1

A REALITY CHECK FOR PERSONALIZED MEDICINE

We are in a new era of the life sciences, but in no area of research is the promise greater than in personalized medicine.
—Barack Obama, as a senator introducing the bill that became the Genomics and Personalized Medicine Act 2007

THE SOARING PROMISES MADE BY ADVOCATES OF PERSONALIZED medicine are probably loftier than those in any other medical or scientific realm today. In addition, the range of therapies covered by personalized medicine is even greater than then-Senator Obama realized. Direct-to-consumer genetic testing, personal tailored drug regimes, private umbilical cord blood banking, and "enhancement" technologies all come under that rubric. Part of this book's own promise is to introduce you to personalized medicine's lesser-known variants, illustrating how they all chime together in their hymns and psalms in praise of what I call "Me Medicine."

Sometimes, the clarion calls for these new technologies are delivered with almost messianic fervor, as in the case of this paean from Francis Collins, a former codirector of the Human Genome Project:

We are on the leading edge of a true revolution in medicine, one that promises to transform the traditional "one size fits all" approach into a much more powerful strategy that considers each individual as unique and as having special characteristics that should guide an approach to staying healthy. Although the scientific details to back up these broad claims are

still evolving, the outline of a dramatic paradigm shift is coming into focus. . . . You have to be ready to embrace this new world.[1]

Do I? Why? I'd like to see more evidence before I decide. It's not that I'm afraid of new biotechnologies—I've spent my working life analyzing them and their ethical implications. Nor is it because I don't necessarily believe the promises will come true, although there are good reasons to doubt that they will ever really amount to a "dramatic paradigm shift."

Certainly, vast sums are pouring into personalized medicine: plans to spend $416 million on a four-year plan were announced in December 2011 by the National Institutes of Health,[2] and interest from the private sector is also intense. But the Human Genome Project (HGP) was also very generously funded, without having so far produced correspondingly weighty results for translational medicine, even a decade after it was announced that the human genome had been fully sequenced.[3] "Indeed, after 10 years of effort, geneticists are almost back to square one in knowing where to look for the roots of common disease."[4] Productivity in drug development actually *declined* after the HGP announced its completion, as did new license applications to the Food and Drug Administration.[5]

And we've been here before: other supposed "paradigm shifts," including gene therapy and embryonic stem cell research, haven't yet translated into routine clinical care either. Likewise for personalized medicine, current genetic tests and molecular diagnostics only apply to about 2 percent of the population, according to a March 2012 report from United Health's Center for Health Reform and Modernization.[6] A Harris poll of 2,760 patients and physicians in January and February 2012 indicated that doctors had recommended personal genetic tests for only 4 percent of their patients. This is hardly the stuff of a paradigm shift, at least not yet.[7] Some experts call the genomic revolution merely a "myth," arguing that at most we're witnessing a process of incremental change, one consistent with past trends in diagnostic innovation.[8]

Yet despite the lack of substantial evidence that personalized genetic testing is actually having a huge effect, the publicity around it may well be doing so—not necessarily for the best. I'm concerned that *Me Medicine* is eclipsing what I call *We Medicine*, so that we're losing sight of the notion that biotechnology can and should serve the common good. In my view, we would be wrong to prioritize personalized health technologies at the expense of public health measures, which have brought us comparative freedom from the ill health that plagued our ancestors. I see a pattern here—not only a similarity

among all the apparently disparate forms of personalized medicine but also a familiar political formula: "private good, public bad."

Personalized medicine consciously appeals to the idea of the individual making free choices about her health, but in a much more sophisticated way than the simplistic stereotypes about free markets in healthcare versus welfare states, which were played out to tiresome length in the debates over the Patient Protection and Affordable Care Act 2010. Because it's much more palatable medicine—excuse the pun—it may not look like it's even part of that debate at all, but it is. If we take the Me Medicine fork in the healthcare road, we can't simultaneously go down the We Medicine route—the road less traveled by, in Robert Frost's phrase.

For example, there's been considerable growth in private umbilical cord blood banks, which charge a fee to store cord blood in an individual "account" for the newborn in the hope that stem cell technology will eventually allow the blood to be used as a sort of personal spare-parts kit. With one or two exceptions, these banks reserve the blood for the child's private use (Me Medicine), but there are also public cord blood banks (We Medicine) that actually achieve better clinical results.[9] Yet if enough parents bank their babies' umbilical cord blood privately, there won't be a sufficient supply for public cord blood banks, although those can be seen as both medically and ethically superior.

At the moment, perhaps surprisingly, the United States leads the world in the overall number of public cord blood banks. Despite our famous cult of individualism, we're tops in We Medicine there, but we won't stay that way if current trends toward private banking continue. Here and elsewhere, what may look like innocent individual consumer choices will shape how we as a society assure our health and that of future generations. So we need to think long and hard about how we want to prioritize the claims of Me and We rather than just hopping aboard the personalized medicine bandwagon like the great majority of commentators. This book is intended to let you make up your own mind about how you see those priorities, by giving you accurate, up-to-date medical and scientific evidence and locating the new technologies in their ethical and political context.

First, however: what exactly are these new personalized technologies, and how can they make such grand claims? Unlike this book, most works treat the various aspects of personalized medicine as separate developments, with different diagnoses and prognoses. The various techniques do at first look disparate. *Direct-to-consumer genetic testing*, in which a limited selection of genetic

analyses are performed on a sample of saliva or a cheek swab, is probably the most familiar of the Me Medicine technologies. The field, which includes a number of "big players," such as the California company 23andMe, has been widely publicized by journalists who tried "retail genetics" out for themselves.[10] Along with the example of *private cord blood banking*, another increasingly familiar example of Me Medicine is *pharmacogenetics* or *pharmacogenomics*. Here, genetic typing is used to determine a patient's probable response to drugs, such as cancer treatments, and to tailor the pharmaceutical regime personally. Although, as we've seen, the percentage of patients undergoing such genetic diagnostics and treatments is still in the low single figures, *chemical* or *neurocognitive enhancement technologies* are even further away from everyday clinical practice, although they too have provoked column inches about what one of their most prominent opponents calls "the case against perfection."[11]

What do all these apparently disparate technologies have in common? Essentially, they're linked by two largely unchallenged assumptions: that "individual" is better than "social" and that we're on the cusp of a "true revolution in medicine" to make it more individualized. But are these assumptions justified? They may or may not be—that's what we'll discover as we go along—but the really interesting question is why so few have challenged them. The bookstores are full of somewhat dewy-eyed and often uncritically "pro" books about personalized medicine, such as Misha Angrist's *Here Is a Human Being: At the Dawn of Personal Genomics*; Francis Collins's *The Language of Life: DNA and the Revolution in Personalized Medicine*; Kevin Davies's *The Thousand-Dollar Genome: The Revolution in DNA Sequencing and the New Era of Personalized Medicine*; Thomas Goetz's *The Decision Tree: Taking Control of Your Health in the Era of Personalized Medicine*; Eric Topol's *The Creative Destruction of Medicine: How the Digital Revolution Will Create Better Health Care*; and Lone Frank's *My Beautiful Genome: Exploring Our Genetic Future, One Quirk at a Time*. But the book you're reading now doesn't take a knee-jerk "anti" position; it just aims to be balanced.

We need to ask why so many multinational firms, researchers, and—yes—presidents of the United States have all bought into personalized medicine. We urgently need a disinterested and balanced critique of personalized medicine's origins, the commercial interests that lie behind it, and the dynamics of its marketing as what I term *retail therapy*, that is, medical treatment and diagnostic regimes conceived as consumer goods. Just as the body itself has been commodified—the argument of my previous book, *Body Shopping*—so

medicine is increasingly seen as a commodity, in both insurance-based and more socialized healthcare systems.

Historically, it was not Me Medicine but We Medicine—programs like public vaccination, clean water, and screening for tuberculosis—that brought us reduced infant mortality, comparative freedom from contagious disease, and an enhanced lifespan. Yet today, many of these public programs seem to be increasingly distrusted, even detested. Some U.S. campaigners against the measles, mumps, and rubella (MMR) vaccine have allegedly accused physicians who administer the vaccine of being in the same league as Nazi concentration camp doctors.[12] Vaccination programs are in profound trouble in many parts of the world. In India, a similar though less virulent reaction has arisen against what might seem like a model public health campaign, the vaccination of young girls against the human papillomavirus implicated in cervical cancer.[13] In Muslim areas of northern Nigeria, a country which accounts for about 45 percent of polio cases worldwide, a World Health Organization vaccination campaign was boycotted as a Western plot to spread HIV and AIDS through adulterated injections.[14]

In contrast, when a new medical development combines scientific mystique and the wand-waving word "personal," the reaction worldwide will probably be overwhelming adulation. That was very much the case when the Korean researcher Hwang Woo Suk announced in 2005 that he had successfully created eleven "patient-specific" stem cell lines. Hwang was pointing toward the possibility that eventually everyone could have a personal spare-parts kit, overcoming the problem of immune rejection when organs are transplanted.[15] "After Hwang's article was published, he turned into a sacred figure."[16] The reaction, in both East and West, was so euphoric that Hwang offered to set up a worldwide franchise of his method, with satellite laboratories in California and England—before his claim was revealed to be totally false. He hadn't created a single successful cell line, even though he had published his "findings" in the prestigious journal *Science*—fooling both the editors and the scientific world at large.

But how was that possible? Although it's a bit speculative, perhaps one reason is the spell cast by the idea of personalized therapy. Some of that unconfined joy and uncritical adulation had a genuinely scientific appeal—that is, if the technique had worked, and if it hadn't required dangerous levels of hormonal stimulation to produce the human eggs that the technique demanded in huge quantities.[17] But it also seems plausible that Hwang's supposedly patient-specific stem cells appealed because they pushed the right buttons in our

psyches: the ones marked "personal" and "individual." The possibility of a commercial franchise mooted by Hwang before his unmasking indicates that pushing those buttons is also important and attractive to corporate interests.

It's hard to explain why else ferreting out the truth took determined campaigning by a not-very-well-known Korean feminist group, Korean Womenlink, and the subsequent acknowledgment by Hwang's principal colleague, Gerald Schatten, that the methods used in sourcing the eggs had been ethically dubious, eventually leading to a recognition of the scientific inaccuracy of the claim. It's also difficult to understand why more attention wasn't paid to improving the rate of tissue rejection through further advances in the already promising field of immunology, as a few scientists did argue at the time.[18] That would mean that we could recruit a wider range of tissue donors without having to worry about tissue matching, to avoid rejection of the transplant, or the alternative of heavy and risky doses of immunosuppressants. We could concentrate on practical methods of improving the success of altruistic donation from others rather than on our own speculative personal spare-parts kits.

But that's the dull alternative of We Medicine, isn't it? How can it compare with the exciting promise of personalized medicine? Here's the story of someone who did test that promise at no little risk to himself. Like Collins, he's one of the new "evangelists" of Me Medicine. His story might help us begin to piece together the reasons why so many observers have joined that new movement. There's also a dominant theme of threat running through his story, which I will consider later in this chapter and explore throughout this book as one possible hypothesis explaining the rise of Me Medicine.

THE NEW EVANGELISTS

In writing his 2009 book *Experimental Man*, David Ewing Duncan—the chief correspondent of National Public Radio's "Biotech Nation" and director of the Center for Life Science Policy at the University of California, Berkeley—had himself tested for 320 chemical toxins and up to ten million genetic markers. He spent twenty-two hours having magnetic resonance imaging and underwent the drawing of 1.7 liters of blood. The total cost of all the tests that Duncan endured was between $150,000 and $500,000. That's the range Duncan himself gives, which seems more than a little vague, but many of the tests were supplied gratis by the genetic testing industry. Whichever end of the dol-

lar scale turns out to be most accurate, he still consumed a great deal of medical resources.

Although you might think that there's nothing particularly liberating about being an experimental guinea pig on such a scale, Duncan urges readers of the book and visitors to his website to sign what he calls a "Personalized Health Manifesto": "an old-fashioned call to arms and action plan for a new age of health care."[19] We heard the same campground-meeting rhetoric from Francis Collins. Personalized medicine seems to be becoming the equivalent of nineteenth-century American revivalism.

Back in the 1840s, when the students at Mount Holyoke seminary were called on by their college president Mary Lyon to stand up and testify to their desire to lead a Christian life, the young Emily Dickinson was one of the few who remained in her seat. "They thought it queer I didn't rise," she remarked afterward. "I thought a lie would be queerer." Similarly, Duncan reportedly called on attendees at the U.S. National Undergraduate Bioethics Conference in 2011 to demonstrate their conversion to personalized medicine with a show of hands. Only one modern-day Dickinson's hand remained down. "Too bad," Duncan reportedly said. "It's happening anyway."[20] To be fair, Duncan actually concludes in his book that the direct-to-consumer genetic tests he tried are mostly disappointing. He advises not placing too much reliance on the results—yet. But when the science is perfected, his reasoning seems to run, what's not to like?

To start with, that "when" has every appearance of being an "if," although many proponents of personalized medicine make very big claims indeed. It's been asserted that a baby could have her genome fully sequenced at birth, along with her susceptibility to particular diseases. She could then enjoy the benefits of made-to-order diagnostic tools and drugs throughout her lifetime.[21] That really is the Holy Grail of personalized medicine, but it makes huge and currently unfounded assumptions about how much genetic and genomic medicine is actually able to predict. Most major diseases are caused by the interplay of many genes rather than one, and they arise from both environmental and genetic causes.[22]

Proponents of personalized medicine's benefits point with some justification, however, to the evolving area of biomedicine known as pharmacogenetics or pharmacogenomics. For example, the drug warfarin is an oral anticoagulant commonly used to prevent or manage venous thrombosis (clotting). It's sometimes difficult to determine the correct dosage for an individual patient: thinning the blood excessively can be an unwanted side effect, carrying its

own risks. But now, warfarin dosage can be tailored to identify particular patients at increased risk of bleeding by sequencing two genes that account for most of the variation in how people react to the drug. Even here, there's some skepticism about whether pharmacogenetics has actually improved outcomes for patients[23] and whether more extensive reliance on personally tailored drug regimes requires a "leap of faith,"[24] as I'll discuss at greater length in chapter 3. Nonetheless, if sufficient evidence were amassed to show that pharmacogenetic dosage of warfarin is clinically effective, this would exemplify one meaning of personalized medicine that does seem genuinely beneficial: drug treatment tailored to the patient on an evidence-based model for better clinical care.

Whether that's really personalized in the sense of *individualized*, however, is arguable. In the warfarin example, individuals are classified into *groups* according to which allele (variant) of the relevant gene they have. It might be better called "small-group medicine," though that's nowhere near as catchy. Personalized medicine in the warfarin example is still more "We" than "Me," even though warfarin is frequently cited by Me Medicine advocates as proof that truly individualized medicine is already a reality.

Even the biotechnology industry–linked Personalized Medicine Coalition concedes that pharmacogenetics is about population subgroup response to particular drugs. It's still an improvement, they argue, because only 50 percent of the population responds to a typical drug—a figure that can be translated into a higher probability through pharmacogenetics.[25] Of course, this is an improvement, but it's still not really *personalized* medicine: a probability applies by definition to a statistical *group*. The phenomenon of statistical independence means that no probability can tell you with certainty that you as an *individual* will or will not respond to a drug, any more than the 50 percent probability that a coin toss will come up heads can predict whether the next toss will come up tails.

Evangelists for personalized medicine often adduce the discovery of blood types as the pioneering example of individualized care. Yet that, too, is about assigning individual patients to serum groups (A, O, B, and AB), which are further divided into subgroups by rhesus type (positive or negative). The discovery of blood groups did revolutionize transplant surgery, and so it could count as a genuine example of a paradigm shift—but whether it's truly "personalized" is arguable.

Advocates of personalized medicine frequently play on the stereotype that traditional medicine ignores our individuality. For Eric Topol, hidebound

conventional therapies require "creative destruction" in favor of a genuinely individualized medicine:

> This is a new era of medicine, in which each person can be near [*sic*] fully defined at the individual level, instead of how we practice medicine at a population level, with mass screening policies for such conditions as breast or prostate cancer and use of the same medication and dosage for a diagnosis rather than a patient. We are each unique human beings, but up until now there was no way to establish one's biologic or physiologic individuality.[26]

Likewise, the Personalized Medicine Coalition asserts that "physicians can now go beyond the 'one size fits all' model of medicine to make the most effective clinical decisions for individual patients."[27] Francis Collins used similar language when he predicted that personalized medicine will "transform the traditional 'one size fits all' approach into a much more powerful strategy that considers each individual as unique."[28]

Yet good practitioners have always relied on close observation of the particular patient. As Hippocrates said, "It is far more important to know what person the disease has than to know what disease the person has." The notion of "whole-person treatment" didn't originate with pharmacogenetics or direct-to-consumer genetic testing. Indeed, as Collins himself admits, taking a family history, that staple of old-fashioned medical practice, still reveals risk proclivity for particular diseases more accurately than consumer genetics.[29] And looking at the family, by definition, means moving beyond the individual, from Me to We.

So it seems fair to say that personalized medicine is nowhere near as new or innovative as it claims to be—nor as successful. Direct-to-consumer genetic testing, for example, is likely to yield conflicting results because the methods are not standardized and the disease probabilities are not universally accepted by experts. These "retail genetics" firms test for forms of genetic information (single nucleotide polymorphisms, or SNPs, single-letter differences in DNA between individuals), but none of them tests for the same set of SNPs. Much to his consternation, David Ewing Duncan received three frantically different assessments of his heart attack risk from three different genetic testing companies. The director of deCODEme, Kari Stephansson, even telephoned him personally from Iceland to urge him to start taking cholesterol-lowering statins right away—but the other tests had rated him at medium or

low risk of developing dangerously high cholesterol. As Duncan puts it in a laconic chapter subheading, "I'm doomed. Or not."

Yet Duncan remains an ardent advocate of personalized medicine. Even more critical observers tend not to go beyond the biomedical reasons for doubting whether personalized medicine really has a future.[30] I'm not dismissing those medical and scientific doubts: they are valid and valuable. The recommendations of medical professional bodies, like the evidence-based judgment on DTC genetic testing of the American Society for Clinical Oncology,[31] are entirely appropriate to the task and competence of the observers. But for this book's purposes—a comprehensive and skeptical survey of all the various trends toward Me Medicine—we need to go further.

Let's break out of the biomedical box and introduce four wider social, political, and ethical reasons why people might be tempted to buy into personalized medicine: (1) threat and contamination, (2) narcissism and the "bowling alone" phenomenon, (3) corporate interests and neoliberalism, and, finally, (4) choice and autonomy. After a preliminary appraisal here, these four possible hypotheses will be evaluated against each of the specific medical developments examined in successive chapters. By the end of the book, we should have a much clearer idea of the profound social and political reasons why Me Medicine threatens to edge out We Medicine and a rational program for doing something about it, if that's what we decide is appropriate.

Four Approaches to Understanding the "Me Medicine" Versus "We Medicine" Phenomenon

1. Threat and contamination
2. Narcissism and "bowling alone"
3. Corporate interests and political neoliberalism
4. The sacredness of personal choice

THREAT AND CONTAMINATION

In his book *Experimental Man*, subtitled *What One Man's Body Reveals About His Future, Your Health, and Our Toxic World*, David Ewing Duncan reveals that his testing program—testing in all senses—was motivated not just by intellectual curiosity but by a sense of threat and contamination. Unbeknownst to his mother, an environmental activist, Duncan spent his idyllic Kansas

boyhood wading in streams full of chemical runoff or mining the "motherlode" of a landfill site for old bottles, broken machines, steering wheels, and, as it turned out, heavy metals. Brought up to believe that he came from a family of long-lived individuals, he describes feeling fragile for the first time when he discovers that his genes can't protect him against the abnormally high levels of toxic residues in his blood. In a circular and ironic relationship with threat, the Experimental Man project that he underwent to take control of his health actually left him feeling more at risk than ever before.

That's one sense of threat, but there are also others that might help to explain the rise of personalized medicine. Contamination and pollution as powerful motivating fears can, of course, extend to many forms of "dirt" and impurity.[32] The UK system of altruistic blood donation is increasingly being bypassed by people wanting to bank their own blood for future use. Frightened by possible contamination of communal blood banks by HIV and BSE (bovine spongiform encephalopathy, or "mad cow disease"), patients scheduled for operations may now choose to avoid that threat by banking their own blood in advance.[33] Once the epitome of We Medicine, that marvel of efficiency and altruism depicted by Richard Titmuss in his influential book *The Gift Relationship*, the UK national blood service now risks being transformed into a form of Me Medicine. The model for blood use would then become one of depositing in a personal account rather than donating to or drawing on a communal resource.

Personal or "autologous" blood depositing is still only practiced in a minority of cases: the patient must be healthy enough to withstand not only the procedure but also the withdrawal of blood beforehand. But more people would do it if they could. A Eurobarometer survey of European public opinion found that 25 percent of respondents would only accept their own blood if they needed a transfusion. Another 23 percent would also be willing to take blood from a known person such as a friend or relative, though not from a stranger.[34] That brings the total who want nothing to do with communal blood up to roughly half the European survey population: powerful evidence of a growing sense of threat and contamination in what was once seen as the quintessential symbol of social solidarity, blood donation.[35]

In the United Kingdom, the Factor VIII hemophiliac controversy and the emergence of an untreatable variant of Creutzfeldt-Jakob Disease (CJD, a form of dementia possibly linked to mad cow disease) do at least give patients some reason to fear a threat from communal blood. But we'll see in chapter 4 that private umbilical cord blood banking for an infant's personal future use is also on the rise, although the actual evidence indicates that rather than

reducing the threat of danger, it may actually pose a risk to the baby.[36] Yet *perceived* threat is highly relevant, as is evident in the lengthy but sometimes inaccurate lists of diseases from which private banks claim the baby can be protected by banking the blood.

The link between toxin threat and personal genetics was consciously built into the Human Genome Project itself, the British geneticist Helen Wallace maintains.[37] Using documents obtained through litigation, she's produced extensive evidence, which I'll examine critically in the next chapter, purportedly demonstrating that Big Tobacco threw itself into funding genetic and genomic research in the hope of narrowing down those who were "genetically susceptible" to tobacco smoke, thus reassuring the majority of the population that they were at no risk from smoking.

Wallace claims that the tobacco industry even promoted the idea that an unknown gene both drove particular people to smoke and made them genetically vulnerable to carcinogens in cigarettes. No such genetic basis for wanting to smoke or for being particularly susceptible to smoking ever materialized, of course. But the notion of splitting off certain vulnerable individuals, the framing of smoking as a consumer choice, and the background sense of threat all fit uncomfortably neatly into the pattern of Me Medicine.

These examples all draw on physiological threats, but it might well be said that the current state of healthcare leaves us all feeling threatened for financial or political reasons, such as spiraling costs, the difficulty in finding insurance, and the reluctance of many family doctors to take on new Medicare patients. Even in the United Kingdom and elsewhere in Europe, austerity cuts mean that unified and universal healthcare is increasingly under threat. Although the United Kingdom still formally retains the National Health Service, in March 2012 a government-sponsored bill, condemned by medical professional bodies, introduced radical new provisions that have been criticized as likely to lead to "cherry-picking" of better-off patients and neglect of the less wealthy.[38] In April 2013, responsibility for public health—We Medicine—is to be transferred from the unified National Health Service to cash-strapped local authorities, who may not all be able to provide the same level of service.[39] So here, too, threat is a dominant motif, possibly leading British patients to feel that in future they'll have to take charge of their own health to a greater degree, "topping up" their NHS coverage with personal insurance plans and establishing their individual genetic risks for certain diseases.

Yet it also seems possible that personalized medicine *itself* could produce new kinds of threats, and thus patients would simply be exchanging rather

than eliminating forms of risk. For example, if patients are ranked pharmacogenetically according to how well they're likely to respond to expensive drugs, those less likely to respond may well be denied treatments that they would have received on a "one-size-fits-all" model of prescribing.[40] This is the downside of what is more commonly presented as a major advantage of pharmacogenetics: that tailored drugs will "spare expense and side effects" for those who are genetically less likely to benefit from a particular treatment.[41]

Given that its most ardent defenders present containment of rising medical costs as a major attraction of personalized medicine, we can assume that this is indeed high on the agenda. Just as those who believe in reincarnation typically think that in a previous life they were emperors rather than galley slaves, so might we all think we will be among the genetic elite who will get the enhanced new products of pharmacogenetics. But what if we're among the new untouchables instead?

In all these circumstances, it's natural to feel that you're going to be on your own if you fall ill and that it makes sense to try to forecast and minimize your risk by finding out all you can about your genetic propensity to particular diseases. Do-it-yourself genetic testing, for example, is presented as one means to that end. Sometimes firms play up the risk-minimization angle quite directly: for example, a DTC firm offering to rate young adults' sports abilities by genetic proclivity has been accused of playing on scare stories about deaths in young athletes.[42] More frequently, however, DTC firms present themselves as "empowering" their customers, hijacking the rhetoric of the 1960s.[43] For example, 23andMe's website asserts: "The company was founded to empower individuals and develop new ways of accelerating scientific research."

The virtuous twin of threat might appear to be promise, upon which Me technologies such as neurological or genetic enhancement clearly play. But it's worth noting that the promises made by enhancement are for individuals or a comparatively small elite: they will never be mass technologies. Indeed, that designer cachet might be part of the sales pitch. That brings us to a second possible explanation for the rise and rise of Me Medicine: narcissism.

NARCISSISM AND "BOWLING ALONE"

23andMe, Knome, deCODEme, and MyGenome: is it only a coincidence that the words "me" and "my" are part of the brand name for so many DTC genetic testing companies?[44] Or is retail genetics part of a more generalized trend

toward narcissism and self-absorption? "No single event initiated the narcissism epidemic; instead, Americans' core cultural ideas slowly became more focused on self-admiration and self-expression. At the same time, Americans' faith in the power of collective action in the government was lost."[45] Jean Twenge and Keith Campbell, authors of *The Narcissism Epidemic*, remark on the use of "I," "me," and "my" as branding devices outside biomedicine—notably the repetition of "I" in the iPod, iPhone, and iPad. (Even if the "i" is in lowercase, it's still all about "me.") David Ewing Duncan actually suggests that eventually we will each own a handheld device, which he jokingly but appropriately terms an "iHealth." On it, he predicts, we'll track our genomes and most recent scans, inputting environmental data as we go through the low-tech drudgery of everyday life.[46]

The concept of a narcissism epidemic isn't strongly medical or scientific, although Twenge and Campbell do produce evidence of a recent rise in narcissistic personality traits on psychological profile tests taken by college students. Mainly, however, they delineate a sense of entitlement that has permeated popular culture and has changed child-rearing practices to overemphasize the child's intrinsic specialness, at the expense of an awareness of others' needs. Twenge and Campbell reserve particular scorn for notions about needing to love yourself first before you can love anybody else. As an NBC public service announcement puts it, "You may not realize it, but everyone is born with their one true love—themselves."[47] Narcissism in this sense is different from individualism—and more pernicious.

> America has always been an individualistic nation, but it was focused on ideas of individual liberty, freedom from tyranny, and fundamental equality—values that emphasized independence, not narcissism. But when these powerful ideas were supplemented by the new values of self-admiration and self-expression, the results were ugly.[48]

Although Twenge and Campbell don't make the connection to DTC genetic testing, they do argue that the Internet—on which retail genetics depends—promotes narcissistic behaviors, such as endlessly refining your MySpace page or fattening up your list of Facebook "friends" to emphasize quantity rather than quality of interactions. You could also see personalized medicine, particularly retail genetics, as a response to celebrity culture. Acres of genetic analysis all about your individual genome, the extra option of an ancestor-tracing service offered by some DTC firms, the chance to join a social network

of other customers offered by some services—all these features could well make purchasers feel that they're as newsworthy as celebrities and that their body's idiosyncrasies are the stuff of drama. Narcissism might go hand in hand with the "genetic mystique" described by Dorothy Nelkin and Susan Lindee in *The DNA Mystique: The Gene as Cultural Icon*: "Just as the Christian soul has provided an archetypal concept through which to understand the person and the continuity of the self, so DNA appears in popular culture as a soul-like entity, a holy and immortal relic. . . . It is the essential entity—the location of the true self—in the narratives of biological determinism."[49] The genetic mystique is intertwined with the idea of "genetic exceptionalism," the implicit assumption that genetics and genomics reveal more profound truths than other sciences. Normally, these two concepts accompany genetic determinism—the proposition that genes determine our behavior, as found in media articles claiming that scientists have discovered genes determining everything from voting patterns[50] to becoming a ruthless dictator.[51]

In the case of retail genetics, however, the marketing is predicated not on genetic determinism but rather on its opposite: an underlying assumption that we are in control of our behavior so that we can alter unhealthy eating or exercise patterns, for example, to counter a genetic predisposition to heart disease. (We'll see in chapter 2 that these promises, however, are more honored in the breach than in the observance.) When combined with the "ideology of wellness,"[52] geneticization means that those who are well can then take credit not just for their superior genes but also for their initiative in counteracting any "inferior" ones.

It's odd to see genetic exceptionalism divorced from genetic determinism: the more usual assumption is that genes dictate not only who we are but also what we do. Yet genetic exceptionalism is actually strengthened by avoiding the incoherence of genetic determinism. After all, do your genes dictate that you believe that your genes dictate what you believe?

The notion that retail therapy plays on narcissism and the genetic mystique seems initially plausible, whether or not that sense of narcissism is growing as exponentially as Twenge and Campbell assert. It also accords with the analysis in Robert Putnam's influential book *Bowling Alone*. Putnam argues that in the last third of the twentieth century, political, civic, and religious participation all declined, along with voluntarism, trust, and reciprocity. A sense of "we"-ness went missing in just thirty years, he says, and was replaced instead by the virulent culture wars that still dominate American politics.

> The dominant theme is simple: For the first two-thirds of the twentieth century a powerful tide bore Americans into ever-deeper engagement in the life of their communities, but a few decades ago—silently, without warning—that tide reversed and we were overtaken by a treacherous rip current. Without at first noticing, we have been pulled apart from one another and from our communities over the last third of a century.[53]

Putnam particularly contrasts the "civic-minded" World War II generation with their supposedly more self-centered children, the generation that came of age in the 1960s and 1970s.[54] This seems to me an overworked and inaccurate comparison. The so-called Greatest Generation may well have been heroic in wartime, but in many cases the trauma of their experiences left them cold and inward-turned. Michael Cunningham's novel *The Hours* captures the claustrophobia of the 1950s well, with its fraught description of a postwar housewife's suicide attempt as an escape from her stifling and conformist family life. Toni Morrison, whose novel *Home* likewise desentimentalizes the period, has described her urge to "take the scab off the 50s, the general idea of it as very comfortable, happy, nostalgic . . . Oh, please."[55]

Putnam admits that the 1950s weren't such a golden age for African or Hispanic Americans, but he insists that at least for whites, "engagement in community affairs and the sense of shared identity and reciprocity had never been higher."[56] Yet even if he's right about the quantity of civic engagement, that doesn't say anything about its quality: the uses served by that togetherness. Core civic organizations of the 1950s included the likes of the Masons and the Daughters of the American Revolution: one resolutely excluding women, the other recruiting women to protest against any form of progressive policy. At the extreme, Putnam acknowledges that Ku Klux Klansmen also engage in community affairs and share a sense of identity. As Grand Wizard Jeff Coleman said, "Really, we're just like the Lions or the Elks. We want to be involved in the community."[57]

By contrast, the stereotype of the 1960s generation as hedonistic hippies leaves out the Vietnam draft resistance, women's liberation, and the civil rights movement. Many, such as Medgar Evers, the three "Freedom Riders" killed in Mississippi in 1964, and, of course, Martin Luther King, died or went to prison for those collective causes. It demeans their memory to label the entire 1960s generation as self-centered individualists. And if that's true, then the notion of remorseless decay from a golden age of immediate postwar togetherness becomes less plausible.

The Narcissism Epidemic and *Bowling Alone* are both premised on the claim that "social capital"—a set of connections among individuals and norms of reciprocity—is in grave decline. Yet as we've seen, Putnam does recognize that social capital is good for the "in" group but may redound against outsiders. On the logical principle of the excluded middle—the proposition that one factor cannot explain both an effect and the absence of an effect—the social capital explanation runs into difficulties. Does it create a greater willingness to help the socially excluded, or can it actually result in group closure against the dispossessed?

This paradox has important implications for Me Medicine. On the one hand, the supposed *decline* in social capital could explain the current focus on "Me"-ness: the feeling that you're responsible for your own health. That would be the implication suggested by *The Narcissism Epidemic* and *Bowling Alone*. It might also be an explanation for the rocketing growth of cosmetic surgery. In the words of Martha Hennessey of the Catholic Worker movement, "Americans have retreated into collective narcissism."[58] The only thing we do collectively, in this view, is to agree that we're allowed to focus entirely on ourselves.

However, more "Me"-ness in medicine and social policy generally could also be explained by an *increase* in social capital, one developed through group closure. It all depends on what the group stands for, not on the mere fact of its being a group, and on how it attains its unity and purpose. Since writing *Bowling Alone*, which gave the impression that social solidarity was a terminal case, Putnam has praised the teams who canvassed for President Obama in the 2008 Democratic primaries as harbingers of a revived sense of bowling together. That's all well and good, but their nemesis, the Tea Party, is also a grassroots grouping, albeit one with significant support in high financial places.[59] The sense of shared identity among Tea Party members likewise depends on a common platform, which they would see as self-reliance and independence. It also depends on rallying the troops against the opposition, defined variously as immigrants, Washington bureaucrats, bankers, or political leftists, in a collective fashion, although in the paradoxical name of individualism.

It's been suggested that Americans are most likely to vote in favor of redistributive social and health programs if they see "people like us" as the beneficiaries.[60] This nasty side effect of group identification isn't softened by community integration; rather, the reverse is true. "The greater the racial and ethnic diversity of the community, and the more likely it is that voters see

their tax dollars going to assist 'the other,' the lower the support for any spending, be it on health, schools or welfare."[61] When a federal healthcare program with overtones of We Medicine is proposed by a president who embodies "the other" to some white Americans, you might speculate that a wholesale flight into Me Medicine is only to be expected.

While psychological factors like group identity or narcissism are intuitively plausible explanations of the rise of Me Medicine, they only take us so far. In fact, they actually produce contradictory predictions about whether We or Me Medicine is likely to result from a decline in communal identity. Let's consider another possible hypothesis: corporate interests and political neoliberalism.

CORPORATE INTERESTS AND POLITICAL NEOLIBERALISM

> Should scientists see themselves as part of a worldwide NGO [nongovernmental organization], upholding a set of shared values? I think that's exactly the way they used to be in previous centuries . . . and actually that international fellowship is by no means gone, but it's threatened when people try to walk both sides of the line, mingling scientific contribution with profit-making activity. . . . We in Western society are going through a period of intensifying belief in private ownership, to the detriment of the public good. Individual selfishness is held up as the best way to advance civilization, and through the process of globalization these beliefs are being exported to the world as a whole, making it not only less just but also less safe.[62]

In this quotation, the Nobel prize–winning geneticist John Sulston sounds at first as if he's saying that scientists are becoming solitary bowlers or selfish narcissists. Actually, he's criticizing the way in which the "business model" of science is changing from public to private benefit: what he calls "an intensifying belief in private ownership, to the detriment of the public good." Sulston doesn't just present this transformation in atomized individual terms, nor does he see it as primarily psychological, in the way of the narcissism model. Instead, he's suggesting that "through the process of globalization," a political and economic transformation, science is moving from We to Me.

Personalized medicine hasn't just sprung up in a political or economic vacuum. It has coincided with the ascendancy of "neoliberal" political ideology, which, as Sulston argues, has affected science and medicine profoundly.

This viewpoint isn't unique to Sulston: it is taken up and analyzed at considerable depth in Philip Mirowski's cleverly titled *Science-Mart: Privatizing American Science*. As a professor of both economics and philosophy of science, Mirowski is well qualified to track what he believes to be a deliberate political effort over the past four decades to incorporate neoliberal economic and political policies into academic science.

Neoliberalism

The package of economic and political measures known as neoliberalism typically includes the following policies:

- "Rolling back the state" through abolishing regulatory legislation and making stringent cuts in public spending, while simultaneously
- increasing the involvement of private corporations in key governmental functions, effectively privatizing areas of public provision such as education, health, and scientific research, thus
- transferring public wealth to private corporations through awarding monopoly contracts and outsourcing necessary services. The underpinning rationale is
- viewing markets as the only necessary form of discipline in any economy, in the belief that markets automatically correct their own mistakes, while simultaneously using public-sector funds to subsidize loss-making private activities. All these policies are premised on
- downplaying the notion of the public good or even denying that there is any such thing.

Neoliberalism—also known variously as "free-market economics," "globalization" (the term used by Sulston), or the "Chicago school," after the university associated with its leading exponent, Milton Friedman—gained political ascendancy in the United States and United Kingdom during the early 1980s. It is distinguished from nineteenth-century liberalism by its politically conservative tendencies: John Stuart Mill's liberalism was in some ways quite radical, for example, in his proposals that women should gain the vote and enter Parliament. Modern neoliberalism, however, is associated with the "neoconservative" movement—although, confusingly, in American politics a "liberal" is someone of the moderate political left.[63]

The hallmark of neoliberalism is the belief that state intervention, and in particular the welfare state, is harmful to free markets, which are the true

creators of wealth.[64] The influential political theorist Michael Sandel believes that "market triumphalism" is now so entrenched that rather than *having* a market economy, we quite simply *are* a market economy: markets control and define our society, with nonmarket moral values increasingly edged out.[65] Those values might well include those that Putnam praises: civic feeling, compassion, solidarity, altruism, and a sense that there is such a thing as the common good.

This dominance of the market is the source of the ideology of "private good, public bad," which I linked earlier in this chapter to the rise of Me Medicine and the decline of We Medicine. If the notion of common welfare is to be distrusted, and if interventions such as public health programs are regarded as interference with individual rights, We Medicine will automatically be suspect. Hostile reactions to vaccination programs, for example, aren't just a matter of a few vituperative cranks: they're sanctioned in an indirect way by a more general climate of distrust for any state initiative.

But although the official message of neoliberalism is "hands off," the actual policies pursued everywhere from banking to biotechnology involve state intervention to subsidize loss-making activity for the private sector. For banks, that's meant the losses made on junk bonds and subprime mortgages; for science, it's the non-profit-making research and development phases. In both cases, we often witness the conversion of the asset to private hands once it's profitable: what the sociologist Stuart Hall calls "siphoning state funding to the private sector."[66] In the UK banking sector, for example, the government rescued the failed bank Northern Rock with taxpayers' money, to avoid another collapse like that of Lehman Brothers in the United States. But it then overrode calls to keep the bank in national hands and sold it in November 2011 to Virgin Money, reportedly for something like half what it had paid for it.

In the United States, the Bayh-Dole Act of 1980 encouraged private capital to enter the scientific marketplace and promised to subsidize any losses incurred in the process. "To allow wealth from discoveries to be realized, the Act turned the principle of capitalism on its head: 'private risk yields private loss or gain' became 'public risk yields public loss or private gain'—a form of 'heads I win, tails you lose.'"[67] In April 2012, the Obama White House announced its "National Bioeconomy Blueprint," which "outlines steps that agencies can take to drive the bioeconomy" in a time of economic uncertainty, much in the spirit of Bayh-Dole.[68] Mention of any risks from genetic engineering or other technologies is confined to a footnote, otherwise framed as "beyond the scope of this document."[69]

We can trace this same neoliberal trajectory in the development of firms such as deCODE Genetics, which depended on the free public resource of the Icelandic national population database but retained all profits for itself.[70] It's also evident in the way that private umbilical cord blood banks in the United Kingdom often piggyback on NHS hospital staff provision and rely for their marketing appeal on the hope that stem cell research—typically funded by government research councils and thus by the taxpayer—will "add value" to the stored blood.

So it's not just a coincidence that personalized medicine has flourished at the same time that the majority of governments throughout both the developed and developing world—including India and China—are pursuing neoliberal policies. In many cases, the profitability of Me Medicine depends directly on those policies. At the highest governmental levels, public backing has been solicited to underpin private-sector profit making from biotechnology.

In Executive Order 13326 of September 2001, President George W. Bush established the Presidential Council of Advisors on Science and Technology (PCAST). This was a private-sector body with cabinet-level status—as if it were an arm of elected government. Its mandate was to "assist the National Science and Technology Council [the public body] in securing private sector involvement in its activities." Under President Obama, a new Executive Order, number 13539, reestablished PCAST on a less obviously proindustry footing but retained private-sector involvement. Its mission is now to "solicit information and ideas from the broad range of stakeholders, including but not limited to the research community, the private sector, universities, national laboratories, State and local governments, foundations, and nonprofit organizations."[71]

Where does the biotechnology industry see profits in personalized medicine? It's crucial to bear in mind the adage about capitalism not serving existing markets so much as creating demand where none existed before. Even the solidly middle-of-the-road Nuffield Council on Bioethics in the United Kingdom remarks of personalized medicine that "personalisation is sometimes represented as a response to demand, but in some cases at least it seems to be a case of supply looking for demand."[72] Private cord blood banking and retail genetics are both perfect examples of creating demand where none existed before. Who would have predicted twenty years ago that you could get people to pay to bank their infant's umbilical cord blood or to have a spit sample analyzed to predict their personal propensity to common diseases?

Even pharmacogenetics, which goes back further than either of those technologies and has a stronger evidence base, also demonstrates political and

economic elements. The PCAST report of 2008 states quite openly that industry's interest in pharmacogenetics is dictated not only by scientific developments but also by cost and market considerations. Because trial and control groups can be genetically matched more closely, pharmacogenetics potentially reduces the size, cost, and duration of expensive clinical trials. With over 70 percent of drug trials now performed in the private sector,[73] the drug industry sees cutting trial costs as crucial to profitability (even though prominent critics such as Marcia Angell, the former editor of the *New England Journal of Medicine*, think that the industry actually spends far more on lobbying than on product development).[74] The PCAST report also holds out the hope for industry that failed trials might still work on subsectors of the clinical population, so that research investment made in dud drugs wouldn't go to waste.

Even more important, for a pharmaceutical industry facing the expiration of patent protection on many of its best-selling drugs is finding new markets. By breaking an existing medication down into different "size ranges" and persuading customers that they can't simply rely on a one-size-fits-all product, pharmaceutical companies can create new niche markets. Similarly, private umbilical cord blood banking taps into a huge potential market—all expectant mothers who can afford it, plus grandparents—with a "product" that no one could have dreamed of before but that diligent parents and grandparents may now wrongly believe is essential to the child's future health.

It would be even more advantageous for the pharmaceutical industry if the individual patient could be persuaded to pay for genetic typing out of her own pocket, so that she would then know which of the niche pharmaceuticals is her "size." Although they're too imprecise at the moment to allow for that, and while they test for only a fraction of relevant SNPs, retail genetic tests accustom healthcare consumers to the idea of personalized drug regimes. In some cases, the link isn't just psychological: it's much more direct. Before it shut down its DTC service after being acquired in summer 2012 by Life Technologies, Navigenics had begun offering an additional pharmacogenetics service for its existing DTC customers: "Genetic insights from Navigenics can help you and your doctor select medications that may be right for your genetic makeup."[75]

Now that the thousand-dollar whole-genome scan has become a reality, customers could conceivably have all their personalized genetic information ready for access when needed, so that prescribing on a pharmacogenetic model could become much more commonplace. And if customers pick

up the tab for genetic testing, none of this will have cost the drug companies a bean. So the costs of diagnostics are beginning to be transferred from the public health system or insurers to the private individual while profits are transferred from the private individual to private companies. This process is quite consistent with the flow of income predicted by the neoliberal economic model.

Another potential source of profit from personalized genetic testing lies in biobanks—tissue and data repositories that can be sold to other firms or mined for research. Why are major retail genetic companies willing to sell direct-to-consumer tests at fire-sale prices? In chapters 2 and 7, I'll examine the possibility that the test could be a loss leader for a potentially lucrative biobank—particularly because of clauses specifying that the genetic analysis remains the property of the firms. A central National Institute of Health biobank was one of the demands made on government by the private interests in PCAST. But without a nationalized health service to recruit donors free of charge, which has benefited the 500,000-genomes-strong UK Biobank, there's no alternative for U.S. corporations but to recruit privately, as cheaply as possible. Some observers think that the acquisition of health and genetic data, as well as a patent portfolio, is the real business strategy of the retail genetics industry.[76] This supposition began to look highly plausible in June 2012, when 23andMe was awarded a potentially profitable patent on a genetic variant that appears to protect against a high-risk mutation for Parkinson's disease.

Those customers who buy these tests probably labor under the illusion that they continue to own their personal data and their tissue samples. That argument was put forward in a recent blog debate by neoliberal proponents of retail genetics who oppose FDA regulation of the tests: that it's not up to government to tell people what they can do with their own bodies and with information about their bodies.[77] But that argument is mistaken: as I'll elaborate in chapter 2, once tissue has left the body, common law traditionally treats it as *res nullius*—no one's thing. Originally that tissue was presumed to have no value because it was diseased. But modern biotechnology has radically altered the financial position, although the legal position is largely unchanged.[78] That's left a vacuum for corporations, researchers, and universities to claim legal ownership of the tissue once it's in their hands.[79]

Precisely because so few consumers realize that they're actually surrendering ownership of their tissue to the firm once they've sent off the sample, and because the corporate interests in retail genetics are often powerful, consumers are vulnerable. Me Medicine is typically portrayed as empowering, but the

real power and legal rights rest with the corporate interests in this case, particularly when they're backed up by neoliberal government policy. Those same policies increasingly spell trouble for We Medicine policies in public health and funding for medicine outside the private sector, as the grim prospect of austerity measures in the public sector stretches out into the foreseeable future.

In addition, Me Medicine could well increase the demands by patients on healthcare systems, for example, if they've bought retail genetic tests that reveal false positives seemingly requiring treatment when they're actually perfectly healthy. (Think back to David Ewing Duncan's urgent phone call from Kari Stephansson of deCODE Genetics, insisting that Duncan should go onto statins immediately because of results that were later contradicted by other DTC services.) Such extra demands on healthcare services are a sort of externality: the costs are passed on to public or private insurance systems. Whether it's a public or a private provider who picks up the tab, in neither case are they borne by the direct-to-consumer test provider.

Risk sharing is the principle behind both insurance-based U.S. health care and UK semisocialized medicine—even if the groups across which the risk is shared may differ. That principle is threatened when risk stops being shared because low-risk individuals identify themselves as such through personal genetic tests and high-risk patients are either booted out of the scheme altogether or limited to a very minimal package of health options. So the conflict between neoliberal ideology and social solidarity, Me and We, is central here and in many other areas. In chapter 7, I'll provide a much more extended discussion of the notion of the public commons. Now, however, I want to move on to the final hypothesis about why Me Medicine is on the rise: the elevated status in our culture of choice and autonomy.

THE SACREDNESS OF PERSONAL CHOICE AND INDIVIDUALISM

We've already seen that personalized genetic testing plays heavily on the first-person singular: deCODEme, Knome, 23andMe, and their like. That's the personal part: the choice part is equally important. Autonomy and its partner, choice, are the paramount values in the dominant paradigm of medical ethics[80] and, arguably, in society as a whole.

In medical ethics, autonomy originally played an important role in elevating patient-centered care over medical paternalism, which is the notion that "doctor knows best" in judging the interests of the patient. The ideal of patient-centered medicine insisted instead that the wishes of competent adult patients should be respected, even if it meant refusing potentially life-saving treatment. Autonomy is also central to the Declaration of Helsinki principles for research ethics, to protect those who might be coerced into consenting to take part in trials. Autonomy came to be seen as the most important of the "four principles" (along with beneficence, nonmaleficence, and justice), in the approach that dominated the teaching of medical ethics for many years in the United States and United Kingdom.[81] Outside observers, however, have contended that the overemphasis on autonomy has impoverished medical ethics as a whole.[82]

Yet the supremacy of autonomy and individual choice in medical ethics hasn't gone unchallenged.[83] "The choice model falsely reduces all ethics to whether something is genuinely chosen, which results in minimising all other injustices."[84] Feminist bioethicists have asked whether autonomy is too individualistic and if it needs to be balanced with a focus on relationships and power.[85] Some medical ethicists have examined the comparative claims of autonomy and trust[86] or have advocated a more communitarian approach.[87] Others have followed such thinkers as Hans Jonas in arguing that in an age of unpredictable technological change, we need to think more about our communal responsibilities than our individual rights.[88]

More sophisticated concepts of autonomy do distinguish between acting on your immediate inclination and acting in accordance with your stable value system, arguing that only the second kind of choice is genuinely autonomous.[89] But that seems a long way from the manner in which personal choice is used as a mantra in personalized medicine, as later chapters will show.

The exalted place of personal choice is not a cultural universal. In France, for example, the values of solidarity and protection for the vulnerable regularly trump free markets, choice, and individualism in framing bioethics laws.[90] Likewise, the Nordic countries are concerned that their more communal values may be threatened by an overemphasis on choice in consumer medicine.[91] But in the United States, it's been said, liberals are almost as prone as conservatives to elevate individual freedom over the welfare of society.[92] By selecting the "right to choose" as likely to be the most psychologically and politically effective counterweight to the "right to life" in the abortion debates,

progressives unwittingly hitched their wagon to what later turned out to be the ubiquitous neoliberal ideology of choice.

It's much the same with commercial "surrogacy" (more accurately termed pregnancy outsourcing, since the "surrogate" mother is the real mother in our common-law system). There, paternalism—denying someone freedom of choice—is used as a knockdown argument against which there's meant to be no recourse: "That doctors would be so paternalistic as to deny women the option of using a surrogate if the surrogate were willing to do so is simply outrageous."[93] The same tactic is used with organ sale: "To ban a market in organs is, paradoxically, to constrain what people can do with their own lives."[94] But some see this maneuver as a form of censorship—and censorship is not known, of course, for enhancing individual choice:

> [This] argument shows why focusing only on autonomy silences other ethical concerns, as to deny the validity of choice or the permissibility of a chosen act is to be "paternalistic," "disempowering," "moralistic," "patronising"—and lots of other not so nice things: . . . paternalism is a particularly dirty word in ethics. As a result it becomes impossible to critique any practice if someone—anyone—has chosen it—as to do this is apparently to deny and undermine someone's autonomy. . . . In this way then the consent model reduces all ethics to choice and silences and trumps other ethical concerns. This does not protect the individual, but leaves him or her vulnerable and open to exploitation.[95]

In a less blatant manner—but probably only because the debate hasn't really got going yet—discussion about direct-to-consumer genetic testing has centered on whether it enhances personal responsibility for detecting and directing your own future health or whether the information available to consumers is too misleading to allow a genuinely informed choice. Those questions matter, but they aren't the end of the affair. In particular, they have nothing whatsoever to say about the harmful effects of Me Medicine on We Medicine, particularly when denial of free choice is used summarily to dismiss vital public health measures such as vaccination programs or travel restrictions during epidemics.[96]

Choice isn't a knockdown argument in personalized medicine. As with prostitution or pregnancy outsourcing, even if individuals make choices, those choices influence and are influenced by the social context in which the practice is embedded. It is a blatantly false assumption that whatever you do,

you've chosen to do—and that you've made your individual choice independently of any social, political, or economic factors. That's actually a very simple point, but it has to be made and repeated constantly in our culture. In the unfamiliar context of a new biotechnology such as retail genetics, there's a particular temptation not to think through the wider social consequences but simply to fall back on the old familiar argument: "what's the problem, if that's what people choose to do?"

The philosopher Zahra Meghani argues that we always have to understand individual medical choices, such as whether to go abroad to buy eggs or to hire a "surrogate" mother, in the context of global neoliberalism and its core policies: privatization, deregulation, and commodification.[97] Rather than an apolitical, one-size-fits-all argument like choice, we also have to understand local realities. Of course, it's not just the Third World that possesses its own local realities: very particular factors characterize American culture as well. In this chapter, I've made a start on examining some of those factors that might be particularly relevant to the push for consumer medicine—including a sense of threat, consumerist narcissism, and corporate interests. Taking personal choice at face value closes down that analysis before it's even properly begun: it's a lazy argument that does none of the necessary work.

The effect of the failure by those on the political left to challenge the mantra of personal choice is that progressives have too readily retreated from challenging the neoliberal deregulation of biotechnology and corporate interests when representatives of those interests accuse them of wanting to limit consumers' freedom of choice.[98] They haven't done all they could to identify the phenomenon of Me Medicine and to challenge its reliance on personal choice as a knockdown argument. Simultaneously, progressives have found it difficult to challenge the reaction against communitarian forms of medicine as wrong because they limit individual choice—the argument used to lambast President Obama's healthcare plans, vaccination programs, or swine flu epidemic restrictions.

The situation is worsened in the United States by the "stem cell wars," in which it was assumed that progressives would automatically be on the side of science, standing against the evangelical right's campaign to outlaw embryonic stem cell research. Liberals and progressives may be tempted to ignore moral issues in the new biotechnologies because they fear being lumped in together with the religious right. In the case of new biotechnologies such as direct-to-consumer genetic testing and enhancement, the corollary is that they may be unwittingly prone to support Me Medicine against We Medicine,

even when their sympathies would more naturally lie with the latter. These issues are nothing if not complicated: I'll examine a particularly tough one for political progressives in chapter 3: the development of supposedly "race-specific" drugs such as BiDil.

While the notion of the social contract may still be more or less intact in Scandinavia, it was never particularly strong in the United States, and even among academics and activists it's been weakened—inadvertently—by well-grounded liberal critiques of the way in which it favors one sex or race over another. The social contract as an instrument of civic subordination was brilliantly analyzed by Carole Pateman in her 1988 book *The Sexual Contract* and by Charles Mills in his 1997 work *The Racial Contract.* Pateman's crucial insight was that liberal contractarian theory is blind to the way in which the "original position,"[99] from which the state is constructed by voluntary contract, is not really "original" at all. It must be preceded by another sort of compact, in which male domination over women has been established through the mechanism of the patriarchal family, since those establishing the contract in the "state of nature" are generally assumed to be men. Mills builds on this insight to demonstrate how even after the abolition of slavery, people of color likewise continue to be subordinated and oppressed through the mechanism of a supposedly consensual contract in liberal democracy: the consent of the governed.

In their collaboration *Contract and Domination*, Pateman and Mills differ crucially on how refractory the concept of contract really is. While Mills thinks that contract theory can be "modified and used for emancipatory purposes,"[100] Pateman continues to maintain that contract is inherently an instrument of domination—although other feminists have argued that what's wrong with the sexual contract is not that it is a contract but that it is sexual.[101] Because the so-called marriage contract—actually not a legal contract at all—was blatantly oppressive, feminists had good reason to distrust the social contract more generally. But along with the other factors sketched out in this chapter, that skepticism may have inadvertently encouraged distrust of "We"-ness when it represents false inclusivity.

Unconstrained commodification of the body seems to Pateman to make the concept of the social contract even more suspect. "Commodification is proceeding at such an extraordinarily rapid rate; there is virtually nothing left now that is outside the reach of private property, contract and alienation," she remarks to Mills in a dialogue at the outset of their joint book. "That is one reason why I'm much less happy than you with trying to salvage contract

theory."[102] But without some notion of common interests in healthcare embodied in something like contractual form, what protects us against the unstoppable rise of Me Medicine? That may sound like pastry in the stratosphere, but international agreements and treaties such as the European Patent Convention have been used to good effect in protecting the human genome, as the joint property of humanity, against "the great genome grab" of commercial patents. Likewise, Article 14 of the 2005 UNESCO Universal Declaration on Bioethics and Human Rights introduces a principle of social responsibility for health, transcending shopworn individualistic bioethics.

I'll return to these considerations in the final chapter, when I try to establish how we can reverse the trend elevating "Me" above "We" in how we use modern biotechnology—how we can reclaim it for the common good. Now it's time to analyze that technology in greater detail. In suggesting four possible reasons why "Me" is privileged over "We"—threat, narcissism, corporate interests, and the sacredness of choice—I've begun by situating the technology in its wider cultural and political context. The next step is to apply those four hypotheses to four areas of Me Medicine: retail genetics, pharmacogenomics, private umbilical cord blood banking, and enhancement technologies.

2

"YOUR GENETIC INFORMATION SHOULD BE CONTROLLED BY YOU"

Personalized Genetic Testing

In June 2011, at the third annual Consumer Genetics Show, the biotechnology company Illumina Incorporated unveiled its *MiGenome* application for the iPad tablet computer. (That's a double dose of the first-person singular: the possessive "my" added to the "I" in iPad.) Once you'd had your entire genome sequenced by Illumina—at a price of $9,500, reduced from the previous $19,500—*MiGenome* would ostensibly allow you to check your susceptibility to genetically based disorders. You could also find out how, given your genetic makeup, you would probably respond to particular drugs. *MiGenome* would display your entire genome, but if even the reduced price was too much for your pocketbook, you could buy a cheaper testing package, which would provide the results for a more limited range of genetic markers. As we discussed in the last chapter, like *MiGenome*, these "retail genetics" tests are steeped in the "Me" brand, with company names such as 23andMe, deCODEme, and MyGenome.[1]

Even when government has tried to regulate the consumer genetics sector, it has unwittingly accepted the language and underpinning philosophy of Me Medicine. In Massachusetts and Vermont, for example, proposed genetic privacy legislation declares, in identical language, that "genetic information [is] the exclusive property of the individual from whom the information is obtained."[2] But our common law traditionally has held that we have no property

in tissue once it's left the body—whether through the minor inconvenience of a "spit kit" or a major surgical procedure. It was considered *res nullius*—no one's thing—because it was presumed to be diseased and to have no commercial value. So, no, you don't necessarily own your tissue or the information derived from it—still less own it exclusively. Whether it would be a good thing if you did will be discussed in a later section of this chapter—but the Massachusetts and Vermont legislators seemed unaware that you don't. The language of "I, me, mine" is by no means straightforwardly appropriate to genetic information, common though it is.

Yet oddly enough, the Vermont bill also stipulates that genomic information should be part and parcel of *We* Medicine. Elsewhere, in section 9336(e), the proposed statute states:

> Information derived from the sequence of the human genome shall be part of the public domain and shall not be considered the property of any individual. Nothing in this chapter shall be considered to grant an ownership right to any individual or entity utilizing the publicly held information from the sequence of the human genome in the furtherance of a venture or enterprise, including any genetic goods, products, or services.[3]

What could explain such a blatant contradiction? Possibly the legislators were trying to distinguish between *the* human genome, conceived as the common heritage of humanity,[4] and *a* human genome, exclusive to one individual. Or perhaps they were grappling, without fully realizing it, with the intricate and genuine conflict between Me and We Medicine, as emblematized by direct-to-consumer (DTC) personalized genetic testing. Their concern in the second quotation is "the sequence of the human genome in the furtherance of a venture or enterprise, including any genetic goods, products or service"—and the most visible and contentious of those services, at present, is DTC genetic testing. Another New England state, Connecticut, already prohibits it, requiring a doctor to be the intermediary between test and patient.

Consumerized genetic testing has become a lightning rod for controversy, both because it involves a direct link between researcher, industry, and consumer and because it is predicated on premises that genomic research does not fully support. Furthermore, different DTC companies offer different results for identical DNA samples. It's not yet possible to aggregate independent risk factors into a net risk score.[5] Reliability has not been certified, and no professional organization standardizes the tests.

Although it's still not a huge sector in terms of dollars or customers, retail genetics has become a highly visible symbol for personalized medicine more generally. Recently it has also become the site of conflict between those who think that buying into DTC genetic testing should be a matter of personal choice and those who believe that it needs public regulation. About half of U.S. states either prohibit or limit it, like Connecticut, but the rest leave it alone. So there's a clash of Me and We ideologies, with proponents of direct-to-consumer genetic testing using the individualistic language of empowerment, choice, and responsibility against the notion that society has an interest in limiting potential risks.

As the 23andMe website says, "Take charge of your health and wellness: let your DNA help you plan for the important things in life." The firm also declares: "We believe your genetic information should be controlled by you."[6] A former direct-to-consumer genetic testing firm, Navigenics, stated: "We use the latest science and technology to give you a view into your DNA, revealing your genetic predisposition for important health conditions and empowering you with knowledge to help you take control of your health future."

At first glance, that mission seems laudable. Particularly when DTC genetic testing is targeted not at comparatively trivial traits such as athletic ability or earwax buildup—and yes, you can get tests revealing your supposed personal predisposition to both of those—it could be seen as harmless at worst and even admirable in more serious cases to confront your genetic risks. That seems particularly plausible for tests of your risk of passing on inherited diseases to your offspring, rather than your own susceptibility. In fact, some bioethicists argue that parents at risk for possibly life-threatening conditions have a moral duty to undergo genetic testing in the form of preimplantation genetic diagnosis of the embryo—a responsibility that they claim could and should even become a legal requirement.[7]

In January 2010, a company called Counsyl began offering a $349 saliva sample test to identify alleles for common but serious hereditary illnesses such as cystic fibrosis and sickle-cell disease. For those and other recessive genetic conditions, prospective parents can be carriers without manifesting the disease themselves. Having yourself tested seems quite a responsible thing to do before you start a family—intrinsically recognizing "We"-ness with your potential child.

So is it anything more than trivially symbolic that retail genetics uses the language of "I, me, and mine" so readily? To begin analyzing these questions,

we first need to get a better understanding of the historical background of personalized genetic testing.

"THE REST OF THE POPULATION CAN BE ALLOWED TO PUFF AWAY CONTENTEDLY"

The announcement, on June 26, 2000, of the draft sequencing of the entire human genome generated tremendous optimism and excitement, which still linger in the aura surrounding personal genetic testing. In chairing a joint announcement with Prime Minister Tony Blair, President Bill Clinton called the announcement of the Human Genome Project's draft results "a day for the ages."[8] Clinton went on to declare, "This landmark achievement will lead to a new era of molecular medicine, an era that will bring new ways to prevent, diagnose and treat disease."[9]

It was widely expected that common diseases would be found to have a considerable genetic component and that once the genetic code was cracked, clinical cures would quickly result. In 2001, the Human Genome Project's director Francis Collins and his colleague V. A. McKusick predicted that there would soon be reliable genetic tests for up to a dozen common conditions, so that general practitioners would essentially become genetic counselors.[10]

Two years later, there were a dozen private companies advertising genetic susceptibility testing for individuals to purchase via the Internet, but very little progress had been made in tracking the genetic causes of the most widespread forms of illness. By 2009, the number of these testing firms had risen to thirty, some offering very specialized testing for characteristics such as athletic ability—blazoned under the advertising slogan "Olympic success might be in your future!"[11] In 2011, the consumer genetics industry was estimated to include nearly one hundred companies.[12] These firms' strategy has rested not so much on the very patchy medical and scientific evidence base as on convincing venture capital that a demand for personalized testing exists, thereby creating high expectations for returns—and then creating the demand from consumers to match.[13]

Compared to the logarithmic increase in the number of retail genetics companies, there's been nothing like the same exponential rate of growth in genetic medical diagnostics, let alone cures.[14] As one journalist put it: "After 10 years of effort, geneticists are almost back to square one in knowing where

to look for the roots of common disease."[15] For example, in the major area of cardiovascular illness, a twelve-year study of 19,000 women found no significant correlation between 101 genetic variants linked to heart disease in genome-scanning studies and the actual incidence of such disease.[16] This study typifies the position for common illnesses caused by many genes—but not by genes alone. Unfortunately, those common diseases are the biggest killers.

There's been a great deal of discussion about why the Human Genome Project seems not to have fulfilled its scientific promise. One major surprise was that the human genome contained far fewer genes than expected: between 23,000 and 25,000, rather than the predictions of as few as 50,000 and as many as 140,000. (You may recall a certain amount of shamefaced speciesism at the time, comparing our paltry number of genes to those of fruit flies and other so-called primitive creatures.) But you might think that fewer genes would mean simpler diagnostics and less complicated pathways to therapies, so that if anything, Collins and McKusick's prediction would have been too modest.

Instead, subsequent developments showed that our comparatively limited palette of genes can create complex color shadings. Variation is hidden in a diversity of nonlinear interactions between the proteins coded by genes[17] and between genes and environmental factors affecting the way they're expressed.[18] That second set of factors, studied by the emerging science of *epigenetics*, involves modifications to our genetic material affecting the ways genes are switched on or off. While each of our cells contains the same genetic "code," that code can produce everything from eyeballs to teeth. We're really only just beginning to unravel the full complexity of the epigenetic modifications that ensure that each cell does what it's supposed to.

Already, however, there's a radical change of mood in genomic science—and "science is just as prone to mood swings and fashions as any other human activity." Although "there was a period when the prevailing orthodoxy seemed to be that the only thing that mattered was our DNA script, our genetic inheritance . . . that can't be the case. . . . The field is now possibly at risk of swinging a bit too far in the opposite direction, with hardline epigeneticists almost minimizing the significance of the DNA code. The truth is, of course, somewhere in between."[19]

Even at the time the draft human genome sequence was announced, it was already known that there were no "good" or "bad" genes, just complex relations between networks of genetic and epigenetic factors.[20] Only for a very small minority of illnesses is there a direct one-to-one correlation between having a particular form of a gene and manifesting a disease.

Single-Gene Disorders and Mendelian Genetics

The Mendelian genetics that you learned in Biology 101 is based on experiments done in the 1860s with plant characteristics whose variations are caused by single genes: in the peas with which Mendel worked, for example, the variations included wrinkled versus round seeds, tall versus dwarf stems, or grey versus white seed coats. In each case, one characteristic is dominant and the other recessive, with the phenotype (the physical appearance) determined by the dominant allele in the genotype (the genetic makeup of the plant). If, for example, a pea plant has one allele for wrinkled seeds and one for round seeds, the seeds in the pods will be round, with the recessive wrinkled allele suppressed by the dominant round one. But if crossed with another pea plant that also has one wrinkled and one round allele, there's a one-in-four chance that the new offspring plants will inherit two recessive wrinkled versions of the gene and display the wrinkled seed form.

In a very few human medical conditions, Mendelian genetics does apply straightforwardly: for example, in Huntington's disease, which is a *dominant* condition linked to a single gene. Inheriting one unfavorable allele of that gene from *either* parent is sufficient for the disease to be manifested, because the disease-producing allele is dominant over the "healthy" variant from the other parent. By contrast, in *recessive* conditions such as cystic fibrosis, the child must inherit two disease-linked alleles, *one from each parent*, before the condition manifests itself. If only one parent conveys the unfavorable allele to the embryo, the dominant "healthy" allele from the other parent effectively cancels it out. Mendelian genetics also applies to beta-thalassemia, sickle cell disease, and Canavan's disease, but comparatively few illnesses are purely "in the genes." Even for Huntington's disease, things aren't that simple: the age of onset depends on the number of repetitions of the genetic marker.

More typically, the way in which common diseases are linked to tens or even hundreds of genes, each explaining only a tiny fraction of the variance between healthy and sick individuals, means that genetically based diagnosis in any particular case is at best a probability rather than a certainty. Family history is still a better predictor than genetic analysis of common conditions like cardiovascular disease.[21]

There's also a subtle but crucial difference between predicting the likelihood of a particular *individual* contracting a particular disease and testing entire *populations* for genetic susceptibility.[22] This distinction—another form

of Me versus We—is highly relevant to personalized direct-to-consumer testing. Although the DTC companies assert that their tests are not the equivalent of a doctor's individual diagnosis, one study found that a third of customers believed that they were in fact purchasing a diagnosis.[23] Yet the results are not individual diagnoses but rather comparisons of how any individual stands in comparison with general populations when it comes to the likelihood of contracting a particular disease.

So how could the Human Genome Project scientists have believed that the majority of common diseases would follow anything like the one-to-one Mendelian pattern? If they themselves knew better, why did they allow the impression to be given that things would be much simpler than they've turned out to be? Teasing out the answer requires us to look at the history of the project—in particular, at the possible tension between the massive amounts of public money that poured into it and the private interests of commercial firms, particularly tobacco companies.

The Human Genome Project (HGP) appears to be a genuine exemplar of We Medicine, at least in its original conception—regardless of whether some of its applications were later converted by commercial genetic testing companies into Me Medicine. It was certainly public in its original funding, through the U.S. National Institutes of Health, UK charity the Wellcome Trust, and the UK Medical Research Council. By releasing into the public domain some 1.8 million genetic markers called SNPs (single nucleotide polymorphisms, explained at greater length in the next section of this chapter), the publicly funded HGP also laid the basis for the private genetic testing companies to market their SNP-based wares.[24]

But some researchers have asked whether the HGP's grand aims for humankind were in fact dictated by private commercial interests from the very start. Those interests, they allege, were always focused on Me rather than We—using genome research to identify *individuals* who were particularly susceptible to lung cancer if they smoked and not on identifying *population* propensities to a much greater range of illnesses. What's the evidence for this astounding claim?

As early as the 1950s, the tobacco industry began to promote the idea that an unknown gene both drove people to smoke *and* predisposed them to lung cancer. It was in the industry's interest, some researchers allege, to promote genetic screening in order to convince ambivalent smokers that they had no need to quit.[25] In the words of a memorandum sent by the public relations firm Burson-Marsteller to the tobacco firm Philip Morris: "A simple test

might eventually be devised to tell a smoker whether or not he is at risk. This would put the burden for any consequence from smoking on the individual and would clear the way for the non-susceptible population to smoke with a clear conscience."[26]

Then, as the industry consultant Frank Roe put it: "the rest of the population can be allowed to puff away contentedly and without serious risk."[27] This strategy clearly puts the burden of responsibility entirely on the individual. We Medicine measures such as public campaigns to raise awareness of the fatal risks of smoking would be pointless if those members of the general public who were not genetically susceptible ran no risk.

That single memorandum wasn't just an isolated occurrence. The industry's Council for Tobacco Research gave evidence to the U.S. House of Representatives in 1994 that it had already awarded nearly $225 million to sponsor "pioneering work in identifying familial cancers, the role of genetic factors in cancer formation and the identification of oncogenes [cancer-related genes]."[28] Scientists funded by the tobacco industry allegedly published spurious findings to convince funders that human genome sequencing would be useful in predicting who develops common diseases.[29]

No one claims that tobacco-funded scientists *deliberately* falsified results; rather, "the false claims resulted from poor science and a process by which tobacco-funded scientists benefited from fast-tracked careers, financial and political support, and access to the media to promote the industry's messages: that cancer is a genetic disease and prevention depends on screening people's genomes so that lifestyle and medical advice can be targeted at those at high genetic risk."[30] Even when the research wasn't spurious, it was orchestrated with a view to determining one-to-one individual susceptibility of the Mendelian kind. It's no surprise, if this is true, that human genome sequencing hasn't turned out to be as useful in unraveling common diseases as the grander claims suggested it would be, since common diseases rarely fit the simple Mendelian model.

These are unsettling charges, but they have been made by several separate groups of researchers, are backed up by extensive data gathering, and draw from damaging documents revealed by the tobacco firms only after litigation forced their hand. These sources have revealed secret meetings between leading scientists and British American Tobacco as early as 1988, before the launch of the HGP. Genewatch UK researchers also claim to have uncovered links between the tobacco industry and Kari Stefansson, president of one of the original DTC companies, deCODE, now part of U.S. biotech firm Amgen.

Meanwhile, work published by the Mayo Foundation for Medical Education and Research has drawn attention to the consistency of the tobacco industry's strategy, from pre-HGP days to the present.[31]

Although the genetic basis for tobacco addiction may originally have looked like an industry pipedream—excuse the pun—it now appears more scientifically plausible. In the past, however, the industry sought to *deny* that nicotine was addictive. Now their strategy, according to the Mayo researchers, is to accept that smoking is indeed addictive but to subvert genetic research into narrowing the risk of addiction to "unsafe" smokers.

> The search for a genetic basis for smoking is consistent with industry's decades-long plan to deflect responsibility away from the tobacco companies and onto individuals' genetic constitutions. Internal documents reveal long-standing support for genetic research as a strategy to relieve the tobacco industry of its legal responsibility for tobacco-related disease. Industry may turn the findings of genetics to its own ends, changing strategy from creating a "safe" cigarette to defining a "safe" smoker.[32]

This quotation indicates that the history behind the Human Genome Project and the search for an individualized model of responsibility for health isn't *just* history. That's important because it deflects the charge that all this is merely of interest to historians of medicine. But even if we accepted for argument's sake that the motivating forces behind personalized genetics were tainted, that wouldn't allow us to conclude that the science is necessarily faulty. To evaluate that question, we need to look at a different set of evidence.

EVALUATING PERSONALIZED GENETIC TESTING

The testing package offered by Illumina would sequence your entire genome: that is, it would determine the order of every single one of your base pairs, resulting in a library or personal genomic database of three billion letter combinations and potentially laying the basis for genuinely personalized medicine.[33] Whole-genome sequencing is what the Human Genome Project achieved for the first time, with final results announced in 2003, following the highly publicized launch of the draft sequence in 2000. But those results weren't personalized; that is, no single individual was sequenced. The se-

quenced genome was a composite of several anonymous people recruited through advertisements in the *Buffalo News*.

Mapping this composite genome required $3 billion in funding and thirteen years of research. Since then, the cost of whole-genome sequencing has tumbled so fast, assisted by $14 million in grants for that purpose during 2011 from the National Human Genome Research Institute, that the thousand-dollar genome is now here, as was announced in January 2012. Going that figure one decimal point better, a report from the JASON group of science advisers at the nonprofit Mitre Corporation predicted that "the $100 genome is nearly upon us."[34]

Whole-genome analysis takes the raw data obtained from sequencing and applies filters that target certain parts of the genome, dimming the "noise" of less relevant data. Since the genomic scientist and entrepreneur Craig Venter published the complete sequence of his own genome in 2007, a number of celebrities, from Glenn Close to James Watson (of double helix fame), have had their entire genomes sequenced. Meanwhile, the Personal Genome Project run by George Church at Harvard has enrolled a growing number of subjects—with sixty-four genomes completed at the time of writing—for whole-genome analysis, the first guinea pig being Church himself.[35] (Although itself not for profit, the Personal Genome Project has a link to Google Health for phenotype collection, and Google in turn has a potential link to 23andMe through its cofounder Sergei Brin, who is married to 23andMe's CEO, Anne Wojcicki.)

Comparatively cheap whole-genome analysis may perhaps become standard in the future—or it may not. We saw that Illumina charged nearly ten times as much as a "thousand-dollar genome," even though the firm has reduced its prices. Yet a thousand-dollar test is considerably more expensive than the cheapest packages offered by leading DTC companies, which typically range from $399 to $2,000 but can come in as low as $99—or in some cases, free, provided that the genetic data is treated as the property of the firm and that customers agree to provide additional information about their health. On August 1, 2011, under the slogan "Roots Into the Future," 23andMe announced free testing for ten thousand African American customers, on condition that the data and DNA samples remain in the company's hands.

Even when they don't offer their services free of charge, how do these companies achieve their bargain-basement prices? Essentially, they don't sequence the entire genome: they concentrate on a far smaller number of markers—up to 1.8 million (that may seem like a lot, but it's still a far cry from three

billion). This strategy brings down the price, but it has also been criticized for diminishing the scientific value of the enterprise. Consumer genetics firms all choose to sequence different sets of markers, and thus they return very disparate results.[36] Researchers from the Erasmus University Medical Center in the Netherlands and Harvard Medical School examined two widely available tests and found that their results for common diseases such as diabetes and prostate cancer were radically inconsistent because of the low numbers of markers involved and the small amount of genetic variance that each marker explains.[37]

What Is an SNP?

The main target of DTC genetic testing is the single nucleotide polymorphism (SNP), a point where the genomes of different individuals vary by a single DNA base pair.[38] These markers are derived from genome-wide association studies (GWAs), population-level genomic research aimed at determining the correlation between common diseases and certain areas of the human genome. Researchers compare people with the disease and similar people without the illness, obtaining DNA from each participant and placing it on sequencing chips, which analyze the person's genome for strategically selected markers of genetic variation, that is, SNPs.[39] They then determine whether particular SNPs are associated with particular diseases by statistical significance techniques, converting the numbers into disease susceptibility risk figures.

Clearly, a higher level of significance is required to establish a definite disease susceptibility association if the number of SNPs is limited, since each SNP only covers a fractional amount of association with any of the common diseases. But commercial DTC firms must of necessity limit the number of SNPs that they examine. Of the leading retail genetics companies, 23andMe covers about 600,000 SNPs, and deCODEme, roughly 1.2 million. Navigenics had tested for about 1.8 million markers, of which 906,000 were SNPs and the remainder probes for copy number variation.[40]

Yet even Navigenics tests were found in a study led by the founding director of the Cleveland Clinic, Dr. Charis Eng, to provide imperfect guidance on their own—without family history–based assessment—for any individual's personal risk of developing three common forms of cancer (breast, prostate, or colon).[41] While family history indicated that eight individuals were at high

risk for breast cancer, only one of the eight was classified as high risk when assessed via personal genetic testing. Overall, family history assigned twenty-two individuals to the hereditary elevated risk category, but DTC testing identified only one of these individuals as high risk. The researchers also assessed nine individuals with hereditary risk for colorectal cancer, five of whom had proven mutations defining inherited colorectal cancer syndromes. None of the nine was classified as high risk when assessed through DTC analysis.

Eng and her colleagues are convinced that family health history is still the gold standard in personal disease risk assessment—and it's cheaper too. She adds that this type of information can be readily gathered by the patient—which might actually enhance your autonomy and sense of responsibility for your own health more effectively than paying a corporation for a spit test. (In fact, taking your own family history could combine "Me" and "We" quite nicely.)

As Martin Richards has written of his own experience of DTC testing, "The companies' literature seems to promise that they can tell us more about ourselves than we can know for or by ourselves alone. In that sense they actually undermine our autonomy."[42] Perhaps DTC tests might even decrease your sense of individual control if you find that the results you've paid good money for contradict one another, or if you realize that nothing can be done about the condition to which you've now been told you're susceptible.

There's also a very real risk that asymptomatic healthy people may come to define themselves instead as merely "presymptomatic," making us all patients from the cradle to the grave.[43] As George Church of the Personal Genome Project says, "Even if these highly predictive and actionable [variations] are considered rare, everyone is at risk and should be just as willing to spend on this as on fire insurance and other unlikely contingencies."[44] Church's view illustrates the way in which direct-to-consumer genetic testing plays, whether deliberately or not, on a sense of threat. But how does permanent patienthood enhance our autonomy?

For those who have a family history of risk for genetically linked cancers, it's perhaps a different matter—but not all that different. The most recent policy update from the American Society of Clinical Oncology[45] accepts that genetic testing for personal cancer susceptibility is now a routine part of clinical care, especially for high-penetrance mutations like the alleles of the *BRCA1* and *BRCA2* genes implicated in some breast and ovarian cancers. However, the society also notes that such cancers, though serious, account for only a small percentage of all cancers.

Cancer-related combinations of sequence variants have been identified through genome-wide association studies, along with over one hundred

relatively common SNPs linked to parts of the genome associated with cancer in a yet undetermined way. Their penetrance varies with epigenetic, lifestyle, and environmental factors. The American Society of Clinical Oncology believes that testing for these SNPs is of uncertain clinical value, because the risk is generally too small to serve as the basis for clinical decision making.[46] By contrast, a family history of breast and ovarian cancer, for example, would alert a clinician to order a direct and specific test for the *BRCA1* and *BRCA2* genes implicated in some such tumors. (In any case, *BRCA1* and *BRCA2* testing isn't offered by many DTC companies because of restrictive and expensive patent protection on those genes, raising the cost of the tests to as much as $3,500.)[47]

There's also a substantial risk of false positives and false negatives, which is exacerbated by patients' cognitive bias in favor of attributing more certainty to genetic information than the probabilities warrant. Andrew Wilkie, Nuffield Professor of Pathology at the University of Oxford, believes that "Patients and families want answers that give them certainty."[48] But unfortunately, that's not how genetic analysis generally works. Even though there is an unusually strong correlation between the *ApoE4* genetic allele and Alzheimer's disease, for example, 77 percent of people with the unfavorable allele *don't* develop Alzheimer's disease—so identifying the allele implies a false positive for them—while 47 percent of people who *do* manifest Alzheimer's disease don't have the mutation (a false negative). If a genetic test can't confer *absolute* certainty in this case, where the association is unusually strong, then it's all the more unlikely to provide the certainty that patients crave in other situations. "Is this technology just a distraction from focusing on the large preventable environment component?" Wilkie asks, focusing squarely on "Me versus We."

The American Society of Clinical Oncology guidelines recognize that some commentators[49] claim that DTC genetic tests do good by making patients feel in charge of their own health and by motivating them to pursue healthy behaviors. However, the society argues that these untested benefits must be balanced against iatrogenic (doctor-induced) harm and low clinical utility. The oncologists fear that they may be put in a difficult position if they haven't requested the original test, but the patient wants a follow-up. This isn't just a matter of medics protecting their professional position: there are genuine worries about the need for counseling, interpretation, and professional advice when a genetic susceptibility to cancer is revealed.

The society is also concerned about the lack of an evidence base: over 40 percent of the genomic variants used in commercial assays haven't been replicated in meta-analyses involving many studies, which is the gold standard for clinical evidence. No published studies have yet assessed the reliability of the algorithms used by the retail genetics companies to create the risk estimates fed back to patients. "Because these tests have uncertain clinical validity, they are not currently considered part of standard oncology or preventive care," the guidelines conclude.[50]

But will the patient who has paid hundreds or thousands of dollars for a test accept that it has no value beyond the merely "recreational"—and that her doctor is entitled to refuse to act on its findings? Even the genetic testing industry's own newsletter, *Genomics Law Report*, thinks not. It's quietly skeptical of 23andMe's disclaimer that its products are for recreational use only, pointing out quite cannily that consumers won't part with several hundred dollars unless they really think their health will benefit.[51] After all, didn't the 23andMe website urge patients, "Take care of your health and wellness"?

In fact, it's far from certain that the test results actually motivate consumers to make healthy lifestyle changes, as the DTC companies often claim that they do. A study in the *New England Journal of Medicine* of 3,639 retail genetics customers found no significant improvements in their diet or exercise regimen.[52] Likewise, a smaller study involving in-depth interviews with twenty-three "early adopters" revealed that very few intended to make any changes in their lifestyle, whatever the tests showed.[53] It's a well-worn truism that morbidity and premature mortality in the developed world arise in very substantial part from smoking, sedentary behavior, and excessive consumption of food or alcohol. None of us needs an expensive test to tell us how far up we need to pull our socks.

It's the specific commercialized form of direct-to-consumer testing for SNP variation that has aroused the greatest skepticism in the medical world and the most serious concern in regulatory agencies. Although in March 2012 the NIH set up something called the Genetic Testing Registry to improve transparency about genetic tests, it doesn't include direct-to-consumer genetic testing services.[54] That same month, a report from the U.S. Institute of Medicine warned that commercially available genomics tests require much more stringent regulatory oversight and more transparent data sharing, after a pharmacogenomic test for chemotherapy regimes against cancer, reported in and then retracted from the high-status journal *Nature Medicine*, proved to

be worthless. The IOM report extended beyond retail genetics, also urging tighter controls for genomic tests ordered in clinics. According to the chair of the IOM report committee, Gilbert Omenn, "Nothing short of patient safety and public trust are at stake."[55]

The Government Accountability Office pulled no punches when it published its report from a four-year investigation of ten tests from four retail genetics companies under the headline "Direct-to-Consumer Genetic Tests: Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practices."[56] In that same year, the Food and Drug Administration did act speedily to prevent Walgreens from stocking over-the-counter "Insight" retail genetics kits from Pathway Genomics, while maintaining an ongoing investigation into the companies more generally. But Jeremy Gruber of the Council for Responsible Genetics complains that for the most part, "There has been an abdication of leadership in overseeing genetic tests," which "puts a level of uncertainty into the discourse that neither benefits the industry, researchers or consumers."[57]

Given such strong warnings, why is personal genetic testing still being touted as the epitome of personalized medicine? And why does personalized medicine continue to be endorsed by such prestigious figures as Margaret Hamburg of the FDA and Francis Collins of the NIH?[58] Although the IOM report does give cause for concern, we shouldn't fall prey to premature judgment against the whole of personalized medicine because of the scientific and medical failings of some forms of genetic testing, particularly retail genetics. That judgment remains to be drawn, on the additional basis of the rest of the evidence in this book.

Nevertheless, insofar as DTC genetic testing is the self-proclaimed vanguard of the personalized medicine movement, caution is in order—particularly when leading proponents of personalized medicine rest much of their case on the validity of DTC tests. After describing his own experience of retail genetics, Collins writes: "This is a book about hope, not hype. . . . If you are interested in living life to the fullest, it is time to harness your double helix for health and learn what this paradigm shift is all about."[59]

The evidence base, however, simply doesn't bear out Collins's contention that consumerized genetic testing is about hope and not hype. That's why many government and professional bodies want to limit or even ban direct-to-consumer genetic testing, for sound scientific and clinical reasons. In the United States, the numbers are split: twenty-five states allow DTC tests with no restriction, thirteen prohibit them altogether, and twelve only allow some

types of tests or require a doctor's involvement.[60] In 2008, California served cease-and-desist orders on twelve DTC genetic testing companies, including 23andMe and Navigenics—requiring them to obtain licenses like traditional clinical laboratories. New York did the same, with the result that some companies ceased their operations in the state altogether.[61]

Those who favor controls, however, often come up against this attitude: "What I do with my genome is nobody's business but my own. Even if I've made a bad buy in purchasing three DTC test kits that return wildly disparate results, is that any worse than buying a used car that turns out to be reluctant to start on a frosty morning?" No legislator would ban the sale of used cars altogether just because some used cars are lemons, this argument runs, although deceptive marketing can be regulated. Why should a consumer's decision to buy into retail genomics be treated any differently? Isn't that excessively paternalistic?

That free-market reasoning seems to lie behind the decisions by the UK's Human Genetics Commission and its Nuffield Council on Bioethics not to prohibit DTC genetic tests altogether or even to regulate them more closely—only to advocate voluntary self-regulation by the industry. The Human Genetics Commission, an advisory body (since disbanded) that included industry representatives, produced nothing more than recommendations of a "common framework of principles" for consumer genetic testing services—guidelines called insufficient even by the *Lancet*, a journal whose political leanings are hardly the equivalent of *Mother Jones*'s.[62] At a public meeting of the HGC in London that I attended on May 12, 2009, one commission member argued that it would be wrong to require evidence of medical need or medical utility for DTC tests when other forms of information available to the public—particularly religious proselytizing—don't have to meet any such test of truthfulness.

Yet buried in an appendix—not highlighted in the summary or main text—the Nuffield Council's report admits that a "strong majority" of respondents to the consultation wanted more regulation of private genetic testing services. The council report also recognizes that other European countries—France, Germany, Austria, and Switzerland—ban DTC testing altogether and that a 2009 survey by the consumer magazine *Which?* showed that four out of five UK readers want retail genetics to be strictly regulated. Nevertheless, the report blandly recommended that "[DTC] companies should voluntarily adopt good practice."[63]

I think that this solution is quite insufficient and that the paternalism charge is actually back-to-front. As I said in my own response to the Nuffield

Council consultation: what people actually want is regulation, which turns the usual argument about paternalism on its head. If it is paternalistic to deny people what they want, then the genuinely paternalistic course is to allow unregulated genetic testing, not to prevent people from getting unregulated genetic tests on spurious grounds of individuals' "right to know."

WHO OWNS THE GENOME?

It's quite misleading to liken buying a genetic test to any other consumer decision, because our bodies and our genomes aren't just consumer items. In our traditional common law, tissue donors, presumably including people who send a spit sample or cheek swab in for DTC analysis, don't have any ongoing property rights in that tissue. I may own my car or house, but I don't own my tissue once it's taken from my body. Because of this gap in the law, and because people are unaware that there is a gap in the first place, DTC genetic testing companies have been able to follow the lead of other biotechnology corporations and researchers in amassing exclusive rights in tissue held in "biobanks." No DTC customer has yet challenged that position, but if they did, the common-law position would probably be upheld against them.

Biobanks, cell lines, and patents can represent tremendous value: the principal asset in the portfolio of many biotechnology companies lies in the "promissory capital" stored in their patents and databases.[64] (For example, according to a company statement for the fiscal third quarter ended March 31, 2012, 81 percent of total revenue for the biotechnology firm Myriad Genetics was accounted for by tests it offers on the breast-cancer-related genes *BRCA1* and *BRCA2*, for which it holds monopoly patents.)[65] The commercial value of biobanks, cell lines, and genetic patents is becoming better known now, following on from the bestselling story of how tissue from a terminally ill African American woman, Henrietta Lacks, became the source of the multi-billion-dollar HeLa cell line.[66] But the Johns Hopkins researchers who first developed the HeLa line—although they took the tissue without the consent of Lacks or her family—had no commercial motives. They made the banked cell line readily available to other scientists without charge, in the old spirit to which John Sulston looked back nostalgically when he wrote about the way scientists used to see themselves as part of a global community with shared values.[67]

In contrast, biobank and database development is the DTC companies' principal strategy for commercial growth, many observers think.[68] Lori An-

drews, a well-respected medical lawyer and professor, has even declared, of the direct-to-consumer genetic testing world, "Some companies are just a front end for biotech companies that use it for research."[69] If that's true, it would explain why firms are willing to sell the tests at a knockdown price or even to offer them for free, in the case of African Americans. Because black Americans are woefully underrepresented in genomic databases, their DNA could be a valuable resource for the company that can claim "brand edge" in it.

TruGenetics has given free DNA tests to the first ten thousand customers—regardless of race—willing to hand over their results for research. Likewise, 23andMe has offered a $99 test on the condition that the genetic analysis information remains in the firm's own biobank and that customers provide additional health and lifestyle data. By June 2011, 23andMe was able to announce that one hundred thousand customers had stored their genomic data with the firm, giving the company one of the world's largest genetic databases.

Why are these biobanks potentially valuable? Because the amount of variation in disease susceptibility contributed by each gene is typically so small (especially when epigenetics is taken into account), only mass databases can reveal statistically significant results. Conversely, whole-genome screening for large populations might eventually yield information that can be used to make a more accurate individual diagnosis.[70]

So the most promising aspects of genetic Me Medicine actually depend on We Medicine, in the form of collective databases. Particularly when the possible income from genetic patents is taken into account, these biobanks are a globally traded store of value: "biocapital."[71] Whether that capital should be shared collectively or held by individual firms is a controversy to which I'll return in the conclusion of this chapter and at greater length in chapter 7.

This value of biocapital in genetic databases is obvious from the explicit way in which retail genetics companies stake their claim on both the genomic data and the physical DNA banked with them. That might surprise most customers, who may well assume that they own their DNA even if they've stored it with the DTC companies. But while clients own the printout of their SNP analysis, they almost certainly have no rights in the biobank or in the DNA sample they stored there.

That principle was ratified in a 2002 court case called *Greenberg et al. v. Miami Children's Hospital Research Institute, Inc.* The parents of children with a fatal genetic condition called Canavan's disease had contributed tissue, information, and money to a database and biobank for the condition but were found to have no subsequent rights of control or ownership.[72] (This case is

discussed at greater length in chapter 7.) Our law generally holds that once tissue has been removed or changes hands as a "gift," no further rights can be claimed by the donor. But just to eliminate any doubts, a "privacy statement" on the 23andMe website reads: "We may allow a commercial research organization access to our databases . . . so that . . . the organization can search without knowing the identities of the individuals involved, for the correlation between presence of a particular genetic variation and a particular health condition or trait. We may receive compensation from these research partners."

What's really at issue here is not your *genetic privacy* but the *private property* held by the testing firm in the database—which 23andMe unequivocally but legitimately calls "our" databases, you'll note. Precedents, including but not limited to the *Greenberg* case, have established an inequitable legal position: researchers, universities, and commercial companies can hold property in tissue and control its uses, but the individuals from whom the tissue was taken have no such rights. With such an imbalance of power in favor of commercial interests and against individuals, it's not paternalistic to think that those who already hold all the cards need to be subjected to some form of regulation; it's just realistic.

While the "no property" rule in excised human tissue originally dates back to the period before there was value in DNA biobanks or other body "products," the case that really set it in stone for the biotech age was *Moore v. Regents of the University of California* (1990). At the age of thirty-one, in 1976, John Moore had developed a rare cancer called hairy-cell leukemia. The condition required his spleen to be removed: that much was uncontested, since it had swollen to over twenty times its normal size. But Moore was also told by his surgeon, Dr. David Golde, that he needed to return frequently to donate samples of his hair, blood, sperm, and other tissue. Each time he was asked to sign a consent form, reading: "I (do, do not) voluntarily grant to the University of California [Golde's employer] all rights I, or my heirs, may have in any cell line of any other potential product which might be developed from the blood and/or bone marrow obtained from me."

Moore began by circling "do," even though he had doubts. "You don't want to rock the boat," he remarked in a later interview. "You think maybe this guy will cut you off, and you're going to die or something." But after Moore moved cities, Golde continued to insist that his patient must come down to Los Angeles for his "treatment," even though perfectly good hospital facilities were available in Moore's new home of Seattle. At this point, Moore's

suspicions began to propagate. On his next visit, he circled "do not," resulting in a flurry of urgent phone calls from Golde's office instructing him to correct his "mistake."

It was then, in 1983, that Moore decided to take legal action, filing suit for "conversion" (unauthorized use of another's property). His lawyer, Jonathan Zackey, discovered that two years earlier Golde had already filed for a patent on the three-billion-dollar "Mo" cell line, which turned out to have unusually powerful and valuable immune cells. Although Moore was mainly incensed at the abuse of his trust, he was advised that his best chance lay in making a property claim.

But Moore failed in his legal action for conversion against Golde; his research associate Shirley Quan; the biotechnology firm Genetics Institute, Inc.; the drug company Sandoz Pharmaceuticals; and the Regents of the University of California. The final judgment from the California Supreme Court reiterated the common-law "no property in the body" principle. Judges siding with the majority expressed their fears that allowing tissue donors to have any rights in lines derived from their cells would inhibit scientific research and undermine human dignity, by creating a marketplace in body parts. In his dissent, however, Justice Broussard scoffed that tissue was *already* being valued in dollars and cents. Everyone stood to make a profit from Moore's tissue except Moore.

> Far from elevating these biological materials above the market, the majority's decision simply bars *plaintiff* [Moore], the source of the cells, from obtaining the benefit of the cells' value, but permits *defendants* [Golde et al.], who allegedly obtained the cells from plaintiff by improper means, to retain and exploit the full economic value of their ill-gotten gains free of the ordinary common law liability for conversion.[73]

This lack of say was extended beyond individual patients like Moore to entire groups of biobank tissue donors in *Greenberg* and another case, *Washington University v. Catalona* (2006). William Catalona, a respected urologist and surgeon who developed the prostate-specific antigen test for prostate cancer, had created a research biobank containing over 270,000 serum, blood, and DNA samples, along with 3,500 prostate tissue samples, much of which material came from his own patients. When Catalona decided to leave Washington University in St. Louis and take up a new post, he sent letters to all the patients he'd treated during his twenty-five years there. Six thousand men agreed to

Catalona's request that their samples should move with him to his new job at Northwestern University so that he could carry on with his research.

But Washington University went to court, claiming that the men's samples belonged neither to the donors nor to Catalona himself but to the university, as Catalona's employer. Both the district and the appeal courts agreed with the university, dismissing the statements made in court by some of the men about why they wanted their tissue to go with Catalona: they trusted his work and hoped he could find a cure. The Supreme Court declined to hear the case, so that decision is final—and it has important implications for who owns genomic data in DTC genetic testing biobanks. Not the individual donors, is the likely answer.

One patient, Richard Ward, had said, "Washington University was where Dr. Catalona was, so that's where I was [for my operation]." Another man, James Ellis, declared: "I have six grandsons and the one thing I want to do is what I can to make certain they don't go through what I've gone through, and my family's gone through, for the last fourteen years. And I [can't] think of anybody that I would have more faith in to do the kind of research that might help my grandsons on my samples, my tissues, my body parts, than Dr. Catalona."[74] But what James Ellis didn't realize—as most people probably don't—is that the no-property rule meant that the biobanked materials were no longer *his* samples, *his* tissues, or *his* body parts. The courts ruled that because the consent form that the patients had signed was on stationery headed "Washington University," the men should have realized that they were permanently transferring ownership of their tissue to the university, not to Catalona. On the issue of "whether individuals who make an informed decision to contribute their biological materials voluntarily to a particular research institution for the purpose of medical research retain an ownership interest allowing the individuals to direct or authorize the transfer of such materials to a third party," the judgment declared, "the answer is 'no.'"[75]

Catalona illustrates how few powers tissue donors have over "downstream" uses made of their cells, especially when commercial interests are at stake. In this case, a substantial coalition of academic institutions and medical researchers filed *amicus curiae* (advisory "friend of the court") briefs on behalf of Washington University, asserting that their business interests would be threatened if researchers such as Catalona could take valuable databases with them or if donors were given a say. Those bodies included the American Cancer Society, the Mayo Clinic, the American Council on Education, the Association of American Medical Colleges, and the Association of American Uni-

versities, along with many individual medical colleges, including Stanford, Cornell, and Johns Hopkins. Catalona had already been rapped over the knuckles for altruistically proposing to share two thousand samples with researchers from another university—the sort of thing we naively imagine that disinterested medical researchers do all the time, in their search for scientific truth and human betterment. "Just from a cost recovery scenario," the university's business manager had scolded in a memo to the vice chancellor for research, "this should be worth nearly $100,000."[76] In one of the very few cases to hold that the common law *does* confer a property right in excised tissue, *Yearworth v. North Bristol NHS Trust*, there was no commercial value in the tissue involved, namely, stored samples of several men's sperm taken before their operations for cancer and subsequently ruined through negligent storage by the hospital. Although some commentators think that this 2009 English judgment "signals a sea change in judicial attitudes toward patients' rights,"[77] the circumstances only pitted a handful of patients against a single not-for-profit hospital. Additionally, this was a case in which there was a clear intention by the patients *not* to donate the tissue unconditionally to someone else but to retain it for their own personal future use. That scenario didn't apply in *Catalona* and probably wouldn't be true of any case involving a DTC genetic testing company.

And, of course, the *Yearworth* judgment isn't binding in the United States. While U.S. judges could draw on the reasoning of the British judges in *Yearworth* if they so chose, they aren't obliged to hold by its verdict. However, the reasoning is certainly relevant on the western shores of the Pond. The English court said: "*In this jurisdiction* developments in medical science now require a re-analysis of the common law's treatment of an approach to the issue of ownership of parts or products of a living human body."[78] Those developments in medical science certainly aren't confined to England. Indeed, commodification of genes is further advanced in the United States than in the United Kingdom, particularly where genetic patenting is concerned. Many U.S. genetic patents aren't valid in Europe, and the NHS has taken a conscious decision to ignore the *BRCA1* and *BRCA2* patents because they're felt to impede national patient care.

In the United States, the issue of genetic patents has recently been contested in *Association of Molecular Pathology v. Myriad Genetics*. A coalition of concerned professional organizations, physicians, patients, and the American Civil Liberties Union successfully obtained a district court judgment against the restrictive *BRCA1* and *BRCA2* patents in early 2010.[79] That judgment was

overturned on appeal in July 2011, but only in a split 2–1 decision, so both parties petitioned the Supreme Court to settle the issue. In March 2012, however, the court granted *certiorari* (review) only long enough to instruct the Court of Appeals for the Federal Circuit to reconsider its decision in light of another case that had just been decided, *Mayo v. Prometheus*. But on August 16, 2012, the appeals court upheld its original decision that the *BRCA1* and *BRCA2* genes as patented by Myriad were not a natural composition of matter but rather a manmade product. In November, however, the Supreme Court agreed to review the case in 2013.

While cases determine policy in common-law systems, so, of course, do statutes. That's why the Vermont and Massachusetts bills could be highly significant in establishing who owns the genome and genetic information. We've already seen that the two bills both propose to make genetic information "the exclusive property of the individual from whom the information is obtained." That covers the data, but what about the banked DNA itself? The proposed Vermont legislation goes on to confer upon genetic material the status of "real property subject to one's individual control and dominion in accordance with generally held precepts of property law in Vermont."[80] But the "generally held precepts of property law in Vermont," as in the rest of the English-speaking world, traditionally have *denied* that tissue taken from the body is like real estate or other forms of personal property.

So that provision of the Vermont bill really would be a major change from the common-law position—as would the way the Massachusetts bill contemplates genetic information being made into heritable property. Under its terms, people can bequeath to their surviving spouse or any other legatee the right to use their genetic information. If heirs could withdraw the data at will, that would radically undermine the exclusive rights that retail genetics companies now hold in their databanks. The resulting uncertainty would certainly be a disincentive for other firms to buy into the DTC companies' biobanks, if they had no way of knowing exactly which files and what information they were purchasing.

Even more fundamentally, the Massachusetts bill recognizes the inherent monetary value of genetic information.[81] Section 1(b) stipulates that before entering into a contract to share genetic material or genetic information—presumably including a contract with a DTC company—people must be notified orally and in writing that "their donation is a commodity and is of some material value." (A similar provision would apply in Vermont.) Furthermore, if the biobank intends to commercialize the genetic information, the individ-

ual donor in both states must be made aware and compensated at a fair market value.[82]

This provision threatens the retail genetics companies' business plans—and to be fair, it's hard to see how the companies could know in advance what a reasonable market value would be. There needs to be some sort of retrospective way of determining what amounts donors are owed after pharmaceutical firms or other commercial users of biobanks have drawn up their contracts with the DTC companies. Before that happens, however, you can be pretty sure that the retail genetics firms' attorneys will be dusting off their copies of *Moore*. Of course genomic DNA "is of some material value"; so was Moore's tissue—to the tune of $3 billion. But that wasn't enough to turn it into his property, as the California Supreme Court held.

If the Vermont and Massachusetts bills go through, they will almost certainly be challenged in court, raising dilemmas about precedence of statute over case law and issues about contending state jurisdictions. Whether they will raise a constitutional issue and make it into federal courts is another interesting question. Given how fundamental the no-property rule is in the common law and how influential are the business interests involved, it seems likely that the issue would be pursued, but it's unclear what constitutional rubric would cover it.

While DTC genetic tests are marketed with a message touting individual responsibility—as the poster child for Me Medicine—databases and biobanks derived from many people's contributions could be seen as rightfully as a We resource, a form of commons. Already the retail genetics companies use "We" as a marketing message, along with "Me": 23andMe, for example, promotes "sharing and community" by setting up a social network of its users—called, notably, 23andWe. "Our features also give you the ability to share and compare yourself for family, friends and people around the world," the website promises.[83] But this supposed commitment to community anything more than a way of increasing market share and widening the customer base? It does nothing to change the ownership of the data, which remains private to 23andMe and the business partners whom the firm permits to mine its databases.

More genuinely communitarian associations than any commercial firm—groups of people with common genetic risk profiles for particular diseases—have started to take advantage of the "We"-ness of the Internet. One such group is FORCE (Facing Our Risk of Cancer Empowerment), a forum and advocacy network for women with a family history of breast and ovarian

cancer relating to the *BRCA1* or *BRCA2* genes. Another genetic interest group, for parents of children with the genetic condition PXE (pseudoxanthoma elasticum), has pioneered a joint ownership model of patent rights with a commercial firm, plowing profits back into further PXE research. In both these cases, however, only specific medical conditions are involved, and thus the groups are limited in size and influence.

David Winickoff, a Berkeley political scientist who has devised a new model of charitable trusts for biobanks that has been taken up by many commentators,[84] thinks that even heterogeneous groups such as DTC customers could have some communal property rights, if there's sufficient political and commercial will. For example, they could have something like representatives on a shareholder's association, even if they don't actually hold equity shares. That would certainly give them a lot more say than Catalona's patients or 23andWe's social network, but will it happen?

Given the view from leading medical bodies that DTC genetic testing has few benefits for the donor no matter how low the price, customers could and should be protected by consumer legislation. Alternatively, given that the common law has traditionally been loath to view individuals as owning their bodies and that regulatory bodies have been somewhat slow off the mark, it might be more effective and legally coherent to limit retail genetics companies' untrammeled downstream rights in biobanks. The Vermont and Massachusetts bills may contain contradictions, but they do demonstrate that there is some political momentum away from simply letting the market decide and toward recognizing that opting for retail genetic testing isn't just an individualistic consumer choice.

THREAT, NARCISSISM, CORPORATE INTERESTS, AND CHOICE RECONSIDERED

Let's now revisit those four possible reasons why Me Medicine is edging out We Medicine, applying them to personalized genetic testing.

The first hypothesis introduced in the previous chapter concerned a society-wide sense of *threat and contamination*. Toxic threat is actually much more intimately linked to the history of the Human Genome Project than most people realize, according to the documents uncovered by Helen Wallace and others. They allege that the tobacco companies intended to camouflage the threat by spreading the word that the risk was confined to genetically pre-

disposed people—those whose genes made them susceptible both to addiction to nicotine and to the carcinogens in tobacco smoke.

Wallace goes so far as to say that the origins of the Human Genome Project suggest that personalized medicine began life as a public relations message invented by the tobacco industry and was promoted to undermine public health strategies such as smoking prevention.[85] Although this may sound like a conspiracy theory, it's not a theory at all but rather the outcome of careful and systematic gathering of empirical evidence. However, the rationale of the HGP was also genuinely entwined with concern about genetic damage to public health from toxins such as tobacco smoke and radiation. When the burden was shifted to susceptible individuals, that communal concern was lost.

In the modern context of personalized genetic testing, the sense of threat is sometimes a factor. We've seen that leading proponents of personalized genetic testing play on the sense that everyone is at risk, as George Church put it. Avoiding the threat to the unborn child from undiagnosed genetic disorders in the prospective parents is implicit in the marketing message of Counsyl's genetic testing service. Although that might seem like a responsible thing to do, the British consultant geneticist Frances Flinter remarks of this development, "It plays unnecessarily on people's fears."[86]

On the other hand, optimism rather than fear is the brand for DTC companies selling genetic matchmaking services—such as Scientific Match, which promises to put you in touch with partners whose genetic makeup will supposedly enable you a better sex life and a high natural immune response in any children you may have together. Boosterism is also rampant in the claims from companies offering to test your children for the *ACTN3* gene allele involved in athletic performance.[87] More generally, the retail genetics companies' websites are imbued with a sense of excitement about scientific progress, of which you too can be part just by sending in a spit sample and paying your fee.

So although some customers of DTC testing services, such as David Ewing Duncan, may be motivated by a sense of environmental contamination, on the whole, promise seems far more central than threat in explaining the rise of retail genetics. But is that promise inflated? I'll examine that question at greater length in chapter 3, which discusses pharmacogenomics, probably the area that comes closest to fulfilling the promises of personalized medicine. For now, it's worth noting that while individualized genetics more generally—not just DTC testing—can claim advances in identifying disease pathways, diagnostics for a limited number of single-gene disorders, and some early success in tailoring treatment regimes, it still falls short of widespread clinical applications.

> Continuous discoveries of new surprises about the genome call into question the claim that personalized medicine is almost here, or that individualized drug therapy will soon be a reality. In fact, it probably never will be, or at least not by DNA testing alone, because most genotype-phenotype associated studies are hampered by limited size and therefore decrease in statistical power.[88]

The real threat, in my view, is that despite its imperfect evidence base, personalized genetic medicine will edge out the more pressing needs of public health: that Me will shove We aside. President Obama's proposed budget for 2012 committed the federal government to a 2 percent overall cut for the Department of Health and Human Services—the first in the department's history, despite our graying population—but a 2.4 percent increase for the National Institutes of Health. Francis Collins of the NIH planned to use the funds to focus on "leveraging new genomics technologies in disease and health research and translational science, and in pursuing goals in personalized medicine."[89] But Obama's budget also proposed a staggering 90 percent *decrease* in the budget of the Centers for Disease Control's Office of Public Health Genomics. As the medical lawyer Jonathan Kahn explains:

> The OPHG conducts some very valuable population-based analyses of the role of genomics in improving the public's health. For example, it recently funded the Michigan Department of Community Health to increase the number of health plans that have policies consistent with U.S. Preventive Services Task Force recommendations for genetic risk assessment for hereditary breast and ovarian cancer. Public health genomics, however, is not a money maker. The sort of research supported by the OPHG does not lead to new products that can be developed and marketed by large pharmaceutical corporations.[90]

Yet it's the Centers for Disease Control that deal with such genuine and massive threats to public health as swine flu and other pandemics. (In chapter 6, I'll examine those threats, and the virulent reaction against vaccination, at greater length.)

Some threats, it seems, are more equal than others. If threat does go anywhere toward explaining the rise of Me Medicine, it's because threat has already become individualized in many people's minds: threats to *my* baby or *my* own health, for example, rather than a viral epidemic that could threaten

all of *us*. But what explains that individualization in the first place? What about the second possible explanation, narcissism and "bowling alone"?

Narcissism works best as an explanation for "recreational genetics" but less well for the one-third of customers who think that they're buying a diagnosis. Those individuals aren't necessarily in the fell grip of a narcissism epidemic; they're just misled about the effectiveness of SNP testing as compared with more traditional measures, such as systematic family history taking.[91] This theme will recur in later chapters: other forms of personalized medicine, particularly private umbilical cord banking, are also medically less effective than the more community-minded alternative (in that case, public cord blood).

"Me" often markets itself as clinically superior to "We": that's an essential premise of personalized medicine. The evidence base doesn't always bear that claim out, but people may not be aware of the evidence. That doesn't make them narcissistic; it just means that they're not as well informed as they need to be. Part of this book's mission is to examine that evidence base so that people can make themselves better informed.

Nor is it narcissistic to be confused about the difference between predicting with certainty whether *I as an individual* will develop a particular disease and estimating the probabilistic susceptibility for a *population*. Direct-to-consumer genetic tests identify our disease risks through probabilistic assessments, based on our genetic similarities to others with common diseases that have a known incidence, as derived through genome-wide association studies. So actually they rely on "We"-ness even as they proclaim their "Me"-ness.

> Scans are personal in the usual sense that, like much of what doctors tell us, they are about ourselves. . . . This is a geneticized medicine which predicts our future health and disease. But it attempts to do this by pointing not to the individuality of our genetic natures, but to our genetic similarities with others. It identifies our disease risks through our genetic similarity with others with a known experience of common disease.[92]

The related "bowling alone" hypothesis works a bit better than narcissism, if you consider the way in which 23andWe or the recreational ancestry services claim to be forging a new kind of connectedness.[93] Like the recent rise of alternative kinds of civic togetherness that Putnam identified after the 2008 election, those forms of genetic testing could be seen as a new form of social network. Initiatives such as "Roots Into the Future," a free retail genetic testing offered by 23andMe to ten thousand African Americans, may reach minority

ethnic groups who never fitted that well into the benign picture of 1950s togetherness, as Putnam himself admits.

The legal scholar Dorothy Roberts believes that most of her fellow African Americans aren't interested in finding out about their ancestry in America and often can't do so even if they try, because no one kept birth and death records for slaves.[94] But Alex Haley's bestseller *Roots* tapped into their deeper desire to trace their African ancestry. "Roots Into the Future" plays on both Black Pride and the appeal of cutting-edge technology, drawing in potential customers for more complete and more expensive versions of the testing service. On the other hand, it's also entirely plausible to interpret "Roots Into the Future" as a way of extending market share for the companies involved while claiming to promote togetherness. And the resulting biobank of comparatively rare African American genotypes is valuable biocapital.

Corporate interests and neoliberalism, the third hypothesis, strike me as much more powerful explanations of retail genetics than narcissism. The Canadian scholar Roxanne Mykitiuk believes there's a significant affinity between the "new genetics" and the central neoliberal policy of privatization—not just in the sense of outsourcing previously government-run services to the private sector but also of privileging the private above the communal.[95] The entire premise behind genetic testing—not just the economics—can be seen as neoliberal: "The diversion of attention from social to molecular causes and solutions reinforces privatization, the hallmark of the neo-liberal state that pervades every aspect of public policy."[96]

But let's be a little more precise: taking part in that area of Me Medicine known as retail genetics doesn't necessarily mean abandoning your commitment to your regular healthcare provider, which may be partly or even wholly publicly funded (as with Medicare or the NHS). The problem isn't so much the private sector replacing the public as the public being overwhelmed by additional demands created by private DTC companies without being given any additional resources—even while suffering major cutbacks under austerity programs. In other words, the public will have to prop up the private again, which many commentators believe to be the reality, though not the rhetoric, of neoliberalism.[97] One reason why doctors are concerned about retail genetics, as we've seen from the professional guidelines, is the potential overload on the medical profession, health insurers, and a national health service like the United Kingdom's.

Neoliberalism is sometimes defined by its critics as socialism for the corporations and the free market for individuals. That's simplistic but catchy—

and quite appropriate to the way in which private capital has relied not only on a permissive U.S. regulatory regime in patenting but also active government backing in developing the blue-sky science that can then be "translated" into profit-making services such as retail genetics. True, the private sector also provides venture capital, for example, through Google's links with 23andMe. But deCODEme relied on the initial public resource of the national Icelandic database, which the government made available to the firm on an opt-out basis: it was assumed that Icelanders had allowed the use of their data unless they explicitly withdrew.

Developments in retail genetics mirror a more general trend in biotechnology and biomedicine, according to Mariana Mazzucato, a professor of science and technology policy at the University of Sussex and the author of *Risks and Rewards: Understanding the Innovation-Inequality Relationship*:

> Where would GSK and Pfizer be without the $600 billion the US National Institutes of Health has put into research that led to 75% of the most innovative new drugs in the last decade? The state's role . . . was not just about correcting "market failures." What the state did was to take on the greatest risk, before the private sector dared to enter—acting as an "entrepreneurial" state. In biotech, venture capital entered 15 years after the state invested in the biotech knowledge base. . . . In biotech, venture capital has entered late and made a killing from an industry it did not create.[98]

Given that the state bore the financial risks, you might think it should have some say in regulating biotechnology industries, but that's not how it works. The antiregulatory agenda adopted by the UK's Human Genetics Commission and Nuffield Council is typical of much policy response in advocating no more than voluntary self-regulation by the retail genetics industry. As I've argued already, and as the British political scientist Stuart Hogarth agrees, when surveys show that people want regulation, "It's a paternalistic neo-liberal agenda to say they're somehow misguided."[99] Oddly and ironically enough, he says, industry actually claims to want a code of practice. Contravening the wishes of both the public and the industry in the name of market freedom bespeaks an ideological platform such as neoliberalism rather than a practical strategy.

Yet as we've seen, roughly half of U.S. states do regulate retail genetics, which the neoliberal hypothesis wouldn't predict. Along with regulation by the FDA and individual states, corporate ownership rights in human tissue

and genetic patents are being challenged by individual court cases such as the *Myriad Genetics* lawsuit. Neoliberal ideology doesn't rule unchallenged in the political realm. It would be a simplistic mistake to attribute the success of Me Medicine to that and that alone—although it's also a salutary correction to the way in which it's so rarely mentioned in the usual treatment of buying genetic tests as a purely individual choice.

In terms of the fourth hypothesis, individual *choice*, personal autonomy, and individual self-discovery are certainly foregrounded by many writers of personal genomic odysseys.[100] Martin Richards, however, accuses retail genetics of actually *undermining* autonomy. He argues that the DTC companies claim to be able to tell us more about our innermost selves than we can know through our own cognition. Likewise, wrong information, in the form of a false positive or false negative, could easily undermine rather than enhance rational choices and a sense of being master (or mistress) of your own health. The sense of being a patient from cradle to grave also weakens our sense of personal agency rather than enhancing it.

So choice and autonomy are not actually being served, despite the retail genetics companies' rhetoric claiming "genetics just got personal." But we need to go further, moving from the descriptive (*is* autonomy actually the key value in personalized medicine?) to the normative (*should* autonomy be the key value that we want to see medicine serve?). As I suggested in chapter 1, there's been a reaction against that assumption in recent writings on medical ethics. Skepticism about whether autonomy is paramount hasn't really spread beyond academic circles, however, and even there, it's probably a minority view. As other commentators have also argued,[101] autonomy and choice are still largely regarded as knockdown arguments in general public debate.

I've argued that in fact, these quintessential Me Medicine values don't fit all that well even where they're very strongly touted, as they are in retail genetics, and that they shed more heat than light—no matter how central they are to brand strategy for the DTC firms. They form a poor fit with the reality of who has property rights in and autonomous control over the stored tissue sample. Maybe "your genetic information should be controlled by you," or maybe not: that's a normative question, with the "should" giving it away. Descriptively, however, that's not how it really works in retail genetics. The language of individual ownership of your health largely masks the collectivization and privatization by firms of your genetic data.

In the final chapter, I'll develop a more complex analysis of how communal values, such as the notion of a genetic commons in which we all share, might

inform medicine more satisfactorily than autonomy and choice. Before doing so, in the penultimate chapter I'll look at case examples indicating that our devotion to choice and autonomy, in the instance of vaccination refusal, potentially compromises both our ability to achieve those We Medicine values and our health itself. But both those chapters are some way down the line. Let's move on now to the second practical example of Me Medicine: pharmacogenetics and pharmacogenomics.