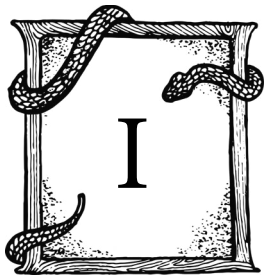
Tablet

Needle Points

Why so many are hesitant to get the COVID vaccine, and what we can do about it ◆ By Norman Doidge



The Unexpected Occurs

SINCE MY DAYS in medical school, I have had a fascination with the kernel insight behind vaccination: that one could successfully expose a person to an attenuated version of a microbe that would prepare and protect them for a potentially lethal encounter with the actual microbe. I marveled at how it tutors an immune system that, like the brain, has memory and a kind of intelligence, and even something akin to "foresight." But I loved it for a broader reason too. At times modern science and modern medicine seem based on a fantasy that imagines the role of medicine is to conquer nature, as though we can wage a war against all microbes with "antimicrobials" to create a world where we will no longer suffer from infectious disease. Vaccination is not based on that sterile vision but its opposite; it works *with* our educable immune system, which evolved millions of years ago to deal with the fact that we must always coexist with microbes; it helps us to use our own resources to protect ourselves. Doing so is in accord with the essential insight of Hippocrates, who understood that the major part of healing comes from within, that it is best to work *with* nature and not against it.

And yet, ever since they were made available, vaccines have been controversial, and it has almost always been difficult to have a nonemotionally charged discussion about them. One reason is that in humans (and other animals), any infection can trigger an archaic brain circuit in most of us called the behavioral immune system (BIS). It's a circuit that is triggered when we sense we may be near a *potential* carrier of disease, causing disgust, fear, and avoidance. It is involuntary, and not easy to shut off once it's been turned on.

The BIS is best understood in contrast to the regular immune system. The "regular immune system" consists of antibodies and T-cells and so on, and it evolved to protect us *once a problematic microbe gets inside us*. The BIS is different; it evolved to prevent us *from getting infected in the first place*, by making us hypersensitive to hygiene, hints of disease in other people, even signs that they are from another tribe—since, in ancient times, encounters with different tribes could wipe out one's own tribe with an infectious disease they carried. Often the "foreign" tribe had its own long history of exposure to pathogens, some of which it still carried, but to which it had developed immunity in some way. Members of the tribe were themselves healthy, but dangerous to others. And so we developed a system whereby anything or anyone that seems like it might bear significant illness can trigger an ancient brain circuit of fear, disgust, and avoidance.

It can also trigger rage, but rage is complex, because it is normally expressed by getting close to the object, and attacking it. But with contagion, one fears getting too close, so generally the anger is expressed by isolating the plague-bearer. The BIS is thus an alarm system specific to contagion (and, I should add, to the fear of being poisoned, which before the development of modern chemistry often came from exposure to living things and their dangerous byproducts, such as venoms). Thus it can also be triggered by nonanimate things, like body fluids of some kinds, surfaces others may have touched, or even more abstract ideas like "going to the grocery store." There is one exception: The BIS doesn't get or stay activated in people who don't feel vulnerable, perhaps because they have good PPE, or because their youth gives them strong innate immunity, or because they know they're already immune, or because they're seriously misled or delusional about the reality of the disease. For everyone else, though, what might trigger the system is rather plastic; but once triggered, the system is involuntary.

The BIS is, I would argue, one of the instinctual reactions that missed appearing in medical textbooks perhaps because we've not had a pandemic on this scale for 100 years. Because it focuses on *potential* bearers of disease, the BIS triggers many false alarms, since an infected person may at first show only the mildest and nonspecific symptoms, such as a cough or sniffle, before they become deathly ill; that's why even a small exhalation or a surface touched by a stranger could trigger the BIS. Were it a medical test of danger, we would say this system tends to err on the "false positive" side. We see it firing every day now, when someone drives alone wearing a mask, or goes for a walk by themselves in an empty forest masked, or when someone—say with good health and no previous known adverse reactions to vaccines—hears that a vaccine can in one in 500,000 cases cause death, but can't take any comfort that they have a 99.999% chance of it not happening because it *potentially* can. Before advanced brain areas are turned on and probabilities are factored in, the BIS is off and running.

One of the reasons our discussions of vaccination are so emotionally radioactive, inconsistent, and harsh, is that the BIS is turned on in people on both sides of the debate. Those who favor vaccination are focused on the danger of the virus, and that triggers their system. Those who don't are focused on the fact that the vaccines inject into them a virus or a virus surrogate or even a chemical they think may be poisonous, and that turns on *their* system. Thus both sides are firing alarms (including many false-positive alarms) that put them in a state of panic, fear, loathing, and disgust of the other.

And now these two sides of the vaccination debate are tearing America apart, at many levels: families, friendships, states, and the federal government. It's even affecting the country's ability to deal with the pandemic, splitting hospital staffs and sundering relations between the scientists studying it.

As of this writing, in the United States about 85% of people over 65—the age group most at risk—are fully vaccinated against COVID (more if you include those who had one shot). Fifty-seven percent of the overall population is fully vaccinated. But around June, the rate of vaccination slowed drastically—down to less than 1 million a day from 3.4 million daily in April, even though many more people (age 12 and up) were now eligible. Five million people who got the first shot had not gone to their follow-up appointment. States started sending vaccines back, while some vaccination sites were empty. In response, U.S. public health officials appeared to believe that the number of people who would voluntarily take the vaccine had reached a ceiling. The change could be seen from the top of the messaging system, with President Joe Biden switching from persuasion to coercion—of the armed services, federal employees, and, as of Sept. 9, of everyone working for companies with 100 employees or more, a category that includes about 100 million Americans.

In a way, this should be the least likely time in history for vaccine hesitancy. For years, vaccinologists explained vaccine skepticism by noting that it largely existed because few had lived through a large-scale pandemic, and because vaccines had already eradicated so many serious diseases that it gave rise to complacency about the threat. But today's vaccine hesitancy is happening in the midst of a pandemic, in which over 700,000 Americans have died. And a recent Rasmussen poll found that a staggering one-third of Americans "believe officials are lying about vaccine safety."

It seems to me especially vital that we broaden our understanding of the history and current state of vaccines because, over the summer, many who chose vaccination for themselves concluded that it is acceptable to mandate vaccines for others, including those who are reluctant to get them. That majority entered a state of "crystallization"—a term I borrow from the French novelist Stendhal, who applied it to the moment when a person first falls in love: feelings that may have been fluid become solid, clear, and absolute, leading to all-or-nothing thinking, such that even the beloved's blemishes become signs of their perfection.

Crystallization, as I'm using it here, happens within a group that has been involved in a major dispute. For a while there is an awareness that some disagreement is in play, and people are free to have different opinions. But at a certain point—often hard to predict and impossible to measure because

> "It's not about COVID-deniers or anti-vaxxers, but about the vaccine hesitant—those who are concerned and anxious about COVID but *also* anxious about these new vaccines."

Fig. 1 No empathy? 'An important mental capacity has been lost.' (Courtesy the author.)

it is happening in the wider culture and not necessarily at the ballot box—both sides of the dispute become aware that, within this mass of human beings, there is now a winner. One might say that *a consensus arises that there is now a majority consensus*. Suddenly, certain ideas and actions must be applauded, voiced, obeyed, and acted on, while others are off limits.

One person who understood how this works intuitively was Alexis de Tocqueville. In democracies, as long as there is not yet a majority opinion, a range of views can be expressed, and it appears there is a great "liberty of opinion," to use his phrase. But once a majority opinion forms, it acquires a sudden social power, and it brings with it pressure to end dissent. A powerful new kind of censorship and coercion begins *in everyday life* (at work, school, choir, church, hospitals, in all institutions) as the majority turns on the minority, demanding it comply. Tocqueville, like James Madison, was concerned about this "tyranny of the majority," which he saw as the Achilles' heel of democracy. It isn't only because divisiveness created a minority faction steeped in lingering resentment; it's also because minorities can sometimes be more right than majorities. (Indeed, emerging ideas are, by definition, minority ideas to start with.) The majority overtaking the minority could mean stamping out thoughts and actions that would otherwise generate progress and forward movement.

It is a fascinating moment when this sort of crystallization happens in a mass culture like America's, because seemingly overnight even the definition of legitimate speech (or thought or action) also changes. Tocqueville observed that quite abruptly a person can no longer express opinions or raise questions that only days before were acceptable, even though no facts of the matter have changed. At an individual level, people who were within the bounds can be surprised to find themselves "tormented by the slights and persecutions of daily obloquy." Once this occurs, he wrote, "your fellow-creatures will shun you like an impure being, and those who are most persuaded of your innocence will abandon you too, lest they should be shunned in their turn."

In the midst of a pandemic, seeing the unvaccinated as "impure" is no surprise, because of course they could carry contagion. But as Tocqueville pointed out, this *also* occurs when there is no contagion, and we begin to experience those who are on the wrong side as "impure"—as in failing the purity test—and react to them as though they are dangerous. That we do this even when there is no pandemic suggests that there is, along with realistic fear of infection, something else going on here—a sense that those with whom we may disagree are impurities in the body politic, bad people who need to be taught a lesson, even punished.

A June 2021 Gallup poll found that, among the vaccinated, 53% now worry most about those choosing not to get vaccinated, "surpassing concerns about lack of social distancing in their area (27%), availability of local hospital resources and supplies (11%), and availability of coronavirus tests in their area (5%)." True to the BIS's impulses, this fear is metastasizing into disgust, even hatred, of those who—because they believe or act differently—are now perceived as threats: On Aug. 26, in a front-page story in the *Toronto Star*, my local newspaper, a resident was quoted as saying: "I have no empathy left for the willfully unvaccinated. Let them die" (see figure 1).

In the midst of such a death wish for fellow human beings, even the person quoted understood that an important mental capacity has been lost: empathy, or the ability to model other people's minds. When we lose that en masse, the results can be tragic, not least because getting through this must be a group effort.

As I understand it, there are two main approaches to public health in liberal democracies, and both have been tried historically in different places. One begins voluntarily, out of respect for civil liberties, but switches to coercion when some voluntary ceiling, deemed insufficient, is reached. Ideally, this intervention is based on the principle of least-necessary coercion. The benefit to this is that it may work to get more people vaccinated in shorter order. But it also conveys that the government does not trust its citizens to make good decisions on their own, a condescension that in turn—this is human nature 101—eventually generates resentment, even revolt, and the disengagement of significant segments of the population. The other approach, participatory public health, sees the need for coercion as a sign that something in the public health outreach itself has failed; if a ceiling is reached, society's leaders should not simply resort to force but rather confront the flaws in their own leadership—that they should double-down on their responsibility to generate trust in the public. The goal of participatory public health is not to crush, but to better engage.

In that spirit, what follows is an attempt by a physician and neuroscience writer and someone who got vaccinated, early and voluntarily, to understand those who have not made this choice. This essay is not about COVID-deniers or anti-vaxxers, who oppose vaccines on ideological grounds. Nor is it about the activists or political figures who feed off and benefit from the corrosive discourse around vaccines. It is instead about the vaccine hesitant—those who are concerned and anxious about COVID but *also* anxious about these new vaccines. These are the people who are not yet vaccinated for reasons that the majority may not understand—and which are often more anchored in history and experience than the majority would suspect. They are the Tocquevillian minority that the majority is threatening with job loss and other restrictions.

One needn't agree with the decisions or actions of the vaccine hesitant in order to learn something from them and about them, and about society as a whole. They pay attention to, and are vigilant about, different issues than the vaccinated, and have strong feelings about the people and institutions involved in our public health—particularly politicians, the drug regulatory process, and pharmaceutical companies. For many, vaccine hesitancy is not simply about the vaccines; it's about the absence of faith in the wider systems that brought us the vaccines. "Public health moves at the speed of trust," notes physician and author Rishi Manchanda. If we want our public-health system to function better—safer, swifter, in ways that more effectively safeguard the lives and livelihoods of all citizens—it must be rooted not in coercion but in confidence, and not only among the majority.

The Kernel Brilliance of Vaccines

THE KERNEL IDEA of exposing a person to a weakened form of a pathogen or toxin, known colloquially as "like to treat like," long preceded modern medicine, and came in stages and through observation. Paracelsus, who was said to have treated persons during a plague in 1534, noted that "what makes a man ill also cures him." During the ancient plague of Athens (430-425 BCE), the historian Thucydides noted that those who, like himself, got the plague and then recovered, never got the plague again. Chinese writing alluded to inoculation in the 10th century, and in the 16th century, Brahmin Hindus were inoculating people with dried pus from smallpox pustules. Similar practices, which were common in Turkey in the 1700s, were brought to England by the remarkable Lady Montagu, the English ambassador's wife. But when some, such as King George III's son, died on being inoculated with the smallpox, many became reluctant to undergo the procedure.

A key advance occurred when farmers in England in the 1700s noticed that dairymaids who milked cows got "cowpox" on their hands from the udders. Cowpox was a very mild illness compared to smallpox, which had a 30% mortality rate by some estimates. It was observed that the maids with cowpox were immune to the dreaded smallpox. An English cattle breeder named Benjamin Jesty, who had himself contracted cowpox and was thus immune to smallpox, decided—supposedly on the spur of the moment—to intentionally inoculate his wife and children with cowpox. They remained immune to smallpox 15 years later.

The English physician Edward Jenner, learning of this, began systematically exposing patients to cowpox, including an 8-year-old boy named James Phipps. He exposed James to cowpox and then exposed him to smallpox to see if he'd contract it (an experiment conducted quite obviously without informed consent). The boy survived, and was vaccinated 20 times without bad effect, said Jenner, who reported on the benefits of the procedure in warding off smallpox in a series of cases. He was initially ridiculed for the idea, but in the end prevailed. The phenomenon was soon called "vaccination"—from *vaccinia*, the Latin for cowpox virus species (*vacca* being "cow").

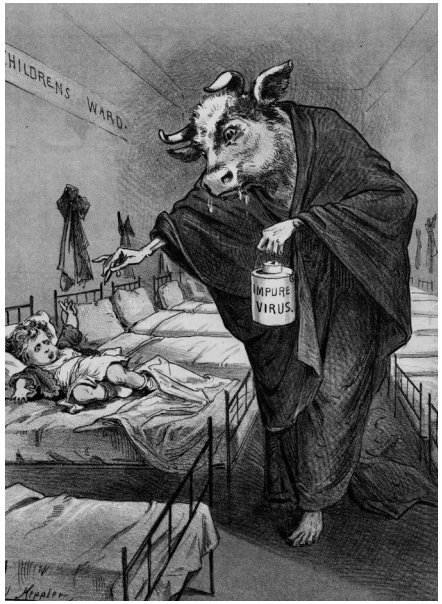


Fig. 2 The cow lent its Latin name to the term for *vaccinations*, which have existed in the popular imagination as menacing monsters for more than a century, as in this cartoon from *Puck* magazine. (Bettmann/Getty Images.)

Some have even wondered whether the ancient Western symbol for the medical arts and healing still used today, the Rod of Asclepius, a serpent wrapped around a staff, may itself be an allusion to the kernel idea that something dangerous can also protect; according to Greek myth, Asclepius was said to have healed people with snake venom, which can have some medicinal properties that were written about by Nicander. And, interestingly, the same image appears in the Torah, in Numbers 21:8: "And the Lord said unto Moses, Make thee a fiery serpent, and set it upon a pole: and it shall come to pass, that every one that is bitten, when he looketh upon it, shall live. And Moses made a serpent of brass, and put it upon a pole, and it came to pass, that if a serpent had bitten any man, when he beheld the serpent of brass, he lived."

All of which is to say that the heal-harm paradox is a deep archetype in the human psyche. And it came not from Big Pharma but from everyday, often rural observations—one might even call them "frontline" observations about how nature works, and how the immune system behaves.

Among the great triumphs of vaccination are the elimination in the United States of the scourge of polio, and the eradication of smallpox throughout the world. Indeed, perhaps because of these successes, many of us nostalgically imagine that their development and public acceptance came easily. But the real history shows a more textured picture. A number of polio vaccines had to be tried. The initial vaccine studies had very little oversight, and the first vaccines left some children paralyzed. The first truly effective vaccine, the Salk, had problems too; in 1955, a bad batch of over 120,000 doses from the Cutter Pharmaceutical Company contained the live polio virus, causing 40,000 cases of polio and killing 10. "The Cutter incident," as the event is now known, revealed the vulnerability of the systems that produce vaccines, and remains one of the sources of the nightmare that so haunts the hesi-

tant: getting the dreaded disease from the treatment. The incident was followed by efforts to improve the regulatory systems so that similar tragedies wouldn't be repeated.

In the public's mind, perhaps the greatest triumph of vaccination was the midcentury worldwide eradication of smallpox—a horrifying scourge that was lethal in 30% of cases. The history as it is often told attributes the victory solely to vaccines, but as British physician Richard Halvorsen has written, it was not simply the product of a single "blockbuster" vaccine or campaign, as is so often described, but rather a regime of multiple public health measures instituted alongside vaccination.

The details here are quite interesting. Beginning in the 17th and 18th centuries, there were a number of mass campaigns of inoculation with smallpox, and then vaccination with cowpox, that led to a decline in smallpox in the 19th century. By 1948, some physicians in England thought the illness was sufficiently well-managed that mass vaccination of infants, which carried some risks, could wind down. And so mass vaccination was replaced by a new, more individually focused strategy: If a case was reported, public health officials isolated the person and their contacts, and the contacts were vaccinated. This was called "the surveillance-containment strategy." It worked. After that cessation of vaccination in England, a few cases occurred there in 1973 and 1978—but both were based on laboratory accidents. According to Halvorsen, the World Health Organization came to the same conclusion and also adopted the surveillance-containment approach elsewhere. In 1980, the disease was declared eradicated.

But alongside the public health system's triumphant eradication of polio and smallpox from the 1940s through the 1970s, there was a horrifying chapter as well—one that included staggering abuses by public health and medical authorities. The Tuskegee experiment, conducted by the U.S. Public Health Service (PHS) from 1932 until 1972, sent out representatives to find African American men with syphilis, who were told that they would receive treatment for their "bad blood." No treatment occurred. The officials gave these men a placebo instead of penicillin, which would have saved them. This was done so the investigators, by watching the men die slowly, could study the natural course of the devastating disease.

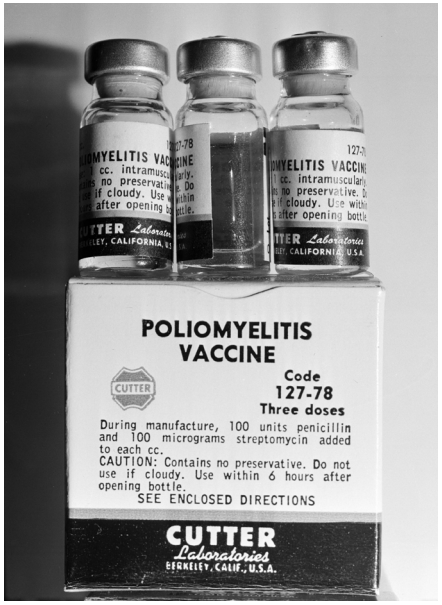


Fig. 3 First shipment of Polio vaccine, 1955. The 'Cutter incident' revealed the vulnerability of the systems that produce vaccines. (Photo by Los Angeles Examiner/USC Libraries/Corbis via Getty Images.)

During the same period of time, the U.S. public health system oversaw 70,000 sterilizations of "mentally deficient" people with learning problems, the blind, and the poor, and also forcibly removed the uteruses of African American and Indigenous women, all as part of an international eugenics movement that swept through public health. Psychedelics and other drugs were given to people in mental institutions without telling them, often leading to nightmare trips, and dangerous campaigns were undertaken based on only partial knowledge, such as the widespread radiation of healthy children's thymus glands (a key part of one's immune system), which later caused cancers. All these programs used abstract "population-based" thinking, dehumanizing people into numbers to be toyed with in the name of science and progress.

None of the public health abuses during this period involved informed patient consent, and yet they were government-sponsored, lauded, and justified in the name of the greater good. It took the revelation of Nazi medical experiments on Jews and others to give rise to

a new ethics of consent for research subjects. The Nuremberg Code of Ethics of 1947, along with the 1964 Declaration of Helsinki originally developed by the World Medical Association, required physicians and scientists to obtain the informed consent of all research subjects. This breakthrough led to the normalization of patient consent not just for research subjects, but for those undergoing all medical procedures—and became a bedrock of what many of us in the medical field now see as an inviolable code of ethics.

But in the late 1970s and 1980s, there were new controversies. In 1976, a swine flu outbreak occurred at Fort Dix, New Jersey. Fearing that the country was on the cusp of a pandemic, the U.S. government approved a vaccine and undertook an aggressive rollout that involved 48 million people. But there were two unforeseen developments: First, the epidemic receded on its own, and rather quickly. Second, 450 vaccinated people came down with a neurological disorder called Guillain-Barré syndrome (in greater numbers than would be expected during that period). After producing and distributing the vaccine so quickly, the government then reacted with caution, but the idea that a vaccine could cause damage stuck in the public's mind. "This government-led campaign was widely viewed as a debacle and put an irreparable dent in future public health initiatives," wrote Rebecca Kreston in Discover, "as well as negatively influenced the public's perception of both the flu and the flu shot in this country."

That skepticism might have emerged so sharply because the swine flu "debacle" occurred against the backdrop of another contemporaneous event. In the 1970s a number of parents began arguing that their children were left with serious brain problems and seizures after receiving the diphtheria-pertussis-tetanus vaccine. Numerous vaccine-related lawsuits followed, and the parents scored many legal victories, costing pharmaceutical companies millions of dollars. It cost 12 cents to make a dose of the DPT vaccine in 1982, but within a few years, the cost increased 35-fold thanks to litigation awards, and as a result companies started leaving the vaccine business. To this day, there is disagreement about the primary cause of the brain problems, with some of the parents insisting it was the vaccine, and vaccine advocates arguing that these children actually had a genetic condition called Dravet's syndrome, possibly brought to the surface by the vaccination, but which they would have suffered from anyway.

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There is little disagreement, though, about what happened next. In 1986, the last pharmaceutical company still making the DPT, Lederle, told the government it would stop making the vaccine. Companies making vaccines for other diseases were also being sued, and also stopping production. The government grew very concerned, and in 1986 Congress passed the National Childhood Vaccine Injury Act (NCVIA). The act established a new system for vaccine-related injuries or death linked to childhood vaccinations, wherein companies were indemnified from being sued for safety problems. (Soon after, the program was enlarged to include adult vaccination injuries.) If anyone believed that a child or person was injured by a vaccine, they could take the complaint to a newly established vaccine court, run by the U.S. government, and plead their case. If they won, the government would pay them damages from a fund it created out of taxpayer money.

This might have seemed the best possible solution: The country retained a vaccine supply, and citizens had recourse in the event of harm. But because companies were indemnified from any harm their vaccines might cause, they no longer had a powerful financial incentive to rectify existing safety problems, or even improve safety as time passed. Arguably, they were financially disincentivized from doing so. The solution shifted liability for the costs of safety problems from the makers onto the taxpayers, the pool that included those who were arguably harmed.

This atmosphere of suspicion spread in the 1990s, with even greater explosiveness and toxicity, during the vaccine autism debate. The landscape of the vaccine discourse in the United States—never simple or one-dimensional to begin with—was becoming even more complicated and hostile.

To understand the polarized psychological reactions to vaccination now, as well as what to do about it, it is essential to disentangle three things:

First, there is the *kernel idea* behind vaccination as a treatment, arguably one of humanity's greatest medical insights.

Second, there is the process by which a particular vaccine is produced, tested for safety and efficacy, and regulated—i.e., the *execution* of the core insight, which, as we know, can vary in success from one vaccine to the next, or fail completely. (We've not yet been able to make an AIDS vaccine, for instance.)

Third, there is the way in which those who produce the vaccine, and the public health officials in charge of regulating and disseminating it, *communicate* to the public.

Only a person who rejects that first kernel idea could sensibly be called an "anti-vaxxer." Many people accept the kernel insight and have been vaccinated multiple times in the past, but have come to doubt the execution or necessity of a particular vaccine, and hence also come to doubt the claims made in the course of disseminating it. They become *hesitant* about that particular vaccine, and defer or avoid getting it.

One reason hesitancy can take hold in relatively low-trust societies is that reluctant vaccinees typically have no direct relationship with those mandating vaccinations, and thus no personal evidence that those people are trustworthy. For a regular medication, a physician needs and has the ability to convince one patient at a time to take a particular drug. This is why pharmaceutical companies have huge marketing budgets to sway individual physicians and patients alike. In the case of vaccines, companies need to convince only a few key officials and committees, who then buy their product and market it for them to an entire population. For companies producing vaccines, mass marketing is replaced almost entirely by political lobbying.

A number of events occurred in the 1990s that suggested the growing enmeshment between the pharmaceutical industry and scientists involved in drug production and approval decisions—along with the role of profit in the whole arrangement—was becoming an endemic problem. In 2005 the Associated Press reported that "two of the U.S. government's premier infectious disease researchers are collecting royalties on an AIDS treatment they're testing on patients using taxpayer money. But patients weren't told on their consent forms about the financial connection." One of them was helping to develop an interleukin-2 treatment, tested around the globe. The problem, as those reports noted, was that "hundreds, perhaps thousands, of patients in NIH experiments made decisions to participate in experiments that often carry risks without full knowledge about the researchers' financial interests."

One of the two people running these experiments was a researcher named Dr. Anthony Fauci, who first rose to prominence a decade before in the AIDS crisis. Not only was the assertion about royalties true; it was also perfectly legal. Royalties for public service scientists were first allowed under the Bayh-Dole Act of 1980, which had attempted to remedy two related problems: the lack of reimbursement for government-funded research, and retaining top scientists who were being lured away from public work by the private sector. This act and other federal regulations permitted the NIH, for instance, to collect proceeds if its research made money in the private sector, and allowed individual government scientists to collect up to $150,000 a year in royalties on treatments they developed.

At the time, Fauci said he tried to alert patients to his royalties, but his agency rebuffed him, arguing that he couldn't do so under the law. The nondisclosure of the researcher's interest was changed after the scandal, but damage had been done. In the minds of some elements of the public, there was something fishy going on between the government and the pharmaceutical industry—and it had something to do with money and a willingness to disregard or dilute informed consent.

These suspicions heightened in the 2000s, as key physicians began revealing to the public that Big Pharma had been involved in a number of major abuses of its relationships with government, patients, physicians, and journals. One of the first to break this story was Marcia Angell, who had been editor of the *New England Journal of Medicine*, arguably the most important medical journal in the United States at the time. In her 2004 book, *The Truth About the Drug Companies: How They Deceive Us*

"Vaccines are a one-size-fits-all intervention—administered en masse."

and What to Do About It, she argued that the companies spent far more on marketing, administration, public relations, and rebranding than they did on research, and that they actually discovered very few new effective drugs. Instead, they used "lures, bribes, and kickbacks," to get drugs taken up by physicians. Angell showed how these companies penetrated medical schools, conventions, and organizations, often passing off marketing as "education," which they provided free of charge.

More to the point, Angell argued that government agencies were highly compromised. She demonstrated how conflicts of interest permeated the U.S. Food and Drug Administration, which gave "expedited" reviews and approvals for drugs with major side effects like heart attacks and stroke (such as Vioxx and Celebrex), and some with no serious benefit. Angell also revealed that "many members of the FDA advisory committees were paid consultants for drug companies. Although they were supposed to excuse themselves from decisions when they have a financial connection with the company that makes the drug in question, that rule is regularly waived." She documented multiple instances of committee members discussing decisions on safety violations committed by the very companies that paid them, from which they did not recuse themselves.

Angell's book, which was published to great acclaim, was impossible to dismiss as fringe. "Dr. Angell's case is tough, persuasive, and troubling," claimed *The New York Times*. Publisher's Weekly wrote: "In what should serve as the *Fast Food Nation* of the drug industry, Angell ... presents a searing indictment of 'big pharma' as corrupt and corrupting." Over the next few years, the kinds of abuses she documented made it to the courts. As these trials became public, Americans who suffered from serious side effects caused by the drugs involved took notice.

In 2012, physician Ben Goldacre of Oxford University published *Bad Pharma*, in which he explored fraud settlements for pharmaceutical companies covering up known adverse events, including lethal ones, and hiding information, including about safety. The book's subtitle—*How Drug Companies Mislead Doctors and Harm Patients*—was key: Physicians often didn't know the wool was being pulled over their eyes, or what had been kept from them. But when the practices of large pharmaceutical companies were examined in the courts, with internal documents reviewed, one illegal activity after another was revealed. Goldacre's list makes one shudder:

> *Pfizer was fined $2.3 billion for promoting the painkiller Bextra, later taken off the market over safety concerns, at dangerously high doses (misbranding it with 'the intent to defraud or mislead') ... the largest criminal fine ever imposed in the US, until it was beaten by GSK [GlaxoSmithKline].*
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> *In July 2012, GSK received a $3 billion fine for civil and criminal fraud, after pleading guilty to a vast range of charges around unlawful promotion of prescription drugs, and failure to report safety data.*
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> *Abbot was fined $1.5 billion in May 2012, over the illegal promotion of Depakote.*
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> *Eli Lilly was fined $1.4 billion in 2009.*
>
> *AstraZeneca was fined $520 million in 2010.*
>
> *Merck was fined $1 billion in 2011.*

After Goldacre's book was published, the fines kept coming. Johnson & Johnson was made to pay $2.2 billion in 2013, which included, according to the Justice Department, "criminal fines" for having "jeopardized the health and safety of patients and damaged the public trust"; in 2019, the company was fined another $572 million for its role in the opioid epidemic, and then fined a whopping $8 billion by a jury in a different case—an amount that will no doubt be reduced, but which signals public outrage at the violations.

These huge fines, year after year, involve popular drugs taken by tens of millions of patients, with negative effects—including death. Stories of devastation have become lore in many families and communities. The circle of concern is even wider if you include those who may not have been personally affected, but are aware of this problematic legal history. When you personally take a medication, you tend to notice news about it, especially bad news. Whether or not you've experienced any negative effects yourself, you are naturally alert to their existence. Each time a Big Pharma company is in the courts and in the media because of some problem, the seeds of skepticism are planted in the minds of many Americans.

And not just skepticism of the companies themselves. The transgressions mentioned above were only possible on such a scale because of a textbook case of regulatory capture, consisting of a mixture of perverse incentives and priorities, a tolerance for nontransparency, and, in some

Fig. 4 In 1995, the FDA approved Oxycontin for short-term serious pain, like terminal cancer or postoperative pain. (Photo, 2019, by Brendan Smialowski / AFP.)

cases, an apparent culture of collusion. The FDA bills Big Pharma $800 million a year, which in turn helps pay FDA salaries. Regulators also often get jobs in the pharmaceutical industry shortly after leaving the FDA or similar bodies; there is a huge incentive to impress, and certainly not to cross, a potential future employer.

It's useful to see how this works by examining a case that became famous as a tale of epic greed and corruption, and in which patients and physicians were misled and deceived, only after patients, families, activists, and even whole communities yelled themselves hoarse about it for years.

In 1995, the FDA approved Oxycontin for short-term serious pain, like terminal cancer or postoperative pain. This approval was based on legitimate scientific studies related to these narrow experiences. The FDA then made it available for minor pains, with around-the-clock daily usage, in 2001. *That* approval (for long-term use) was *not* based on any studies. According to a *60 Minutes* report in 2019: "Equally suspicious but legal [was] the large number of key FDA regulators who went through the revolving door to jobs with drug manufacturers."

The opioid epidemic has, to date, left half a million Americans dead.

This same compromised regulatory system allows Big Pharma to pay for, and play a key role in performing, the very studies that lead to the authorization of its own products. For decades, it was not just common for authors of studies to receive payments from the very companies making the medicines being tested; it was also systematically hidden. Drug companies secretly ghostwrote studies of their own drugs; Goldacre shows how they conscripted academics to pretend they had authored them. The papers were then submitted to mainstream journals, whose imprimatur would give the studies credibility, allowing these drugs to become the "standard of practice."

Sixteen of the 20 papers reporting on the clinical trials conducted on Vioxx—the anti-inflammatory and pain medication that got FDA approval in 1999, then was taken off the market in 2004 for causing heart attacks and strokes—were ghostwritten by Merck employees, then signed by respected scientists. Merck ultimately agreed to pay out $4.9 billion in Vioxx lawsuits. The academics who lent their names to the studies could then stuff their CVs with these articles, receive promotions and higher salaries within academia, and ultimately get more consulting fees from pharmaceutical companies, at which point they are seen as "experts" by a trusting public.

In the current regulatory environment, companies run the studies of their own products. A Danish study found that 75% of drug company self-studies assessed were ghostwritten. A leading U.S. editor of a specialist journal estimated that 33% of articles submitted to his journal were ghostwritten by drug companies. These impostures don't get adequately investigated by Congress because the pharmaceutical and health industries are now the highest-paying lobby in the country, having doled out at least $4.5 billion in the last two decades to politicians of both parties. "Pfizer's PAC has been the most active," STAT reporter Lev Facher writes, "sending 548 checks to various lawmakers and other industry groups—more checks than the actual number of elected officials in the House and Senate."

While Goldacre's book shows the many ways that drug studies have been rigged to deliver certain outcomes, one doesn't always have to rig

a study to get the same result. Among the most common techniques is to delay the reporting of medication side effects until after the patent runs out—and then use the bad publicity to sell a new replacement medication, which is still on patent.

Polls repeatedly show that the chief concern among the vaccine hesitant is about side effects, or at least effects that don't show up right away. The latest edition of the standard textbook in the field, *Plotkin's Vaccines*, has an excellent chapter on vaccine safety, which notes: "Because reactions that are rare, delayed, or which occur in only certain subpopulations may not be detected before vaccines are licensed, postlicensure evaluation of vaccine safety is critical." Postlicensure first requires FDA approval, so for most vaccines that means more follow-up after the typical two-year approval process—at least several years of it.

In 2018, *The New York Times*' pro-vaccine science writer, Melinda Wenner Moyer, noted with shock that she learned it was not uncommon among vaccine researchers to take the attitude that censoring bad news about their research was necessary, and that some who didn't were ostracized by their peers:

> *As a science journalist, I've written several articles to quell vaccine angst and encourage immunization. But lately, I've noticed that the cloud of fear surrounding vaccines is having another nefarious effect: It is eroding the integrity of vaccine science. In February I was awarded a fellowship by the nonpartisan Alicia Patterson Foundation to report on vaccines. Soon after, I found myself hitting a wall. When I tried to report on unexpected or controversial aspects of vaccine efficacy or safety, scientists often didn't want to talk with me. When I did get them on the phone, a worrying theme emerged: Scientists are so terrified of the public's vaccine hesitancy that they are censoring themselves, playing down undesirable findings and perhaps even avoiding undertaking studies that could show unwanted effects. Those who break these unwritten rules are criticized.*

Moyer went on to quote authorities who argue that smaller studies, and even inconclusive ones, often give us the first glimpse of an insight or problem. And this is to say nothing of the wider issue: If scientists play down their undesirable findings in potentially mandated medicines, as Moyer found them to be doing, they are not just missing opportunities for good science; they are potentially generating anti-scientific misinformation. "Vaccine scientists will earn a lot more public trust, and overcome a lot more unfounded fear, if they choose transparency over censorship," she wrote.

By the time Moyer published her article in 2018, many Americans were already long in the habit of questioning certain elements of their public health, in part because of this hornet's nest of corruption and regulatory capture. But this habit could also be explained in part by the general trend in medicine over the past two decades toward recognizing the superiority of individually tailored interventions, or personalized medicine, which acknowledges that different people have different risk factors, genetics, medical histories, and reactions to medical products. It is now commonplace for people to take responsibility for their own health because this is precisely what we have been telling them to do—encouraging them to get to know their own unique risk factors for disease, based on their own individual histories and genetics.

Vaccines, in contrast, are a one-size-fits-all intervention—administered en masse by those who know nothing specific about vaccinees or their children. When political and medical authorities change policies from day to day, and public health recommendations in one jurisdiction or country differ from those in others, questions will be asked. The public has been assured that we in health care recognize that the era of medical authoritarianism, and the ugly practices that led us to require informed consent, are behind us. This means that whenever there is a treatment on hand, the burden of proof to demonstrate that it is safe and effective must fall on *those who offer it*. It means we must never stifle questions, or shame people for being anxious.

I am a psychiatrist and a psychoanalyst, and I deal with people's anxieties—and their paranoia too. Many people think "the anxious" are necessarily weak (one medical colleague calls the vaccine hesitant "wimps"). But this is, if not entirely wrong, a superficial way of understanding anxiety. Anxiety is a signal. It evolved to get us to pay attention to something—sometimes an external threat, and sometimes an internal one, such as an ignored feeling or forbidden thought threatening to emerge from within. Anxiety can be neurotic. It can even be psychotic. It can also

Fig. 5 The United Kingdom's Central Council for Health Education (1927-1968) promised to protect your children. (Creative Commons license.)

save your life, because dangers do exist. When people don't experience *enough* anxiety, we say they're "in denial."

Thus, in some situations, the capacity to feel anxiety can be an advantage, which is likely why it is preserved in evolution in so many animals. Aristotle understood this very point long ago; as he noted, the courageous person, say a soldier, can and should feel anxious—he is facing a danger, after all, and his wisdom tells him there is risk. What distinguishes the courageous person from the coward is not that they don't worry or fear, but that they can still manage to move forward into the dangerous situation they cannot avoid facing. All of which is to say that the presence of anxiety alone is not dispositive of sanity or insanity: It, alone, does not tell you whether the anxiety is well or ill-founded. The same goes with distrust. Sometimes distrust is paranoia, and sometimes it is healthy skepticism.

As of a September 2019 Gallup poll, only a few months before the COVID-19 pandemic, Big Pharma was the least trusted of America's 25 top industry sectors, No. 25 of 25. In the eyes of ordinary Americans, it had both the highest negatives and the lowest positives of all industries. At No. 24 was the federal government, and at No. 23 was the health care industry.

These three industries form a neat troika (though at No. 22 was the advertising and public relations industry, which facilitates the work of the other three.) Those inside the troika often characterize the vaccine hesitant as broadly fringe and paranoid. But there are plenty of industries and sectors that Americans *do* trust. Of the top 25 U.S. industry sectors, 21 enjoy net positive views from American voters. Only pharma, government, health care, and PR are seen as net negative: precisely the sectors involved in the rollout of the COVID vaccines. This set the conditions, in a way, for a perfect storm.

A New Plague Descends

IN FEBRUARY AND early March 2020, it became clear that the disaster that had swept through Wuhan was becoming catastrophic in Bergamo. As frontline health care workers were dying in both China and Italy, the virus had also spread throughout Western Europe and arrived in North America. Early reports of the case fatality rate reached over 14.5% in Italy in the spring, and in Spain, Sweden, and other hot spots it was over 11%, devouring the elderly in every affected country. PPE often didn't exist for frontline health care workers. Bodies were stored in refrigerated trucks. Citizens were told masks would not protect them, and there were

no known outpatient treatments. While hospitals could provide oxygen, this was often insufficient, and so victims were put on ventilators, which may have made some cases worse, and was a horrible way to die.

While much of the United States was terrified, there was some light: Dr. Anthony Fauci, the physician-scientist now running the country's pandemic defense, seemed able to answer most press questions, projected an affable, avuncular persona, and spoke in ways people could understand, which is what the nation required. Even skeptics had hopes: Fauci seemed steady when events took unexpected turns, explaining that we were learning as we went along. He said the lockdown would be for 15 days, to "flatten the curve." When that didn't work, he explained why, argued that it should be extended, and much of the nation went along. In a United States exhausted by its hyperpolarized political scene, here was someone who had worked with both parties, advising every president since Ronald Reagan. For those on the right, he could be seen as an employee of and messenger for President Donald Trump; for those on the left, he was a longtime public servant who had headed the same institution, the National Institute of Allergy and Infectious Diseases (NIAID), since 1984, and played vital roles in the fights against AIDS and Ebola. There was a widespread sense that Fauci was the right man at the right time.

But then there were flip-flops on masks: After claiming the science showed that masks were unnecessary, Fauci later said they were absolutely necessary, but wouldn't be for the vaccinated, until, eventually, they were. There were also disputes about lockdowns: Initially introduced as temporary to flatten the curve, they were later extended to become a new way of life, in order to save lives. But then some states like Florida, which didn't impose long and severe lockdowns, had lower age-adjusted mortality than states like New York, which did. Then, another issue emerged that was not simply scientific, but also political.

Since the earliest days of the pandemic, many regular people struggled to make sense of its origins. The Chinese Communist Party had claimed the virus emerged from a wet market while denying any connection to virology labs located nearby. There was obviously a cover-up unfolding in China, with arrests of citizen journalists and detentions and disappearances of Wuhan physicians who witnessed the first cases, and who would have ideas about where it started.

Various observers argued that there was reason to consider that COVID may have leaked from the Wuhan Institute of Virology, and perhaps even may have been engineered by gain-of-function (GoF) research, in which a natural virus is made more contagious and lethal, ostensibly to see if the scientists can "get ahead" of nature, and to study how it operates in order to make new vaccines or medications, or for biological warfare. GoF is so controversial that in 2014 President Barack Obama put a moratorium on it. In 2017, Drs. Fauci and Francis Collins, then director of the NIH, who had opposed the moratorium, succeeded in having it lifted.

But Fauci asserted that the scientists who were in a position to judge the COVID situation concluded that its origin was natural. The media followed suit, and called those who thought otherwise "conspiracy theorists." *The New York Times*, *Washington Post*, and others called the possibility of a lab leak a "conspiracy theory" that had been "debunked" (see figure 6).

In the meantime, a master narrative began to emerge: Once upon a time, life was relatively normal and safe, and then the pandemic came, and life as we knew it suddenly changed in awful ways. The only way out, the only path back to a world without COVID, would be to make a vaccine—as quickly as possible. Until then, everyone would have to do their part to "stop the spread," which meant that basic social functions would have to cease, including school for millions of children. Thousands of small businesses would have to close, and civil liberties rolled back. It would be a difficult time, but eventually we would have the vaccine, and COVID would be over—as long as everyone got it, of course. But then, who wouldn't want to?

Fig. 6 Screencaptured *Washington Post* headline from Feb. 17, 2020. The *Post* later issued a correction, changing the headline to 'Tom Cotton keeps repeating a coronavirus fringe theory that scientists have disputed.'

On this point, Bill Gates, of Gavi, the Vaccine Alliance, and the largest private contributor to the WHO, was very direct: "The ultimate solution, the only thing that really lets us *go back completely to normal* and feel good … is to create a vaccine," he said.

If you asked researchers or most physicians in the spring of 2020 how long it normally takes to produce a vaccine safe enough to administer to patients, many would have pointed out that the average *fast* vaccine takes 7-10 years, and that the first vaccine might just be one of several required to end a given crisis—because often the first is not the best.

This seemed too long. Gates predicted that there would be problems moving quickly because companies would have to produce a one-size-fits-all vaccine that could have different effects on different groups, including pregnant women, the undernourished, and people with existing comorbidities. "People like myself and Fauci," Gates said, "are saying 18 months [to make the vaccine] … If everything went perfectly … there will be a trade-off: We'll have less safety testing than we typically would have … we just don't have the time to do what we normally do." The solution he noted was that "governments will have to be involved because there will be some risk and indemnification needed."

In August, that solution was reached. As The Intercept reported on August 28, "an amendment to the PREP Act … stipulates that companies 'cannot be sued for money damages in court' over injuries caused by medical countermeasures for Covid-19. Such countermeasures include vaccines, therapeutics, and respiratory devices." The only exception to this immunity would be if death or serious physical injury is caused by "willful misconduct." Indemnification for vaccines was, as discussed above, not unique; what was new was that the companies producing them were indemnified *before* the vaccine was even made and fully assessed—knowing it would all be done faster than ever before.

As the nation agonized over mounting deaths, the race for a vaccine was moving quickly—if too opaquely for some. In September 2020, a number of scientists began openly worrying about the nontransparency of the vaccine trials, and whether this could wind up affecting vaccine hesitancy.


Vaccine Makers Keep Safety Details Quiet, Alarming Scientists

Researchers say drug companies need to be more open about how vaccine trials are run to reassure Americans who are skittish about getting a coronavirus vaccine.

Fig. 7 Headline from *The New York Times*, Sept. 13, 2020.

The New York Times ran several articles on this, reporting that AstraZeneca, Pfizer, and Moderna had each withheld their study protocols from outside scientists and the public (see figure 7). Withholding protocols guarantees that outside researchers can't know how participants are selected or monitored, and how effectiveness or safety are defined, so they can't really know what exactly is being studied. Pharma companies have traditionally argued that not only the trial patents but the clinical trial data belong to them—that it's proprietary, even though the studies' results impact millions. This is part of a kind of "traditional secrecy" in the field. Delaying protocol release conveniently means that it is a company's press releases, not the verified science, that dominate the public's all-important *initial impression* of its product.

That the government's regulatory agencies go along with all this—it is, in fact, standard practice—doesn't assuage the public; for many, it makes the whole process appear corrupt. And it doesn't help that, according to the conflict-of-interest disclosures of the authors of the Pfizer and Moderna vaccine clinical trials, some of the authors are employed by these companies and often have stock options.

The essence of the scientific method is conducting experiments that everyone can objectively see and verify; transparency is the bedrock of experimental science, and the means to ultimately dispel doubt. Moreover, in terms of the scale of public involvement, the experience of the summer and fall of 2020 was unlike any other in the history of medicine. Never before had studies of this size and consequence been run so quickly, or a medicine been produced so quickly to be given to hundreds of millions of people.

These studies were called phase III clinical trials, and if they had positive results, then the vaccine could be given to hundreds of millions of people on the basis of an FDA Emergency Use Authorization. But how long were the patients followed in these two studies after their second dose, to assess safety and efficacy? Two months. On that basis the vaccines were given to over a hundred million people.

One must not confuse the perhaps immaterial fact that the vaccines were *made* quickly from the arguably more important fact that they were *tested* on people for only a short time. These vaccines were developed so quickly in part because the new mRNA technology allows quicker production, and because parts of the production lines that in the past were staged out over time were, in this case, set up simultaneously with the help of huge cash infusions. All else being equal, there's a serious argument that it might be hugely advantageous to be able to produce new vaccines so quickly. "If you can intervene with let's say a 40% effective vaccine 4 months before you can intervene with an 80% effective vaccine, you save more lives with the 40% effective vaccine that's delivered 4 months earlier," Dr. Barney Graham of the National Institutes of Health pointed out. "Being fast in an outbreak setting in some ways is more important than being perfect."

Still, it was obvious as early as the fall that some testing steps *would* be skipped. "We'll have less safety testing than we typically would have," Gates noted. "We just don't have the time."

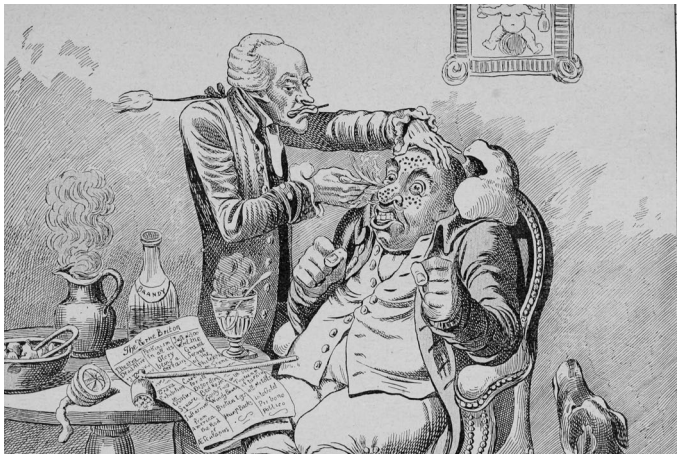

Fig. 8 Mistrust of vaccinations has a long history. A British 1907 caricature shows a grotesque doctor vaccinating a patient against smallpox, using all forms of quackery. (Photo by Smith Collection/Gado/Getty Images.)

Must that be a problem? Why, especially during a pandemic, wouldn't we want to quickly distribute any vaccine that appears to work even somewhat effectively to those who are willing to take on any potential risks that may go with less safety testing? Some people might even decide for themselves that a raging pandemic is a dangerous enough threat to outweigh every other possible concern.

But what we shouldn't do, if we want to maintain public trust and cohesion, is act as though there is no chance that any legitimate concern could ever possibly emerge, or that we know more than we really do after only two months of study. With complex biological systems, we simply can't presume that just because we have a fantastic idea for a treatment, the safety we hope for and see at the start will necessarily hold over time.

Take the classic case of thalidomide. It was originally a sedative, used for anxiety, and later tried for nausea. It worked, leading some to "theorize" that it could prevent nausea in pregnant mothers. In practice, once on the market, it did. But it also caused serious birth defects in children. It took longer than nine months, and enough cases, to realize that these side effects came from the drug, and even more time to overcome the drug company's opposition to the facts.

The same applies to any of the major drugs pulled off the market for causing cancer, heart attacks, and diabetes. They don't always cause dire consequences immediately, or in everyone. Sometimes these drugs set a process in motion immediately, but it takes scientists a year or many years to pick up the trend in a population at large. Working from first scientific principles and based on what we already know, we can often develop a neat theory about what might work. But because we don't know what we don't know, it often doesn't turn out as we expect. That is why empirical science developed as a way to test our theories. Empirical science is always, by definition, science after the fact.

This is especially important given the specific kind of vaccine that was being approved in the United States—the mRNA vaccine—which was a first-of-its-kind. Instead of exposing a person to the virus itself in attenuated live form (like the MMR) or killed form (like the polio shot or flu shot)—which is how many of the other vaccines we've come to

know work—in the mRNA vaccine a person is exposed to an artificially made genetic messenger, mRNA, that goes into their cells and directs them to make part of the virus, which then triggers antibodies. Early on in the rollout, both the pharma PR industry and the press emphasized how novel these vaccines were, and how this unique technique would produce a vaccine so quickly. But when some side effects started to emerge, and people got nervous, officials and the companies' own PR teams changed their message: These techniques were now presented as not new at all, but as having been around a long time. The hesitant notice flip-flops in communication like this. At best, it makes them wonder about the lasting veracity of public health messages; at worst, it makes them deeply suspicious.

Over the course of the summer of 2020, while the clinical trials were ongoing, outside scientists still had no access to what exactly was being measured and hence studied, so there was no external check on or observation of the process, despite much of the research having been funded by government: Marketing and distribution would be done by the government, the government would be providing the customers, and the government would even pay for the consequences of safety problems that might arise. Withholding protocols rather than disseminating them as widely as possible was, under such circumstances, a sign of outlandish chutzpah. And the governmental agencies that are supposed to advocate for the public—in this case, the FDA, CDC, and NIH—countenanced it.

In September 2020, one bit of secrecy was lifted: It turned out that AstraZeneca had stopped its clinical trial twice. The first pause was not even announced; the second one was, but neither the U.K. public nor the FDA nor scientists were immediately told why. Before they ever found out, however, AstraZeneca CEO Pascal Soriot did privately disclose the reason—two cases of serious neurological damage—to the JP Morgan investment bank. To some, this said much about who, exactly, this process was designed to benefit.

"The communication … has been horrible and unacceptable," vaccine advocate and virologist Dr. Peter Hotez said. "This is not how the American people should be hearing about this." Scientists started to demand to see the protocols. Hotez and others "criticized obtuse statements released by government officials, including U.K. regulators who he said failed to supply a rationale for resuming their trials." Government officials and the regulators, who most citizens assume are there to keep these processes honest, seemed instead to be partners in the obfuscation.

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In November 2020, the exciting news arrived: We had vaccine liftoff. Phase III trials of the Pfizer and Moderna vaccines were said to be 95% and 94.5% efficacious, as Fauci and the company press releases announced, and the Emergency Use Authorization was granted on the basis of these two-month studies, allowing distribution of the vaccines to millions.

"Efficacious" is the term used to describe how effective a treatment is in the artificial situation of a clinical trial with volunteer patients, a group not always representative of the wider population; "effective" is the term used to describe how a treatment works in the real world. The media quickly assumed the two were the same. To them, hearing that a vaccine was "95% efficacious" meant it was practically perfect, which the press repeated over and over.

But what exactly were the vaccines "efficacious" at doing? Stopping viral transmission? Preventing severe illness, or reducing hospitalization, or ICU admissions? Preventing death? Efficacious for how long? And efficacious in whom? In the elderly, who were most vulnerable to death? Without clear definitions and answers to these questions—typical of much of the coverage—Americans only had a limited idea, really, of what these vaccines had been shown to do in the narrow universe of clinical trials, let alone what they'd do when given to the public. In fact, they didn't receive answers to a single one of these questions.

Moreover, there was still a cloud of mystery surrounding the trials. After pressure mounted in the wake of the AstraZeneca revelation in September, the four major Western vaccine manufacturers finally released their protocols, each over 100 pages long. After the protocols were released, Peter Doshi, an associate editor at the *British Medical Journal* who does research into drug approval processes and how results are communicated to the public, tried to sound an alarm: "None of the trials currently underway are designed to detect a reduction in any

serious outcome such as hospital admissions, use of intensive care, or deaths," he said.

Only one of the studies, of the Oxford AstraZeneca, looked at whether vaccinated individuals were less likely to transmit virus by doing weekly polymerase chain reaction (PCR) swabbing. Vaccinated people had lower viral loads, were less likely to have a positive COVID test, and were positive for shorter durations—very good news indeed, though not automatically applicable to the other mRNA vaccine studies. So what were these clinical trial studies that showed 95% and 94% efficacy looking at, if not saving lives and viral transmission?

Consider that researchers can set up a study to examine whether a vaccine prevents a person from experiencing any or all of the following events, sometimes called "endpoints":

An asymptomatic infection (the patient is carrying the virus, but the case is so mild that they don't know it, even though it is shown to be present by a positive virus test).

A clinically symptomatic infection that is mild (and might be confused with a common cold).

A clinically symptomatic infection that is moderate.

A clinically symptomatic severe infection that requires hospital admission.

A clinically symptomatic severe infection requiring ICU admission, and even a ventilator.

A clinically symptomatic severe infection that ends in death.

What were the events, or "the endpoints," that the phase III Moderna and Pfizer studies claimed to be examining? They said they looked at any clinically symptomatic infection "of essentially any severity" as the primary endpoint. But therein lies the rub.

As Doshi explained, "Severe illness requiring hospital admission, which happens in only a small fraction of symptomatic covid-19 cases, would be unlikely to occur in significant numbers in trials. … Because most people with symptomatic covid-19 experience only mild symptoms, even trials involving 30,000 or more patients would turn up relatively few cases of severe disease."

How few serious cases, in terms of deaths, were there? In the Pfizer trial, not a single person died of COVID-19 in either the vaccine or the placebo group. The report that Moderna gave to the FDA on Dec. 17, 2020, on its trial specifically said it considered death "a secondary endpoint," and added that "there were no deaths due to COVID-19 at the time of the interim analysis to enable an assessment of vaccine efficacy against death due to COVID-19." By publication date, one person had died in the placebo group.

Go over that again: In the study period for the two new mRNA vaccines, only one person out of 70,000 died a COVID death. Now ask yourself, without knowing the demographic markers of the trial participants but knowing for a fact that hundreds of thousands of people were dying from the virus: Does this seem to you like an appropriate way to study severe illness? Moderna told the *BMJ* in August 2020: "You would need a trial that is either 5 or 10 times larger or you'd need a trial that is 5-10 times longer to collect those events."

In a talk based on her *Lancet* article, given to the *BMJ*'s "COVID19 Known Unknowns: Vaccines" webinar in February 2021, Dr. Susanne Hodgson, National Institute for Health Research academic lecturer in infectious diseases at the University of Oxford, stated: "The current RCTs that are ongoing are … not powered to assess efficacy against hospital admission and death."

In the same webinar, Doshi presented on the transparency issue. Having read the protocols and then the phase III trial studies of the Pfizer, Moderna, AstraZeneca, and Sputnik (Russian) vaccines, he wanted to check the raw data from the studies in order to verify it—that is, he wanted to see not just final charts, tables, averages, percentages, and conclusions, but to look over the individual cases. Most of the studies had a line in them that claimed such data was available upon request. According to Doshi, he wrote to the drug companies that had authored the studies and asked to see it. But he wasn't permitted.

"Each time a trial is published there is this data sharing statement and everything sounds good, until you read the fine print," he said. "Pfizer, for example, says that it is sharing data *upon request*. Except it is actually not planning to do so for a very long time. I asked. The same for Moderna. The same for the Oxford AstraZeneca and the Russian vaccine. They all said they will be sharing the data, just not yet. And most are tying the data release to the end of the trials. So we have a situation where the vaccines are being administered to the masses but data isn't being shared because the sponsors say the trials are ongoing."

Pfizer data, he learned, might arrive in January 2025. Moderna said it *may* be available ... once the trial is complete (sometime in 2022). Other companies were similarly vague. To date, approximately 4 billion people have already got these vaccines—many receiving a first-of-its-kind mRNA genetic formulation, without outside sources reviewing the raw study data. Given that the companies won't release this data in a timely manner, it is reasonable to assume that public health officials in different countries that approved the vaccines have not seen the raw data either, or run verification checks.

Given all this, it is difficult to assuage those who distrust the systems that delivered the vaccines: At least one of these vaccines, the Moderna, was supported by the NIH and NIAID, which may have joint ownership in intellectual property that undergirds the vaccine. That means their budgets stand to benefit from sales, and individual government employees may get royalties for them. Though it would fall to the FDA to officially approve the vaccines, the advice to enact vaccine mandates would come from a small network, and would be based on studies that were authored in some instances by people who are employees of the companies themselves, which were testing their own products. And when a remarkably trusting public and a few scientists requested a look at the raw data, they got stiffed.

One can only imagine how enriched our knowledge would be if it were otherwise—if, to take just one example, the raw data were available and verified by the hive mind of world scientists, who, drilling down, could see for whom the vaccine was most effective, and who was most at risk of serious side effects, in order to follow them longer than two months and to protect those groups of people in the future. The confidence this would have inspired in a vaccine produced so quickly might have been astonishing—a miracle not only of human scientific advancement, but of the human capacity for persuasive communication and the social progress it can generate.

> "When public health officials distrust the public, the public will come to distrust them."

Alas, that's not what we got. The train was already barreling out of the station. When the first vaccines were rolled out in December 2020, Fauci received his Moderna shot, announcing that he wanted to get publicly vaccinated as a "symbol" for everyone in the country. "I feel extreme confidence in the safety and the efficacy of this vaccine," he said. As to the question of how sick the patients in the study were, he said: "With regard to Pfizer it was 95% efficacious not only against disease that is just clinically recognizable disease, but *severe* disease." And he said much the same was found for the Moderna vaccine: It prevents severe disease.

By the spring of 2021, the master narrative—the necessity of using one main tool, the vaccine, "to vanquish the enemy"—was working brilliantly. Government data from Israel and the U.K. showed the vaccines weren't just "efficacious" in clinical trials, but also "effective" in the real world. In an April 28 article in the *Harvard Gazette* titled "Vaccines can get us to herd immunity, despite the variants," Dr. Ugur Sahin, the chief executive of BioNTech, which developed the mRNA vaccine for Pfizer, was quoted saying that Europe would reach herd immunity in July or August. The virus would no longer be able to spread.

In the U.K., Freedom Day was set for June 21 (later changed to July 19), and the return to normal in other vaccinated countries seemed not far behind. On April 22, Israel, considered the world's most vaccinated country (except for some even tinier nations), for the first time recorded no daily COVID deaths. Pfizer's CEO—who called Israel "the world's lab," not only because it was highly vaccinated but because it was vaccinated early, giving the world a glimpse of its future—announced in February that the experiment was going marvelously, saying, "current data shows that after six months the protection is robust" and "there are a lot of indicators right now that are telling us that there is a protection against the transmission of the disease." The U.K., the second most vaccinated large nation, had a terrible death count in January. But on May 10, there was not a single COVID-19 death in all of England, Northern Ireland, and Scotland.

President Biden assured the American people confidently: "If you're vaccinated, you're protected. If you're unvaccinated, you're not"—reiterating that being vaccinated "is a patriotic thing to do." This was a riff on CDC Director Dr. Rochelle Walensky's statement: "If you have two doses of the vaccine, of the mRNA vaccines, you're protected. You don't need to wait for a booster, you're protected."

Over the spring, Walensky became an increasingly prominent face. In the months since Biden was inaugurated, a slew of officials who had advised the Trump administration were out of the picture—Dr. Robert Redfield (as head of the CDC), Dr. Deborah Birx, and Dr. Scott Atlas—and a new cohort was ushered in. More and more, Walensky became a visible voice of public health.

In April, during a White House press briefing barely four months after distribution of the first vaccine doses began, Walensky announced that the "CDC recommends that pregnant people receive the COVID-19 vaccine." But if you checked the CDC website that day—as many pregnant women and their physicians of course did—you would have found something different: "If you are pregnant, you may choose to receive a COVID-19 vaccine," but "there are currently limited data on the safety of COVID-19 vaccines in pregnant people." In the press briefing, Walensky had cited a study from the *New England Journal of Medicine*, about which she said: "no safety concerns were observed for people vaccinated in the third trimester or safety concerns for their babies."

The study did claim that there was no increased instance of fetal death or neonatal death, which was very reassuring. But it was unable to answer one of the main questions many pregnant women are concerned about: Will these new vaccines have adverse effects on my baby's development after birth? The study's authors made clear that they didn't have enough longitudinal data on women in the first or second trimester of pregnancy to draw conclusions about women vaccinated in those two trimesters (when different organ systems develop), and that their study was therefore "preliminary": "Preliminary findings did not show obvious safety signals among pregnant persons who received mRNA COVID-19 vaccines. However, more longitudinal follow-up, including *follow-up of large numbers of women vaccinated earlier in pregnancy, is necessary* to inform maternal, pregnancy, and infant outcomes" (emphasis added).

Recall that the vaccine rollout began in December 2020, for older people. This study only looked at safety data on women in various stages of pregnancy from Dec. 14, 2020, to Feb. 28, 2021, a two-and-a-half-month period. Many women become more vigilant in pregnancy about what they eat, and what they put into their bodies. So it should come as no surprise that more than one woman who was either pregnant or trying to conceive began wondering about a question that one of my colleagues asked me: *If at the time of the study, the vaccine had only been available for two-and-a-half months, wouldn't that mean—if it's still true that human gestation is approximately nine months—that literally no one who had been vaccinated early in pregnancy had yet followed through to a full-term pregnancy?*

None of this is to insinuate an opinion about the use of the vaccines in pregnancy; we are here discussing how simplifications of what scientific studies actually show at a particular moment—even when they turn out, ultimately, to be right—can generate distrust. I would venture that what young families wanted to hear was something both reassuring *and* reflective of whatever trustworthy data was available to date—like "we are working on a longer study, and feel hopeful about it, but for now we at least know if vaccinated in the third trimester, there is little chance the vaccine will lead to a death." That, I believe, would have quelled anxiety. But the government and its messaging partners chose a different posture—one that suggested certainty when important data was still yet to come. A lesson in human nature: When public health officials distrust the public, the public will come to distrust them.

Take, for example, an article by Kimberly Atkins Stohr, senior opinion writer and columnist for the *Boston Globe*, who got the Johnson & Johnson vaccine in April, a week before the FDA put a pause on it because of blood-clot complications. As Atkins indicates, the FDA admitting that there might be a problem, as opposed to hiding it, made her more—not less—likely to believe that the institution is on top of monitoring the vaccines. "I want others to view this pause not as reason to doubt the drug, but a reason to believe in it," she writes.

The mainstream media in the United States also often downplayed potential problems, and even demonized those who took them seriously—portraying white Christian Republicans as the last redoubt of COVID vaccine skepticism in America. But if white Americans in red states have had

high rates of hesitancy, African Americans and Latinos have too. As we've seen in the case of African Americans, hesitancy is based at least in part on well-earned distrust. In the U.K., in March 2021, vaccination rates were very high in the "white British" group (91.3%), and British Christians had the least hesitancy, whereas vaccination rates were lower in the Black African and Black Caribbean communities (58.8% and 68.7% respectively), and among Muslims, Buddhists, Sikhs, and Hindus. In Canada the typical vaccine hesitant person is a 40-year-old woman who tends to vote Liberal.

A January Gallup poll showed that 34% of U.S. frontline health care workers (who are both more exposed to COVID and more educated in health) said they did not plan to get vaccinated, and an additional 18% were "not sure" what they would do. Given the WHO's own definition of the "vaccine hesitant"—people who delay or are reluctant to take a vaccine—one could say that 52% of frontline U.S. health care workers were vaccine hesitant at the beginning of the year. It was hard to argue that these were people who got *all* their information from a few rancid conspiracy websites. In fact, many of these professionals are vaccinated for other illnesses. Nor can we argue that frontline workers are overly anxious and cowardly; many are exposed to active COVID regularly.

Fig. 9 Anti-vaccine protest, San Diego, Calif., September, 2021. The U.S. media often portrayed white Christian Republicans as the last redoubt of COVID vaccine skepticism. (Photo by Sandy Huffaker/Getty Images.)

At other times, we are told that the hesitant are only those with the least education. But a Carnegie-Mellon and University of Pittsburgh study showed that "by May [2021] PhDs were the most hesitant group." In May, Sen. Richard Burr of the U.S. Senate Committee on Health asked Fauci how many employees of the NIH, the nation's premier health sciences research institution, had been vaccinated. "I'm not 100% sure, Senator, but I think it's probably a little bit more than half, probably around 60%," he said. The senator asked the same question of Dr. Peter Marks, director of the Center for Biologics Evaluation and Research at the Food and Drug Administration, about the FDA's employee vaccination. "It's probably in the same range," he answered.

In studies in the West, the hesitant repeatedly express, as the top reason for their reluctance to get vaccinated, concerns about what we might call "future unknown effects." In a May study of Britain, for instance, 42.7% cited this as their biggest fear. The hesitant were not particularly concerned about trivial short-term side effects like sore arms, fatigue, or a passing fever or headache. Only 7.6% were distrustful of "vaccination" generally. In the United States, a multi-university study of over 20,000 people found safety concerns, or uncertainty of the risk, as the top reason given for vaccine hesitancy—59%. Only 33% agreed that vaccines are thoroughly tested in advance of release. The authors reported "massive differences between the vaccinated and unvaccinated in terms of their trust of different people and organizations," including the CDC and FDA. An IPSOS-World Economic Forum survey of 15 countries showed that in all 15 countries, the leading reason the reluctant gave was fear of side effects, exceeding all other concerns by far. In all countries surveyed, the number of people who said they were "against vaccines" (i.e., the anti-vax position) was generally a minor fraction of those who hadn't yet been vaccinated.

A common theme in France, Britain, and the United States, in fact, is distrust of the vaccine troika—Big Pharma, government and public health, and the health care industry—and an insistence that individuals should have the right to decide whether to get vaccinated. These similarities are worth paying attention to, because they suggest that the attempt to explain the phenomenon by using the group identifiers American media is so fond of—sex, race, religion, and political affiliation—falls short, and shifts attention away from the real issues creating distrust.

On May 11, Fauci appeared in front of a Senate hearing. "The NIH and NIAID categorically has not funded gain-of-function research to be conducted in the Wuhan Institute of Virology," he said. Yet, in a circumvention of the Obama administration's 2014 moratorium, and to the disapproval of many in the U.S. scientific community, Fauci's agency did fund a U.S. company called EcoHealth Alliance, which then facilitated GoF research in collaboration with the Wuhan Institute of Virology. Indeed, from June 2014 to May 2019, Fauci's agency funded both EcoHealth and Peter Daszak—a well-known GoF researcher who subcontracted the grant to the Wuhan lab, where GoF research on bat viruses was conducted and led by Dr. Shi Zhengli—and which wasn't subject to the U.S. government moratorium.

Dr. Francis Collins, then head of the NIH, had told the House Appropriations Subcommittee that the NIH did not fund GoF in Wuhan. But later, after Fauci reversed his prior claim and said it was possible, Collins also backtracked. "We of course do not have internal insight as to what was going on in the Wuhan Institute of Virology," he said. Both reversals came only after the plausibility of the lab leak theory started to gain mainstream acceptance, and public pressure mounted.

While Fauci's denial in the Senate might have been technically accurate, it was misleading: Neither agency *directly* funded this kind of research, but did do so through a third party. As it turned out, Fauci himself wrote in 2012 that he, like GoF critics, could imagine "an important gain-of-function experiment involving a virus with serious pandemic potential," whereby "an unlikely but conceivable turn of events" leads to an infection of someone in the lab "and ultimately triggers a pandemic." Nonetheless, he wrote, for "the resulting knowledge" such research might yield, it was worth the risk.

In June, the question of what Fauci knew and when he knew it came up in his emails, which showed that, although he denied to Congress that his organization funded experiments at the Wuhan Institute of Virology, it had. On Feb 1, 2020, Fauci sent two emails to his staff about a "gain of function" study the NIH had approved, in which he referred to "SARS Gain of Function." His denial of NIH involvement ultimately proved unconvincing, since funding of it was already part of the NIH committee and grant paper trail. Shi Zhengli, the head of the Wuhan Institute of Virology, co-authored a paper about constructing a superlethal virus, which appeared in *Nature Medicine* in 2015, and specifically thanked the NIH and EcoHealth for funding her work. A 2017 research article, also with Shi Zhengli as co-author, not only qualifies as GoF research, but "epitomizes" it—and specifically states that it was funded by an NIH-NIAID grant.

All this was important because it was part of the larger story that the public was following. Learning that the agencies and officials charged with leading Americans out of the pandemic in fact had links to a Chinese lab with a history of safety violations, and which also appeared to be involved in dangerous experiments that might be linked to the outbreak in Wuhan, was for many profoundly unsettling.

Meanwhile, the enmeshment between the FDA and pharma was becoming more relevant. In June it was announced that Stephen Hahn, who had led the FDA from Dec. 17, 2019, until Jan. 20, 2021, during which time the agency approved the Moderna and Pfizer vaccines, became the chief medical officer of Flagship Pioneering, the venture capital firm that launched Moderna in 2010 and now owns $4 billion of Moderna stock. On June 27, Scott Gottlieb, who headed the FDA before Hahn, joined the board of Pfizer.

On June 3, three scientists from an FDA advisory committee—Dr. Aaron Kesselheim, professor of medicine at Harvard Medical School, Joel Perlmutter, M.D., a neurologist at Washington University in St. Louis, and David Knopman, M.D., a neurologist at the Mayo Clinic—resigned because of the way an Alzheimer's drug, Aduhelm, was approved. In a letter, Kesselheim claimed that the authorization of Aduhelm—a monthly intravenous infusion that Biogen has priced at $56,000 per year, which some worry could bankrupt Medicare—was wrong "because of so many different factors, starting from the fact that there's no good evidence that the drug works," that it was "probably the worst drug approval decision in recent U.S. history," and that this "debacle … highlights problems" with the FDA advisory committee relationship.

It's worth translating this episode into plain English: In the middle of the biggest vaccine rollout in U.S. history, which the government determined to be the only way out of the pandemic, but which also faced stiff headwinds of deep-seated popular hesitancy, the FDA approved a drug that would line a pharmaceutical company's pockets with billions of taxpayer

dollars, even though studies showed the drug did little but raise false hopes.

Kesselheim wasn't being rash, as it was apparently the second time he had seen this kind of thing up close. In 2016, the director of the FDA's Center for Drug Evaluation and Research, Dr. Janet Woodcock, approved a drug called eteplirsen over the objections of all the main FDA scientific reviewers. The grounds for the approval were not that patients got better—they didn't. Rather, a kind of lab value, which can function as a "biomarker" (or indicator of disease), improved—another pharma trick. That was taken as good enough evidence to approve the drug. As Kesselheim and co-author Jerry Avorn later warned in *The Journal of the American Medical Association*, "speeding drugs to market based on such biomarker outcomes can actually lead to a worse outcome for patients."

Soon after Kesselheim's departure in June, the FDA's two top vaccine officials announced they were also leaving. Reports explained that Dr. Marion Gruber, director of the FDA Office of Vaccines Research & Review and a 32-year agency veteran, and Dr. Philip Krause, a 10-year veteran, were leaving because of outside pressure by the Biden administration to approve boosters before the FDA had completed its own approval process. Meanwhile, Pfizer, doing more "science by press release" (a technique that often jacks up a company's stock), was calling for boosters while "hailing great results with COVID-19 boosters and shots for school-age children."

In a piece in the *Lancet* on Sept. 13, Gruber, Krause, and multiple international colleagues raised a red flag about pushing through a booster in the general population:

> *There could be risks if boosters are widely introduced too soon, or too frequently, especially with vaccines that can have immune-mediated side-effects (such as myocarditis, which is more common after the second dose of some mRNA vaccines, or Guillain-Barre syndrome, which has been associated with adenovirus-vectored COVID-19 vaccines [like the AstraZeneca, or Johnson & Johnson]. If unnecessary boosting causes significant adverse reactions, there could be implications for vaccine acceptance that go beyond COVID-19 vaccines. Thus, widespread boosting should be undertaken only if there is clear evidence that it is appropriate.*

The Pfizer study was surprisingly tiny: Only 306 people were given the booster. As vaccine researcher David Wiseman (who did trials for rival Johnson & Johnson) pointed out at the FDA meeting, "there was no randomized control" in the Pfizer study. The subjects were younger (18-55) than the people who are most at risk of COVID death or serious illness, and were followed only for a month, so we didn't actually know how long the booster would last, or if adverse events might show up after the 30 days. They were not followed clinically, so there was no information on infections, hospitalizations, or deaths. Rather, only their antibodies were measured—precisely the kind of shortcut that was taken with eteplirsen.

The study was too small, and the FDA panel held two votes on approval. In the first, it voted overwhelmingly (16 to 2) against approving Pfizer boosters for all ages; in the second vote, the panel supported boosters only for people over 65 or special at-risk groups.

And yet, in mid-August, Biden began publicly supporting boosters for all. Why? On Sept. 16, the *Los Angeles Times* reported that the president was following the advice of Fauci and the NIH, with the help of Dr. Janet Woodcock—the same FDA official who overrode FDA reviewers in the eteplirsen incident. Woodcock was by that point acting FDA commissioner, and was going around the FDA committee once again.

It was not only the Pfizer booster study that was weak. A *New England Journal of Medicine* study, based on Israeli Ministry of Health data, claimed that third-shot boosters give 11 times the protection of two. The entire study lasted only a month, and thus showed it was protective for that period, but not whether it would last as long or longer than the second shot's protection.

During the spring of 2021, another wrinkle had emerged. Along with the widespread attacks on scientists who had criticisms of the simplified master narrative (including ones from major universities like Harvard, Yale, Stanford, Rockefeller, Oxford, and UCLA), many average Americans learned that certain major stories weren't as widely known as they might have been, thanks in part to censorship by Big Tech.

In May, Facebook announced that it would no longer censor stories about the lab leak theory, which was how many people found out that it was in fact a viable scientific theory in the first place. (Facebook's idea of transparency is telling you when it's stopped censoring something; the same goes for YouTube.) But in July, the WHO itself admitted that it had been too hasty in ruling out a lab leak. (Nicolas Wade's excellent May 2 article, by contrast, showed the technical virological reasons for why the virus might well have come from GoF research.) We also learned more about Big Tech's motives when it was revealed that Google's charity arm had funded the same GoF researcher that the NIH had funded—Peter Daszak of EcoHealth. At times, Big Tech's censorship of "misinformation" coincides with its financial interests: Amazon, which has banned (and unbanned) books critical of the master narrative, has been looking into developing a major pharmacy division.

Meanwhile, three U.S. medical boards—the American Board of Family Medicine, the American Board of Internal Medicine, and the American Board of Pediatrics—went beyond censorship by threatening to revoke licenses from physicians who question the current but shifting line of COVID thinking and protocols. This forced doctors who had any doubts about the master narrative to choose between their patients and their livelihoods.

Things got so bad globally that Amnesty International eventually issued a report on this crisis: "Across the world, journalists, political activists, medical professionals, whistle-blowers and human rights defenders who expressed critical opinions of their governments' response to the crisis have been censored, harassed, attacked and criminalized," it noted. The typical tactic, the report's authors say, is "Target one, intimidate a thousand," whereby censors justify these actions as simply banning "misinformation" and "prevent[ing] panic." The report goes on: "Evidence has shown that harsh measures to suppress the free flow of information, such as censorship or the criminalization of 'fake news,' can lead to increased mistrust in the authorities, promote space for conspiracy theories to grow, and the suppression of legitimate debate and concerns." Censorship nourishes the weed it purports to exterminate.

It is, of course, vital that public health officials be able to lead in a crisis, convey consistent messages, and even ask citizens to change their behaviors. But the only way public health can legitimately ask for this change, is because the policies it recommends are based on a scientific process that is solid enough to withstand scientific criticism and debate. Why else should anybody listen? Science is not itself dogma or an authoritarian discipline, but the opposite: a process of critical inquiry, and the method *requires* ongoing debate about how to interpret new data, and even what constitutes relevant data. Science, as the Nobel Prize winning physicist Richard Feynman pointed out, requires questioning assertions:

> *Learn from science that you must doubt the experts … When someone says science teaches such and such, he is using the word incorrectly. Science doesn't teach it; experience teaches it. If they say to you science has shown such and such, you might ask, "How does science show it—how did the scientists find out—how, what, where?" Not science has shown, but this experiment, this effect, has shown. And you have as much right as anyone else, upon hearing about the experiments (but we must listen to all the evidence), to judge whether a reusable conclusion has been arrived at.*

Note how emphatic Feynman is that it's not just the few who conduct the experiments, or even just "the experts," who have a right to discuss and *judge* the matter. This is especially true in public health, because the field is so broad and composed of many disciplines, from those that deal narrowly with viruses to those that deal with mass behavioral changes.

When public health and allied medical and educational organizations censor scientists and health care professionals for debating scientific controversies—thus giving the public the false impression that there are no *legitimate* controversies—they misrepresent and grievously harm science, medicine, and the public by removing the *only* justification public health has for asking citizens to undergo various privations: that these requests are based on a full, unhampered, and open scientific process. Those who censor or block this process undermine their own claim to speak in the name of science, or public safety.

If we didn't get to have a properly open scientific process, what did we get instead? Government enmeshment with legally indemnified corporations, public health officials misleading Congress, multiple honest regulators leaving the FDA because of inappropriate approvals, FDA heads

taking Big Pharma jobs directly related to products they had just been involved in approving, a possible lab leak that couldn't be discussed as such for more than a year so that it couldn't be clearly disconfirmed, faceless social media platforms admitting that they control what we see and don't see, and institutional censorship of many kinds.

If you were trying to create the perfect conditions for public skepticism about vaccines in the midst of a pandemic, could you have done any better than this?

Over the summer, the master narrative started to show cracks. By Aug. 18, Israel had the world's third-highest number of new cases per capita. The Health Ministry retroactively released numbers showing that by mid-summer the Pfizer vaccine, which had been used in Israel extensively, was only 39% effective in preventing COVID infections, though much more effective in preventing severe disease. But additional data showed that, at a time when 62% of the entire Israeli population had been vaccinated, over 60% of Israel's 400 hospitalized COVID cases were patients who had been fully vaccinated. This meant the vaccine was much more leaky than expected.

By Sept. 14, Israel's Health Ministry Director General Nachman Ash reported that the country, even more heavily vaccinated than it had been in the summer, with 3 million (mostly elderly) of its 9 million citizens already having had a *third* shot, was now recording 10,000 new COVID cases a day. "That is a record that did not exist in the previous waves," Nachman said. It was also the highest number of COVID cases per capita of any country, beating out Mongolia and making Israel the "COVID capital of the world just months after leading the charge on vaccines."

Many argued correctly that, yes, these breakthrough cases do occur, but they are usually mild, and the vaccines are very good at protecting people from severe illness and death. But then conflicting statistics began to emerge. Israeli hospitals were so overloaded they were turning away COVID patients. Four hundred died in the first two weeks of September. Hospital staff were worn out, and in a traumatic state, with one hospital director describing the situation as "catastrophic," adding that "the public knows absolutely nothing about it." Israeli Ministry of Health statistics from August showed that of those deaths that had been classified, more than twice as many who died were fully vaccinated (272) as opposed to those who were not vaccinated (133). By late September, the data was in for the fourth wave, and Dr. Sharon Alroy-Preis of the Ministry of Health revealed to the FDA Vaccine Advisory Committee that "what we saw prior to our booster campaign was that 60% of people in severe and critical condition were immunized, doubly immunized, fully vaccinated and as I said, 45% of the people who died in the fourth wave were doubly vaccinated."

Israeli vaccine czar Salman Zarka doubled down, and said the country now had to contemplate a fourth dose in another five months: "This is our life from now on, in waves," he said. Israeli Prime Minister Naftali Bennett echoed this on Sept. 13, blaming six patients who were hospitalized because they "were not fully vaccinated"—by which he meant they had only had two jabs. Divisive terms are easily turned on those who recently used them: Now, the stigma that attended "the unvaccinated" also applied to the vaccinated-but-not-vaccinated-enough.

Throughout the pandemic, Israel had extensive lockdowns. In contrast, Sweden became famous for never having locked down. Israel and Sweden have about the same size population (9 million and 10 million, respectively), and have almost identical rates of double-vaccinated people, if you take in all ages including children (63% Israel, 67% Sweden). If anything, Israel has the edge over Sweden because 43% of Israelis are also triple

"Across the world, journalists, political activists, medical professionals, whistleblowers and human rights defenders who expressed critical opinions of their governments' response to the crisis have been censored, harassed, attacked and criminalized." —Amnesty International

Fig. 10 An Israeli man prepares for his vaccination, December, 2020. Israel achieved high rates of vaccinations, but the number of deaths per million remained comparable to Sweden's. (Photo by Amir Levy/Getty Images.)

vaccinated. Yet the difference in the number of hospitalized patients is staggering. For the week of Sept. 12, 2021, Israel had 1,386 COVID hospitalizations, which was four times that of Sweden (340). Israel had a rolling seven-day average of 2.89 deaths per million, compared to the much lower number of deaths in Sweden (0.15).

What can account for this? Many argue that because Sweden (where public health works on a voluntary, participatory basis) never locked down, many more people there were exposed and got natural immunity. The Swedes had hoped to protect the most vulnerable in nursing homes, which they failed to do because of poorly trained staff—but in this they were no different from most Western nations that *did* lock down. Sweden also suffered more deaths per 100,000 than Israel overall. But through the summer of 2021 Sweden dropped to about 1.5 deaths a day from COVID. Its hospitals were never overwhelmed, suggesting that, once Sweden's natural herd immunity was established, combined with its vaccines, it was now more protective than Israel's largely vaccine-based immunity.

This wasn't what the master narrative had promised. Israel was the world's lab experiment because, being so early to *complete* a vaccine rollout on a large scale (about three months ahead of the United States), it was supposed to be a glimpse of everyone else's future. Its people did seem to be among the first to break free of COVID. But they were now the first to show that the vaccine could wane. It's not that the vaccinated in the United States weren't doing better than the unvaccinated in terms of hospitalization for COVID; they definitely were. The fear, rather, was that this might only prove to be a short-term benefit.

In the summer, the CDC, behind on reporting its own U.S. data in real time, had been advised that the Pfizer vaccine was leading to breakthrough cases in the vaccinated in Israel. But it did not share this hole in the master narrative with outside public officials until one month later, as *The Washington Post* reported. "What is very concerning is that we're not seeing the data … it needs to come out," said former head of the CDC Tom Frieden. "What you can criticize the CDC for, validly, is why aren't you talking about the studies you're doing of breakthroughs?" Because there had been such a lag time, some people wondered if the CDC was hiding something. "And these are the people who are potentially friendly to CDC," said Frieden, "so you know you're in trouble when even your friends are suspicious of your motives."

In the United States, a Mayo Clinic study found the Pfizer vaccine was 42% effective at stopping people from getting infected between January and July. In the U.K., nearly 50% of new COVID cases in the summer were among the vaccinated; each day there were about 15,000 new symptomatic cases in people who had been partially or fully vaccinated. As of July 15, new cases among the unvaccinated (17,581) were falling, and new cases among the fully or partially vaccinated (15,537) increasing, and set to overtake the vaccinated. According to the CDC, of the 469 attendees at Provincetown, Massachusetts celebrations in July that tested positive for COVID, 74% had been fully vaccinated. Ultimately 900 people were infected. Scientists determined that those with such vaccine breakthrough infections can carry viral loads as big as infected unvaccinated people. Vaccinated people were not just infecting others;

they were also clearly not completely immune themselves, though perhaps they were infectious for a briefer period.

The CDC also emphasized this study to support its new policy of asking the vaccinated to wear masks. On CNN, Wolf Blitzer asked Walensky if she got the messaging wrong, and hadn't been nuanced enough. She answered that breakthrough infections tended to be mild. Blitzer then asked whether those who are vaccinated and had breakthrough infections could pass the virus on to older or more vulnerable people. Walensky answered: "Our vaccines are working exceptionally well. They continue to work well for delta, with regard to severe illness and death, they prevent it. *But what they can't do anymore is prevent transmission.*" She said so to suggest to people who were vaccinated that if they were going home to people who were immunosuppressed, or frail, or with comorbidities, they should wear a mask. It was a nuanced response, and admitted a problem. A performance like that might have, because it was honest, enhanced vaccine confidence.

Unfortunately, the mainstream media was so overcommitted to a master narrative that promised 95% effectiveness for the vaccines (which, it also believed, implied stopping transmission) that it was caught off guard. Instead of asking whether scientists had compared the infectiousness of the vaccinated with that of the unvaccinated, the media took Walensky's statement to mean that vaccinated people with breakthrough infections were *just as* likely to infect others as those who were not vaccinated and now had COVID. In this way, the episode transmitted more reasons for the vaccine hesitant to have doubts.

Internal documents showed that at this point the CDC was scrambling to change its messaging, moving from the master narrative simplification that "vaccines are effective against disease" to the idea that vaccines are essential because they protect against death and hospitalization. The agency even changed its official definition of what a vaccine does from producing immunity to a specific disease to producing protection from it.

The FDA had originally said that a vaccine less than 50% effective (defined as reducing the risk of having to see a doctor) would not be approved by regulators. Now something that appeared to the public to be significantly less effective was being not just approved but *mandated*: According to Israel's Health Ministry, the Pfizer vaccine data showed that in those who were vaccinated as early as January (about five months prior), it was only 16% effective. A large study in Qatar also showed the vaccine waning at five months; in the United States, a Mayo Clinic study found the Pfizer vaccine had dropped to 42% effectiveness, while the CDC found it dropped to 66%, in just under four months of use. U.S. statistics showed that the vaccinated were still overall *far less* likely to get infected than the unvaccinated, or to get serious illness. But Israel had been vaccinated earlier than the United States. So what lay ahead for America?

It is noteworthy that this was the moment U.S. government officials and the media chose to assert, soon on a daily basis, that the country was now in "a pandemic of the unvaccinated," even though it was now clear that the vaccinated could get infected and transmit the virus. Every day, famous Americans including entertainers, athletes, and politicians who had been doubly vaccinated were having "breakthrough" infections. The message that "this is only an epidemic of the unvaccinated … is falling flat," noted Harvard epidemiologist Michael Mina.

By this point, the hesitant were no longer the only ones who had doubts. There were many anecdotal reports of great worry about breakthrough cases among the vaccinated (including among those who put much faith in vaccines because their immune systems were compromised by age or illness). Headlines about waning vaccines expressed despair that this pandemic might never end.

Instead of addressing how this disappointment might affect people, U.S. public health talking heads and Twitter-certified human nature experts turned now to behavioral psychology, a very American form of psychology, to deal with the crisis—treating their fellow citizens like children or lab rats to be given rewards when "good" and punishments when "bad." Some seemed to relish telling people that if they didn't just do what the experts told them to do, they'd lose their jobs, their place in school, or some other basic need, like mobility (see figure 11).

Other, more data-driven thinkers, including pro-vaccine physicians like Eric Topol—head of Scripps Research and a man who regards the production of the mRNA vaccine as "one of science and medical research's greatest achievements"—now seemed quite concerned about the Israeli data. Topol assembled many articles showing how vaccinated populations *still* fare much better relative to unvaccinated populations in

the United States. But he also pointed out that breakthrough infections can't just be written off as simply caused by the new delta variant escaping vaccine protection. Israeli data showed the potency of the vaccines was fading after five months, contrary to what Pfizer claimed. Thus, the data showed that the earlier one was vaccinated, the less protection one had against delta. That finding was crucial, because it meant that the new wave in Israel was not simply caused because a new variant came along. The vaccines were losing potency over time.

Fauci and Surgeon General Vivek Murthy stuck to their guns, continuing to emphasize to the public that the vast majority of all COVID deaths—99.2% according to Fauci and 99.5% according to Murthy—were among the unvaccinated, a narrative that was picked up by news outlets, which started reporting obsessively about states with high unvaccinated rates and filling the news cycle with one story after another about stupid, retrograde Americans succumbing to COVID, their final wish not being for those they loved but for their medical practitioner to broadcast to the world their vaccine regret.

But, as David Wallace-Wells showed on Aug. 12 in *New York Magazine*, Fauci's and Murthy's numbers were not rooted in what was currently happening in America; they were instead based on the COVID death data *from Jan. 1, 2021, to date*. If you think this through, you'll see what's obviously wrong: For the first months of the year, few Americans were yet vaccinated, so of course most deaths would technically be among "the unvaccinated." "Two-thirds of 2021 cases and 80% of deaths came before April 1, when only 15% of the country was fully vaccinated," Wallace-Wells wrote, "which means calculating year-to-date ratios means possibly underestimating the prevalence of breakthrough cases by a factor of three and breakthrough deaths by a factor of five." What we desperately needed was a comparison of vaccinated to unvaccinated people by each month. But, as Wallace-Wells noted grimly: "Unfortunately, more accurate month-to-month data is hard to assemble—because the CDC stopped tracking most breakthrough cases in early May."

Wallace-Wells cited a *New York Times* analysis that claimed the vaccines were working to suppress severe outcomes from COVID infection by more than a factor of 100 for some states. But as Topol told Wallace-Wells, "The breakthrough problem is much more concerning than what our public officials have transmitted .... We have no good tracking. But every indicator I have suggests that there's a lot more under the radar than is being told to the public so far, which is unfortunate." The result, Topol said, was a widening gap between the messaging from public health authorities and the meaning of the data emerging in real time. "I think the problem we have is people—whether it's the CDC or the people that are doing the briefings—their big concern is, they just want to get vaccinations up. And they don't want to punch any holes in the story about vaccines. But we can handle the truth. And that's what we should be getting."

On Aug. 23, FDA approval of the Pfizer vaccine came through. It was based on the same patients who were in the study that previously included only two months of follow-up, but which now had six months of follow-up. With the approval, Pfizer officially stopped the randomized control trials

Fig. 11 'If people didn't just do what the experts told them to do, they'd lose their jobs, their place in school.' Watch the tweeted video here.

and informed the controls they never got the vaccine. Now that they know they are not vaccinated, the controls may well choose (or be mandated) to get vaccinated, so we won't be able to follow them as a control group any more. That means the only randomized control trials we have of these vaccines are just six months long. Should some independent party—not a drug company—want to do a new RCT of the vaccine, they will find it almost impossible to do so, because it will be hard if not impossible to find people who were not vaccinated, or not already exposed to COVID.

This is especially important because we don't yet—we can't yet—have any good randomized control trial data to rule out long-term effects. Vaccine supporters, including government officials, will say: "There's not been a serious side effect in history that hasn't occurred ... within six weeks of getting the dose." But, as Doshi and others argue, there are examples of long-term problems that come to light *after* two months. (For example, Doshi points out that it took nine months to detect that 1,300 people who received GlaxoSmithKline's Pandemrix influenza vaccine after the 2009 'swine flu' outbreak developed narcolepsy thought to be caused by the vaccine.)

Myocarditis—inflammation of the heart tissue—is a rare but real side effect in young males (about ages 16-29) that did not show up in the two-month long trials that led to the Emergency Use Authorization, even though those studies included males as young as 16. It was not generally recognized by the scientific community or our safety report systems until four months into the vaccine rollout. We are still learning about how this manifests in vaccinated males. In general severe myocarditis can lead to scarring, and even cause death, so it must be taken seriously and followed long term. Right now, Paul Offit, professor of vaccinology at the University of Pennsylvania, says that most cases are mild and resolve on their own. The actual FDA approval for the Pfizer vaccine acknowledges higher rates of myocarditis and pericarditis in males now, and states the obvious: "Information is not yet available about potential long-term health outcomes. The Comirnaty [the new name for the Pfizer vaccine] Prescribing Information includes a warning about these risks." An Israeli study found that, in boys aged 12-15, myocarditis occurred in only 162 cases out of a million, but this rate was 4-6 times higher than their chances of being hospitalized for a severe case of COVID.

But, to get a sense of the complexity of the decision facing parents, in the United States the situation keeps changing, with more and more cases of children now showing up in hospitals for COVID. The decision is further complicated by the crucial fact that COVID can cause myocarditis as well. And we are just now learning that different vaccines seem to cause myocarditis at different rates. As of October, several countries— including Norway, Sweden, and Denmark—have put the Moderna vaccine (which is especially potent) on pause for younger people, and Iceland has suspended it for all ages. But these countries are not ending childhood vaccination, just recommending different vaccines. We are lucky to have options. But we could use good studies comparing the COVID-induced myocarditis rates and vaccine-induced myocarditis rates by age and sex.

Which is why it's so unfortunate that the RCTs were not much larger, and that they didn't go on longer. Had they continued, and if their data ever became transparent, it could really help us in assessing long-term safety in a more reassuring way—that's what RCTs are good at. One can more persuasively demonstrate that a vaccine doesn't have these effects if there is a proper vaccine-free, COVID-free control group. But if vaccines continue to be pushed as the one and only answer, we will never know if certain health problems emerge, because there will be no "normal" vaccine-free group left for comparison. It's a development that is quite disconcerting, for it suggests a wish *not* to know.

When the pandemic first broke, many were certain that the developing countries—with their inability to afford vaccines, malnutrition, crowded cities, and lower numbers of health care workers—would be universally devastated. But that prediction turned out not to be true.

The population of Ethiopia is about 119 million— just over one-third of the United States. COVID vaccination rates are very low there: 2.7% have had at least one shot, 0.9% have had two. As of Sept. 28, 2021, the country recorded only 5,439 COVID deaths over the course of the entire pandemic. If the United States had such a death rate per capita, it would have lost just over 16,000 people, rather than over 700,000.

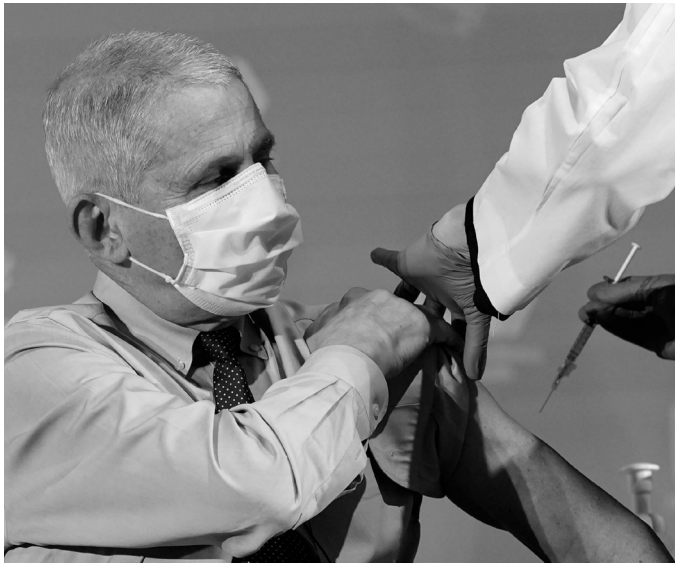

Fig. 12 Dr. Anthony Fauci receiving his first dose of the COVID-19 vaccine on Dec. 22, 2020 in Maryland. For many individuals, the decision to vaccinate remains complex. (Photo by Patrick Semansky-Pool/Getty Images.)

Why does Ethiopia have such comparatively low numbers? It was not that the country was late to the pandemic. It recorded its first case in March 2020. It had three comparatively small "waves" in July 2020, April 2021, and most recently in August and September 2021. During these "waves," the daily deaths averaged about 37, 47, and 48 people a day. The country had very brief lockdowns in select harder-hit towns at the beginning of the pandemic, and brief periods during which large gatherings, schools, stadiums, and nightclubs were closed. Then, during the second wave of April 2021, hospital capacity and oxygen supplies were stretched.

But by June 2021, Ethiopian physician friends with whom I was in weekly contact told me that they could see the second wave receding, as numbers were decreasing and hospital occupancy with COVID cases was going down. All this occurred with only about 1% of the country vaccinated (mostly the country's health care workers, the elderly in key hot spots, and the vulnerable). Now, the third wave appears to be receding, especially in the capital, Addis Ababa. The Ethiopian physicians I know, extremely skilled, are also more accustomed to serious infectious disease than many Western physicians, and have a different attitude toward herd immunity. When they saw that death counts were low compared to other countries, they didn't advocate to keep the country closed, observing, as one put it, "it's running through, taking its natural course, and lockdowns will only delay resolution."

For part of the COVID period there has been armed conflict in one Ethiopian province, which could be affecting the numbers. Still, how are numbers anywhere close to this low even possible, and what might be learned? Interestingly, neighboring Kenya also reports a similarly low death rate. Clearly, what determines the death count in at least some countries is far more than vaccination rates. There is the average age of the population (in Ethiopia, the median age is 19.5 years; in the United States, 38.3), population density (Ethiopia is about 80% rural), travel within the country (Ethiopians rarely travel outside their own province, or far from their villages), ventilation (most Ethiopians live in thatched huts, and even in the cities, homes are draftier and more open), sun exposure (hence vitamin D levels protected), exercise (Ethiopians are always walking, with three cars per 1,000 people), and possible seasonal effects. They also had fewer lockdowns, and so may have more natural immunity. Crucially, levels of obesity, being overweight, and Type 2 diabetes are almost nonexistent in Ethiopia, but epidemic in the United States, the U.K., and Australia.

Staggeringly, none of these factors is even mentioned in the master narrative, yet their cumulative potency in protecting a population seems, in Ethiopia, for the last 18 months until now, to have been very protective. A study of 160 countries in 2020 showed that the risk of death from COVID is 10 times higher in countries like the United States where the majority of the population (67.9%) is overweight. CDC data shows that a whopping 78% of all hospitalized cases in the United States, and therefore those most at risk of death, suffered from obesity. By lowering immunity, obesity increases the chance of severe illness, and also decreases vaccine efficacy, as has been shown with the flu vaccine.

Another key element left out of America's master narrative is the role of natural immunity. After 18 months of near total silence about it, Fauci was asked by CNN's Sanjay Gupta about a study that showed natural immunity provides a lot of protection, better than the vaccines alone. Gupta asked Fauci if people who already had COVID needed to get vaccinated. "I don't

have a really firm answer for you on that," Fauci said, "that's something we are going to have to discuss …." Instead, the U.S. administration and media still maintain, with a kind of ideological fervor, that *everyone* must get vaccinated, even the already immune. On the face of it, this is a strange assumption, because vaccines work by triggering our preexisting immune system, and by exposing it to part of the virus. If our bodies can't produce good immunity by exposure to the virus, they won't usually be able to produce it by exposure to a vaccine (which happens in immune-compromised people all the time). Vaccine immunity relies on the body's ability to produce natural immunity.

An epidemiologist named Dr. Martin Makary of Johns Hopkins University showed that about half of unvaccinated Americans have been exposed to the virus, and are therefore already immune. By December 2020 over 100 million Americans had been exposed to the virus, and 120 million by Jan. 31, according to a Columbia University study. Now, 10 months later, with the more infectious delta variant, the number is probably closer to 170 million, or half the country. Are the immune unvaccinated safe for others to be around? According to Makary, we have more than 15 studies showing that natural immunity is very strong, and lasts a long time—so far the length of the entire pandemic—and it is effective against the new variants. The reinfection rate for someone who had COVID was shown to be 0.65% (in a Danish study) or 1% (in a British study, and some others). A number of studies suggest it may last for years; even when antibodies go down, cells in the marrow are ready to produce them.

There is one CDC study often used to justify vaccinating the already immune, but it is an outlier. To its credit, the study begins by stating that "few real-world epidemiological studies exist to support the benefit of vaccination for previously infected persons." It then purports to show that COVID vaccine immunity is 2.3 times as protective as natural immunity, based on a single two-month study from Kentucky. Makary says the study was "dishonest," and asks why the CDC chose just two months of data to evaluate, when it had 19 months' worth on hand, and "why one state when you have 50 states?" But perhaps the key weakness, as Harvard's Martin Kulldorff points out, is they used a positive PCR test to measure whether someone was infected, and not whether the person actually experienced a symptomatic infection—the key point. The problem with the PCR test is it is good at detecting viral RNA, but can't distinguish whether the materials are intact particles, which are infectious, or merely degraded fragments, which are not.

But when actual symptomatic infection has been looked at, natural immunity comes out better. A huge Israeli study of about 76,000 people—the largest on the subject—has compared the rate of symptomatic reinfection in those who had been vaccinated (the "breakthrough" infection rate) with the symptomatic reinfection rate of those who had COVID. The data has been circulated (though not yet peer reviewed) and it is consistent with other studies showing better protection for the previously infected. It found that people who had a previous COVID infection and beat it with natural immunity in January or February 2021 were 27 times less likely to get a symptomatic reinfection than those who got immunity from the vaccine. A Washington University study showed that even a mild infection gives long-lasting immunity. Along with Makary of Johns Hopkins, among those on record willing to question the need for vaccination of the already immune are Drs. Kulldorff (the Harvard epidemiologist), Vinay Prasad (a hematologist-oncologist and associate professor of epide-

Fig. 13 Anti-vaccine protesters outside the San Diego Unified School District office, ahead of debate over forced vaccination mandate for students, Sept. 28, 2021, San Diego, California. (Photo by Sandy Huffaker/Getty Images.)

> "The European Union has a Digital Covid Certificate, which is not limited to proof of vaccination. You can get one and travel if you have been vaccinated or if you have 'recovered from COVID-19.'"

miology and biostatistics at the University of California San Francisco), Harvey Risch (a Yale epidemiologist), and Jayanta Bhattacharya (a Stanford epidemiologist).

Offit, who is on the FDA Vaccine Advisory Committee, is an interesting case, as he both argues for mandates but concedes that it's reasonable for the already immune to not want to be vaccinated. Asked by the pro-vaccine Zubin Damania, a Stanford-trained internist who goes by the pseudonym ZDoggMD on his viral interview show, what he would say to someone who asks: "Why should I be forced, compelled, mandated to get a vaccine when I have gotten natural COVID?" Offit answered, "I think that's fair. I think if you've been naturally infected, it's reasonable that you could say, 'Look, I believe I am protected based on studies that show I have high frequencies of memory plasmablasts in my bone marrow. I'm good,' I think that's a reasonable argument." The problem, as Offit noted in another interview, "is that bureaucratically it's a nightmare.

But a bureaucratic problem is not a scientific one, which is how this is widely presented. And the question is: a problem compared to what? Several million immune people fired and now resentful of public health? When asked by ZDogg whether there might be a test that can prove a person has had COVID and recovered (and thus has natural immunity), Offit explained that there is a blood test for antibodies to the nuclear protein of the virus, which could show up if someone has had the virus and is now immune. Imagine how much mental anguish and needless societal disruption might be relieved if, among the billions we are spending, we spent enough to make such tests widely available.

Indeed, the very fact that we frame the threat debate between the "vaccinated" and the "unvaccinated" has always been peculiar; some epidemiologists point out that the categories we should be thinking of instead are the "immune" and those who are "not immune." The European Union has a Digital Covid Certificate, which is not limited to proof of vaccination. You can get one and travel if you have been vaccinated *or* if you have "recovered from COVID-19." This allows travel among all EU member states. American officials always proclaim they are "following the science," but obviously, if the science gave clear orders, then European scientists would have received them too.

Let's say, for the purposes of argument, that you accept natural immunity as equally good or better than vaccine immunity. What are the ethical consequences? Vaccinating people who have had COVID without informing them that the data says they don't need it overrides both informed consent *and* the classic medical ethic of not treating without a medical necessity. When one gives any intervention that is not medically necessary, or especially beneficial, then the cost-benefit analysis of risk versus little or no benefit is weighted in favor of risk, which overrides the first principle of Hippocratic medicine: "First do no harm."

It's also arguably selfish to vaccinate those in wealthy countries who already have natural immunity, for it deprives poor countries, short of vaccines, of protection for their vulnerable populations. It is not lost on the vaccine hesitant that vaccine exemptions for those who already had COVID would immediately slash the projected profits of Big Pharma. (Pharma knows that poor countries might not be able to afford the leftovers at full fee.)

Vaccination is a tool, a means to an end: immunity. But the American government has made the means, vaccination, the new end. This strange substitution, or reversal, reveals the master narrative to be the expression not of science, but of a new kind of scientistic ideology, which we might call "vaccinism." But vaccinism is not a treatment; it's a mindset, one that takes a wonderful invention—which, if used properly and carefully, can be outstandingly productive—and makes it the only tool worth having, until it becomes, at times, counterproductive. It makes no exceptions; indeed, it is insulted by the idea of any exemptions. In its all-or-nothing approach, it is the ideological mirror of anti-vaxxism.

Getting Out

SCIENCE HAS HAD many surprises for us in this pandemic. We've learned that while the vaccines don't always stop the spread, they do protect the vaccinated from getting severe disease and death for a number of months. We've learned, as *The New York Times* points out, that "an unvaccinated child is less at risk of serious COVID illness than a vaccinated 70-year-old." We've learned that Emily Oster, the author and academic who first called that fact to our attention was mistreated for months because she was off-narrative. But she was ultimately vindicated, and this abuse of scientists and academics who seek the truth was also part of the pandemic era norm. We've also learned that you are safer in a room, or even on a plane, with people who have recovered from COVID than you are with people who were vaccinated (especially over four months ago). In other words, the immunity of those who suffered COVID is holding up so far.

So, why doesn't good news like this sink in?

I submit that it's because of our old friend, the behavioral immune system. Many people's mental set for the pandemic was formed early on, when the BIS was on fire, and they were schooled by a master narrative that promised there would only be one type of person who would not pose danger—the vaccinated person. Stuck in that mindset when confronted by unvaccinated people, about half of whom are immune, they respond with BIS-generated fear, hostility, and loathing. Some take it further, and seem almost addicted to being scared, or remain caught in a kind of post-traumatic lockdown nostalgia—demanding that all the previous protections go on indefinitely, never factoring in the costs, and triggering ever more distrust. Their minds are hijacked by a primal, archaic, cognitively rigid brain circuit, and will not rest until every last person is vaccinated.

To some, it has started to seem like this is the mindset not only of a certain cohort of their fellow citizens, but of the government itself. Moreover, because COVID vaccine hesitancy is based in significant part on distrust of the government and related institutions, it has to be understood not only in terms of vaccines, but in the context of the pandemic more broadly—first and foremost, in other words, of the experience of lockdowns.

For many, trust was broken by the lockdowns, which devastated small businesses and their employees, even when they complied with safety rules, such that an estimated one-third of these businesses that were open in January of 2020 were closed in April of 2021, even as we kept open huge corporate box stores, where people crowded together. These policies were arguably the biggest assault on the working classes—many of whom protected the rest of us by keeping society going in the worst of the pandemic—in decades. That these policies also enriched the already incredibly wealthy (the combined wealth of the world's 10 richest men—the likes of Jeff Bezos, Mark Zuckerberg, Bill Gates, and Larry Page—is estimated to have risen by $540 billion in the first 10 months of the pandemic), and that various politicians who instituted lockdowns were regularly caught skirting their own regulations, solidified this distrust.

And yet, it is the unvaccinated whom many leading officials still portray as recklessly endangering the rest of the country. "We're going to protect vaccinated workers from unvaccinated coworkers," President Biden has said. The unvaccinated are now presented as the sole source of future variants, prolonging the pain for the rest of us. For those in favor of mandates, the vaccine is the only way out of this crisis. To them, the vaccine hesitant are merely ignorant, and defy science. We tried to use a voluntary approach, they believe, but these people are Neanderthals who must now be coerced into treatment, or be punished. Among the punishments called for is not just loss of employment, but also of employment insurance, health

care, access to ICU beds, even the ability to go to grocery stores.

It is not trivial to override the core felt sense, in a democracy, that if anything is one's own, it is one's body. The idea of the state or a doctor performing a medical procedure forcibly on a person, or drugging them into compliance without their consent, is an abiding, terrifying theme of many science fiction dystopias, and it is a fear that runs *very deep* in the modern psyche. This fear runs deeper in some people than their fear of the virus, or losing their jobs or pensions, as we are seeing. History shows that these are not just fantasies: Past medical and public health abuses really did make use of forced injections of drugs, operations, sterilizations, and even psychiatric abuses—in totalitarian and democratic societies both.

Moreover, to say to the unvaccinated, "But it is in the name of the greater good!" is to make the utilitarian argument that we must strive for *the most good for the greatest number of people*. A version of utilitarianism is often the governing philosophy of public health. But this raises a series of questions: How are we measuring the good? Is it the same for all people? Should it be up to your 89-year-old grandmother, who has little time left, to decide whether to spend the remaining years of her life in total isolation, or risk COVID but see her loved ones? And the bigger questions: Can you explain how you are helping the group when, by overriding individual rights, you degrade the group as a whole by weakening each individual within it? Are you aware that the greatest evils in history have also always been done in the name of that abstraction, "the greater good"? Without first answering such questions, utilitarianism is but a shallow form of arithmetic, one passing itself off as moral philosophy.

It is not irrational for people to insist that public discourse seriously engage questions like these, and that any state compulsion related to people's bodies be based on a flawless, air-tight argument that is well-communicated. That has not happened.

What, in rational political and public health terms, is the state's best justification for mandating that people be injected en masse with a medicine?

The first justification for mandates is they get us to herd immunity faster. But as Stanford epidemiologist Jay Bhattacharya and Arizona State University economist Jonathan Ketcham note, "we have good reason to doubt that, if most everyone got vaccinated, we'd achieve herd immunity." This is because, as we've seen, current vaccines are fading at about five months.

Even scientists who believe vaccines will help get us to herd immunity are divided on what percentage of the population needs to be vaccinated to get us there. Early in the pandemic, Fauci said we needed as low as 60%-70% to reach herd immunity, but as time went on he increased the numbers. In December 2020, when *The New York Times* noticed Fauci was "quietly shifting that number upward," he explained he was generating these percentages based on a mix of the science and what he felt the public was ready to hear, admitting: "We really don't know what the real number is." President Biden recently said that we could need 98% of Americans to be vaccinated to reach the goal.

Is there a scientific consensus behind the 98% claim? In fact a number of epidemiologists and infectious disease experts and officials dispute that we need a number anywhere near it. Even those who are pro-mandate, like Dr. Monica Ghandi, professor of clinical medicine at the University of California San Francisco, believes that "There is no evidence that we need that high of a vaccination rate [98%] to get back to normal." Other countries, like Denmark, have opted for a 74% vaccination rate as accept-

Fig. 14 St. Paul, Minnesota. For many, trust was broken by the lockdowns. (Photo by: Michael Siluk/UCG/Universal Images Group via Getty Images.)

able in order to lift certain restrictions, especially if the most vulnerable are vaccinated at a higher rate. Norway lifted all restrictions when it got to a 67% vaccination rate.

The point here is that the science is shifting, sometimes by the day. It is reasonable for people who notice this to feel concerned about it, and it is—at the very least—churlish to present them as merely irrational.

The second justification for mandates is that the state has an obligation to protect those who cannot protect themselves from an infectious disease passed on to them by others—i.e., the unvaccinated do not have "a right" to "recklessly endanger" and infect others. As many have pointed out, it is hard to describe our current moment quite this way, since vaccines, and now boosters, are freely and widely available, so people can protect themselves if they wish. Of course, this reveals the real problem, which is that vaccinated people do not, in fact, get comprehensive immunity—as in the case, for example, of the polio or measles vaccines.

And on this, there is increasing scientific agreement: We can't "eradicate" this mutating virus at this point. This is likely not a case like smallpox, which was eradicated because both the virus and the vaccines met a host of criteria. Donald Ainslee Henderson, who directed the WHO smallpox eradication campaign, wrote that smallpox was uniquely suited for eradication because it didn't exist in animal reservoirs, it was easy to identify cases in even the smallest villages by its distinctive awful rash (so a test for it wasn't needed), the vaccine gave immunity that lasted a decade, and natural immunity was easy to identify by the scars smallpox left. COVID satisfies none of these conditions.

"If we are forced to choose a vaccine that gives only one year of protection," said Larry Brilliant, an epidemiologist also involved in smallpox elimination, "then we are doomed to have COVID become endemic, an infection that is always with us." He and five other scientists have since argued together that COVID is not going away, because it's growing in a dozen animal species, and variants allow it to pop up in places that once beat it back. (Indeed, this is the reason that some scientists argue we need over 90% of people vaccinated, to keep America safe from a virus that will pingpong around the unvaccinated parts of the globe for years.) As Brilliant and colleagues wrote recently: "Among humans, global herd immunity, once promoted as a singular solution, is unreachable."

So, if it's correct that we can't eradicate the virus, and we can't get a lasting vaccine-induced herd immunity, what is our goal? It would be, to use Monica Gandhi's phrase, "to get back to normal." It would mean accepting some natural herd immunity and putting more focus on saving lives by other means alongside vaccines—including better outpatient medications to catch COVID early and keep people out of the hospital; lowering our individual risk factors; and speeding delivery of vaccines to the highly vulnerable when an outbreak occurs, and prioritizing them over people who are already immune.

That the justifications originally given for mass public mandates are so weakened is one of COVID's many unexpected challenges, one that requires flexible thinking, new kinds of planning, and above all acknowledgement, lest its denial becomes yet another example of bungled trust.

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In tackling the trust problem generally, we can return to the two kinds of public health systems, the coercive and the participatory. The United States has all sorts of mandates, but also continues to have significantly high rates of vaccine hesitancy and vaccine avoidance. In contrast, Sweden is the leading example of a participatory public health model. "Sweden has one of the highest vaccination rates in the world, and the highest confidence in vaccines in the world. But there's absolutely no mandate," Kulldorff—again, one of the world's leading epidemiologists, a specialist in vaccine safety, and consultant to the ACIP COVID-19 Vaccine Safety Technical Subgroup—notes. "If you want to have high confidence in vaccines, it has to be voluntary .... If you force something on people, if you coerce somebody to do something, that can backfire. Public health has to be based on trust. If public health officials want the public to trust them, public health officials also have to trust the public." Just as pharma's indemnification removed its incentive to improve safety, so do mandates remove public health's incentive to have better, more consistent communication—to listen, understand, educate, and persuade—which is what builds trust.

Kulldorff is echoed by Zubin Damania, a physician and internet personality who goes by the name ZDoggMD, and who is by my estimate

one of the most effective persuaders of the vaccine hesitant. "I've been so wrong in the past about things," he noted, in one video.

> *I actually at one point in my career felt that shaming anti-vaxxers was a good idea because they were so dangerous to children. This was the pre-pandemic stuff, and it never works to convince anti-vaxxers. I would rarely ever get emails from people saying, 'Hey I was on the fence and you convinced me with your crazy rant about how stupid anti-vaxxers are … Then I started to wake up a bit … Why is it people feel the way they do? And when you really dig into it, you go, I can empathize with that. Actually we share the same goal, which is our kids should be healthy, so, and you really think this is going to help, so of course you are going to, in fact I should love you for trying to do the right thing for your kids …*

Indeed, demonizing people for having doubts is the worst move we can make, especially since there *are* serious problems in our drug and vaccine regulatory systems. Some health organizations have become concerned enough about the effects of non-transparency that a group has formed, made up of the Leslie Dan Faculty of Pharmacy, University of Toronto, Transparency International, and the WHO Collaborating Centre (WHO CC) for Governance, Accountability, and Transparency in the Pharmaceutical Sector. In a report released recently, the alliance analyzed 86 registered clinical vaccine trials across 20 COVID vaccines, and found only 12% have made their protocols available as of May 2021. Scores of key decisions affecting the public were never made available. The U.S. government should immediately give the public and outside scientists access to raw data on which studies are based, and the minutes of meetings where major decisions are made on policies like mandates; we need the kinds of transparency Peter Doshi has asked for from pharma, and Kesselheim did from the FDA. Doshi and some colleagues from Oxford have asked, for instance, what the rationale was for the regulatory agencies to allow pharma companies not to choose hospitalization, death, or viral transmission as "endpoints" in the authorization studies. Let's see the internal deliberations; let's see the minutes of crucial meetings. All these researchers are doing is being true to the motto of the Royal Society, the first national scientific institution ever established: *Nullias in verba*, "Take Nobody's Word For It."

Acknowledging severe problems in regulatory agencies or within pharma doesn't mean believing that everything that system produces is tainted, or that all the people in those institutions are corrupt. In fact, it defends those with the most integrity—because it is they who are most frustrated by a system that requires radical restructuring and new leadership. Even if—especially if—we think of ourselves as "pro-vaccine," we should want to rescue this extraordinary technology from the flawed and broken system of poor regulation, insufficiently transparent testing, and manipulative messaging.

But many are choosing instead to replace this conversation about the system underlying the vaccine rollout with vaccine mandates—a strategy that troubles even some of those who have been very invested in the success of the vaccines.

"Right now with these vaccine mandates, and vaccine passports, this coercive thing is turning a lot of people away from vaccines, and not trusting them for very understandable reasons," Kulldorff says. "Those who are pushing these vaccine mandates and vaccine passports—vaccine fanatics I would call them—to me they have done much more damage during this one year than the anti-vaxxers have done in two decades. I would even say that these vaccine fanatics, they are the biggest anti-vaxxers that we have right now." Those congratulating the United States on mandates "working" conveniently leave out that each of those "wins" is potentially a recruit for a resentful army that does not believe in vaccines. Imagine a scenario—already unfolding in Israel—in which regular boosters are deemed necessary: How easy do you think it will be to drag those people into this action every six months? Wouldn't it have been more effective to have enabled them to own these actions for themselves much earlier—thereby making it more likely that they would sustain them?

There are ways for all of us, medical professionals or not, to stop the bleeding, beginning with changing our orientation to those who are skeptical.

I have to return here to ZDogg, whose widely watched videos have attempted to persuade the hesitant to get vaccinated. "I love the coronavirus vaccines," Damania has said. "They work, they save lives, they prevent severe disease. Immunity is our only way through a pandemic, whether it

is naturally being infected or being vaccinated." And yet he too believes that mandates are "going to set back the cause of vaccination and increase tribal division."

Instead of coercion, he offers engagement. When a viewer (in the chat, or in a personal email to him) raises concerns, Damania doesn't minimize it or go around the problems; he works through them. He addresses conflicting studies, bringing on some of the world's finest epidemiologists and public health experts, and shows us the real world of physicians and scientists agreeing and disagreeing. He acknowledges when the science is not as airtight as officials present it. And he doesn't use a one-size-fits-all approach, if he can avoid it: If a person raises a personal health issue—an allergy, or immune issue, or cardiac problem—he factors it in, and sometimes a person decides to get the shot. Sometimes they decide not to, and he wishes them well. As a result, people feel listened to, and in turn become more open to listening to what he has to say. Whether one agrees with his advice or not (I often agree, or come to agree, but not every time) his respectful approach seems to me irreproachable, and, to judge from the results, effective.

In addition to primary care physicians, those who are "pro-vaccine" (but not professionals) also have a role to play here, in acknowledging that some of their fellow citizens' distrust is utterly warranted: The seemingly bottomless lining of pharmaceutical pockets; the unconscionable censorship of scientists; the grotesqueness of seeing the rich, unmasked at a Met Gala, waited on by a masked servant class; the downsides of and controversy around masking schoolchildren, and more. If they are not listened to when they are obviously right, why would they listen to others?

Some might come to the end of this essay and wonder why I—so cognizant of all the problems with the U.S. regulatory process and study transparency—got vaccinated.

I did so when I had time to think through my own situation, as many physician friends did. We knew that COVID was for many a beast not taken lightly. Like them, I used an individualized approach, which ideally everyone should be able to do with their own

physicians if they have special health issues. For me, this meant taking into account how prevalent the virus was at the time in my area, its lethality and possible long-term effects in someone my own age, sex, with my own health history, and the probability of side effects known at the time, and my own response to vaccines in the past, and the fact that I had no allergies to the additives. There were transparency problems with the clinical trials, which meant there was a lot we did not know, but already by the time I got my own shot we did have some knowledge that the vaccines were lowering deaths. While factoring in my own risk tolerance, I tried not to pretend I knew more than I really did, about COVID or the vaccines.

Of course governments will not want to rely on a system in which everyone is encouraged to go to their physician for some kind of individualized discussion. But we are not talking about everyone here. We are talking about people who remain unconvinced, after our public health system has done its best at a mass-marketed vaccine campaign. It is a minority of citizens, but a sizable one. We can either choose, as we have, to coerce them with economic and social deprivation. Or we can work to better engage them.

For Tocqueville, "the tyranny of the majority over the minority" is the ever-present danger in democracies, the remedy for which, John Stuart Mill argued, was a protection of minority rights, and, above all, the right to continue speaking—even if a majority opinion seemed to be crystalizing. Mill, son of the man who helped invent utilitarianism, in the end was influenced and changed by Tocqueville's notion of the tyranny of the majority, and pointed out that the tyranny unique to democracy gave rise to "the peculiar evil of silencing the expression of an opinion" in the social sphere, in our so-called free societies. It moved him to write his great plea for free speech, in On Liberty:

> *Protection, therefore, against the tyranny of the magistrate is not enough: there needs protection also against the tyranny of the pre-*

vailing opinion and feeling; against the tendency of society to impose, by other means than civil penalties, its own ideas and practices as rules of conduct on those who dissent from them; to fetter the development, and, if possible, prevent the formation, of any individuality not in harmony with its ways, and compel all characters to fashion themselves upon the model of its own. There is a limit to the legitimate interference of collective opinion with individual independence: and to find that limit, and maintain it against encroachment, is as indispensable to a good condition of human affairs, as protection against political despotism.

To find that limit and maintain it becomes the difficult but essential task when a plague besets a democracy—especially one that wishes to remain in good enough condition to survive it. ◆

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To make sense of the pandemic—how it is transforming life around us and how it is affecting our individual psyches—read Norman Doidge's Journal of a Plague column in Tablet magazine.

Use your smartphone camera to scan the QR code.

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