Drugs for Life:
Managing Health and Happiness through Facts and Pharmaceuticals

Joseph Dumit
Introduction

[Cartoon v1] [Cartoon v2] (these will be cover of book?)

There is a cartoon of a doctor talking to a man in an examining room with the caption: “Your blood pressure is off the chart, you’re over weight, out of shape and your cholesterol is god-awful. In short I find you perfectly normal.” The same cartoon also has a different caption: “The good news is that your cholesterol level hasn't gone up. The bad news is that the guidelines have changed.” In this paper I want to tell a story of how the health industry works such that both of these captions make sense. They are both funny, and their intersection points to a new kind of health, where to be normal is to have symptoms and risk factors that you should worry about, and at the same time, to not know whether you should be worrying about yet more things. To be normal, therefore, is to be insecure. In fact, to not worry about your health, to not know as much as you can about it, and to act on that knowledge, is to be irresponsible. There are even public relations campaigns featuring people who are “The Picture of Health,” warning, “You may look and feel fine, but you need to get the inside story.” Feeling healthy becomes itself a sign that you need to be careful and go in for screening.

Health in America today is defined by this doubled insecurity: never being sure enough about the future -- always being at risk -- and never knowing enough about what you could and should be doing -- always knowing that there is more information out there. Paradoxically, this insecurity continues to grow despite there being an equal growth in research about risks, screening, and treatments, and a constant growth in the amount of medicine consumed each year -- as if the more we know, the more we fear; and the more we fear, the more preventive actions and medications we need to take. This 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 different prescription-only drugs per year. Of course, the range is wide, with many people prescribed few or no drugs each year.

According to the pharmacy benefits companies and insurance companies, 11% of Americans were prescribed cholesterol lowering drugs last year, 40% of all those over 50. More than 20% of women over 40 were prescribed antidepressants in 2002, almost 10% of boys 10-14 were prescribed Attention-deficit disorder drugs. These people are us, the generalized “you” of the cartoons and the object of pharmaceutical marketing. These numbers are the flipside of the cost of healthcare. Overall healthcare costs were over two trillion dollars last year, with prescription drugs accounting for about 10% of that or $203 billion.

If our health is so insecure, why are the cartoons funny? One reason they make us laugh is because they reveal the anxieties we feel about our own health and they carry the trace of how it has changed. Being overweight and having high cholesterol is normal now in the sense that we are aware that the average American has these characteristics. The doctor diagnoses the patient as typical, despite the symptoms. Normal and healthy are severed, and this is funny because they didn’t used to be. Less than 50 years ago, we
didn’t even know about cholesterol as a risk factor. The very concept of a “risk factor” was created alongside the innovation of large-scale prospective clinical studies.

In the 1950s, medicine started becoming thoroughly “statistical”. The large-scale Framingham Heart Study tracked the habits, health and illnesses of an entire town. Public health researchers began to amass evidence that smoking “caused” lung cancer and increased mortality, not in everyone though. These studies helped produce notions of populations “at risk”, and of mass health. They represented an essential movement of public health from vaccinations (which definitely prevented some illnesses) to statistics, in which biomarkers like cholesterol, and high blood pressure “correlated” with health problems. The result was that “risk” became an object of intervention.

At the same time, the postwar pharmaceutical industry was getting started -- growing out of pre-war medicine companies, but newly empowered both by war growth and national prominence and by the FDA granting status to “prescription-only” drugs, which didn’t exist before. This new industry lost no time imagining mass markets for drugs, and in targeting doctors as the gatekeepers to this market. Many classic sales tactics and strategies were invented by the pharmaceutical industry and their armies of “detail men” or drug representatives.

Also in the 1950s, a new form of study was also being invented: the randomized control trial, or randomized clinical trial. In its ideal form it 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 they were getting. This rendered the trial a fair and objective test in which the only difference was the treatment. The advantages of RCTs were many, including the ability to detect incredibly minute differences between two treatments, such as that one treatment worked three percent better than the next one, which often meant that one treatment might help 103 out of a 1000 get better and the other only 100. This was both a stunning form of objective measurement, and a bizarre one at the time: it meant that the treatments were so close that no doctor or patient would be able to experience the difference, instead, they would have to rely on the clinical trial results to tell them which drug was better. Many doctors at the time rebelled against this medicine by statistics, but the government, the drug companies, and many doctors and public health officials were thrilled to have a clear-cut way of knowing what worked.

As these trends interacted with each other -- risk factors as targets of public health intervention, clinical trials as instruments to recognize smaller and smaller health risks and treatments, and the pharmaceutical industry growing in size and power -- they came to generate the new notion of health that we laugh at in these cartoons. The sheer size of the pharmaceutical industry meant that it could afford to pose questions of health risks at these smaller levels and farther into the future, and that the government would be more or less compelled to let industry conduct that research, because it was otherwise too expensive. Clinical trials can include over 100,000 patients in some cases, and today span hundreds of hospitals and doctors, and many countries.

This “industrialization” of clinical trials happened because the risk factors (like cholesterol and hypertension) identified could be paired with drugs. And these drugs would be taken not to cure the condition, but to reduce the risk factor and potential future
events (like heart disease or heart attacks). These drugs would be taken chronically, every
day, for life. And this was a massive market!

In the first cartoon, what is not revealed is how many prescriptions the patient will
be put on for being “perfectly normal.” The other cartoon gets even more nervous
laughter because many of us have had the experience of finding out from our doctors or
from the newspaper that new guidelines for health mean that we are now “at risk” and in
need of remediation. We joke amongst ourselves about the constant stream of new
findings that this food is now carcinogenic or that drug has newly discovered side-effects.
We joke because we are essentially helpless in the face of a stream of information that
reveals our current knowledge to be incomplete and even itself dangerous.

As soon as a risk factors could be paired with treatments, the world changed.
Historian Jeremy Greene traced the extent to which the cholesterol went from being a
disputed object to a public health emergency through the work of a public-private
partnership: the National Cholesterol Education Program (NCEP). The NCEP was funded
by the pharmaceutical company Merck in order to create awareness among doctors and
the public of the need for their new drug Mevacor. The NCEP helped invent the concept
of treatment guidelines that reified the notion of “high risk” precisely in order to provide
a benchmark for both risk reduction and market size.

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 being ill and as therefore
requiring life-long treatments, often through life-long pharmaceutical use -- drugs for life.
Today, chronic diseases are said to affect 125 million Americans. These are not the
chronic illnesses studied by medical anthropologists that painfully disordered one’s life
and disrupted one’s biography. 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, which assumes that most people are healthy at their core, and that most
illnesses are temporary interruptions in their lives, identified by persons as felt suffering.
Chronic diseases, like diabetes, cystic fibrosis, and Huntington’s, although well-known
for centuries, were exceptions to the basic paradigm of inherent health. Beginning in the
1960s and 70s, and becoming common by the 1990s, a very different notion of illness has
taken 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 (they are
never absolute healthy), rather it is a temporal, relative, experiential term (they “feel
healthy today”). In the words of Elizabeth Beck-Gernsheim: “All of us are affected, we
are all risk carriers.”

Diabetes and Huntington’s are regularly invoked together today as paradigmatic
templates for many conditions that were not even illnesses before. The older notion and
elements of chronic illness is not gone, of course; these notions coexist, and we are quite
good at code-switching between both views. But this new notion of illness is one that is
now promoted to us in advertisements and in awareness campaigns throughout our daily
life. As an index of this paradigm shift, “health” itself no longer exists as a trend in
pharmaceutical reports. It often only appears in quotation marks. A 2005 report on
pharmaceutical consumption trends by ExpressScripts stated: “2004 was in fact a
‘healthier’ year than 2003.” They placed ‘healthier’ in quotes because only five of the top
25 most consumed drug types went down in use (those given for acute conditions, like
infections, where a patient calls a doctor. For all other classes like cholesterol-lowering, anti-depressant, and anti-hypertensive drugs, there was significant growth in both the percentage of people taking them, and in the number of pills that each person consumed. So “healthy” is in quotes as if it were literally a legacy term, one no longer meaningful. Increased consumption of a “preventative” or “chronic” drug confounds the analysis of “health.” If you find out you have high cholesterol and start taking a statin: are you sicker (because you have an elevated risk) or healthier (because you are reducing that risk)? The distinction between healthy treatment and chronic illness seems to be dissolving.

When the risk of a disease comes to be seen as a disease in itself, then clinical trials can be designed to test treatments for that risk factor. 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 of facts about treatable risks, facts we then are faced with acting on or ignoring at our peril. Even if we have questions about 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 cartoons and this book are now in place: the cartoons are funny because they mark the transition from a notion of health based on (1) symptoms you feel that make you call on the doctor, (2) signs the doctor reads to diagnose you as ill, and (3) prescribe treatment for you, that (4) ideally cures you and returns you to health. In its place we have a new mass health model in which (1) you often have no experience of being ill or symptoms your doctor can detect, but (2) you or your doctor often discover that you are at risk via a screening test, that (3) is based on clinical trials that show an efficacy of a treatment in reducing that risk, and (4) you may be prescribed a drug for life that will have no discernible effect on you and in which you neither return to health nor are officially ill (only at risk). The cartoons mark 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 newly need treatment. Health and illness are not used in these cartoons because they are old-model terms, in their place are biomarkers of risk like cholesterol and chronic treatments.

Along with this transformation in health is the remarkable fact that the prescription rates are only projected to keep growing. Healthcare has been and is expected to continue to grow around 7% per year through 2017, drugs growing over 7% per year, and personal healthcare spending growing about 6.5% per year. The growth rates for almost all classes of drugs have been in the low double digits for a decade, with prescription rates for kids growing upwards of 30% per year. 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. The figures do match the fears, and according to many surveys, Americans are spending more time, more energy, more attention, and money on health. Health clearly is not simply a cost to the nation to be reduced; it is also a market to be grown.

Moral panics over kids, adults, and increasing pharmaceutical rates catch us in a double bind. On one side it seems ‘crazy’ that so many kids could really be so sick and
need life-long medicines, or that 25% of women 25-45 are on antidepressants, or that the average insured 60-yr-old be on more than 15 drugs, with all of these rates increasing. These seem like a dystopian science-fiction story. On the other side, there are facts to back up these claims, epidemiological surveys to show the prevalence of illness, 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 to understand this double-bind of ever-increasing diagnosis and pharmaceutical consumption in the U.S. and discovering the consequences of our redefinition of health and illness during the past two decades.

Why you should read this book

This is a book about how the American, middle-class, common sense view of health and illness, risk and treatment, works; how it came into being, and how it is resulting in more and more drugs for life. It is for everyone who takes a prescription despite not feeling sick, who has wondered why there are almost no studies that help people or their doctors know when to stop taking a drug (ChX). 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 (ChX & Y). 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 (ChX & Y). And it is for those who think there is something fishy about all of those pharmaceutical commercials on TV and in magazines telling you how desperate you should be, if only you'd do a mini-self-diagnosis and go talk to your doctor (ChX).

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 pharmaceutical company profits and disease expansion. Even though our the US Food and Drug Administration (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. The recent books by Marcia Angell, Jerry Avorn, Ray Moynihan, David Healy, and others, and the detailed reporting by the Seattle Times in “Suddenly Sick,” are each worth mining for how many ways there are to manipulate the health system—from controlling research results, to ghostwriting medical articles allegedly penned 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 most drugs are produced first for profit and second for health means that there is a structural contradiction in medicine requiring vigilant watchdogs.

But in this book, I want to take a different approach. I want to focus on the emergent effects of the outsourcing of research to for-profit drug companies. For the past five years, I have been conducting fieldwork on pharmaceutical marketing—attending conferences, talking with marketers, researchers, doctors and patients, and surveying the large literature produced by marketers about their strategies. I have come to conclude that underlying the continual growth in drugs, diseases, costs and insecurity is a relatively new definition of ourselves as inherently ill, of health as reduction in risk, treatment for prevention, and self-evidence as fundamentally insecure. 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 they will define.

Interested in how we enter into relationships with facts and how logics come to seem natural to us, I began to systematically study the ways in which pharmaceutical facts are defined and circulate. Pharmaceutical marketers, in particular, had a highly developed set of strategies for directly managing not only the manufacture of clinical trials so that they produce the largest number of potential patients as possible, 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 they were diseases. 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.\textsuperscript{xii}

In the paragraph, taken from a \textit{Wall Street Journal} article, a set of populations statistics are emphasized that intensify an argument about the dangers of not listening to doctors and clinical trial data. 200 million people worldwide is presented as a new target number, one out of every thirty persons in the world. Universal screening programs and mass pharmaceutical regimes are regularly appearing in the news, with the line between good use and abuse increasingly hard to draw. The 21\textsuperscript{st} century has already seen recommendations for mandatory cholesterol screening starting at age 20 for all Americans and standard pharmaceutical treatments for the approximately 30\% of the population expected to be at high risk when tested. Children are subject to screening for obesity and other risk factors for heart disease in similar ways. Each of these screens works by setting a number, a threshold, which when crossed, triggers a diagnosis of risk or disease and a recommendation for treatment. Underlying the controversies surrounding mammograms, PSA prostate cancer tests, and other screens concern whether, in the light of a stream of evidence suggesting a lower threshold might help more people, there could be \textit{any reason} not to make the test more sensitive.

In this logic, clinical trials are the ground of truth. They decide our risk and couple it with what we \textit{should} do about it. Implicitly health is the key value, health in the form of reducing risk now. Drugs are acceptable, even desirable as a form of treatment. Planet-wide drugs for life become standard medicine. The transition from \textit{is} (risk) to \textit{ought} (the proper and required response) depends on implicit premises. The first of these is that health is a key value, a paramount one supplanting all others.\textsuperscript{xiii} To this is added what historian Robert Aronowitz calls the preventive revolution: if a health \textit{risk} can be reduced, it should be.\textsuperscript{xiv} Finally, a rule of treatment substitutability is invoked: even if heart disease may be prevented through environmental or social change, or through diet and behavior, each of these can be evaluated alongside drugs on the same cost/benefit scale of overall population risk reduction, compared to these costly, troublesome
solutions. Drugs are acceptable, even desirable as a form of individualized prevention. Each of these assumptions is positive, each is empirically based and theoretically sound. Even the consequence, planet-wide drugs for life as a standard risk reduction strategy, makes sense.

The increasing growth in medication consumption was on my mind when I attended a “neuroethics” meeting in which questions of informed consent, brain privacy from scanning, lie-detection were the key topics. The increasing use of psychopharmaceuticals as unethical was not a topic however. So after a talk, I went up to Dr. Smythe (an MD-PhD top researcher) and asked whether he was worried at all about the fact that then the average prescriptions per year for an American was over five. 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 really could not believe it. 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 life-long statins. 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, and that obligated preventative pharmaceutical treatment. This means that almost all of these people do not feel ill and do not experience any symptoms, most of them would not even suffer a heart attack. They will only know that they are ill or are at risk when they are tested and find out that they have a score below the threshold for health defined by the clinical trial. And why thirty? Why wasn’t I on a statin? Shouldn’t I know my cholesterol score at least? Ethnographically, this was one of those moments when you realize that you are the alien.

Since then, when I mention the encounter and my reaction, I’ve been reminded over and over by doctors that they are not at all surprised, they know that is how things are. But they are a bit disturbed when we start to work out the implications of this view of facts. These include: illness is now a threshold that one crosses without knowing it, that threshold is outside of the doctor’s expertise, the clinical trials the threshold are based on may not have asked pertinent questions, and the questions that are asked almost always are about how to increase medication. These characteristics are not secret, except that they are taken for granted and therefore hidden in plain sight. They were once controversial, but they are now conventional.

First, in this scenario, 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, and the treatment 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. Health is thus not exactly a state one is in, but a relative category: it would be healthier to be on the drug (if you are over 30).

Second, the key actor in the statement is not the drug or the age limit, but the clinical
trials. They are where the experience of illness seems to have gone when it left the body. Clinical trials provide the researcher with the answer to whether someone needs treatment or not. As with the person himself, the doctor in this case cannot tell whether that person is ill. The doctor does not even diagnose. Rather, she uses the same algorithm that everyone does: if a person is over thirty, then he or she should be probably be put on cholesterol-lowering drugs. Neither health nor illness are states of being then, but states of knowledge; they are epistemic. This means that the questions asked by the clinical trials determine what counts as illness and risk and treatment. The control of these design questions, as we’ll see in chapters X through Y, has shifted from doctors to clinical researchers to pharmaceutical company researchers to pharmaceutical company marketers.

Furthermore, the disempowerment of the doctor is continued in many of the direct-to-consumer advertising campaigns such as the TV commercials one sees a great deal in the U.S. These ads often portray an active consumer-become-patient who paid attention to the TV or a website and recognized a risk that had been missed by their doctor, or even a misdiagnosed. They can self-diagnose online or even by listening to their symptoms defined in the ad, and people are increasingly arriving at their doctors’ offices with demands rather than questions. Doctors, in turn, due to multiple pressures of limited patient time, keeping up with rapidly changing information, and the constraints of HMOs and insurance, are quite vulnerable to these demands. Third, the relation of the researcher to the state of knowledge is narrated as one of deep submission. Marking clinical trials as “the latest” may seem like an authoritative move, but it also implies that what the researcher may have told the patient the day before was, now, false. Here the cartoons are more sinister: health and illness and treatment are continually subject to revision. The consumer as potentially at risk must maintain a vigilance with regard to health information. Health must become an preoccupation, and indeed it has. [ADD CURRENT PEW STUDY]

This shift in knowledge began in the 1960s according to historian of medicine Jeremy Greene, as pharmaceutical companies and clinical researchers developed the concept of “risk factors” that identified population-level traits and increased one’s chances of having an medical problem. “Know your number” public-health campaigns for cholesterol were aimed at mass prevention through mass awareness. But here we see the mechanism of this revision and a problem: the latest clinical trials and guidelines based on them are dependent on which clinical trials have been conducted, and which ones have not; and on how the population studied was defined. As we will see in the next chapter when an expert patient tries to review research on a treatment and conduct his own meta-analysis, the clinical trials he wanted to have been run had not been run.

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 (“5 or more 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 could help determine whether someone would actually benefit from a treatment. As we will come to understand then, because large-scale clinical trials are run by pharmaceutical companies as investments, the only trials they can afford to run are those that result in more
treatments.

These four characteristics of mass health – chronic treatments for risk reduction, health as epistemic, based on limited clinical trials, and ever increasing numbers – and how they came into being, are the subject of this book. Not sixty years ago, most doctors fiercely opposed all of these characteristics, insisting on symptomatic diagnosis, etiological treatment, their personal experience, and drugs that cured. In the 1960s, the full potential of mass health started to become visible, implying exactly the researcher's statement – 5 or more drugs for life at minimum – and this potential was met repeatedly with disbelief, disavowal, denial and jokes. It became apparently true and absurd at the same time. Yet by the 1990s, mass health had become gospel and second nature.

Mass health is both necessary and insufficient. Large-scale clinical trials do distinguish better drugs from worse ones, and the risk they measure is a kind of truth. 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 better for our overall well-being or for our economy.

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1 Greene, 2006.
2 [Marks]
3 See clinical trials
4 Greene 2006.
5 Anselm Strauss, Arthur Kleinman and others
6 {Beck-Gernsheim, 1995 #75} Risk and pharmaceuticals, especially psychopharmaceuticals, are the object of a growing body of social science scholarship. A number of these scholars have used a discursive analysis of the self in the late twentieth century to develop important critiques of the geneticization, somaticization, molecularization, and psychiatrization of society. These analysis focus on how the promise of therapy and the threat of risk form the kinds of persons we take ourselves to be: beings influenced by biology and amenable to social control in the through what we take to be self-chosen or managed freedom. They attend to the uses by hegemonic institutions – school, the workplace, healthcare, the military – of pharmacological and genetic discourse for what Foucault called governmentality, acting on our actions so that we act in accordance with their objectives.


vii (CMMS 2008a; IIR 2008; CMMS 2008b). IIR projects that the faltering economy in 2008 may slow the pharmaceutical industry growth to 4.5 or 5% in 2009, but CMMS sees the growth accelerating due to “the projected leveling off of growth in the generic dispensing rate, an expectation of new drugs continuing to come onto the market, and evolving treatment guidelines that call for earlier introductions of pharmacotherapy.” (CMMS 2008a, 2).

viii (Express Scripts 2007).

ix “The health share of GDP is projected to reach 16.3 percent in 2007 and 19.5 percent by 2017.” (CMMS 2008b).

x (Express Scripts 2007; NCHS 2007).

xi Angell, Avorn, Moynihan, Healy, Seattle Times.


xv Wilkes’ articles.