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Better Healthcare Newsletter from Patrick Malone



"Reputation, reputation, reputation! Oh, I have lost my reputation! I have lost the immortal part of myself, and what remains is bestial."

— *William Shakespeare, 'Othello'*

Because they are made up of human beings, they are imperfect organizations. But for decades, the federal Centers for Disease Control and Prevention (CDC) and the federal Food and Drug Administration (FDA) have won global acclaim for their efforts to safeguard Americans.

U.S. taxpayers, with a shared commitment to improve the nation's health, have provided largely enthusiastic support so federal experts

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FDA had plentiful issues already

BY THE NUMBERS

\$5.2 billion

President's FY2020 budget authorization for the CDC. That

But at a historic moment, when we needed these agencies to step up to a grave health challenge not seen in a century — a pandemic caused by a novel coronavirus — the government's medical scientists have stumbled.

That, alas, opened the door to what has been months of unprecedented anti-science assaults by political partisans, starting with the nation's commander-in-chief. The United States may long suffer the consequences of 2020 as the *annus horribilis* for public health, medicine, and science — and especially the CDC and FDA. As with any grave condition, listing its symptoms and harms may be the start to a desperately needed remedy, so let's get to the diagnosis.

Stakes could not be higher for Americans as politicians rip at U.S. health agencies



The fortunes of government agencies in Washington, D.C., or Atlanta, Ga., may not seem consequential to many Americans, but in the case of the CDC and the FDA, the public has gotten a stark view of how the work of these federal bureaucracies really does matter, affecting:

- [School kids and whether they are safe to attend classes in person](#)
- [The religious and whether they can worship safely in churches indoors](#)
- [Travelers and how they can fly, ride, or cruise safely, especially with face coverings](#)

22,776

Calls fielded in 2018 by CDC's 24/7 Emergency Operations Center with urgent medical-scientific information and assistance requests from clinicians, hospitals, state health departments, and the public.

69

Peer-reviewed publications from the CDC, including the Morbidity and Mortality Weekly Reports. The MMWR are foundational for scientists and public health experts, a respected source to update them on trends in infectious diseases, Covid-19 included.

45

Prescription drugs that successfully underwent FDA review (including rigorous clinical trials) and were approved for markets.

1.9 billion

Number of views by public of information on CDC websites. The figure has soared during the pandemic.

QUICK LINKS

[Our firm's website](#)

[Read an excerpt from Patrick Malone's book:](#)

- All of us and whether [potent drugs can be shoved into wide use](#) with scant evidence for their usefulness or safety
- The nation and whether hundreds of millions of us should be [inoculated with rapidly developed vaccines](#), unless they undergo rigorous testing for their safety and effectiveness

In brief, as these bullet points underscore, the stakes could not be higher for Americans in ensuring that the CDC and FDA not only live up to but exceed their hard-won standing in safeguarding the nation, and, indeed, the world. This is a role that taxpayers have committed billions of dollars of support to over the long and storied histories of the agencies — ever since the FDA was formally founded in the 1930s, and the CDC was established in 1946.

Federal medical scientists have helped eradicate smallpox around the planet and wipe out polio in this country. They have fought a catalog of disease outbreaks and pioneered research to better deal with an array of illness and injury. They have battled threats to the quality and safety of the nation's food, prescription drugs, and medical devices.

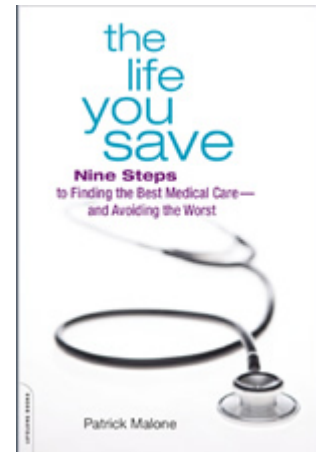
An unprecedented assault

The White House, without a doubt, should demand the best from U.S. agencies and their staffs, especially in a crisis. The president should challenge and question these scientists. But the current assault on the nation's expertise in medicine and science escalated shortly after the harms of the coronavirus leaped into public consciousness, with federal staffers also making missteps early on.

President Trump already had saddled the agencies with weak leaders. Since the start of the pandemic, he has mugged, muzzled, and sidelined them, substituting their expertise with the “gut feelings,” evidence-free imaginings, and fringe views of his own or others in his orbit.

This led some of the nation's [most prestigious medical and scientific publications](#), as well as scores of Nobel laureates, to take the unprecedented step of dropping their political neutrality to oppose Trump's re-election. [The national academies of science and medicine](#), made up of top leaders in the fields, have assailed politicians' science denialism, especially regarding the pandemic response. [Media outlets have reported](#), widely and deeply, about the [noisy, public repudiation by the White House](#) of globally accepted, science-based public health knowledge. The administration's months-long anti-science jag has been jaw-dropping not only for its extremism but also for its impunity — it has lumbered on as hundreds of thousands of Americans have died due to an uncontrolled novel coronavirus and ~9 million have been

[Nine Steps to Finding the Best Medical Care — and Avoiding the Worst](#)



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PAST ISSUES

World sees a sickly U.S. health system, wobbling in pandemic and a divisive election
The Covid-19 vaccine: Will 'warp speed' produce safe, effective protection for billions?
Covid-19 and nursing homes: Should families sue?

Infuriating the White House

As reported in detail by the Pulitzer Prize-winning investigative web site [ProPublica](#), officials at the CDC infuriated the White House in important ways, including by:

- Insisting that the United States reject a coronavirus test recommended by the World Health Organization, in favor of a CDC-developed model that the agency botched and delayed
- Imposing, with the FDA, narrow rules as to which patients might be tested — strictures that early on blinded experts as to the potential spread and extent of the pandemic
- Their inability to extract reliable intelligence about the explosion of coronavirus cases in China, a notably closed and authoritarian nation. U.S. officials would note that they were hamstrung in their global information-gathering efforts by budget cuts — ordered earlier from the top.

A fast-decaying relationship between the White House and its own medical scientists further fell apart when [one of the CDC's top experts on epidemics warned](#) that the Chinese deaths and infections constituted a health crisis that demanded attention. Stocks fell on Wall Street, and the president fumed as he returned from an overseas visit. Trump pushed back, praised the Chinese public health response, and argued that the U.S. cases known at the time were few and quickly resolving.

At one point, with Dr. Robert Redfield, the CDC chief, grinning in the background, [the president also contended, falsely, that coronavirus tests](#) were so abundant that “anyone who wants one can get one.” He later would tell the nation the disease would magically vanish.

His top intelligence officials, of course, were briefing Trump on the increasing severity of the coronavirus outbreaks, soon to be declared a global pandemic. The president, [in tape-recorded interviews, told journalist Bob Woodward](#) that his national security experts warned him Covid-19 was deadly, far worse than the flu, and highly contagious because it appeared to be an airborne infection. Trump said to Woodward that he decided to downplay the blaring alarms because he did not want to panic Americans. Still, members of his administration [briefed affluent partisans in private about the significant risks](#) the coronavirus could pose to the economy, and some of them followed up by making millions from quick stock sales before the market nosedived. More nonsense would follow.

The president, in the pell-mell conclusion to his re-election campaign, has [accused health workers of profiteering by hyping the coronavirus](#)

[Inequities require urgent redress](#)
[Taming the cognitive biases that mess with our decision-making](#)

[You Can Eat This... But Why Would You?](#)

[Looking Ahead: Preparing for Long-Term Care](#)

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[Standing Tall Against a Fall](#)

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How did we get to this state of decline with once pre-eminent experts and federal agencies?

Medical science undercut in plain view



It will take historians — or maybe a blue-ribbon investigative panel — awhile to catalog all the ways that political partisans have eroded the credibility of federal health agencies, particularly during the pandemic.

The public, however, has gotten an eyeful of how politicians' meddling and micro-managing of medical scientists works:

Researchers gather evidence and conduct studies to formulate recommendations and guidelines, notably about how the public can best safeguard itself against the coronavirus — based on the best available knowledge at a given moment. The White House simply disagrees, rarely if ever citing evidence but often making experts aware of political exigencies (constituencies or special interests that demand attention). Angry calls occur as do tense meetings. Emails fly, particularly to top agency leaders who hold their jobs at the behest of the president. [Jobs get threatened](#). [Experts get shunted aside](#), demoted into positions of exile. The leader of the free world also berates and bullies medical scientists with childish name-calling, especially on partisan or social media.

Political meddling becomes a norm

This has occurred with attempts by the 11,000 staff at the CDC to battle Covid-19 in schools, places of mass gatherings — and especially in sites of worship — and on public transportation, event timelines and media reports show. As ProPublica reported:

“As a historically lethal pandemic raged, the White House turned the CDC into a political bludgeon to advance Trump's agenda, alternately blocking the agency's leaders from using their quarantine powers or

“Once seen as an apolitical bulwark, the CDC endured meddling on multiple fronts by officials with little or no public health experience, from Trump’s daughter Ivanka to Stephen Miller, the architect of the president’s immigration crackdown. A shifting and mysterious cast of political aides and private contractors — what one scientist described as young protégés of Trump’s son-in-law, Jared Kushner, ‘wearing blue suits with red ties and beards’ — crowded into important meetings about key policy decisions.”

The White House got angry and frustrated at what it deemed to be a slow and clunky CDC system for collecting national pandemic data. [Key members of the White House coronavirus task force also grumbled](#) about the agency’s experts analyzing and communicating information about cases, infection rates, and testing. So, to the consternation of public health agencies, doctors, and hospitals nationwide, the administration ripped away the information responsibility from the CDC. Rather than fixing or tweaking an established system, the White House hired a private tech firm to take on the tasks. The system, those outside the administration said, did not work well and was worse than what existed, further taxing already harried health workers.

The White House controlled crucial data that the public would need to assess the severity of the pandemic. Fortunately, media groups and institutions like Johns Hopkins stepped in and gathered the vital information, communicating it better, too. Still, the president [became a prime source of misinformation](#) about public health measures, including with his [bizarre insistence that increased testing was to blame for rising coronavirus infections](#). This falsehood became an administration mantra, a giant show of ignorance: It was like claiming that just taking pregnancy tests produces more kids.

Public displays of defiance

Meanwhile, the president and his minions went out of their way to show their defiance of simple, evidence-based, common-sense steps for the public to protect against Covid-19. As the political season wore on, partisans mocked face covering and distancing and made them political and divisive issues. The president dwelled more on his complaints with low-flow bathroom fixtures than on the high value of hygienic measures like hand washing.

[Morale sank](#) among public health staff, especially at the CDC. Experts headed to the exits as the staff at the national agency charged with “disease prevention” realized their leaders were not protecting them or medical science. Instead, the White House had adopted a plan of D’s: deny, deflect, downplay, and defy the rising toll of infection and death, along with any (expert) information that did not comport with figments formed in incurious minds. [Really? A guy whose claim to fame was pillow- and mattress-top-making](#) snagged the ear of the leader of the free world on global health issues? Was it any better that the White House embraced a West Coast radiologist who [promotes a "herd](#)

At the FDA, the situation was equally unsettling, even for drug regulators who, over the years, had sought to be more accommodating to political forces allied with Big Pharma and the medical-device industry. The president and his men, arguing for emergency action, dynamited norms and accepted practices as they grasped at an ever-changing bunch of “Hail Mary” ways to treat the coronavirus. This stayed true, even intensified, when the president was infected with and medicated for Covid-19.

Flitting among desperate drug claims

Facts failed to stop the president from falsely asserting that he would ensure all patients who need monoclonal antibodies, as well as the anti-viral drug Remdesivir, would get them, affordably and maybe even free. How many Americans, however, could get the elite care offered to a president — [treatment that likely cost more than \\$100,000 for a short stay](#)? These claims came from the same president who, with those in his evidence-free orbit, have:

- Hyped the [anti-malarial drug hydroxychloroquine, now debunked](#) as a coronavirus treatment
- Pushed the [unproven use of convalescent plasma](#), a treatment using antibodies from recovered Covid-19 patients' blood to help the infected
- Mused on the [dangerous introduction directly in the body of bleach and other disinfectants](#)
- Flirted with [wild fictions about oleandrin, a supplement derived from a poisonous bush](#).

The White House vituperation against the FDA, CDC, and federal health experts has only stepped up and has included conspiracist accusations that long-time personnel are part of a “[deep state](#)” [determined to undermine the president](#).

Trump has pounded on the FDA and its commissioner over the agency's announced commitment to ensure the safety and effectiveness of vaccines now in development to protect patients against the coronavirus. The president had made clear that he wanted an emergency approval of vaccines before election day — and that will not occur.

ProPublica quoted a CDC expert, however, on the sustained damage that has resulted from the relentless assault on his agency and federal health programs, in general:

important currency of public health: trust, the confidence in experts that persuades people to wear masks for the public good, to refrain from close-packed gatherings, to take a vaccine. Dr. Martin Cetron, the agency's veteran director of global migration and quarantine, coined a phrase years ago for what can happen when people lose confidence in the government and denial and falsehoods spread faster than disease. He called it the 'bankruptcy of trust.' He'd seen it during the Ebola outbreak in Liberia in 2014, when soldiers cordoned off the frightened and angry residents of the West Point neighborhood in Monrovia, the capital.

"Control of a pandemic depended not just on technical expertise, he told colleagues then, but on faith in public institutions. Today, some CDC veterans worry that it could take a generation or longer to regain that trust. 'Most of us who saw this could be retired or dead by the time that's fully fixed,' one CDC official said."

Leadership and resources lacking



The undermining of federal health agencies may have plunged to new lows in recent days. But it was a hallmark of this administration almost from the start. This was writ plain in the leaders chosen to run complex operations, and the slashed budgets the White House proposed for them.

The current administration, [as specialty journals have reported](#), may look better in financial terms for scientific and medical research due to what's happened on Capitol Hill — not at the White House.

Trump and his people for three years running have sought to slash health and science funding, only to see Congress resist and support, sometimes generously, programs the White House opposed. As a cancer experts' publication, for example, reported:

"In his [2021 fiscal year budget proposal](#), Trump aimed to cut the [National Cancer Institute] budget by \$559 million, reduce [the National Institutes of Health] spending by 7%, and axe \$44 million of funding to

administration's attitude to cancer research funding.”

Problems starting at the top

Leadership matters. And in this area, the president's failures have been marked.

The White House's initial priority was to repeal and replace the Affordable Care Act, loathed by the Republican Party for more than a decade now. Trump, with no experience in governance and little in politics, heeded GOP advisors who told him that he needed his top medical-scientific figure — the head of the giant Health and Human Services agency (which includes the CDC and the FDA) — to have legislative experience to boost the planned takedown of Obamacare in Congress.

So, the administration started with [HHS headed by Dr. Tom Price, a Georgia orthopedist](#) and former congressman from the Atlanta area who soon became part of the failed GOP-Trump effort to repeal the ACA. Price also had a penchant for spending taxpayer dollars on pricey military and private flights across the country and the world. The petty pilfering led to Price's ouster.

Trump also made an early pick of [Dr. Brenda Fitzgerald](#), an obstetrician-gynecologist, to lead the CDC. The onetime head of the Georgia Health Department (and ally of Price) had her own problems, chiefly her major financial holdings. She also could not see the challenges of owning and acquiring shares in tobacco companies while heading an agency that had led the public health battle against the proven harms caused by Big Tobacco.

The VP's crowd takes hold

As the administration settled in, Vice President Pence apparently gained greater pull with Trump about health matters, because suddenly those in his orbit rose into top health jobs. This was not necessarily a good sign, since [Pence was a prominent science denier](#) as a radio talk-show host and politician. When he was Indiana governor, his administration presided over one of Hoosiers' worst public health calamities, the disastrous handling of an HIV-AIDS outbreak.

But [Pence-connected politicians](#) soon headed HHS (Alex Azar, a Big Pharma executive and a lawyer, not a doctor nor a scientist) and the Center for Medicare and Medicaid Services (Seema Verma, a health policy wonk and health company consultant). They have spent a [chunk of their time in office feuding and attempting to undercut each other](#), with Verma also under fire for [throwing millions of taxpayer dollars at GOP consultants](#) in sketchy ways to build her political and professional reputation. Azar has shown himself to be a loyalist and survivor, though less than an adroit political infighter. (Her agency also has performed poorly in protecting residents of nursing homes and other long-term care facilities.)

standing. Though he heads the nation's biggest health agency, he learned hours before an administration news conference that he would not chair the national task force on the coronavirus, a job that went to Pence instead. The White House, as reported by [the news site Politico](#), also jammed up Azar's works with political operatives. These included political "liaisons," plants who were responsible to report outside the chain of command to the White House about agency doings. These staffers also weighed in on staffing and personnel issues. That might have been of less concern to the experts in the agencies, except, as Politico reported, a top White House liaison at HHS went in weeks from being a University of Michigan senior and star athlete to having a say about national health policy matters in the midst of a pandemic. What?

HHS staff and other medical scientists bristled far more at the White House's installation in a top communications post of [Michael Caputo, a lobbyist and political operative with zero health care background](#). Caputo sought to restrict federal experts from public outreach and public health communications — vital roles in a pandemic. He sought to be the handler and muzzle for Drs. Fauci and Brix. He demanded authority to clear an array of medical-scientific material, and he brought in dubious characters, including a Canadian university lecturer, to help him argue with his own agency's experts and findings.

Caputo's mischief came to an end when he was caught in a recorded rant, replete with conspiracy theories, about HHS. He took sick leave, even as he had planned to divert hundreds of millions in HHS funding to a cheery national advertising campaign about the pandemic. That initiative would have run in the midst of the president's re-election efforts, and, it would have [given an acting crew of Santa and his elves early access to a coronavirus vaccine](#) as a reward for participating.

FDA has its share of problems

At the FDA, the administration has not been stumble-free. The president's first pick charmed many in the nation's capital, because Dr. Scott Gottlieb, a Big Pharma entrepreneur, think tank scholar, internist, and onetime agency staffer, seemed more open, communicative, and congenial than many of the GOP appointees.

But he could, like many in the administration, carry water for corporate interests. Critics assailed his early decision to seek more studies on nicotine, notably its addictive qualities. This also was part of Gottlieb's decision to [postpone a planned FDA crackdown](#) on a rising new way that young people were abusing nicotine — with e-cigarettes and "smokeless" consumption or vaping. Gottlieb soon found his agency and nation engulfed in a public health crisis, as high-tech entrepreneurs exploited social media and the FDA regulatory loopholes to make vaping a youth craze and health menace. Gottlieb's FDA played whack-a-mole with Big Tobacco and vaping interests, which seemed to stay a step ahead of regulators' every effort to control vaping abuses. Gottlieb left the agency as it dealt with sales of illicit vaping products that were hospitalizing and killing kids across the country. (To his credit,

To replace Gottlieb, the White House found a cancer specialist with a reputation for talking tough (and often straight) and in finding himself amid institutional messes and seeking to clean them up. Though Dr. [Stephen Hahn had no political experience](#), he rose through the ranks in academic medicine at the University of Pennsylvania School of Medicine and MD Anderson Cancer Center, so he knew about internecine battling. He was a GOP donor but not a partisan die hard. He kept his FDA advisers few and close, forgoing outreach to his well-known and well-connected predecessors.

As Hahn was settling into his new role, the [White House sent him its hand-picked people](#), notably his top communications officer. She had worked for Republicans in Congress and briefly as a broadcaster for the fringe One America News broadcasting operations. She had no science, medical, or health care background, and helped prepare materials for Hahn to discuss the FDA's decision to grant emergency use authorization for a coronavirus therapy. But Hahn, a respected and published researcher, made an egregious statistical error in a news conference about convalescent plasma, a goof he was forced to retract. He and the FDA have found themselves pummeled by both the White House and the medical-scientific establishment since.

Religious conservative picked for CDC

In the meantime, at the CDC, the staff waited and watched after Fitzgerald's ouster. Hopes ran high that the agency's chief deputy and interim chief, Dr. Anne Schuchat — an internist and globally respected expert on infectious diseases and epidemics — might overcome politics and ascend from the ranks to the agency's top job. The White House, instead, tapped Redfield. He had worked with the CDC before and had the credentials as a virologist and head of an institute at the University of Maryland.

He also checked key boxes for the White House political crowd, because the deeply devout Redfield had become an admired figure in medicine for the religiously conservative. They reached out to him for his support on abstinence-only sexual practices and supported him after he fell out with the medical establishment over his extreme views on HIV-AIDS. He advocated early on for mandatory testing of military personnel for the illness — without privacy protections. He has been tied to plans for harsh quarantines of those with HIV. The [Pulitzer Prize-winning health journalist Laurie Garrett](#) wrote of Redfield in a 2018 "Foreign Policy" article headlined, "Meet Trump's New, Homophobic Public Health Quack" — before he took his post:

"The CDC will not thrive with Redfield as its leader. He will not serve as a powerful advocate for strong science, expansion of global health and domestic HIV efforts, or separation of religious and empirical perspectives in decision-making."

Might save agencies' credibility.



What responses would be appropriate to the politicization and undercutting of federal health agencies?

Well, how about more resistance from some of these outfits and their leaders? Much more. And resignations, if necessary.

That was the counsel offered to Redfield by Dr. William Foege, who served as CDC director from 1977 to 1983, spanning the Carter and Reagan administrations. [As NPR reported of a leaked letter](#) the much-admired Foege wrote to Redfield:

"The [pandemic] situation in the U.S. 'is a slaughter and not just a political dispute ... We have 75 years of experience at CDC on how to handle outbreaks And we've learned a lot of lessons. And it appears to me that every one of those lessons has been violated.' Those mistakes include: lacking a strong federal strategy — which has led to 50 states having 50 different plans; ceding the CDC's authority as a source of credible, timely information to the opinions of myriad academics across the country; and maintaining an isolationist 'America First' policy and refusing to coordinate with other countries during a pandemic that spans the globe.

"In just six months, the CDC's reputation has gone 'from gold to tarnished brass,' Foege wrote, which could make it difficult for the agency to recruit top scientists and set global standards, as it has for decades. 'It's incredible that one person or a group of people can tarnish your reputation to that degree ... It's going to be hard to regain that position.'"

Foege told Redfield that he should apologize to CDC staff, and lay out his plans to do better. And he quoted Auschwitz survivor Primo Levi, writing to his distant successor: "If you know how to prevent torture and don't do it, you become the torturer. This is the burden I found myself

FDA commissioner gets an earful

Dr. Eric Topol, a cardiologist and internationally known researcher at the Scripps Institute in San Diego, reached out in similar fashion to the FDA's Hahn, in a [published "Dear Colleague" letter](#). He took him to task for his error in discussing convalescent plasma, his failure to quickly correct his wrong, and the FDA's emergency approval of the treatment. He cautioned him that he was putting his professional standing, as well as his agency's reputation, at grave risk in seeming to acquiesce to political pressures from the White House, especially with coronavirus vaccine development:

"You have one last chance, Dr. Hahn, for saving any credibility and preserving trust in the FDA at this critical juncture amidst the pandemic ... tell the truth ... Tell us that you are capable and worthy of this pivotal leadership position and that you will not, under any condition, authorize a SARS-CoV-2 vaccine approval before the full Phase 3 completion and read-out of a program. Otherwise, you need to resign. We cannot entrust the health of 330 million Americans to a person who is subservient to President Trump's whims, unprecedented promotion of unproven therapies, outrageous lies, and political motivations. You have two choices to do the right thing. We cannot and will not rest until you make that choice."

Topol noted on social media that he was pleased that Hahn responded, and the doctors have opened a robust discussion.

Despite the White House's aggressive campaign to score a political win by having the FDA grant emergency approval for a coronavirus vaccine (several of which are still in the crucial third phase of clinical trials), [Hahn and the FDA have stood fast](#). The agency, with support from Fauci and the NIH and others in the medical-scientific community and even Big Pharma, has insisted that the public must be assured any prospective vaccine is safe and effective — or it may not reach sufficient levels of use to be helpful in the battle against the virus.

The president is fuming, according to reports, and [Azar is said to be ready to fire Hahn](#).

[Redfield has not stepped forward](#) in similar fashion. As ProPublica reported:

"The months of defeats were taking a toll. Redfield looked beaten. When his boss, HHS Secretary Alex Azar, upbraided him, he could only mumble, 'Yes sir' or 'I understand, sir'" or 'I agree, sir,' according to people who heard these exchanges."

But the CDC recently did post new guidelines about face coverings for those on public transportation — an advisory that reportedly displeases the White House, which, for example, had left it up to individual airlines to set policies on the issue and have them flouted by obdurate passengers.

bullying, won't push him out. He says he tries to stick to business (quoting the "Godfather" movie) and never take anything personally. He has made clear that as an expert and physician, he thinks the stakes are too high — preventing potentially hundreds of thousands of deaths and millions of illnesses — to let meddling and insults prevent him from doing all he can.

Supporting public health

For those of us who are not leaders in our field or holders of high office, what should we do about the CDC, FDA, and other federal health agencies?

Well, please vote. Please take the time to research with rigor, and think critically about not only the events involving the agencies discussed in this newsletter but the entirety of the federal pandemic response, as well as the way health care has gone in this presidential term.

It may be worth considering, too, the bluntness with which the incumbent has talked about public servants — the men and women who have committed their lives and careers to our health. Besides denigrating the staff in federal health agencies, the president has maligned exhausted and overwhelmed front-line care givers. He has asserted without evidence that doctors, nurses, technicians and others who risk their own health and lives every day have exaggerated Covid-19's toll because they are profit-gouging with these patients.

Within the federal government, and with pertinence to public health personnel, Trump has just issued an executive order that, critics say, targets U.S. workers. The president, in a complaint that others have made, too, has contended civil service rules protect poor performing government workers. And [he wants to reclassify a raft of people](#) — potentially including folks like [Dr. Fauci](#) — so the White House can fire them faster and easier. No taxpayer would argue with legitimate efforts to ensure federal employees earn their pay. But the president is not a king, nor a chief executive on a reality TV show. He can't snap his fingers and yell at people, "You're fired!" This is a complex issue that a leader might need to build consensus on, including with public hearings on Capitol Hill, before enacting needed reforms, right?

Once this election is over, here's hoping that we all can turn down the tensions. We need to work together to get the nation in a far better place, especially with its health and medical services and public health. We're all weary of the coronavirus and how it has harmed so many and disrupted lives and livelihoods. But medical and scientific experts have toiled to end the pandemic and to protect the public. We need to recognize that, even to honor the sacrifice. It is unacceptable that public health officials, including at the local, state, and federal levels, have been threatened and forced from their posts for doing their jobs. The pandemic has underscored for us all how much more we need to advance science, medicine, and public health — including providing the people in it the resources and support to make the world a safer, better

I, of course, wish that you and yours stay safe and healthy in what's left of the year and beyond!

Photo credits from top: *CDC*, medical entomologist Janet McAllister peers into a microscope in Fort Collins, Colo., lab. She hasn't spent much time there recently, deployed on multiple pandemic-related duties elsewhere across the country. *CDC* photo shows members of the Epidemic Intelligence Service prepping to investigate Utah coronavirus outbreak. *NBC News video capture* shows Trump and face-covering Fauci at coronavirus task force news conference. *Voice of America montage* depicts top U.S. health officials (Pence, Birx, Surgeon General Jerome Adams, Fauci, Azar, Hahn, Redfield, and Verma) *CDC photo* shows Dr. Dana Meaney-Delman discussing the structure of the government's Covid-19 response with colleague Dr. Joe Bresee. *CDC photo* shows microbiologist Amy Kirby taking floodwater samples for research on urban antibiotic resistance.

Strange targets: scientists, doctors, nurses, care givers



Political partisans have picked a peculiar target in scorning public health professionals, including those at the Centers for Disease Control and Prevention and in state and local health agencies.

The doctors, nurses, counselors, researchers, statisticians, and educators who pursue careers in this field [make a commitment to improving the health of others](#). They investigate outbreaks of communicable and infectious diseases, as well as taints to the nation's food, water, and air.

Their work can be stressful and demanding, often occurring in uncertain and risky circumstances — not to mention in pursuit of remedies under significant time and resource constraints. They may put themselves and their loved ones at heightened risk with their exposure to the sick, injured, dying, and dead. They often may be responding in emergencies and crises near and

FDA had plentiful issues already



Strange times can create unusual circumstances. This newsletter includes an example that may be startling to some: Yours truly writing kind words and in defense of the federal Food and Drug Administration as political partisans carve into the agency and its work.

This position has its sound reasoning.

The FDA, as the public's federal watchdog, inarguably needs to be more (not less) rigorous in its oversight of Big Pharma and medical-device makers. And taxpayers need to discourage intervention by politicians, even in the name of a pandemic emergency, to push pro-industry policy making and practical changes at the FDA to speed medications and devices to the market.

Big Pharma has howled for some time now at politicians, regulators, and the public for fixes to the oversight system — and the industry has gotten its way. But as [NPR reported](#), based on a [study posted online on the JAMA Network](#):

being of their own loved ones.

Many of the experts in this field, employed by the government, may accrue modest benefits after long service. But they often do not earn salaries that are close to what they might enjoy in the private sector with their comparable education (often including advanced degrees), experience, and accomplishments. [As noted health journalist Laurie Garrett reported](#) in an Opinion article for CNN:

“[M]ost scientists and physicians working in HHS make less than \$170,000 a year. I scrutinized nearly 1,000 pages of payroll listings at the Department of Health and Human Services and found few CDC employees who earn more than \$150,000 annually. Some make considerably more than that, thanks to Title 42, a policy that gives federal agencies flexibility on salary limits in order to lure outstanding scientists and other professionals into government work. Nearly all of those scientists are classified as Medical Specialists, 138 of whom earn more than \$250,000. All but 13 work at the National Institutes of Health, engaging in basic scientific research.

“Just two individuals make more than \$350,000, ranking them the most highly paid federal employees after the President (who is paid \$400,000): [Anthony Fauci](#), director of the National Institute of Allergy and Infectious Diseases, and [Rachel Sherman](#), deputy commissioner of the Food and Drug Administration. Having run NIAID since 1984, Fauci is the longest serving Institute director in NIH history. He has been an adviser to five presidents, architect of the HIV program PEPFAR, the 24th most-cited scientist in history and recipient of every major biomedical award besides the Nobel Prize, including the Presidential Medal of Freedom and the National Medal of Science.”

By way of comparison, [the average annual pay pre-pandemic](#) for an orthopedist in private practice was \$511,000, while plastic surgeons were paid \$479,000, and cardiologists received \$438,000. The [American Association of Pharmaceutical Scientists reported](#) that the mean total compensation for its reporting members in 2019 was \$193,400.

the evidence it relies on in making those decisions is getting weaker ... As a result, there are more ... treatments on the market but less proof that they are safe and effective.”

[Jonathan Darrow](#), a lawyer with [Harvard Medical School's Program on Regulation, Therapeutics, and Law](#) and lead author of the JAMA work that scrutinized FDA drug policies and practices for the quarter century since 1983, told public radio that ““There has been a gradual erosion of the evidence that’s required for FDA approval.” As a result, patients and physicians “should not expect that new drugs will be dramatically better than older ones.”

Darrow and colleagues at Boston hospitals and research institutions found that “half of recent new drug approvals were based on only one pivotal clinical trial instead of the two or more that used to be the norm ... And the reliance on surrogate measures — stand-ins for presumed patient benefits — has increased. In the case of cancer drugs, a surrogate measure could be shrinkage of tumors instead of improvements in survival after treatment,” NPR reported.

By accepting less evidence, federal regulators have stepped back from their tough oversight over prescription drugs, so that products in 2018 got through reviews in 10 months versus the 2.1 years it took in the late 1980s and 1990s. And that was before Big Pharma started spending big on lobbying to persuade members of Congress that drug approvals needed to be sped up, so innovations could benefit patients sooner. The argument had urgency, following too many medical experts’ lead-footed response to the HIV-AIDS crisis.

But the Republican-dominated Congress has, for example, sent a misguided signal to regulators at the FDA by tying increasing sums in their budget to fees the agency collects from Big Pharma for ensuring its products are safe and effective.

With medical devices, [investigations by various media outlets have raised serious doubts](#) about the stringency and the transparency with which the FDA conducts its oversight of a booming industry. My blog long has detailed how costly lawsuits must accrue into big numbers of cases

advance their health and well-being. But this is an [area of health care that always struggles with under- or roller-coaster-funding](#). The money and resources flow during crises, then they vanish. As a news article noted:

“Since 2010, spending on state public health departments has dropped 16% per capita, and the amount devoted to local health departments has fallen 18%, according to [an [analysis](#) by two news organizations.] At least 38,000 state and local public health jobs have disappeared since the 2008 recession, leaving a skeleton workforce for what was once viewed as one of the world’s top public health systems.”

In seeking to assist under served and neglected individuals and communities, public health officials often toil on behalf of unpopular populations — the poor, minorities, the physically and mentally ill, and those with substance problems. Public health officials may impose safeguards that can aggravate the public, as they have since at least the time that authorities in ports battled the black plague by forcing crews to stay aboard ships.

Still, as the [independent Kaiser Health News service and the Associated Press reported](#), public health pros have been subjected to unusual public ire during the coronavirus pandemic:

“Vilified, threatened with violence or in some cases suffering from burnout, dozens of state and local public health officials around the U.S. have resigned or have been fired amid the coronavirus outbreak, a testament to how politically combustible masks, lockdowns and infection data have become ... A review by KHN and The Associated Press finds [as of early August that] at least 49 state and local public health leaders have resigned, retired, or been fired since April across 23 states. The list has grown by more than 20 people since the AP and KHN started [keeping track](#) in June.”

The reporters delved into the expert exodus, reporting:

“Many of the firings and resignations have to do with conflicts over mask orders or shutdowns to enforce social distancing ... Despite the scientific evidence that such measures help prevent

organization found that the FDA had stashed huge numbers of aggregated product complaints in undisclosed files.

[The agency offered an unacceptable “reform”](#) of its medical-device oversight, effectively allowing new devices to bootstrap themselves on to the market simply by showing “substantial equivalence” to existing products, some decades old and, critics said, considerably different.

Stat, the medical and scientific news site, [quoted Holly Fernandez Lynch, a health policy expert and University of Pennsylvania professor of medical ethics](#), and her savvy take on the pandemic and its potential to worsen and to create regulatory issues for the FDA:

“It’s a political agency, and it has a political appointee at the head, but it has maintained a reputation for decades of being a science-focused agency. There have definitely been slip-ups, but the level of interference that we’re seeing from the White House is so concerning.”

Other experts quoted in the Stat article argued that it can be too easy to expand “exigent” or “emergency” use of raw political power to influence FDA decisions on prescription drugs, treatments, and medical devices.

[“Why not? Why not try things? What have we got to lose?”](#) President Trump has asserted as he has muscled the public and regulators to, frankly, become guinea pigs for several different coronavirus medications or treatments. He and other Republicans also have said the push for nostrums in the pandemic is akin to dubious “right to try” laws that they say can give terminal patients hope by allowing Big Pharma to supply them unproven drugs as a last resort.

But [cancer patients already confront increasingly tough choices](#) with an increasing array of costly drug treatments that may have minimal benefit with the quality or length of their lives. Drug makers have gotten skilled at persuading FDA regulators to approve cancer drugs based on “surrogate endpoints,” technical findings, for example, that medications may slow tumor growth without halting a cancer or bettering or extending patients’ lives.

matter what health experts tell them. 'It's not a health divide; it's a political divide,' [said Lori Tremmel Freeman, CEO of the National Association of County and City Health Officials]. Some health officials said they were stepping down for family reasons, and some left for jobs at other agencies ... Some ...were ousted because of what higher-ups said was [poor leadership](#) or a failure to do their job. Others have complained that they were overworked, underpaid, unappreciated or thrust into a pressure-cooker environment."

The damages occurring to the public health field will not only harm the current battle against the coronavirus but also Americans well-being in the days ahead, Tom Inglesby, director of the UPMC Center for Health Security at Johns Hopkins, told the reporters:

"Inglesby said it was deeply concerning that public health officials who told 'uncomfortable truths' to political leaders had been removed. 'That's terrible for the national response because what we need for getting through this, first of all, is the truth. We need data, and we need people to interpret the data and help political leaders make good judgments.'"

pandemic, may have thrown the kitchen sink at coronavirus patients. But such approaches can mask which therapies are most beneficial, and politically forced approvals for drugs and treatments may block the public and researchers from the hard work of rigorous, randomized clinical trials that are the gold standard in determining the safety and effectiveness of medications and therapies.

The issue of how to not only protect the FDA from inappropriate political influence while also ensuring it functions well is complicated. Those interested may wish to take a look at a [2019 proposal from seven former commissioners](#), arguing that a key step in improving the agency and its work would be to remove it from the sprawling Health and Human Services department and make it an independent operation.

Recent Health Care Blog Posts

Here are some recent posts on our patient safety blog that might interest you:

- A Virginia criminal case, while focusing on claims of fraud against the federal government, also has exposed a long-running and nightmarish pattern of what [prosecutors assert has been a Chesapeake gynecologist's rampant mistreatment of his patients](#), many of them women of color and poor. Dr. Javaid Perwaiz is on trial because authorities say he "manipulated records to cover crimes that enriched him but endangered pregnancies, sterilized women unnecessarily, and pressured them into needless procedures to finance his lavish lifestyle," the Washington Post reported.
- [Christmas arrived before Halloween for a notorious Big Pharma firm](#). Federal prosecutors effectively gave its family founders and its executives gilded skates, so they can slide away for now from major criminal charges and severe financial penalties for their part in fostering the opioid abuse and drug overdose crisis that has killed hundreds of thousands of Americans and cost the

- For residents of nursing homes and their loved ones, new and disturbing information has come out on long-term care facilities' persistent failure to safeguard the vulnerable from the coronavirus that has killed tens of thousands of the institutionalized and infected hundreds of thousands of them and their caregivers. Six months after the pandemic exploded across the country, more than a quarter of nursing homes nationwide are "reporting shortages of personal protective equipment (PPE) and staff, and almost half have staff infected with Covid-19," according to the AARP, the country's largest advocacy group for older Americans.
- Democrats on the House Oversight Committee are [pounding Big Pharma executives for price gouging](#), publishing an 18-month investigation of the soaring costs of select prescription medications and grilling high-paid corporate leaders on whether those meds' spiking prices were all too prevalent in the profit-ravenous drug industry. The prescription medications targeted by the lawmakers included "Celgene and Bristol Myers Squibb's Revlimid cancer treatment, which saw its price hiked 23 times since 2005, and Teva's multiple sclerosis drug Copaxone, which went up in price 27 times since 2007," reported the independent, nonpartisan Kaiser Health News service.
- With the Covid-19 pandemic ensuring that even more dollars are flooding into health care than ever, nefarious parties — including doctors, nurses, and other licensed professionals — have targeted ordinary Americans and the federal government in big-time scams. [U.S. prosecutors have punched back with a nationwide fraud crackdown](#). They announced that they have charged 345 individuals for "submitting more than \$6 billion in false and fraudulent claims to federal health care programs and private insurers, including more than \$4.5 billion connected to telemedicine, more than \$845 million connected to substance abuse treatment facilities, or 'sober homes,' and more than \$806 million connected to other health care fraud and illegal opioid distribution schemes across the country."

WE'RE LOOKING AHEAD TO A HEALTHY 2021!

Sincerely,



Patrick Malone

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