



Promoting Global Health

The Case for a Global Health Impact Labelling Campaign





(Tosamanganga hospital: maternity ward by Medici con l’Africa, 2012. Flickr)

1. Introduction

Every year doctors diagnose 10.4 million people with TB, every day more than 4,932 people get AIDs, every two minutes malaria kills a child (WHO, 2017b; WHO 2017c; UNAIDS, 2017). The world’s largest health problems afflict poor countries and their poorest inhabitants (WHO, 2004). Although clean water and adequate shelter do much more for the global poor than pills, many people suffer and die from diseases that primarily afflict the global poor --like malaria, TB, and HIV/AIDS -- because they lack access to essential medicines they need to avoid and combat serious illness (UN, 2017a; UN, 2017b). 1 Most people in low-income countries cannot afford even basic medicines, like antibiotics (WHO, 2011). Moreover, little R&D on new drugs and technologies focuses on the diseases that cause the most death and disability around the world. Consider R&D spending on diabetes vs. malaria, TB, and HIV/AIDS:

Condition	Global Burden of Disease (million DALYs)	% of Total Global Burden of Disease	R&D Funding (US\$ millions)	R&D Funding (US\$ millions per DALY)
Diabetes	49.8	2.02%	376,000	7,550
HIV/AIDS	88.7	3.60%	10,400	117
Malaria	69.6	2.82%	2,400	35
TB	50.9	2.06%	1,400	28

The chart above measures the diseases’ health consequences in Disability Adjusted Life Years (DALYs). DALYs include estimates of disability alleviated as well life lost. In constructing estimates of the DALYs lost to different diseases around the world, the Institute for Health Metrics and Evaluation’s (IHME’s) Global Burden of Disease (GBD) study assigns every year lived with a disability a fraction of the value of a year of healthy life (multiplying the number of cases by length of time lived with the disability and a disability weight arrived at via a global survey) (Solomon et. al., 2012). Similar disparities between R&D and need are pervasive across a wide range of diseases (HME, 2017). What follows suggests that by collecting and analyzing data on global health, people can come up with new ways to improve poor peoples’ access to essential drugs and technologies. To illustrate how data can help, it presents a new model that synthesizes health systems data to evaluate medicines’ global health impact -- the morbidity and mortality these products alleviate (in DALYs). It then suggests utilizing information about medicines consequences (organized by drug, disease, country, and company) to create incentives for positive change. This Global Health Impact Index and similar ones provide mechanisms for incentivizing pharmaceutical companies and other organizations to extend access to essential drugs and technologies around the world. The highest rated companies can receive a Global Health Impact label to use

1. This is a chapter from a forthcoming book published by Oxford University Press entitled *Extending Access to Essential Medicines: The Global Health Impact Project* which draws on previous work in from Hassoun, N. (2012). Global health impact: a basis for labeling and licensing campaigns?. *Developing World Bioethics*, 12(3), 121-134. DOI: 10.1111/j.1471-8847.2011.00314.x. Copyright of *Developing World Bioethics* is the property of Wiley-Blackwell and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder’s express written permission. However, users may print, download, or email articles for individual use. It also draws on some material in with permission from Hassoun, N. (2014). Globalization, global justice, and global health impact. *Public Affairs Quarterly*, 28(3), 231-258. Retrieved from <http://www.jstor.org/stable/43574660> and Hassoun, N. (2016). Advancing the sustainable development goals and human rights to health: Evaluating global health impact and increasing access to essential medicines United Nations Secretary General’s High Level Panel on Access to Medicine, Retrieved from [http://www.unsgaccessmeds.org/inbox/2016/2/16/contributionn-hassoun; and](http://www.unsgaccessmeds.org/inbox/2016/2/16/contributionn-hassoun; and impact and increasing access to essential medicines United Nations Secretary General’s High Level Panel on Access to Medicine, Retrieved from http://www.unsgaccessmeds.org/inbox/2016/2/16/contributionn-hassoun; and)

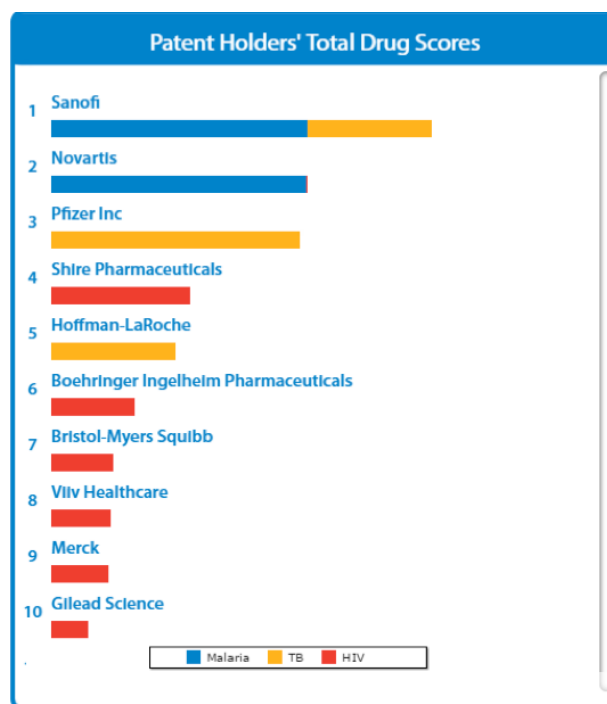
on their products (e.g.). 3 If people prefer to purchase goods from, and invest in, Global Health Impact certified companies, companies have an incentive to use the label to garner a larger market share. Having an index evaluating pharmaceutical companies' products also opens the door to other fruitful social activism. Socially responsible investors, insurance companies, and universities might take the ratings into account in deciding where to place their investments, what products to include in their formularies, and how to license their new drugs and technologies.

Moreover, the chapter suggests, providing information in an easily accessible format can open the door to addressing key global health problems in other ways. Policy makers interested in trying to improve access to medicines and researchers, and regulators, evaluating policies aimed at doing so can use the Global Health Impact Index alongside others to evaluate progress. Regulators can use such indices as standards against which to evaluate innovations and company efforts. Researchers can mine the data their underlying models provide to locate global health impact's most significant causes and consequences (and to answer many important questions). Good data cannot solve all global health problems. Nevertheless, the data can help researchers implement new initiatives, complementing existing mechanisms, for addressing the access to medicines problem. Those primarily interested in this proposal's philosophical implications can skim the more technical parts of this chapter.

2. Creating a Good Rating System

The Global Health Impact model is an objective, output-based, rating system that measures the disability-adjusted life-years (DALYs) companies' drugs avert around the world. Again, DALYs include estimates of disability as well as mortality (Solomon et. al., 2012). The Global Health Impact Organization -- a collaboration of researchers from universities and civil society organizations around the world dedicated to measuring pharmaceutical products' global health consequences to advance access to essential medicines -- guides the model's development (for information about the organization and its quality control mechanisms, see: global-health-impact.org). They estimate medicines' effects around the world.

Figure 3.1 Company Rating on the Global Health Impact Index

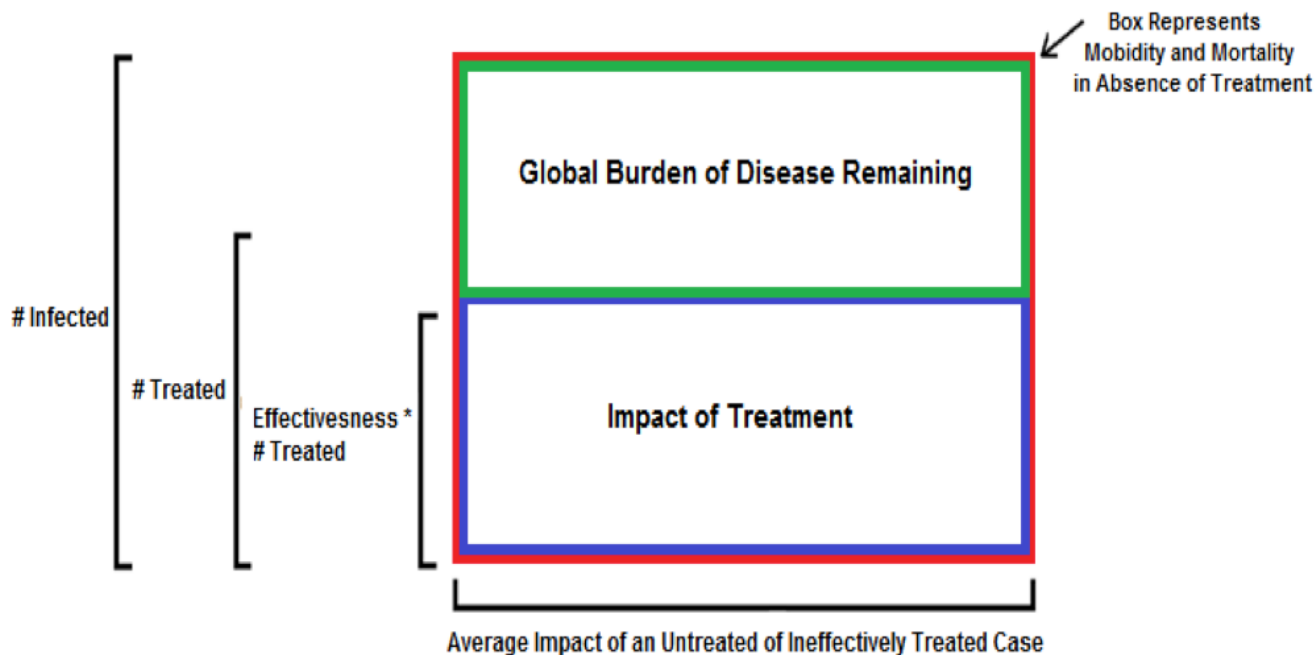


Although the calculations can get complex, the basic idea behind the model is simple. Researchers construct it in two (rough) steps. First, they evaluate key medicines impacts. Second, they rate companies by aggregating their drugs' estimated global health consequences. This provides the basis for ranking companies on their relative or absolute standing (see the discussion below).

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Consider the basic approach. The model uses data on incidence, the population proportion treated effectively, and the global disease burden to estimate treatment impact. Supposing that the disease burden remaining results from either people who do not receive treatment or who are ineffectively treated, researchers estimate the average impact of an untreated-or-ineffectively-treated case. Next, they calculate treatment impact as the number effectively treated times such an untreated-or-ineffectively-treated case's average impact.

Figure 3.2: Conceptual Model



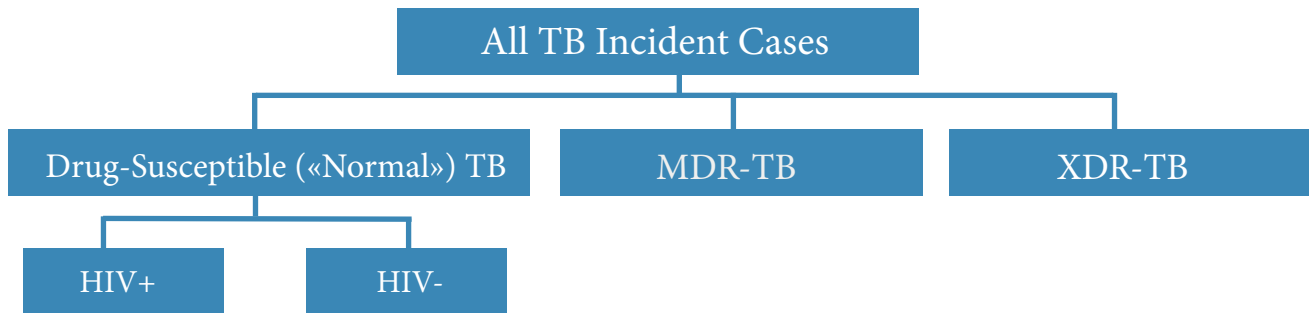
More precisely, using data on incidence, the number treated, and drug efficacy, Global Health Impact researchers figure out the number who need a drug who are treated effectively (and the number either untreated or ineffectively treated). Again, the model assumes the global disease burden that remains after treatment results from untreated and ineffectively treated cases. So, using the top box's height and data on the global disease burden remaining after treatment from the IHME (the top box's area), the model estimates the boxes' length. Call this "an untreated or ineffectively treated case's average impact." Finally, the model estimates treatment impact by multiplying the number effectively treated (the bottom box's height) by an untreated or ineffectively treated case's average impact (its length). Obviously, this simplifies things significantly, but see (global-health-impact.org) for further details and (Hassoun, 2016d) for a brief mathematical summary of the modelling approach.

Moreover, much of the modelling effort still goes into estimating the parameters in the overall formula (see the supplementary file in PLoS (Hassoun, 2015c) for some explanation/examples) and Global Health Impact researchers account for many complexities in implementing the general approach (Hassoun, 2016a; Hassoun 2015a). Amongst other things, they use disease models and sub-models for breaking down treatment percentages by disease state and regimen. To give you just one example, with TB, Global Health Impact researchers look at treatments for drug susceptible TB in HIV+/- patients, multiple drug-resistant (MDR)- and extremely drug-resistant (XDR)- TB separately. Researchers have to model resistance rates to various drug combinations and use data on resistance and treatment guidelines to get estimates of MDR-TB regimen treatment percentages. Moreover, they take into account the fact that HIV/AIDS and drug resistant TB regimens usually require longer treatment periods by dividing regimens scores by a measure of the length of treatment.



(Child and a Doctor by bananaglobal, 2016. iStock)

Figure 3.3: Breakdown of TB by Type and Patient Group in Model

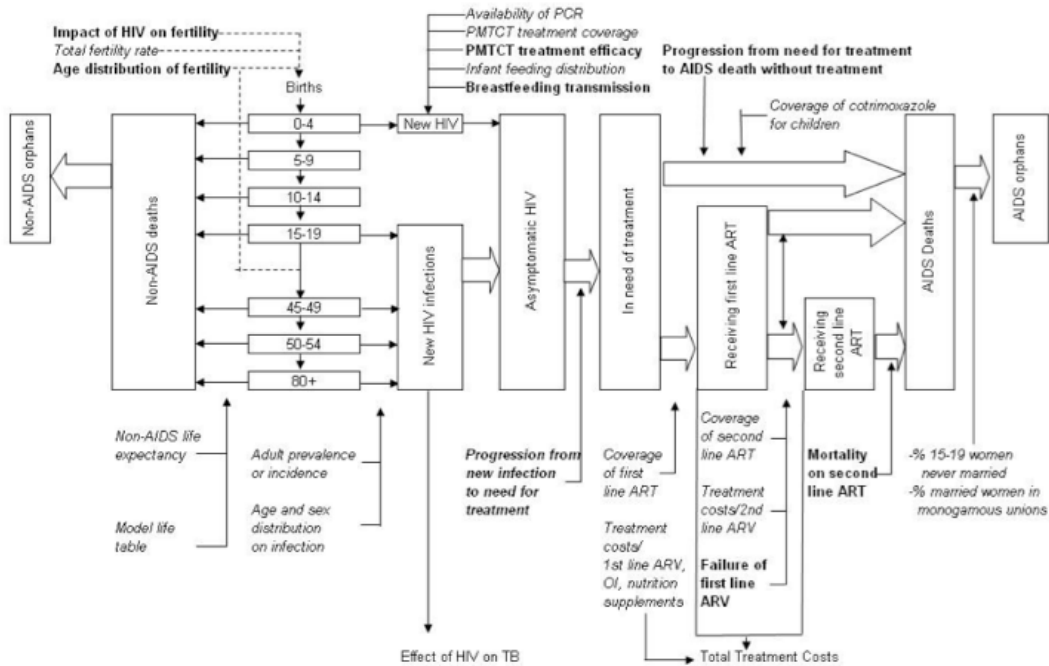


Interested readers can see (Hassoun, 2015c; Hassoun, 2016c) and global-health-impact.org for more information on the models’ results, limitations, and advantages as well as some possible refinements.

Let me just note here that the model’s methodology is significantly different than that embodied in previous models. Avenir Health (previously The Futures Institute), for instance, produces several dynamic models focused primarily on HIV/AIDS. Their AIDS Impact Model (AIM), for example, looks at “the consequences of the HIV epidemic, including the number of people living with HIV, new infections, and AIDS deaths by age and sex; as well as the new cases of tuberculosis and AIDS orphans” (Futures Group, 2015; USAID, 2018). Their Prevention of Mother-to-Child Transmission (PMTCT) model “evaluates the costs and benefits of intervention programs to reduce transmission of HIV from mother to child” including information on seven possible treatment regimens as well as other interventions (Futures Group, 2015; AVERT, 2018). Their Lives Saved Tool (LIST) considers the impact of different child health interventions on child mortality. However, none of their models combine in a simple, transparent, consistent way estimates of the death and disability averted by medicines for malaria, TB and HIV/AIDS (Kahn et al., 2017; World Health Organization, 2014; Stover and the US Agency for International Development, 2009; Winfrey et al., 2011; Friberg and Walker, 2014; Avenir, 2018).

Avenir Health’s models (and similar ones) also rely on different kinds of information and make different assumptions than the Global Health Impact model (Kahn et al., 2017; World Health Organization, 2014; Stover and the US Agency for International Development, 2009; Avenir, 2018; Novartis Global, 2017). It is easy to see, for instance, the different kinds of information and assumptions used in AIM in this diagram of the model’s structure:

Figure 3.4: AIM Model



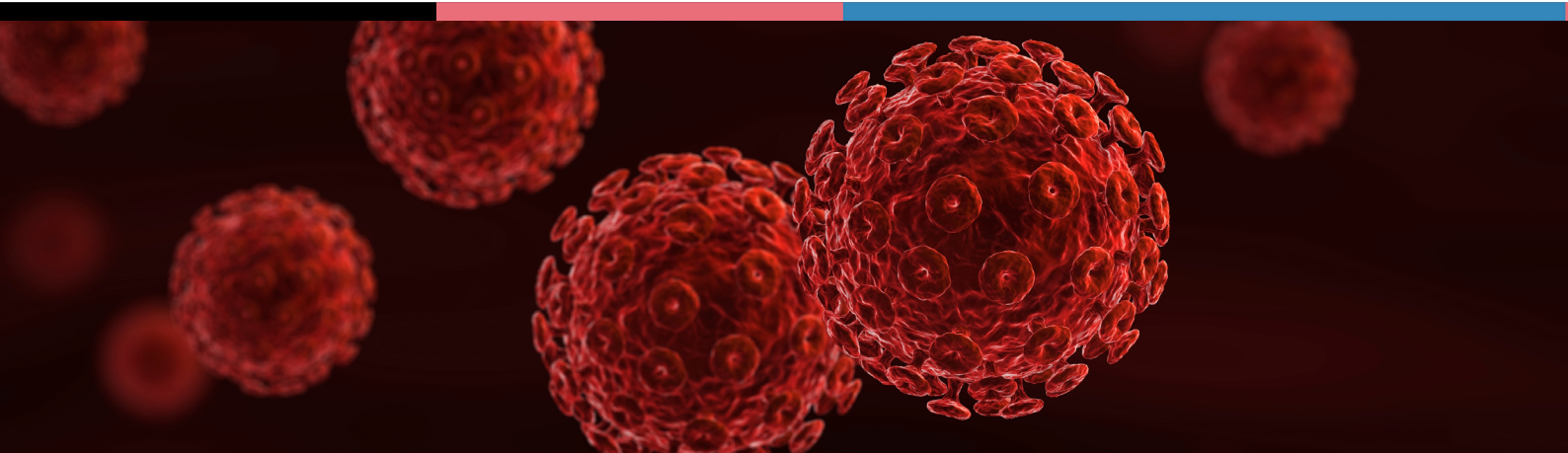
From: (Stover, 2009, 5)

AIM assumes information “about the past and future course of adult HIV incidence and treatment coverage” as well as “the survival period from HIV infection to AIDS death, the age and sex distribution of new infections, and the perinatal transmission rate” (Stover, 2009, 5). Moreover, there are many additional assumptions in the demographic model upon which AIM draws (Stover, 2009). More generally, many traditional epidemiological models try to predict the future course of epidemics using (e.g.) data on demographic change, individual behavior, and transmission rates etc. (Kahn et al., 2017).

Different models have different advantages and limitations. The advantage of traditional epidemiological models is that they have some predictive power (and can show the likely course of epidemics and the need for treatment), but the limitation is that there is a lot more uncertainty in trying to predict the future. What the Global Health Impact Index does is use existing data on the need for drugs, their efficacy, and treatment percentages to estimate interventions’ impacts on the global burden of disease. I think knowing what the best health systems data says about treatment impact is just as important, and may be as useful, as using more specific models to predict the evolution of diseases over time even in distributing health resources.

The Global Health Impact Index also provides some data (necessary for the labelling and other initiatives this book advances) that traditional models omit. Until recently, these models did not measure health impact in DALYs or look at many particular medical interventions’ consequences (Avenir Health, 2018; Kahn et al., 2017; Wilson, 2018). To date, they do not cover the number of medicines the Global Health Impact models do nor do they compare impact on diseases in as consistent and comparable way (as Global Health Impact Index does). Perhaps most significantly, the Global Health Impact models are different from traditional epidemiological models in looking at companies’ roles in pharmaceuticals’ supply chains. Once it calculates drug scores, the Global Health Impact team partners with Cornell’s Law School to collect data on the medicines’ patent holders.

Using the data it collects on patent holders, the Global Health Impact Index rates originator companies based on their inventions’ aggregate impacts (in DALYs averted). Suppose one company has four drugs that save about 1 million DALYs each. Suppose a second company has two drugs that save about .5 and 1.5 million DALYs each. The first company’s drugs have a greater impact (they save 4 million DALYs together) than the second company’s drugs (that, together, save 2 million) (Avenir, 2018; CDC, 2012).



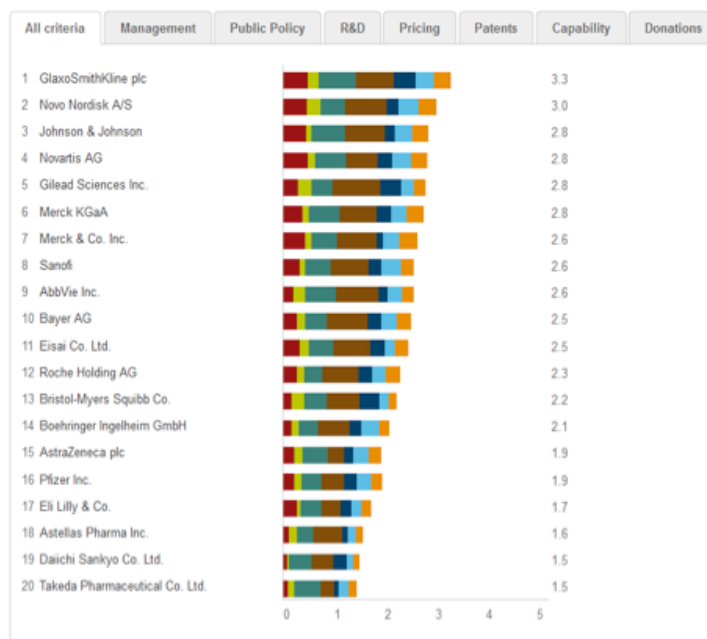
(Science Research Microscope, iStock)

In the future, the Global Health Impact Organization will also provide different indexes rating distributors and innovators. The pharmaceutical market is complicated. Some companies patent drugs that other companies developed. Some buy the rights to drugs others have patented or license drugs developed in the public sector. Often companies license out their drugs' manufacturing and distribution to other companies or enter into co-marketing agreements. For now, Global Health Impact focuses on companies with patents on key medications so that the Index can incentivize new drug development (Rafols et al., 2012). Moreover, companies that hold the patent on a drug can often affect their drugs' accessibility. These companies usually control licensing, co-marketing, distribution, and manufacturing rights. In the future, Global Health Impact will present a distribution index using the WHO's Global Price Reporting Mechanism database to evaluate companies' contributions to manufacturing/distribution.

If Avinir Health's models (or similar ones) expand significantly, it may be possible to use their estimates of treatment's consequences instead of those the Global Health impact Index provides but, because one of the Global Health Impact Index's main objectives is to provide information on companies, I think another -- and perhaps more apt -- comparison to the Global Health Impact Index is in the Access to Medicines and other corporate social responsibility indexes.

Consider the most well-established, Gates Foundation funded, corporate social responsibility index. The Access to Medicine Index rates companies along several dimensions including their R&D, patenting, pricing, and drug donation programs, but does not (yet) support a labelling campaign (Access to Medicine Index. 2016). It aims to improve access to medicine.

Figure 3.5: Select Access to Medicines Index Ratings



From: (Access to Medicine Index, 2014)



(Pakistan Child, iStock)

Unfortunately, the Access to Medicine Index has some serious problems. Although it is improving, companies get significant credit for things that like “commitments” and “transparency” that may not actually improve global health. After all, companies can have good policies but terrible outcomes. Moreover, the Access Index does not have a unified scientific basis for deciding what to measure, how to measure it, or how to combine their measures into a single index. The 2016 methodology specifies the weights on each of the Index’s parts as follows: innovation (10%), commitments (15%), transparency (25%), and performance (50%). The components (that make up each of these parts) are then weighted as well: Management (10%), Compliance (10%), R&D (20%), Pricing (25%), Patents (15%), Capacity (15%), and Donations (5%) (Access to Medicine Index, 2016b, 35, 40-50). It seems another index altogether is necessary to figure out which weightings accurately capture how much things the Access to Medicine Index measures contribute to improving health. Companies can lower prices, for instance, yet not improve health if the main barriers to access lie elsewhere. Finally, the Access to Medicine Index solicits input from many stakeholders (pharmaceutical companies, doctors, non-governmental organizations etc.) even when their interests compete with ensuring everyone access to the essential medicines they need (Access to Medicine Index, 2016b; Access to Medicine Index, 2017).

The Global Health Impact Index is a more objective, and output-focused, rating system that rewards companies based on how their drugs actually affect global health not just on the resources they put into creating, and helping people access, essential drugs and technologies. It does not just reward companies for their investments as that can make it seem like they invest more in helping than they do. This is a real concern given that pharmaceutical companies probably exaggerate their R&D costs (Angell, 2004; Light and Warburten, 2011). Furthermore, rewarding investments creates no incentive for efficiency and productivity. If people care that everyone can access essential drugs and technologies, I believe they should reward companies based on their drugs’ impacts. Moreover, the Global Health Impact Index has a unified rationale for measuring what it does – it aims to incentivize companies and other organizations to save the greatest number of lives and alleviate the most disability so it looks at how many DALYs different medicines’ save. Moreover, it does so using the best available data from international organizations and the academic literature. It does not rely on the information pharmaceutical companies provide.

Consider how evaluating companies on the Global Health Impact Index, but not the Access to Medicines Index, gives them an incentive to do whatever helps their medicines reduce the disease burden as much as possible. To improve the Global Health Impact scores, companies can create new efficacious drugs, come up with improvements on existing drugs, or increase access to treatment. Some relatively cheap, or even free, ways to greatly improving impact scores exist. To improve the Global Health Impact scores, companies can reduce prices for medicines in developing countries or help people secure the nutrition they need for effective treatment. They can collaborate with countries, or international organizations, to help people secure treatment or increase new drug development.

The Global Health Impact Index focuses on evaluating companies’ drugs’ global health consequences in a rigorous way, and not on companies’ efforts or policies, so no one should object that the Index scores depend on many other factors besides companies’ innovations -- including country-level health system performance, international aid efforts, and what other drugs already exist. To see why, consider one concrete example.



(Children Poverty, iStock)

Suppose a company offers a new product for a disease that requires expensive genetic testing and no programs designed to provide that testing, or no agreed upon strategy for doing so, exist. Even if the company gives their drug away, it may have a low score on the Global Health Impact Index because most countries do not have genetic testing in place to identify candidates for their medicine. It may even score lower than a second, much less generous, company scores because it is easier to diagnose the diseases the second company's drugs address. Nevertheless, each company gets as much credit as its drugs have impact. The first company can increase the credit it receives if it can also help people figure out if they have the disease so that more people receive treatment. It can partner with organizations that help developing countries' health systems secure diagnostic services or come up with cheap ways to diagnose patients in the private sector (e.g., with something similar to the new home test kits for HIV/AIDS available in the US).

Once Global Health Impact researchers rate companies, they need empirical evidence to specify exactly how to rank them. Chapter 6 presents some such evidence, but researchers need further evidence to decide how best to do so. What they should do depends on consumers' willingness to purchase different products from Global Health Impact certified companies and markets for these products' size. Researchers need to pay attention to how much companies have to do to secure (and maintain) different ratings to maximize the incentive for increasing global health impact. Using the evidence, they can determine if giving only top rated companies the highest ranking will maximize the incentive to increase global health impact or if they should use a continuous rating system or something with different grades.

To see how the rating system works, suppose that the evidence supports giving just the top 15% (here the top two) companies on the Index the highest rating (as Chapter 6 discusses, empirical evidence is necessary to decide where exactly to set the bar). On the original Index, Novartis (alleviating 6.4% of malaria, TB, and HIV/AIDS' burden) would barely rise above the threshold while Pfizer (alleviating 6.2%) would fall just below it. Consumers can choose Novartis's Excedrin over Pfizer's Advil as well as other alternatives. However, it would not take much for Pfizer's drugs and technologies to have a larger impact than Novartis' drugs and technologies. Realizing this, Novartis also has a reason to extend access on their essential medicines (or to come up with new medicines for the diseases in the model) to remain certified, to improve their brand perception, and to secure greater sales. To estimate the incentive's size, note that Pfizer's 2016-consumer-product-revenue was US\$52.824 billion (Pfizer, 2016). If securing a higher-rank increases their sales by 2% on average, this creates US\$1.05 billion incentive for them to increase their global health impact. Some companies may resist making some products more widely available if it limits their ability to profit from them. Still, many of the things people need in the developing world do not make companies much profit simply because the people who need them cannot afford to pay very much.

Importantly, the Global Health Impact Organization is expanding the Index overtime to encourage companies to make sustainable changes in their policies for the long term, not just pursue policies that pay off in the short term. So even if another company beats out Pfizer, Novartis, or Sanofi in the next iteration, the competition will continue. This ensures that the Index gives appropriate weight to rewarding long-term investments that actually improve global health.

There are other ways the Global Health Impact Organization might modify this rating system to increase its ability to incentivize positive change. To ensure that companies do not get too much credit for producing slight variations on standard drugs and technologies, researchers can consider how much improvement each drug offers over the next best alternative by subtracting the best old drug or technology's expected benefit from the new drug or technologies' expected benefit. (Though market competition also constrains the amount of credit companies receive as new technologies continue to replace old ones). If researchers can also evaluate companies' policies' health consequences, the Global Health Impact Organization can also incentivize them to increase their impact in other ways. Researchers might evaluate companies' charitable efforts or outreach programs, for instance. They can also adapt the Index to estimate medicines' cost-effectiveness.

Even though the Global Health Impact analysis is constantly improving, the Index creates incentives to improve global health and it is possible to use a better index if one is developed. Researchers just have to establish a feasible bar over which companies must pass to receive Global Health Impact certification and the rating system must correctly rank companies (ordinally). So although the rating system is not perfect, it creates incentives for companies and other organizations to extend access to medicines around the world.



(Pills by Stevepb, 2016. Pixabay)

3. Creating a Good Rating System

Consider one way the Global Health Impact rating system can encourage pharmaceutical companies to extend access to essential drugs and technologies. Suppose The Global Health Impact Organization gives companies a label to use on their products. Companies have an incentive to use the Global Health Impact label to garner a larger market share. Suppose Sanofi, for example, receives the label based on its ranking; it can use the Global Health Impact label on Bullfrog sunscreen. Sanofi then has an incentive to do so because people, in some cases, prefer to purchase Bullfrog to the alternative brands. Similarly, suppose Novartis receives the label and uses it on Excedrin. If even relatively few consumers prefer Global Health Impact products, that creates a significant incentive to use the label. For some estimate that the market for analgesics, alone, will reach US\$26.4 billion per year by 2022 (Allied Market Research, 2016). Companies can use the label wherever they market their products.

The label will give companies an incentive to do things that save more lives and alleviate more disability. It gives Sanofi and Novartis reason to continue to partner with the Medicines for Malaria Venture to develop new medicines for this devastating disease and to make their medicines more widely available (Hassoun, 2012a; Novartis, 2016). For other companies can compete to secure a higher Global Health Impact ranking and secure the label – beating out Sanofi and Novartis -- by saving an even greater number of lives and alleviating more disability. Again, suppose the bar was set so that only the top 15% of companies could secure the label on the original Index. Then Pfizer would only have to do a bit more with its TB medicines (or develop something new for malaria or HIV/AIDS) to secure the label instead of Novartis when the Global Health Impact organization releases its next iteration of the rating system.



(Medicines by Bicanski, 2016. PIXnio)

We should explore this option, given other labelling campaigns' success. There is good experimental, and quasi-experimental, evidence that consumers buy many products with "ethical" labels (Hiscox and Smyth, 2011; Hainmueller, Hiscox, and Sequeira, 2015; Hiscox, Broukhim, and Litwin, 2011). Moreover, when they do so, that helps people around the world (Raynolds, 2002; Calo & Wise, 2005; Milford, 2004; Ronchi, 2002; Bacon, 2005; Taylor, 2002; Imhof & Lee, 2007).

Similar labeling initiatives -- including (RED), Fair Trade, and Organic labels -- have a large impact (Fair Trade Labelling Organization, 2018). Big Fair Trade markets exist in Europe and the US. By 2002, about 50,000 retail outlets (97% of roasters) including Starbucks, Peet's, and Green Mountain sold Fair Trade certified coffee (Raynolds, 2002). By 2011, retailers sold 88,000 tons of Fair Trade coffee around the world and made €200 million from Fair Trade coffee in the United Kingdom alone (Fairtrade, 2012). By 2015, more than 800,000 small coffee farmers belonged to Fairtrade cooperatives or associations. And it is not just coffee (Fair Trade Labelling Organization International, 2018). By 2011, people spent approximately 500 billion Euros on Fair Trade certified goods (Fairtrade Labelling Organizations International, 2012). By 2015, producers made about €138 million (Fairtrade Labelling Organizations International, 2016). RED and Buy Pink -- for companies willing to donate some profit from selling a product to AIDS and breast cancer research, respectively -- are also successful. (RED) allows companies to make a single product red in exchange for a contribution to the Global Fund. By 2010, it provided US\$150 million to the Global Fund and was one of its largest contributors (Global Fund, 2010). The United States Department of Agriculture (USDA) Organic label, Leadership in Energy & Environmental Design (LEED) certification for green buildings, Forest Stewardship Council (FSC), and Smart Wood Certified Forestry sustainable forestry labelling are likewise growing (USDA, 2015; Hansen and Bratkovich, 2015; Fernholz et. al., 2010; LEED, 2015). Ethical consumption is generally rising. In the United Kingdom (UK), for instance, expenditure on ethical goods and services in energy, housing, household items, transportation, personal items and subscriptions almost doubled between 2002 and 2007 (Co-Operative Bank, 2007). By 2015, the average UK consumer spent approximately €580 on ethical goods and services per year (UK Population, 2016; Rodionova, 2015). This compares favorably with per capita spending on foreign aid (€212/yr).

In some ways, Global Health Impact certification differs from other ethical consumption campaigns but here, and in subsequent chapters, I argue that these differences support the prospects for a Global Health Impact label. Global Health Impact certification differs from Fair Trade, in part, because it ranks firms rather than products. It also focuses on helping poor people access medicines to improve their livelihood rather than on improving their livelihoods directly or stopping exploitation. However, some other important ethical consumption initiatives encourage consumers to discriminate between products made by highly ranked firms and others and focus on helping people access essential medicines. ISO 14000 certification -- which evaluates companies' and other organizations' environmental management efforts - provides one example (ISO, 2009; ISO, 2015). The Pink label rewards firms who are contributing to breast cancer research (Carter, 2015; The Breast Cancer Research Foundation, 2017b).

Global Health Impact certification probably most closely resembles the (RED) campaign where firms that invest in global health can use the (RED) package on one product. Again, (RED) is one of the largest contributors to the Global Fund and, in 2005, the Global Fund provided about 20% of the international funding for HIV/AIDS programs and about 65% of the funding for TB and malaria programs (Komatsu, et. al, 2010; Henry J. Kaiser Family Foundation, 2006). By November 2017, (RED) contributed over US\$500 million to support Global Fund HIV/AIDS programs in Africa and impacted more than 90 million lives (RED, 2017; Global Fund, 2017). Global Health Impact certification differs from (RED) in that it rewards companies for their drugs' actual impact (not their investments) and the Global Health Impact Organization give companies a label to use on everything they make. However, these differences suggest it can have an even greater effect.

Consider how a Global Health Impact label can create large incentives for positive change and why companies will try to increase their health impact to secure the label. One percent of the market in analgesics alone is worth over US\$346 million (Global Industry Analytics, 2010). Larger markets for other pharmaceutical products exist. Some state that consumer health care sales were US\$217 billion in 2016 (Johnsen, 2016). Top products include cough, cold, and heartburn medicines, laxatives, oral antiseptics, antidiarrheal medicine, eye care products, acne remedies, anti-itch medications, anti-smoking products, first aid care, and sunscreens (Stone, 2015). If companies can secure 1% more consumer sales in a US\$217 billion market, that is more than US\$2 billion worth of incentive for them to do so. Plus companies can benefit in other ways from improving their brand perception (e.g. employee recruitment and retention, socially responsible investment etc.). Developing a new drug per year probably does not cost US\$2 billion and companies can extend access to many existing drugs to millions of people for much less than this (see Chapter 4 for discussion of Merck's drug donation program to get a sense for the scale of what companies might do for much less than this).

Patients, doctors, and insurance companies may not always prefer Global Health Impact drugs and technologies. Sometimes people need one particular medicine to treat their condition, in which case its Global Health Impact status does not matter much.

Many drugs have equally good competitors, however. In 2017, almost 80% of US prescriptions were for generic drugs (Business Wire, 2017). When an equally good competitor for a patented drug exists, patients, doctors, and insurance companies can take the ratings into account. More importantly, many over-the-counter medications have equally good competitors and there are many other consumer healthcare products too. Again, the sales of consumer health care products may have hit US\$217 billion in 2016 (Johnsen, 2016). This market includes many drugs made by major pharmaceutical companies including Nicorette, Monistat, and Claritin that have reasonable competitors.

If researchers also rank generic companies, Global Health Impact labelling has greater potential influence. The global generic drug market may have exceeded US\$74 billion in 2014 and consumers are often willing to buy generic (Palmer, 2017). So the fact that pharmacies usually do not carry more than one generic of the same molecule should provide no objection to this ranking (people might prefer a Global Health Impact labelled generic medication to its patented competitors). If Global Health Impact good sales amount to an additional 1% of consumer health care product and generic medicine sales, that yields almost US\$3 billion incentive for pharmaceutical companies to become Global Health Impact certified (Palmer, 2017; Johnsen, 2016; Healthcare Packaging, 2012). This number looks big enough to incentivize even Pfizer to do some good. Many big companies have over-the-counter divisions. Despite a big slump in consumer sales in 2012, for instance, about a third of Novartis' income came from their over-the-counter medicines (Bennett, 2012).

Furthermore, pharmaceutical companies make many things besides drugs – from diet drinks to lotion and pet vitamins to mouthwash. Pfizer, for instance, makes parasiticides, anti-infectives, biologicals, allergy, cancer, pain, metabolic disease, production, nutritionals and food safety products for animals. Besides their pain management, dietary supplements, respiratory, topical, and gastrointestinal medicines for people, they have “a full line of infant formulas, follow-on formulas, growing-up milks and prenatal and adult supplements” (Pfizer, 2010). So, they could use the Global Health Impact label on these products too.

Finally, governments, insurance companies, and pharmacy benefit managers (PBMs) who administer prescription drug programs for private insurers and healthcare plans can create additional incentives for companies to extend access to essential drugs and technologies using the Index and/or label. Both public and private insurance companies and PBMs can create incentives for positive change by giving (some) preference to (medically equivalent) Global Health Impact drugs on their formularies. Highly ranked companies can lobby insurance organizations to encourage them to do so. Alternately, researchers can create a similar rating system measuring insurance companies', and PBMs', impact to motivate them to consider companies' Global Health Impact scores.

Although some companies may try to undercut the Global Health Impact label, or game the system, by lobbying for higher ratings or creating counterfeit labels, highly ranked companies should support it. If researchers keep the rating standards transparent and simple, and educate consumers and health care professionals about the Global Health Impact label, consumers may trust it and view alternatives with suspicion. This is the case with Fair Trade labels, for instance. Governments can even regulate the label as the US did, however imperfectly, with "Organic" labels.

Ultimately, whether Global Health Impact initiatives work depends on how people respond. For the label to work, for instance, consumers must support it. The last chapter provides some empirical evidence that they will and explains how to secure further evidence. The book primarily aims, however, to make the case for further inquiry.



(Medicalscience by Gabe Biencycki, 2010. Pixnio)

4. Global Health Impact Licensing

Having a Global Health Impact certification system for pharmaceutical companies also opens the door to many other ways to incentivize companies to extend access to essential drugs and technologies. Global Health Impact certification can form the basis for corporate social responsibility (CSR) initiatives, for instance (IISD, 2017). Socially responsible investment companies can include in their portfolio Global Health Impact companies. CSR initiatives have a large impact on firm performance and shareholders likely invest more in socially responsible companies (Erhemjamts et. al., 2013; Flammer, 2015). Alternately, the Global Health Impact Organization can link high scores on the Index to other company benefits, e.g., priority review for important medications (Towse et. al., 2011). If only companies with high ratings can secure the vouchers, that likely decreases their market value but increases the incentive for companies to get high scores by extending access on essential medicines more broadly. Such policies might positively affect global health (again, researchers need empirical analysis to see).

The Global Health Impact Index might even encourage new kinds of social activism. An organization like UAEM might, for instance, implement a Global Health Impact licensing campaign by convincing universities to give licenses only to highly rated companies (or at least to give preference to such companies). Alternately, the American Medical Student's Association, which uses metrics to put pressure on pharmaceutical companies and universities to improve policies, might launch such a campaign.

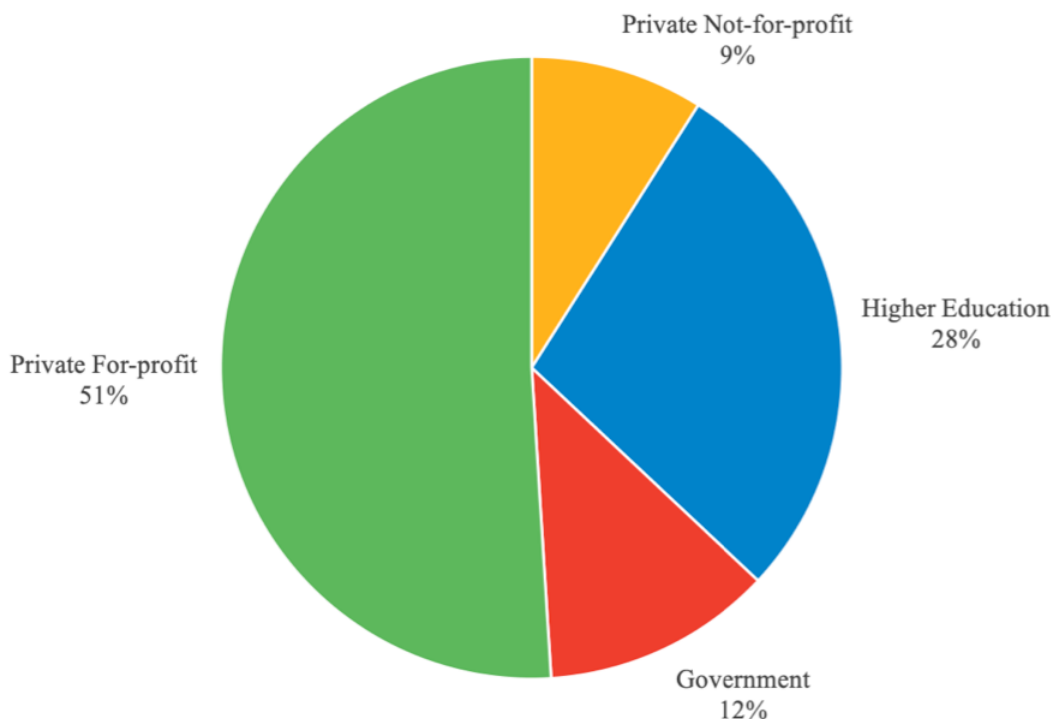
Universities have embraced other licensing proposals. UAEM has, for instance, gotten some universities to accept their Equitable Access License (i.e. open-access license) (Universities Allied for Essential Medicine, 2009). As a result of their efforts, the University of California Technology Transfer Advisory Committee issued the following guideline to technology licensing offices on all campuses: “life-saving UC medical research should be licensed to drug companies in ways that make the resulting products affordable to low-income patients in developing countries” (Collinsworth, 2010). UAEM has also convinced many other universities to agree to implement open access licensing policies for developing countries.

Although universities compete intensely for research money and are increasingly governed as corporations, professors and students can often hold them to account. UAEM has developed a university score card that evaluates their efforts to promote global health to encourage them to improve their practices. They can expand this score card to look at whether or not universities adopt the proposed criteria for licensing on the basis of the Global Health Impact Index (UAEM, 2013; Stephan, 2012).

Pharmaceutical companies rely, to a large extent, on university research and development. Universities have developed many drugs and technologies including vaccines, tests for osteoporosis and breast cancer, and the “gene splicing technology that initiated the biotechnology industry” (Association of American Universities, 1998). Many big pharmaceutical companies license in, or acquire, a large percentage of their drugs (by, for instance, purchasing small biotech companies) from universities (Angell, 2007). In 2000, a US Senate report found that federal funding supported the development of 15 of the 21 most important drugs. In 2002, “Pfizer licensed in 30 percent of its drugs, and Merck 35 percent” (Angell 2004, 71). Bristol-Myers Squibbs’ licensed all of its best selling drugs in 2003. And, by 2013, more than 50% of companies R&D pipeline was coming from external sources (Schuhmacher et al., 2016; Levy, 2013). Pharmaceutical companies probably acquire even more of their most innovative drugs from universities. “Nearly all HIV/AIDS and cancer drugs are based on outside research -- most of which is university research sponsored by the National Institutes of Health (NIH)” (Angell, 2007).

On a conservative estimate, universities in high-income countries do about a third of all R&D. The percentage is likely even greater as companies have a large incentive to over report R&D and include marketing costs as R&D.

Figure 3.6: R&D in High Income Countries



Modified from: (de Francisco & Matlin, 2006, 41)

Companies did not benefit much from university technology until recently. In 1980, the US congress passed the Bayh-Dole Act which allowed universities to patent their research and to license it to third parties (Consumer Project on Technology, 2005). Before the Act passed, universities received less than 250 patents per year. In 1996, universities received over 2,000 patents, “executed nearly 2,200 licensing agreements and received royalty income from licensing of US\$242 million” (Universities Allied for Essential Medicine, 2007). Between 1980 and 2007, academic research resulted in over 1,500 start-up companies (de Francisco & Matlin, 2006, 41). In 2014, universities held at least 42,015 active licenses (AUTM, 2014). Many other countries have implemented similar legislation in recent years (Graff, 2007). It is not obvious, however, that the laws have resulted in more innovation (Giuri, 2013). Though the assistance universities’ technology transfer offices provide may help with licensing, these property rights may reduce the number of spin-off companies created -- previously patents were retained by individuals, not their employers.

Furthermore, pharmaceutical companies rely more and more on universities for medical research. Recently in-house pharmaceutical research has lagged (NIHCMF, 2002; Paul et al., 2010; Schuhmacher et al., 2016). In light of its dry pipeline, the pharmaceutical industry is “searching ever more desperately for drugs to license from small biotechnology companies and universities” (Angell, 2004).

Because pharmaceutical companies depend on university’s licenses, universities could, conceivably, influence these companies’ policies. If, for instance, universities’ licensing agreements require sales of their technology go to highly rated companies, companies have a large incentive to meet Global Health Impact standards. Of course, universities often create new start-up companies or license to start-up companies that cannot themselves receive Global Health Impact certification. These companies test and develop products using university technology. Eventually, however, their owners sell these companies, or their technology, to larger companies that could receive Global Health Impact certification. So, contracts need down-stream licensing clauses. Universities might adopt a Global Health Impact licensing policy voluntarily. Their technology transfer offices could agree to implement Global Health Impact licensing practices.

At the University of Pittsburgh, for instance, the head of the Office of Technology Management (OTM) has this decision-making capability. The OTM would probably also need the support of the Chancellor, if the policy negatively impacted the university’s ability to sell licenses (Vanegas, 2007; Wang, 2012). Northwestern University made US\$1.36 billion from a single drug in 2011. Depending on how researchers set the Global Health Impact standards, the policy might not negatively impact the sale of university licenses. At least, researchers should carry out the requisite econometric analysis to determine the likely impact on all of the relevant stakeholders (including universities and the poor).

Technology transfer offices already use some non-financial criteria when deciding to whom to license their products. The Bayh-Dole Act encourages universities to license to small, US companies, and universities acquiesce without complaint.

If the technology transfer offices at some universities refuse to sign on to voluntary programs, however, professors and researchers might have an impact because they sign agreements to allow universities to license patents resulting from research they create. Although some researchers at major universities receive industry funding, industry funds only 7% of university research (AUTM, 2005; AUTM, 2007). Obviously, this funding does not all come from the pharmaceutical industry.

Universities may consider the Global Health Impact Index in deciding which companies to partner with since:

...universities hold an avowed commitment to creating and disseminating knowledge for the public good, and they have pledged to see the technologies they develop deployed to benefit the world. Campus decision makers are insulated from lobbies that may dominate political arenas; they are expected to be responsive to students and faculty; and they operate in an environment where reasoned debate, not power, is expected to be the currency (UAEM, 2007).

As the Association of University Technology Managers put it, universities do not only care about monetary benefits but want the new drugs and technologies they develop to “be used to further the public good” (AUTM, 2005, 35).

Students could also encourage professors and universities to engage in Global Health Impact licensing. They might follow United Students against Sweat Shops’ (USAS’) example. USAS has helped convince campuses to buy “sweat-free” clothing made at factories approved by the Worker Rights Consortium. If a Global Health Impact licensing campaign only succeeded as well as USAS’s campaign did by 2012, this proposal could create more than US\$840 million worth of incentive for pharmaceutical companies to become certified every year. That exceeds the cost of developing a new drug on many estimates (Millman, 2014). This incentive might suffice to double the number of drugs produced for neglected diseases between in 1975 and 1999 in a similar time-frame (Trouiller et al., 2001).



(Kids by tortugadacorp, 2017. Pixaboy)

5. The Global Health Impact Initiatives’ Advantages

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Using global health impact information (perhaps with associated campaigns) has some advantages over, and avoids some problems with, the main alternatives for increasing access to essential medicines around the world. The Global Health Impact Index creates incentives to both help people access existing drugs and technologies and do new R&D for the world’s worst health problems. Most alternatives address only one issue.

Consider a few alternatives to help people access existing drugs and technologies (Hoffman, 2014; Berdud et al., 2016). Pharmaceutical companies can price drugs differentially; offering them at different prices for different markets (Flynn et al., 2009; Danzon and Towse, 2003; Danzon et al., 2013; Williams et al., 2015). Alternately, countries can reduce medicines’ costs via compulsory licensing (WTO, 2001; WTO, 2006; WTO, 2017). Countries can issue licenses to produce and/or import these products without approval by the company holding the patent. Or, activists can try to repeal the WTO’s TRIPS agreement or, barring that, modify it to allow poor people to secure essential medicines at, or below, the marginal production costs (Lanjouw and Jack, 2004). Many governmental and non-governmental organizations can also do much more to extend access on essential medicines to people who need them.



(India Child, Max Pixel)

Although companies do some differential pricing, they have also resisted differential pricing (Kanavos et al., 2004). In some cases, companies may suffer financially if they lower their prices. It may be difficult to prevent people from re-importing cheaper drugs across borders, even with different packaging (Elek et al., 2016). Moreover, companies may have trouble selling expensive drugs to the richest people in poor countries (Flynn et al., 2009). Reference-based pricing (where countries consider the prices offered in other countries in deciding what they are willing to pay for pharmaceutical products) may also limit companies' ability to price differentially. (Though the net effect of both reference-based and differential pricing is not clear as pharmaceutical pricing is not transparent, there is some evidence that prices are higher in poorer countries) (Morgan et al., 2017; Danzon et al., 2013; Elek, et al., 2017; Vadoros, Sotiris and Kanavos, 2014). Moreover, the consequences of differential pricing -- like reference-based pricing --, probably depend on how decision makers implement the policies. In any case, companies do not pursue differential pricing to the extent required to adequately protect global health (Williams et al., 2015).

Similarly, while compulsory licenses have decreased medicine prices in many countries, companies often resist compulsory licensing (Hassoun, 2015c; Lee and Son, 2017; Attaran, Beall and Kuhn, 2012; Beall and Kuhn, 2015; Correa, 2018). When South Africa passed its Medicines Act, many big pharmaceutical companies sued because the Act encouraged generic competition for AIDS medicines (Barnard, 2002; Outterson, 2006). It was only after protracted negotiation, and negative media attention, that the pharmaceutical companies withdrew their lawsuit. Still, South Africa did not go on to import generic medicines (Barnard, 2002; Reichman, 2009; Outterson, 2006; GHW, 2005). At companies' behest, the US Trade Representative singles out other countries in its 301 Reports for not enforcing foreign intellectual property rights. So, they may face trade sanctions (USTR, 2017). The US also uses bilateral trade agreements and "diplomatic and political pressure to undermine countries that produce generic medicines and/or consider importing them" ((Oxfam, 2002) cited in (GHW, 2005, 106)).

Worse, countries without their own manufacturing capacity often cannot secure the drugs they need even if they do issue compulsory licenses (Barnard, 2002; Outterson, 2006; GHW, 2005; Hassoun, 2015c; Lee and Son, 2017; Attaran, Beall and Kuhn, 2015; Attaran, Friedman and Besten, 2003). TRIPS requires countries like India, Brazil, and Thailand that export essential drugs and technologies to issue compulsory licenses to do so (Barnard, 2002; Steinbrook, 2007; WTO, 2017). Few countries have agreed to export drugs under a compulsory license (WTO, 2006). The first was Canada, which issued a compulsory license to export TRIPVAR, an AIDS medication, to Rwanda (Goodwin, 2008). However, given international and Canadian laws' complexity, Canada was yet to export a single pill three years after issuing the license (Goodwin, 2008). Moreover, even when compulsory licenses are implemented, the costs of medicines may still be substantially higher than medicines provided through international procurement efforts (which may attract multinational generics manufacturers, increase competition, and alleviate concerns about medicine quality) (Danzon, Mulcahy and Towse, 2013). Together these facts may explain why few low-income countries have utilized compulsory licenses (Beall and Kuhn, 2012; Correa, 2018; Son and Lee, 2017; Attaran, Beall and Kuhn, 2015). To make compulsory licensing more effective, countries should consider adopting clear patent guidelines and procedures for granting the licenses. They should also better train judges and patent examiners (Correa, 2018).

Moreover, there was a large social movement, backed even by the (then) Pope, to prevent the TRIPS agreement (Martin, 2002). Ultimately, it failed (WTO, 2006). Pharmaceutical companies want control over the drugs they develop in every market. So countries cannot realistically return to the pre-TRIPS situation. Health advocates find it difficult to modify the agreement at all to allow greater access to essential medicines in poor countries (Drahos and Mayne, 2002; Asrar, 2016).

Finally, there are many barriers to other ways governmental and non-governmental organizations try to extend access to existing medicines. Countries can not only negotiate with companies for lower drug prices and formulary placement, use reference based pricing, support parallel importation, and compulsory licensing, but they can limit patent terms (e.g. by facilitating market entry for generic and biosimilar medications) and utilize international resources (e.g. patent pools and drug procurement and distribution). Some other promising reforms include reducing patient co-pays, implementing policies to improve prescribing practices and results, and paying for medicines based on their performance (Maniadakis et. al., 2017; Boehm et. al., 2013; Prasad, 2017; Glasgow, 2001). Non-governmental and international organizations can support country efforts to extend access on existing medicines, e.g., by funding efforts to do so, advocating for legal change, and so forth. Still, effective options are often limited. Countries not only face international pressure and lack of resources. They have to overcome problematic laws and practices. In the US, for instance, it is illegal for Medicaid part D to negotiate for lower prices or rebates and the Food and Drug Administration (FDA) has blocked parallel importing citing safety concerns (Prasad, 2017). Many pharmaceutical companies also attempt to reduce competition from firms offering generic and biosimilar medicines by (e.g.) initiating lawsuits and paying competitors to with-hold entry. Moreover, there is significant resistance to other proposed reforms (from reducing copays, to giving prescribers feedback on patient outcomes and value- and reference- based pricing) (Prasad, 2017). As President Trump put it, when he reneged on campaign promises to require pharmaceutical companies to disclose prices and allow Medicare to negotiate directly with companies, a “tangled web of special interests” oppose lowering high drug prices (Pear, 2018). In short, the requisite changes may be difficult, though there is significant room for improvement.

Alternatives to Global Health Impact campaigns, that encourage R&D on essential drugs and medications for neglected diseases, include prize funds and grants (Kremer and Glennerster, 2004; Outterson, 2006). Global health organizations and foundations often offer prizes or agree to buy medicine from any company that develops a new drug or technology (e.g., for malaria) at a set price. They often give grants for research on neglected diseases. The Gates’ Foundation recently collaborated with Novartis to test new antibiotics for TB, for instance (Jarvis, 2006).

Neither alternative captures the free market’s efficiency. The agencies offering prize funds or grants have to decide what neglected diseases, or other problems, they want to address. They might help people more effectively in other ways. They also have to decide how much to pay for a given invention. “These decisions are likely to be associated with substantial inefficiencies due to incompetence, corruption, lobbying by companies and patient groups and gaming” (Pogge, 2008, 243).

Aidan Hollis and Thomas Pogge suggest creating a second (voluntary) reward system for new R&D (Hollis and Pogge, 2008). Under this system, pharmaceutical companies will not receive a limited monopoly for their inventions. Rather, they propose rewarding inventors based on how much their inventions contribute to ameliorating the global disease burden. Inventors would have an incentive to invest in whatever R&D, infrastructure improvements, pricing systems, or donation programs most ameliorate global disease burden. They can even price their drugs below marginal production cost to capture a greater reward from a global fund. The fund would give inventors an incentive to collaborate with, rather than protest against, generic companies, country governments, and non-governmental organizations trying to alleviate the global disease burden. If they work out the design details properly, Hollis and Pogge’s proposal will not create an incentive for companies to prefer drugs that treat affluent patients’ chronic diseases or disorders. Rather, it will give companies an incentive to invest in those drugs that prevent the most death and alleviate the most suffering. In earlier work, Pogge said that the “cost of the plan might peak at around US\$45 - 90 billion. With all the world’s countries participating, US\$45 billion amounts to 0.1% and US\$90 billion to 0.2% of the global

product” (Pogge, 2007, 18). In the proposal developed with Hollis, they revise this estimate to US\$6 billion (Hollis and Pogge, 2008).

Unfortunately, Hollis and Pogge’s proposal also has a few problems. First, their proposal relies on collecting new, difficult to secure, data from clinical trials (Selgelid, 2008). Partly for this reason, their proposal is expensive and depends on developed country taxpayers, or donors, who have historically done little to help the global poor. Unless countries fund it well, it cannot generate a large enough incentive for companies to risk investing in new drugs and technologies.

Tim Hubbard and Jamie Love offer a slightly different proposal to increase access to essential medicines. They suggest a global treaty to finance R&D where, for instance, countries can use prize funds to fulfill their obligations (Hubbard and Love, 2004). They support mandatory contribution and open access to resulting technology. The contribution system might function like a competitive pension plan where employers or individuals direct their investments towards those R&D firms they believe most effective (Hubbard and Love, 2004). Prize funds require less bureaucracy than centralized R&D organizations. They are also more efficient.

Unfortunately, advocates may also find it difficult to implement Hubbard and Love’s proposal. The pharmaceutical industry may resist a mandatory R&D prize fund that requires open access to resulting technology. Moreover, like Hollis and Pogge’s proposal, it relies on developed countries signing an international treaty to support R&D. Even if they agreed, countries might not follow through and actually require people to invest in R&D. Again, developed countries rarely fulfill their duties under international law to aid the global poor.

There are other ways countries, international institutions, and non-governmental organizations can try to increase research and development on essential medicines, though doing so is difficult. They can try, for instance, to cultivate public private partnerships like the TB Alliance or International Partnership for Microbicides that create new technologies to address major global health problems. Alternately, they can expand other push or pull mechanisms for incentivizing new innovation and greater access (Danzon and Towse, 2003; Stevens and Huys, 2017; World Intellectual Property Organization, 2017; Plotkin, 2008; Attaran, 2004). Many of the most promising proposals will cost a lot to implement and sustain. Many address only part of the access problem.

The Global Health Impact project avoids some problems outlined above and does not compete with other mechanisms for incentivizing access. First, many pharmaceutical companies have an incentive to support Global Health Impact campaigns, while most (if not all) companies lack the incentive to do enough differential pricing, and almost all have an incentive to resist compulsory licensing and a return to the pre-TRIPS situation. Second, Global Health Impact certification does not undermine the free-market’s efficiency. The Global Health Impact Organization does not decide what diseases or problems companies should address, nor does it need to determine how much to pay for inventions before they exist. Researchers evaluate companies’ products based on how much they actually help people (though researchers need to expand the Index to every disease to create incentives to address them all and beyond medicines to create incentives to address health problems in ways that do not involve them at all). Third, the Global Health Impact Index focuses on companies’ output and can incentivize them to do new R&D on neglected diseases as well as extend access to existing drugs and technologies. Fourth, researchers need not collect expensive data to create the Global Health Impact Index, though it benefits from, and incentivizes, improvements in existing diseases surveillance systems. Fifth, although the Global Health Impact project is not as ambitious as Hollis and Pogge’s proposal, it is practical and relatively low cost. Although it costs something to administer a trademark like Global Health Impact, it costs nowhere near the US\$45-90 billion (or even US\$6 billion) price tag for the Health Impact Fund (Hollis and Pogge, 2008). The total revenue and support for Fair Trade USA (formerly Transfair USA), the primary Fair Trade labelling organization in the US, was US\$20,271,633 in 2016 (Fair Trade USA and Good World Solutions, 2017). So, unlike Hollis and Pogge’s proposal, Global Health Impact certification does not require taxpayer support. It may also be easier to implement, and less costly, than many other governmental, and non-governmental, initiatives. Finally, the Global Health Impact Index does not compete with other mechanisms for incentivizing access. Rather, people can use it along with all of the other methods canvassed here to bring even greater global health benefits.



(Drug Research, iStock)

6. Objections

Taking a broad enough view of what promotes public health, there is little reason to worry that pharmaceutical companies, researchers, or consumers can better direct their efforts elsewhere (Marmot and Wilkinson, 2006; Brock, 2014). Better access to existing drugs and technologies or more R&D on diseases affecting the poor cannot solve poor people's greatest health problems on their own. War, natural disasters, polluted water, and inadequate food present some of the biggest obstacles to health in developing countries. Prevention and poverty alleviation are also incredibly important. Some anti-retrovirals, for instance, do little for the poor when they lack adequate nutrition. Still, medicines help keep people alive and well enough to avoid disasters and access the clean water and nutrition that they need (just as clean water and adequate nutrition help people access medicines and ensure that they are effective). People should promote health in many other ways and support Global Health Impact initiatives. Global Health Impact campaigns can lead companies to come up with new drugs or treatment regimens that work well in the poorest places and improve access to clean water etc. to increase their drugs' impacts. Whether or not new vaccines against HIV/AIDS, malaria or TB, or better access to existing medicines, can do as much for people as vitamin A supplements, or building a few more wells, people do not (and should not!) have to choose between them. If the people who need them can access effective medicines, that might even free up resources for other attempts to improve public health. In any case, people should support Global Health Impact campaigns and provide food, vitamin supplements, and wells.

Having different certification levels can help ensure that the Global Health Impact rating system does not make it appear that pharmaceutical companies are doing better than they are (as the next chapter argues that most companies do not do enough to extend access on essential medicines to the global poor and many companies also fail to respect rights). Researchers can give only the best companies a "gold star" label and give others "silver" or "bronze" labels.

To secure regulatory approval, however, it is essential that consumers cannot misinterpret the label as suggesting that particular products are good for their health. The FDA explicitly specifies that product labels cannot mislead consumers by suggesting that purchasing labelled products will improve their health. For this reason, perhaps researchers need a label design that omits the word "health" and that emphasizes the fact that the initiative will help the poor. Perhaps rather than "Global Health Impact Certified" a label could read "Global Access Company" or "Equitable Access Company." (Moreover, to prevent blowback, the Global Health Impact Organization should prohibit companies from using the label on products that may harm health).

A different worry is that companies can benefit from the Global Health Impact label even if they are not overall good corporate citizens. Some companies may benefit just because they are large or have large consumer product lines with successful products. Others manufacturing and distributing impactful drugs may lobby for patent protections and set high prices. Companies may also try to improve their rating on the Index by reducing investments into drugs for other pressing global health problems. Unless Global Health Impact certification considers companies' behavior, it cannot stop them from acting unethically.



(Doctors by Julien Harneis, 2009. Wikipedia)

Looking at companies' drugs' global health impact does not condone bad behavior. The Global Health Impact rating system aims to create the largest possible incentive for extending access on essential medicines and fulfilling individuals' rights to health. In doing so, it does not preclude competition from smaller companies, those without commercially successful products, or those without large consumer portfolios. In fact, some such companies do relatively well on the Index and it at least improves their reputation (Hassoun, 2015c). The rating system does not incorporate everything, but companies' scores fall if their lobbying and pricing policies constrain access or if they focus on less pressing health needs. Furthermore, researchers are expanding the Index to incorporate other major global health threats and evaluate different parts of the pharmaceutical supply chain. Still, it is important that everyone utilizing the Global Health Impact Index understands exactly what it does and does not mean – it is not a general stamp of approval for good behavior. Other rating systems – like the Access to Medicines Index – focus on companies' policies and commitments. The Global Health Impact Index focuses on outcomes to encourage companies to combat disability and save more lives.

More pressingly, highly ranked companies may try to distract the public from their generally poor behavior in other arenas. Suppose, for instance, that another organization launched a campaign to get companies to stop fighting compulsory licensing in developing countries by lobbying US trade-representatives. Companies might respond by holding a media event to promote their Global Health Impact status and undermine the campaign. Since companies control many resources, they would probably win a battle in the press.

Companies hardly need a label, however, to hold a public relations event and undermine campaigns to get them to improve their practices. Companies can promote their charitable programs or even start new programs to get good publicity. Those involved in the attempt to get pharmaceutical companies to improve their practices should not blame each other if companies abuse their efforts. Rather, they should stand together.

Eventually, an appropriately impartial and transparent, non-governmental group, like Oxfam International or MSF, may oversee the Global Health Impact Organization and help counter any industry pressure. Alternatively, governments or an international organization, like the WHO, can provide the requisite oversight (as the US government does with the USDA Organic label and the International Standardization Organization does with the ISO 14000 environmental management standards, which help firms monitor their environment impact). I suspect, however, that researchers should keep the Global Health Impact Organization firmly situated within academia for as long as possible as every organization has different priorities. Discussions with health policy makers suggest, for instance, that international organizations often manipulate data at different points during their funding cycles alternately to show need and impact (Hassoun, 2014b). The Global Health Impact Organization's current home in the Institute for Justice and Wellbeing insulates it from political pressures and allows members of academia to work together with civil society to promote positive change.

If other problems arise, the Global Health Impact Organization has institutionalized mechanisms and procedures for addressing them. Researchers from universities and civil society organizations from around the world, dedicated to measuring pharmaceutical products' impact on global health to advance access to affordable medicines, develop and oversee the rating system. All the Organization's members administering the rating system accept a conflicts of interest policy and agree to abide by its code of ethics. The Organization has an advisory board to address unforeseen problems as they arise. It has also held several workshops to solicit feedback on the model from academia, civil society, and the pharmaceutical industry after launching it at the WHO in 2015. No rating system is perfect, but there is reason to believe this one can help promote health and human rights.



(Healthy Lifestyle Medicine African Black Boy Holding Colorful Pills Background by borgogniells, 2015. iStock)

7. Conclusion

This chapter suggested that collecting and analyzing global health data can help improve poor peoples' access to essential drugs and technologies. To illustrate how data can help, it presented a new model synthesizing health systems data to evaluate medicines' global health impact. It then suggested using this information to create incentives for positive change. It considered, for instance, an initiative to create a Global Health Impact label. Other ethical labels have a large impact and, given the large market in pharmaceutical technology, the prospects for a Global Health Impact label are good. Global Health Impact certification has advantages over, and complements, alternative mechanisms for addressing the access to essential medicines problem. The final chapter explains how to gather data on Global Health Impact initiatives and presents some preliminary evidence to support the labeling initiative, in particular. However, information on medicines global health consequences is useful for many other reasons too. It can support policy and research as well as social activism. Policy makers can use the data to evaluate innovations and company efforts. Researchers can mine the data to locate global health impact's most significant causes and consequences. This can help policymakers create, evaluate, and improve policies. Although good data cannot solve all the world's health problems, it can make a significant difference in many people's lives.

Notes

1. The WHO has compiled an essential medicines list, in part, by considering medicines' cost. Again, however, I use the term only to indicate medicines that address dire health needs, irrespective of cost.
2. The WHO has even convened an Intergovernmental Working Group, the Secretariat on Public Health, Innovation and Intellectual Property to examine solutions to the second problem and create a global strategy to secure "needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries" (WHO, 2016a). One option the Working Group supported that is not discussed in what follows, but merits significant consideration, is patent pools -- though they will not address pricing issues (WTO, 2007).
3. For previous work on this topic, see: (Hassoun, 2012a and Hassoun, 2012b). For other labelling ideas, see (Eyal, 2012) and for criticism, see: (Hassoun, 2013c).
4. For similar proposals, see: (Hubbard and Love, 2004).
5. The original Index focuses, in particular, on first-line drugs for malaria, first- and second- line HIV/AIDS medicines and treatments for drug-susceptible, multi-drug resistant, and extremely drug resistant TB.
6. When possible, researchers do this at the country-level.
7. The average impact is an average over all untreated or imperfectly treated cases. If treatment effectiveness is 80%, researchers consider 20% of cases ineffectively treated. When actual effectiveness data do not exist, the model uses data on drug efficacy. Efficacy's meaning obviously varies by disease. For HIV, e.g., researchers normally establish efficacy by looking at viral load suppression. Researchers must do further work to more accurately translate outcomes into DALY-impact in the future.
8. Other alternatives for HIV/AIDS include the World Bank and Burnet Institute's Optima models; the East-West Center's AIDS Epidemic Model; the Institute for Disease Modeling's Epidemiological Modeling Software EMOD; the University of California, San Francisco's Global Health Decisions model. For a helpful review, see: (Kahn et al., 2017). Another useful tool for health resource allocation is the WHO CHOICE platform, which looks at the cost-effectiveness of various interventions. See: (World Health Organization, 2014).
9. Perhaps because Global Health Impact models are significantly different than, and have some advantages over, traditional epidemiological models, the Global Fund considered using the Global Health Impact Index rather than Avinir Health's models in calculating their health impact in 2015. Like several of the other companies/organizations offering epidemiological and agent-based models, Avinir employs dozens of scientists, has large grants including financial support from international institutions, and at least one of their advocates played an important advisory role to the Global Fund in making this decision. That said, the head epidemiologist at the TB section of the WHO has been very supportive of Global Health Impact efforts and international organizations' interest attests to the fact that the scientific basis for the Global Health Impact models is strong.

10. Published results of WHO CHOICE analysis for malaria, TB, and HIV/AIDS have limited geographical coverage and examine only some therapies (e.g. drugs susceptible but not drug resistant TB treatment) utilizing large assumptions across regions and treatment types. On the other hand, the methodology has the advantage of estimating program level costs and benefits of implementation and the WHO has analyzed the program level costs and benefits of administering drugs from many other diseases (Hogan et al., 2005; Baltussen et al., 2005; Morel et al., 2005; World Health Organization, 2018).
11. Companies do less R&D on new drugs and produce fewer new drugs, in part, because they effectively outsource these tasks. However, they still invest a lot in drug development (Rafols, et al., 2012).
12. Ideally, researchers can see which companies have marketing authority around the world and consider other ways to aggregate drugs' impacts.
13. To see which companies hold the patents on medicines, researchers rely primarily on FDA patent applications, patent searches, and companies' annual reports and would like to thank Cornell's Legal Research Clinic for assistance. See: global-health-impact.org.
14. If researchers can ascertain international institutions' contributions to this procurement effort, they may proportion credit for procurements to these organizations and improve, e.g., on the Global Fund's method for calculating the lives saved with their interventions.
15. This is not to deny that it is important to secure input from all the relevant stakeholders, including pharmaceutical companies, to create a good and sustainable rating system. It is important, however, that the mechanisms for doing so isolate decision-makers from undue influence by industry. Companies should not get to set priorities for evaluation.
16. Ideally, researchers would look at medicines' marginal impacts but formulating the correct counterfactuals and gathering the data to do so is difficult. For discussion and explanation see below and (Hassoun, 2013b). I explain some ways researchers are improving and expanding the model across intervention types, and time, as well as potential areas for future development below. Also, see: (Hassoun, 2015c; Hassoun, 2016c).
17. The Index need not incentivize every company to participate but does not depend on their good will as it gives them financial and reputational incentives to pay attention to their rating. For discussion, see: (Brock, 2014; Hassoun, 2014a).
18. Researchers might also consider the problems associated with drugs and technologies in estimating their net benefits (e.g. some drugs have pretty bad side effects that researchers should probably take into account, others require difficult-to-implement treatment regimens).
19. Researchers can conduct other analyses. They might, for instance, forecast expected changes in effectiveness given changes in other variables like cost or modify the impact measure by dividing it by a measure of company profits. Currently researchers use DALYS but they might weight them in various ways to account for different views about the value of life vs. disability or of addressing different diseases (e.g. orphan diseases or diseases of the poor). For one possibility, see: (Esposito and Hassoun, 2016).
20. Sensitivity analysis suggests that companies' relative rank is quite stable. Some uncertainty is acceptable as long as this does not affect whether companies are close to crossing the bar for certification.
21. For some preliminary evidence that the label can affect brand perception, see the last chapter.
22. Which companies have (RED) products may change over time and some labels are also based on relative rather than absolute performance – like Energy Star where products compete only within classes (though see the discussion of this particular label's problems in the Introduction to Part 3) (Brooks, 2016).
23. The world's biggest pharmaceutical company, Pfizer, had revenues of about US\$48 billion per year in 2008-9 (Pfizer, 2009). However, several smaller companies hold patents on key drugs.
24. US\$ 2 billion exceeds the cost of developing a new drug on many estimates (Millman, 2014). But, again, even if companies will not develop new drugs for this amount because they want to preserve future markets, they can help people access existing medicines much more easily.
25. Sometimes companies may not want to use a label on generic products if they would prefer their customers buy their higher priced brand name drugs. Nevertheless, they can choose to use the label only on their brand name products if that is the case (Healthcare Packaging, 2012).
26. Some observe that the agriculture lobby succeeded in lowering the standards for what qualifies as organic. But, even if one prefers higher standards, the USDA does oversee pesticide use and other farming practices that motivated the organic movement in the first place (USDA, 2017; Wilce, 2014).
27. Even the Norwegian government uses some socially responsible investment criteria in investing its pension funds (Follesdal, 2007).
28. This proposal is different from the Global Health Impact proposal advanced here. Universities could take into account Global Health Impact status in issuing licenses where doing so does not constrain access even if they are not willing to embrace equitable access licensing.
29. These included captopril (Capoten), fluoxetine (Prozac), acyclovir (Zovirax), AZT, acyclovir, fluconazole (Diflucan), foscarnet (Foscavir), and ketoconazole (Nizoral). For more information, see: (JEC, 2000).
30. University technology transfer yielded around US\$25 billion in 1996 (AAU, 1998).
31. On changing patterns in pharmaceutical company innovation, see: (NIHCME, 2002).
32. Furthermore, a lot of funding for universities comes from government, so this graph probably understates the government's role.
33. The Stevenson-Wydler Act similarly helped NIH-funded research receive patents and get licensed to drug companies. The companies market the drugs and then sometimes patent them for other uses. If a similar campaign could get the NIH to give preference to highly-rated companies, this might help people access essential medicines and technologies as well. After all, the NIH has helped create essential drugs like AZT (developed by the NIH in conjunction with Duke University and then licensed to GlaxoSmithKline) (Angell, 2004, 57).
34. The Association of University Technology Managers licensing surveys provide information about almost 200 major universities' budgets, research expenditures, and licensing agreements as well as other useful information. See: (AUTM, 2007; AUTM, 2005; AUTM, 2014; AUTM, 2016).
35. Another point of contact between universities and companies is when companies want to do clinical and pre-clinical trials. Universities could allow research funding only from Global Health Impact certified pharmaceutical companies, even if it does not result in university owned intellectual property. Unfortunately, university researchers, whose careers depend on such research contracts, may reject this policy.
36. The University of Pittsburgh's Office of Technology Management alone generated US\$7.1 million in revenue in 2007 from licensing, equity cash-outs, and legal fee reimbursements from licensees. They earned US\$4.9 million in licensing revenue alone and their equity in the start-up Novecea generated US\$92,000. Finally, they sold their spinout Stentor Inc. for US\$6.7 million (OTM, 2007, 7-8).
37. The moral case for encouraging Universities to consider Global Health Impact status is probably much stronger than giving preference to small US businesses.
38. About 20% of Stanford faculty members had industry funding in 2004. About 30% of Stanford's faculty resided in the medical school (Delgado, 2005). Of course, not all of this funding was from pharmaceutical companies, but pharmaceutical companies probably fund some non-medical faculty so it seems reasonable to suppose that 20% of the medical faculty had pharmaceutical funding at Stanford. If that is right, about 7% of Stanford's faculty is funded by pharmaceutical companies. Another way of getting at the proportion of industry funding from pharmaceutical companies is to suppose that the percentage of the medical faculty at Stanford receiving industry funding is about the same as the percentage of medical faculty receiving industry funding on average. If it is, then 25% of medical faculty at Stanford had industry funding. Again, other industries may account for some of this funding but pharmaceutical companies may fund non-medical faculty as well. So it seems reasonable to conclude (again) that about 7% of the Stanford faculty had pharmaceutical funding. Stanford, however, has a large medical school and most universities and colleges probably receive much less industry funding.
39. The reason people should embrace this campaign would probably differ from USAs's since it is different to make goods that essentially, and directly, rely on the labor of the poor than to make goods that simply ignore the needs of the poor. See discussion in subsequent chapters.

40. This assumes that universities do 30% of pharmaceutical companies' research and that similar success ensures that at least 2% of these research funds benefit the poor. Since US academic centers spent over US\$42 billion in R&D in 2005, 2% of US\$42 billion is US\$840 million per year (Hassoun, 2012a; AUTM, 2007). Moreover, as noted above, universities only get about US\$240 million per year from licenses but they get more from the biotechnology companies they create. For instance, "Columbia University, which patented the technology used in the manufacture of Epogen and Cerezyme, collected nearly US\$300 million in royalties from more than 30 biotechnology companies over the seventeen-year life of the patent" (Angell, 2004, 71). And some of this incentive would presumably come from other downstream companies bound to give preference to highly rated companies in selling their technologies. How much incentive this proposal can generate depends on how much universities demand.

41. It is, of course, possible that a proposal addressing only one issue will be more effective. But, as addressing both matters, I believe the proposal has an advantage everything else being equal. Some argue that people should support projects that are already having an impact, as there will be fewer transition costs and less negotiation and agreement necessary to secure positive outcomes (Brock, 2014). It is not obvious that existing projects will have a larger impact than new ones, however (Hassoun, 2014a). Moreover, given that the access problem persists, I believe that new ideas are important. See, also, Chapter 4 for related discussion.

42. There are many other promising ideas in the literature as well, though I do not have the space here to canvas them all. Many innovative licensing and intellectual property strategies merit serious consideration (Abramowicz, 2003; Faunce and Nasu, 2008; Danzon and Towse, 2003). Some suggest better predicting demand for medicines for neglected diseases (Boldrin and Levine, 2008). Others encourage developing countries to form alliances with each other and reform their patent offices (Yu, 2008; Drahos and Mayne, 2002). Yet others endorse international organizations' move towards promoting development (Lerner, 2008). Some even suggest changing university licensing practices to allow greater access to university research (Evans, 2008).

43. Although intellectual property rights encourage new drugs and technologies' development, these rights may also prevent the poorest from securing existing drugs and technologies. With some exceptions, the TRIPS agreement requires WTO member countries to recognize other countries' patents. The so-called "TRIPS-Plus" provisions require countries to allow "ever-greening" patents beyond the 20-year mark and discourage generic competition. Pharmaceutical companies can apply for patents on many "trivial or irrelevant" aspects of their drugs and technologies like packaging or dosing regimens to extend protection beyond their primary patent life. Competing companies must notify them before producing generics and the originator gets an automatic 30-month extension on their patent. Sometimes they try to extend protection further with legal action. Often generic companies must test drugs again before putting them on the market even if they are equivalent to patented versions. This expensive testing can delay generic entry into the market. See: (FTC, 2002; Sell, 2004; NIHCFM, 2002).

44. This may also limit countries' ability to do reference-based pricing.

45. "The combined worth of the world's top five drug companies is twice the combined GNP of all Sub-Saharan Africa" (GHW, 2005, 103). In 2002, the 10 largest pharmaceutical companies made over \$39 billion, more than half Fortune 500 companies' total profits. By 2014, the top 10 companies had made \$89.8 billion in profits, with an average margin of 19.6% (Anderson, 2014). "With such profits at stake, it is no surprise Big Pharma invests a huge amount of money in protecting... [patents]" (GHW, 2005, 10).

46. Similarly, when Thailand issued a compulsory license for efavirenz, an HIV/AIDS drug produced by Merck, the US government was displeased. See: (McDermott, 2006).

47. To learn about Australia's difficulties in extending access to essential drugs and technologies to its population under TRIPS, see: (GHW, 2005, 106). The administrative burden of trying to issue a compulsory license may also provide a roadblock to doing so (GHW, 2005, 106).

48. A more recent alternative is another licensing and rating system – Universities Allied for Essential Medicines' (UAEM) Global Access Licensing Framework and their metric for rating university technology transfer offices (UAEM, 2016). UAEM has promising initiatives and it is probably too soon to know if they will succeed. Their metric, however, looks only at universities' policies and actions rather than their impact (UAEM, 2010; UAEM, 2013, 52; UAEM, 2015).

49. Some argue that such alternatives are more cost-effective than prize funds. People need to offer large prizes for companies to risk not developing an acceptable invention quickly enough. See: (Kremer and Glennerster, 2004).

50. A bidding system might provide a partial solution to this problem. On this, see: (Pogge, 2007).

51. Hollis and Pogge's proposal is similar in some ways to the proposal advanced in (Hubbard & Love, 2004). Hubbard and Love suggest separating out markets for R&D from markets for products (putting the latter in the public domain and funding the former through tax contributions or competitive tender systems).

52. It is not clear that people ought, on Pogge's moral theory, to try to minimize the global disease burden rather than the disease burden of those everyone's shared institutions have harmed (until everyone's human rights are satisfied). Because this is a complicated (and partly empirical) question, I will not discuss this difference between our initiatives further here.

53. Selgelid's delightful article discusses some difficulties in framing the rating question and evaluating companies' efforts. The issues he raises merit further consideration.

54. It is not at all clear how Pogge estimates his program's cost, but it might cost a bit more than he imagines as drug companies report average R&D costs in the hundreds of millions (Angell, 2004; Hoffman, 2014; Berdud et. al 2016).

55. Companies can get credit for improving access to clean water insofar as that improves medicines' impacts on the original Index, but not just because clean water improves health directly. However, I am not convinced that having a narrow remit is a problem for the project. Few people object to efforts to improve clean water because they do not also help people access essential medicines. Although the Index can do more than one thing, it need not do everything.

56. (Brooks, 2016) points out that R&D is expensive, so it is an advantage of the proposal that companies can increase their Global Health Impact scores in many ways – though we have seen that it may well generate a large enough incentive to stimulate new drug development.

57. The counter-factual relative to which something counts as an improvement should probably approximate the current situation as closely as possible. Some other ways to deal with any bad incentives this creates exist. For discussion, see: (Selgelid, 2008).

58. When I asked in 2009, Fair Trade USA had never even had a lawsuit to defend their label though two people at the organization helped prevent abuse by contacting those who infringed their copyright. They relied primarily upon their customer base for monitoring (Sinclair, 2009).

59. One might worry about focusing effort only on measurable outcomes. However, few deny that it is important to measure progress and, I believe, this is only a problem if that is the only way people try to achieve positive change.

60. Researchers can also expand the Index to take into account other things like companies' profits or policies (e.g. they can divide impact scores by a measure of companies' size) if doing so better promotes global health

61. This would also keep the rating system from creating incentives for mergers and acquisitions or monopolies that might decrease competition in the industry and reduce global health impact overall (Brooks, 2016). Presumably, however, the rating system would then create less incentive for larger companies to address the most pressing global health problems and reduce the resources available for doing so.

62. Health advocates might, of course, create a label based on both indexes, but I believe that it is better to focus on improving outcomes directly where possible.

63. I am less concerned about effects on non-essential drug markets. Some companies that do not make essential medicines make personal care products that compete with pharmaceutical companies' over-the-counter personal care products. If pharmaceutical companies receive a label and that reduces the competition for personal care products, I believe that is a small price to pay for incentivizing greater access to essential medicines.