of developed countries.²⁰⁴ Responding to pressure from disease advocacy groups

²⁰¹ M.H. Kottow, *Who Is My Brother's Keeper?*, 28 J. MED. ETHICS 24, 24 (2002).

²⁰² Kale & Perucca, *supra* note 28, at 1200.

²⁰³ See Mindy Jane Roseman & Alice M. Miller, *Normalizing Sex and Its Discontents: Establishing Sexual Rights in International Law*, 34 HARV. J. L. & GENDER 313, 329 (2011) (noting the "emergence of national and transnational HIV activism in the latter part of the twentieth century"); Harold Hongju Koh, *Different but Equal: The Human Rights of Persons with Intellectual Disabilities*, 63 MD. L. REV. 1, 9–10 (2004) (discussing "the formation of . . . a 'transnational human rights network' that has worked to expose worldwide discrimination against persons with intellectual disabilities").

²⁰⁴ See Laurie Garrett, *The Challenge of Global Health*, 86 FOREIGN AFF. 14, 23 (Jan.–Feb. 2007) ("Diseases and health conditions that enjoy a temporary spotlight in rich countries garner the most attention and money. This means that advocacy, the whims of foundations, and the particular concerns of wealthy individuals and governments drive practically the entire global public health effort. Today the top three killers in most poor countries are maternal death around childbirth and pediatric respiratory and intestinal infections leading to death from pulmonary failure or uncontrolled diarrhea. But few women's rights groups put safe pregnancy near the top of their list of priorities, and there is no dysentery lobby or celebrity attention given to coughing babies."); *see id.* at 27–28 ("[N]othing is being done to replace the health-care workers who once dealt with malaria, dysentery, vaccination programs, maternal health, and other issues that lack activist constituencies."); *see also* Colleen C. Denny & Ezekiel J. Emanuel, *US Health Aid beyond*

will lead to resources flowing toward more transnationally powerful groups—new pacemakers for those with heart disease or expensive drugs for those with HIV—even while less powerful groups such as malaria sufferers miss out on beneficial interventions, or the population at large suffers from reduced spending on education and infrastructure. While patients should be informed about the risks and benefits of second-best interventions, patient advocacy groups must make their case for funding to their fellow citizens and community members; they should not be permitted to short-circuit the decision-making process by appealing directly to interest groups within developed countries.²⁰⁵

The power and potentially distorting effect of transnational disease advocacy also presents a challenge for private and nonprofit philanthropists and funders. I would not uniformly criticize the philanthropic provision of interventions that are not maximally cost-effective, such as the provision of guide dogs for the blind rather than interventions to prevent blindness.²⁰⁶ When *private citizens* do good, they are not required to maximize the good they do nor to distribute that good impartially; people enjoy latitude when fulfilling duties of charity.²⁰⁷ The money Paul Farmer and his colleagues spent on rescuing those on

PEPFAR: *The Mother & Child Campaign*, 300 JAMA 2048, 2049 (2008) (proposing moving aid away from HIV treatment and toward pediatric and prenatal care).

²⁰⁵ See *Northwestern Univ. v. City of Evanston*, No. 00-C-7309, 2002 WL 31027981, at *5 (N.D. Ill. Sept. 11, 2002) (noting that “when a small, organized block of adjacent landowners opposes a zoning change, the block often gets its way,” and citing the work of economist Mancur Olson); see also David B. Spence, *A Public Choice Progressivism, Continued*, 87 CORNELL L. REV. 397, 436 (2002) (suggesting how the outsize pull of special interest groups can be overcome within a democracy).

²⁰⁶ But see Toby Ord, *The Moral Imperative toward Cost-Effectiveness in Global Health*, Ctr. Global Development Essay (Mar. 2013), available at <http://www.cgdev.org/publication/moral-imperative-toward-cost-effectiveness-global-health> (“We could . . . use our entire budget to provide a single guide dog, helping one person overcome the challenges of blindness, or we could use it to cure more than 2,000 people of blindness. If we think that people have equal moral value, then the second option is more than 2,000 times better than the first. Put another way, the first option squanders about 99.95 percent of the value that we could have produced.”).

²⁰⁷ See, for example, *Vidal v. Girard’s Ex’rs*, 43 U.S. 127, 197 (1844) (refusing to require of a charitable bequest that “the scheme of education by him prescribed, is such as we ourselves should approve, or as is best adapted to accomplish the great aims and ends of education”); see also Michael W. McConnell, *The Supreme Court’s Earliest Church-State Cases: Windows on Religious-Cultural-Political Conflict in the Early Republic*, 37 TULSA L. REV. 7, 29 (2001) (noting that “[Justice Story’s 1844 decision [in *Vidal*] relied on . . . the proposition that philanthropists have great latitude in directing the objects of their charity”); Jeremy Waldron, *On the Road: Good Samaritans and Compelling Duties*, 40 SANTA CLARA L. REV. 1053, 1071 (2000) (“When we think about beneficence, we may regard it as (in the technical philosophical sense) an imperfect duty: a duty that commands concern for the welfare of others, but which is understood to leave a certain amount of latitude for free choice in determining what to do about it. For example: I meet many beggars as I walk around New York, and I am sure it would be wrong not to give money to any of them; but I am (almost) equally sure it would distort my moral situation to require me to give money to each, or

death's door in Haiti and Boston could have been spent, as Farmer himself grants, on more cost-effective interventions.²⁰⁸ Such interventions would have helped more people and saved more lives. But Farmer did far more good than he would have had he used that money to pay himself a higher salary, or even to provide patients in the developed world many treatments that are routine and acceptable there.

However, providers of private charity must be mindful of their impact on public authorities. For instance, even if HPV vaccination is initially privately subsidized, accepting free vaccinations may later commit a government to spending its own resources on vaccination rather than on more pressing aims.²⁰⁹ And philanthropic aid for patients with specific medical conditions frequently diverts equipment, funding, and expertise away from efforts to treat other conditions, improve public health, or pursue non-health aims.²¹⁰ The solidaristic motivation that supports providing the same expensive treatments worldwide for conditions, like HIV, from which people in the developed and developing world both suffer, has as its less savory side the deprivation of those who suffer from diseases unknown or ignored in the developed world.

VI. CONCLUSION

Wealthy countries face a pressing challenge in the twenty-first century: controlling the rise in medical costs.²¹¹ In many cases, they have been unable to stem the tide of rising costs, and, even where costs have temporarily leveled

to say that I am required to use specified criteria to figure out who to give money to and who to refuse.”).

²⁰⁸ See Farmer & Gastineau, *supra* note 130, at 664 (“We didn’t argue that it was ‘cost-effective,’ not did we promise that such efforts would be replicable.”).

²⁰⁹ See Ouedraogo et al., *supra* note 90, at 316.

²¹⁰ See Lawrence O. Gostin, *Meeting the Survival Needs of the World’s Least Healthy People: A Proposed Model for Global Health Governance*, 298 JAMA 225, 225 (2007) (“International health assistance is provided in an ineffective way that does not enhance the capability for human functioning. Most funding is driven by emotional, high-visibility events, including large-scale natural disasters such as the Asian tsunami; diseases that capture the public’s imagination such as the human immunodeficiency virus and AIDS; or diseases with the potential for rapid global transmission such as hemorrhagic fever, severe acute respiratory syndrome, or pandemic influenza. These funding streams skew priorities and divert resources from building stable local systems to meet everyday health needs.”); Garrett, *supra* note 204 (reporting statement of Botswanan physician Ndwapi Ndwapi that “Botswana’s future rests on its ability to fully integrate HIV/AIDS care into the general health-care system, so that it no longer draws away scarce doctors and nurses for HIV/AIDS-only care”).

²¹¹ See, for example, Korobkin, *supra* note 12, at 524–25 (reviewing data on rising American health care costs).

off,²¹² they may rise again as economic fortunes improve. But developed countries, with their higher per capita incomes, are in a much better position to face these costs than developing countries are. Imposing rising health care costs on these nations would be disastrous.

Developed countries and international bodies like the WHO stand at a crossroads between two different approaches to international health. One approach would extend what Haavi Morreim called the “unitary standard of care”²¹³ globally, mandating that the global poor must receive the same standard of care as the global rich if they are to receive any care at all, or entitling every citizen to the highest standard of care at state expense. The WHO’s approach to HIV treatment and medical donation, and the Colombian *tutela* approach to the right to health, seem to adopt the unitary standard. In contrast, the WHO’s willingness to accept different standards of care for antiepileptic medications, antibiotic treatment for meningitis, and the pertussis vaccine, as well as *Soobramoney’s* approach to the right to health, reflect a willingness to accept differentiated standards in order to control costs while helping more patients. This Article has described the two approaches and argued in favor of differentiated standards.

Even if Americans choose to retain the unitary standard domestically in the face of growing domestic inequality, mandating a single standard of care across international borders jeopardizes the health of the global poor and holds their healthcare systems and budgets hostage to the choices of the wealthiest and most health-conscious patients in the developed world. During the debate over the DEAA, Senator Ted Kennedy—one of the most passionate defenders of universal health care in the U.S.²¹⁴—criticized the ban on exporting unapproved drugs as “‘arrogance’ which threatened to deny needed drugs to those in countries in which they had been approved.”²¹⁵ More recent efforts to globally mandate a single standard of care threaten a similar outcome, not only for patients who are deprived of beneficial second-best treatments and instead

²¹² See Meghan S. Stubblebine, Note, *The Federal Medical Loss Ratio: A Permissible Federal Regulation or an Encroachment on State Power?*, 55 WM. & MARY L. REV. 341, 379 (2013) (describing evidence that health care cost increases slowed in the U.S. during 2012).

²¹³ E. Haavi Morreim, *Cost Containment and the Standard of Medical Care*, 75 CAL. L. REV. 1719, 1725 (1987) (“[M]alpractice law presumes that there is a unitary standard of care that a physician owes to each patient he undertakes to treat.”).

²¹⁴ See Barry R. Furrow, *Health Reform and Ted Kennedy: The Art of Politics . . . and Persistence*, 14 N.Y.U.J. LEGIS. & PUB. POL’Y 445, 457–66 (2011) (detailing Kennedy’s commitment to universal health care); see also *Bohrer v. City Hosp., Inc.*, 681 F. Supp. 2d 657, 678 (N.D. W. Va. 2010) (noting that Kennedy sponsored the “law which created the federal support for Community Health Care Centers”).

²¹⁵ Hatton, *supra* note 37, at 440 (quoting 132 CONG. REC. S5661 (daily ed. May 8, 1986) (statement of Sen. Kennedy)).

receive nothing, but also for their fellow citizens whose infrastructure and educational system are undermined by the pressure to provide high-cost interventions to needy patients.

In rethinking the norms and mandates that govern global health, public, nonprofit, and private decision makers should look to international environmental law, which has explicitly allowed for different standards of care in different countries: “Environmental standards, management objectives and priorities should reflect the environmental and developmental context to which they apply. Standards applied by some countries may be inappropriate and of unwarranted economic and social cost to other countries, in particular developing countries.”²¹⁶ This language from the Rio Declaration of 1992 is echoed in other human rights documents, such as Agenda 21 and the Stockholm Declaration.²¹⁷ Global health decision-makers should follow environmental law’s lead. Rather than internationally mandating the standard of care adopted in wealthy developed countries in pursuit of the well-intentioned but ultimately misguided goal of avoiding double standards, they would do better to adopt a more nuanced and flexible approach that allows developing countries to pursue a variety of paths toward public health and fiscal sustainability.

²¹⁶ United Nations Conference on Environment and Development (UNCED), Rio Declaration on Environment and Development, Principle 11, U.N.Doc. A/Conf. 151/5 at 4, *reprinted in* 31 I.L.M. at 878.

²¹⁷ *See* UNCED: Framework Convention on Climate Change, May 9, 1992, *in* REPORT OF THE INTERGOVERNMENTAL NEGOTIATING COMMITTEE FOR A FRAMEWORK CONVENTION ON CLIMATE CHANGE ON THE WORK OF THE SECOND PART OF ITS FIFTH SESSION, INC/FCCC, 5th Sess., 2d Part, at Annex I, U.N. Doc. A/AC.237/18 (Part II)/Add.1 (identical text to the Rio Declaration); UNCED, Agenda 21, ch. 2, ¶ 2.20, Annex II, U.N. Doc. A/CONF.151/26/Rev.1 (1992) (“[A]ccount should be taken of the fact that environmental standards valid for developed countries may have unwarranted social and economic costs in developing countries.”); Report of the United Nations Conference on the Human Environment, 26th Sess., Principle 23, U.N.Doc. A/CONF.48/14, 11 I.L.M. 1416, 1420 (1972) (“[I]t will be essential in all cases to consider the systems of values prevailing in each country, and the extent of the applicability of standards which are valid for the most advanced countries but which may be inappropriate and of unwarranted social cost for the developing countries.”); *see also* Elliot B. Staffin, *Trade Barrier or Trade Boon? A Critical Evaluation of Environmental Labeling and Its Role in the “Greening” of World Trade*, 21 COLUM. J. ENVTL. L. 205, 262 (1996) (“Because each country’s economic and environmental conditions are different, developed countries should not attempt to export their environmental values or harmonize environmental laws around the globe.”).