

JUSTICE

and the

Human Development Approach to International Research

by ALEX JOHN LONDON

The debate over when medical research may be performed in developing countries has steered clear of the broad issues of social justice in favor of what seem more tractable, practical issues. A better approach will reframe the question of justice in international research in a way that makes explicit the links between medical research, the social determinants of health, and global justice.

The intimate relationship between disease and conditions of social and economic deprivation has been at the center of an intense debate about the ethics of international medical research for more than a decade. But while this debate has at times been high-pitched and divisive, behind it lies a broad area of agreement.¹ On the one hand, most commentators accept that medical research can and should play an important role in efforts to address the profound health needs of developing world populations.² It is often noted, for example, that 90 percent of the world's research dollars are spent on diseases that affect only 10 percent of the world's population—the so-called 10/90 research gap—and that this imbalance in research priorities contributes

to the pervasive lack of access to effective medical care in the developing world.³ On the other hand, there is also widespread recognition that the sheer extent of health needs in the developing world, combined with poverty and social deprivation, make populations there highly susceptible to abuse and exploitation.⁴ While medical research is capable of generating important benefits, it can also impose significant burdens. Too often in the past, the burdens of research participation have been borne in the developing world while the fruits of those endeavors are enjoyed principally in developed nations.⁵

Unfortunately, the debate about the ethics of international research has not adequately considered the relationship between research and basic issues of social justice that are raised by these background considerations. For instance, although it is recognized that clinical trials in the developing world must respond to the health needs and priorities of

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the host country, there has been little discussion of the fundamental relationship between a community's health needs and the broader conditions of social justice that help to shape those needs. And while an intense debate has raged over the standard of care that should be provided to research participants, most of it has centered on the interpretation of the international guidelines for research.⁶ Broader issues of social justice are centrally relevant to this topic as well, but they have been addressed only at the margins. In fact, the debate about justice has become synonymous with the question of who gets access to the fruits of successful research.⁷ An intense focus on the guidelines for international research has effectively confined this debate to the question of whether, and to what degree, research sponsors must ensure that any interventions shown effective in a clinical trial are made *reasonably available* to the host population.⁸

In part, no doubt, the reluctance to address the relationship between international research and broader questions of social justice stems from a desire to stick to what are perceived as more tractable practical issues and to avoid thorny philosophical disagreements over different theories of justice. In the discussion that follows, however, I argue that avoiding an explicit and systematic analysis of important background issues of social justice has not prevented substantive and controversial positions on those issues from influencing the current narrower debate. In fact, the desire to avoid these issues has structured debate so as to filter out and exclude information that connects relatively local topics in international research to broader issues of global justice, the social determinants of health, and human development. This results in a way of framing central issues in international research that is essentially biased in favor of what Brian Barry calls "justice as mutual advantage."⁹ As a result, someone

who approaches this topic wanting to remain agnostic about controversial issues in global justice may find herself formulating the basic problem in a way that tacitly presupposes a particularly anemic theory of justice.

I begin with an illustration of how agnosticism about broader issues of social justice can lead to what I call the "minimalist view." Later, I will reframe the question of justice in international research in a way that makes explicit the links between medical research, the social determinants of health, global justice, and human development. Eventually, I argue for what I call the "human development approach" to international research ethics.

Constructing the Minimalist View

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developing world reveals that they are staggeringly pervasive, profound, and urgent. People in the developing world who live in poverty and toil under some of the world's poorest social conditions also bear some of the heaviest burdens of sickness and disease. Of the 3.5 million deaths from pneumonia each year, 99 percent take place in developing countries, where pneumonia claims the lives of more children than any other infectious disease.¹⁰ To some degree, people in the developing world are more likely to die from pneumonia because they cannot afford the low-cost antibiotics widely available in developed nations. Twenty-seven cents (U.S.) for a five-day regimen of antibiotics is more than a day's income for roughly 1 billion people.¹¹ Also, in rural commu-

nities and other places where the health care infrastructure is not well entrenched, hospitals and clinics may be too far away to get to.

Poverty and poor social conditions also make those in the developing world more susceptible to a wider array of illnesses. Pneumonia is more common in the developing world, for example, because children are more likely to be malnourished and to suffer from medical conditions that weaken their immune systems. Where sanitation is poor and the drinking water is unsafe, diarrhea-related diseases such as cholera, dysentery, typhoid fever, and rotavirus claim the lives of nearly two million children under the age of five.¹² In developed nations, in contrast, such infections are much less common and are more easily treated when they occur. Similarly, of the roughly 1,600 children infected with HIV every day, approximately 90 percent live in the devel-

oping world. Africa alone is home to some 70 percent of the world's HIV-positive individuals, even though the continent contains only about 10 percent of the world's population.¹³ In developed countries, the use of costly anti-retroviral medications has dramatically reduced the rate of mother-to-child transmission of HIV and greatly extended the lives of HIV-positive adults,¹⁴ but precisely where the burden of HIV/AIDS is the greatest, these interventions remain largely unavailable.

One of the goals of collaborative international medical research is to address the profound health-related needs of the developing world. At the same time, medical research is also capable of imposing additional burdens on participants and the communities

in which they live. The problem, then, is how to ensure that research actually benefits people in the developing world without further exacerbating their already profound deprivation.

What I am calling the minimalist view frames the fundamental problem of justice in international research in terms of two salient variables: the needs and vulnerabilities of the host population, and the capacity of research to benefit and to burden. In order to remain agnostic about controversial theories of justice, the minimalist view turns to the values that have been most clearly worked out in research ethics. First, it imposes a requirement of *nonmaleficence*, which rules out any research initiative that would make either participants or the broader host community worse off than they would have been had the research not occurred. Medical research should not add to or exacerbate the burdens those in the developing world already face. Second, it imposes a requirement of *beneficence*, which requires that a proposed research initiative must also provide some benefit to the host community. Participating in or hosting a research initiative must serve the interests of the host community so that it is better off than it would have been had the research not taken place.

These requirements do not specify how significant the improvement over the status quo must be for a research initiative to be permissible, nor do they specify how the host community must benefit from the research initiative. There are principled reasons, however, that make the minimalist reluctant to specify further substantive constraints on research. According to the minimalist, these details about the level and type of benefit require value judgments that are best left to the discretion of those in the host community. From this point of view, in fact, imposing stronger restrictions on international medical research appears misguided at best, and positively malevolent at worst, because it would prevent host

communities from participating in research that might provide them with *some* benefits. Stronger restrictions on international medical research are therefore viewed as working against the interests of developing world populations. Further, the minimalist is inclined to see stronger restrictions as unjustifiably paternalistic, on the grounds that they limit the autonomy of developing world populations to decide for themselves which research activities are worth participating in.

In effect, the minimalist position derives the requirements of justice from the accepted pillars of contemporary bioethics, and of research ethics in particular. A just research initiative is one that faithfully adheres to the standard values of nonmaleficence, beneficence, and respect for autonomy. Put in slightly different terms, the minimalist holds that any research initiative that satisfies the conditions of nonmaleficence, beneficence, and respect for autonomy is permissible because it offers *fair terms of cooperation* to the host community. Medical research is a collaborative activity, and the minimalist's requirements ensure that the benefits of research do not accrue solely to the sponsoring party while the host community bears all of the burdens. They leave room for host communities to bargain for the best terms of cooperation that they can get and prohibit agreements that do not somehow serve the interests of the disadvantaged party. Initiatives that meet these conditions are viewed as fair because they provide mutually beneficial terms of cooperation that each party can freely accept.

Minimalist views are readily discernible even when these requirements are not explicitly stated. For example, roughly a decade ago, the ethics of international research came into the spotlight after a series of clinical trials of a short course of AZT to inhibit mother-to-child transmission of HIV. The trials were carried out in developing countries and employed a placebo-controlled design. Critics

charged that use of a placebo was unacceptable given that a regimen of AZT, widely used in the developed world, was known to be effective at preventing mother-to-child transmission. Among the defenses commonly offered of the placebo control was that it did not deny participants care that they would have otherwise received, and that it did not impose new or additional health burdens on participants.¹⁵

Similar considerations have motivated efforts to reform international guidelines such as the Declaration of Helsinki. During the debate over the declaration's requirement that subjects in clinical trials receive the "best proven diagnostic and therapeutic method," one proposed revision would have required only that subjects "not be denied access to the best proven diagnostic, prophylactic, or therapeutic method that would otherwise be available to him or her."¹⁶

Perhaps the most explicit articulation of the minimalist tenets has come from proponents of the "fair benefits" approach to international research.¹⁷ This approach is critical of the requirement, enshrined in the Declaration of Helsinki and elsewhere, that researchers ensure that members of the host community can obtain interventions proven effective by a clinical trial. From the standpoint of the fair benefits approach, the "reasonable availability" requirement is overly restrictive both of important international research and of the ability of developing world populations to receive a wide range of potential benefits that can come from hosting a research initiative. They argue that host communities should decide for themselves what constitutes fair benefits for research participation. They also describe a mechanism by which the host community could bargain for a wide range of benefits, and they define a package of benefits as fair if members of the host population agree that it is a sufficient return for the burdens associated with the research. Plainly, then, the "fair benefits" view embraces the non-

maleficence requirement, the beneficence requirement, and respect for autonomy through democratic consultation.

"Justice as Mutual Advantage"

To bring both the critical force and the dramatic consequences of the minimalist view into stark relief, consider a research initiative proposed in 2001 by the pharmaceutical firm Discovery Laboratories. Discovery wanted to conduct a placebo-controlled clinical trial of their new surfactant drug, Surfaxin, in impoverished Latin American communities where neonatal intensive care units are poorly equipped and children do not currently have access to surfactants (substances that are produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen and to maintain proper airflow through the respiratory system). Discovery Laboratories would upgrade and modernize the intensive care units in the host countries so that all of the children in the clinical trial would receive improved medical care. Half of the children in the trial would then receive Surfaxin, and the other half would receive a placebo.

Although Surfaxin was not intended primarily to benefit children in the developing world, Discovery Laboratories and its defenders argued, in effect, that the trial would satisfy the conditions that define the minimalist view. As Robert Temple of the Food and Drug Administration put it, "If they did the trial, half of the people would get surfactant and better perinatal care, and the other half would get better perinatal care. It seems to me that all the people in the trial would have been better off."¹⁸ From this point of view, both the drug company and the host population are better off if the trial takes place than if it does not, so the trial meets the beneficence requirement.

Additionally, in the minimalist view, providing roughly 325 dangerously ill newborns with a placebo does not violate the nonmaleficence requirement because newborns in these communities do not otherwise have access to surfactants—the newborns on placebo are not worse off than they would otherwise have been. The minimalist takes such treatment to be consistent with the relevant "standard of care," which he identifies as the treatment that participants would have received had there been no clinical trial, and then argues that since the standard of care is not reduced, trial participants are not made worse off.¹⁹

Critics of the trial argued vociferously that it was unethical to use a placebo-controlled design and that a

creating scenarios in which *everyone is worse off*.²⁰

This example brings into stark relief one of the more controversial aspects of the minimalist position. The minimalist view accepts the status quo in the host community as the appropriate "normative baseline" against which proposed research initiatives are evaluated—meaning that the status quo is treated as the threshold of a person's moral entitlements in this particular sphere. On this view, the scope and content of the moral claims that research participants can legitimately assert against researchers or their sponsors is determined by the status quo in the counterfactual circumstance in which the trial does not take place and things continue in the host community as they were. Since

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trial not designed to vindicate an intervention specifically for use in the developing world should not be conducted there. As a result, Discovery Laboratories changed the design of the trial and relocated it to the United States. From the standpoint of the minimalist view, however, these critics succeeded only in depriving already burdened populations of benefits that would have resulted in improved medical care and access to life-saving interventions for desperately ill children. Moreover, if the trial showed Surfaxin to be effective, the drug would have been available on the open market. From the perspective of the minimalist, there are many reasons that researchers and their sponsors should be as generous as possible when carrying out international research initiatives, but *requiring* more than the minimalist conditions risks

the beneficence and nonmaleficence conditions also take the status quo as their baseline, the minimalist position appears to offer a operationally precise framework that avoids controversial theories of justice.

But the minimalist's conditions together do constitute a particular view of justice in international medical research, namely what Barry calls "justice as mutual advantage."²¹ Initiatives that meet these conditions are viewed as *fair* because they provide mutually beneficial terms of cooperation that each party can freely accept. But as Barry notes in a discussion of principles of reciprocity or fair play in general, while these principles specify terms that cooperative endeavors must meet in order to be fair, they do not "say that it is unfair for a practice that would, if it existed, be mutually beneficial, not to exist."²² In other words, because justice as reciprocity

requires the existence of a cooperative endeavor, it does not generate any obligation to engage in cooperation where none exists. Nor does it place restrictions on how the relative advantage of each party may influence this bargaining process. The fact that part of what motivates the minimalist position is precisely a recognition of the health needs in the developing world is ironic, then, since nothing in the beneficence or the nonmaleficence requirements indicates that those in the developing world are entitled to more than the status quo outside of the context of international medical research. These conditions only specify entitlements that people have if medical research occurs.

Taken together, these features seem to make the minimalist view attractively realistic. The minimalist does not hold important medical research hostage to moral ideals that, though they may be noble, would ultimately deny both researchers and potential subjects some benefits. Accepting the status quo in the host community as the normative baseline for assessing research captures the way things are on the ground, as it were. To those who would challenge this move, like me, the minimalist will claim that it is not enough to show that people in the developing world are entitled to a higher baseline than their current status quo. One must go further and establish that this entitlement imposes specific requirements on researchers or their sponsoring agencies.

Why the Minimalist Approach Is Inadequate

This familiar approach to international research is at best incomplete, however, and at worst question-begging. The crucial problem is that it screens out precisely the information necessary to determine (a) whether the population in a host community has a legitimate claim or entitlement to more than the status quo, and (b) who, if anyone, has the obligation to meet such claims.

Three key features of the minimalist position screen out morally relevant information. The first of these is that, as just noted, the minimalist accepts the status quo as the appropriate normative baseline for evaluating international research initiatives. As a result, it in effect assumes that members of the host population do not have grounds to claim an entitlement to more or better than they currently receive. Beginning moral inquiry from this starting point, however, simply begs the most important questions of justice. (In order to avoid begging the question, the minimalist must justify this substantive normative claim on independent grounds.)

The minimalist position appears justified in adopting this normative baseline in part because of its failure to situate the health needs of individuals in the developing world within a broader social, political, and economic context—the second feature that screens out morally relevant information. The health of individuals and their ability to influence it is fundamentally shaped by the way basic social structures influence the capabilities and the range of opportunities of those whose lives they govern. Abstracting the health needs of a community from this larger context therefore excludes the information necessary to evaluate the extent to which important rules, practices, and social structures influence those needs. This precludes a cogent assessment of how individuals and other entities, foreign or domestic, have influenced these social structures. Lacking that understanding, we are unable to assess whether identifiable parties have duties to provide individuals in those populations with more or better than they currently experience. Finally, if we do not understand the broader social factors that are responsible for generating or exacerbating the health needs of developing world populations, we are unlikely to attend to the root causes of a community's health problems.

Third, even though the minimalist position recognizes that medical re-

search is a collaborative activity, because it limits the scope of its concern to this one activity, abstracted from its social, political, and economic context, it in effect treats any consideration of the character and quality of the basic social structures in the host community as unnecessary. Those structures are simply treated as given. This prevents one from distinguishing cases in which populations suffer because of the failures of less-than-decent social structures from cases in which decent social structures are overwhelmed by natural disasters. As a result, the minimalist position prevents one from assessing the extent to which individuals in the host community have a legitimate claim against their own government to better conditions. It also keeps one from assessing the influence of third parties, such as foreign governmental and corporate entities, on the community's basic social structures.

The Moral Relevance of Social and Political Determinants of Health

In order to illustrate these points, I consider some parallels between Amartya Sen's groundbreaking work on famine²³ and the broader health needs of developing world populations. Famines are commonly viewed as natural disasters caused principally by a combination of poverty and poor food production. Sen showed, however, that these factors alone do not account for the occurrence of famines. For example, in 1979-1981 and 1983-1984, Sudan and Ethiopia experienced declines in food production of 11 or 12 percent and, like a number of other countries in sub-Saharan Africa, suffered massive famines. During the same period, however, food production declined by 17 percent in Botswana and by a precipitous 38 percent in Zimbabwe,²⁴ yet these countries did not suffer the ravages of famine. According to Sen, the reason for this difference in outcomes can be traced to differences in the social and political structures of

these countries. Botswana and Zimbabwe had rudimentary democratic social institutions that enabled them to stave off famine. They implemented a series of social support programs targeted at enhancing the economic purchasing power of affected groups, while also supplementing food supplies. Mass starvation occurred in Sudan and Ethiopia because the dictatorial regimes in those nations failed to take such relatively simple social and economic steps to safeguard their citizens' interests.

These lessons should broadly inform our view of sickness and disease in the developing world.²⁵ For example, HIV-AIDS is devastating many populations in sub-Saharan Africa. In some nations, as much as 30 percent of the population is HIV-positive and infection rates continue to climb. In sharp contrast, Senegal has been able to limit both the prevalence of HIV-AIDS and the rate of new infections to about 1 percent of the population. The principal cause of Senegal's success lies not in advanced technology or great wealth, but in the government's longstanding, grassroots investment in its human resources. In Senegal, information about HIV-AIDS and many other sexually transmitted diseases has been disseminated through an assortment of educational programs. Such programs represent a particularly prominent instance of the government's willingness to forge ties with community and religious leaders in order to encourage social activism. Empowering individuals with information and opportunities for activism enhances the public's capacities for communal interaction, free expression, and political participation, and so creates a social context in which people can more effectively safeguard and secure their welfare.

This focus on education and activism has been further enhanced by the judicious use of scarce resources. Senegal closely monitors its blood supply and distributes millions of

condoms free of charge. It invests in monitoring and treating many sexually transmitted diseases, especially in target populations such as commercial sex workers, young people, truck drivers, and the spouses of migrant workers. Additionally, as part of a program of perinatal care, it has begun to offer antiretroviral drugs to pregnant women, although on a very limited basis. There remains room for improvement in Senegal. Still, the country's multisectoral approach to HIV-AIDS, and to public health in general, illustrates the positive health effects of policies that strive to protect citizens' basic capacities for agency and welfare.

As these examples show, the basic political, legal, social, and economic institutions of a community have a profound impact on the health status of community members. Because

the service of, the common good of the community's members.²⁶ In other words, a morally permissible division of labor must strive to secure for individuals what Rawls called the "fair value" of their basic capacities for welfare and human agency—meaning that the division of social labor should be designed so as to give each person an effective opportunity to cultivate and use their basic intellectual, affective, and social capacities to pursue a meaningful life plan.²⁷ Social structures that do not meet this minimal requirement create conditions in which some are denied effective opportunities to develop their basic capacities while others enjoy a rich array of opportunities and benefits. In the most extreme cases, these are the social conditions in which starvation, sickness, and disease flourish. The harms that result in such cases cannot

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they determine the distribution of basic rights and liberties within a society, these structures set the terms on which individuals may access basic goods and resources such as food, shelter, education, and productive employment, as well as more specialized health care resources. They therefore determine the opportunities available to individuals to develop and exercise their basic human capacities.

Whether members of a community have a justified claim to something beyond the status quo depends crucially on whether the terms of social cooperation set by the community's social structures can be endorsed by community members as basically fair. As a minimal condition of fairness, it must be possible to see the fundamental structures of a community as organized around, and functioning in

be dismissed as accidents of nature or justified by reference to the common good. They represent a failure to use the state's monopoly on force and control over basic social structures to advance the interests of community members. Those who suffer in these cases can legitimately claim, as a strict obligation of justice, an entitlement to relief from such hardships.²⁸

Duties of Rectification

Now it remains to show how these and similar considerations might alter or affect the rights and obligations of researchers and their sponsoring entities. To do so, I shall distinguish three classes of issues that might affect the obligations of researchers and their sponsoring entities.

When the minimalist view excludes consideration of the broader social, political, and economic context in which research takes place, it screens out the kind of information that would reveal whether the researcher has relationships to groups or organizations that have contributed to the plight of members of the host community. These relationships, if they exist, could generate a special duty to aid those populations, grounded in a duty of rectification.²⁹

At the most general level, duties of rectification may attach to all citizens of democratic nations whose policies and international activities have contributed to the plight of those in the developing world. In a series of recent articles, Thomas Pogge has argued that Western democratic nations have contributed greatly to the poverty and poor health of the global poor simply by recognizing and supporting what he calls the “international resource privilege.” Any group that succeeds in wresting control of the national government in a developing country is recognized as having the legitimate authority “to borrow in the name of its people and to confer legal ownership rights for the country’s resources.”³⁰ Not only does the existence of this privilege provide a powerful incentive for the unscrupulous to seize power in a developing nation, but it provides a convenient mechanism for consolidating power and then wielding it for the enrichment of a privileged few.³¹ Employing power in this way, of course, can saddle a developing nation with disastrous long-term debt and prevent most of the population from sharing in the benefits generated by their country’s natural resources. Instead, the benefits are enjoyed primarily by a ruling elite in the developing world and by governments and corporations in the developed world.

A duty to aid grounded in this kind of pre-existing relationship would apply to medical researchers insofar as they are citizens of the basically democratic nations that have contributed to and benefited from

such policies. The obligations may be strengthened if researchers are employed or funded by governments or private entities that have actively supported such policies. Alternatively, duties of rectification may attach to researchers who work for or are funded by entities that have contributed more directly to the plight of developing world populations. For example, one reason drugs are so scarce in the developing world is their cost. Many individual pharmaceutical companies played an active role in the negotiation of the TRIPS agreement at the World Trade Organization, and the pharmaceutical lobby has used its considerable influence on U.S. and E.U. trade representatives to enforce the companies’ patent rights. The TRIPS agreement allows countries to produce or import generic versions of beneficial medications in cases of national emergency, but the Western pharmaceutical industry has aggressively pressed for trade sanctions or taken active legal action against countries that have tried to implement this emergency clause.³² In doing so, it has blocked legitimate efforts to provide medicines to some of the populations that need them most.

Unmet Obligations within Host Communities

As I noted, one of the defining problems of social structures that violate the minimal condition of basic fairness is that those structures fail to allocate scarce social resources around the goal of serving the common good. By failing to invest scarce social resources in the basic capacities of community members and denying the population access to social resources to which they have a legislative claim, they help to create conditions of deprivation in which sickness and disease flourish.

In such cases, resources that domestic authorities may be willing to make available for research purposes may not be “available” in a more fundamental moral sense: those who control them may have a prior moral

obligation to deploy them in the service of other ends.³³ Moreover, although the use of monetary and material resources may be particularly important in this regard, there are other social resources that matter as well. For example, regimes can fail to serve the common good by neglecting basic social institutions altogether, by misappropriating or misdirecting the time and energies of their personnel, or by inappropriately restricting or occupying important institutional spaces. These failures can generate prior moral claims that the community members have against their own authorities, and such claims may constrain the range of cooperative or collaborative relationships in which researchers may permissibly engage.

Depending on the particulars of different cases, some of these factors may be more relevant than others. The fact that the minimalist view excludes as irrelevant the information that makes it possible to determine both the presence and the significance of such factors illustrates the poverty of that approach.

Taking Basic Interests Seriously

Duties of rectification and unmet obligations within host communities are both rooted in pre-existing relationships. To this extent, they are consistent with the minimalist’s assumption that questions of justice arise only within the terms of a cooperative relationship. But this view of justice itself has serious shortcomings, as the following hypothetical at least begins to show.

Assume that researchers and entities from the developed world do not have any prior relationships with populations in the developing world and, in addition, that no international research initiative would utilize any material, institutional, or human resources from the host community. Would the minimalist’s conditions ensure that fair terms of cooperation exist between researchers and potential trial participants since trial partic-

ipants would still stand to benefit from research participation? Certainly the research initiative would not move them as far above their baseline as they might be entitled, but perhaps this would not then be an entitlement that could be asserted against researchers and their sponsors.

Were this the case, the toll that morally problematic social structures exact from individuals in the developing world would constitute something of a boon for medical research. Clinical trials can be inefficient in developed countries in part because it takes a long time to recruit subjects when the condition one wants to study is not common and when potential participants have access to health care alternatives. In the developing world, by contrast, medical conditions are often widespread, and potential participants frequently have few treatment alternatives.³⁴ These purely structural features put research sponsors

in a much stronger bargaining position than members of the host community in the developing world. Whereas the needs of the community are urgent and often time sensitive, sponsors can usually find alternative locations for a trial, and they may have less at stake than the community members if negotiations drag out. Moreover, whatever their individual preferences, researchers are frequently under pressure from funding agencies to use scarce resources only for research purposes, narrowly construed, which puts a cap on the kind of benefits that researchers can offer a host population even if they want to offer more.

If this characterization is right, then the commitment to a *bargaining* model for determining just outcomes is one of the problems with the minimalist position. The requirement that acceptable bargains must provide each party with a net benefit is perfectly consistent with agreements in which the distribution of those benefits is hugely disproportionate. More-

over, such results may actually be encouraged by the use of a bargaining model, since a bargaining model assumes each side has a rational incentive to provide as few concessions as possible in exchange for as large a return as possible. Similarly, since this framework defines as "fair" any outcome the host community is willing to accept, it recognizes no moral grounds on which to object to lopsided divisions of benefits that reflect such dramatic imbalances in power.

By allowing inequalities in power to justify inequalities in entitlements, this view effectively accepts Hobbes's view that "the value or worth of a man is, as for all other things, his

to portray rampant sickness and disease in the developing world as a threat to global prosperity or national security—to the affluence and security of the developed world.³⁶ This highlights important deficiencies in the minimalist approach: The minimalist view does not require or facilitate a focus on root causes; instead, to the extent that it benefits the developing world at all, it leads people to address the symptomatic manifestations of deeper problems. Furthermore, the minimalist view encourages a piece-meal and ad hoc approach to the needs of those in the developing world, for two reasons. It allows the decision to provide aid to be deter-

The human development approach begins from a premise that has deep roots in liberal political theory—namely, the idea that justice is properly about basic social structures and whether those structures guarantee community members the "fair value" of their most basic human capacities.

price, that is to say, so much as would be given for the use of his power; and therefore is not absolute, but a thing dependent on the need and judgment of another."³⁵ Disease and lack of access to medical care function as valuable commodities whose use-value gives people a place at the bargaining table. Those who lack the "good fortune" to suffer from a condition interesting to science are consigned to die in silence because the power differential in their case is so great that they cannot either help or harm potential collaborators. The minimalist position does not deny that, from the moral point of view, equals should be treated equally. However, it allows equality to be defined—often implicitly—by power: those who are equally situated in their capacity to help or to harm one another deserve equal treatment.

Within the minimalist framework, those who care about the plight of disadvantaged people simply because they are fellow human beings are forced to resort to eloquent attempts

mined primarily by interests in the developed world rather than by needs in the host community, and it does not differentiate between types of need that research might address.

At a deeper level, however, the debate about justice and international medical research needs to confront explicitly the more traditional liberal view that how power is distributed and exercised is itself a question that falls under the purview of a theory of justice.³⁷ After all, the distribution and exercise of power has a profound impact on other fundamental aspects of human agency and experience that provide far less arbitrary grounds for claims to equal consideration from the moral point of view.³⁸ When we approach the problem of assessing potential collaborative research initiatives from this broader perspective, therefore, we must at the very least leave conceptual room to consider whether the interests that are frustrated or defeated by less-than-decent social structures are so fundamental as

to generate a duty on the part of others to assist them.³⁹

It is a fact of the contemporary world that even moderately affluent individuals and entities have the ability to affect the lives of distant people. It is also a fact of the contemporary world that whether people are able to cultivate basic capacities for agency and welfare, and to live a life in which they find meaning and value, is too often determined by their place of birth rather than by any features of their individual character. These facts have led a variety of moral theorists to argue that claims of justice cannot be limited to the boundaries of the contemporary nation-state.⁴⁰ Although these theorists' arguments may be controversial, they are both coherent and compelling. Yet the minimalist position leaves no conceptual space within which such possibilities might be articulated and assessed.

In the end, I suspect that we have more than enough moral reasons to aid those in the developing world. If we take the basic interests of others as especially strong reasons for acting, then we cannot remain indifferent to the plight of those living in poverty, disease, and social deprivation. This duty may apply broadly to people in the developed world, but it would be particularly relevant to researchers and their sponsoring entities, whose activities directly affect people in the developing world. Those in the developed world who have actually contributed to the underlying social factors that create and perpetuate conditions of deprivation in the developing world would have special duties to provide aid there. Medical researchers may incur such obligations insofar as they are citizens of basically democratic nations whose policies have contributed to stark global inequalities, or insofar as they are funded by entities with such obligations.

Some of these factors may be more salient in some situations than in others. At the very least, they illustrate that an adequate framework for evaluating the ethics of international research initiatives must be robust

enough to assess the relevance of these factors in particular cases and to incorporate the results of this assessment into its evaluation of particular research initiatives.

The Human Development View

I have argued that the minimalist approach to justice in international research has several fundamental deficiencies. The first stems from the extent to which it abstracts the health needs of developing world populations from the broader social, political, and economic context in which they exist. The second stems from the way it evaluates proposed collaborative research partnerships in isolation from the web of existing social, political, and economic relationships in which the parties are already enmeshed. As a result of these two deficiencies, it prevents us from understanding whether populations in the developing world have a legitimate claim to better conditions. Similarly, because it treats all cases of collaborative research as though no grounds for such claims exist, it accepts a bargaining model that permits researchers and their sponsoring entities to carry out research initiatives in the developing world that serve the interests of populations in the developed world as long as the host population gets some benefit it is willing to accept. Given the nature of this particular bargaining model and the dramatic disparities in bargaining power that will shape this process in the real world, however, the minimalist approach does little to bring attention to the root causes of the developing world populations' most pressing health needs. As a result, it perpetuates an ad hoc and piecemeal approach to the health needs of populations that already bear the greatest burden of disease and deprivation.

Now I turn to an approach to international research that overcomes these deficiencies. What I call the human development approach begins from a premise that has deep roots in liberal political theory—namely, the

idea that justice is properly *about* the basic social structures I have mentioned here and whether those structures guarantee community members the "fair value" of their most basic human capacities.⁴¹ It uses this idea to define a particular vision of human development and to assess both the health needs of host communities and the terms on which collaborative research initiatives may be carried out. It then holds that the duty to aid people in the developing world should be understood as a duty to engage our energies and resources in this project.⁴² Finally, it uses this larger framework to specify the proper scope and limits of collaborative international research initiatives and the extent to which they can play a role in discharging the duty to aid.

To begin with, "human development" is understood in this view as the project of establishing and fostering basic social structures that guarantee to community members the fair value of their most basic human capacities. This project is grounded in the recognition that perhaps the most important determinant of health within a community is the extent to which its basic social structures guarantee members of the community opportunities for education, access to productive employment, control over their person and their personal environment, access to the political process, and the protection of their basic human rights.⁴³ More important than the sheer economic wealth of a community, in fact, is whether the community directs the available resources to creating and sustaining the right social conditions.⁴⁴

Because the health status of individuals is affected by a matrix of political, social, and economic factors, the project of creating and sustaining the conditions that foster health requires a coordinated, multisectoral approach that is sensitive to these interrelationships. The health-related institutions of a community, including its public health and health care institutions, can contribute to this process in two fundamental ways.

First, they can facilitate development by targeting rudimentary health problems that can impede the ability of community members to function in ways essential to the development process.⁴⁵ Literacy and education are powerful determinants of a person's ability to safeguard her own health and take advantage of economic opportunities; providing basic nutrition and rudimentary health care are therefore important because the sick and undernourished are less likely to attend school and less able to concentrate and to learn if they do.

Second, health-related institutions address health needs of community members that persist as the process of development proceeds. In other words, although other elements of the basic social structures of the community provide individuals with some important social determinants of health—education, nutrition, and respect for basic human rights—the health-related institutions target the health needs of individuals that these other measures do not alleviate.

The human development approach treats clinical research as one important element within this larger division of labor. The research enterprise represents a permissible use of a community's scarce public resources and is a permissible target of social support when it functions to expand the capacity of the basic social structures of that community to better serve the fundamental interests of that community's members. Therefore, if clinical research is to be permissible, it must function as a part of a division of labor in which the distinctive scientific and statistical methods of the research enterprise target and investigate the means of filling the gaps between the most important health needs in a community and the capacity of its social structures to meet them.⁴⁶

When the human development approach is applied to the research carried out within liberal democratic nations of the developed world, it

captures important ideals that are often explicitly embraced by developed communities. In different ways and with varying degrees of success, these communities recognize the need to invest in a robust array of social institutions that protect community members' basic social, political, and economic opportunities, thereby safeguarding the social determinants of health. These ideals help to attract public support for health care and public health institutions. Significant public support is also provided to domestic clinical research as an engine of discovery that can push back the boundaries of knowledge in order to enhance the community's health-related institutions. *As a result, these communities often assess research that receives public support by asking how it is contributing to equity in the capacity of the community's health care institutions to address the needs of the diverse populations that those institutions serve.*⁴⁷

ment approach also provides a framework for assessing the extent to which researchers and their sponsoring entities must secure additional resources to make the fruits of successful research available to members of the host population, or to provide ancillary benefits. The imperative to try to make the results of successful research available within the host community increases in inverse proportion to the capacity of that community's basic social structures to translate those results into sustainable benefits for community members. To the extent that the host community cannot translate the results into sustainable benefits for its population on its own, an imperative exists either to build partnerships with groups that would be willing to augment the community's capacity to do so, or to locate the research within a community with similar health priorities and a more appropriate health infrastructure. Similarly, the imperative to provide

The human development approach holds that research initiatives are permissible only if they expand the capacity of the host community's basic social structures to meet the community's health priorities.

In the international context, the human development approach holds that collaborative research initiatives are permissible only if they are a part of, or contribute to, a fair social division of labor in the host community. In particular, they must directly and indirectly expand the capacity of the host community's basic social structures either to meet the distinctive health priorities of that community's members or to meet their basic health needs under distinctive social or environmental circumstances.⁴⁸ Health needs are distinctive and are prioritized according to whether they cannot be ameliorated through the application of existing knowledge and resources.

Once this necessary condition has been satisfied, the human develop-

an array of ancillary benefits to community members increases in inverse proportion to the community's capacity to treat or ameliorate the ancillary health problems that researchers are likely to encounter. This imperative is best understood as a duty to partner with governmental and nongovernmental agencies to use the research enterprise as a kind of anchor point around which aid can be coordinated. Such obligations are most pressing in exactly those cases in which community members have the strongest claims to assistance.

Human Development and the Duty to Aid

In the human development view, the duty to provide aid in the develop-

ing world is understood as a duty to create and sustain social structures that secure individuals' capacities for welfare and human agency. As a result, this approach specifies the conditions under which clinical research represents a permissible means of discharging the duty to aid. It is worth emphasizing, therefore, some respects in which the human development approach attempts to forge a bridge between the non-ideal circumstances in which we live and the aspirational goal of alleviating the most severe impediments to the health and welfare of populations in the developing world.

To begin with, when a duty to aid exists, it is owed equally to all with an equal claim. When evaluating potential means of discharging this duty, therefore, we must give priority to responses that strive for what Henry Shue refers to as full coverage.⁴⁹ As Shue notes, one of the basic functions of decent social institutions is to create a division of labor in which particular duties are assigned to individual agents or groups of agents. Where no single person could discharge a duty to aid every individual in the developing world, social institutions can provide a mechanism through which duty bearers can pool and magnify their individual efforts.

A central focus of international aid efforts should be an investment of monetary and human capital in improving the basic social institutions in developing countries, including what Prabhat Jha and colleagues refer to as the "close-to-client" health system in these countries.⁵⁰ Even a relatively modest increase in international aid targeted in this way would transform the health needs of community members.⁵¹ After all, 90 percent of the avoidable mortality in low and middle-income countries stems from a handful of causes for which effective interventions already exist.⁵²

Although much more needs to be done to make the fruits of existing knowledge available to the most burdened communities, the human development approach recognizes that

collaborative international research still has an important role to play in fostering development. Existing interventions must still be augmented with new or improved vaccines, antibiotics, and other tools. While the burden of rectifying past injustices and the harmful legacy of unjust social institutions cannot be laid entirely at the feet of researchers, researchers and their sponsors can make a distinctive contribution to this effort by *investigating ways of filling the gaps between a community's health needs and the capability of its social institutions to meet those needs*. By requiring that international research target health needs that cannot be feasibly or more efficiently met with existing knowledge and resources, the human development approach articulates the conditions under which clinical research can help narrow the 10/90 research gap.

At the institutional level, therefore, the human development approach requires changes in how international research is evaluated. Mechanisms need to be developed to facilitate reflection by various stakeholders, at various stages of research development, on how research might promote human development. We must move away from an over-reliance on the largely reactive IRB review mechanism toward a more proactive model in which issues of justice are considered much earlier in the research process. The human development view is not intended as a punitive tool that IRBs can use to frustrate valuable research. It is intended to provide a framework that informs the deliberations of researchers, research sponsors, and governmental and private entities as they make decisions about what scientific questions should be explored, which research initiatives should be funded, where research should be carried out, and how research can benefit those who most need aid.

This view of development also provides a needed corrective to what amounts to an inappropriately narrow focus on inequalities in income

or wealth in the literature on global justice. A common theme in this literature is that the duty to aid requires a significant transfer of wealth from developed to developing nations. Carrying out this redistribution of wealth would supposedly alleviate the conditions of poverty that provide the ecological niche in which sickness and disease flourish. Similarly, greater economic prosperity would provide the extremely poor with a broader range of opportunities and the resources necessary to meet more of their most basic needs.⁵³ To be sure, the development and maintenance of basic social structures is not cost free, and failure to provide monetary and socio-political support for the reform or expansion of such structures will impede a community's ability to achieve full coverage. But whether a transfer of resources will improve the social and economic conditions of community members depends crucially on the ends to which such resources are employed. Filling the pockets of regimes that do not employ existing resources to safeguard and secure the basic interests of all citizens does not guarantee that additional resources will trickle down to community members. For these reasons, even if those in the developing world are owed a greater share of global resources, the duty to aid must target more than financial transfers. It must focus on improving those elements of the host community's basic social structure that affect individual agency and social opportunity, while taking interim steps to mitigate the adverse effects of existing social structures on the health and welfare of those who are subject to them. This dual focus on resources as well as individual agency and social opportunity is central to the kind of multisectoral approach that defines the human development view.

Even if one does not recognize a duty to aid, however, or even if one recognizes the duty but believes it will not soon be honored on a large scale, this approach still provides a more equitable foundation for a collaborative

partnership between communities. It permits researchers to target interventions that will enhance health structures in the developed world only under the condition that the same benefits accrue to the host population. This condition is easily fulfilled, for example, when developed countries collaborate on research that targets a common problem. When doing research in developing nations, it might be fulfilled if researchers can find host communities in which the target of a research program represents a health priority and where the resulting intervention could be implemented within the health structures of the host community. Once the appropriate match between research target and community is achieved, attention can focus on how best to coordinate the efforts of local and foreign entities to use this research as an anchor for coordinating ancillary benefits aimed at enriching the community's other important social structures.

Microbicides and Surfaxin

Let me close with an illustration. Consider the justification for international research aimed at finding a safe and effective vaginal microbicide, an agent delivered in gel form that would reduce the odds of HIV transmission, and perhaps secondary STI transmission, during heterosexual, vaginal intercourse.⁵⁴

Enhancing the basic capabilities and social opportunities of women is an important development goal.⁵⁵ Roughly half of the global burden of HIV/AIDS is borne by women, and in southern Africa more than one in five pregnant women are HIV-positive.⁵⁶ The complications of HIV/AIDS are increasing maternal death rates during labor, and vertical or maternal-fetal transmission of HIV still accounts for approximately 90 percent of new pediatric HIV infections—600,000 annually—the vast majority of which occur in the developing world. When used properly, condoms are good at preventing hori-

zontal or partner-to-partner transmission of the HIV virus. But condoms are often not used consistently because men often dislike them and men tend to have more control than women over what happens in their relationships. As a result, the range of options available to women—who are already a disadvantaged social group and have a higher susceptibility to contracting HIV from heterosexual intercourse than men⁵⁷—may be further restricted by men's preferences and behavior.

Developing a safe, effective, and affordable microbicide would thus contribute to several important development goals. It would provide an intervention that expands the range of options available to women to safeguard their own health. Given the influence of gender inequalities on condom use, this positive effect would not necessarily be achieved just by emphasizing condom usage more strongly. Also, because it could help to reduce the frequency of HIV transmission to women, it could contribute to a reduction in transmission to children. Finally, by targeting the needs of an often disadvantaged subpopulation within the larger host population, such research would contribute to social equity.

Similar arguments could be mounted on behalf of vaccine research and more effective treatments for a variety of tropical diseases. They cannot be marshaled in support of initiatives like the Surfaxin trial. Several effective surfactant agents are widely used in the developed world, and there is nothing about Surfaxin that would make it particularly attractive to communities in the developing world. Many Latin American countries need improved neonatal care, but that need could be more effectively and efficiently addressed, for larger numbers of people and on a more sustainable basis, with existing medical knowledge and resources.

From the minimalist standpoint, this conclusion looks inefficient because it prevents Discovery Laboratories from expeditiously pursuing its

research agenda and along the way benefiting people in the developing world. This view, however, presupposes that there is no significant moral obligation to aid that is prior to and independent of the terms of a proposed research initiative. If this presupposition is rightly abandoned, we can focus on the more pressing issue, namely, the inefficiency of trying to benefit communities in the developing world by endorsing an effort to provide an ad hoc patchwork of benefits in exchange for participating in trials that are targeted at the health needs of developed world populations. From this standpoint, it is the minimalist position that is inefficient: it represents an extremely inefficient means of closing the 10/90 gap and addressing the most pressing health priorities of communities in the world that suffer the heaviest burdens of disease and deprivation.

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 18. S. Shah, "Globalizing Clinical Research," *The Nation*, July 1, 2002, 23-28, at 28.
 19. For a similar statement in the context of perinatal HIV intervention trials, see C. Grady, "Science in the Service of Healing," at 36. For critical assessment of such views, see A.J. London, "The Ambiguity and the Exigency: Clarifying 'Standard of Care' Arguments in International Research," *Journal of Medicine and Philosophy* 25, no. 4 (2000): 379-97.
 20. There may be cases, however, where the minimalist will require that researchers or their funding agencies make the fruits of a research initiative available in a stronger sense. If, for instance, the host population itself must allocate significant resources to carry out a clinical trial—whether in terms of money, personnel, or something else—then a stronger guarantee might be needed to ensure that the research initiative as a whole does not violate the beneficence requirement. That is, guarantees of free access or price reductions may be required. Such guarantees compensate for the burdens assumed by the community in facilitating the particular research initiative. Here again, though, the reasons for requiring such an agreement derive from the more fundamental need to ensure that the nonmaleficence and the beneficence conditions are met, and respect for the autonomy of the host community requires that it judge whether the compensations repay the costs.
 21. B. Barry, *Theories of Justice* (Berkeley: University of California Press, 1989), 8.
 22. B. Barry, "Humanity and Justice in Global Perspective," in *Ethics, Economics, and the Law*, ed. Pennock and Chapman, 231.
 23. A. Sen, *Poverty and Famines* (Oxford: Clarendon Press, 1981), and A. Sen and J. Dreze, *Hunger and Public Action* (Oxford: Clarendon Press, 1989).
 24. A. Sen, *Development as Freedom* (New York: Anchor Books, 1999), 178-80.
 25. This point has been argued persuasively in numerous contexts by Solomon R. Benatar. See S.R. Benatar, "Justice and Medical Research: A Global Perspective," *Bioethics* 15, no. 4 (2001): 333-40; S.R. Benatar, "Global Disparities in Health and Human Rights: A Critical Commentary," *American Journal of Public Health* 88, no. 2 (1998): 295-300; and S.R. Benatar, "The HIV/AIDS Pandemic: A Sign of Instability in a Complex Global System," *Journal of Medicine and Philosophy* 27, no. 2 (2002): 163-77. See also A.A. Van Niekerk, "Moral and Social Complexities of AIDS in Africa," *Journal of Medicine and Philosophy* 27, no. 2 (2001): 143-62.
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 27. For the concept of "fair value" applied to basic liberties, see J. Rawls, *A Theory of Justice* (Cambridge: Harvard University Press, 1971). For the link between this concept and human capabilities, see C.M. Korsgaard, "Commentary: G.A. Cohen: Equality of What? On Welfare, Goods and Capabilities and Amartya Sen: Capability and Well-Being," in *The Quality of Life*, ed. M.C. Nussbaum and A. Sen (Oxford: Oxford University Press, 1993): 54-61.
 28. It is a central tenet of liberal political theory that control over public resources and the operation of social structures is justified only to the extent that they serve the common good of those whose lives they govern. In Locke, for example, this claim is expressed in the idea that legitimate authority is vested in governmental entities in the form of a trust that grants the government discretion in the exercise of authority only insofar as its activities are consistent with the central objective of the trust itself: advancing the good of the people.

29. This argument is briefly explored in the context of international research in R.A. Crouch and J.D. Arras, "AZT Trials and Tribulations." It also figures prominently in the articles by Solomon Benatar cited above. For the most explicit articulation of duties of rectification, see R. Nozick, *Anarchy State and Utopia*, (New York: Basic Books, 1977).

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31. T.W. Pogge, *World Poverty and Human Rights* (Cambridge: Polity Press, 2002), chs. 4 and 6.

32. U. Schüklenk and R.E. Ashcroft, "Affordable Access to Essential Medications in Developing Countries: Conflicts between Ethical and Economic Imperatives," *Journal of Medicine and Philosophy* 27, no. 2 (2002): 179-95. C. Barry and K. Raworth, "Access to Medicines and the Rhetoric of Responsibility," *Ethics & International Affairs* 16, no. 2 (2002): 57-70.

33. The claim that social resources may not be morally free for research purposes need not presuppose that there is a one-to-one correspondence between any particular basket of resources and the entitlements of a specific individual. In other words, we need not be able to identify a specific person who is entitled to the time of a particular official or to the use of a particular institutional space. It presumes, rather, that a necessary condition for the moral authority to control important social resources is that such control be directed at providing full coverage to the basic rights of those affected. In other words, one of the basic functions of decent social institutions is to facilitate a division of labor in which specific individuals are assigned the special duty of matching or assigning baskets of social resources to individuals with the appropriate claim. Full coverage, therefore, refers to the goal of being able to address each legitimate claim in a meaningful way. On the concept of "full coverage" see H. Shue, "Mediating Duties," *Ethics* 98, no. 4 (1988): 687-704.

34. On these factors as "selling points" for using developing world populations in medical research see J. McManus and T. Saywell, "The Lure to Cure," *Far Eastern Economic Review*, February 8, 2001, 32-37.

35. T. Hobbes, *Leviathan* X, 16.

36. D.L. Heymann, "The Urgency of a Massive Effort against Infectious Diseases."

37. S. Freeman, "Reason and Agreement in Social Contract Views," *Philosophy and Public Affairs* 19, no. 2 (1990): 122-57.

38. On different efforts to define the space of moral equality and for a defense of a particular version of the capabilities approach see E.S. Anderson, "What is the

Point of Equality?" *Ethics* 109 (1999): 287-337.

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49. Shue, "Mediating Duties."

50. Ibid.

51. Pogge, "Responsibilities for Poverty-Related Ill Health," at 79.

52. Jha et al., "Improving the Health of the Global Poor."

53. See G. Sreenivasan, "International Justice and Health: A Proposal" *Ethics & International Affairs* 16, no. 2 (2002): 81-90. Sreenivasan claims that "Any plausible and complete ideal of international distributive justice . . . will at least require better-off states to transfer *one percent of their gross domestic product* (GDP) to worse-off states." See also T.W. Pogge, "Eradicating Systematic Poverty: Brief for a Global Resource Dividend," *Journal of Human Development* 2 (2001): 59-77.

54. On microbicides, see A. Stone, "Microbicides: A New Approach to Preventing HIV and Other Sexually Transmitted Infections," *Nature Review Drug Discovery* 1, no. 12 (2002): 977-85.

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