DRUGS FOR LIFE

How Pharmaceutical Companies Define Our Health

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INTRODUCTION

A doctor tells his patient, "Your blood pressure is off the chart, you're overweight, out of shape, and your cholesterol is god-awful. In short I find you perfectly normal."

A doctor tells his patient, "The good news is that your cholesterol level hasn't gone up. The bad news is the guidelines have changed."

These two jokes are both funny, and their intersection points to a new kind of health, one in which to be normal is to have symptoms and risk factors you should worry about, and at the same time to not know whether you should be worrying about yet more things. In fact, to not worry about your health, to not know as much as you can about it, and to not act on that knowledge is to be irresponsible. Some public relations campaigns feature people who are the "picture of health" but yet warn, "You might look and feel fine, but you need to get the inside story" (fig. 1). It appears to be that feeling healthy has become a sign that you need to be careful and go in for screening. To be normal, therefore, is to be insecure: this is the subject of my book.

Health in America today is defined by this double insecurity: never being sure enough about the future—always being at risk—and never knowing enough about what you could and should be doing. Paradoxically, the insecurity continues to grow despite there being an equal growth in research about risks, screening, and treatments and constant growth in the amount of medicine consumed each year—as

FIGURE 1 "'Are You the Picture of Health?'" poster for the Centers for Disease Control and Prevention's Screen for Life Campaign. *Source*: Centers for Disease Control and Prevention, Campaign for Colorectal Cancer Screening (retrieved May 5, 2005, from www.cdc.gov/screenforlife).

if the more we know, the more we fear; and the more we fear, the more preventive actions and medications we need to take. In the first joke, what is not revealed is how many prescriptions the patient will be given for being "perfectly normal." The growth in pharmaceutical consumption is actually quite astounding. Put simply, Americans are on drugs. The average American is prescribed and purchases somewhere between nine and thirteen prescription-only drugs per year, totalling over 4 billion prescriptions in 2011 and growing.[1] The range is wide, however, and many people are prescribed few or no drugs each year.

According to medical data companies and national surveys, 8 percent of Americans aged twenty to fifty-nine, and 44 percent of those over sixty were prescribed cholesterol-lowering statins in 2008. More than 20 percent of women over forty were taking monthly antidepressants in 2005–2008, and more than 6 percent of adolescents were prescribed attention-deficit disorder drugs (fig. 2).[2] These people are us, the generalized "you" of the jokes and the object of pharmaceutical marketing. These numbers are the flipside of the cost of healthcare. Overall healthcare costs were over $2 trillion in 2011, prescription drugs accounting for about 10 percent, or $203 billion, of that amount.

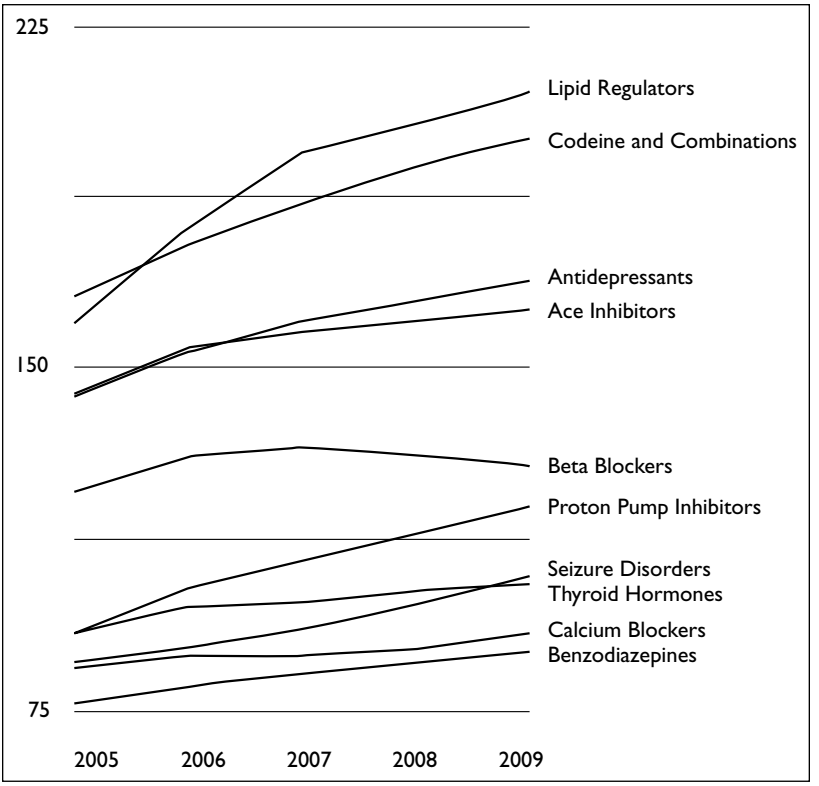

FIGURE 2 The top therapeutic classes of drugs by U.S. dispensed prescriptions (in millions), 2010. *Source*: IMS National Prescription Audit PLUS, IMS Health.

If our health is so insecure, why are such jokes like the ones mentioned above funny? One reason they make us laugh is that they reveal the anxieties we feel about our health, and they carry the trace of how it has changed. The first joke reminds us that being overweight and having high cholesterol is normal now because the average American has these characteristics. The doctor diagnoses the patient as being typical, despite the symptoms. The other joke often earns even more nervous laughter because many of us have experienced finding out from our doctors or from the newspaper that new guidelines issued by national committees for health mean we are now at risk and in need of remediation. We joke among ourselves about the constant stream of new findings that tell us we are now at high risk, or that another drug has newly discovered side effects, or that a food we like is now carcinogenic. We joke also because we are essentially helpless in the face of a stream of information that

reveals our current knowledge to be incomplete and maybe even dangerous. Normal and healthy are severed, and this is anxiously funny because it didn't used to be that way. Fifty years ago we didn't even know about cholesterol as a risk factor. In fact, the very concept of a risk factor was created alongside the innovation of large-scale prospective clinical studies.

In the 1950s, medicine began to rely on statistics. The large-scale Framingham Heart Study tracked the habits, health, and illnesses of over 5,000 members of a town in Massachusetts for decades. Public health researchers began to amass evidence that smoking "caused" lung cancer and increased mortality, although it was not universal.[3] These studies helped produce notions of populations "at risk." They represented an essential movement of public health from vaccinations, which definitely prevented some illnesses, to statistics, a shift in which biomarkers like cholesterol and high blood pressure correlated with health problems. The result was that risk became a target of medical intervention.

The 1950s also saw the rise of a new form of study: the randomized control trial, a clinical trial that in its ideal form was a double-blind study in which one treatment, usually a drug, was compared to another or to a placebo such that neither the doctors nor the patients knew what treatment the patients were getting. This rendered the trial a fair and objective test in which the only difference was the treatment. The advantages of these clinical trials were many, including the ability to detect incredibly minute differences between two treatments. For example, one could determine that one treatment worked 3 percent better than another one, which often meant that one treatment might help 103 out of 1,000 get better and the other treatment only 100 out of 1,000. This was both a stunning form of objective measurement and a bizarre one at the time: it meant that the treatments were so similar in effectiveness that no doctor or patient would be able to experience the difference but instead would have to rely on the results of the clinical trial to tell them which drug was better. Many doctors rebelled against such medicine by statistics, but the government, the drug companies, and other medical professionals as well as doctors and public health officials were thrilled to have a clear-cut way of knowing what worked.[4]

At the same time, the postwar pharmaceutical industry was getting started, growing out of prewar medicine companies but newly empowered

by expansion during the war into national prominence and by the Food and Drug Administration's (FDA) granting of status to prescription-only drugs, which had not existed before. This new industry lost no time in imagining mass markets for drugs and in targeting doctors as the gatekeepers to this market.[5] The pharmaceutical industry and its armies of detail men, or drug representatives, invented many now-classic sales tactics and strategies.

The industrialization of clinical trials happened because drugs could be paired with risk factors: for example, Diuril with hypertension, Orinase with diabetes, Mevacor with high cholesterol. The drugs would be taken not to cure the condition but to reduce the risk factor and potential future events, such as heart disease or heart attacks. And the drugs would be taken chronically, every day. The pharmaceutical industry had found diagnoses whose markets could be grown to massive proportions.[6]

Clinical trials can increase the productivity of prescriptions, creating more drugs for more people for longer periods of time. According to pharmaceutical industry analysts, "Clinical trials are the heart of the pharmaceutical industry,"[7] and, conversely, pharmaceutical companies are the main force behind clinical trials. Pharmaceutical companies make money by selling medicines for which they hold a patent and FDA approval to market. The FDA approves drugs on the basis of evidence from the clinical trial, which allows the patent owner to sell it exclusively until the patent runs out. This can be up to fourteen years, but usually it is less. Pharma companies are therefore constitutionally insecure, continually losing their products and needing to come up with a constant stream, or pipeline, of new drugs to be thoroughly tested through clinical trials.

Because they see clinical trials as investments, pharma companies start with the question of how to research a treatment so it can be indicated for the largest possible market. They do this because they measure the value of clinical trial research via the total number of potential treatments that can be sold over the patent life of the drug. This has a number of consequences. Chronic treatments, especially long-term risk-reduction prescriptions, will generate a much larger market than acute treatments. One-time treatments like vaccines that actually prevent illness are "more likely to interfere with the spread of the disease than are drug treatments, thus reducing demand for the product,"[8] while mental illness treatments are highly valued precisely because these illnesses

"share the distinction of not being cured by these pharmacological treatments. This makes the market even more attractive. The patients have to take the drugs chronically."[9]

With these clinical trials in hand, the pharma companies' and advertisers' objective is to "maximize the number of new prescriptions" and to make sure consumers stay on their medication as long as possible. In their accounting, potential patients who are not taking medication are counted as prescription loss. Making us aware and personalizing this risk so that we see our need for treatment are two of their strategies. Others involve getting us to ask our doctors about these conditions and drugs and developing relationships with us so that we keep taking our meds. These processes may seem harsh and uncaring, as they are manifestly prioritizing profits over health—but this is their job: maximizing sales of treatments. Marketers explicitly celebrate such growth.

These three trends—risk factors as targets of public health intervention, clinical trials as instruments to pinpoint smaller and smaller health risks for treatments, and growth in the power and size of the pharmaceutical industry—interacted with each other. And they came to generate the new notion of health that we laugh at in doctor–patient jokes. The sheer size of the pharmaceutical industry meant that it could afford to pose questions of smaller and smaller health risks and of risks in the more distant future. It also meant that government would be more or less compelled to let industry conduct the research because otherwise it was too expensive. Today, clinical trials can include more than one hundred thousand patients and can span hundreds of hospitals and doctors in many countries.

Medical observers have noticed that the vast majority of illnesses today are treated as chronic and that being at risk for illness is often treated as if one had a disease requiring lifelong treatments, drugs for life. Today, chronic diseases are said to affect 133 million Americans, one out of every two adults.[10] These are not the chronic illnesses studied by medical anthropologists that painfully disorder one's life and disrupt one's biography.[11] The recent reformulation of chronicity represents a shift in the basic paradigm of health and disease, a paradigm shift away from an inherently healthy body. The old paradigm assumes that most people are healthy at their core and that most illnesses are temporary interruptions in their lives, identified by persons as the experience of suffering. Chronic and genetic diseases like diabetes, cystic fibrosis, and Hunting-

ton's, although well-known counterexamples, were exceptions to the basic paradigm of inherent health. Beginning in the 1960s and 1970s and becoming common by the 1990s, a very different notion of illness took center stage, one in which bodies are inherently ill, whether genetically or through lifestyles or traumas. Health for the chronically ill is not an existential term in that they are never absolutely healthy; rather, it is a temporal, relative, experiential term, that is, they feel healthy today. In the words of Elizabeth Beck-Gernsheim, "All of us are affected, all of us all risk carriers."[12]

Diabetes is regularly invoked as a paradigmatic template for many conditions that were previously not thought of as illnesses. The older notion and examples of chronic illness are not gone; these notions coexist, and we are quite good at inhabiting and switching between the paradigms. But the new notion of illness is more prevalent because it is now promoted to us in advertisements and in awareness campaigns throughout our daily life. As an index of this paradigm shift, health itself is starting to disappear in pharmaceutical reports. The word often appears in quotation marks. A report in 2005 on pharmaceutical consumption trends by Express Scripts stated "2004 was in fact a 'healthier' year than 2003." It placed *healthier* in quotation marks because only five of the top twenty-five most widely consumed drug types decreased in use: these were the five classes given for acute conditions like infections, in which a patient calls a doctor. For all other classes of drugs, like cholesterol-lowering, antidepressant, and antihypertensive medicine, there was significant growth in both the percentage of people taking them and in the number of pills each person consumed. Increased consumption of a preventive or chronic drug confounds the analysis of health. If you find out you have high cholesterol and start taking a statin, are you sick because you have an elevated risk? Or are you healthier because you are reducing that risk? The distinction between healthy treatment and chronic illness seems to be dissolving. So *healthy* is in quotes as if it were literally a legacy term, one that no longer has meaning.

When the risk of a disease comes to be seen as a disease in itself, then clinical trials can be designed to test lifelong treatments for that risk factor, and this is a vastly bigger market. Treatments that reduce risk ostensibly could be indicated for all of us since we are all at risk for most diseases. Even a small risk can be targeted by a clinical trial, and its reduction can be measured if the trial is large enough. The result is a set

TABLE 1 **Health Models**

INDIVIDUAL HEALTH MODEL	MASS HEALTH MODEL
Symptoms interrupt the patient's life and drive him or her to the doctor.	Little or no experience of symptoms until attention is called to them.
Doctor takes history and examines patient to make diagnosis.	Patient or doctor takes checklist or screening test and discovers treatable risks.
Doctor prescribes treatment.	Clinical trials indicate treatments.
Treatment returns patient to health and is discontinued.	Treatment often has no discernible effect and is indefinite.

of facts about treatable risks, facts we then must act on or ignore at our peril. Even if we question the relevance of those facts to ourselves as individual patients, if there are no other facts to contradict them, we must act on the facts we have.

All the pieces for understanding the jokes and this book are now in place: the jokes are funny because they mark the transition from an old to a new notion of health (see table 1). The old idea is based on symptoms you feel that make you call on the doctor, symptoms the doctor reads to diagnose you as being ill and to prescribe treatment for you that ideally cures you and returns you to health. In place of this older paradigm we have a new mass health model in which you often have no experience of being ill and no symptoms your doctor can detect, but you or your doctor often discover that you are at risk via a screening test based on clinical trials that show some efficacy of a treatment in reducing that risk; you may therefore be prescribed a drug for life that will have no discernible effect on you, and by taking it you neither return to health nor are officially ill, only at risk. The first joke marks the irony of this transition: you are normal even while you have many illnesses that need treatment, and you stay the same while coming to be newly diagnosed and in need of treatments. The terms health and illness do not appear in the jokes because they are old-model terms; in their place are biomarkers of risk like cholesterol and chronic treatment guidelines.

Along with this transformation in health is the remarkable fact that the prescription rates are projected to keep growing. Healthcare spending has been growing and is expected to continue to grow around 4 to 8 percent per year through 2020; drug growth is expected to be more

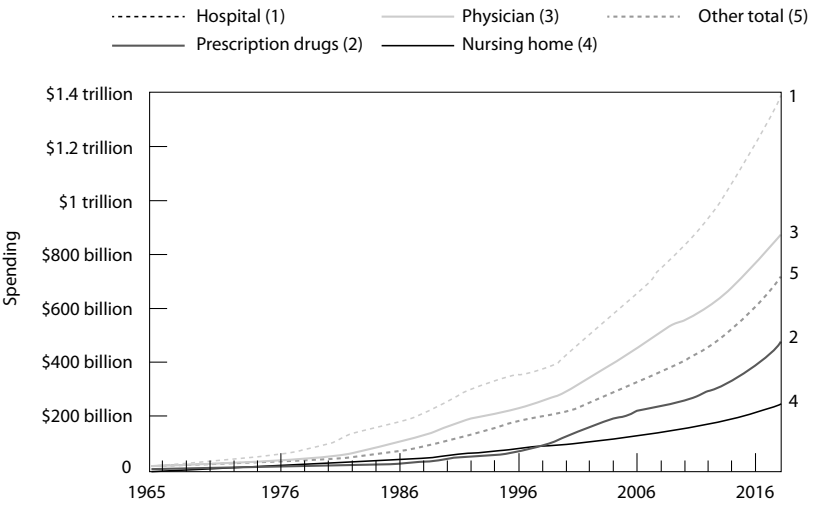

FIGURE 3 Personal healthcare expenditures, by type of expenditure, 1965–2018, based on data from the U.S. Department of Health and Human Services, 2009. *Source*: RAND Health (retrieved December 10, 2010, from www.randcompare.org).

than 7 percent per year; and personal healthcare spending is growing by about 6 percent per year (fig. 3).[13] The growth rates for almost all classes of drugs have been in the low double digits for a decade, with prescription rates for children growing the fastest. Similarly, both the prevalence (the number of people on each drug) and the intensity (the size of the yearly prescription) are projected to continue to grow in all drug categories for the foreseeable future.[14] The figures match our fears, and according to many surveys Americans are spending more time, more energy, more attention, and more money on health.[15] Health is not simply a cost to the nation to be reduced; contradictorily, it is also a market to be grown.

A notion of health driven by market forces seems like a dystopian science fiction story. On one side it seems crazy that so many kids could really be so sick and need lifelong medicines and that so many of the rest of us are on so many drugs, with all of these rates increasing. On the other side, there are facts to back up these claims, epidemiological surveys to show the growing prevalence of illnesses and clinical trials to demonstrate the need to treat. If anything, the facts imply that we are not doing enough screening and treating. Too much and too little at the same time. My research has been aiming to understand this double bind of ever-increasing diagnosis and pharmaceutical consumption in

the United States and to discover the consequences of our redefinition of health and illness over the past two decades.

WHY YOU SHOULD READ THIS BOOK

> **"'Get well soon'? We prefer, 'Stay healthier longer.'" (see fig. 4)**
> —MAGAZINE AND SUBWAY ADVERTISEMENT FROM PFIZER (2007)

This is a book about the current American, middle-class, commonsense view of health and illness, risk and treatment, and how it works. It is also about how this view resulted in people consuming more and more drugs for life. The book is for everyone who takes a prescription despite not feeling sick, and for anyone who has wondered why there are almost no studies that help people or their doctors know when to stop taking a drug (see chapter 5). It is a book for expert patients, who comb the internet for information and think they know how to get to the bottom of facts and make the right decision (see chapters 1 and 6). It is for those who wonder why the cost of healthcare keeps going up and why most of the solutions seem to result in even more screening tests and more drugs (see chapters 3 and 4). And it is a book for those who think there is something fishy about all of those pharmaceutical commercials on television and in magazines suggesting that you really should do a mini-self-diagnosis and go talk to your doctor (see chapter 2).

Explaining this continual growth in drugs, diagnoses, costs, and insecurity can take many forms. One key approach involves following the money and tracing connections between the profits of pharmaceutical companies and disease expansion. Even though the FDA has probably the safest regulatory standards in the world, it also controls the largest market in the world. So the incentives to cheat are staggering. Recent books by Don Light, Marcia Angell, Jerry Avorn, Ray Moynihan, David Healy, and others and the detailed reporting by the *Seattle Times* in the series of articles entitled "Suddenly Sick" are all worth mining to discover how many ways the health system is manipulated: from controlling research results, to ghostwriting medical articles allegedly written by doctors, to influencing guideline committees, to hyping clinical trials, to funding disease awareness campaigns and activist groups in order to drive drug sales. The fact that most biomedical research is underwritten by private industry and therefore that most drugs are produced first for profit and

FIGURE 4 "'Get well soon'? We prefer, 'Stay healthier longer.'" Advertisement by Pfizer, *New Yorker*, February 12, 2007, 23.

second for health means there is a structural contradiction in medicine, one requiring vigilant watchdogs.[16]

I want to take a different approach here. For the past eight years I have been conducting fieldwork on pharmaceutical marketing—attending conferences; talking with marketers, researchers, doctors, and patients; and surveying the extensive literature produced by marketers about their strategies. I have concluded that underlying the continual growth in drugs, diseases, costs, and insecurity is a relatively new understanding of ourselves as being inherently ill. Health has come to be defined as reduction in risk. Treatment is prevention, and we have an increasingly insecure notion of our well-being because we have outsourced its evidence to clinical trials. Together these definitions are reinforced and amplified by the pharmaceutical industry, which sees clinical trials as investments, and measures the value of those investments by the size of the market in treatments it will define.

My interest was in how we enter into relationships with these mass health facts and how their logics come to seem natural. This led to a systemic study of how pharmaceutical facts are defined and how they circulate. Pharmaceutical marketers in particular have a highly developed set of strategies not only for directly managing the manufacture of clinical trials so that they produce the largest number of potential patients, but also for ensuring that the discussions of clinical trials in the media, in doctors' offices, and online constantly reinforce a sense that any measurable health risks must be treated immediately, as if the risks themselves were diseases.

The interaction between the redefinition of health and the growth of treatment was on my mind when I attended a neuroethics meeting in 2002 at which questions of informed consent, brain privacy from scanning, and lie detection were the main topics. The increasing mass prescription of psychopharmaceuticals as an ethical concern was not a topic, however. So after one talk I went up to a leading clinical researcher (a medical doctor with a PhD) and asked whether he was worried at all that the average American was on at least five prescriptions per year. His response was quick and sure:

> I think being on five or more drugs for life is a minimum! Based on the latest clinical trials, almost everyone over thirty should be on cholesterol-lowering drugs.

At the time I could not believe my ears. I was astonished at how easily he pronounced these phrases, how natural he found it that clinical trials could seriously suggest that every adult be put on lifelong statins.[17] Each part of his comment assumed a world in which biomedical facts in the form of trials set thresholds for asymptomatic biomarkers like cholesterol or even age that obligated preventive pharmaceutical treatment. This meant that almost all of these average Americans would not feel ill or experience any symptoms, and most of them would not even suffer a heart attack. They would know only that they were ill or at risk when they were tested and found out they had a score below the threshold for health as defined by the clinical trial. Or they would find out that being over thirty meant they were now at high risk. And why thirty? I'm over thirty, why wasn't I on a statin? Shouldn't I know my cholesterol score at least?

When I speak of this encounter with other doctors, I am told over and over that this is how things are. But even they are a bit disturbed when we start to work out the implications of this view of facts.

First, illness is not felt, and there are no symptoms that drive a person to the doctor. Instead, as we'll see in the next chapter, some sort of screening test determines whether or not that person has crossed a line and needs to be treated. The line measures not a state of illness or ill health, but a state of risk as well as a treatment that would ideally reduce that risk. It is ambiguous whether the person who should be on the cholesterol-lowering drug is ill, but it is clear that it would be healthier to be on the drug because it would reduce the risk of getting heart disease in the future. The historian Robert Aronowitz called this the preventive revolution: if a health risk can be reduced, it should be.[18] Health is thus not exactly a state one is in but a relative category: you would be healthier if you were on the drug, especially if you are over thirty.

Second, the principal agent in the statement is not you, the drug, or the age limit, but the clinical trials. The trials are where the experience of illness seems to have gone when it left the body. They provide the researcher with the answer as to whether someone needs treatment or not. Like the person himself, the doctor in this case cannot tell whether she is ill. The doctor does not even diagnose. Rather, she uses the same algorithm that everyone else does: if a person is over thirty, then he or she should probably be put on cholesterol-lowering drugs. Neither health nor illnesses are states of being: they are states of knowledge; they are episte-

mic. This means that the questions asked by the clinical trials determine what counts as illness and risk and treatment. And the control of these design questions, as we'll see in chapters 4 through 6, has shifted from doctors to clinical researchers to pharmaceutical company researchers to pharmaceutical company marketers.

Furthermore, the disempowerment of the doctor is compounded by many of the direct-to-consumer advertising campaigns such as TV commercials. These ads often portray active consumers-become-patients who paid attention to the TV or a website and recognized a risk that their doctors missed or even misdiagnosed. Consumers can self-diagnose online or even by listening to their symptoms as defined in the ad, and increasingly they are arriving at their doctors' offices with demands rather than questions. Doctors, in turn, because of the multiple pressures of limited patient time, keeping up with rapidly changing information, and the constraints of health maintenance organizations and insurance, are quite vulnerable to these demands.[19]

Third, the relation of the researcher to the state of knowledge is narrated as one of deep submission. Referring to "the latest" clinical trial may seem like an authoritative move, but it implies that what the researcher may have told the patient the day before is now false. Here the jokes are more sinister: health and illness and treatment are continually subject to revision. The consumer as being potentially at risk must maintain vigilance with regard to health information. Health must become a preoccupation. And indeed it has.[20]

Finally, it may not be surprising that the latest clinical trials almost always recommend more treatment for more people. But the researcher's happy sense of the trend quoted above, "Five or more drugs for life is a minimum!" is still disturbing. Declaring a minimum implies an open-endedness to the number of drugs we should be on for life. Given the logic and authority of his claim, it seems that only large-scale clinical trials can help determine whether someone would actually benefit from a treatment. As we will see in chapter 4, because large-scale trials are run by pharmaceutical companies as investments, the only trials they can afford to run are those that, if successful, will return that investment through indicating more treatments.

These characteristics of mass health—chronic treatments for risk reduction, health as known through limited clinical trials, ever-increasing numbers of drugs—are the subject of this book. They are not secret, ex-

cept that they are taken for granted and therefore hidden in plain sight. But they were quite controversial when they were emerging. Just sixty years ago most doctors fiercely opposed all of these developments, insisting on symptomatic diagnosis, etiological treatment, the ability to personally diagnose, and the idea that drugs were prescribed to cure diseases. In the 1960s the full potential of mass health started to become visible, implying exactly what the researcher stated: five or more drugs for life at minimum.[21] This potential was met repeatedly with disbelief, disavowal, denial, and jokes. It became true and absurd at the same time. Yet by the 1990s mass health had become gospel and second nature, part of common sense.

Mass health is both necessary and insufficient. Large-scale clinical trials do distinguish better drugs from worse ones, and the risk they measure produces a kind of truth (chapter 5). The allure of clinical trials is that all successful, well-run ones must have asked relevant questions and therefore reveal treatments that we should follow. The problem is that there are better and worse questions to ask, better and worse ways of framing populations. And good questions for increasing market size do not necessarily translate into a better sense of health and overall well-being.

MAXIMUM TREATMENT

> **The goal of the launch phase is to influence the physician–patient relationship to maximize the number of new prescriptions. Marketers can generate significant product sales by motivating physicians and patients to take action and by influencing their interaction.**
>
> —BOLLING, "DTC: A STRATEGY FOR EVERY STAGE"

This declaration, which appeared in the journal *Pharmaceutical Executive*, aimed at making direct-to-consumer marketing more effective by using "a strategy for every stage"; the goal of such pharmaceutical marketing is explicitly stated: not to cure people or to identify those who should be cured, but to grow the number of new prescriptions as much as possible. The logical extension of risk and its grammatical personalization through biomedical facts combine with marketing here to produce a new regimen of treatment maximization.

On one level the problem can be simply stated: health as a paramount

value in our life is defined in part by clinical trials that have to build in assumptions about health, normality, and risk.[22] As there is no logical limit to risk or health, the practical result for pharmaceutical companies is an unlimited imperative. They want to maximize prescriptions by expanding the market of those at risk, defining clinical trials as broadly as possible, and persuading us that all risks are, in fact, conditions that must be treated now with drugs. It is true that, aside from outright fraud, there are limits to what clinical trials can be made to say. Trials do regularly fail and even backfire on the companies that sponsor them. But the point here is that actuarial risks have now been redefined as symptoms. Risk is now a subjunctive present illness: treated as if diseased. Treatment maximization in the era of biomedical clinical trials imposes order where before there was social negotiation and an unstated assumption that illness was defined by patients.[23] For instance, the following type of comment appears quite regularly when new clinical guidelines are published:

> Only a fraction of people with high cholesterol are on statins, despite a barrage of drug-company advertising backed up by guidance from public-health officials. About 11 million Americans currently take one of the statins, while some public health experts say that at least 36 million should probably be on one. Globally, the discrepancy is even more dramatic: About 25 million are taking the pills while an estimated 200 million meet guidelines for treatment.[24]

In this paragraph, taken from a *Wall Street Journal* article published in 2004, a set of population statistics are emphasized that intensify an argument about the dangers of not listening to doctors and clinical trial data. Two hundred million people worldwide, one out of every thirty persons on the planet, is presented as a new target number. Universal screening programs and mass pharmaceutical regimes regularly appear in the news, and the line between good use and abuse is increasingly hard to draw.

The intersection between market logic and the infinite logic of risk is one of incredibly productive tensions. When marketers say their aim is to maximize the number of prescriptions—first, the new prescriptions and, second, the length of time one stays on them—they express a logic of generalized medication. They aim at the maximum number of prescriptions each of us can be made to take. It looks, therefore, like phar-

maceutical companies have found a way to grow health via clinical trials, redefining health as treatment, in part by expropriating the means of diagnosing illness through screening tests that tell us and our doctors that we need treatment. Increasingly they use clinical trials to co-produce disease definition, diagnostic test, and treatment as a bundle. The bottom line is that they have exchanged any interest in reducing treatments for the goal of increasing them. No matter how obvious this might seem now, I didn't see the connections right away, even when pharmaceutical researchers said it directly: "No one is thinking about the patients, just market share."[25]

Viewed systemically, this capacity to add medications to our life by lowering the level of risk required to be at risk is what I call surplus health. Surplus health research aims to constantly increase the total number of medicines we consume. A clinical trial designed to *reduce* the amount of medication people take and still save lives sounds like a win-win solution: the company has a better drug to sell that will be more targeted, and people will get better faster. But actually this kind of trial is remarkably rare, even counterintuitive. If successful, such a trial would take a large number of people out of a risk category, essentially telling them they had less risk than they thought. The drugs they were taking to gain health would no longer be seen to do so. In the joke for this scenario, the doctor would tell the patient, "Good news, you haven't changed, but the guidelines have!"

I have talked with doctors as part of my fieldwork, and they, too, have been struck by this oddness. Most trials are set up so that either they are successful and a new, more intensive treatment regimen is indicated, or they fail, and the status quo prevails. Only the trials that backfire and find excessive side effects result in reduced treatment. My doctors are troubled by how easy it is to put people on medication because they meet guideline criteria, but how difficult it is to get them off. Often no studies are conducted to determine when it would be better or safer to stop giving a medication to a patient, even while there are very few studies of the long-term effectiveness or safety of those medications.[26] None of these studies interest drug companies because, again, they would shrink the market for treatments. The general trend is that the only trials conducted by the industry are those that would grow the market by increasing the amount of medication in our collective lives. The health facts we have and the empirical data for pharmaceutical consumption in the United States

bear this out. It might seem that publicly funded trials can easily correct this problem, but the economy of such trials and the way even public trials subscribe to the logic of health as risk reduction suggest it is not clear how to do this. By unraveling the dysfunctions within our emergent health systems I want to take a crucial step in that direction.

THE ELEPHANT IN THE ROOM

The pharmaceutical industry is a massive elephant. Like the blind men of the famous parable, we each catch hold of a tiny piece of it—leg, tail, trunk—and think we have a handle on it: it is strong and solid, it is hairy, it moves like a snake. From about $880 billion dollars of sales for 2011, the industry is expected to grow approximately 5 percent a year in the future. Its top ten companies employed 960,000 people in 2009. More than 32,000 clinical trials actively recruited volunteers across 167 countries as of April 2012. More than 2.4 million Americans participated in clinical trials in 2006.[27] While these numbers may seem large, within the health industry they represent a crisis. Four out of every five clinical trials are delayed because of problems in enrolling enough people. In the United States, the problem is that Americans are already on too many drugs and therefore their bodies are not clean (or "treatment naïve") enough to be proper test subjects.[28] As a report by the consulting firm Ernst & Young indicated, "The number of trials has doubled in the past 10 years, forcing companies to seek trial participants in emerging markets outside of the saturated areas in the United States and Western Europe. . . . Emerging markets such as India, China, and Russia offer drug companies a volume of potential subjects, and trials can often be executed at reduced costs."[29]

There are entire literatures devoted to studying the pharmaceutical industry and clinical trials, including reports by economists, critics, and now ethnographers and science studies scholars. These studies include Andrew Lakoff's *Pharmaceutical Reason*, as observed in Argentina; Jeremy Greene's *Prescribing by Numbers*, a history of midcentury pharmaceutical studies and marketing; Anne Pollock's *Medicating Race*, on heart disease and normal treatment; Steven Epstein's *Inclusion*, a history of the practices of clinical trial activism in the United States; Kristin Peterson's work on clinical trials in Nigeria and wider anticlinical trial activism; and Stephen Ecks's and Cori Hayden's studies of the practices of the generics industry and logics in India and Mexico, respectively.[30]

Adriana Petryna's anthropology of the global clinical trials industry and Jill Fisher's study of doctor-run clinical research organizations attend to the phenomenally large outsourcing by the pharmaceutical industry itself, resulting in what Petryna calls "ethical variability." She writes, "There has been little or no public discussion of how outsourcing and offshoring generate novel strategies of evidence making: providing new opportunities for manufacturers to create the data they want and to arbitrage it in the context of regulatory drug approval."[31] As ethnographies, these works detail the ways in which the people caught up in disaggregated industries come to have incentives and worldviews that keep them from understanding the collective effects of their work. They are able to substitute regulatory compliance for ethics and local legality for collective health. Kaushik Sunder Rajan has been studying sites in India where deindustrialization has forced millworkers into situations in which they are being recruited in large numbers as presumed volunteers into clinical trials. Crucially, they are valuable only to the extent that they are anonymous, individualized, healthy, and relatively unmedicated. As Sunder Rajan puts it, their informed consent, even if conducted in the most ethical mode possible, must be understood structurally: "Ethics does not just legitimate experimental subjectivity, it actively depoliticizes it."[32]

Together, these ethnographies capture portions of the elephant. The phenomenal size and continued growth of the pharmaceutical industry depend on these global processes. At the same time, growth depends on the ability to continually change and enlarge the definition of health so that more and more drugs can be prescribed to those who can pay. In this book I try to get a handle on the changing nature of health, given that clinical trials are almost entirely run by drug companies.

My book studies these naturalized logics of clinical trials and risk treatment in American culture. Using a combination of ethnography, interviewing, and media analysis, I focus on how these logics are produced, maintained, and embodied in speech and text. Here I follow Marilyn Strathern in defining culture as "the way analogies are drawn between things, in the way certain thoughts are used to think others. Culture consists in the images which make imagination possible, in the media with which we mediate experience."[33]

I began this study with a survey of the mass media, constructing a database of newspaper and magazine articles about clinical trial results and medical risk guidelines and collecting television and print advertise-

ments for pharmaceuticals. I analyzed these for how notions of risk and evidence were presented and how the activeness or passivity of patients were portrayed. In order to observe how people talk about drugs, risks, and evidence, I analyzed online patient newsgroup discussions. I then conducted a series of interviews with persons taking pharmaceuticals and with doctors, focusing on how exactly they learned new medical facts and how they incorporated these facts into their daily practice. Using the methods of grounded theory to analyze these datasets, I identified logical structures of their arguments, grammatical forms of identification and justification, and regimens of lived practices.[34]

The second part of my research focused on the explicit production of pharmaceutical marketing strategies. I attended a pharmaceutical marketing conference and conducted three workshops with pharma marketers at the Massachusetts Institute of Technology. I analyzed major marketing journals, websites, and business press coverage of pharma marketing. My aim was to document the forms of pharmaceutical companies' explicit attention to creating and maintaining mass notions of health and to formulate a series of hypotheses regarding the ways in which facts, risks, and pharmaceuticals are talked about and incorporated as taken-for-granted parts of everyday life.[35]

I have presented my preliminary findings in a series of talks over the past several years at academic conferences, but also, importantly, I have engaged in a form of constant ethnographic engagement. This has included sharing my talks with marketers, including one who designed a pharmaceutical campaign I write about in this book. I consulted with two marketing firms in which my contribution was to present my ongoing research and discuss with them the changing nature of pharmaceutical consumption. In addition, I was invited to present to a number of groups of doctors in forums, including in grand rounds; in each case a lively debate followed my presentation, a discussion in which we collectively critiqued and sharpened my analyses.[36]

Together, the *logic*, *grammar*, and *regimen* of pharmaceuticals form the results of my research. Logic names the ways in which concepts make sense together. The grammar of biomedical facts tells us about ourselves—who we really are, our personal levels of risk, our symptoms, our future—it helps narrate ourselves as being responsible for ourselves, for our choices, our past, our genes, and our visits to the doctor. It constitutes a moral grammar. Biomedical facts identify risks and induce fear,

anxiety, hope, and occasionally denial. Through a personalizing grammar, they create a relationship between us and truth that in most cases we must learn to live with, counter with other facts, or try to forget. These ways of talking about ourselves and becoming persuaded of the truth of our illnesses and treatments I call objective self-fashioning. Because we have invented ways of living with facts, facts in turn become instruments through which marketers manipulate our lives. In addition to logic and grammar we must add an analysis of a pharmaceutical regimen in which prescription maximization replaces health as the force driving treatment innovation and our healthcare behaviors in seeking information and taking medications.

The book is thus an ethnography of the cultural work being done in the name of risk, screens, drugs, and clinical trials. I trace how our ideas of health and illness have transformed in such a way that it has become thinkable that every adult should be taking a preventive cholesterol-lowering drug and every troubled adolescent an antidepressant. By *our* and *we* in this paragraph and throughout this text, I do not claim to speak for all patients or Americans. Instead, following Strathern's approach, I want "simply to identify myself with those who are exposed—whether they wish for it or not—to a range of ideas and images now in cultural currency." These ideas and images are the medical facts, and marketing specifically addresses us as patients or would-be patients.[37]

The methods of media analysis, interviews, fieldwork, and ethnographic engagement have enabled me to create a thick description of how it comes to be common sense for the mass media, doctors, and patients to talk about planet-sized markets and everyone being on five or more drugs for life. We may dispute these claims, but, more important, we do not find them, as many people did before 1990, absurd or unthinkable. We can see how they might make sense to others, and we can imagine that, if presented with the right data, we would come to accept and even advocate them. We share, in other words, the sense that fact-questions about clinical trial data, risky foods, and preventive pharmaceuticals are good questions. Anthropologically speaking, this sense of what makes a good question is a good basis for understanding culture.

The aim of this book is to make our common sense about health seem a bit strange—through seeing the process as a whole, including how it comes to inhabit us, how it is promoted, and how it undergirds the very possibility of a health industry based on a need to grow. The book works

to touch and to comprehend a very small piece of the drug industry elephant: corporate health research. Small as it is, I think it is a crucial piece to understand, because if I am right in my analysis of it we will need more than regulatory change. The very idea of corporate health research is a problem we are grappling with. So in this book I isolate that issue and temporarily pass over the many other problems, including corruption, price, bioethics, and poverty, so that we may clearly see just how natural and embedded the notion of health as growth has become.

THE STRUCTURE OF THIS BOOK

Understanding how the continual growth in pharmaceutical consumption has become common sense requires tacking back and forth between a patient–citizen point of view and a pharmaceutical company point of view. Part of my aim in doing this is to show that there are many things on which we all agree, including processes and trends that are not good for either our health or our wallets. Therefore each chapter works out the logics of these two points of view, how they come to make sense and serve as the basis upon which we make decisions. Each chapter can be read separately, but together they show that our healthcare is in need of systemic change.

Chapter 1, "Responding to Facts," examines the ideal smart consumer who encounters a medical fact, like a test result, that forces him or her to make a decision. This protopatient immediately becomes an intense researcher, critically examining the clinical trials available, interviewing doctors, scanning the internet, and weighing options, only to find that despite a large number of studies there are not enough appropriate facts to make a proper decision. The person has become an expert patient and yet something seems wrong with the world of medicine. There is not enough time, however, to get to the bottom of it because a decision has to be made.

Chapter 2, "Pharmaceutical Witnessing and Direct-to-Consumer Advertising," takes the next step and looks at how marketers see us as patients-in-waiting who need education and advertising in order to be brought up to speed on the risks and conditions we should be treating. This chapter details the incredibly fine-grained stages that are used to manage how we come to learn that we *may* be ill and at risk. Clinical trials are part of marketing. They are designed to produce the largest markets,

and they are run to yield the types of facts that will motivate the largest population possible to consider treatment. Newspaper articles, awareness campaigns, pamphlets in doctors' offices, patients groups, and advertisements are all part of coordinated campaigns to gain our attention and stoke our anxieties. I repeat again that this is not in itself wrong; it is the logic of our mass health to be extensible. Yet the dilemma is that these are the only facts we have.

Chapter 3, "Having to Grow Medicine," steps back by realizing that a pivotal question is not where to draw the line, but who draws the line. The fact that most clinical trials need to be designed and run by pharmaceutical companies as investments is the assumed condition of the world right now; everyone, including the companies' critics, seems to agree that they are the only ones who can afford to study mass illnesses. Corruption aside, the real issue is that clinical trials are driven by the need to grow the market in medicine and that this is a very different goal for a clinical trial than arriving at the best therapy for people. Pharmaceutical companies are not shy about admitting this impulse—making money is their livelihood—and, as we shall see, they feel this pressure as being inexorable and blame us for putting them in this position. In a guidebook for pharmaceutical employees, for example, two analysts complain that "one of the significant problems for the pharma industry is that of the 400 disease entities identified, only 50 are commercially attractive by today's requirements of return on investment (ROI). Society needs to find a way to make more diseases commercially attractive if it wants Pharma investment in treating any of the other 350 diseases affecting hundreds of millions of people."[38] The analysts are explaining that, as companies who need to grow in order to survive, pharma can afford to do research only on treatments that have a chance of becoming massively huge markets. This has led to the expanding role of marketing in designing clinical trials within pharma companies, allowing those in marketing to make decisions that formerly were in the hands of scientists and clinicians. It is not that companies don't want to eliminate suffering, but they must attend first of all to the bottom line. As another analyst put it, "Pharmaceutical companies tend not to invest in tropical medicines because they are unlikely to recoup their investments."[39]

Chapter 4, "Mass Health: Illness Is a Line You Cross," investigates how clinical trials came to occupy such a critical role in how we think about health. Since the 1950s statistical medicine has slowly transformed

health to the point where most of the drugs we take are not to address symptoms we suffer but to reduce our chances of having symptoms in the future. Understanding the notion of risk reduction is incredibly confounding because it is essentially infinite: no matter how much risk we reduce, we still have the 100 percent risk of dying. Where to draw the line thus becomes an ethical and social question, not just a technical and clinical one. This chapter considers the logic of health as risk reduction and how medical professionals have grappled with it over the past half century and more.

Chapter 5, "Moving the Lines, Deciding on Thresholds," looks at how pharmaceutical companies decide how much risk we should treat. It examines their creative strategies for using clinical trials to extend medicine to more and more of our life, under the banner of making us healthier, but only if we can become so by taking more medicine. Treating us earlier, treating us longer, turning risks into treatable conditions, and finding more and more risks to treat are explicit strategies they discuss in their journals and at conferences. Their facts are the most prevalent and sometimes the only facts about our health that are available, and this is why it is hard to find the answers we are often looking for, for example, when to get off of a drug or whether a drug will really help us.

Chapter 6, "Knowing Your Numbers: Pharmaceutical Lifestyles," returns to the expert consumer in all of us and asks what we can do in the face of this marketed field of facts. It looks at how consumers and patients have taken at least three different rational ways of responding to the increasing facts about more and more risks and drugs. One mode of response is to live in constant struggle between one's desires and one's fear of unhealthy consequences, that is, to live against health. Another mode is to change one's lifestyle entirely with the goal of being healthy, that is, to live for health. A third response is to take drugs in order to enjoy one's lifestyle, to take statins in order to continue eating steak, a personal variant of DuPont's slogan, "better living through chemistry." Each mode involves negotiating a constant stream of intense, often worrying health facts. And we all oscillate among these modes and experiment with practices of resisting health.

My hope is that each chapter in this book will challenge readers' ways of seeing health, risk, facts, and clinical trials. Each is designed to show how much these concepts have become the very tools used by pharmaceutical companies to grow markets, to the point that there is no simple

way to imagine how to live life without drugs. Early readers have told me that it often seems like an anti-self-help book, emphasizing how hard it is to act and how little we know about the drugs we take because we haven't, as a society, prioritized the right questions. Policy recommendations are beyond the scope of the book, but in the conclusion I outline how clarifying the way health has been transformed into mass risk reduction and working through the way in which facts themselves have come to be managed might allow us as a society to figure out a way to reverse this spiral and head in a better direction.