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## 11 THEORIZING JUSTICE IN HEALTH RESEARCH

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Although several theories of justice have been developed exclusively for or have a major focus on health care, public health, and health policy,<sup>1–5</sup> they surprisingly do not include an explicit focus on health research. Instead, theoretical considerations of justice have informed debates on health research ethics primarily through discussions of principles of distributive justice and, more recently, principles of nonoppression and nondomination. These principles and related concepts (such as disadvantage, exploitation, vulnerability, and solidarity) have been applied to health research issues that have an identifiable justice dimension.

In this chapter, I pursue two goals. The first is to critically examine the meanings and roles of various *principles* of justice in research ethics contexts that have been discussed in this volume and highlight some of the most promising lines of inquiry that are likely to persist and deepen over the coming years. The second is to make the case for a complementary, but significantly different, approach: to gauge the extent to which current *theories* (rather than principles) of justice might be systematically mobilized, expanded, and specified to build relevant and sophisticated approaches to justice in health research, domestically and globally. Such a theoretical move might be advantageous for articulating a coherent approach to the range of issues that come under the "health research" heading, broadly construed, including research in basic biomedical sciences, clinical settings, public health, health policy, social determinants of health, health systems, and health-focused social and behavioral sciences.

## Debates on Principles of Justice in Health Research

In this section I discuss the main principles of justice that have played, and continue to play, a major role in research ethics debates, namely, principles of distributive justice and principles of nonoppression and nondomination. Though principles of distributive justice were at first used to protect subjects from the potential harm of research, those principles were next mobilized to increase access to the benefits of research. Nonoppression and nondomination are more recent “umbrella” principles of research ethics that are attentive to pervasive structures of domination and related power imbalances, which are irreducible to distributive concerns.

### *The Belmont Report and Principles of Distributive Justice in Subject Selection*

Although issues of justice in health research were brought to the forefront of public debate in the United States before the publication in 1979 of the *Belmont Report* by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, it is arguably *Belmont* that framed the debate in formal justice language.<sup>6-8</sup> Against a historical background of grave injustices toward members of vulnerable populations, the *Belmont Report* claims that subject selection should be guided by principles of distributive justice, that is, moral norms providing guidance for fair procedures and substantive criteria for the allocation of burdens/risks and benefits/opportunities.

As a starting point, the *Belmont Report* assumes that any departure from egalitarian distributions among parties is in need of justification. Unequal distributions are justified only if they satisfy a formal principle of justice (like cases ought to be treated alike) and a material principle of justice (identifying morally relevant differences between parties). The *Belmont Report* cites several examples of criteria that might plausibly specify material principles of distributive justice in different contexts: age, experience, merit, effort, deprivation, need, and societal contribution.

Importantly, the *Belmont Report* does not endorse any single principle of distributive justice. Rather, its strategy is to rule out criteria for the selection of individuals or groups in health research that, if endorsed, would lead to injustice. These criteria include social undesirability, availability (e.g., prisoners, institutionalized patients), manipulability, and vulnerabilities of various sorts (e.g., those associated with “social, racial, sexual, and cultural biases institutionalized in society”).

The *Belmont Report* also claims that social justice requires that entire classes of subjects should not disproportionately bear the burdens of research

relative to its benefits, even if individuals within those groups have given valid consent to research. The central concern here is with the potential for exploitation of research subjects who might be taken unfair advantage of, although the term “exploitation” is used only once in this regard when referencing Nazi experiments on unwilling prisoners. Exploitation is sometimes combined with wrongs caused by lack of, or deficiencies in, informed consent. However, the *Belmont Report's* concern goes clearly beyond consent issues. Its position is in sharp contrast with classical liberal and libertarian conceptions of justice.<sup>9</sup> The defenders of these conceptions<sup>10,11</sup> deny that patterns of distribution of benefits and burdens are morally significant, no matter how unequal they are. They do not concede that the demands of justice go beyond the protection of autonomous choice from fraud or coercion, and see no harm in consensual forms of exploitation.

The *Belmont Report's* conception of justice and its focus on distributive justice principles leads it to advocate a protective approach to subject selection within the mandate of the National Commission, which was geared toward the protection of the rights and interests of biomedical and behavioral research subjects. The *Belmont* principles were soon translated into basic US federal research regulations.<sup>12</sup> This protective approach has been undeniably serviceable in shielding certain populations from burdens and risks associated with research. However, since the mid-1980s debates on the regulation of research and principles of justice have been reignited, with a move from protection from the potential harm of research to access to the potential benefits of research (see, e.g., Chapter 3).<sup>13</sup> In the following sections I explore some of these debates focusing on the way principles of justice have been deployed to contest or modify the protective approach.

### *Distributive Justice-Based Arguments for the Right to Participate in Research*

One strand of a justice-based critique of the protective approach advocates for the right of research participants to decide what level of burdens/risks and benefits/opportunities is individually acceptable to them. It is tempting to view this trend as a simple revival of the classical liberal or libertarian conception of justice in research because it seems, at first glance, to limit the ethical obligations of researchers and other parties to respect for the autonomous consent of informed adults. This is, however, emphatically not the case. This line of critique of the protective approach is theoretically, and has been historically, compatible with the acknowledgment that the distribution of burdens/risks and benefits/opportunities among groups matters too.

The point can be made by turning to the rich history of patient advocacy groups that have challenged barriers to access to investigational drugs. This movement started in the 1980s with AIDS advocacy. It was both antipaternalistic and sensitive to social justice. As Steven Epstein has argued, antipaternalistic claims that sponsors, investigators, regulators, and institutional review boards (IRBs) should not substitute their judgments for individuals' own informed evaluation of risks and benefits came hand in hand with the justice concern that research itself is potentially a benefit that should be shared on the basis of need, rather than the ability to pay, like libertarians would posit.<sup>14</sup>

Building on patient advocacy movements, the idea of a right to the benefits of research was later expanded to cover individuals' and communities' right to post-trial benefits (including, according to some, a say on what those benefits should be). This question has become prominent in debates over the exploitation of research participants, especially in international research conducted in low- and middle-income countries (see Chapter 10).<sup>15-17</sup>

In a nutshell, we need to use caution in interpreting the often-described move from protection to participation, which includes but is not limited to debates and regulatory decisions as to which populations should be labeled "vulnerable," and what judgments of vulnerability entail (see Chapter 6). As the protective model was not solely based on concerns for social justice but also on concerns for autonomy, the participative approach is not exclusively based on autonomy. It is often animated by a deep social justice ethos.

### *Principles of Nonoppression and Nondomination*

Despite its importance, the distributive frame misses some important considerations of justice that are not narrowly focused on distributing goods of some kind. This line of argument is extremely influential in thinking about justice issues in health research and comes under different labels, such as principles of nonoppression and nondomination.

In that regard, the work of Iris Marion Young is seminal.<sup>18</sup> It is informed by the justice claims of various social movements (including feminism) and provides conceptual tools for analyzing the limits of the distributive frame. Young argues that by highlighting the burdens and benefits that individuals have to shoulder, distribution-focused theories of justice contribute to obscuring the role of institutional contexts in generating oppression and domination.

The concepts of oppression and domination are central to her thesis. "By domination I mean structural or systemic phenomena which exclude people from participating in determining their actions or the conditions of their

actions" (p. 31).<sup>18</sup> In a parallel and influential literature, Philip Pettit construes domination as arbitrary or unchecked control over another's choice.<sup>19</sup> According to Young, oppression is a broader term that overlaps with domination and encompasses exploitation, marginalization, powerlessness, cultural imperialism, and violence.<sup>18</sup> Structural injustices occur when social processes and institutions established by powerful actors serve as background institutional rules and accepted social norms. These rules and norms are imposed on large groups of persons who are not powerful in these same ways. However, powerful actors do not generally have any direct causal responsibility for social injustices of this sort. Their responsibility is indirect: they contribute to create or maintain unjust social structures, and they draw many benefits from the *status quo* and their interactions with other powerful actors under favorable institutional and social design.

Principles of nonoppression and nondomination have changed the lens through which justice issues are framed in health contexts to stress aspects of social relationships that otherwise go unnoticed. However, the future of approaches using these concepts depends on the careful use of several distinctions. First, conflicting conceptions of nonoppression and nondomination need to be explicitly articulated.<sup>19,20</sup> Second, these conceptions should be connected to other moral and political demands and aspirational ideals. Third, explicit and justified statements as to whether, why, and how various actors have specific responsibilities for preventing, resisting, removing, or minimizing structures of oppression and domination in research contexts are necessary. Finally, arguments are needed to vindicate or rebut the claim that the structures of contemporary international health research systematically wrong participants or researchers in low- and middle-income countries. The following examples illustrate this point.

These principles of justice shed new light on the economic model dominant since the 1990s in which powerful pharmaceutical companies increasingly offshore research (international multicenter randomized trials) and outsource trial-related tasks to specialized commercial entities, such as contract research organizations and site management organizations. The claim here goes beyond complaints that international research is exploitative because the benefits of research are not fairly shared. The more fundamental concern is that the realities of the current economic model of international research effectively prevent affected populations and their governments from influencing the research agenda and organization.<sup>22,23</sup>

Next, consider the dramatic underrepresentation of women's perspectives and interests in research that is not reducible to a problem of unfair distribution of the benefits and burdens of research that could be corrected by

increasing the proportion of women enrolled in clinical trials (see Chapter 6). A long-standing problem of no less significance is that the research agenda reflects oppressive social norms that reinforce the view that women are mere "vessels and vectors," rather than persons with their own voice, rights, and interests. Oppression does not merely disempower potential research participants; the lack of female researchers in certain domains also affects the research agenda and priorities. Historian Jessica Martucci<sup>24</sup> has, for instance, shown that the study of breastfeeding practices immensely benefited from the involvement of female researchers. The same argument has been made with respect to pervasive racial prejudices and injustices, which translate into problems in subject selection and in difficulties that major research institutions face, even when they acknowledge their deficiencies, in recruiting and retaining health researchers and bioethicists from diverse, underrepresented, and disadvantaged backgrounds. On these issues, one can only concur with Michael Marmot, "At the end of every scientific paper there is a familiar coda: more research is needed, more research is needed. What, I wondered, if we added a new coda: more action is needed. It need not be discordant with the first" (p. 17).<sup>25</sup>

Finally, there is growing attention to patient-led research (PLR), that is, research projects spontaneously initiated by patients who self-organize in selecting a research question, study design, data collection and analysis method, and dissemination of study results. One of the main arguments in favor of facilitating PLR is that they serve "the individual right to scientific and cultural participation and the common good of a more participatory scientific culture" (p. 218).<sup>26</sup> This right, if there indeed is such a right, cannot be derived from principles of distributive justice but might be tightly connected to a principle of nondomination, which precludes exclusion from certain valuable social practices and presses respect for individuals as knowers, not merely as bodies instrumental for the conduct of research. In addition, by taking the lead in setting the research agenda, patients transform tacit institutional models of what constitutes the "social value" of science and who is entitled to define it.

The recognition of the PLR would correct a salient form of domination, what Miranda Fricker<sup>27</sup> calls an epistemic injustice, that is, a wrong done to someone specifically as a knower. Epistemic injustice primarily reflects a prejudice in the economy of credibility: the wrongful, habitual nonacceptance of an individual's testimonial based on negative stereotypes. Fricker's theory can be readily applied to patients' advocacy organizations' claim that they have been wrongfully excluded from health research and need to be included in the determination of research priorities and design. Through this lens, PLR appears to be a new step for self-advocacy groups, which claim expertise both

in theoretical knowledge and experiential, socially situated knowledge.<sup>28</sup> PLR challenges the view that science is a social practice with exclusive authority claims on the legitimate production of generalizable health knowledge. Thus, the problem of participation leads to issues related to the principles of nonoppression and nondomination that will each likely be the focal points of debates in the years to come.

### *Principles of Justice Beyond Subject Selection*

Although many discussions of principles of justice in research focus on subject selection, they have also been deployed to cover other territories, some of which were briefly touched upon above (e.g., selection of knowledge producers). Another important territory is the allocation of financial and nonfinancial resources to health research.<sup>29</sup> Should resources be allocated to health research rather than to other important social goods? How should resources be equitably distributed between multiple valuable and sometimes competing ends (health, social value, economic development, educational opportunity, etc.) and between current and future generations? How should resources be allocated between basic biomedical science, where likely benefits are more long-term, and clinical, public health, and health systems research, where hoped for benefits are more proximate?

In addition, considerations of justice play a central role in choice of the criteria for setting research priorities and in determining what counts as a fair process for making priority decisions within health research. Which health research questions and which causes of burdens of disease should be given priority? Racial and gender discrimination (see, e.g., Chapters 6 and 7).<sup>29</sup> Considerations of compensatory justice often compete with more traditional criteria for resource allocation, such as the potential for the prevention or treatment of diseases that are the most widespread, alter life expectancy negatively, impact our ability to address health issues that afflict the young or than the old or to treat illnesses that cause the most pain and suffering.

### **Another Route: Developing Theories of Justice in Health Research Contexts**

Having examined the principles of justice at play in health research ethics debates, I turn to a different approach. Could *theories* of justice enlighten health research issues? Two reasons motivate my inquiry. First, principles of justice are not stand-alone norms. Their meaning and justification depend upon theories of justice, broadly understood as systematic articulations of a

conception of justice. For example, the discussion on the recognition and regulation of PLR has led some to propose a "new social contract" for research (p. 218).<sup>26</sup> However, the framework of the social contract is perhaps not the most helpful way to justify the research enterprise and its oversight. PLR could be grounded in competing theories of justice that have no recourse to ideas of the social contract. Similarly, debates over an alleged obligation to participate in research would benefit from a more systematic articulation of the theories of justice underlying research. Some theories of justice have the potential to assign responsibilities for conducting and funding research, and provide precise guidance for setting priorities. Finally, theories of justice can certainly assist in identifying and addressing the most pressing justice issues, beyond the distribution/oppression/domination distinctions that intervene in debates about principles of justice.

Second, extant attempts to use theories of justice as the starting point for an inquiry into research ethics are either incomplete because they are focused on a limited territory (e.g., international clinical trials<sup>30,31</sup> or health systems research<sup>32</sup>), or unsatisfactory because their methodological approach is problematic. The latter critique can be leveraged against David Buchanan and Franklin Miller.<sup>29</sup> These authors compare the specific and different ramifications of several theories of justice in health research contexts, and wrongly assume that those theories are directly relevant to health research contexts (see my comments on Rawls below). In order to fill this gap and supplement approaches based on principles of justice, I explore a different approach that draws on contemporary debates in political philosophy on justice theory. Rather than advocating a particular theory of justice, my goal is to circumscribe the main features of theories of justice that would be well-positioned to be expanded and specified to advance debates over the fullest range of issues in health research contexts. To do this I proceed in three steps. I first explore the site of theories of justice (i.e., the kinds of objects that are appropriately governed by the principles of justice specified by a theory). I next turn to the scope of theories of justice (i.e., the range of agents to whom considerations of justice apply). I finish by turning to the goals of theories of justice (i.e., the job a theory of justice is supposed to accomplish).

### *The Site of Theories of Justice*

The site of justice refers to the kinds of objects that a theory of justice is designed to cover.<sup>33</sup> These can include, for example, the actions or character of individuals, private interactions between individuals, nonprofit or for-profit private associations (e.g., universities, nongovernmental organizations,

private foundations, business firms, labor unions, religious institutions, private hospitals), and basic social, economic, and political institutions.

Theories of justice always select one or several related objects as the site of justice. This is why they often acknowledge that the remaining territories, which are not of significance to their projects, require theories of justice of their own. Major theories of justice identify different sites of justice, not all of which fit well with health research as an enterprise that involves institutions, associations, and individuals. Here, my focus is on alternative ways to characterize the site of *social* justice considering the sharp contrast between John Rawls's and Norman Daniels's theories on the one hand and Madison Powers's and Ruth Faden's theory on the other.

The starting point of any contemporary theory of social justice is the work of Rawls. In his words, "the primary subject of [social] justice is the basic structure of society" (p. 7).<sup>34</sup> What Rawls means by the basic structure of society is disputable but arguably he is interested in the most basic rules of social cooperation for mutual advantage that govern the social, economic, and political institutions that have the deepest and most pervasive impact on people's lives. Examples include basic constitutional entitlements (fundamental liberties and rights), rules that secure fair equality of opportunity in employment and education beyond nondiscrimination based on race, gender, or religion, and the most general rules that constrain the distribution of income and wealth, such as the tax system and inheritance laws.

Does a Rawlsian understanding of social justice directly cover health research institutions and practices? The short answer is no. The principles that govern the basic structure do not directly apply to nonbasic public institutions (e.g., public research institutions), private associations (e.g., pharmaceutical companies), or individuals' actions (e.g., investigators, citizens as potential research subjects). Moreover, the principles of justice that govern these territories are not derivable from the principles of social justice. Hence, Rawls's own theory has the potential to offer only limited guidance for justice issues in health research. What a Rawlsian perspective can directly offer is a critique of background conditions under which health research takes place, including general laws that permit the accumulation of wealth, creating deep inequalities that impact health and the capacity to invest in research or influence its agenda.

Can a Rawlsian theory of justice be modified so as to cover health research? Our best chance is to examine Daniels's attempt to expand Rawls's theory of justice to health contexts.<sup>1-2</sup> Daniels is acutely aware that Rawls's characterization of the site of justice raises a serious obstacle for his project when he notes that, "The most promising strategy for extending Rawls's theory simply

includes health-care institutions and practices among the basic institutions involved in providing for fair equality of opportunity" (p. 45).<sup>1</sup> The argument for the inclusion of health-care institutions to broaden the site of justice is that Rawls erroneously adopts a simplified idealizing assumption that individuals are "normal, active, and fully cooperating members of society over the course of a complete life" (p. 302).<sup>2</sup> Once we endorse a more realistic assumption, Daniels argues that shortfalls from normal functioning due to illness negatively impact the opportunity range of at least some people. Therefore, the scope of application of the principle of fair equality of opportunity should not be restricted to employment and education (as Rawls believed). A more capacious account of opportunity is needed. Daniels argues that universal access to reasonable care is necessary (though not sufficient) to secure the health needs of individuals. In recent years, Daniels has extended his account beyond health care to cover other pathways through which individuals' and populations' health needs are met. His focus is now on a broader range of "socially controllable factors that affect population health and its distribution" (p. 30).<sup>2</sup>

The important point here is that the extension of Rawls's theory to health care requires a substantial modification of that theory, but still, in its present form, Daniels's theory does not explicitly cover health research. One promising way to extend Daniels's theory has been explored by Bridget Pratt and colleagues.<sup>31</sup> They persuasively argue that if Daniels conceives the goal of health care to be providing optimal care to everyone, then health research is necessary. Daniels's egalitarian and maximizing goal has implications in terms of the range of health research that can be supported on the basis of his theory compared to alternative views. Those who deny that health care needs to be optimal in any sense of the term will give support to a much narrower range of health research.<sup>35,36</sup> Those who set a higher standard of what counts as optimal health will lend support to a wider range of health research.<sup>4</sup>

In contrast to Rawls's view and Daniels's amended Rawlsian approach, some theories endorse from the outset a broader understanding of the subject matter of social justice and are thereby equipped to cover a broader range of issues in health research. For instance, Powers and Faden write that, "questions of justice emerge from the operation of the totality of social institutions, practices, and policies that both independently and in combination have the potential for profound and pervasive impact on human wellbeing in all of its essential aspects" (p. 5).<sup>3</sup> The purview of their theory is not limited to basic social, economic, and political institutions, or even to health care and public health institutions. It includes any institution and nonprofit or

for-profit private association involved in practices that have a profound and pervasive impact on individuals' well-being.

Powers and Faden work with a multidimensional understanding of well-being that encompasses six core elements that are necessary for a decent human life: health, cognition, personal security, personal attachments, the enjoyment of equal respect of others, and self-determination. Central to their theory is the idea of unjust disadvantage. A person is unjustly disadvantaged if he or she suffers deprivation in at least one of these elements of well-being because social arrangements put others in a superior position. It is especially urgent to alter these social arrangements if they create or reinforce patterns of systematic disadvantage that compound the effects of various deprivations on some individuals or groups.

Powers and Faden's theory has the potential to offer particular insights on justice in health research. One reason is that health research and its findings can have a profound and pervasive impact on health through a variety of social institutions and practices. But the reach of health research extends as well to several other core dimensions of well-being, such as personal security, reasoning capacities, personal emotional attachments, respect by others, and self-determination.

For example, health research can identify particularly important threats to well-being such as the potential life-long impact of deprivation in early childhood. But the impact of early childhood deprivation reaches other dimensions of well-being. They may cause deficiencies in cognitive development, undermine the ability to form emotional attachment to others, and ultimately prevent one from leading a life that is, in its broad contours, self-determining.

Because well-being is a multidimensional concept and because deficiencies in health status are often (but not always) causally linked to deficiencies in other dimensions of well-being, health research needs to track the impact of health interventions and policies on all relevant dimensions of well-being. Besides its role in tracking well-being, health research also has the potential to further the dimensions of well-being irreducible to health. For example, research on reproductive policies may identify means that make it easier for people to control whether and with whom they become parents, and thereby enhance self-determination and attachment. Investment in health research can further personal security, particularly for women, by, for example, supporting new technologies that women can use to prevent sexually transmitted infections or pregnancy without dependence on the cooperation of abusive partners.

A downside of this theory is "mission creep": it might unduly extend the responsibilities of health institutions (and therefore their already

overwhelmed agents) to domains traditionally under the purview of other institutions. Note, however, that it also goes the other way round: this theory entails that institutions usually in charge of other elements of well-being, such as personal security, have overlapping responsibilities with health institutions. Although this objection is fair, it is not fatal. Any theory of justice not committed to artificially separate "spheres" of justice has to explain how responsibilities for protecting and promoting well-being have to be socially distributed in a manner that is efficient, procedurally, and substantially fair, psychologically acceptable to situated and bounded agents, culturally appropriate, and politically feasible. This is certainly an area for future investigation that would benefit from localized discussions, rather than purely theoretical debates on fairness in the allocation of responsibilities that lack the desirable level of granularity.

To conclude, how the site of justice is characterized within a theory has strong implications with respect to the range of issues a theory can address in health research contexts and the conceptual tools it can deploy.

### *The Scope of Theories of Justice*

Marmot<sup>25</sup> provides staggering descriptions of health inequalities between and within countries. Take life-expectancy at birth. He cites the 2012 WHO data showing that it has a spread from forty-six years in Sierra Leone to eighty-four in Japan.<sup>37</sup> But Marmot notes that in wealthy countries the social gradient of health (i.e., the linking of social position with health) is also arresting: life expectancy varies by twenty years for men in certain areas of Baltimore and Glasgow.<sup>25</sup>

While research identifies health disparities, it does not answer the normative question: Is improving the lot of the disadvantaged at home as morally significant as the welfare of the disadvantaged abroad, who might be doing worse in absolute terms? There is no easy answer, and in particular, the defenders of "global health" should not beg the question. If "global health" is primarily construed in terms of the scope of the problems we are facing (e.g., infectious diseases, poverty-related ill health), and not in terms of their location (i.e., beyond the borders of high-income countries), then its empirical and normative focus could include domestic inequalities as well as international ones.<sup>38,39</sup> Here, philosophical debates on the scope of justice might prove useful for clarifying our options and their justification. The scope of justice "refers to the range of persons who have claims upon and responsibilities to each other arising from considerations of justice" (p. 232).<sup>33</sup> Are obligations of justice limited to members of a particular country? If obligations of justice extend

beyond national borders, is their content thinner and their strength weaker than in the domestic arena? Three families of theories offer various answers to these questions.

Strong "statist" theories claim that obligations of justice arise only within nation-states. A variety of reasons are invoked in support of that claim. Thomas Nagel, for instance, has argued for a distinctively political conception of justice according to which the scope and the site of justice are coextensive.<sup>40</sup> Obligations of justice arise between citizens of democratic states who are subject to coercive laws that affect their life prospects. As no global authority exerts a similar type of legal coercion, citizens of affluent countries and their states do not owe any obligation of justice to the global poor. What they owe them is a humanitarian duty of assistance that arises because of the absolute level of need of some populations that the affluent are in a position to help. Hence, even if there are genuine moral duties of assistance, these have a strict and low cut-off point: the satisfaction of basic needs rather than the higher standards set of well-being, human flourishing, or, as Marmot puts it, the goal of bringing the health indicators of everybody to match the top fifth of the best-off populations.<sup>25</sup> With respect to health research funding, strong statist would deny that there is any obligation of justice to allocate part of the research fund of affluent states to researching diseases and conditions that do not affect their own citizens. Alternatively, they might argue that moral duties of assistance might support the allocation of some research funding to causes (whatever those are) of severe burdens of disease in parts of the world where there is substantial suffering and need, or that improving the health of disadvantaged populations is instrumentally justified to promote domestic health and national security.

At the other end of the spectrum, some authors defend cosmopolitan theories of justice that do not restrict obligations of justice to members of a particular society but instead take the view that national boundaries are irrelevant to duties and claims of justice.<sup>41</sup> Several strategies are open to cosmopolitans.<sup>42</sup> They may argue that affluent nations impose on the global poor an international order in ways that make their transactions substantially nonvoluntary, if not outright coercive. Another strategy is to argue that the current distribution of wealth and power is due to past wrongs that need to be rectified and to present forms of structural injustice in the design of global institutions and forms of exchange from which affluent nations wrongfully benefit. A third strategy is to argue for cosmopolitanism directly from people's common humanity that provides them all with the same bundle of rights claims.

Whatever strategy is adopted, for cosmopolitans the current global distribution of wealth and power is unjust. Cosmopolitan reasoning directly

challenges the view that states and private funders should give priority to the health research needs of the members of their society. It provides a strong theoretical rationale for claiming that inequalities of the magnitude of the "10/90 gap" (i.e., the claim that 10 percent of worldwide expenditure on clinical research is allocated to health issues that affect 90 percent of the world's population<sup>43</sup>) is unjust and that research resources should be allocated in ways that track the global burden of disease, and not a national one. Nonetheless, strong differences among cosmopolitan views persist. Depending on their determination of the factors that are believed to trigger duties of justice, each theory provides a rationale for health research funding, interventions, and priorities that addresses health inequalities that have a specific source (e.g., inequalities caused by past wrongs, including domestic wrongs due to pervasive racial or class-based discrimination).

Hybrid theorists reject both strong statism and cosmopolitanism.<sup>2,44,45</sup> They agree with cosmopolitans about basic universal rights claims and the moral arbitrariness of restricting duties of justice to cocitizens. But they also argue that nation-states have special obligations toward their own citizens and/or residents that go beyond their global obligations of justice to all. These theories therefore provide various arguments for a range of just priority-setting criteria in allocating health research funds that do not simply track the global burden of disease and might have the theoretical space to accommodate the view that reducing the domestic social gradient of health is a moral imperative of equal significance. In addition, hybrid theories would require the development of specific international agencies and rule-making bodies that would channel and fairly distribute resources, as well as regulate international research.<sup>2</sup>

To sum up, the scope of justice delineates the obligations of justice due to non-co-nationals and can play a role in specifying the normative goals of "global health" and research to address health inequalities. Importantly, the scope of justice does not cover all moral duties and concerns (e.g., humanitarian assistance). Solidarity, too, should inform our moral sensibility to justice and help us recognize, beyond the realm of legitimate rights claims, the significance of mutual interdependence, care, and concern, and motivate us to "stand up beside" others, be they close-by or far away.<sup>46,47</sup>

### *The Goals of Theories of Justice*

In this last section, I will contrast two possible goals of a theory of justice, ideal and nonideal theorizing, which bear on the methods used to approach justice problems in health research. A theory of justice might develop a conception

of a perfectly just state of affairs (e.g., at the interpersonal or societal level) and of the set of more requirements that are jointly necessary and sufficient to govern it. This is what Rawls calls "ideal theory" (pp. 8–9).<sup>34</sup> He argues that ideal theory has conceptual and normative priority over finding out what is normatively required to address urgent real-world injustices. A vision of an ideally just society offers tools for evaluating the justness of the situation we now face. However, to become more action-guiding in the actual world, where unjust inequalities are part of the background, additional considerations would be needed. These considerations would move us closer to the perfectly just society that the theory identifies and defends. The latter point is important, since my aim is not to argue that ideal theory should be avoided in health research ethics. Aspirational moral, social, and political values are indispensable. The point is that ideal theory has to be carefully supplemented by empirical, theoretical, political, and normative considerations that bridge the gap between the ideal and the actual.

In contrast to ideal theories, some theories set themselves the task of diagnosing and treating the most pressing injustices that occur in real-world settings. These "nonideal" theories approach justice issues by comparing different "feasible" social and institutional arrangements that would enable either reducing injustices or advancing justice.<sup>48</sup> To achieve these ends, nonideal theorists mobilize the best scientific understanding of human behavior and its motivation, of the functioning of institutions and social practices, and of the actual causal structure of the natural and social world. They concede neither a conceptual nor a normative priority to the vision of a perfectly just society over the task of identifying and addressing real-world injustices. However, there is room for debate as to whether pure nonideal theory is even possible or whether the introduction of some idealizing assumptions in modeling societies and institutions is unavoidable and should be acknowledged (see below).

The nonideal/ideal theory debate can shed light on some heated debates in research ethics, such as the moral obligation to participate in health research. Rosamond Rhodes has made an ideal theory argument in favor of the obligation to participate in research.<sup>49</sup> Social contract theories purport to establish the legitimacy of political authority and the moral obligations of citizens of a state who give consent to a mutually beneficial and enforceable hypothetical contract. According to Rhodes, any reasonable person should accept an obligation to periodic service as a research subject because general cooperation is necessary to advance medical science from which all parties stand to benefit through improved medical care. Refraining from participation would constitute unjust free-riding, a breach of "biological citizenship," as anthropologists would put it.



This argument determines research participation obligations assuming that individuals live in a society that is in all other respects just. Society's politically enforceable moral norms derive from a hypothetical contract that individuals comply with. Now, pressed as to whether she *actually* defends a legal or even an all-things-considered moral obligation to participate in research, Rhodes responds in the negative:

My argument is about justice in the allocation of research risks and burdens in the context of a reasonable expectation to have a share in the rewards. In the U.S. today, in numerous explicit and veiled ways, medical resources are not distributed in accordance with justice. So long as the benefits of research are unjustly allocated here, we lack the justification for allocating the risks and burdens of research based on equality. (p. W17)<sup>50</sup>

Given that background justice conditions necessary to ground a universal obligation to participate in research are not satisfied in the United States, it is unclear how much Rhodes's argument from ideal theory contributes to a morally significant discussion in research ethics since it lacks bridge arguments for meaningful implementation of the view. What concrete actions and policies would move us closer to conditions for the ideal allocation of the burden of research?

In contrast, consider another proposal in defense of a justice-based obligation of patients to contribute to the production of medical knowledge.<sup>44</sup> Here, the main objective is to build an ethical framework for a way of reorganizing health-care systems that would not rely on the current distinction between clinical research and clinical practice inherited from the US National Commission's *Belmont Report*.<sup>6,51</sup> In "learning healthcare systems" (LHS), research and practice would be continuously integrated into knowledge development and application in health-care delivery, rather than segregated.<sup>52,53</sup> LHS raise fundamental questions: through what mechanisms should learning activities be ethically regulated, no matter where they fall along the research-practice continuum, and why? What are the ethical obligations of health-care providers and patients in LHS? Faden and colleagues argue that patients have an obligation to participate in certain limited learning activities based on norms of common purpose and reciprocity:

[Some] learning activities—such as participation in a registry, reviews of deidentified medical records, and being interviewed by health care staff to better improve the patient care experience—are likely to

be instances in which patients do have an obligation to participate, *assuming* that the activities have a *reasonable likelihood* of improving health care quality and that appropriate data security protections are in place. *These conditions are probably met currently* in integrated health care systems that have invested in secure electronic health records and have mechanisms in place to adjust local norms of care in direct response to the result of learning activities. (*emphasis added*) (p. S23)<sup>52</sup>

Although the authors do not present their work as a case study in nonideal theory, it embodies some of its characteristics. They make no idealizing assumption about the virtues of individuals or the justice of society in general; they make limited idealizing assumptions about how the improved health-care system would function, but carefully evaluate the distance between what currently obtains in existing integrated health-care systems and what the model demands. Their model is built in sufficient proximity with the real world so as to enable the representation of a realistic transformation of current systems, without losing its normative bite.

## Conclusion

In this chapter I have discussed the role that principles of justice have so far played in debates on the ethics of health research. My claim is that the move from the *Belmont Report* that inspired a protective approach to health research to an approach stressing the access to the potential benefits of research should not be interpreted as the endorsement of a conception of justice solely concerned with respect for autonomous decisions of individuals. On the contrary, the movement in favor of increased access to the opportunity to participate in health research goes hand in hand with a more expansive conception of the principles of justice that ought to govern research. These principles include a requirement of nonoppression and nondomination, in addition to the fair distribution of the benefits and burdens of research among individuals and groups. They have informed and continue to feed the debate on the ethics of health research.

Although traditionally, justice issues in health research have been discussed through the lens of principles of justice, I argue in this chapter for an alternative approach. In my view, theories of justice developed in political philosophy or biomedical and public health ethics need to be expanded and specified to provide coherent approaches to the fullest range of health research justice issues. Each theory of justice has its own strength and weaknesses, and my goal was not to argue in favor of one of them. Rather, I delineated the main

features of these theories that would enable them to be responsive to the distinctively justice-related challenges of the contemporary research enterprise.

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