

CHAPTER 3

Diagnostic Inflation

*Alice: "But I don't want to go among mad people."
Cheshire Cat: "Oh, you can't help it, we're all mad here."
LEWIS CARROLL, Alice's Adventures in Wonderland*

*Medical research has made such enormous advances that
there are hardly any healthy people left.
ALDOUS HUXLEY*

DIAGNOSTIC INFLATION HAS many, many causes and will require many cures. Some of the problems are inherent to psychiatry and need curing from within the profession. But a number of powerful outside forces flexed their muscles, grabbed hold of *DSM-IV*, and used clever methods to encourage its misuse. They succeeded in changing diagnostic habits in ways we never imagined possible and lacked the tools to control. The past thirty years have witnessed a frightening vicious cycle. Diagnostic inflation has led to an explosive growth in the use of psychotropic drugs; this then produced huge profits that have given the pharmaceutical industry the means and the motive to blow up the diagnostic bubble into an ever-expanding balloon. The coinage of psychiatric diagnosis has

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been cheapened, making "normal" a scarce commodity. Just as happens with monetary inflation, the bad money drives the good out of circulation and resources allocation is distorted. The wasted effort devoted to those who don't have real disorders deprives those who do from receiving badly needed psychiatric diagnosis and care.

Causes of Diagnostic Inflation

Following the Pied Piper of Diagnostic Inflation in the Rest of Medicine

Psychiatry didn't invent diagnostic inflation—it has just blindly followed the crowd in turning seeming wellness into dreaded sickness. The rest of medicine got there first by promoting the idea that all of us need to have regularly repeated batteries of screening tests to find out what might be going wrong with our bodies, even before we are experiencing any symptoms of illness. What an appealing goal—screen early to prevent disease before it can gain traction and cause harm. Not only would this reduce human suffering, but it would also save money. Detect cancer before it can spread; treat the slightest increase in blood pressure before it causes heart disease; control blood sugar before it becomes full-fledged diabetes; stop bone loss before osteoporosis causes fractures. At its most telling extreme, people subjected themselves to yearly full-body CAT scans to clearly visualize every internal nook and cranny—until it became clear that the test was worse than the disease. The risks of getting cancer from the X-ray exposure far outweighed any potential benefit in picking up early cancers. Preventive intervention would be wonderful, if only we had an accurate way to identify who needs it. But most early screening picks up lots of people who are better left alone.¹

The hype for prevention has been everywhere. Breakthroughs in medical science are breathlessly announced daily. New tests are constantly being devised and the thresholds of abnormality of old tests

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ered—creating hordes of new patients. Doctors order expensive batteries of every conceivable test on every patient, just to be on the safe side. Advertisements promote the benefits of screening and the horrors of letting disease go unfettered. The screening scare tactics have won an enormous financial success for their promoters, but the evidence shows that with few exceptions (e.g., screening for lung cancer in smokers or colon cancer in everyone), the testing is often not good for the patients—not really improving outcomes, while further burdening them with aggressive, expensive, and unnecessary treatments. And the waste to society runs to hundreds of billions of dollars a year that could be better used treating really sick people who are currently uninsured. Preventive medicine is a terrific goal gone badly astray because it became industrialized and enslaved by profit and hype.

Sanity is beginning to prevail. Recently, nine professional societies have initiated a “Choosing Wisely” campaign, publishing a list of forty previously heralded tests and procedures that had been vastly overused.² Prostate cancer screening is no longer recommended—it failed to save lives and resulted in much needlessly aggressive surgery. Breast cancer screening has been much truncated. No more CT scans for headaches or X-rays for back pain. And it turns out that bronchodilators and oxygen don’t work for most people with chronic obstructive pulmonary disease.³ The list is long and telling. Evidence-based medicine is demonstrating that the push to prevention has been excessive, premature, and evidence based.

Early identification of illness suffers from the “needle in the haystack” problem. Screening tests routinely set their bar low so as not to miss people who need identifying but in the process inevitably wind up mislabeling lots of people who don’t.^{4,5} The benefits to the few, if any, are outweighed by the harms to the many. Some of the misleading evidence for early intervention comes from the good faith enthusiasm of clinical researchers and practitioners eager to help patients fight disease. But best advice for them comes from the White Rabbit in Alice in Wonderland: “Don’t just do something, stand there.”

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And the profit motive also plays a part. Fifty years ago, President Eisenhower presciently predicted the economic and social damage that would be caused by a too-powerful military-industrial complex.⁶ In a parallel development, we have witnessed the explosive growth of a too-powerful medical-industrial complex comprising Big Pharma, insurance companies, testing laboratories, equipment and device makers, hospitals, and doctors—all eager to expand the market by creating a new reservoir of allegedly "about-to-be-sick" well people who need testing and treatment to avoid ever becoming sick in the future.

The United States spends almost twice as much on per capita medical care as the rest of the world.⁷ This is a terrific drain on our economy and our \$2 trillion investment has paltry returns. We get mediocre medical outcomes, excessively test and treat those without need, and fail to provide adequate care for many in great need. You probably couldn't design a less efficient or less equitable system if you tried hard to do so.

Meanwhile we neglect what are the best forms of prevention—i.e., promoting exercise, proper diet, moderation in alcohol use, abstinence from tobacco and drugs. These extremely useful and remarkably cheap prevention measures aren't profitable for the medical-industrial complex and therefore lack its powerful and well-financed sponsorship. The biggest improvement in the health of our country in the last thirty-five years came from the relatively inexpensive campaign to reduce smoking—not from the enormously expensive efforts of the medical-industrial complex. A similar campaign to reduce overtesting and overtreatment would save us money and make us healthier. Let's hope that "choosing wisely" helps to correct the excesses of preventive medicine.

And let's hope that the snake oil of premature preventive medicine doesn't spread to psychiatry. Those who promote the value of wider boundaries for psychiatric disorder make the argument that identifying and treating the mildly mentally ill will help them avoid later becoming the severely mentally ill, drawing support from the pre-

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sumed glowing success that has been achieved by medical screening and early intervention.⁸ But there is a serious fly in this ointment—early intervention in medicine is mostly a flop and provides a terrible model. Psychiatry is wrongheadedly copycatting the very worst aspects of American medicine—the combination of harmful excess for some, combined with heartless neglect for others.

Is Our Stressful Society Making Us Sicker?

One theory says that rates of mental illness are rising because we live under extreme pressures from a speeded-up, stressful society. Perhaps it is hard to be normal because our modern world is driving us crazy. This suggestion is difficult to disprove, but I find it completely unconvincing. Among the hundreds of thousands of generations of our ancestors who have ever walked this earth, we are undoubtedly the luckiest—extraordinarily privileged to live now and to live here. Previous generations (as well as people currently living in less favored parts of our crowded globe) suffer daily catastrophes that are unimaginable to most of us. Life has always been, and will always be, enormously stressful in one or another way. Indeed, our mental discomforts can preoccupy us as much as they do only because most of us don't have to worry about our next meal or the threat of being eaten by a passing tiger.

A second variant of the toxic environment hypothesis is that rates of mental illness have been driven up by physical, rather than emotional, stresses. The most popular version of this is the completely discredited, but ever lingering, belief that vaccination causes autism.⁹ Other environmental causes seem equally implausible—fluctuations in diagnostic rates follow a time course much more consonant with fashion than with toxin.

The only environmental pollutants to have a proven substantial impact on mental disorder are alcohol and drugs. These hit the brain with a huge wallop that can mimic virtually all the psychiatric symp-

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toms in the book. But alcohol and drugs can account for only a small part of diagnostic inflation. Tellingly, it is the childhood disorders not much affected by substances that have recently expanded the most.¹⁰

A third theory has it that we are not sicker than before, just better able to spot previously missed sickness. Some part of diagnostic inflation is surely desirable—picking up previously missed cases. But only a part, and probably a small one. Diagnostic labels can't be applied with surgical precision to accurately distinguish those who truly need a diagnosis from those who don't. At the extremes of severe illness and complete health, the distinction is indeed obvious. But the boundary between mental disorder and normality is so fuzzy that whenever we quickly expand the use of psychiatric labels to identify some few people who do need help, we misidentify many others who don't.

Human nature is stable and resilient. There has been no real epidemic of mental illness, just a much looser definition of sickness, making it harder for people to be considered well. The people remain the same; the diagnostic labels have changed and are too elastic. Problems that used to be an expected and tolerated part of life are now diagnosed and treated as mental disorder. The application, or withholding, of a sickness label in these boundary situations determines how we see ourselves as individuals and as a society. If we create an overly broad definition and apply it liberally, we readily recruit an army of new "patients," many of whom will have been much better left to their own devices. We are not a sicker society in any real sense—even if we see ourselves that way.

Societal stress is not causing more real mental illness, but there are other societal trends that do promote the sense that we are getting sicker. Our world is homogenizing—we have increasingly less tolerance for individual difference or eccentricity and instead tend to medicalize it into illness. The youngest boy in the class isn't the most active because he is just a young boy—instead he must have ADHD and should be put on a pill." And our society is becoming increasingly perfectionistic. Falling short of complete happiness or failing to have

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a worry-free life is too often translated into mental illness. Our goals are set too high and our expectations are unrealistic—especially when it comes to our kids.

New Fads Promote Diagnostic Inflation

Fashions in psychiatric diagnosis have recently become almost as fickle as the popularity of rock stars, trendy restaurants, and travel destinations. Because there are no biological tests or clear definitions that distinguish normal from mental disorder, everything in psychiatric diagnosis depends on very easily influenced subjective judgments. Whenever rates of a mental disorder jump explosively, the safe bet is always on fad. Assume that many, if not most, of the newly identified “patients” are really “normal enough.” They have been mislabeled and will likely be overtreated.

Psychiatric fads start when a powerful authority gives them force and legitimacy. The *DSM* system, and the “experts” who fashioned it, have been the main fashion setters—the driving force in identifying new mental disorders and defining milder forms of those that had been previously described. Unfortunately most experts suffer from an intellectual conflict of interest that biases them toward diagnostic inflation. Focused on their specialized research, they miss the big picture—always worrying so much about not having a diagnosis for a patient who needs one that they ignore the risk of mislabeling someone who doesn’t. There is also an emotional element. Experts become true believers who really come to love their pet diagnoses and want to see them grow. While each one presses for only a small expansion, their aggregate pressure blows up the inflationary balloon. In my thirty-five years of herding experts, not once has anyone ever suggested raising the bar to narrow the scope of his pet area.¹²

The media and the Internet feed on and feed fads. In the wired modern world, false epidemics can be spread like wildfire fueled by the

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24/7 coverage. Some of the spotlight is extremely valuable—leading to better public understanding and acceptance of mental disorder, but many stories breathlessly hype diagnostic inflation. "Autism is one in eighty!!!" "The test and cure for Alzheimer's are just around the corner!!!!" "Does your child have ADHD?? "Bipolar is underdiagnosed says Harvard doctor!!!!" And the Internet provides wonderful support, social interaction, information, and destigmatization for people with psychiatric symptoms—but also undercuts normality, as essentially healthy people incorrectly self-identify themselves as sick in order to gain the comforts that come with admittance to the group. Celebrities also play their part as exemplars of diagnoses and endorsers of treatments.

Of course, the biggest promoter of recent fads has been drug company marketing. But that is a sad story in itself that we will get to soon.

DSM Becomes Too Important for Its Own Good

Human nature being what it is, the prevalence of any psychiatric diagnosis will rise artificially whenever it is a gatekeeper to something valuable. In a simpler world, psychiatric diagnosis was once based only on perceived clinical need. But now that it has gained powerful (and unwelcome) influence on many administrative and financial decisions, these decisions have also reciprocally obtained a powerful influence on the rates of diagnosis. Diagnostic inflation is promoted whenever a physician provides an "up-diagnosis" to help a patient gain access to something valuable—like disability benefits or school services. If autism, ADHD, or pediatric bipolar disorder is a prerequisite to being admitted to a small class with lots of individual attention, equivocal cases get shoehorned into these categories, and soon an epidemic is born.

In like fashion, "mental disorder" increases whenever there is high unemployment. Some of the people laid off will get a new diagnosis

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because they have developed symptoms, others because it will make them eligible for disability. Because veterans' benefits require a diagnosis of PTSD, PTSD gets overdiagnosed. There is a paradox—trying to help by providing a diagnosis may wind up hurting. Many returning vets from Iraq and Afghanistan are having trouble landing jobs because of the stigma associated with their diagnosis of PTSD. And overdiagnosis distorts allocations across the system, reducing resources and benefits for those who most need them.

The most senseless driver of diagnostic inflation is the way medical insurance works in the United States. To get paid, the doctor must make an approved diagnosis. This is intended to prevent frivolous visits. But the unintended effect is just the opposite of prudent cost control. A premature rush to a reimbursable psychiatric diagnosis often results in unnecessary, potentially harmful, and often costly treatment for problems that would have disappeared on their own. It would be a lot cheaper and better for insurance to reimburse the doctor for watchful waiting and counseling, rewarding him for not jumping to diagnostic conclusions that are very costly in the long run. This perfectly sensible solution is the policy in the rest of the world.

Epidemiology Miscounts

Every so often, the newspaper will report that rates of psychiatric disorder are climbing, sometimes dramatically. The best current examples are autism and attention deficit disorder. Don't believe the numbers. The "rates" have been generated by psychiatric epidemiologists, using a method that is inherently flawed and systematically biased in the direction of overreporting.

How can an entire field of scientific endeavor have gone so far astray? It comes down to simple dollar-and-cents considerations. Epidemiological studies have to sample huge numbers of people in the general population, usually using telephone interviews. It would be too

expensive to employ clinicians in so extensive an endeavor—so the studies rely on the cheap labor provided by lay interviewers who have no clinical experience and no discretion in judging whether symptoms are clinically meaningful. They make their diagnoses of psychiatric disorders based on symptom counts alone with no consideration of whether the symptoms are severe or enduring enough to really warrant diagnosis or treatment.

This results in rates that are always greatly inflated. Psychiatric symptoms in mild form are widely distributed in the general population—from time to time, almost everyone will have some sadness or anxiety, and others may have difficulty concentrating or be a bit eccentric. But isolated or mild symptoms alone do not define psychiatric disorder—they must cohere over time in a specified way and also cause significant distress or impairment. Epidemiologic studies routinely ignore these crucial requirements. They mistakenly diagnose as psychiatric disorder symptoms that are mild, transient, and lacking in clinical significance.¹³

Results generated in this rough-and-ready way are no more than an upper limit on the prevalence of any given mental disorder. They should never be taken at face value as a true reflection of the real extent of illness in the community. Unfortunately, the exaggerated rates are always reported without proper caveat and are accepted as if they are an accurate reflection of the real prevalence of psychiatric disorder. Disraeli exaggerated only a tad when he said: "There are three kinds of lies: lies, damned lies, and statistics."

The epidemiologists are good bean counters, but they are not clinicians and probably don't know any better. Pharma is less innocent—the results are used to promote the misleading notion that psychiatric disorder is everywhere. The National Institute of Mental Health also likes high rates because they support budget requests to Congress—if mental disorder is everywhere, we should be spending a lot more to research its causes.¹⁴

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Easy-to-Use Drugs Make Excessive Drug Use Far Too Easy

Before the 1950s, the psychotropic drug business was small, and the available drugs were terrible. The opiates and the barbiturates were popular with patients but were nonspecific in their effects and caused big-time problems with addiction and overdose. Bromides, paraldehyde, chloral hydrate, and Miltown were all pretty useless and had hard-to-take side effects.

By the time I began prescribing psychiatric drugs in the 1960s, these old medicines had been mostly superseded by the newly discovered and specific wonder drugs in psychiatry—Thorazine for psychosis, lithium for mania, and Elavil and Nardil for depression. But giving these medicines to patients was still a relatively new thing and a big deal. I trained on the first unit in the United States to use lithium, and we were frankly scared to death of it—an overdose could kill patients or destroy their kidneys, and we were not yet completely sure what were the most effective doses and the safest blood levels. It turned out that the Thorazine doses we were using were way too high and transformed our agitated patients into drugged zombies. The antidepressants available at the time were all extremely risky for use with suicidal outpatients—just a week's worth of pills could be lethal. And they made life miserable for many of the patients taking them—mouth forever parched, bowel movements few and far between, and fainting on standing up a frequent risk. Because the medicines could cause arrhythmias, a fancy cardiac workup had to precede their initiation. Nardil required extremely strict dietary precautions because it interacted dangerously with many foods and with red wine—a little blue cheese, fava beans, or Chianti could be deadly. All of the first psychotropic drugs were so risky and unpleasant to take that only the sickest patients received them, and only well-trained psychiatrists felt comfortable prescribing them.

The next new wave of “wonder” drugs came in the 1970s. The ben-

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zodiazepines, Librium and Valium, changed everything and set a new tone—from now on Pharma's emphasis would be on developing and marketing medications that produced less intrusive side effects and were less likely to cause death from overdose. This allowed the focus of care to shift away from the very small cohort of really sick patients to the wider world of the worried well. Before long a large percentage of the U.S. population was taking easy-to-take psychiatric medicine. And because treating patients with "benzos" required no great expertise, primary care physicians took over most of the prescribing. These drugs soon were so wildly successful they became part of the American way of life, and the drug companies realized that psychiatric medicines would become their gold mine. Of course, it turned out that Librium and Valium (and even more, their dreadful younger sib Xanax, introduced in the 1980s) were really quite addicting and not so benign in overdose, particularly when mixed with alcohol or other drugs that depress respiration. They were a great boon to the drug companies, but not to the patients.

Next came the inexorable march of the SSRI antidepressants in the late 1980s and early 1990s—a classic marketing success story. Prozac became a knockout best seller, even spawning a best-selling book by a psychiatrist touting its value not only as an antidepressant but also as a cosmetic drug that could make you better than well.¹⁵ Every year or two thereafter, a new SSRI would appear—Zoloft, Paxil, Celexa—and each would also in turn become a runaway best seller. The marketing of these easy-to-use drugs was closely tied to the marketing of what were (according to the drug companies) easy-to-make psychiatric diagnoses. Soon the SSRIs were also prescribed for panic disorder, generalized anxiety, social phobia, OCD, PTSD, eating disorders, premature ejaculation, and compulsive gambling, and as a general pick-me-up. Sure, there were side effects—some frequent (like reduced sexuality); some rare but dangerous (like agitation, suicidality, and violence). But SSRIs fit so neatly into everyday life that 20 percent of women now take them. Diagnostic inflation will always be an inevitable consequence of an aggressively marketed, easy-to-take pill.

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The newer generation of atypical antipsychotics (Risperdal, Zyprexa, Seroquel), introduced in the mid-1990s, are an even more astounding and frightening marketing triumph. Initially they seemed a big step forward—not in efficacy, but in having a much more favorable side effect profile. A patient on traditional antipsychotics had an absolutely characteristic look, easily spotted from far down the hallway—the fixed stare, rigid posture, tremors, abnormal movements, and drooling were dead giveaways. Switched to an atypical, the patient looked and often felt much more normal. Soon these much easier to give and easier to take drugs were climbing to the top of the charts, beating all sales records. This couldn't have been accomplished within the confines of the narrow schizophrenia market. First, the drug companies had to get an indication for bipolar disorder and then they had to advertise a conception of bipolar disorder so broad as to be unrecognizable. Antipsychotics were soon being prescribed promiscuously, even by primary care physicians, to patients with garden-variety anxiety, sleeplessness, and irritability. The paradox is that dangerous drugs capable of causing massive obesity, diabetes, heart disease, and a shortened life span now account for \$18 billion a year in sales. Primary care physicians are prescribing potentially dangerous medications, outside their competence, for people who should not be taking them. Proof again that drugs that are too easy to give and too easy to take will be taken far too often, especially when the lots of money is behind them. In retrospect, the unpleasant side effect profiles of early psychiatric drugs had the value of preventing their overuse and of keeping diagnostic inflation in check.

Disease Mongering by Big Pharma

Big Pharma is really big and incredibly successful. Worldwide sales exceed \$700 billion each year—half in North America and one fourth in Europe.¹⁶ And the profit margin, at a whopping 17 percent, is among the

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highest of any industry.¹⁷ Why so big and why so successful? The companies justify their high prices and enormous returns by touting their research efforts to advance medical science and improve patient care. This is mostly fluff. Pharma spends twice as much money (\$60 billion) on promotion as on research, and too often they fund the wrong kind of clinical research, done in the wrong way, and with the wrong motives—avoiding lines of inquiry that might actually teach us something important, in favor of surefire "experimericals" that are mostly intended to promote marketing, not discovery.¹⁸

The surest guarantee of profit is to "me-too" over and over again. Developing a drug that might make a real difference for patients is financially risky. The smarter play for exec bonuses and shareholder dividends is to fiddle slightly with existing compounds—just enough to make them patent-ready lookalikes of compounds already on the gravy train. Companies can double the life of their monopoly patent protection by making the most trivial of changes—turning a right-handed drug to a left-handed one that has identical effects or changing slightly the duration of action. The second surest way to raise revenue and extend patents is to find new market worlds to conquer for an existing drug—by doing research that will get it used by kids or for a diagnosis different from the one originally approved. The market geniuses guide the research effort, not the science types, and the result is predictable—great sales, lousy discovery.

To make matters worse, the research is often performed poorly and presented in an incredibly biased way. The data are proprietary and closely guarded; negative results are routinely buried; tiny, trivial, or chance positive findings are hailed as the second coming; investigators are corrupted; and sometimes scientific papers are ghostwritten by company hacks. Side effects and complications are measured perfunctorily and barely reported. There is never a fair risk/benefit/cost calculus—the benefits are exaggerated, the risks minimized, the costs ignored. Drug pricing has no relation to real cost or value and instead reflects Pharma's monopoly position in the market and its dominance

over politicians. At its worst, Pharma research is a deceptive shell game meant to seduce and mislead, rather than enlighten doctors and the public. The claim that drugs are so expensive because they require so much research is pure smoke screen.

A quick review of the last sixty years shows that the drug companies do not have an enviable research record in psychiatry. The most exciting period of discovery in psychopharmacology occurred in the 1950s—and drug company research had absolutely nothing to do with it. The first antipsychotics, first antidepressants, and first mood-stabilizing drugs were all found by pure lone ranger serendipity, a tribute both to the observational skills of their discoverers and to the home-run effectiveness of the drugs. An alert French surgeon noticed that a drug called Thorazine, used preoperatively to prevent nausea, also happened to calm down his patients and made them indifferent to the stress of the procedure. He passed this nugget on to his psychiatrist brother-in-law, and before long the first specific antipsychotic was born. MAO inhibitors that were used to treat tuberculosis were noted to also cheer up the patients, and we had our first antidepressants. And lithium had an unexpected calming effect on laboratory animals that led to its use in mania. None of these breakthroughs was expensive or industrial—all were the product of a good set of eyes and a prepared brain. Like penicillin, the first drug in each class worked so well you didn't really need a double-blind study with hundreds of patients to know that you were on to something big. None of the subsequent sixty years of drug company research has ever once come up with a new product that exceeded the efficacy of the early drugs that were discovered in this way by accident.¹⁹

Unfortunately, all the low-hanging fruit was picked at the beginning of drug development and the pickings since have been slim and mostly cosmetic. Although late to the starting gate, Pharma quickly caught on to the commercial potential of psychotropic drugs. Many new products were developed and brought to market in the 1960s. The tricyclic antidepressants were an extremely valuable addition to clini-

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cal care but had severe limitations as moneymakers because of their troubling side effects and potential for lethal overdose. The real blockbuster breakthrough to the big bucks came when Valium and Librium became household staples. It is an open question whether they contributed more harm or good to patients—they calmed people down but often addicted them and caused all sorts of withdrawal problems. But Pharma had learned a great lesson from them—the real money was in the “user-friendly” medicines that would appeal to a mass consumer market. The SSRIs introduced in the 1980s were the perfect vehicle—no more effective than their predecessors, but much more easily tolerated and safe in overdose. Similarly, the newer antipsychotics were no more effective than their predecessors and carried much worse long-term risks, but were easier to take. This bears repetition—never once has Pharma created a product that exceeded the effectiveness of the drugs available sixty years ago. It has hit many marketing home runs, but usually strikes out when it comes to research. Not an enviable research record after all this time and all this ballyhoo.

Pharma's skills lay elsewhere—it is really ingenious and remarkably effective when it comes to marketing and lobbying. Sixty billion dollars a year will go a long way to sell products and buy politicians. In recent decades, the drug companies have efficiently hijacked the medical enterprise by exerting undue influence on the decisions made by doctors, patients, scientists, journals, professional associations, consumer advocacy groups, pharmacists, insurance companies, politicians, bureaucrats, and administrators. And the best way to sell psychotropic pills is to sell psychiatric ills. Drug companies have many methods of doing this: TV and print media adverts; co-opting most physicians' continuing medical education (often provided at the most expensive restaurants and the nicest resorts; doctors in training and medical students come cheaper—a pizza will do); bankrolling professional associations, journals, and consumer advocacy groups; invading the Internet and social networking sites; recruiting celebrity endorsements. And at one per seven doctors, the drug company sales

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force (consisting of the most beautiful people this side of Hollywood) has sometimes outnumbered the patients in the waiting room.

Only a very few people have severe mental illness, many more have mild mental illness, but the real mother lode of market share is the worried well. Pharma wants to strip-mine that mother lode and has achieved fantastic revenues by promoting the idea that many of life's expectable problems are mental disorders due to a "chemical imbalance" that can be solved with pill popping. The most creative advertising brains and the most extensive market research help push product into places it had never been before. The pitch to customers is that life is perfectible, if only they will take the simple brain-toning steps to perfect it. The subliminal promise is that beyond curing illness, pills can also help achieve a better way of life through chemistry. If you go to the dentist to correct your less-than-perfect teeth, why not go to the doctor to correct your less-than-perfect brains? No one ever need settle for less than happiness and success. Selling new lifestyles works well for selling cars and beers and perfumes and designer clothing—so why not for selling pills? The message is illustrated with compelling graphic images: the rain stops and the sun shines through when you take an antidepressant; the sad sack becomes the confident leader; the couch potato a well-muscled runner. For kids, the cute little frowning rock becomes the cute little smiling rock. The ads always enjoin us to "Ask your doctor." Of course, the companies have already wired the doctor with a similar message and have provided him with handy free samples to speed you out of the office immediately after you have popped the crucial question.²⁰

Many doctors are witting or unwitting agents in the pervasive drug company marketing campaign to sell new diagnoses. "Education" and "research" can become sheep's clothing covering what is really a wolfish marketing pitch. A large stable of psychiatry's "thought leaders" are recruited to help drumbeat the wondrous benefits that accrue from drugs and to downplay the harms. Things are becoming better now, but for a time Pharma used thought leaders to exert dominance

over psychiatry's educational and research programs. The dozens of industry-sponsored symposia at the annual meeting of the American Psychiatric Association offered the best speakers and the only food and attracted the biggest audiences. Most of weekly grand rounds held at hospitals and medical schools throughout the country were funded by Pharma and led by big-name faculty conveniently supplied by its "speakers' bureaus."

I know about the "thought leader" issue firsthand because I used to be one. My participation with the pharmaceutical industry goes back thirty years and has taken a variety of forms. In the 1980s, I was vice-chair of the APA program committee responsible for organizing its annual meetings. I went along with a group decision to accept drug-company-sponsored symposia—made on the grounds that the topics and speakers offered would be of interest to the membership—not anticipating that before long these would become so popular as to completely overshadow the rest of the meetings and so biased as to be more commercial than disinterested science. For fifteen years I was director of an outpatient clinic at Cornell that occasionally performed drug-company-sponsored research studies. Many of the thousand or more talks I have given over the years were financed directly or indirectly by drug company money. I developed a series of expert consensus guidelines that were industry funded. And as chair of psychiatry at Duke University I presided over a department that had extensive industry sponsorship for a number of its research and educational programs. In none of these activities did I ever once say or publish anything I did not believe to be completely accurate, and I often said and published things that made drug company representatives wince with pain. I always recognized the risk that hidden strings could be attached and don't think I was ever restrained by them to present things in a biased way. But in retrospect, it was unseemly to have participated in so many activities that could be construed as indirect drug marketing. And I saw the slippery slope facing those who had a deeper involvement and fewer scruples.

If everyone has the ill, then all must take the pill.²¹ Already huge, the market in psychotropic drugs is constantly growing. When the adult market seemed saturated, the drug companies expanded their customer demographics by pushing product onto children—it is not by accident that all the recent epidemics of psychiatric disorder have occurred in kids. And children are particularly choice customers—bring them on board early, and you may have them for life. At the other end of the life cycle, companies targeted the elderly, selling antipsychotics like hotcakes in nursing homes. Pharma has not been constrained by the fact that children and the elderly are the two most difficult demographic groups to diagnose accurately or that they are the most vulnerable to harmful drug side effects or that excessive use of antipsychotics in nursing homes results in increased mortality. And, even more troubling, it is the very most vulnerable of kids who get the most medicine—those who are economically disadvantaged or in foster care.²²

Seven percent of Americans are now addicted to a legal psychotropic drug.²³ Prescription drug abuse has become a bigger problem than illicit drug abuse. If there is a conceivable way to sell a new diagnosis so that people will incorrectly believe they have it, drug companies will have figured it out and will do it successfully—if sometimes illegally. Big Pharma seems to feel above the law. Almost all of the companies have absorbed huge fines and even criminal penalties as punishment for their illegal sales practices.²⁴ Drugs are approved by the Food and Drug Administration only for the treatment of those mental disorders for which studies indicate there is sufficient efficacy and safety. Although doctors are given the discretion to prescribe a medicine “off-label” for other uses, it is strictly illegal for drug companies to encourage them to do so. The drug company “Hall of Shame” (see below) shows how flagrantly Pharma flouts the law. A seemingly hefty fine of \$1.3 billion may be no more than affordable chump change and the cost of doing business, considering the enormous revenues that can be earned through shady marketing. Only much bigger fines and tighter regulations can tame this beast. And doctors should be cautioned that

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DRUG COMPANY HALL OF SHAME PREPARED BY MELISSA RAVEN PHD

DATE	COMPANY	FINES/SETTLEMENTS	DRUG(S)	CULPABLE ACTS
August 2012	Johnson & Johnson	\$181 million civil	Risperdal	Off-label promotion ²⁵
July 2012	GlaxoSmith-Kline	\$3 billion: \$1 billion criminal, \$2 billion civil	Paxil, Wellbutrin, Avandia	Off-label promotion; failure to report safety data (Avandia) ²⁶
May 2012	Abbott	\$1.5 billion: \$700 million criminal, \$800 million civil	Depakote	Off-label promotion ²⁷
April 2012	Johnson & Johnson	\$1.1 billion criminal	Risperdal	Off-label promotion to children and elderly; fraudulent marketing tactics ²⁸
January 2012	Johnson & Johnson	\$158 million	Risperdal	Off-label promotion, misrepresentation of safety ²⁹
September 2010	Novartis	\$422.5 million: \$185 million criminal, \$237.5 million civil	Trileptal	Off-label promotion, for bipolar disorder, neuropathic pain ³⁰
September 2010	Forest	\$313 million: \$164 million criminal, \$149 million civil	Lexapro, Celexa, Levothroid	Off-label promotion, for children and adolescents; false claims; distribution of unapproved drug (Levothroid) ³¹
April 2010	AstraZeneca	\$520 million civil	Seroquel	Off-label promotion, targeting geriatricians, PCPs, pediatricians ³²
September 2009	Pfizer	\$1.3 billion criminal, \$1 billion civil	Geodon, Lyrica, Bextra, Zovox	Off-label marketing ³³
January 2009	Eli Lilly	\$1.415 billion: \$515 billion criminal, \$800 million civil	Zyprexa	Off-label promotion, for dementia, agitation, aggression, hostility, depression, and generalized sleep disorder ³⁴
September 2007	Bristol Myers Squibb	\$515 million civil	Abilify, Serzone, among others	Illegal marketing and pricing; off-label promotion ³⁵
July 2007	Purdue	Nearly \$635 million civil fines, penalties, and restitution payments, \$500,000 criminal	OxyContin	Fraudulent misbranding, causing false claims to be filed ³⁶
2004	Warner-Lambert (Pfizer)	\$430 million: \$240 million criminal, \$190 million civil	Neurontin	Off-label promotion, for bipolar disorder, pain, migraine, alcohol withdrawal ³⁷

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off-label prescribing is out of control, is often harmful, and sometimes constitutes a form of malpractice.

Placebo Response Sells Pills

The word *placebo* comes from the Latin meaning "I please." And do placebos ever please. The "placebo effect" refers to people getting better because of positive expectations independent of any specific healing effect of the treatment. The placebo effect is very effective—people routinely get great results from treatments that have nothing whatever to do with their illness. It is probably fair to say that placebo is the greatest broad-spectrum wonder drug ever invented—cheap, effective for almost all but the most severe of man's ills, and with very few side effects.

But the placebo effect also causes a very serious problem—it keeps people taking expensive, and sometimes harmful, pills they don't need for conditions they don't have. The history of medicine is littered with dreadful treatments that were often much more dangerous than the diseases they were meant to cure. Magical thinking has allowed doctors to inflict (and patients to accept) great harm while claiming illusory benefits—the doctor's orders dutifully followed even when completely ineffective or quite hurtful. Long-suffering patients have been given emetics to help them vomit up their sickness; purgatives to help them defecate it; leeches to suck it out; and skull holes to release it. They were dunked to the point of almost drowning; subjected to high fevers; wrapped in cold packs; and spun in special chairs or from ropes hanging from the ceiling. All sorts of substances we now fear greatly as highly toxic poisons were once treasured as healing nostrums. The placebo effect is the only way to explain this rogue's gallery of what now seem obviously silly, even sinister treatments that have caused millennia of needless additional suffering to people who were already sick enough to begin with. The placebo effect is a kind of medical magic

that gives doctors an undeserved authority and accounts for their frequent belief in really bad treatments.

The wonders of placebo response arise from a number of different causes—sometimes independent, sometimes interacting. Most important perhaps is “tincture of time.” Time may not always be the best healer and it certainly doesn’t heal all wounds, but it always has been and still is the most efficient and safest way to deal with many of life’s physical and psychological problems. Time heals so well because many of our ills are short-term, situational, and self-limited—our bodies and our minds are programmed to be resilient without any active effort on our part.

Next comes the enormous power of hope and expectation. People get better if they believe in a treatment and have full confidence that it will help them get better—however irrelevant or even dangerous it may be. Life has always been painful and perilous. The power of positive thinking is part of our psychology because it has conferred such a strong selective advantage on those fortunate enough to have it. Perhaps the swift had the early edge in the evolutionary race, but it was the enduring who made it to the finish line—and survived to become our ancestors. Being able to overcome the discouragements and disadvantages of illness by responding well to fake medicine was a sure path to evolutionary success.

Brain imaging proves that the placebo effect has strong biological as well as psychological roots. My favorite example comes from wine tasting, not medicine. It has long been known that people routinely rate a wine as much better if they are told it costs ninety dollars a bottle, rather than ten dollars. This proves how suggestible we are. But brain imaging tells us something even more fascinating and fundamental about human nature. Your brain’s pleasure centers actually light up more when you think you are drinking the costlier wine, even if you’re not. Expectation isn’t all of experience, but it certainly does shape a goodly portion of it. Similarly, placebo pain pills dampen the brain’s response to painful stimuli; placebo antidepressants mimic the brain effects of real antidepressants; placebo Parkinson’s pills stimu-

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late the brain's dopamine system; placebo diabetes pills affect blood sugar; placebo caffeine and Ritalin have a stimulating impact on brain centers; and placebos profoundly affect the immune system. Placebo response is an important part of our reaction to everything. And it is very deeply built into the way our brains work—animals are also terrific placebo responders.

The social factor is also important—being a placebo responder helps maintain key relationships and supports precious communal rituals. We are highly social animals who function well only as part of a group and who threaten the group's welfare when we are not functioning well. The medicine man and his patients have always shared the need to believe in the healing power of the currently fashionable theories, rituals, chants, incantations, diagnostic and testing procedures, and medicines. Even if it had no specific value, a healing ritual offers the great promise of ridding the individual of his illness and the group of the sicknesses in its individuals. Responding well to placebo is essential to remaining a valued member of the group—which made it less likely you would be left behind as too sick when everyone broke camp. And being able to enlist the confidence and hope of the sick patient has always been and still is the most essential skill in a great shaman or a great modern doctor. The technical skills of medicine are becoming increasingly routine and may soon be done better by computer programs—but the shamanic skills of medicine will always be important to patients and to society.

Modern drug companies have made big bucks capitalizing on the power and ubiquity of the placebo response. The best way to get great results with a pill is to treat people who don't really need it—the highest placebo response rates occur in those who would get better naturally and on their own.^{38,39} The really brilliant marketing trick was to persuade doctors to treat patients who weren't really sick, while at the same time convincing normal people that they were really sick. Expanding market share to include the worried well not only greatly enhanced the customer pool, but it also ensured the most satisfied of

customers. Placebo responders often become long-term loyalists to medication use even when the medication is perfectly useless, both because they have no way of knowing it played no role in their getting better and because they are often untroubled by side effects—a cunning combination that creates the dream customer base for drug companies and their shareholders.

In surveys, most doctors admit to sometimes using relatively inoffensive pills as placebos—a way of giving the patient something tangible on the way out the door.⁴⁰ If the prescribing of placebos was ever accepted as ethical practice, they would undoubtedly rise to the very top of the sales charts. To paraphrase Voltaire, the art of medicine sometimes consists in amusing the patient while nature cures the disease.

In veiled form, placebos are already the great, if unrecognized, success story of drug company marketing. A good deal of medication use in psychiatry (and in medicine) is based on the tried-and-true leveraging of the placebo effect. There are only two differences between now and shaman times or medieval alchemy. First, the marketing of what are essentially expensive placebo products has become well-oiled, massively financed, worldwide, and devastatingly effective. Second, you now need to have a *DSM* diagnosis to get a prescription for an expensive pill that often has no more usefulness than would a placebo—a great boost to diagnostic inflation. And the crowning irony is that, like wine tasting, it may be that the higher the price, the more effective the otherwise useless pill. How great for the drug companies.

Two brilliant marketing successes illustrate the financial as well as healing, power of placebo. Almost three fourths of the 11 percent of the U.S. population now taking antidepressant drugs have no current symptoms of depression.⁴¹ Some of these people would soon get quite sick again were they to stop the pills—they need them as prophylactic protection against the return of a chronic or recurring depression. But many loyal customers are unwitting placebo responders who got well spontaneously (but don't know it) and are afraid to rock the boat. A

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significant portion of the \$12 billion spent each year on antidepressants in the United States rewards the drug companies for promoting the overly widespread use of what to many patients are no more than highly advertised, oversold, and very expensive placebos prescribed for a fake diagnosis.

And here's another case in point—the strange success story of Buspar, how it became one of the surprise best-selling drugs of all time despite having little or no efficacy. When Buspar first came on the market, I told its drug company executive that it surely would be a huge flop because it didn't work. He said nothing but smiled knowingly, probably because he understood something that was beyond my naive comprehension. The seeming great disadvantage of having little (if any) efficacy against anxiety was more than counterbalanced by Buspar's also having almost no side effects. Being the perfect, easy-to-use, and expensive placebo was just the right prescription for bringing in huge profits.

Let's do an interesting thought experiment. Suppose we could eliminate the magic of placebo response, or at least reduce through education its impact on patient behavior. The immediate effects would be both bad and good—dramatically reduced perceived efficacy of many medicines, but also dramatically reduced unnecessary diagnosis and treatment. Of course, this thought experiment will never become real—magical thinking is too much a necessary and useful part of human nature. But it would be nice if people could be more skeptical of drug company claims that the worries and miseries of everyday life are just a “chemical imbalance” that can be cured with a pill.

How Primary Care Took Over Much of Psychiatry

Primary care physicians (PCPs) now do most of the prescribing of psychiatric drugs: 90 percent of antianxiety drugs; 80 percent of antidepressants; 65 percent of stimulants; and 50 percent of antipsychotics.⁴²

Pharma did the math—there are only forty thousand psychiatrists in the United States but about ten times as many PCPs. Why not recruit PCPs to write prescriptions for psychiatric drugs? The message to them was loud, clear, and heavily promoted—psychiatric disorders are often missed and easy to treat with a magic pill. This was clinical nonsense but marketing gold. The message went down easily because the new pills went down easily—with relatively few immediately troubling side effects for patients and uncomplicated directions for use by doctors. Who needs a psychiatrist when the medicine is so safe and easy to use? Insurance companies pitched in by preferring PCPs over psychiatrists because they were cheaper (at least in the short run), especially once they were squeezed by diminishing reimbursements into doing seven-minute visits.

Anywhere between 25 to 50 percent of patients seen in primary care present with at least some emotional distress as part of the reason for coming to the doctor.⁴³ Most of the patients treated by PCPs have mild disorders—precisely the ones most likely to have a placebo response. Once recovered, the patient will usually misattribute his improvement to a medicine that did nothing and feel compelled to stay on it unnecessarily and for prolonged periods. This represents the perfect market opportunity—an army of patients primed by advertising to ask the doctor for a pill. And the doctor primed to respond promptly, since most of his education in psychiatry had come from the helpful drug company salesperson—who also happened to have a handy supply of free samples. Harried PCPs are underpaid and overworked, and have minimal training in psychiatry. Convenience sometimes trumps good care, and the quickest way for them to speed the patient out of the office is to reach for prescription pad or free sample. Psychiatric medications can do a lot of good when properly prescribed, but a lot of harm when handed out so casually and after such incomplete diagnostic evaluations.

The inevitable result has been diagnostic inflation and massively excessive medication use. It makes absolutely no sense to do most of our

psychiatric diagnosis and treatment in primary care settings. Accurate diagnosis requires expertise and simply can't be done properly in the seven minutes most PCPs now get to spend with patients—especially when the patients have been primed by false advertising to demand the wrong thing. Overprescription of psychotropic medication by PCPs has become a serious threat to public health, but has pushed Pharma revenue through the roof. There is almost never a justification for the use of antipsychotic and antianxiety medication in primary care, but it is done all the time.

The fault lays mostly with the system, not the doctor. Ideally primary care should be the valued linchpin central to all medical treatment; instead, our skewed specialist-happy care delivery has left it devalued and terribly underfunded. PCPs man the crucial entry point to the healing world and are forced to deal with the widest array of medical, surgical, and psychiatric problems—a very tall order indeed. Often the PCP is the caregiver with best overall and longest term familiarity with the patient and the one to whom the patient goes for the aches and pains of his life as well as his body. He is the health provider of first, and perhaps last, resort, as often the patient can't afford specialty care or it may be unavailable.⁴⁴ Some PCPs handle their role as "psychiatrists" beautifully, but many are dangerous amateurs who do more harm than good—especially when they are ~~not~~ pressured by the misleading drug company marketing and are forced to shoot from the hip by insurance industry time constraints.

Bad Consequences of Diagnostic Inflation

Where Have All the Normals Gone?

In the early 1980s, about a third of Americans qualified for a lifetime diagnosis of mental disorder.⁴⁵ Now about half do.⁴⁶ And Europe is catching up fast at well over 40 percent.⁴⁷ Some people think these are

underestimates—more carefully done prospective studies actually double the lifetime prevalence. If you believe the results, our population is almost totally saturated with mental disorders. One study found that by age thirty-two, 50 percent of the general population had already qualified for an anxiety disorder; more than 40 percent for mood disorder; and more than 30 percent for substance dependence.⁴⁸ And another study moved even closer to the proposition of almost ubiquitous sickness—by the tender age of twenty-one, more than 80 percent of young adults had already met criteria for a mental disorder.⁴⁹ The trumpeting of inflated rates has fueled drug company claims that we are underdiagnosed and undertreated—keeping the vicious cycle spinning.

Evidence of diagnostic inflation is everywhere. There have been four explosive epidemics of mental disorder in the past fifteen years. Childhood bipolar disorder increased by a miraculous fortyfold⁵⁰; autism by a whopping twentyfold⁵¹; attention deficit/hyperactivity has tripled⁵²; and adult bipolar disorder doubled.⁵³ Whenever rates skyrocket, some portion of the rise represents previously missed true cases—people who really need the diagnosis and the treatment that follows from it. But more accurate diagnosis can't explain why so many people, especially kids, suddenly seem to be getting so sick.

The Glut of Drugs

Psychotropic drugs are now among the very top best sellers for the drug companies. Their stock prices would be cut by more than half were it not for the antipsychotics, antidepressants, stimulants, anti-anxiety agents, sleeping pills, and pain meds. Each year, 300 million prescriptions are written for psychiatric drugs in the United States alone.⁵⁴ At the very top of the Pharma hit parade are the antipsychotics at a resounding \$18 billion a year. Antidepressants produce a hardy \$12 billion a year, despite the fact that many are now off patent and

sold in cheaper generic versions. Fifteen years ago, stimulants were a rounding error in drug company sales at a measly \$50 million a year. Now with direct-to-consumer advertising and heavy marketing to doctors, sales have been juiced up to a hefty \$8 billion a year.⁵⁵ And because primary care doctors love to prescribe them, antianxiety agents are eighth in sales among drug classes—even though they probably do much more harm than good.

The biggest puzzle is the huge success of antipsychotic drugs. Despite their dangerous side effects and narrow indications, they are being given out like candy. Antipsychotics have proven usefulness only in treating the disabling symptoms of schizophrenia and bipolar disorder, but this has not stopped drug company seduction promoting their general use for anyone having trouble sleeping, or run-of-the-mill anxiety, or depression, or irritability, or eccentricity, or the temper tantrums of youth, or the crankiness of old age. More than 3 million Americans are already on board, with a (shareholder satisfying) growth rate of 20 percent a year. The number of prescriptions for antipsychotics has doubled in ten years, up to 54 million and counting. Off-label use has also doubled—undeterred by the big fines that don't seem so big when you consider the ill-gotten gains they enable. How could this happen? Big bucks. An advertising budget of \$2.4 billion per year spent on Abilify and Seroquel has catapulted these two very so-so and not-so-safe drugs to fifth and sixth place as revenue producers among all of the many medicines sold in America. The full court press on primary care doctors has them inappropriately prescribing an antipsychotic for 20 percent of all their anxiety disorder patients.^{56, 57, 58} This massive misuse of antipsychotics is crazy and shameful—a triumph of marketing might over common sense and good medical practice.

There is no way of knowing what should be the optimal level of prescription drug use in our society. Enthusiasts argue that the high rates of pill taking reflect the advances in psychiatric diagnosis and treatment—providing benefits heretofore unavailable to people previ-

ously ignored and in need. To some degree, this is true. But I have no doubt there has been a wild overshoot of false demand promoted by false drug company advertising, gullible doctors, careless prescribing habits, and the wholesale transfer of psychiatric diagnosis and treatment to untrained and harried primary care doctors. We have become a pill-popping society, and very often it is the wrong people who are popping the wrong pills as prescribed by the wrong doctors.

Its undue influence over medical practice is not Big Pharma's fault; it is ours. A drug company does not begin life or maintain itself as a non-profit or charitable entity chartered with the goal of promoting public health in the most efficient and effective way. Quite the opposite. A drug company is a multinational corporation whose main goals are profit, market share, and survival. In any conflict between shareholder greed and customer need, bet on the shareholder. This is the predatory nature of the beast—it is not the tiger's fault it is a carnivore. But it is our collective fault for allowing the drug companies free rein to prey on our weakness. Government, doctors, patients, the media, advocacy groups—all were largely bought off by drug company money and power. Drugs used well are a powerful tool of psychiatry and a godsend for the patients helped. But too often, drugs are used promiscuously in a way that approximates the quackish practice of medieval alchemists. Thomas Sydenham must have had in mind trigger-happy prescribers when he said: "The arrival of a good clown exercises a more beneficial influence upon the health of a town than twenty asses laden with drugs."

Too Much Polypharmacy

It has become distressingly common for doctors to prescribe multiple psychotropic drugs, often in high and dangerous doses and without any rhyme or reason. It is no surprise that drugs prescribed by doctors now account for more emergency room visits for overdoses than do street drugs and are also increasingly responsible for accidental iatro-

genic deaths.⁵⁹ The interacting sedating side effects of the combination of narcotic pain medicine and psychotropic drugs can be especially deadly (a particular problem in the military).⁶⁰

There are many tributaries to this surging river of polypharmacy. Sometimes it represents treatment creep—the previous drugs aren't working very well so new ones keep getting added without ever sunsetting the ineffective ones. Sometimes it results from diagnostic creep—exuberance in making multiple diagnoses followed by enthusiasm in prescribing multiple medications. Sometimes the cause is doctor creep—a drug-seeking patient getting all the meds he can from different doctors blind to one another's prescriptions. Then there is Pharma creep—aggressive marketing that encourages promiscuous prescription. And finally, there is the easy availability of diverted prescription drugs, which encourages polypharmacy by self-prescription—people who decide to add their friend's stimulant or Xanax or narcotic pain medicine to their own often already bloated treatment regimen.

Some doctors seem to use the same combination of medications on every patient, regardless of symptom presentation. The prescribed doses are sometimes high enough to cause serious problems on their own and are especially dangerous if the patient pushes the envelope by drinking alcohol, using drugs, or even taking a few extra pills. The wildest prescribers tend to accumulate deaths over the years, usually without inviting much-needed discipline or increased supervision.

All this said, polypharmacy is sometimes rational and even necessary. The combination of antipsychotic and antidepressant works much better than either alone in treating bipolar disorder or psychotic depression. When a patient has had a definite but partial response to one drug, another may be needed to get a full response. And rarely does adding a pill for sleep make sense. But most polypharmacy is unnecessary, unsupported by research, unmonitored, harmful, and even dangerous.

Too Little Psychotherapy

There is no organized psychotherapy industry to mount a concerted competitive push-back against the excessive use of drugs. Psychotherapy is a retail, individualized, preindustrial craft that doesn't lend itself to the wholesale industrial standardization of product and people that has been so lucrative for Pharma. The different psychotherapies and their practitioners are extremely fragmented and lack the financial resources needed to break the drug company monopoly of the airwaves. Talk doesn't pay—psychiatrists who provide psychotherapy along with medication during a forty-five-minute outpatient visit earn 41 percent less than do psychiatrists who provide three fifteen-minute medication management sessions.⁶¹ The percentage of visits to psychiatrists that included psychotherapy dropped from 44 percent in 1996 to 1997, to 29 percent in 2004 to 2005.^{62,63}

Psychotherapy also lacks a unified, catchy message to counter the seductively misleading drug company promo "it is all chemical imbalance." But psychotherapy does have a much more important and truthful story to tell—that it performs as well as drugs when compared head-to-head in people with mild to moderately severe problems.^{64, 65, 66} Though psychotherapy takes a bit longer to work and costs more upfront, it has more enduring beneficial effects, and that may make it cheaper and better in the long run than long-term medication. Taking a pill is passive. In contrast, psychotherapy puts the patient in charge by instilling new coping skills and attitudes toward life. Japan has caught on to this advantage. Until recently, all of its psychiatric treatment was medication based, but now the government is making a concerted national effort to break the drug monopoly by promoting cognitive therapy as an alternative—because it works well and is cost-effective.

The Power to Label Is the Power to Destroy

Merriam-Webster defines the word *stigma* as an identifying mark, a specific diagnostic sign of disease, or a scar or spot on a plant or animal. Some dictionaries even use "the stigma of mental illness" as the best specific example of the disadvantages suffered by those who are marked. Being "normal" and fitting in with the pack are a key to survival. Evolution has wired into human nature an uncharitable wariness and lack of compassion for those who are different and don't satisfy tribal standards.

Having a mental disorder label "marks" someone in ways that can cause much secondary harm.⁶⁷ Stigma takes many forms, comes from all directions, is sometimes blatantly overt, but can also be remarkably subtle. It is the cruel comment, the unkind smirk, the exclusion from the group, the lost job opportunity, the rejected marriage proposal, the ineligibility for life insurance, the inability to adopt a child or pilot a plane. But it is also the reduced expectation, the helping hand when none is needed or wanted, the solicitous sympathy that one cannot really be expected to measure up. And the secondary psychological and practical harms of having a mental disorder come only partly from how others see you. A great deal of the trouble comes from a change in how you see yourself—the sense of being damaged goods, feeling not normal or worthy, not a full-fledged member of the group.

It is bad enough that stigma is so often associated with having a mental disorder. But the stigma that comes from being mislabeled with a fake diagnosis is a dead loss with absolutely no redeeming features. Labels can also create self-fulfilling prophecies. If you are told you are sick, you feel and act sick, and others treat you as if you are sick. The sick role can be enormously useful when someone truly is sick and needs respite and care. But the sick role can be extremely destructive when it reduces expectations, truncates ambitions, and results in a loss of personal responsibility.⁶⁸

And when a society allows the overdiagnosis of a significant proportion of its individuals as "sick," it becomes an artificially "sick" society rather than a resolutely resilient one. Our ancestors lived through wars and privations unimaginable to us—without resorting to an overdose of labels and an overuse of pills.

Turning Bad into Mad

Diagnostic inflation is an ever-present danger at the boundary between psychiatry and the law. "I would rather be hung as a man than acquitted as a fool." So screamed Charles Guiteau to the jury during his trial for the assassin of President James Garfield in 1881.⁶⁹ He was renouncing the insanity defense offered by his lawyers—preferring instead to be seen as a messenger of God sent to save the United States from an evil administration. Better to be convicted as a criminal than absolved as a mental patient because this would reduce the credibility of his claims. Setting a precedent that continues to this day, many doctors testified on both sides of this landmark case—some seeing Guiteau as crazed, others as a sane, if misguided, criminal.

This debate rages on with no solution. Are political terrorists like the Unabomber or the Norwegian mass murderer Anders Breivik best considered political criminals or mental patients? When assassins strike public figures or innocent bystanders, the media always questions whether they are crazy, never wonders how much they were egged on by venomous political discourse or how they so easily got that semiautomatic. Many (perhaps most) political assassins and mass murderers are on the fuzzy boundary between the merely strange and the legally insane. Depending on your perspective, they can plausibly be seen as either violent political or religious extremists or as delusional psychotics. The adversarial testimony of expert psychiatric witnesses on both sides of this divide invariably cancels out. Ultimately it is a societal, not a medical, choice, whether to consider such individuals

mad or bad. Most defendants would, like Guiteau, much prefer to be punished than treated—lest their message be muffled. I would agree with them. Except in the clearest cases to the contrary, diagnostic inflation should be tamed in the courts. Bad should usually trump mad.

Paying the Bill for Diagnostic Inflation

No one has calculated the total direct and indirect monetary costs of diagnostic inflation, but it must add up to a vast fortune of wasted resources. First, there is the cost of all the unnecessary and overpriced drugs and the doctors' visits needed to prescribe them. Add to this the downstream costs that arise from the many and expensive complications that arise from excessive drug use. In the short term, this includes the costly emergency room visits and hospitalizations for overdoses. Then there are the long-run massive but hidden costs of treating the medical and psychiatric complications caused by medication use—most especially the secondary obesity, diabetes, and heart disease. And how do we cost the lost years of life for those who die early because of the harmful short-term or long-term impact of unnecessary drugs?

Next we have to add the cost of lost work productivity. Linking psychiatric diagnosis to disability artificially inflates both—those who are mislabeled are more likely to become absentees or to stop working altogether. Holland and Denmark discovered that national sick days and disability skyrocketed when a psychiatric diagnosis or work stress was a readily accepted reason for not working. The disability decision is often an irrevocable moment in a person's life: gaining disability is a wonderful short-term respite from terribly worrying financial pressures, but it may lead to chronic vocational invalidism.

Then there are the costs of other services provided to people mislabeled as mentally ill—the mental health and medical visits, the added school services, training programs, and so on. It seems harsh to be-

grudge these to anyone, and in the individual case a caring clinician will be tempted to up-diagnose to help his own patient get the benefit. But budgets are usually a zero-sum game—helping this person who has only a marginal need will mean depriving someone else who has a crying-out-loud need.

Finally, we come to the forensic and correctional costs of diagnostic inflation. A single death penalty sentencing hearing can cost \$5 million for endless and futile debates on the presence or absence of a highly dubious mental disorder. A year in a psychiatric hospital for someone inappropriately committed under an SVP statute costs more than a year at Harvard. Civil lawsuits based on creative claims of psychiatric damage drag on seemingly forever and eat up treasures in legal bills and fees for expert witnesses. Psychiatry and the law often don't mix well—but they always cost a lot whenever they become entangled.

The enormous waste caused by diagnostic inflation goes unchecked because there are no feedback controls to contain it and no economic incentives to promote careful diagnosis. Waste never enters into the considerations of those who develop the *DSMs* or those who apply it or to the drug companies who profit from it. Parents understandably want services for their child and consumer advocacy groups understandably want services for their constituents. It always appears that someone else is paying the bill and no one is minding the store to ensure rational and fair allocations. The net result is inevitable: unnecessary demand created by diagnostic inflation results in wasted expenditures, while those in desperate need remain badly underserved.⁷⁰

Diagnostic inflation is a public health and public policy dilemma that urgently needs solving. Costs will be further amplified by the extension of health insurance to some 34 million more Americans under the Affordable Care Act, especially given its requirement that insurance include comprehensive care for mental disorders. These are wonderful policy changes. A greater investment is certainly needed to shore up our badly shortchanged mental health system. But the additional expenditures are unpredictable, likely to be in the many billions

each year, and because of diagnostic inflation, the money will be spent where it is likely to do least good.

Curing diagnostic inflation will be an uphill struggle, with steps to be described later. But first we have to understand the large role diagnostic fads have played in the psychiatric past, the grave damage they are doing in the present, and the significant risk that new fads will create mayhem in the immediate future.