Prescription for the People

An Activist's Guide to Making Medicine Affordable for All

Fran Quigley

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INTRODUCTION

The high cost of essential medicines is a big problem. Recently, here in the United States where I live, social media and even lawmakers exploded in anger over a 400 percent-plus increase in the lifesaving allergy medicine EpiPen. Similar outrage occurred when a young pharmaceutical corporation chief executive officer (CEO) increased the price of a critical toxoplasmosis drug by more than 5,000 percent overnight—just because he could. A hundred-plus cancer physicians took to the pages of the prestigious journal *Mayo Clinic Proceedings* to write an impassioned article decrying the greed of the pharmaceutical industry. These physicians complained that drug companies were setting medicine prices so high that one out of every five of their patients was unable to fill his or her prescriptions. In response to all these incidents and the popular outrage they have inspired, patients, caregivers, and politicians from both major political parties have leveled charges of medicine price gouging against the pharmaceutical companies.

Even for those of us who are fortunate enough to not be poor and to have health insurance, the cost of medicines has a big impact. The cost of medicines drains the budgets of our governments, and barriers to accessing medicines lead to more expensive health care treatments and illnesses that drag down our economy. Polls show that three-quarters of Americans believe that drug costs are unreasonable and that those prices reflect the greed of drug companies.[1]

For the poor and the uninsured, access to medicines is a matter of life and death. Millions of people need medicines that are priced at levels they simply cannot afford. These suffering patients face a real problem: their desperate need for affordable drugs clashes with the core business model of a powerful industry.

On one side of that clash are multinational pharmaceutical corporations, which make up one of the most profitable and politically influential industries in history. That industry is determined to protect monopoly prices on patented medicines. On the other side of the clash are the sick and the poor, joined by advocates scattered across the globe in small, usually underfunded organizations. At first glance, it doesn't seem like a fair fight. But patients and medicine activists have won before.

In the midst of the HIV/AIDS crisis of the late 1990s and early 2000s, millions of people were dying because they could not afford lifesaving drugs. Patients and activists who wanted to change this tragic reality faced fierce resistance from a formidable collaboration between Big Pharma and the U.S. government. The multinational corporations and the world's economic superpower were intent on preserving the high monopoly price tags on patented AIDS drugs and to block affordable generic alternatives. But the activists working in the United States, sub-Saharan Africa, South America, and Asia pushed back hard. They flooded the streets with protests, filed lawsuits, and mercilessly heckled the drug companies and politicians. They made a moral claim that medicine should be for people, not profits, and that there is a fundamental human right to essential medicines. That message resonated across the world, and these activists eventually triumphed, reducing the costs of the medicines by as much as 99 percent; setting the stage for a massive global distribution of the drugs. Millions of lives were saved.

But the fruits of that victory, the widespread availability of cheap HIV/AIDS medicines, is an exception to the rule. Whereas millions once died

of untreated HIV/AIDS, now millions die from untreated cancer. Children die because their families cannot afford vaccinations. The episodic drug pricing outrages, such as the reaction to the EpiPen price hike or the overreach of the "Pharma Bro" Martin Shkreli, have not led to systemic change.

So the same activists who pushed for HIV/AIDS treatment, accompanied by a new generation of advocates, are trying to produce a sequel with an even more ambitious script than they followed at the turn of the century. Their aim is to make all essential drugs accessible by reclaiming medicines as a public good instead of a profit-making commodity.

One of these activists' biggest challenges is that the terms of their fight can seem complex and confusing. Too often, calls for reform get bogged down in technical intellectual property terms—*compulsory licensing*, *data exclusivity*, and *patent linkage*—and confusing acronyms for international trade agreements—TRIPS (Trade-Related Aspects of Intellectual Property Rights Agreement), TRIPS-Plus, and TPP (Trans-Pacific Partnership Agreement). This thicket of complexity provides cover for corporations that rely on the for-profit medicine model and are determined to protect the status quo. As one leading medicine activist admitted to me, "The problem we have is that there are only a handful of people in the world who know what we are taking about."[2]

It does not have to be this way. My aim in this book is to help clear away for you the thicket of jargon that surrounds this crisis so that you can effectively argue for a complete shift in the global approach to developing and providing essential medicines. This shift would restore the longtime historical recognition that medicines are a public good, reflecting the global consensus that access to essential medicines is a human right.

Because every cure starts with an accurate diagnosis, in this book I explain how and why the current medicines system is dysfunctional and corrupt. We all want both affordable medicines and innovation in research and development, so I explain the proven approaches to accomplishing that balance. Most of us reject the status quo of corporations making record-breaking profits on medicines that are priced out of the range of the sick and the dying, so I set out the moral and rights-based foundation of the case for universal access to medicines. Finally, if you want to take action and speak out for access to medicines—and I sincerely hope you do—the conclusion to this book is devoted to helping you get started.

I chose to structure the book around twenty-two arguments for why we must reform our medicines system and how to do so. Each chapter contains a single argument. I encourage you to skim the table of contents both before you read the book and afterward. When you need to refer to a particular issue connected with access to medicines—such as the fruits of government-funded medicines research being handed over to corporations for profit-making (chapters 14 and 15)—the table of contents will guide you.

This book is a short one. At the same time, all the points I make here are thoroughly sourced. Many, many researchers and activists have written important detailed analyses of these issues; so you will see hundreds of notes to prior work that backs up the arguments I make here. I have placed those sources in endnotes at the end of the book so you can read the main text without interruption, if you wish.

My hope is that this book will serve as a primer for all who are concerned about access to medicines. My hope is also that this book will buttress the analyses of researchers and the arguments of activists. Most important, my hope is that this book will help you become informed and prepared to play your role in the life and death struggle for access to medicines.

1

People Everywhere Are Struggling to Get the Medicines They Need

Hannah Lyon was just twenty-six years old when she was diagnosed with advanced cervical cancer.[1] To her first set of doctors, Lyon's best-case scenario was chemotherapy and radiation that would extend her life for only a few years. Desperate for a more promising approach, Lyon found a clinical trial at the National Institutes of Health (NIH). There she received cutting-edge immunotherapy, in which her immune cells were removed, genetically modified, and reinserted into her bloodstream. Since the treatment, Lyon's tumors have shrunk more than 80 percent.

But Lyon soon realized that most cancer patients are not so fortunate. She saw fellow patients struggling to pay for the medicines that were their only hope for survival. Lyon learned that others had simply been unable to pay and therefore had died from highly treatable cancers.

Lyon had heard the pharmaceutical industry argument that the high medicine prices are necessary to fund drug research. But, then, during her own treatment at the government-funded NIH, Lyon noticed something. "When I had my cell infusion, there were pharmaceutical reps in the

room, because they want to take that treatment and offer it commercially. So this whole argument that pharma corporations need long monopoly periods to pay for the research . . . well, they are not even the ones *doing* the research! They did not develop that drug. They are just going to take that drug and charge people tons of money."

Lyon began reading about medicine patents and the international trade agreements that protect them. She learned how government-funded research, not corporate investment, is the most important driver in creating new medicines. She discovered that our profit-driven medicines system is neglecting development of lifesaving medicines in favor of lucrative drugs to address hair loss or sexual performance.

Then Lyon happened to see a television interview with Zahara Heckscher, a breast cancer patient who had been arrested while protesting at the Trans-Pacific Partnership Agreement (TPP) negotiations in Atlanta in October 2015. The TPP was the latest in a series of trade deals that proposed to lock in corporate medicine monopolies and lock out suffering patients from the treatment they need. As we learn in chapter 18, the TPP promised to be particularly damaging to patients who need the kind of cutting-edge treatment that both Hannah Lyon and Zahara Heckscher received. So Heckscher had decided to use her status as a cancer patient to raise awareness of the dysfunctional medicines system. "That is amazing," Lyon thought. Then she thought some more. "*I* could do that."

So, on World Cancer Day in 2016, Lyon joined Heckscher in a sit-in at the Washington, DC, headquarters of the Pharmaceutical Researchers and Manufacturers Association (PhRMA). The organization is a coalition of pharmaceutical corporations that spends billions of dollars in political lobbying and campaign contributions, all to protect medicine patent monopolies—and the record-setting profits those monopolies provide. Wearing matching black t-shirts with white lettering that read, "I am a cancer patient. No TPP death sentence," Lyon and Heckscher blocked the building entrance. "We will not leave until PhRMA stops pushing extreme monopolies through the Trans-Pacific Partnership," they said.

Outside, demonstrators from a World Cancer Day action coordinated by the advocacy group Public Citizen could see Lyon and Heckscher lock arms. The crowd got excited and increased the volume on its chants: "Shame on PhRMA!" "TPP no!" By now, someone was filming, so Lyon and Heckscher looked at the camera. "We have a message for Congress

on World Cancer Day. Listen to the cancer patients who will suffer if the TPP is approved."[2] They were arrested and charged with unlawful entry.

Soon after, Lyon and Heckscher formed a new organization, Cancer Families for Affordable Medicine (CancerFAM).[3] CancerFAM is devoted, first, to stopping the TPP and, then, to fixing the other pharma-pushed trade deals and laws that elevate profits over patients. Lyon says advocacy has empowered her and transformed her own cancer story from one of weakness to one of strength. She believes that others can follow the same path.

Sarah Jackson does not have cancer, but she faces the same challenge that many of Hannah Lyon's fellow cancer patients do. The mother of six children, Sarah Jackson has hepatitis C (hep C), a blood-borne virus that can inflame and scar the liver, damaging its ability to filter toxins. Sometimes hep C causes cancer and liver failure. Sarah Jackson's physician has prescribed her a medicine to treat her disease. The medicine is almost certain to cure her before the hepatitis virus can cause irreparable liver damage or trigger liver cancer. The medicine would also prevent her from spreading the virus to others, including any future children she may give birth to.[4]

Sarah Jackson does not live in an impoverished country. She lives in Fort Wayne, Indiana, in the United States, one of the wealthiest countries in the world and the country that spends far and away the most on health care.[5] Nevertheless, Sarah Jackson cannot get access to the medicine she needs.

The medicine that Sarah Jackson's physician has prescribed her is sofosbuvir, a new hepatitis C drug that is controlled under patent by the U.S.-based pharmaceutical company Gilead. Gilead markets sofosbuvir under the names Sovaldi and Harvoni. The company has taken advantage of its monopoly patent power to price Sovaldi and Harvoni at costs that approach $1,000 per pill. The recommended twelve-week regimen cost as much as $100,000.[6]

That price is so forbidding that U.S. private insurance companies and the U.S. Veterans Administration have refused to approve the use of the drug for some patients, even when clinical treatment guidelines called for it.[7] A 2015 study published in the journal *Annals of Internal Medicine* showed that three-quarters of state Medicaid programs block many patients from receiving sofosbuvir despite their doctor's insisting they need it.[8] A U.S.

Senate investigation concluded that only about 2 percent of Medicaid patients with hepatitis C were being treated with sofosbuvir.[9] And the problem is not limited to the United States. A World Health Organization study showed the price of the drug exceeded annual per capita income levels in many countries with high hepatitis C infection rates. For example, in Poland, Portugal, Slovakia, and Turkey, a course of sofosbuvir costs at least two years of average annual wages.[10]

One of the U.S. state programs that rations the use of sofosbuvir is in Indiana, where Sarah Jackson is enrolled in Medicaid. Indiana officials refuse to pay for the medicine for hepatitis C patients until the patients' disease has progressed to the point of causing advanced liver damage. Sarah Jackson has not endured that much damage yet, so her doctor's application to have the medicine provided was denied. The doctor appealed to higher-ups in the program, but to no avail.

Then the doctor put Jackson in touch with public interest lawyers. With the lawyers' help, she has filed suit on behalf of thousands of others in Indiana who were in the same situation, asking for Medicaid to provide the medicine when their physicians say they need it. Sarah Jackson had never intended to become an activist. But, like Hannah Lyon, her illness pushed her in that direction. "There's nowhere else to go," she says. "The doctor tried and now I have no other place to turn."[11]

Rationing plans such as the one in Indiana have angered patient advocacy groups and veterans' organizations, and they have caused a passionate but less public backlash from treating physicians.[12] On the other side, the administrators of the government health care systems are in a tight spot. The state of Kentucky spent 7 percent of its total 2014 Medicaid budget, over $50 million, solely on Gilead drugs to treat just 861 hepatitis C patients.[13] The Veterans Administration was reported to have spent $1 billion on the drugs in the 2016 fiscal year.[14] When a reporter asked him to comment on Sarah Jackson's situation, Matt Salo, director of the National Association of Medicaid Directors said, "With the price of hepatitis C drugs, it is just not feasible to provide it to everyone."[15]

As that comment suggests, Sarah Jackson is far from alone. An estimated 2.7 million people in the United States are infected with hepatitis C, and its complications cause 15,000 U.S. deaths each year.[16] Globally, 150 million are infected and a half-million die from hepatitis C–related causes annually.[17] The World Health Organization calls the disease a

"viral time bomb."[18] In the United States, a recent spike in intravenous drug use, chiefly among young people, has triggered a corresponding burst of new hepatitis C infections.[19] The rate of infection among U.S. military veterans is significantly higher than in the general population, partly due to exposure to blood in combat and training and to transfusions conducted before routine blood screenings began in 1992. According to the Veterans Administration, more than 200,000 U.S. military veterans are likely to have hepatitis C.[20]

The good news for those diagnosed with hepatitis C is that sofosbuvir is a remarkably effective treatment, combining with other drugs to cure the infection in more than 90 percent of patients.[21] The bad news is that Gilead has responded to the high demand for this wonder drug by setting a take-it-or-leave-it price that is 1,000 times greater than the company's manufacturing costs.[22] Advocates and even some government agencies have leveled accusations of price gouging, pointing out that the cost of a full regimen of sofosbuvir in Egypt and India is just $900, a 99 percent reduction from the U.S. price.[23] The Nobel Peace Prize–winning health care and advocacy organization Médecins Sans Frontières/Doctors Without Borders (MSF), estimates that the probable generic cost of the drug regimen would be under $200, or about 1/500 of the price currently charged to U.S. patients.[24]

The response by Gilead to its critics is the boilerplate argument from patent-holding pharmaceutical corporations: high drug prices are necessary to support research and development efforts.[25] But it turns out that government funding was the critical component in the development of sofosbuvir, not corporate investment.[26] As we see in chapter 14, this is a common phenomenon in drug research, with major advancements reliably supported by the same taxpayers who are later required to pay high prices set by corporations that possess government-granted patent monopolies.[27] In the business of medicines, the new product risks are socialized, but profits are privatized.

2

The United States Has a Drug Problem

The corporation Gilead owns the patent on sofosbuvir, the medicine that Sarah Jackson and millions of others with hepatitis C need. That patent awards the corporation a monopoly that allows it to set the price of sofosbuvir at whatever level the corporation believes the market will bear. Gilead has bet that the market will bear an astronomical price for a desperately needed medicine, and that bet has paid off, particularly in the United States, where aggressive pharmaceutical industry lobbying has blocked overall price regulation and even the ability of the government to negotiate the prices of the drugs it purchases itself.[1] Gilead collected $12 billion in hepatitis C drug sales revenue in 2014, at least half of it paid by U.S. government agencies.[2] That kind of income allows the company to pay John Martin, its CEO, as much as $180 million per year.[3]

The crisis caused by monopoly drug pricing is not limited to hepatitis C patients such as Sarah Jackson.[4] There are many other examples of essential medicines being priced out of the reach of patients in the United States and in other wealthy nations. For example, spending on medicine

for diabetes, a disease diagnosed in 29 million Americans, is higher per patient than any other traditional drug class, in part because more than half of diabetes prescriptions filled are for patented drugs.[5] The cost for insulin lispro, marketed by the pharmaceutical corporation Eli Lilly under the name Humalog, increased by 325 percent from 2010 to 2015.[6] There were only two other insulin manufacturers in the United States, Sanofi and Novo Nordisk, and they also hiked their prices over 100 percent in that time span. There is no generic form of insulin, and the lack of price regulation of medicines in the United States keeps prices up to six times higher than in other developed nations, a situation that U.S. Senator Jon Tester (D-MT) labeled "price gouging, plain and simple."[7]

Not surprisingly, U.S. physicians report routinely seeing patients whose lives are at risk because they cannot afford to use the prescribed amount of insulin.[8] A 2017 lawsuit alleging price collusion among the insulin manufacturers includes reports of U.S. patients injecting expired insulin, starving themselves to control their blood sugars, and intentionally allowing themselves to slip into dangerous states of diabetic ketoacidosis so they could get free insulin samples from hospital emergency rooms.[9] In low-income countries, the situation is even more dire. A diabetes patient advocate reported a 2017 conversation with a physician in Cameroon, who shared the story of a young patient's father happily delivering news. "Did you hear? Isabelle died!" the father said with a smile. He was referring to his diabetic daughter (the name here is a pseudonym), whose need for insulin and equipment like syringes and blood sugar test strips had plunged the family into financial distress. "Now we are all able to eat enough, and the other children can get an education."[10]

In addition to insulin, similarly high costs are faced by U.S. patients in need of medicine to address heart disease, high cholesterol, and infections.[11] Vaccines are priced so high that one-third of U.S. family physicians say they are considering ending their practice of offering vaccinations because they cannot afford to buy them and keep them in stock.[12] In 2015, Turing Pharmaceuticals suddenly increased by 5,000 percent the price of its anti-infection drug Daraprim. Overnight, the price rose from $13.50 to $750.00 per tablet, a spike that brought the annual cost of treatment to as much as a half million dollars.[13] From 2007 to 2016, Mylan Pharmaceuticals hiked the price of the lifesaving anti-allergy medicine EpiPen by nearly 500 percent.[14] Although the audacity of these price hikes generated

instant outrage—the two 2016 major-party U.S. presidential candidates called the Daraprim spike "price gouging" (Hillary Clinton) and "disgusting" (Donald Trump)—they were just extreme examples of the common industry practice.[15] From 2012 to 2015, list prices on medicines made by large pharmaceutical corporations rose by over 12 percent per year, far exceeding the less than 2 percent annual rate of inflation over that period and also far exceeding the increase in other health care costs.[16] In 2015, drug prices in the United States rose by almost 16 percent.[17]

Those rising prices are a predictable result of the U.S. approach to medicines, which includes a unique combination of huge government spending on medicines paired with no regulation of medicine prices (a combination I explore more fully in chapter 15).[18] The result is an environment with no price restraints. "Medicare is a huge, guaranteed market," one industry observer says. "So the (pharmaceutical) companies are saying, 'Let 'er rip!' "[19]

So it is not surprising that U.S. patients pay the highest prices for medicine in the world, a per capita cost of about $1,000 per year.[20] Consider this:

- A recent study showed that the median monthly price of branded cancer drugs in the United States was almost $8,700, compared with about $2,600 in the United Kingdom, $2,700 in Australia, and $3,200 in China.[21]
- In the United States, medicines represent 10 percent of national spending on health and nearly 20 percent of spending in employer health insurance plans.[22]
- Overall prescription drug spending in the United States is over $400 billion annually; global spending exceeds $1 trillion.[23] Some European health systems, which unlike the U.S. Medicare program do negotiate drug prices, have even refused to pay for some high-cost medicines.[24]

Ultimately, these whopping U.S. medicine bills are paid by the taxpayers who subsidize government health care programs such as Medicare and Medicaid. They are also paid by private health care systems, whose CEOs' report that rising drug costs are undermining the finances of their companies.[25] Increasingly, the costs incurred by those private companies are passed on to patients. Even when U.S. residents are covered by private insurance plans, those plans usually charge premiums and copayments,

and do not cover costs until a deductible threshold is met. In the last decade, U.S. workers' obligations for those health insurance premiums rose 83 percent and their deductibles rose 255 percent, with 2016 testimony to a U.S. Senate committee identifying prescription drug prices as the biggest reason for those increases.[26] One of the results of this crisis is that medical debt has become the single largest cause of bankruptcy in the United States.[27]

As Sarah Jackson can attest, for many patients, the high cost of medicines simply means that a doctor's prescription goes unfilled. In a 2015 U.S. poll, 19 percent of respondents said they had recently not filled a prescription because they could not afford the price.[28] Another survey reported that 50 million Americans each year skip taking prescribed medication due to the cost.[29] Predictably, there is a human price to be paid for missing medications: multiple studies have shown that persons who struggle to access prescribed drugs are at greater risk of heart attacks, strokes, and other life-threatening health emergencies.[30]

Even when patients do have adequate insurance coverage or can afford to pay out of pocket the cost of the medicine they need, they often discover that the medicine is still not available to them. In the United States, medicine shortages are reported to be "the new normal," with regular gaps in the availability of essential antibiotics, cancer drugs, and anesthetics, among hundreds of other medicines.[31] In 2013, 83 percent of U.S. cancer physicians reported not being able to provide a patient with the preferred chemotherapy at least once in the previous six months. One-third of those physicians reported having to delay treatment or exclude patients from the medicine altogether.[32] Reports of medicine rationing have been registered in the treatment of leukemia, ovarian cancer, bladder cancer, and infections in need of antibiotics.[33] Some U.S. physicians admit they deliberately avoid telling their patients that they are not getting the medicine they need.[34]

Like high prices, these shortages are the inevitable consequence of a medicine system built on a foundation that relies on the motivations of corporations seeking the highest possible profits. If pharmaceutical corporations determine there is not sufficient money to be made producing a medicine, especially compared to other products that they can charge enormous mark-ups for, they have no incentive to make enough of the medicines that have lower profit margins. The shortages are also spurred

on by the secretive, exclusive character of the patent system, which leads to a limited number of manufacturers of the needed drugs.[35]

Even if the medicines that are in shortage are potentially profitable to manufacture, "intellectual property" rights often trump patient needs. For example, when the Cleveland Clinic responded to a shortage of a blood-vessel surgery drug by mixing up its own version in-house, the clinic physicians wanted to share the formula with their colleagues facing similar shortages in other hospitals. But they discovered they could not do so: the Cleveland Clinic had claimed exclusive rights to the combination.[36]

Sometimes drug shortages are the result of quality control issues in the medicine manufacturing process. But that problem too can be traced back to the for-profit nature of the industry because corporations see little urgency in fixing the manufacturing problem for a medicine that produces limited revenue. As a journalist who investigated drug shortages said, "Sometimes what happens is a [production] line goes down, something breaks down and a company, a producer looks at the margins and the economics and says 'well, you know it's not really worth the margins we're getting on this drug in continuing the line—in putting the money in to fix it.' So they let the drug go into shortage. And even if people need it—say it's nitroglycerine which is critical in heart surgery—they just don't produce it."[37]

Instead, for-profit pharmaceutical corporations inevitably focus their investments and their production capacity on medicines that provide a hefty profit. We have already read about one example: the hepatitis C medicine with a 500 percent mark-up (chapter 1). Not surprisingly, there have been no reported shortages of Sovaldi or Harvoni.

3

Millions of People Are Dying Needlessly

Tobeka Daki lived with her two sons in the Mdanstane Township in the Eastern Cape province of South Africa. Her youngest son, Khanya, is eleven years old. She was a breast cancer patient, struggling with a particularly aggressive strain of the disease known as HER2.[1]

Trastuzumab is a medicine that is effective in treating HER2-positive breast cancer.[2] Marketed under the brand name Herceptin by the pharmaceutical company Roche, the medicine is so successful at improving survival rates for HER2 patients such as Tobeka that the World Health Organization has placed it on its "Essential Medicines List," an exclusive category of drugs that are considered necessary to meet the minimum medicine needs for a basic health care system.[3] The development of trastuzumab was so impactful that the story was turned into a Lifetime TV movie, *Living Proof*, starring Harry Connick Jr. as the physician whose research helped show that the medicine would benefit cancer patients. Herceptin has become one of the best-selling prescription drugs in the world.[4]

The cost to manufacture a year's worth of trastuzumab, the recommended length of treatment for a patient such as Tobeka, is about $176.[5] Yet that same amount of medicine is sold by Roche in South Africa at a price of about $34,000.[6] The company holds the South African patent for the medicine until 2033; this means that there are no competitors to push Roche to lower the price. Roche sells over $6 billion of the medicine each year.[7]

The $34,000 price tag for trastuzumab was far more than Tobeka could pay. The same goes for the vast majority of other HER2-positive breast cancer patients in South Africa, where the per capita income is $6,800.[8] Few private insurers cover the drug. The public-sector health care system so rarely provides trastuzumab that physicians in that system usually do not even tell their HER2 patients about the existence of the drug.[9]

When I spoke with Tobeka in March 2016, she explained that her cancer had recently spread to her spine, so she had officially reached the Stage 4 level. Her sons were distraught. One of her fellow patients, with whom she had grown close, had died five days before. "Thousands of people in South Africa die because they cannot access this medicine," she said.[10] Tobeka Daki died in November, 2016. She never received trastuzumab.[11]

The story of Tobeka, Roche, and trastuzumab is just one version of a story that can be repeated for millions of patients and hundreds of lifesaving medicines across the world. The fact that this particular story is set in South Africa is sadly ironic. South Africa was the center of the historic struggle to dramatically increase access to HIV/AIDS drugs, a struggle described in the conclusion of this book. By challenging patent medicine monopolies, South African activists won a victory that ensures that millions of Tobeka's countrymen and countrywomen receive affordable antiretroviral therapy for HIV/AIDS.

But trastuzumab and many other medicines remain protected by patents and priced out of reach. Some say that means that medicine activists won the HIV/AIDS treatment battle but have lost the broader access-to-medicine war. But others say the victory won for HIV/AIDS medicines is possible for other kinds of drugs, too. Lillian Dube, also a South African woman with breast cancer, was struck by the sight of her fellow patients, such as Tobeka, going without the medicine they need. "I am with young women (at our doctor). These are women who are 40, 30, and they have small children," Dube says. "And they have to lose their lives because they cannot afford Herceptin. It should not be like that."[12]

As I show in this book, there are dozens of reasons why Lillian Dube is right: it should not be like that. And there are many activists such as Lillian Dube who are working to change the system. "Until I die, I'll be fighting this," she says.[13]

Ahmed is a little boy, and he is dying. He could be in India or Nigeria or Haiti. And he could be dying from pneumonia or diarrhea or measles.

Unlike Tobeka Daki, Ahmed is not one particular person. He cannot tell his story to an interviewer. He lays anonymous, engulfed in fever, in a hut in a remote village or in a shack in a teeming urban slum. Neither his family nor his government could afford to give him the immunizations that would have prevented his illness. And they cannot afford the antibiotic medicines that would help him survive now.

One out of every five children living in poor countries never receives even the most basic package of vaccinations.[14] Millions do not have access to antibiotic drugs.[15] Ahmed is one of 6 million children in low- and middle-income countries who will die from an infectious disease this year.[16] Chances are that his disease is pneumonia because that is the leading cause of childhood death, in large part because three out of four of the world's children have not been vaccinated against it.[17]

There are massive global efforts to expand the vaccination of children, such as Ahmed. Gavi, the Vaccine Alliance, leverages funding from the Bill and Melinda Gates Foundation and from other public and private sources, to immunize millions of children in low-income countries.[18] MSF delivers nearly 7 million doses of vaccines each year.[19] But even these efforts were not enough to reach Ahmed, and they will not reach millions of other children.

The biggest reason is the cost of the medicines. Dr. Greg Elder, deputy director of operations for Médecins Sans Frontières, says, "The rising price of the basic vaccines package means that we can't afford to protect kids living in crisis."[20] That price for a full package of vaccines in 2014 was sixty-eight times what it was in 2001.[21] The most expensive vaccine in that package is the pneumococcal vaccine, which generates almost $7 billion in sales each year for the pharmaceutical corporations GSK and Pfizer, which control the market for the drug.[22] In late 2016, a determined multiyear advocacy campaign led by MSF finally succeeded in convincing the two chief producers of the pneumococcal vaccine to lower the prices

they charged humanitarian organizations. But advocates cautioned that, even after the price drop, the vaccine was still unaffordable in many poor countries.[23]

Tobeka and Ahmed are not isolated examples. The UN World Health Organization says that one-third of the world's population do not have access to essential medicines.[24] Other UN health officials estimate that 10 million people die each year because they do not receive the medicines that would have saved them.[25] That adds up to one person dying every three seconds—more people each year than the entire population of New York City.

The World Health Organization and others can categorize that number by the diseases that are left unchecked. Over a million die each year from tuberculosis, and a million-plus more from AIDS, malaria, and hepatitis.[26] Those dying from infectious diseases such as these tend to be younger, like Ahmed. But millions more, like Tobeka, die prematurely from untreated noncommunicable diseases such as cancer, cardiovascular disease, and diabetes.[27]

The 2015 annual report of the World Health Organization sounds like a broken record repeating the same tragic notes:

- Access to medicines for noncommunicable diseases "is still very poor in many low- and lower-middle income countries."[28]
- A majority of newborns who need hepatitis B immunizations do not get them, and most cancer patients who need chemotherapy do not get that either.[29]
- New cancer and hepatitis medicines are enormously effective, but as we have learned (chapters 1 and 2), they are "largely unaffordable while under patent, even for many high-income countries."[30]
- For diabetes patients in low-income countries, "essential medicines are frequently unavailable or unaffordable."[31] Same goes for patients in need of mental health medicines.[32]

Even when the lack of medicines is not immediately fatal, it often makes survival a miserable experience: billions of people lack access to opioid analgesics that can ease the excruciating pain of diseases such as cancer.[33] Those lucky enough to be able to buy essential medicines often make enormous sacrifices to do so. As much as 90 percent of people in low- and

middle-income countries pay out of pocket for their medicines, making it the second-largest family expenditure after food.[34] In these countries, medicine costs account for nearly half of all health care spending, drawing resources away from hiring doctors and nurses, building clinics, and buying other supplies.[35]

This crisis has not gone unnoticed. Thomas Pogge, a Yale University philosopher, calls this poverty-induced suffering and death "the morally pre-eminent problem of our age."[36] The global community has recently agreed on a set of Sustainable Development Goals that includes achieving universal access to essential medicines.[37] In 2015, the UN secretary-general convened a High-Level Panel on Access to Medicines, emphasizing the urgency of the situation, and the panel issued a report underscoring that millions are dying of treatable diseases because they cannot access needed medicines.[38]

But the suffering of Tobeka, Ahmed, and millions of others continues. There is no more stark example of our broken medicines system than the Ebola epidemic of 2014.

On October 13, 2014, Dr. Margaret Chan, the director-general of the World Health Organization, provided the keynote address for the sixty-fifth session of the WHO Regional Committee for the Western Pacific.[39] Most conferences like this are highly bureaucratic; the speeches delivered are typically long on platitudes and short on drama. But Dr. Chan's remarks were delivered in the midst of the Ebola outbreak in western Africa, an outbreak she told the attendees had generated more fear than any event in her public health career.

So Dr. Chan took the occasion, and the global media attention to the outbreak, as an opportunity to be remarkably frank. Over 11,000 people will die from Ebola, she said. "The outbreak spotlights the dangers of the world's growing social and economic inequalities," she told the attendees. "The rich get the best care. The poor are left to die."[40]

Dr. Chan was correct. Ebola was a dramatic example of the inequities in the global health care system, inequities that are particularly stark in the field of medicines. The reason Ebola was so frightening and so deadly was that no medicines were available to prevent it or to treat it. It turns out that promising vaccines to prevent Ebola, and drugs to treat it, had been uncovered years before the outbreak. Yet they were allowed to languish without further development. "There is a lesson here," said

Professor Adrian Hill from Oxford University, who led the Ebola response for Britain. "If we had invested in an Ebola vaccine, had it sitting there as the outbreak comes, you could have nipped it in the bud, been able to vaccinate the region when it started."[41]

So why was the Ebola vaccine not developed? Because pharmaceutical corporations saw no prospect of significant profit to be made on the drug. The expected need was limited, and those who would benefit were likely to be too poor to pay high prices. As far back as 2003, Thomas Geisbert, an Ebola researcher, recognized the problem, writing with regret that there was "little commercial interest for developing an Ebola virus vaccine."[42]

After the 2014 outbreak began claiming lives by the thousands, Professor Hill labeled the problem in stark terms. "Who makes vaccines? Today, commercial vaccine supply is monopolized by four or five mega-companies—GSK, Sanofi, Merck, Pfizer—some of the biggest companies in the world," Hill said. "The problem with that it, even if you've got a way of making the vaccine, unless there's a big market, it's not worth the while of a mega-company. . . . There was no business case to make an Ebola vaccine for the people who needed it the most."[43]

The 11,000 people who died from Ebola are just the latest and most visible examples of a core flaw of the for-profit medicine system. Medicines that address the diseases that kill millions of the global poor do not present a compelling business case. The U.S. satirical publication *The Onion* put a sadly accurate spin on the tragic situation, publishing a spoof article entitled "Experts: Ebola Vaccine at Least 50 White People Away,"[44]

So medicines that would save the lives of the global poor go undeveloped. All the while, for-profit corporations rush to market hair-loss cures and erectile dysfunction drugs. Such medicines often duplicate others on the market and are often frivolous compared to other needed medicines. But they still present a good business case, as long as they address the real or perceived needs of consumers who can pay high prices.

As she concluded her October 2014 speech, Dr. Chan did not shy away from identifying the obvious cause for the 11,000 deaths. "Ebola emerged 40 years ago. Why are clinicians still empty-handed, with no vaccines and no cure? Because Ebola has been, historically, geographically confined to poor African nations.

"The R&D [research and development] incentive is virtually nonexistent. A profit-driven industry does not invest in products for markets that cannot pay."[45]

4

Cancer Patients Face Particularly Deadly Barriers to Medicines

In 2013, I was diagnosed with testicular seminoma. Fortunately for me, this is a form of cancer that is highly treatable. Even more fortunate for me, I could access that treatment. I live in an area where top-level care is available, I had good insurance coverage through my employer, and I could afford to pay out-of-pocket costs. I am now healthy and have every reason to believe the cancer is gone.

Some of you may have had your own experiences of cancer, either as a patient yourself or as a friend or family member of someone who has had cancer. There are 14 million new cases of cancer diagnosed annually.[1]

If you or a loved one has faced cancer, you already know about the breathtaking cost of the medicines used in its treatment. In 2012, the U.S. Food and Drug Administration (FDA) approved twelve new cancer drugs. Eleven of them were priced over $100,000 per year per patient.[2] One drug used to treat acute lymphoblastic leukemia, patented by the company Amgen, costs $178,000 for the standard course of treatment.[3] Over the past decade, cancer treatment costs have increased 39 percent in