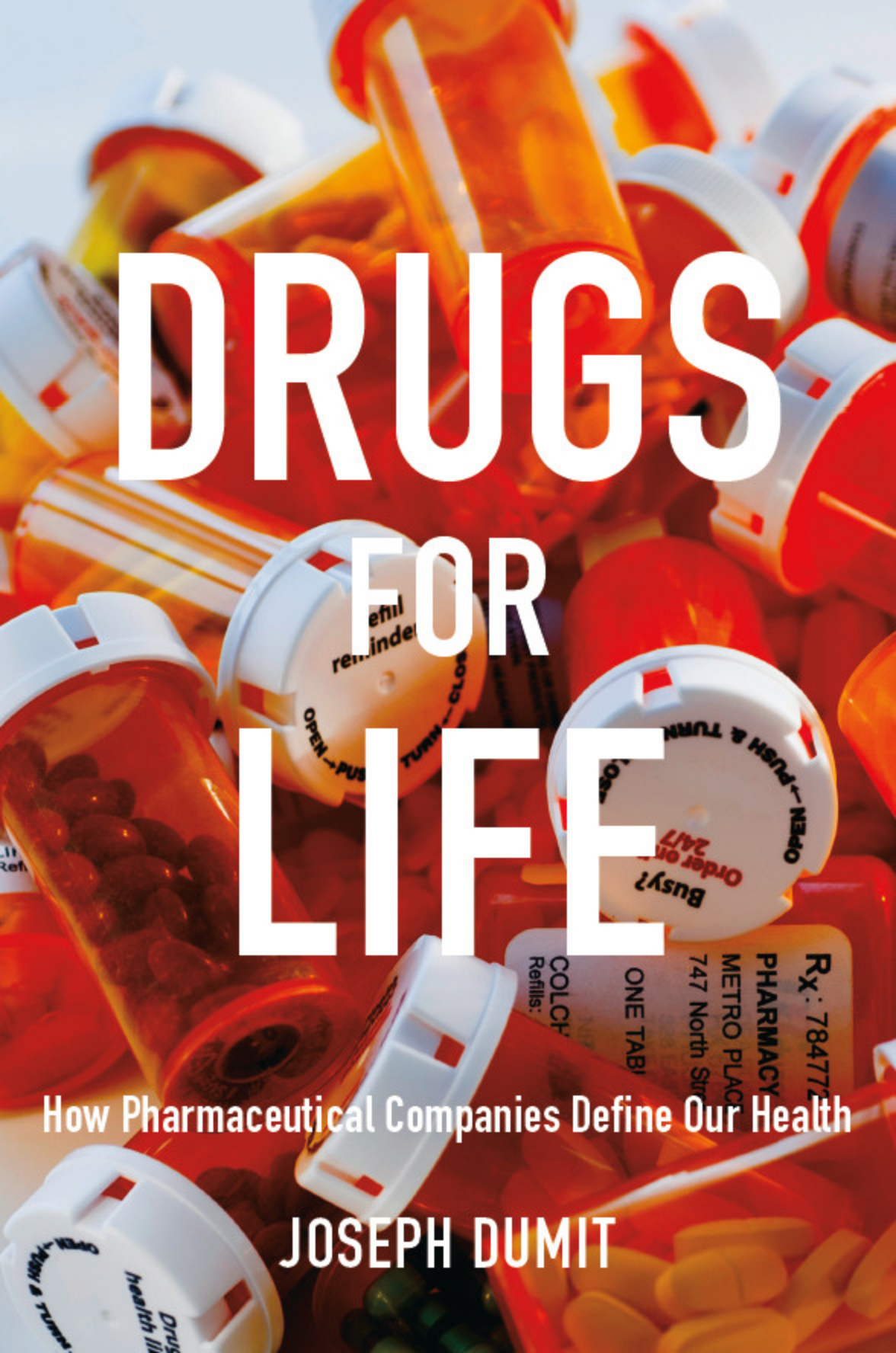




DRUGS FOR LIFE

How Pharmaceutical Companies Define Our Health

JOSEPH DUMIT

DRUGS FOR **LIFE**



EXPERIMENTAL FUTURES

Technological Lives, Scientific Arts, Anthropological Voices

A SERIES EDITED BY

Michael M. J. Fischer
and Joseph Dumit

DRUGS FOR LIFE

How
Pharmaceutical
Companies
Define
Our Health

Joseph Dumit

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for Sylvia

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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.

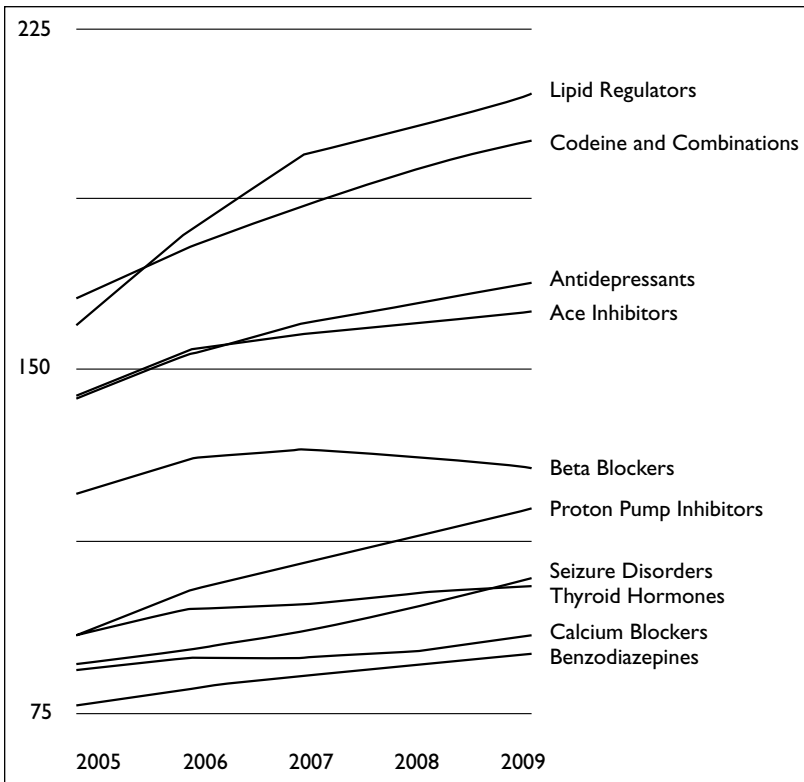


FIGURE 2 The top therapeutic classes of drugs by U.S. dispensed prescriptions (in millions), 2010. *Source:* IMS National Prescription Audit PLUS, IMS Health.

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 co-exist, 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

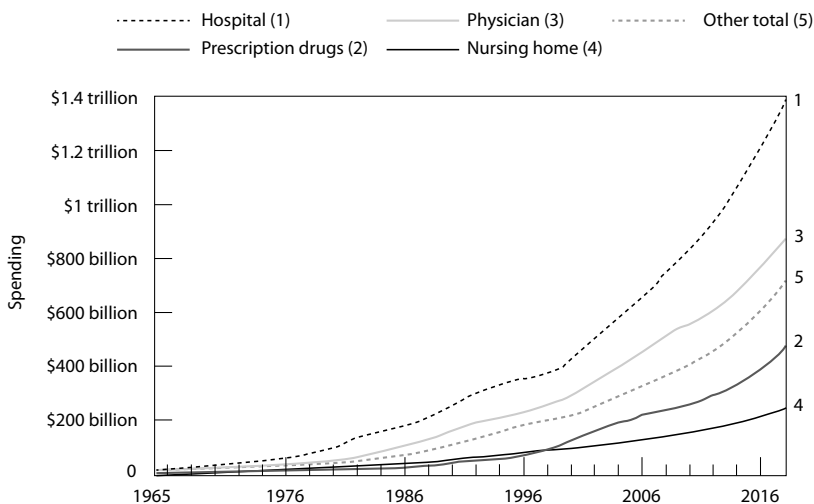


FIGURE 3 Personal healthcare expenditures, by type of expenditure, 1965–2018, based on data from the U.S. Department of Health and Human Services, 2009. *Source:* RAND Health (retrieved December 10, 2010, from www.randcompare.org).

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

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WE PREFER,
'STAY HEALTHIER
LONGER.'

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such as diabetes workshops and other group health classes. And the results are clear. These programs are helping keep people healthy and reducing the economic burden of disease, in some cases decreasing hospital stays by as much as 52%.

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www.pfizer.com

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