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## International Disparities Panel

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## INTERNATIONAL DISPARITIES PANEL

“The access to medicine movement addresses a basic problem: purchasing medicine can be very expensive, but it does not have to be because making medicines is often incredibly cheap.”

**Professor Sean Flynn:**\* I am the Associate Director of the Program on Information Justice and Intellectual Property program at Washington College of Law (PIJIP). One of PIJIP’s activities is focused on public policy solutions to the problems created by the globalization of patents on pharmaceutical products, particularly in underdeveloped countries.

I want discuss access to medicine disparities in developing countries and the link between those disparities and the globalization of patents with the World Trade Organization. I will talk about what we call the “access to medicines movement,” which is an international movement of global health advocates that is focused on the problems and policy solutions that lie at the intersection of intellectual property, trade policy and the right to health.

The access to medicine movement addresses a basic problem: purchasing medicine can be very expensive, but it does not have to be because making medicines is often incredibly cheap. The actual manufacturing process of creating a pill is very inexpensive. An individual pill often contains a very small dose of pharmaceutically active ingredients. The cost of the component chemicals is minor. What is costly is the research and development that goes into the initial invention of that drug.

So what we have in pharmaceuticals is an industry that presents very low marginal costs – the cost of making that next pill – but high fixed costs – the cost of inventing the pill and setting up the manufacturing infrastructure. That is the problem the patent system seeks to solve. If you let the market run free, then new producers will copy the original product and turn out equivalent products in competition with one another until prices approximate the marginal cost of production. That is great for promoting access to the drugs we have now. But why would you create a new drug (or other product) if marginal cost pricing is what

\* Professor Sean Flynn completed clerkships with Chief Justice Arthur Chaskalson on the Constitutional Court of South Africa and Judge Raymond Fisher on the U.S. Court of Appeals for the Ninth Circuit. He also represented consumers and local governments as a senior attorney for the Consumer Project on technology. He served on the policy team advising the Assistant Attorney General Deval Patrick. He also taught constitutional law at the University of Witwatersrand in South Africa.

you can expect from your research and development investment?

The patent law solution to the problem is to grant a monopoly right – what we used to call a franchise – to be the only seller of a new product for a limited time. That right to exclude competition allows the company to charge higher prices and corner all sales for a period, enabling the company to recoup research and development costs plus a potential profit premium. The lure of those supra-competitive profits drives investments in research and development.



Now, recall the important premise in patent law – the franchise is to be limited. To reach the optimum balance between consumer interests in innovation of new products and their interest in accessing affordable products now, the patent right must tailored to the context. No one I know proposes that patent rights should run forever in a given industry or be impervious to all forms of economic regulation that impacts the price patent holder demands. That would expose consumers to perpetual monopoly rents, which few if any economists would endorse as an efficient solution for consumers or the economy more generally.

Now for the second premise: patents pose pricing problems in all industries, but the problems (and therefore need for tailoring of patent rights) are particularly evident in markets for pharmaceuticals and other essential goods.

As we discussed at the onset, in a competitive market the introduction of new suppliers willing to sell at ever-lower above-cost prices will force prices down close to the marginal cost of producing the good. In other words, the restraint on prices in a well functioning competitive market is the cost of production.

Monopoly markets are different. With no additional competitors that can enter, the restraint on price will be a function of demand instead of cost. The monopolist will raise its price above cost until any additional increase, because of the resulting fall off in sales, will be unprofitable. Monopolists cannot profitably set any price. The maximum profitable price will be determined by the willingness and ability of the market to pay. In other words, the maximum profitable price will be a function of the shape and slope of the demand curve.

Patents on medicine can cause particular problems for two reasons. First, drug patents often effectively cover the entire product, rather than an input into a larger product (e.g. a widget in a machine). Where the medicine is truly innovative in the sense of doing something useful for a particular group of patients that no other drug can do, then the monopoly created by a drug patent can be particularly strong. There will be no substitutes consumers can shift to.

Second, needed medicines are essential goods. Access to medicines is necessary to enjoy the full scope of the right to health. Without needed medicines, people will live shorter and less fruitful lives to the disadvantage of themselves and the societies they live in.

This essential element has two implications, one economic and one moral. The economic point is that people will be willing to pay very high portions of their income to access essential products. Imagine how much you would be willing to pay for access to a life saving medicine. Or how about water or electricity in your home. In the latter cases, the essential good is often delivered by a monopoly as well. But we regulate the prices those monopolies can charge because otherwise they could exact very high prices for the services. Would you pay twice your current bill to have water in your home? Three times? Ten times? You might consume less at these prices, but there is really no substitute you can choose.

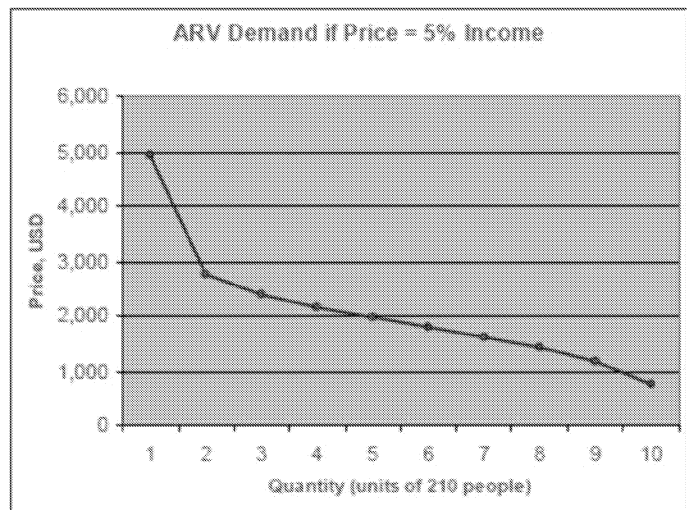
The essential aspect of medicines also brings to the fore a moral component of policy choices in this area. Where government policy is distributing access to goods and services needed to actualize human rights and basic welfare concerns, then equity concerns need to be paramount. If governments can produce a policy that leads to as much or more of the innovation of the necessity while increasing access then (morally) it should. And if it can purchase a good that will demonstrably increase lives and health, then human rights laws may require that.

Now we are ready for our third premise. The problems with pharmaceutical patents will be compounded in countries with high income inequality, which applies to most of what we call the Third World or the group of underdeveloped countries.

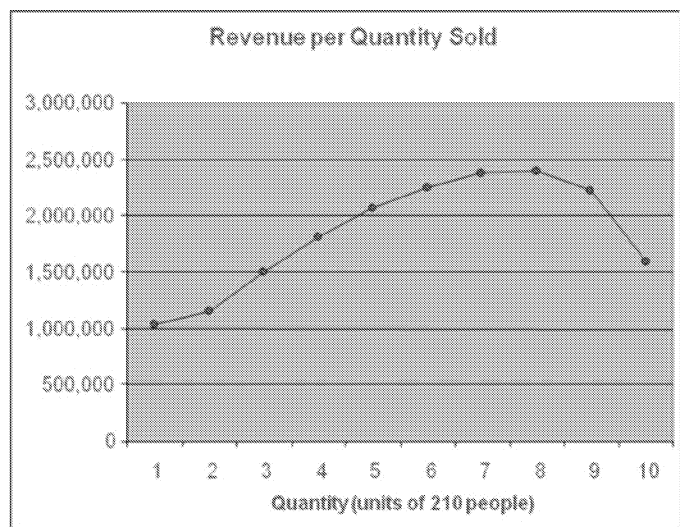
Recall that in the monopoly markets that patents create, price will be a function of the shape and slope of the demand curve. These factors are in turn impacted by the degree of income inequality in a market.

Compare two polar cases – Norway (with the greatest income equality) and South Africa (with the greatest income inequality).

If you assume that the demand curve for an essential good will be driven by ability rather than willingness to pay, then you can construct the shape of that curve based on distribution of income. The figure for Norway is included below.

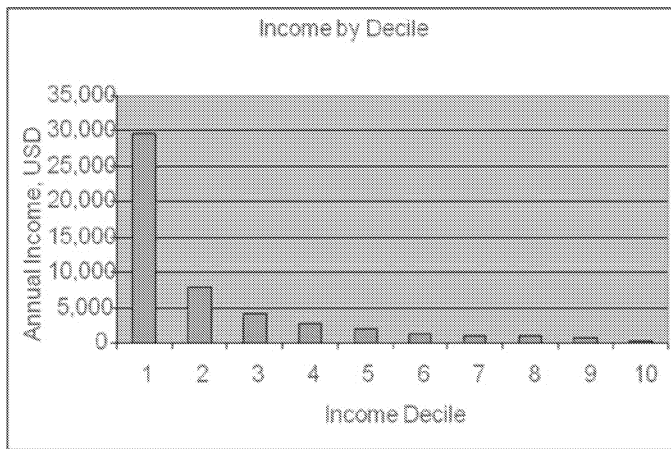


As demand curves go, that one is pretty flat. Small price decreases along the vertical axis will lead to relatively large increases in purchases along the horizontal axis. This creates a profit maximizing incentive for the monopolist to decrease prices to sell more units until about 80 to 90 percent of the population is served, leaving 10 to 20 percent of the consumers as deadweight loss. That fact can be represented in a second figure, which shows the number of sales at each price along the demand curve and the total revenue (along the vertical axis) for each price and quantity sold.



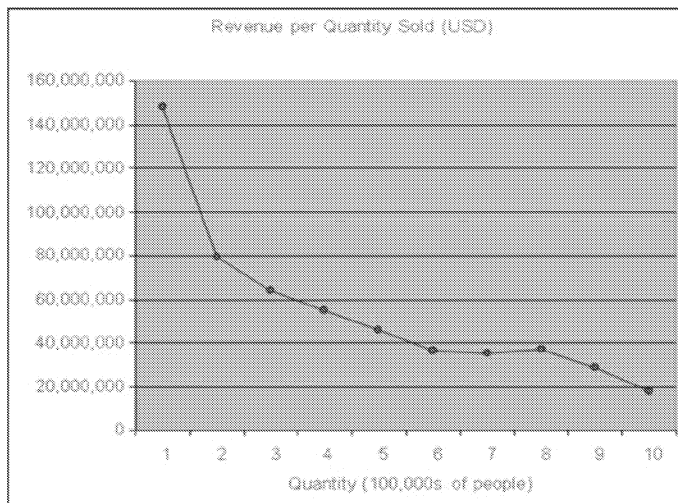
The model predicts that in Norway the social cost we will pay for the incentives to innovate from monopoly provision of the product will be about ten to twenty percent of the population prices out of the market and therefore dependent on social provision of some sort (if there is a right to the medicine in question). Of course in Norway, everyone receives social provision.

Now let us compare this outcome with a demand curve representative of a country with extremely high income inequality. In South Africa, the top ten percent of the people earn first world incomes. But after that, the amount of income in each decile of the population falls off pretty dramatically, creating along flat tail of the demand curve where people have very low incomes.



This creates very different pricing incentives for the monopolist. The demand curve is very steep at the richest segment of the population, meaning that even large price decreases will not lead to large numbers of increased sales. Look at the step between the first and second decile. If the company halves its price it will still be too expensive to reach the next segment of demand. The company would have to decrease its price to about 25% to double its sales – not a profitable choice.

The profit maximizing behavior of the company can be depicted in the chart below.



Essentially, every time the company decreases price to reach a larger segment of the population, it loses money. So the rational company, assuming it has no means to price discriminate between consumers, will set its price to serve the top 10 percent of the population and leave the rest as deadweight loss.

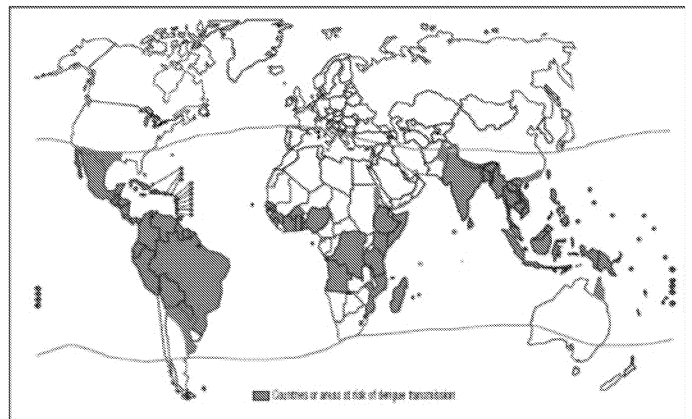
The last premise was that the price of patents in underdeveloped countries with high income inequality is likely to be very high. Correlatively, the contribution to incentives for innovation is likely to be quite low.

If you are choosing a market to innovate for and the reward for innovation is a monopoly, then who are you going to target – Norway or South Africa? Global income distribution essentially looks like the South Africa chart –

with the small segment of national economies being very rich, and long tail of low income nations where the majority of the world's population lives.

This leads to the so-called 10/90 gap. The rough-hand trope is meant to convey that something like ninety percent of global research and development investment on medicines serves the needs of just ten percent of the world's population.

Consider the distribution of Dengue fever, which affects about a million people a year.<sup>1</sup>



Will a company invest in the development of a new treatment for that disease? What about tuberculosis, malaria, sleeping sickness, etc.

The premises outlined above lead to a modest conclusion. Because of the particularities of the impact of patents on pharmaceutical products and of the characteristics of demand in underdeveloped countries with high inequality of income, one-size-fits-all patent-based solutions to the problem of incentivizing innovation for medicines in underdeveloped countries are inappropriate. Patent rights on pharmaceuticals, to the extent they are granted at all, need to be highly tailored in underdeveloped country markets and alternative means of incentivizing research and development for conditions that primarily impact underdeveloped (especially tropical) countries need to be considered.

The international intellectual property law trend has been in exactly the opposite direction. The comparative history of protection of patents in the pharmaceutical industry is one of a myriad of policy tools used to tailor patent rights on pharmaceutical products:

- In Brazil, Argentina, Switzerland and Japan, pharmaceuticals were entirely exempted from patent laws until the 1970s or later.
- In the United Kingdom and Canada, there were special compulsory licensing provisions for pharmaceuticals that allowed governments to open up access to generic competition for pharmaceutical products.
- India created a patent regime that only protected the process of making pharmaceuticals, instead of the end product, which spun into the largest generic pharmaceutical industry in the world, where reverse engineering was used to bring competing products to market in India.

In the 1970s and 80s the pharmaceutical industry, largely based in the U.S. and Europe, led a policy drive to change this state of affairs and globalize patent laws, specifically for pharmaceuticals. The justification was that there was free riding by developing countries on the pharmaceutical research and development expenditures by the United States and other wealthy countries. Ultimately, that policy process led to the inclusion of a specific agreement on intellectual property in the 1994 World Trade Organization Agreement.

The WTO agreement on Trade Related Aspects of Intellectual Property (TRIPS) was the first international agreement setting global minimum substantive standards for intellectual property. All countries are now required to grant patents on products and processes. India's process system is out. No discrimination is allowed by field of technology — which means that pharmaceutical industry-specific measures will have to meet additional justificatory burdens.

Post-TRIPS free trade agreements narrowed the tailoring options and expanded patent rights further.

And now we have the Anti-counterfeiting Trade Agreement (ACTA) which may limit the ability of countries to limit remedies for patent enforcement (e.g. by doing away with injunctions) and may increase the rights of transit countries to seize drugs and other products at the border, thereby limiting the free trade in affordable medications.

We can pause and ask if this was a positive development. Theoretically, there are good aspects of the globalization of intellectual property. It addressed a real free-riding problem regarding what economists call a "global public good." Everyone benefits from a new invention, whether you pay for it or not. When one country pays for the invention of a new medicine, all countries benefit from it. But should poor countries who benefit little from intellectual property protection pay the same — or really more in deadweight loss terms — than the richest?

If your answer is no, which mine is, then you might join the campaign to expand "flexibility" in international IP law and work on thinking up other tools to meet the challenges of incentivizing innovation. This is the agenda of the access to medicines movement.

**Professor Margaret Farrell:**\* I recently took a ten day trip to Cuba with twenty-seven other health care professionals. I count myself as a health care professional because I am a lawyer that works in health care. The rest of the group were doctors, nutritionists, social workers, psychiatrists, and mental health workers, among others. We had a packed itinerary of visiting health care facilities, hospitals and sanitariums and talking to professional involved in providing care in those institutions. I was reflecting on my remarks about health care disparities in Cuba and it called into question what health care disparities in Cuba really are. Is it disparities in access to care or disparities in outcomes and quality of care? Are we talking about disparities among Cubans—rich, poor, urban, rural, minorities? Does the topic include disparities between Cuban citizens receiving care in Cuba and foreign visitors receiving care in Cuba, so called medical tourists? The topic may also include disparities between Cuba and other countries in the world.

Cuba is geographically isolated—an island the size of Pennsylvania. It has eleven million people and most of the population lives in urban settings. The population is primarily made up of people of European decent. There is a small population of mixed races that were immigrants from Haiti—about ten percent of the population. The primary language is Spanish. Cuba's major exports are: nickel, sugar, tobacco, shellfish, coffee and interestingly, doctors. Cuba is a Communist country and it was overtaken in 1959 by Fidel Castro, who was then supported by the United States. At the time of the revolution, there were a fair number of doctors per capita, but the disparities were great. There were 6,000 doctors in the country before the revolution, but about half of them left for Miami after 1959. The Castro revolution left Cuba with essentially no health care system and the country was forced to develop a health care system in isolation.

\* Professor Margaret Farrell attended University of Chicago and Yale University's Law School and has also been a post-doctoral fellow at John Hopkins University School of Hygiene and Public Health. Professor Farrell received a fellowship at the Federal Judicial Center in Washington, D.C, where she conducted research on scientific evidence and expert testimony. She has published articles on a wide range of topics and practice law as a partner at *Ennis, Friedman, Bersoff and Ewing* in Washington, D.C. and worked as a member of Governance and Legal Audit Committee of the White House Health Care Task Force. She is currently Special Master in the United States District Court for the District of Columbia on behalf of the mentally disabled. She studied public health in Cuba and served as a volunteer legal advisor to the Minister of Health and Social Welfare.

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“That basic focus on community and social functioning makes the Cuban delivery system very different. The statistical outcomes of Cuba’s health care system are truly impressive.”

Cuba is also politically and economically isolated — partly by virtue of the U.S. embargo, although the U.S. embargo gets blamed for more of Cuba’s economic problems than it should. As a result of its isolation, Cuba can be seen as a Petri dish experiment in how to create a health care system with few resources. The first thing that Cuba did after the revolution was establish medical schools. Most professors left Cuba after President Batista was overthrown, so students with little experience, who had just graduated from the country’s only medical school, became the medical school faculty. Later, foreign doctors joined the faculty to teach in Havana. Eventually, Cuba developed a system of six year medical schools located in each province and an international medical school with 8,000 students — the Latin-American Medical School in Havana — which draws students from all over Latin America to train in western medicine.

A three-tier system for delivering health care was established. In Cuba, health care delivery system is focused on the family. At the bottom level there are neighborhood clinics that are staffed by a doctor and a nurse who are committed to work in the neighborhood for two years. The doctor lives above the clinic, so he or she really becomes a part of the community. They see most of their clinic patients in the mornings, and in the afternoon, clinic doctors make regular visits to families to assess their health care needs. The family is the basic unit of health care delivery in Cuba. This differs from the U.S. individual-based health care system. Doctors visit each family at least once a year. The medical diagnosis is tripartite—physical, mental, and social health. The doctor examines how well patients are functioning in their families and communities. That basic focus on community and social functioning makes the Cuban delivery system very different.

The statistical outcomes of Cuba’s health care system are truly impressive. Life expectancy in Cuba is a little bit higher than it is in the U.S. Mortality of children under five is 6.5 deaths per thousand births in Cuba and 7.6 deaths per thousand in the U.S. In 2009, newborn deaths in Cuba were five per thousand births, whereas the number was six deaths per thousand in the U.S. Cuba also has the lowest incidence and prevalence of HIV/AIDS of any country in Latin America (and the highest literacy rate). In Cuba there is one doctor for every 170 people. In the U.S., we have one doctor for every 188 people. The World Health Organization (WHO) calculates Cuba’s annual per capita health expenditure at \$229 per person. The U.S. spends more than \$6,000 per person on health care. Although differences in cost of living and average annual incomes make a comparison of health care expenditures in the

two countries difficult, there is a vast difference in the amount of resources that go into Cuba’s system.

The neighborhood health system gets much of the credit. Cuba assumes responsibility for providing health care for its population. The Cuban Constitution, unlike the U.S. Constitution, was amended in 1976 to say that everyone has a right to health protection and care. Cuba guarantees this right by providing free medical and hospital care, offering medical service networks, providing clinics and hospitals with preventative and specialized treatment centers, and by providing health publicity campaigns, medication, regular medical exams, general vaccinations, and other measures to prevent disease.

Thus, in Cuba, health is a positive Constitutional right and the state has a corresponding obligation to provide medical care and treatment to its citizens. Cuba uses the \$229 per person to concentrate on prevention, which results in the country’s very favorable health outcomes. Doctors in the neighborhood clinics are activists. They talk in the schools on a regular basis about sanitation and hygiene, run vaccination campaigns and lead school children in campaigns to eliminate mosquitoes. In addition, since it is a Communist country, Cuba can require their citizens to do things that the U.S. would have to persuade people to do. For example, loss of life due to hurricanes is very low because citizens are required to participate in evacuation drills, are warned and are evacuated by police. Cuba’s low infant and maternal mortality rates also result from a system of close monitoring, maternal residences for high risk mothers, and specialized hospitals. It does not rely on a mid-wife system since health clinics and hospitals are accessible even in rural areas. Cuban citizens seem to feel that they have a civic duty to be healthy and to use the benefits provided to them free by the State.

**Mark Green\*:** What I would like to do is frame my comments around a true story. About a month ago, I had the chance to visit a small hospital on the islands of Zanzibar called Nizium Mojo. Literally translated

\* Mark Green is the former United States Ambassador to the United Republic of Tanzania. As Ambassador, Mark worked tirelessly to create lasting relationships with the government and people of Tanzania to create economic growth and fight disease like malaria. Prior to serving as ambassador, Mark served four terms in the U.S. House of Representatives. He was a member of the House Judiciary and International Relations Committees, and served as an Assistant Majority Whip. From 1987-88 Mr. Green served as secondary school teachers in Kenya through WorldTeach Project, a development organization based at the Phillips Brooks House of Harvard University. Mr. Green attended the University of Wisconsin Eau-Claire and received his law degree at the University of Wisconsin-Madison.

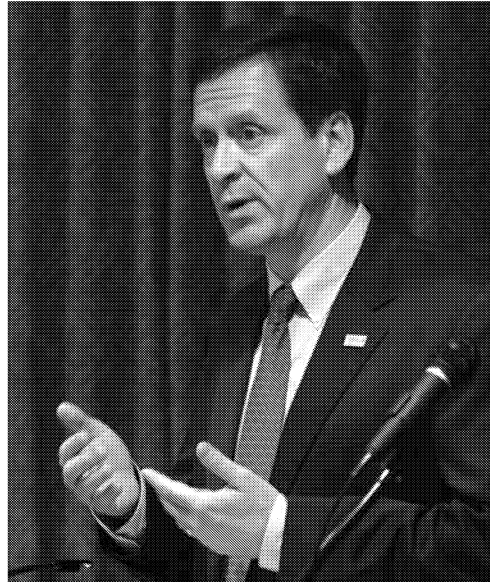
Nizium Mojo means, one coconut tree. There was a terrible cyclone that swept over the islands of Zanzibar and wiped out all the trees but a single coconut tree and that is where they build the hospital. What is really interesting about Nizium Mojo is not the story of how people survived the terrible storm but how the people are surviving the storm of global health challenges each and every day on the islands of Zanzibar.

On the day that I was there, just a month ago, our guide was Dr. Mohammed who is an old friend of mine from my days as ambassador. Dr. Mohammed was also the Principal Secretary of the Ministry of Health and a licensed surgeon. He took us upstairs to the pediatric ward and as we were walking in I saw that there were about fifteen beds. Dr. Mohammed told us that just three or four years ago, there were three children for every single bed in that pediatric ward. On the day that we walked in, there were three children in the entire ward. The first child had what Dr. Mohammed called clinical malaria, not confirmed by a test. The second child was a truly pathetic sight—sickly thin arms, cheeks were drawn, eyes open, but unseemly. The child's eyes had been damaged by Vitamin A deficiency. The third child that we saw was an even more heart rendering sight. Her skin was so badly disfigured that as we were walking up to her, she looked like a burned man. She suffered from severe malnutrition: protein deficiency. Dr. Mohammed looked at the third child and said, "We can help her." This story drives home several important lessons about health disparities, global health challenges and opportunities for change that are out there.

The first lesson is that historic progress is being made right now on a number of global health fronts. As Dr. Mohammed noted, not so long ago, there would have been three children to a bed—forty-five children per ward, not three. The good news is that because of the focus on improving interventions and improving medicines, we have an opportunity in front of us to conquer some of the diseases that were once believed to be inevitable. If you spend any time in Africa, you will meet person after person who will say "I am the oldest," "I was the third born," or "I was the fourth born," because his brothers and sisters died before him in childbirth. However, we are making extraordinary progress, particularly in the area of malaria. On the islands of Zanzibar, 40 percent were infected with malaria just a few years ago, but today that number is less than half a percent. Many actually believe that by 2015 malaria will be entirely eliminated from the islands of Zanzibar. In the area of neglected tropical diseases—lymphatic filariasis or elephantiasis disease—there are now elimination programs for this terrible disease in 44 of the 83 endemic countries. River blindness has already been eliminated from ten West African countries and there are plans to do so in many other countries on the continent. We should first feel good about the progress that has been made and the opportunities that lie ahead.

Secondly, the progress that we are making on diseases like malaria and river blindness and some of the neglected tropical diseases, free up resources to take on other global health challenges. Returning to my Zanzibar story,

a drop from forty-five to three patients means that there are forty more children who are disease-free and able to help their parents, play ball in the streets, or, hopefully, learn in school. More pragmatically, it means there are more beds and health care workers available to take on other challenges out there.



The third lesson is not to look at the challenges of global health through American eyes, as we often do when we talk about numbers. In most places in America, a child is generally either sick or they are healthy. This is not the case in the impoverished nations of the world. Children are never quite healthy in those countries. The child that survives malaria in its earliest days of life will very likely suffer life-long cognitive disabilities, or he or she may be weakened and made vulnerable to other diseases and illnesses. He or she is already likely to suffer from malnutrition and unsafe drinking water. The child may not be suffering from malaria symptoms, but neither is he strong and ready to learn.

On my first night as a volunteer teacher in Kenya some twenty years ago, the school's headmaster took me to the funeral of one-year-old twin boys who had died of measles. I could not believe that the children had died of measles. In Kenya, measles and other complicating factors such as malaria, malnutrition, and parasites cause children to die.

We talk about combating global health challenges, but we must realize that global health is not as black and white as we tend to assume. President Obama's administration has unveiled its global health initiative, designed to build upon the marvelous programs that are already there. We are trying to integrate the services that are provided in some of those programs so that we get stronger health systems to begin with. At Malaria No More, we think integration is a good idea, particularly in the areas of diagnostics and lab facilities. When we talk about health where people are most vulnerable—places like Africa—we cannot look at things in black and white, through American eyes.

We are living during pretty exciting times in global health. As I was getting ready to come here today, the story that broke that King Tut died of malaria. When examined, the mummy was discovered to have a number of afflictions and malaria was one of them. Some of our global health challenges have been with us for a long time. We cannot back down from any global challenge, be it malaria or HIV. Organizations that are devoted to global health must think of ways to expand programs to be most effect and that is what Malaria No More is trying to do.

**Question:** What is the reimbursement rate for physicians in Cuba?

**Professor Farrell:** You will not believe it, but it is \$35 a month. Physicians really want to practice medicine. It is seen as an honor and patriotic duty to serve the communist government in that way. Nevertheless, the physicians we met complained about being over worked, as some of their colleagues had left to practice in other Latin American Countries.

**Question:** Does Cuba isolate those with HIV?

**Professor Farrell:** Yes and no. When AIDS was initially discovered in the 1980s Cuba confined people infected with HIV to sanitariums. When the mechanism of HIV transmission was discovered, those in sanitariums were allowed to leave, but many preferred to remain where the living conditions were better than in their communities. Today, it is voluntary. We visited these sanitariums which were quite adequate with good living conditions. Many people who decided to stay there now leave during the day to work in AIDS programs in the city.

**Question:** The population of Cuba is thirty times less than the U.S. population (11 million to 300 million). Is it not easier to manage the health of a small population, thus explaining Cuba's statistics?

**Professor Farrell:** That is absolutely right. Additionally, cultural ideologies and community differences play an important role.

<sup>1</sup> WHO 2010 report