

Rating Efforts to Extend Access on Essential Medicines: Increasing Global Health Impactⁱ

I. Introduction

Global inequality impacts global health. The rich can, but the poor cannot, access many of the existing medicines they need. About a third of all deaths, 18 million a year or 50,000 every day, are poverty-related.ⁱⁱ There is also a large mismatch between pharmaceutical research and development (R&D) spending and the global burden of disease (GBD).ⁱⁱⁱ Pharmaceutical companies have very little incentive to do new R&D on drugs for the poor (who lack the money to buy them). What should we do to address the consequences of inequality for global health?

One option is to try to restructure the incentives pharmaceutical companies face so that they can extend access on essential medicines to the poor. Several philosophers have argued that this is morally required.^{iv} To date, however, very few philosophers have advanced concrete proposals for doing so.^v Though, many have criticized Thomas Pogge's proposal for a Health Impact Fund that would provide prizes for companies producing new drugs in proportion to their impact on global health.^{vi} That more philosophical work has not been done on potential ways of restructuring the incentives pharmaceutical companies face so that they can extend access on essential medicines to the poor is unfortunate. There is a great need for serious philosophical reflection on this topic. To begin to fill this lacuna, this paper considers the case for a new alternative: Rating companies' efforts to extend access on essential medicines. Very roughly, a rating system would evaluate companies on the basis of the disease burden their innovations might alleviate, their effectiveness, and how many people have access to them.

As I argue at length elsewhere, a good rating system will incentivize companies to promote global health.^{vii} Highly rated companies might, for instance, be given a Global Health Impact (GHI) label to use on all of their -- especially over the counter -- products. This label might be similar to "Fair Trade," "(Product) RED," "USDA Organic," "Smart Wood Certified Forestry," or "Ethos" labels. Highly rated companies might use the GHI label to garner a larger share of the market, as people often prefer to purchase goods from "ethically" labeled companies.^{viii} If Weyth, for example, was highly rated, it could use the label on all of its products, including Advil. If even a small percentage of consumers would prefer products from highly rated companies, the incentive to use the GHI label for analgesics alone could be significant in this approximately two-billion dollar a year market.^{ix} Furthermore, pharmaceutical companies make many products besides drugs -- from diet drinks and lotion, to pet vitamins and mouth wash. So, they could use the GHI label on these products too.

Even if a labeling campaign is not a good idea, a GHI certification system should be of intrinsic interest and would also open the door to other kinds of fruitful social activism. Companies and researchers might use it to gauge R&D efforts. Socially responsible investment companies could include in their portfolio GHI companies. One can also

imagine boycotts of poorly rated companies, lobbying of insurance companies to include GHI products in their formularies, and so forth. Finally, because pharmaceutical companies rely, to a large extent, on university R&D, universities might make it a condition of the sale of their licenses that companies agree to abide by GHI standards. If such a GHI Licensing Campaign was only as successful as United Students Against Sweatshops has been so far in convincing campuses to change their licensing practices, this proposal will create 840 million dollars worth of incentive for pharmaceutical companies to become certified every year.^x That is about the cost of developing a new drug on the highest estimates.^{xi} This much money might greatly increase the rate at which new drugs are produced for neglected diseases.^{xii} This proposal will not solve every health problem but, if successful, it will have a significant impact. I argue elsewhere that there is some reason to believe this proposal is feasible and has some advantages over the main competitors. It can, in any case, be used in conjunction with all of the alternatives.

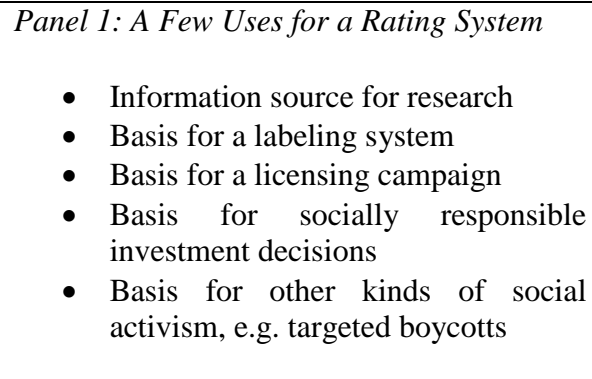


Figure 2: Uses of a Rating System

This paper argues that it is possible to design a good rating system – one that rewards highly rated companies for doing things that actually promote global health. In doing so, it suggests that practical work on promoting global health can yield interesting philosophical questions and conclusions. It makes this case by highlighting some of the normative choices that are important to address in developing a rating system and suggesting that what normative questions arise, and what answers are appropriate, depends significantly on what one is trying to achieve.

II. Rating System Design

To rate companies on the basis of some of their products' impact it is first necessary to decide exactly which drugs, diseases, and population groups to focus on. In previous work, I suggested looking at the US Food and Drug Administration approved "orphan" drugs,^{xiii} but I no longer believe this is the best way to proceed. Too many things that are important for global health are absent from the list. The only malaria drugs on the orphan drug list, for instance, are: Mefloquine (Larium), Quinine Sulfate, and Halofantrine.^{xiv} There are 23 (often combination) treatments for (primarily, *p. falciparum* or *p. vivax*) malaria that the World Health Organization (WHO) found worth examining for resistance

and efficacy.^{xv} It is probably better to just consider some of the drugs for disease that have a large impact on the poor – neglected tropical diseases, malaria, HIV, tuberculosis, and so forth. Though, it is not immediately obvious which diseases have the largest impact on the poor - it depends, in part, on what counts as a disease (or how the diseases are grouped). In the chart below, for instance, diarrhoeal diseases (Rotavirus, Cholera, Dysentery etc.) are grouped and, so, have a much bigger impact in terms of mortality (though the same is true of DALYs) than they would each have alone. Similarly, childhood diseases look significant together but most do not make a significant contribution on their own. Fortunately, there may be room for pragmatic considerations to enter in choosing some sub-set of diseases to focus on in developing a rating system.

Total Deaths	58,772
Childhood Diseases	874
Pertussis	254
Polio	1
Diphtheria	5
Measles	424
Tetnus	163
Diarrhoeal Diseases	2,127

Population (000)

Table 1: Deaths Lost in 2004 to Various Diseases (Worldwide)^{xvi}

Supposing it is possible to settle on a list of diseases by appeal to pragmatic considerations, hard questions will arise about which drugs and population groups to focus on. A reasonable first approximation might be to look at the impact of first-line drugs for those diseases in all the countries where the disease is prevalent (by comparing existing first line drugs to the next best available drug). This is a reasonable place to start even though there are different ways of defining the poorest countries, and sometimes drugs that do not address the diseases prevalent in these countries will have a large impact on global health. For there is good evidence that companies often neglect the diseases prevalent in these countries.^{xvii} So, there is reason for those interested in promoting global health to encourage companies to focus on addressing this oversight.

One might object to limiting the study to any subset of drugs or diseases. More generally, one might worry about creating a rating system for only some of the things companies are doing (extending access on essential medicines to the poor as opposed to improving

health infrastructure or whatnot).^{xviii} For, a partial rating system will give companies an incentive to divert funds to meeting only some needs. They might divert funds away from yet more valuable projects.

This may not, however, pose an ethical problem. It may be permissible for individual researchers and non-governmental organizations (NGOs) working on a label to do what they can to encourage companies to extend access on some drugs for malaria or neglected tropical diseases. This may just provide reason for others to encourage companies to extend access on other medicines or to make appropriate health-related infrastructure investments or whatnot. After all, the money that companies put into extending access on some medicines need not undermine their other attempts to help the poor. The funds need not come from their health-related infrastructure investment budgets, for instance. They could come from their non-essential drug budgets. Consider an analogy. Those who defend child labor often argue that if child labor is eliminated, children and their families will suffer. A child's next-best alternative might be prostitution. Even if this is true, however, it provides no reason to allow child labor. At least it provides no more reason to allow child labor than finding out that a child prostitute's next best alternative is slavery provides to allow child prostitution. Rather, it provides reason to try to both eliminate child labor *and* provide better jobs for adults and schools for children.^{xix} None of this means, however, that it is impermissible for one group to open a school and another to expose child labor. The GHI labeling proposal advanced here is not a complete solution to the problems the poor face in meeting their basic health needs. Still, it may *help* the poor meet these needs.

Moreover, once there is some rating system in place, it may be easier for researchers to gather more information. It may be possible to just start with the available information, eliciting more information as a condition of rating companies once the system is up and running. Some information is sensitive, but the proposal gives companies an incentive to release it.

Supposing we can arrive at a select list of diseases and focus drugs, some of the standard tools for effectiveness analysis may allow us to evaluate companies on that basis. The proposed methodology is, roughly, this. First, consider the burden of disease alleviated by each drug in the relevant countries, e.g. in DALYs. The burden of disease equivalent dosages will alleviate can be calculated using a proxy for access like price, the disease burden information in the WHO's burden of disease (GBD) study, and drug efficacy estimates modeled from efficacy data collected from WHO reports, clinical trials, and meta-analyses of such data (the necessary modeling is sketched in the next section). Consider an illustrative example of how this information might be used. Suppose, for simplicity's sake, that everyone has access to all of the drugs evaluated.^{xx} Suppose disease burden is calculated in DALYs and 34 million DALYs are lost to plasmodium falciparum malaria. Suppose Quinine is effective in about 9% of cases while Mefloquine is effective in about 5% of cases. If the next best alternative to each of these drugs averted 1 million DALYs, at the margin Quinine and Mefloquine might avert about 2.1 and .7 million DALYs, respectively. The next step is to rate companies on the basis of their inventions' (marginal potential) impact. Suppose Pfizer has two drugs that, at the

margin, avert the loss of 2.1 and .7 million DALYs, respectively. Suppose Bayer has one drug that, at the margin, averts the loss of 3 million DALYs. Bayer may be ranked above Pfizer. The marginal impact of Bayer's drug is 3 million DALYs averted, while Pfizer's drugs' marginal impact is 2.8 million DALYs averted. If innovations are evaluated in this way, this rating system will give companies an incentive to produce more effective drugs that address the largest global health problems.

Michael Selgelid might object to looking at drugs' *marginal* impact. Some drugs have a greater impact in combination than alone. Looking at marginal impact is to suppose one particular way of splitting the credit between companies' interventions but it is not clearly the best way. To illustrate the problem, suppose that we decide to measure disease burden in DALYs. Suppose one company's drug averts 2 million DALYs on its own. Then, suppose another company creates a drug that would alleviate 1 million on its own, but together with the first company's drug, helps avert 20 million DALYs. Should the new intervention receive credit for averting 18 million DALYs and the original intervention receive credit for averting 2 million DALYs? Should the 18 million marginal gain be split between the interventions? Should the new company receive all 20 million in credit?

It may be morally acceptable to attribute credit in many ways, but it is clear how the question should be answered in this context. What matters is maximizing the incentive for companies to ameliorate the GBD. If the recommended treatment becomes a combination of two drugs, one might initially think the company producing the new drug should get all the credit for the marginal impact of their creation (18 million DALYs averted). If another company comes along and offers a better drug to be used in combination with the original drug - that, say, saves 21 million DALYs - that company would then receive one million DALYs worth of credit and the other company would receive none.

Selgelid worries that this will give companies an incentive not to put their part of a combination forward (or to withdraw it from the market) until other companies put their part of the combination forward, but I am not sure this will pose a problem for the rating system. Companies that make drugs that might be used in combination have reason to negotiate with each to bring the new interventions forward as soon as possible. The company that expects to make the most from delay will, in theory, just pay the other company, or companies, to be the last one to release the intervention.^{xxi} If, however, things do not work out so well in practice, the rating might be amended to proportion credit differently. It is also possible to refrain from crediting companies that are charged with delaying the entry of their drugs onto the market (or withdrawing their drugs from the market) when this does not benefit the poor.^{xxii}

If this issue can be resolved, the main challenge for estimating existing products' impact is to develop good proxies for burden, effectiveness, and access. A good proxy is one that both tracks the variable of interest and, if manipulated by companies, would yield good results for the poor. Moreover, it must be possible for companies to affect the proxy. One of the things that makes choosing good proxies difficult is that burden, effectiveness, and

access are connected. Given that not everyone can access every drug, for instance, it is not clear how we can tell how effective the drug is for those who do secure it. Nevertheless, subsequent sections will consider just a few of the issues that arise in choosing good proxies for burden, effectiveness, and access independently.

Measuring Burden

One of the main constraints in determining the disease burden any particular intervention might alleviate (as well as access to that intervention and its effectiveness) is data at the global level. Data on disease burden for some diseases may not be available. Perhaps the best source for burden of disease information is the Institute for Health Metric and Evaluation's GBD study (now supported by the WHO and the Gates Foundation). Though, even this study lacks information on many diseases. Still, as discussed above, it may be acceptable to narrow the rating system's focus for pragmatic reasons – researchers might consider only those diseases that have a large impact in developing countries (i.e. the poorest) that appear on the GBD list.

Suppose we limit our attention to deciding between the available measures of disease burden for which global health data is available through the GBD study. For, there is little global data using other measures of disease burden like Quality Adjusted Life Years (QALYs) and the GBD study is one of the best and most comprehensive sources of global burden of disease information available. We must, then, decide whether to use (prevalence or incidence) DALYs or the years of life lost (YLL) to a disease. (The GBD study does not provide information on Quality Adjusted Life Years, for instance.) We must also decide between different ways of modifying DALYs available. The GBD study provides information about DALYs calculated with a 3% discount factor and/or age weights. Discounting gives less weight to the benefit of interventions' impacts in the future, while the age weighting in the GBD study gives more credit to interventions that benefit those in early adulthood as opposed to children or the elderly.

If we must choose between using DALYs or (different estimates of) YLL to a disease, an advantage of using DALYs is that they include some information about the burden of disability due to disease. Some diseases are terrible but do not kill their victims. If the disease burden was only measured in YLL, companies would receive no credit for curing or ameliorating these diseases.

Very roughly, DALYs are YLL to disease plus years lost to disability (YLD).^{xxiii} It is possible to lose a DALY to malaria or tuberculosis, for instance. The YLL is, roughly, a standard life expectation (for women and men) minus the age at death.^{xxiv} The most common (incidence) measure of YLD is roughly disease duration times incidence and disability weight. The original disability weights in the GBD study were based on health care providers' judgments about how bad different disabilities are compared with one another and mortality rates at the population level. Experts were asked questions comparing different disease states to each other and life extension like: "If you had to choose between providing a medication that would extend the life of 1,000 healthy people by one year or 2,000 blind people by one year, which would you do?"^{xxv} These

judgments were made after discussion with other health care providers at an international conference with participation of providers from many different cultures. The experts were asked to give consistent preference rankings.^{xxvi} The GBD study's justification for constructing DALYs in this way appealed to the axiom that the burden of disease for similar health outcomes should be identical – that is, that the only non-health factors that are relevant to the health outcome are age and sex. Though, the methodology continues to evolve.

There are some philosophical issues with the construction of DALYs that are worth noting.^{xxvii} The first is that it is not at all clear whose preferences are the most reliable guides to the actual burden of death and disability.^{xxviii} Those who are sick or disabled (henceforth, simply, *disabled*) often believe that their disabilities are not as bad as others believe them to be. They often have more knowledge about the relevant possibilities (phenomenological as well as factual) but, some argue, their opinions may be distorted by the fact that they have adapted to their poor condition.^{xxix} It really matters whose opinions are used in the current context (though different measures for the size of the burden of disease and what we should do about it may be necessary). If disabilities get less weight in DALY estimates then, on the proposed rating system, companies will get more credit for saving the lives of disabled people but less credit for alleviating their disability. This is because, in effect, disabled peoples' lives are discounted by the weight of their disability in the DALY calculations. Suppose for instance that, given that deaf people assign deafness a lower disability weight than non-deaf people, a company that helps a deaf person hear will avert 10 rather than 20 DALYS. Suppose another company saves the life of that deaf person but does not cure his or her deafness, and saving the life of an (otherwise similar) non-deaf person would be worth 30 DALYS. Once we consider the fact that some DALYS would still be lost to deafness, the second company will get 20 DALYS worth of credit for saving the deaf person's life if we use the deaf people's evaluation (30-10). The second company will only get 10 DALYS worth of credit for saving the deaf person's life on the non-deaf people's evaluation (30-20). Even if the preferences of the disabled *should* ultimately get priority, however, there are no alternative weights provided (e.g. by disabled people) with which we might try to arrive at a better estimate of DALYs lost to different diseases.

If DALYs are selected, however, it is possible to choose between two ways of calculating DALYs (incidence and prevalence measures), whether to discount them, and whether to use age-weighted DALYs. Consider each of these issues in turn.

In trying to measure the DALYs lost to a disease in a given year, incidence and prevalence DALYs deal in different ways with the burden of disabilities. Prevalence DALYs include the disability people are currently experiencing as a result of that disease say, those suffering from lung cancer in 2004 (whenever these people acquired the cancer). Incidence DALYs include a projection of the present and future disability attributable to lung cancer *acquired* in 2004.^{xxx} An example will help illustrate the difference.^{xxxi} Suppose that there are two forty year old men and we want to know the DALYs lost in 2004 and each of the next forty years in which they are expected to live.

- Man 1 acquires a disease in 2004 that kills him.
- Man 2 acquires a disease in 2004 that moderately disables him.

Suppose the weight associated with moderate disability is .25. Suppose the weight associated with death is 1 (for each year a person would otherwise be expected to be alive). Incidence DALYs suggest that forty years of life are lost, in 2004, to the disease that afflicts Man 1. Incidence DALYs suggest that the equivalent of 10 years are lost, in 2004, to disability to the disease that afflicts Man 2 ($.25 \times 40$). In 2005 and so forth, no DALYs are lost.^{xxxii} Prevalence DALYs suggest that 40 years of life are lost, in 2004, to the disease that afflicts Man 1. Prevalence DALYs suggest that the equivalent of .25 years are lost, in 2004, to the disability that results from the disease that afflicts Man 2. In 2005 and so forth, only the equivalent of .25 years would be lost to the disease that afflicts Man 2 (because no new health problems arise in those years and Man 2's disease remains prevalent in each of those years). Incidence DALYs consider the total impact of death and disability that happens in a given year. Prevalence DALYs consider the total impact of death in a given year but consider the disability experienced in that year (that may have been acquired much earlier).

The difference between using incidence and prevalence DALYs might not be important if we do not discount DALYs.^{xxxiii} With discounting, however, this difference is significant. They will not only yield different estimates of disease burden but will give different weight to some diseases over others. Though, in both cases the impact of interventions in the future on both measures will be less (that is just the effect of discounting.) Consider an example from Drew Schroeder's important paper "Prevalence, Incidence, and Hybrid Approaches to Calculating DALYs." Suppose there are two diseases. The first one afflicts 100 people a year and causes a serious disability with a disability weight of .5. The resulting disability lasts for one year. The second disease afflicts two people per year and also causes a serious disability with a disability weight of .5 but the resulting disability lasts for 50 years. Suppose that since the second disease has been around long enough, 100 people have it at any point in time. At any given time, both diseases cause 50 DALYs to be lost if we do not discount whether or not we use incidence or prevalence DALYs ($.5 \times 100$). If we use discounted prevalence DALYs, both diseases will still be judged equally burdensome. If we use discounted incidence DALYs, however, the first disease will look almost twice as bad as the second (at standard discount rates). It is hard to see why the first disease should be counted as worse than the second in terms of the global disease burden (once the second has been around long enough). The second yields just as much disability in every year. So, if we discount DALYs, there is some reason to use a prevalence measure.

But, should we then discount? One rationale for discounting is to track individuals' preferences. People may prefer to give more weight to earlier rather than later health benefits. Alternately, it may be reasonable to discount at the population level to account for the possibility of human extinction. Though, the chance of extinction is nowhere near the standard 3% per year discount rate that is used in calculating DALYs.^{xxxiv} Fortunately, we need not consider whether these arguments are sustainable, or other

philosophical arguments for or against discounting the future, to conclude that there is some reason to discount.^{xxxv} In the current context, uncertainty about what health interventions will be developed in the future provides reason to discount. Drug resistance and new drug development tend to make existing interventions obsolete. Any projected credit companies receive should be discounted for the chance that their interventions will alleviate less health burden into the future. This might, more precisely, be reason to discount estimates of drug effectiveness. However, discounting DALYs will achieve the same result. For, the proposed rating system is $\text{Burden} \times \text{Effectiveness} \times \text{Access}$ and discounting enters into the equation multiplicatively. Although much more reflection on this topic is necessary, there is at least one reason to discount.^{xxxvi}

Finally, consider age weighting. In the GBD study, more weight is given to the disease burden for adults than for children or the elderly. This is because, in some studies, people give preference to years of life lived as a young adult (though, the evidence here is quite mixed).^{xxxvii} One objection to age weighting is that this treats some lives as more valuable than others.^{xxxviii} The fact that the authors assume that all individuals potentially live through every life stage does little to allay this worry. When YLD are calculated, for instance, the effects of disease on those who die young receive less weight. Moreover, insofar as the aim is to give companies an incentive to ameliorate disease in the future, this measure will encourage them to focus on helping young adults. If they do so, those who die young will not benefit as much as they would if companies focused equally on the needs of children. If we really should treat all people equally, perhaps we should not incentivize companies to address diseases that impact young adults, in particular? One possible response to this objection is that the population structure in developing countries is skewed towards younger populations, so if the age weighting better approximates the population structure in these countries, age-weighting may be appropriate as a way of achieving equal treatment across age groups.^{xxxix} Unfortunately, however, there is little reason to think that age weighting will get the population structure right (even for the average disease in the study) as there are usually many children in developing countries. If one is really committed to treating all people equally, it would make more sense to apply age weights that reflect the population age structure in each country using population life tables for these countries (e.g. to weight age groups by their proportion in each country's population).^{xl}

One might object that the preceding argument required a commitment to rewarding companies for helping all people equally. If doing so does not give them an incentive to reduce the GBD as much as possible, perhaps that commitment is unsustainable in light of the purpose of the present study.^{xli}

Though the last section suggested rewarding companies based on how their medicines actually impact poor people's health, and illustrated how this might be done by considering the burden of disease each drug will alleviate in the relevant countries in DALYs, that is not the only possible measure of disease burden. We may not want to incentivize companies to just minimize the DALYs lost. Some ways of reducing this burden may be better than others because, for instance, they help all people equally. There may be reason to credit companies more for reducing the burden in the better

Graph 1. WHO and Collected Data on Chloroquine Efficacy by Country/Region

The next step is to develop the methodology for combining this data and estimating missing data. The global efficacy estimates used in the general explanation of how to design a rating system were simple averages of regional estimates, but it is better to calculate a closer approximation.^{xlvi} Drug effectiveness depends on many things related to different geographic locations (in some climates, for instance, the disease is more or less prevalent and stable and this effects transmission rates and affected individuals' parasite loads, which effects drug efficacy).^{xlvi} Very roughly, one possible way of trying to combine the data is by categorizing each geographical area using estimates of transmission potential derived from vector ecology data (the ME index available from The Earth Institute at Columbia University) and other variables of relevance to drug efficacy for which it is possible to acquire global data.^{xlvi} This will provide the basis for developing a causal model (using regression analysis), in collaboration with experts in biostatistics, with which to impute efficacy estimates to different geographical regions using the collected efficacy data.^{xlvi} Other relevant information includes the size and quality of the study, the year in which it was conducted, the treatment group, and what the drug at issue was compared with (if anything) in the study. Resulting efficacy estimates for all geographical regions will be combined to yield a global efficacy estimate. For the potential uses of the rating system described in the introduction, the results must be precise enough that, once drugs' impacts are aggregated, they issue a consistent ordinal ranking of companies. The disaggregated data might also be useful for guiding targeting interventions.¹

Country	Comparator	Study Area	Sample Size	Age & Sex	Year	Other	Efficacy
Central African Republic	N/A	Bambari, Bangassou, Bangui, Bossangoa, Berberati	268	6-59 months	Sept 1997-Dec 1998	36% success rate in Bangui - high CQ resistance in Bangui only, so 1st-line treatment should be replaced	66.0-75.0%
Chad	SP, AQ	urban centres Bongor & Koumra, southern Chad	301/318 eligible for analysis	6-59 months	2006	more efficacious treatment needed; artesunate + AQ potential 1st-line treatment	76.3%
W Uganda	SP, SP + CQ	Kamwezi health centre and Kyogo sub-dispensary in Kamwezi sub-county in Kabale district, western Uganda	141	> 6 months most over 5 years	October of 2001	CQ still effective, but combo therapy SP + CQ recommended to delay SP resistance	92.5%
Uganda (rural)	SP, SP + CQ	Kabaramaido District, NE Uganda	104/117 had complete follow-up	median age 15 months	Third quarter of 2001	combo therapy most effective; increased CQ efficacy with age = developing some immunity	55.0%
Congo (Democratic Republic)	SP	Seven sites: Kinshasa, Mikalayi, Kapolowe, Vanga, Kimpese, Kisangani, Bukavu	499 ACR	children < 5 yrs	May 2000-Nov 2001	CQ no longer effective in Congo - SP new 1st line treatment	54.6%
Gabon	AQ	Libreville	53	children	Sept 1997-Jan 1998	AQ generally more effective than CQ	45.0%
Mali	SP	Koumantou	224	children	2003-2004	based combo therapy recommended	9.5%
Mozambique	AQ + SP, artesunate + SP, AQ + artesunate	Manhica district	Two studies 80/50	6-59 months	Feb-June 2001/2002	AQ more effective than SP than CQ; combo therapy 100% clinical efficacy	47.1%

Figure 2. Sample of Initial Collected Efficacy data for Chloroquine^{li}

Measuring Access

The obvious proxy for access is price, though price is certainly not the only barrier to access and there are different barriers in different circumstances. Affordability, availability, accessibility, accommodation, and acceptability all affect access.^{lii} So, one might think a good proxy should be disease or drug specific. In some cases, price may be the biggest barrier to access and so measuring price alone might be sufficient. In other cases, health infrastructure might be the biggest problem and it may be possible to reward

companies for collaborating with partners in the developing world who have the ability to deliver their drugs to those in need. The problem with disease specific proxies is that they may not be comparable between cases. How does a price of \$3.50 per Chloroquine pill compare with providing three thousand people measles vaccine for free through a drug donation program? Although it might, in principle, be possible to compare the impact of things like health infrastructure improvements and new public-private partnerships in terms of DALYs saved, doing so would be incredibly difficult. It may be hard even to measure the impact of some of the things companies are doing to improve access. It may be hard to tell, for instance, how much credit a company should get for giving drugs at a small cost to another company with the ability to distribute (and profit from) distributing their medicine to the poor. So, it might be better to limit the scope of the project by focusing only on certain barriers to access, at least initially.

Even if price is the selected proxy for access, it may take some work just to estimate global drug prices. Companies are reluctant to provide this information. In part this is because prices vary significantly in different contexts and companies do not want their customers and competitors to access this information. Fortunately, there are a couple of ways around this problem. It might be possible to work with non-governmental and governmental organizations focusing on health like the World Health Organization, Medicines Sans Frontières, or health ministries to secure a broad range of pricing information. The global fund provides information on the prices for many medications as do many health ministries.^{liii} One nice thing about some country-level regulatory bodies – e.g. in Columbia, Canada, and Brazil – is that they have done reference-based pricing. That means that their prices are set on the basis of other companies' prices. So, relying on their prices as a proxy provides some information about prices in countries in their region.

If decent price data is available it may be important to take into account how often the treatment must be administered over the course of the average (e.g. sick) individual's life. A drug that is given at birth and prevents all future infection may, in effect, cost less than one that has to be given yearly. Perhaps a reasonable estimate of access would be $1/(\text{price per dose} * c * \# \text{ of times it must be given})$. The scaling term, c , may just be necessary to ensure that lower prices (less than a dollar per dose) continue to increase (rather than decrease) impact. Though, perhaps a scaling term should also modulate the impact of price in the rating system to capture its importance compared with disease burden and efficacy in reducing the GBD.^{liv}

If necessary, it is possible to work without information about access and focus on the question: How much good would companies' drugs do if everyone had them? This is still valuable information. It provides a measure of drug quality in light of disease burden. It would be a significant improvement over the status quo if companies focused on producing high quality drugs that could alleviate large burdens. There is even an argument that that is all companies are responsible for doing. Others, e.g. governments or non-governmental organizations, should help fill the breach and provide those drugs to people who need them. Although I believe that this argument is, ultimately, mistaken – it would be best if companies provided drugs that actually alleviate disease burden --

potentially useful drugs are still important.^{lv} Others may help provide them to people in need and, eventually, after the drugs come off patent and technology progresses, they may benefit people (in future generations).^{lvi}

Note, however, that whether or not access is included, the design of a rating system poses difficult questions about relative concern for people in present and future generations. There may be a tradeoff between giving credit for widely available and more effective drugs. Alternately, given resistance rates and changes in disease prevalence and impact, we might have to decide how to specify rewards for drugs that we expect to alleviate larger burdens in the future than in the present. One way of starting to do so is to develop a model of expected present and future drug impact and then consider the realm of possible ethical decisions very carefully.

III. Conclusion

Ideally, a rating system for pharmaceutical companies' efforts to extend access on essential medicines will: 1) Improve the quality of existing essential medicines and 2) stimulate development of multiple new essential medicines. It may succeed in this objective by, for instance, giving companies an incentive to lower prices on, or streamline and invest in R&D on these medicines. This paper has outlined a rating system that might help achieve these objectives by addressing some of the technical and philosophical design issues necessary for rating companies' efforts to extend access on essential medicines to the poor. In doing so, it argued that practical work on promoting global health can yield interesting new philosophical questions and conclusions. For, what normative questions arise, and what answers are appropriate, depends significantly on what one is trying to achieve. Although decisions about some things should not be policy driven, others are more properly pragmatic. So, this inquiry suggests that there is a lot of room for further research on the proper relationship between normative and pragmatic considerations in designing a good rating system.

i I owe thanks to Thomas Pogge, Peter Spirtes, Drew Schroeder, Darrel Moellendorf, Alex London, Barbara Buckinx, Bruce Lee, Yomei Shaw, Debra Oklota, Thom Sergerson, Jocelyn Mackie, and Anna Marie Turner, for extremely helpful discussion as well as those who talked with me about the initial proposal for papers forthcoming in *Globalization and Justice: Shrinking Distance, Expanding Obligations* with Cambridge University Press and “Global Health Impact: A Basis for Labeling and Licensing Campaigns?” forthcoming in *Developing World Bioethics*. I am very thankful to the editors of these works for allowing me to adapt some of the material that appears within them in the current paper. Moreover, I would like to thank those who attended my lecture on this proposal at the Center for Advanced Studies in Frankfurt as well as to the Center, Justitia Amplificata, the Falk and Bekman Foundations, and Academics Stand Against Poverty for supporting my research on this project.

ii World Health Organization (WHO), *World Health Report 2004* (Geneva: World Health Organization, 2004).

iii Frank R. Lichtenberg, ‘Pharmaceutical Innovation and the Burden of Disease in Developing and Developed Countries’, *Journal of Medicine and Philosophy*, 2005, pp. 663 – 690. Julian Culp and Nicole Hassoun, ‘Bridging the Gap in Scientific Research’, in *Debating Science: Deliberation, Values and the Common Good* (Prometheus Press, Forthcoming).

iv Aidan Hollis and Thomas Pogge, *The Health Impact Fund, Making New Medicines Accessible for All: A Report of Incentives for Global Health*, 2008, Available at: <<http://www.keionline.org/blogs/2008/11/27/trade-off-innov-access/>>. James Flory and Philip Kitcher, ‘Global Health and the Scientific Research Agenda’, *Philosophy & Public Affairs*, 2004, pp. 36-65.

v The main exception is Hollis and Pogge, *The Health Impact Fund, Making New Medicines Accessible for All: A Report of Incentives for Global Health*. Though, there are many innovative proposals in the public policy literature.

vi See: Thomas Pogge, ed., *Public Health Ethics*, 2008.

vii Nicole Hassoun, *Globalization and Global Justice: Shrinking Distance, Expanding Obligations* (Cambridge: Cambridge University Press, Forthcoming), Ch. 6. Nicole Hassoun, ‘Global Health Impact: A Basis for Labeling and Licensing Campaigns?’, *Developing World Bioethics*, Forthcoming.

viii (Transfair, 2002; MaxHavelaar Belgium, 2002; EFTA, 2000; Conroy, 2001; McMahon, 2001) cited in: Laura Reynolds, *Poverty Alleviation Through Participation in Fair Trade Coffee Networks: Existing Research and Critical Issues*, (New York: Community and Resource Development Program, The Ford Foundation, 2002).

ix Ibid.

x Ibid. Marcia Angell, *The Truth About the Drug Companies: How They Deceive Us and What To Do About It*, (New York: Random House, 2004), p. 71.

xi This estimate assumes that 30 percent of the drugs these companies rely upon are coming from universities and is in line with other authors’ estimates. Marcia Angell reports, for instance, that “ In 2002, for example, Pfizer licensed in 30 percent of its drugs, and Merck 35 percent” Angell, *The Truth About the Drug Companies*:

How They Deceive Us and What To Do About It. All of Bristol-Myers Squibbs' best selling drugs in 2003 were licensed. Gardiner Harris, 'Will the Pain Ever Let Up for Bristol-Myers?', *New York Times* 18 May 2003.

xii P. Trouiller, E. Torreele, P. Olliaro, N. White, S. Foster, D. Wirth, and B. Pécoul, 'Drugs for Neglected Diseases: A Failure of the Market and a Public Health Failure?', *Tropical Medicine and International Health* 2002, 2002, pp. 945-951.

xiii Food and Drug Administration (FDA), *OOPD Program Overview*, (Rockville: FDA, 2008), Available at: <<http://www.fda.gov/orphan/progovw.htm>>.

xiv Though, with the recent introduction of priority review vouchers, this may change. BIO Ventures for Global Health, *Priority Review Vouchers*, 2011, Available at: <<http://www.bvgh.org/What-We-Do/Incentives/Priority-Review-Vouchers.aspx>>.

xv World Health Organization, *Global Report on Antimalarial Drug Efficacy and Drug Resistance: 2000–2010*, (Geneva: World Health Organization, 2010).

xvi Data from: World Health Organization, *Regional Burden of Disease Estimates for 2004*, 2011, Available at: <http://www.who.int/healthinfo/global_burden_disease/estimates_regional/en/index.html>.

xvii Frank R. Lichtenberg, 'Pharmaceutical Innovation and the Burden of Disease in Developing and Developed Countries', *Journal of Medicine and Philosophy*, 2005, pp. 663 – 690. Julian Culp and Nicole Hassoun, 'Bridging the Gap in Scientific Research', in *Debating Science: Deliberation, Values and the Common Good* (Prometheus Press, Forthcoming).

xviii This objection and response are adapted from: Hassoun, *Globalization and Global Justice: Shrinking Distance, Expanding Obligations*. Hassoun, 'Global Health Impact: A Basis for Labeling and Licensing Campaigns?'

xix Of course, if there were good empirical evidence that all available alternatives to purchasing child labor made goods would be worse for the children, it might be best to purchase the goods.

xx It may also be a necessary to consider the problems associated with medicines in estimating their net benefits (e.g. some drugs have pretty bad side effects that should probably be taken into account, others require difficult to implement treatment regimes). Finally, see preceding note.

xxi In the US, combination therapies have to be tested and FDA approved together so companies have to cooperate in the process of creating them in any case.

xxii Selegid hints at this solution in his delightful article: Selgelid, 'A Full-Pull Program for the Provision of Pharmaceuticals: Practical Issues', pp. 134-145.

xxiii Christopher Murray, 'Rethinking DALYs', in: C. Murray and A. Lopez (eds.), *The Global Burden of Disease* (Cambridge: Harvard University Press, 1996), Ch. 1.

xxiv There are important philosophical questions about whether this is justified. There is a question, for instance, about the relevance of biological differences between men and women, if such exist. Peter Singer, 'All Animals are Equal', in D. Schmidtz and E. Willot (eds.), *Environmental Ethics: What Really Matters, What Really Works*

(Oxford: Oxford University Press, 2002). That said, the difference they postulate is small and there is no easily available information on disease burden without this population bias.

xxv There are many methods for eliciting preferences including person-tradeoff, time-tradeoff, and standard gamble. The methods used continue to evolve. Murray, 'Rethinking DALYs.' Murray and Acharya, 'Understanding DALYs', *Journal of Health Economics* 1997, pp. 703-730. Murray, Salomon, Mathers, 'A Critical Examination of Summary Measures of Population Health', in Christopher Murray, Joshua Salomon, Colin Mathers, and Alan Lopez (eds.), *Summary Measures of Population Health: Concepts, Ethics, Measurement and Applications* (Geneva: World Health Organization, 2002).

xxvi Murray, 'Rethinking DALYs.'

xxvii A serious practical problem is about how the study deals with co-morbidities. See: Murray, Salomon, Mathers, 'A Critical Examination of Summary Measures of Population Health.' There are also reasons to believe the GBD study greatly underestimates the impact of many diseases on the poor. Poor countries often lack good data and the authors are conservative in estimating impact from poor data. This may not be a problem for the purposes of the model, however, if there is little data for *all* of the diseases it includes. Charles H. King and Anne-Marie Bertino, 'Asymmetries of Poverty: Why Global Burden of Disease Valuations Underestimate the Burden of Neglected Tropical Diseases', *PLoS Neglected Tropical Disease* 2008, p. e209.

xxviii For philosophical reflection on the role of preferences in DALYs more generally, see: Daniel Hausman, 'Valuing Health', *Philosophy & Public Affairs* 2006, pp. 256-274.

xxix Murray, 'Rethinking DALYs.' Murray and Acharya, 'Understanding DALYs', pp. 703-730. Murray, Salomon, Mathers, 'A Critical Examination of Summary Measures of Population Health.'

xxx Seasonal variation in prevalence is often taken into account in estimating annual prevalence. Murray, 'Rethinking DALYs.' Murray and Acharya, 'Understanding DALYs', pp. 703-730. Murray, Salomon, Mathers, 'A Critical Examination of Summary Measures of Population Health.'

xxxi For a similar example and a very nice introduction to the distinction and its significance see: Drew Schroeder, *Prevalence, Incidence, and Hybrid Approaches to Calculating DALYs*, (Draft paper presented at the Critical Ethical Choices for DALYs meeting at the Institute for Health Metrics Evaluation, 2011).

xxxiii Though, the method may have a big impact in some cases. See: Adnan A. Hyder and Richard H. Morrow, 'Steady State Assumptions in DALYs: Effect on Estimates of HIV Impact', *Journal of Epidemiology and Community Health* 1999, pp. 43-45. Schroeder, *Prevalence, Incidence, and Hybrid Approaches to Calculating DALYs*.

xxxiv Murray, 'Rethinking DALYs.' Murray and Acharya, 'Understanding DALYs', pp. 703-730. Murray, Salomon, Mathers, 'A Critical Examination of Summary Measures of Population Health.'

xxxv For an interesting philosophical argument against discounting see: John Broome, 'Should We Value Population?', *The Journal of Political Philosophy* 2005, pp. 399-413.

xxxvi It may not be reasonable to discount the impact of all interventions at the same rate.

xxxvii Murray, 'Rethinking DALYs.' Murray and Acharya, 'Understanding DALYs', pp. 703-730. Murray, Salomon, Mathers, 'A Critical Examination of Summary Measures of Population Health.'

xxxviii Sudhir Anand and Kara Hanson, 'Disability-Adjusted Life Years: A Critical Review', *Journal of Health Economics* 1997, pp. 685-702. Murray, 'Rethinking DALYs.' Murray and Acharya, 'Understanding DALYs', pp. 703-730. Murray, Salomon, Mathers, 'A Critical Examination of Summary Measures of Population Health.'

xxxix Alan Lopez, Collin Mathers, Majid Ezzti, Dean Jamison, and Christopher Murray, *Sensitivity and Uncertainty Analyses for Burden of Disease and Risk Factor Estimates*, 2006, Available at: <<http://www.dcp2.org/pubs/GBD/5/Section/864>>.

xl See, for instance: United Nations, *Age Structure of Mortality in Developing Countries*, 1986, Available at: <http://www.un.org/esa/population/publications/Age_Structure_of_Mortality/Age_Structure.htm>. More recent data is available from the WHO which presents life tables as a link of the country pages in their Global Health Observatory, available here: <http://www.who.int/countries/en/>

xli Some think it is conceptually incoherent to take different (incidence and prevalence) perspectives on death and disability as prevalence DALYs do, though I am not sure why it is a problem to do so. See, for instance: Schroeder, *Prevalence, Incidence, and Hybrid Approaches to Calculating DALYs*.

xlii Anand and Hanson, "Disability-adjusted life years: a critical review" pp. 695-702. C. Murray, J. Salomon, C. Mathers, A. Lopez, *Summary Measures of Population Health: Concepts, Ethics, Measurement and Applications*, (Geneva: World Health Organization, 2002).

xliii As the questions for eliciting preferences over health states are often framed, there is a similar ambiguity. Eric Nord, 'The Person Trade-Off Approach to Valuing Health Care Programs', *Medical Decision Making*, 1995, pp. 201-208. Eric Nord, J. Pinto, J. Richardson, P. Menzel, and P. Ubel, 'Incorporating Societal Concerns for Fairness in Numerical Valuations of Health Programmes', *Health Economics*, 1995, pp. 25-39.

xliv Trude Arnesen and Erik Nord, 'The Value of DALY Life: Problems with Ethics and Validity of Disability Adjusted Life Years,' *British Medical Journal*, 1999, pp. 1423-1425.

xlvi World Health Organization, *Global Report on Antimalarial Drug Efficacy and Drug Resistance: 2000–2010*, p. 112.

xlvi Simon Hay et. al., 'A World Malaria Map: Plasmodium Falciparum Endemicity in 2007', *PlosMedicine*, 2009, pp. 0286-0302.

xlvi Disease transmission in the area may be stable or unstable (sensitive or insensitive to natural and man-made perturbations), and the disease can be holo-, hyper-, meso- or hypo- endemic. This can impact which population sub-groups acquire the disease, how severe it is, and so forth. Simon Hay, David Smith, Robert Snow, 'Measuring Malaria Endemicity from Intense to Interrupted Transmission', *Lancet Infectious Diseases*, 2008, pp. 369–378.

xlvi Vector ecology is plausibly exogenous to drug efficacy.

xlix It is, obviously, necessary to include an error term to account for those variables which are important but on which there is no global data and to do the requisite econometric analysis.

I So far this paper has considered how to estimate drug impact only in a single year, but it may be possible to estimate effectiveness over longer periods of time. Since different drugs are effective for different lengths of time and different disease stages, information about the required treatment regime might be incorporated in to an estimate of access. Though, this will raise a host of philosophical questions about, for instance, the separability of times in valuing health states, the importance of impacts on present and future generations, and so forth. See: J. Broome, 'Measuring the Burden of Disease by Aggregating Well-Being', in C. Murray, J. Salomon, C. Mathers, and A. Lopez (eds.) *Summary Measures of Population Health: Concepts, Ethics, Measurement and Applications* (Geneva: World Health Organization, 2002). D. Brock, 'The Separability of Health and Well-Being', in C. Murray, J. Salomon, C. Mathers, and A. Lopez (eds.) *Summary Measures of Population Health: Concepts, Ethics, Measurement and Applications* (Geneva: World Health Organization, 2002). J. Griffin, 'A Note on Measuring Well-Being', in C. Murray, J. Salomon, C. Mathers, and A. Lopez (eds.) *Summary Measures of Population Health: Concepts, Ethics, Measurement and Applications* (Geneva: World Health Organization, 2002).

li The abbreviation *SP* is Sulfadoxine-Pyrimethamine, *C* is Chloroquine, *Q* is Quinine, and *A* is Amodiaquine. *ACR* indicates that the participants achieved adequate clinical results.

lii R. Penchansky and J. Thomas. 'The Concept of Access: Definition and Relationship to Consumer Satisfaction,' *Medical Care*, 1081, pp. 127-140.

liii See, for instance, the Global Fund's information on regional prices here: The Global Fund, PQR Public, 2010, Available at:

<http://bi.theglobalfund.org/analytics/saw.dll?Dashboard&nqUser=PQRExternalUser&PQRLANGUAGE=en&PortalPath=/shared/PQR%20External%20Users/_portal/PQR%20Public&Page=Regional%20Price%20Reference

>. Brazil's ministry of health (Ministerio de Salud) publishes the following list of prices for popular medicines:

Brasil Ministerio de Salud, *Farmácia Popular Do Brasil*, 2011, Tabela de Preços, Available at:

<http://portal.saude.gov.br/portal/arquivos/pdf/tabela_farmaciapopular_abril08.pdf>. Also see: South African Department of Health, *Database of Medicine Prices*, 2011, Available at: <[Database of Medicine Prices](#)>.

liv Information on average age of onset used in calculating the GBD and, in conjunction with life tables and treatment regimes, may be useful in estimating how often the treatments must be administered in the population.

lv One reason it may not be a good idea to focus on price is if third parties, like the global fund, bear the burden of lower prices.

lvi Though, this is by no means certain.