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THE DISTRIBUTION OF BIOMEDICAL RESEARCH RESOURCES AND INTERNATIONAL JUSTICE

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ABSTRACT

According to some estimates, less than 10% of the world's biomedical research funds are dedicated to addressing problems that are responsible for 90% of the world's burden of disease. This paper explains why this disparity exists and what should be done about it. It argues that the disparity exists because: 1) multinational pharmaceutical and biotechnology companies do not regard research and development investments on the health problems of developing nations to be economically lucrative; and 2) governmental agencies that sponsor biomedical research face little political pressure to allocate funds for the problems of developing nations. This paper argues that developed nations have an obligation to address disparities related to biomedical research funding. To facilitate this effort, developed countries should establish a trust fund dedicated to research on the health problems of developing nations similar to the Global AIDS Fund.

INTRODUCTION

The distribution of resources for research and development (R&D) in biomedicine has a direct impact on the progress of the health sciences and the distribution of health. Money spent on biomedical R&D can have a positive impact on disease and disability, longevity, infant mortality, and other measures of the health of a population.[1] Differences in research funding can also

[1] D. Resnik. Setting Biomedical Research Priorities: Justice, Science, and Public Participation. *Kennedy Institute of Ethics Journal* 2001; 11: 181–204.

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be a factor in racial and ethnic health disparities. For many years there have been racial and ethnic disparities in health in the United States (US). While many different factors, such as poverty, discrimination, and educational attainment contribute to these disparities, inadequate research on health problems unique to racial and ethnic minorities also plays a role. In an attempt to address racial and ethnic differences in cancer incidence, mortality and treatment, the National Cancer Institute has developed a programme to fund research on problems uniquely affecting minority and medically under-served groups.[2]

If one compares the developed and the developing world, one also finds great disparities in many different health indicators, such as life expectancy, infant mortality, disability, and quality of life. Once again, many different factors, such as poverty, overpopulation, famine, education, culture and religion, and political and military turmoil, are responsible for these disparities. However, there is little doubt that the global distribution of biomedical research resources plays some role in the health gap between rich and poor countries and that closing this gap would probably have a positive impact on the health of developing nations. According to some estimates, less than 10% of the world's biomedical R&D funds are dedicated to addressing problems that are responsible for 90% of the world's burden of disease.[3] Multinational corporations and government agencies of the developed world spend billions of dollars each year on R&D pertaining to diseases that are of great concern to populations in developed societies, such as cancer, heart disease, diabetes, obesity, and hypertension, while they allocate far less money to research on diseases that are of special concern to the developing world, such as malaria, tuberculosis, yellow fever, and dysentery. (Hereinafter, this paper will refer to this funding disparity as the 90/10 divide.)

This paper will explain why the 90/10 divide exists and what should be done about it. It will argue that the divide exists

[2] Institute of Medicine. 1999. *The Unequal Burden of Cancer*. Washington. National Academy Press.

[3] S. Benatar. Avoiding Exploitation in Clinical Research. *Cambridge Quarterly of Healthcare Ethics* 2000; 9: 562–565. 'Burden of Disease' is a measurement of several different factors related to the impact of a disease on individuals and society including the incidence of the disease, mortality rate, the degree of disability caused by the disease, the impact of the disease on life expectancy, economic and social aspects of the disease, and public health considerations. See: Institute of Medicine. 1998. *Scientific Opportunities and Public Needs: Improving Health Priority Setting and Public Input at the National Institutes of Health*. Washington, DC. National Academy Press.

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because: 1) multinational pharmaceutical and biotechnology companies do not regard R&D investments on the health problems of developing nations to be economically lucrative; and 2) government biomedical research agencies face little political pressure to allocate funds for the problems of developing nations. This paper will argue that the 90/10 divide is unjust, and that developed nations have a moral obligation to address these disparities related to biomedical research funding. To facilitate this effort, developed countries should establish a trust fund dedicated to research on the health problems of developing nations similar to the Global AIDS Fund.

UNDERSTANDING THE 90/10 DIVIDE

To understand the causes of the 90/10 divide, one must explore the economic and political factors that affect R&D funding. First, most of the funding for biomedical R&D is provided by developed nations. From 1981–1995, 12 nations from the developed world – Australia, Canada, Denmark, France, Germany, Italy, Japan, the Netherlands, Sweden, Switzerland, the US, and the United Kingdom (UK) sponsored 80% of all the R&D in the world, with the US by far the leading sponsor of R&D.[4] In 1995, the US spent almost as much on basic research ($41 billion) as ten of the other top countries combined, excluding Japan.[5] For most countries in the developed world, the government is the main sponsor of R&D, although the contributions of private sources of funding, i.e. corporations or foundations, have been increasing over the last decade.[6] In the US, UK, Japan, Sweden, and Switzerland, private funding sources outspent public funding sources by at least a 1.8 to 1 ratio.[7]

In the US, there are four main sponsors of R&D: private industry, which sponsors approximately 60% of R&D; government

[4] R. May. The Scientific Investment of Nations. *Science* 1999; 281: 49–55. Note: these data do not include Israel or Russia, two other developed nations that sponsor a great deal of R&D. It is important to discuss both research (R) and development (D). Research occurs when scientists make a new discovery or invention. Development takes place when engineers and technicians develop reliable methods and procedures for manufacturing, packaging, storing, labelling, and distributing a product derived from the new discovery or invention.

[5] May, *op. cit.* note 5.

[6] Ibid.

[7] Ibid.

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agencies (35%); colleges and universities (3%); and private foundations (2%).[8] Private corporations are by far the leading sponsors of biomedical R&D in the US. In 2001, pharmaceutical and biotechnology companies located in the US spent $45.6 billion on R&D, and 70% of the clinical trials in the US were sponsored by private industry.[9] From 1998–2003, the NIH budget nearly doubled from $15 billion to $27.3 billion. Funding for the NIH is expected to level off in 2004.[10]

Private foundations in the US spent no more than $2 billion on biomedical R&D in 2001.[11] While this amount appears small compared to the billions spent by private companies or government agencies, it is a very significant and growing source of funding, especially for R&D that addresses the problems of the developing world. Indeed, most private foundations that sponsor biomedical R&D seek to distinguish themselves from government and industry sponsors by attempting to bridge the gaps in R&D funding. Private foundations have historically been able to sponsor research that was economically risky or politically unpopular.[12] A good example of this strategy is the Bill and Melinda Gates Foundation, which has focused on addressing global health disparities. Since its establishment in 2000, the Foundation has raised a $24 billion endowment and has spent approximately $3 billion on global health grants, including $500 million on AIDS research and prevention, $100 billion on tuberculosis research and prevention, and $750 million on vaccine research.[13] Another significant private foundation in the US is the Howard Hughes Medical Institute, which spent just over $600 million on biomedical research in 2001.[14] The largest private foundation for

[8] A. Jaffe. Trends and Patterns of Research and Development Expenditures in the United States. *Proceedings of the National Academy of Sciences* 1996; 93: 12658–12663.

[9] D. Resnik. Setting Biomedical Research Priorities in the 21st Century. *Virtual Mentor* 2003; 5: 7. Available at: http://www.ama-assn.org/ama/pub/category/10571.html (accessed July 23, 2003).

[10] D. Korn, R.R. Rich, H.H. Garrison, S.H. Golub, M.J.C. Hendrix, S.J. Heinig, B.S. Masters & R.J. Turman. The NIH Budget in the 'Postdoubling' Era. *Science* 2002; 296: 1401–1402.

[11] J. Cohen. Philanthropy's Rising Tide Lifts Science. *Science* 1999; 286: 214–222.

[12] Ibid.

[13] Bill and Melinda Gates Foundation. Global Health. Available at: http://www.gatesfoundation.org/GlobalHealth/ (accessed July 22, 2003).

[14] Howard Hughes Medical Institute. 2003. Disbursements in Fiscal 2002. Available at: http://www.hhmi.org/about/a610.html (accessed July 22, 2003).

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biomedical research in the UK, the Wellcome Trust, spent about $600 million on research in 2001.[15]

Since most of the world's R&D is sponsored by developed nations, to understand the 90/10 divide one must explore how private companies and government agencies in the developed world allocate their R&D funds. In examining the methods that private firms use to make R&D allocation decisions, one must bear in mind that private firms are in business to make a profit, and that they do this by selling or licensing drugs, biologics, and medical devices. R&D on a new drug or biologic is very expensive. According to industry estimates, it takes an average of 10–12 years and $800 million to develop a new product and bring it to the market.[16] To protect their R&D investments, companies apply for patent protection over their products. During the term of the patent, which usually lasts 20 years, the company will have exclusive rights to make, use, or commercialise its invention. Once the patent expires, the company will still have exclusive rights over the trademarked name that designates its invention, but other companies can make, use, or commercialise the invention under a non-trademarked (generic) name. Thus, a private company will usually have about 8–10 years to recoup its R&D investment while the product is still under patent. Although pharmaceutical companies tend to have high profit margins (10% or greater), R&D funding in biomedicine is a risky business. About 1/3 of new drugs are profitable, and even less become drug 'blockbusters', such as Viagra or Prozac. Companies must also frequently withdraw profitable drugs from the market, due to safety concerns or litigation.[17]

Given these economic facts, it is easy to see why companies decide to set R&D priorities based on factors that affect the profitability of a new product, such as the size of the potential market, consumer demand, the scope of intellectual property protection, the expected time from the laboratory to the market, and liability costs. Very few private companies are interested in spending money on developing vaccines for diseases that afflict the developing world, since consumer demand for these drugs is weak and intellectual property protection is uncertain.[18] Unless private

[15] The Wellcome Trust. 2003. Frequently Asked Questions. Available at: http://www.wellcome.ac.uk/en/1/awtvisfaq.html#3 (accessed July 22, 2003).

[16] Resnik, *op. cit.* note 9.

[17] A. Goldhammer. Current Issues in Clinical Research and the Development of New Pharmaceuticals. *Accountability in Research* 2000; 8: 283–291.

[18] D. Resnik. Developing Drugs for the Developing World: An Economic, Legal, Moral, and Political Dilemma. *Developing World Bioethics* 2001; 1: 11–32.

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companies can expect a good return on their investment, they will probably not invest much money in R&D related to the problems of the developing world. They may, however, decide to allocate some R&D funds to the problems of the developing world if they regard that decision as a donation to a worthy cause justified by a sense of social responsibility.[19]

To understand how government funding agencies make biomedical R&D allocation decisions, one must bear in mind that government agencies are accountable to politicians and the general public.[20] The NIH, for example, is part of the executive branch of the federal government. The President of the United States, through the Director of the Department of Health and Human Services (DHHS), has direct oversight authority over the NIH. Since Congress allocates government funds to the DHHS and NIH, it also oversees the NIH. Although scientific review panels determine which research proposals are funded, public opinion helps to shape the NIH's funding priorities. The NIH consults with members of Congress and the Executive branch, biomedical researchers, physicians, other federal agencies, such as the Food and Drug Administration, and patient advocacy groups to set its funding priorities. Disease advocacy groups have played an increasingly visible and influential role in setting funding priorities at the NIH ever since AIDS activists began to organise themselves in the 1990s. The NIH now spends more money on research on HIV/AIDS than on research on any other disease.[21]

Most of the research sponsored by the NIH has a great deal of significance for the developing world. Patients in developing nations benefit from NIH-sponsored research on HIV/AIDS, cancer, heart disease, alcoholism and drug abuse, and prenatal care. However, the NIH sets aside relatively little money to study problems unique to the developing world. The NIH has only one institute or centre devoted to international research. The Fogarty International Center allocates about $45 million per year on grants to improve global health.[22] While this is not a trivial amount of money, it represents less than 0.5% of the NIH's total budget. If some of the $15 billion that President George Bush

[19] Ibid. D. Brock. Some Questions about the Moral Responsibilities of Drug Companies in Developing Countries. *Developing World Bioethics* 2001; 1: 33–37.

[20] Resnik, *op. cit.* note 1.

[21] R. Dresser. 2001. *When Science Offers Salvation.* New York. Oxford University Press.

[22] Fogarty International Center. About FIC. Available at: http://www.fic.nih.gov/about.html (accessed July 23, 2003).

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recently pledged to spend on the HIV/AIDS crisis in Africa goes to research on the health problems unique to the developing world, then the percentage of the NIH's budget dedicated to the problems of the developing world will increase. However, it remains to be seen whether Bush's promise will materialise, since his proposal requires Congressional approval.

The NIH spends very little money on the health problems of the developing world because there is very little political pressure in the US to sponsor research on these problems. Americans want more research on cancer, heart disease, diabetes, hypertension, depression, obesity, and other diseases that have a significant impact on America's disease burden. US citizens, to put it bluntly, would rather spend their tax dollars on the health problems of their own country than on the health problems of a poor country in Africa, South America, or Asia. Perhaps developing nations need their own disease advocacy group to put political pressure on the NIH. Although the discussion so far has focused on the economic and political conditions in the US, similar conditions also exist in other developed nations.

We have thus arrived at the root causes of the 90/10 divide: the divide exists because biomedical research on the health problems of the developing world is neither financially lucrative nor politically popular. While some private foundations spend a great deal of money on the health problems of the developing world, their contribution is not enough to help close the gap.

THE 90/10 DIVIDE AND INTERNATIONAL JUSTICE

Is the 90/10 divide unjust or unfair?[23] To answer this question, one must provide an account of international justice, since disparities in the distribution of research resources between rich and poor countries concern justice between and among different nations. Although there is not sufficient space in this paper to provide an in-depth analysis of international justice, it will be useful to survey the different views and describe an approach that may apply to the 90/10 divide.

A traditional notion of justice, found in Plato's *Republic*, conceives of justice as a relationship among different people within a nation or state. A just state, according to Plato, is rationally ordered.[24] Other theorists, such as Hobbes, Locke, and Rousseau

[23] This paper will use the words 'justice' and 'fairness' interchangeably.

[24] Plato. 1974 [circa 400 BC]. *The Republic*. Translated by G. Grube. Indianapolis. Hackett.

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have followed this national approach to justice. The basic problem of international justice is to show how there can be justice among nations.[25] Sceptics claim international justice is impossible because: 1) states are not moral agents; 2) moral agreement is impossible among states; and 3) there are no agreed upon legal systems that can enforce international law.[26] A sceptic would argue that there is nothing unfair or unjust about the 90/10 divide, since there are no principles of international justice. The distribution of R&D resources may be a problem of justice within a particular nation, but it is not a problem of justice among nations.

I believe justice among nations is possible. First, even though states lack some of the characteristics of moral agency, such as consciousness or free will, they can act as political agents. States can make collective decisions and take collective action. Second, moral agreement among states, while very difficult, is not impossible. Most of the nations of the world accept the premise that nations should respect each other's sovereignty and avoid military aggression except in self-defence. Third, although there continue to be many problems with agreeing upon international laws and procedures, the nations of the world are working toward forms of dispute resolution, such as the United Nations, the World Trade Organization, and the International Court of Justice.

If international justice is possible, then what is the best account of international justice? Realists treat nations as having independent moral status and regard international justice as a relationship between and among nations. According to realists, geographically sovereign states are politically autonomous agents. The duties and rights of sovereign states are similar to the duties and rights of moral agents. Sovereign nations have the right to make their own laws, govern their own people, defend their territory, promote their own interests, and enter agreements with other sovereign nations. States also have duties to respect the rights of other states.

Critics of the realist approach include sceptics, who reject the notion of international justice, as well as cosmopolitans, who accept the idea of international justice but reject realism. According to the cosmopolitan view, international justice is a relationship among people who happen to live in different states, not a

[25] C. Beitz. 1999. *Political Theory and International Relations*. Second edition. Princeton, NJ. Princeton University Press.

[26] M. Sandel. 1982. *Liberalism and the Limits of Justice*. Cambridge. Cambridge University Press.

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relationship between different states. Political legitimacy derives from the rights and interests of the people who are governed.[27] Control over a territory (geographical sovereignty) is not the same as political sovereignty. Sometimes states are morally justified in violating another state's territorial integrity in order to overthrow or reform an oppressive government.[28] While states play a key role in the implementation of international justice, they have no *sui generis* moral standing.

Since cosmopolitanism avoids the difficulties of realism, but also rejects scepticism, this paper will adopt a cosmopolitan approach to international justice.[29] International justice depends on the relationships between people, not governments. What are some of the principles of international justice? To answer this question, it will be useful to apply three basic approaches to national justice to the international realm.

A libertarian approach to international justice would mirror the libertarian approach to national justice.[30] The libertarian would argue that the rules and principles of justice among politically legitimate nations should respect national rights and sovereignty. A nation, like an autonomous person, has rights to life, liberty, and property, which are limited only by the requirement that the nation not interfere with the rights of another nation. A nation should engage in ethical business practices in its dealings with other nations: it should honour its agreements with other nations, negotiate in good faith, and refrain from fraud, deception, or manipulation. However, a nation has no positive, moral duties to benefit other nations. A nation is free to acquire as much wealth as it can by honest means. The purpose of systems of international laws is to protect the rights of sovereign states, not to redistribute wealth among rich and poor nations.

A libertarian would not view that 90/10 divide as unjust or unfair. Sovereign states are free to make funding decisions based on their interests and goals, provided that they do not violate the rights of other sovereign states or the rights of citizens within sovereign states. The gap in the distribution of research resources between rich and poor nations is as fair as the income gap between rich and poor citizens within the same nation. The morally relevant issue is not that the gap exists but how it has

[27] Beitz, *op. cit.* note 25.
[28] Ibid.
[29] For further argument and discussion, see: Beitz, *op. cit.* note 25.
[30] R. Nozick. 1974. *Anarchy, State, and Utopia.* New York. Basic Books.

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arisen. If the 90/10 divide is the result of a fair process that respects rights, then it is just.

There is not sufficient space in this paper to provide a thorough critique of libertarian philosophy. The main problem with the libertarian view is that it does not give adequate consideration to the plight of the least advantaged members of society.[31] Libertarians have no qualms about huge differences in income, education and health among different people of the same nation or of different nations. Since I believe that a just nation (or community of nations) must have policies that promote the interests of their least advantaged members, I will reject the libertarian approach to international justice and consider other approaches.

A utilitarian approach to international justice would hold that principles of justice should promote the greatest balance of benefits/burdens for all people in the world. Utilitarians tend to favour health policies that maximise social goods at a relatively low cost, such as sanitation, immunisations, birth control, and programmes to fight famine, poverty, and ignorance.[32] If one assumes that reduction in the burden of disease increases utility, then a utilitarian would favour allocation policies that are most effective at reducing the world's overall disease burden. A utilitarian would probably regard the 90/10 divide as unjust because it would produce more net utility to shift some of the world's biomedical research resources from the problems of the developed world to those of the developing world.

One problem with the utilitarian approach to justice, according to many critics, is that justice always depends on empirical facts about connections between means and ends. Utilitarianism makes no special provisions for the least advantaged members of society, because justice is always a function of whatever rules or policies happen to maximise overall utility.[33] Thus, a utilitarian account of justice should be supplemented by some non-utilitarian principles of justice that make special provisions for the least advantaged members of society.

[31] J. Rawls. 1971. *A Theory of Justice*. Cambridge, MA. Harvard University Press.

[32] P. Singer. 1979. *Practical Ethics*. Cambridge. Cambridge University Press. I recognise the important distinction between act-utilitarianism and rule-utilitarianism. For the purposes of this paper, I will examine a rule-utilitarian approach to international justice. M. Häyry. 2002. Utilitarian Approaches to Justice in Health Care. In *Medicine and Social Justice*. R. Rhodes, M. Battin & A. Silvers, eds. New York. Oxford University Press: 53–64.

[33] Ibid. Rawls, *op. cit.* note 31.

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Egalitarians favour rules and policies that promote the interests of the least advantaged members of society, and an egalitarian would probably regard the 90/10 divide as unjust. Egalitarian theories hold that equality is the defining feature of a just society. Of course, egalitarians hold different views about the nature of equality or how to best secure it. This paper will briefly consider how John Rawls' influential theory would apply to the 90/10 divide.

Rawls' theory is very complex, and he revised and reinterpreted his views several times. Readers are probably familiar with his approach to national justice, which he developed in *A Theory of Justice*[34] and revised in *Political Liberalism*.[35] Readers are probably less familiar with Rawls' theory of international justice, which he developed in *The Law of Peoples*.[36] For the sake of brevity, this paper will not discuss Rawls' theory of international justice, but it will consider how his theory of national justice would apply to the 90/10 divide.

Rawls defends two principles of justice. The first principle requires that all members of society have the same scheme of basic rights and liberties; the second, also known as the difference principle, permits social and economic inequalities in society, provided that the inequalities do not interfere with fair equality of opportunity and they benefit the least advantaged members of society.[37] Rawls also argues that the first principle takes precedence over the second, and that fair equality of opportunity takes precedence over allowing for social and economic inequalities that benefit the least advantaged members of society.

Rawls' difference principle addresses the distribution of primary goods in a just society. Primary goods – those things that any rational person would want – include 'rights and liberties, powers and opportunities, income and wealth.'[38] The first principle of justice requires that all rights and liberties in society be distributed equally, but the second principle permits other primary goods to be distributed unequally, provided that there is fair equality of opportunity in society and the least advantaged members benefit from the unequal distribution. Although Rawls

[34] Ibid.

[35] J. Rawls. 1993. *Political Liberalism*. New York. Columbia University Press.

[36] J. Rawls. 1999. *The Law of Peoples*. Cambridge, MA. Harvard University Press.

[37] Rawls, *op. cit.* note 31.

[38] Ibid.

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does not include health as a primary good, one might argue that health promotes fair equality of opportunity.[39]

If we view the equality principle and the difference principle as applying internationally,[40] then the 90/10 divide would be unjust if it: 1) interfered with the basic scheme of rights and liberties, 2) undermined equality of opportunity, or 3) did not benefit the least advantaged members of society. While it seems unlikely that the 90/10 divide interferes with basic rights and liberties, one could easily infer that the 90/10 divide undermines equality of opportunity or does not benefit the least advantaged members of the world. The 90/10 is unjust because it contributes to international health disparities, and these disparities have a substantial impact on the welfare of the world's least advantaged people.

To summarise, from a utilitarian and an egalitarian perspective, the 90/10 divide is unjust. How should individuals and societies respond to this inequity? The remainder of the paper will address this question.

POLITICAL AND ECONOMIC BARRIERS TO CLOSING THE 90/10 DIVIDE

As noted earlier, private foundations are already pulling their weight when it comes to addressing the 90/10 divide. Although these foundations deserve high praise for their extraordinary efforts to address the health problems of the developing world, their efforts are no substitute for commitments from governments or private corporations. However, there are some political and economic barriers to increasing funding from the government and private industry.

The main barriers to increasing government funding for R&D on the health problems of the developing world are political. First, R&D on problems that have their main impact on the developing world do not have as much popular support as R&D on problems that have their main impact on the developed world. Second, even research that has popular appeal will not obtain government support if no advocacy group lobbies the government

[39] N. Daniels. 1984. *Just Health Care*. Cambridge. Cambridge University Press.

[40] Rawls did not believe that the equality principle and the difference principle could be applied internationally. He developed other principles for international justice. I am deliberately misrepresenting his views to simplify my analysis in this paper. For further discussion of Rawl's approach to international justice, see: C. Beitz. Rawls's Law of Peoples. *Ethics* 2000; 110: 669–697.

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for money.[41] Perhaps the developing world needs its own interest group to lobby governments for biomedical R&D funding.

How could an advocacy group convince citizens from developed nations that they should spend their tax dollars on R&D on the health problems of the developing world? First, one could make the moral argument that developed nations have a moral duty, as a matter of international justice, to fund R&D on the health problems of the developing world. However, this argument will not convince people who are sceptical about international justice or who take a libertarian approach to justice. Second, one might make the pragmatic argument that the health problems of the developing world will eventually affect the developed world. In the era of global travel and commerce, diseases in one part of the world can rapidly affect another. HIV/AIDS spread from Africa to the rest of the world. Severe, Acute Respiratory Distress Syndrome (SARS) spread quickly from China to Toronto.

How can one convince pharmaceutical and biotechnology companies that they should invest their money in conducting R&D related to the health problems of the developing world? First, one could make a moral argument that private corporations have a social responsibility to help promote access to medications that are desperately needed in the developing world.[42] Companies can fulfil their social responsibilities through research and development, price reductions for the developing world (also known as stratified marketing or equity pricing schemes), and drug give-aways. However, this argument may not be very convincing to most companies.[43] Even companies that endorse social responsibility may prefer to discharge their duties through charitable causes in the developed world, which can provide more public recognition than charitable causes in the developing world.

Second, one could make the pragmatic argument that private corporations can profit financially from investing money on R&D that addresses the health problems of the developing world. However, there are problems with this strategy as well. As we saw

[41] Dresser, *op. cit.* note 21.

[42] Resnik, *op. cit.* note 18. J. Cohen & P. Illingworth. The Dilemma of Intellectual Property Rights for Pharmaceuticals: The Tension between Ensuring Access of the Poor to Medicines and Committing to International Agreements. *Developing World Bioethics* 2003; 3: 27–48.

[43] Brock, *op. cit.* note 19. U. Schüklenk & R. Ashcroft. Access to Essential Medication in Developing Countries: Conflicts Between Ethical and Economic Imperatives. *Journal of Medicine and Philosophy* 2002; 27: 179–195.

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earlier, private companies make their R&D decisions based on factors that affect profit potential. Most of these factors do not favour investment of R&D funds in health problems that affect the developing world. Although the developing world represents a potentially enormous market, consumers in the developing world do not have enough money to buy medications priced at even nominal levels. Developing nations cannot afford patented medicines and can barely afford unpatented ones. Furthermore, intellectual property protection is uncertain in the developing world. The most significant intellectual property treaty, Trade Related Aspects of Intellectual Properties (TRIPs), which has been signed by members of the World Trade Organization (WTO), allows nations to take various measures, including compulsory licensing and parallel importing from signatory countries, to deal with national emergencies.[44] Several years ago, Pfizer, Merck, Glaxo and other pharmaceutical companies brought litigation to stop developing nations from exercising their rights under the TRIPs agreement. Although these companies eventually dropped the litigation, due to international political pressure, intellectual property rights in the developing world remain contentious. Prior to signing the TRIPs agreement, many developing nations did not honour pharmaceutical patents. In order to encourage developing nations to sign the agreement, developed nations made several concessions to developing nations, such as a phase-in period and provisions to deal with national emergencies. As countries renegotiate the TRIPs agreement, these issues will certainly resurface.[45] One might argue that developing nations should honour intellectual property treaties in order to encourage pharmaceutical companies to make R&D investments in the health problems of the developing world.[46] Conversely, one might argue that this is a high price to pay for medications that benefit the developing world, and that it would be wiser to encourage government investment in R&D for the developing world, rather than rely on pharmaceutical companies to take responsibility for developing new medications.[47]

Given the political and economic obstacles to closing the 90/10 divide, it would be wise to rely on neither the public nor the private sector to take care of the problem. Those who are concerned about the divide should form advocacy groups to

[44] Resnik, *op. cit.* note 18.
[45] Cohen & Illingworth, *op. cit.* note 42.
[46] Resnik, *op. cit.* note 18.
[47] Schüklenk & Ashcroft, *op. cit.* note 43.

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encourage governments from developed nations and pharmaceutical and biotechnology companies to increase the amount of money they spend on R&D on the health problems of the developing world. To facilitate, encourage, and organise investment of R&D funds and lighten the burden faced by any single nation or company, the UN should establish a trust fund to hold and distribute money contributed by governments or private firms from developed nations similar to the Global AIDS Fund. The trust fund could sponsor R&D, including basic research and clinical trials, on the health problems of the developing world. To prevent private firms from gaining exclusive control of its products, the fund could also acquire patents on the medications developed through the fund, and it could issue non-exclusive licenses to developing nations to manufacture and distribute medications. To keep the cost of drugs low, the fund would not charge a fee for licensing. Pharmaceutical companies could also contribute money to the fund as a gesture of their social responsibility to the developing world, with the understanding that they would have no patent rights over medications developed from the fund. They could still sponsor their own R&D related to the health problems of the developing world and continue to pursue the intellectual property rights accordingly, but there would be an intellectual property-free zone of important medications, biologics, and medical devices developed through the trust fund. Private charities could also contribute to the fund. As the world's largest investor in biomedical R&D, the US should set the pace for this trust fund. Large pharmaceutical companies, such as Pfizer, Merck and Glaxo, could also serve as pacesetters for this fund. Although charities and corporations would be able to contribute to the fund, it would not be wise to rely too heavily on private sources of funding. Most of the money for the fund would probably need to come from governments of the developed world.

CONCLUSION

The 90/10 divide in the allocation of biomedical R&D funds exists because governments and private firms in the developed world have not taken a strong enough interest in the health problems of the developing world. These facts explain but do not justify the divide. The divide is unjust, and developed nations have a moral obligation to close this divide. Those who are concerned about the divide should form advocacy groups to lobby governments for funding. The UN should establish a trust fund for bio-

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medical R&D on the health problems of the developing world. New drugs, biologics, and medical devices resulting from R&D under this trust fund should be made available as cheaply as possible.

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