

AAPS Challenges the Food and Drug Administration

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History often repeats itself. Today entrenched bureaucrats at the Food and Drug Administration (FDA) withhold more than 60 million doses of hydroxychloroquine (HCQ) from coronavirus victims, while falsely disparaging the safe medication. In 1932, Josef Stalin notoriously caused the deaths of millions of Ukrainians by withholding grain from farmers as political punishment for their resistance to collectivism.¹ Withholding safe medication from prescribing physicians is shockingly similar to withholding grain from starving farmers. Yet here and now, in 2020 in the United States of America, the FDA is doing that.

A lack of political or legal accountability for the FDA for decades has enabled this travesty. The FDA has unchecked power, for abuse as Stalin's bureaucrats did nearly a century ago. The "regulatory state" in D.C., more popularly known as the "Deep State," asserts a phony expertise, while their real skill is at avoiding judicial review for their misconduct. "Even Justice Douglas, one of the fathers of the administrative state, came to criticize excessive congressional delegations," observed Supreme Court Justice Neil Gorsuch while opposing unaccountable agency rulemaking.²

Since the outbreak of COVID-19 there has been a need for early, affordable, and safe prophylactic treatment for it. HCQ costs less than a dollar a dose and has a 65-year record of safety. If an American plans to travel to Africa, then he can obtain a prescription of HCQ for use as a prophylactic to safeguard against contracting malaria. One AAPS physician from Africa has pointed out that HCQ is consumed like water there, safely and effectively.

Yet the FDA blocks access to more than 60 million doses of HCQ donated to the Strategic National Stockpile, and falsely disparages the medication. President Trump's White House adviser Peter Navarro, Ph.D., explained that the interference by the FDA "is a Deep State blindside by bureaucrats who hate the administration they work for more than they're concerned about saving American lives."³

Background on the FDA

The FDA, which is merely a subagency of the Department of Health and Human Services (HHS), is not authorized to practice medicine. Initially established by the Pure Food and Drugs Act (1906) based on the Commerce Clause of the Constitution, the FDA is authorized today by the Federal Food, Drug and Cosmetic Act (FFDCA) as enacted in 1938. The FFDCA was "not intended as a medical practices act and [would] not interfere with the practice of the healing art[s]." The FDA admits to the physician's freedom to prescribe approved drugs off-label: "Once a [drug] product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in approved labeling" [internal quotation marks omitted, alterations in original].⁴

In 1955, the FDA approved HCQ as a safe medication,

and it has been used successfully ever since by patients. As a long-established "generic" non-patented medication, HCQ costs less than 30 cents per dose at wholesale and thus is affordable for every American, contrary to rival medications like remdesivir, which is administered intravenously at a cost of thousands of dollars per patient for the medication and many thousands more for the cost of a hospital stay.

Traditionally, physicians may lawfully prescribe an FDA-approved drug both for any uses suggested on the labeling itself (i.e., "on-label uses") and in ways that are not prescribed, recommended, or suggested on the FDA-approved labeling (i.e., "off-label uses").

Off-label use of prescription drugs accounts for a significant percentage of all prescriptions, and many off-label uses have become the standard of medical care. For generic medication such as HCQ, on which any patent rights expired long ago, there is no financial incentive for any entity to fund expensive studies to seek FDA approval for off-label uses, and such approval is not customarily sought or granted.

Effectiveness of HCQ

Yale School of Public Health epidemiology professor Harvey Risch, M.D., observed that "75,000 to 100,000 lives will be saved" if the HCQ Stockpile being wrongly withheld by the government were released, and he has decried the politically motivated interference with access to HCQ: It's a political drug now, not a medical drug And I think we're basically fighting a propaganda war against the medical facts."⁵

Dr. Jon Giles, an epidemiologist and rheumatologist at Columbia University Department of Medicine was quoted by NPR as saying: "It's a **very, very safe drug**; it's been used for over 75 years. When I give someone hydroxychloroquine, I don't get an ECG or do blood monitoring" [emphasis added].⁶

An independent analysis of all the studies of HCQ concludes that "HCQ is effective for COVID-19. The probability that an ineffective treatment generated results as positive as the 145 studies to date is estimated to be [only] 1 in 235 billion ($p = 0.0000000000042$)."⁷

Former Stanford University Medical Center Professor Dr. Scott Atlas observed that:

Hydroxychloroquine is super safe.... It's been used for 65 or 70 years, not just prophylactically for malaria, which I used it myself for that many years ago, but also used for people with things like [rheumatoid] arthritis, auto-immune-type diseases. Very safe drug.⁸

The experts' praise of HCQ is supported by numerous studies, including research on thousands of patients at the Henry Ford Health System in Michigan, where HCQ safely reduced COVID-19 mortality by 50 percent.⁹ Dozens of additional studies further demonstrate the efficacy of HCQ as preventive or early treatment for the disease.¹⁰ Dr. Raja Bhattacharya, M.D., et al. have explained that HCQ is effective

as a safe prophylactic for the benefit of health care workers (HCWs):

This study demonstrated that voluntary HCQ consumption as pre-exposure prophylaxis by HCWs is associated with a statistically significant reduction in risk of SARS-CoV-2 [i.e., COVID-19]. The current study also validated the known safety profile for HCQ with no serious adverse events reported by the participants.¹¹

The President of El Salvador, Nayib Bukele, announced that he is taking HCQ as a prophylactic against COVID-19, and that most world leaders were doing likewise: "I use it as a prophylaxis. President Trump uses it as a prophylaxis. Most of the world's leaders use it as a prophylaxis," said President Bukele.¹² President Trump did not contract COVID-19 until October when the prophylactic effect would have worn off.

President Trump shipped HCQ to Brazil in May for use "as a prophylactic to help defend Brazil's nurses, doctors, and healthcare professionals against the virus. It will also be used as a therapeutic to treat Brazilians who become infected."¹³ Subsequently, President Jair Bolsonaro of Brazil took HCQ as early treatment when he contracted COVID-19, and credits his rapid, full recovery to the inexpensive medication.¹⁴

Interference by the FDA with HCQ

Despite this proven record of success for HCQ, the FDA has improperly interfered in two ways with the ability of physicians to prescribe HCQ to patients for early treatment of COVID-19. First, the FDA has falsely disparaged HCQ for use in treating COVID-19, and state governmental entities have relied on these false statements in interfering with physicians' and patients' use of HCQ. Second, the FDA has control over the HCQ Stockpile containing more than 60 million doses of HCQ, to which it has arbitrarily restricted access while it wastes away.¹⁵

As to the wrongful disparagement, the FDA falsely posts on its website that HCQ is generally not efficacious against COVID-19. "FDA revoked the EUA for CQ and HCQ after determining that it is unlikely that CQ and HCQ may be effective in treating COVID-19."¹⁶ The FDA further states, falsely, that "hydroxychloroquine sulfate...can only be used for the treatment of COVID-19 as part of an ongoing clinical trial."¹⁷ The FDA lacks any credible support for its disparaging statements against HCQ's efficacy, particularly for prophylactic and early-treatment uses. HCQ has been approved as safe for 65 years, and the FDA lacks authority to limit off-label prescriptions by posting such a false statement on their website.

It is commonly known by physicians and many patients that antiviral medication is more effective when used early after the exposure to a virus, as recommended for oseltamivir (Tamiflu®) in use against the flu:

Take this medication as soon as flu symptoms appear or as soon as possible after you have been exposed to the flu. Oseltamivir [Tamiflu] works best if you start taking it **within 2 days** of either of these events [emphasis added].¹⁸

Yet the FDA relied on a study that did not administer HCQ until an average of 16.6 days into the progression of COVID-19.

State regulatory officials have since relied upon the false FDA statements to interfere with HCQ access. For example, the Arkansas Department of Health warned against the use of HCQ in both outpatient and hospital settings: "The utilization

of CQ and HCQ for treatment of COVID-19 should be avoided in both outpatient and hospitalized settings."¹⁹

The Federation of State Medical Boards (FSMB)—which directs state medical boards that wield complete authority over licenses to practice medicine—relied on statements by the FDA to order that:

Physicians, nurses, pharmacists, pharmacies and hospitals have an ethical duty to put the needs of patients first, and this includes observing strict prescribing guidelines. On March 28, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for use of oral formulations of chloroquine phosphate and hydroxychloroquine sulfate. The authorization allows these medications to be prescribed by clinicians for hospitalized adult and adolescent patients "for whom a clinical trial is not available, or participation is not feasible." Clinicians should avoid prescribing for themselves or their family members and should be aware that *deviating from the standard of care could put their license at risk* [emphasis added].²⁰

FDA bureaucrats favored remdesivir, despite the fact that a large study conducted by the World Health Organization concluded that it is mostly ineffective against COVID-19. Plagued with conflicts of interest and no accountability, the FDA cited two small studies by Gilead, the owner of the remdesivir drug, in order to grant approval to remdesivir to treat COVID-19, to the dismay of objective observers:

As new COVID-19 cases spike in the U.S., and ahead of an expected winter surge, the FDA just issued its first full approval for a drug to treat the disease—Gilead Sciences' Veklury, formerly known as remdesivir. But the approval closely follows a large trial that showed no benefit for the therapy, and experts quickly questioned the FDA's move.²¹

Meanwhile, more than 10 percent of the National Institutes of Health (NIH) Guidelines Panel have disclosed that they have received funding from Gilead, the manufacturer of remdesivir.²² The inexpensive HCQ, in contrast, offers no opportunity for financial reward for anyone, and thus no conflicts of interest.

A common characteristic of studies cited by the FDA and other opponents of HCQ is the late administration of HCQ, after the window has closed for effective treatment of a virus. Use of HCQ to treat patients hospitalized with COVID-19, for example, is typically long after the opportunity for early treatment, and those studies are often meaningless.

The Emergency Use Authorization

Pharmaceutical companies donated up to 100 million doses of HCQ to the federal government for immediate use in treating COVID-19, as part of their efforts for the "prevention and treatment of the coronavirus outbreak."²³ But on Mar 28, 2020, the FDA arbitrarily and sharply limited use of this HCQ by issuing an Emergency Use Authorization ("EUA"). The EUA was in the form of a letter from Denise M. Hinton, FDA chief scientist, to Rick Bright, Ph.D., director of the Biomedical Advanced Research and Development Authority, on the Request for Emergency Use Authorization for Use of Chloroquine Phosphate or Hydroxychloroquine Sulfate Supplied from the Strategic National Stockpile for Treatment

of 2019 Coronavirus Disease (Mar 28, 2020). The irrational restrictions in the EUA on use of HCQ included the following:

The hydroxychloroquine sulfate may only be used to treat adult and adolescent patients who weigh 50 kg or more *hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible* [emphasis added].²⁴

These restrictions arbitrarily denied patients the use of HCQ for its prophylactic effect by first requiring that patients have COVID-19, typically confirmed by a positive test result, which can take days to obtain while treatment is delayed. The FDA's restrictions denied access to HCQ by non-hospitalized patients, including nursing home residents where the virus has been so deadly,²⁵ and prohibited access by hospitalized patients for whom clinical trials are available but they may end up receiving a placebo in the trial. Never before has an EUA been used to restrict access to medication as the FDA has done.

Foreign Countries Defeat COVID-19 with HCQ

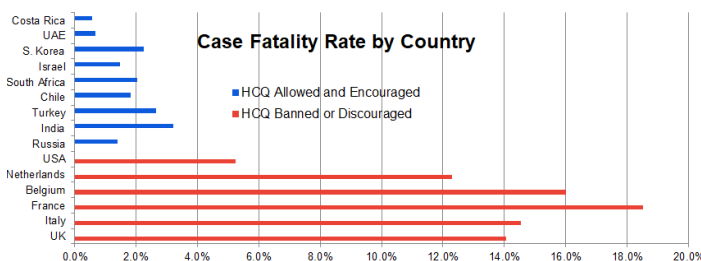
Many foreign governments, including China, India,²⁶ South Korea, Costa Rica, United Arab Emirates, and Turkey, have successfully encouraged use of HCQ for effective early treatment of COVID-19, and for use as a prophylactic for the disease, which has kept mortality from the disease far lower there than in the United States.²⁷ In addition, numerous studies confirm the effectiveness of HCQ as an early treatment of COVID-19.¹⁰

There is a vast and tragic difference in saved lives by countries allowing early and prophylactic use of HCQ compared with the United States, as summarized by Jeremy Snavelly of AAPS as of the third week in June 2020 (see Table 1 and Figure 1).

Table 1. COVID-19 Mortality

Country	HCQ Policy	Mortality rate per COVID-19 case	COVID-19 deaths per 1M population
UK	HCQ is discouraged and mostly unavailable	14%	628
Italy	HCQ's value was not known for the many initial casualties	14.5%	573
France	HCQ is officially disfavored	18.5%	454
U.S.A.	FDA interferes with access to HCQ	5.2%	369
India	HCQ is used prophylactically	3.2%	10
Turkey	HCQ is used as early treatment	2.6%	59
Israel	HCQ is encouraged	1.5%	33
South Korea	HCQ is encouraged	2.3%	5

Source: <https://www.worldometers.info/coronavirus/>



Source: <https://www.worldometers.info/coronavirus/>

Figure 1. HCQ Policy and Case Fatality Rate

In addition, more than 25 articles published since 1982 in peer-reviewed medical journals have reported on the safety of HCQ, and these articles are included in the PubMed database as maintained by the United States National Library of Medicine at the National Institutes of Health.

Injury to AAPS Members

The FDA's wrongful conduct causes injury to AAPS members, which should establish standing by AAPS to sue. Multiple AAPS members have been unable to successfully prescribe a full regimen of HCQ for patients in need of it, due to the FDA's unlawful and irrational restrictions on HCQ. Patients of AAPS physicians have been additionally harmed by being denied access to a full regimen of the potentially lifesaving HCQ. AAPS members have been prevented from successfully prophylactically treating nursing home patients with HCQ by virtue of the FDA's arbitrary restrictions on HCQ.

I represented AAPS in suing the FDA and other federal agencies and officers on Jun 2, 2020, and on Jun 22 we filed a motion for a preliminary injunction to compel the FDA and its co-defendants to stop interfering with access to HCQ and to release its HCQ Stockpile. The district court ruled against our motion on August 14 by granting Defendants' motion to dismiss on the grounds of a lack of legal standing, and indicated that it was inclined to defer to Defendants if standing were found to exist.

AAPS's Appeal

In our appeal we pointed out that legal doctrine is not properly construed in a manner that is disrespectful of life. Like common law principles of private property and trespass, the doctrine of legal standing should not immunize from judicial review agency conduct that contributes to the deaths of hundreds of thousands of innocent Americans. Yet the decision below essentially abdicates all judicial review of the subagency FDA as it impedes access to long-approved, life-saving medication.

A recent tragic news story is illustrative of the need to recognize the primacy of innocent life in the law. On a hot day in Las Vegas, police officers recently discovered a car with an infant locked inside.²⁸ Respectful of property rights, they asked the owner of the car for his permission to smash a window to save the infant. The owner refused consent due to a lack of money to pay for the resultant damage. A delay occurred while deciding what to do. Many law students and practicing attorneys might not immediately recognize how to resolve this conflict between private property rights and the danger to an innocent life. Of course, the officers ultimately broke the window over the objection of the property owner. Tragically, the intervention was too late, and the infant died. Not even the slightest delay is required by law, or consistent with it, when innocent life is at stake.

Likewise, the legal doctrine of standing is not to be construed to immunize a federal agency from judicial review of actions that adversely affect the life or death of many thousands of Americans. For centuries, legal doctrines of private property, trespass, and free speech have not been construed to allow conduct contrary to innocent life.

Nothing good is achieved by giving the FDA free rein for its conduct while hundreds of thousands of Americans

reportedly die from COVID-19. The same arguments presented by the FDA to evade all legal accountability for its conduct could likewise be used to dodge judicial review of an agency's withholding of grain from farmers, or penicillin from patients as was done in the notorious Tuskegee study by the federal government. "The participants ultimately had to resort to the court for compensation and a public admonishment of the study."²⁹ Such non-reviewability opens the floodgates to similar wrongdoing by agencies. It is not a proper exercise of judicial restraint to look away while a federal agency contributes to the deaths of many thousands of innocent Americans.

Anglo-American law requires that government side with innocent life, as expressed in the Declaration of Independence and embodied in centuries of the common law. For example, private property rights were nearly absolute in the common law, but trespass by necessity to preserve life took priority; otherwise, "life itself would be endangered."³⁰ Irrational, anti-life conduct by a federal agency should not evade judicial review, or pass muster when challenged in court.

Defendants accepted donations for use against COVID-19 of more than 60 million doses of HCQ, but Defendants insist on withholding and wasting it rather than releasing it for public benefit as intended by the donors. In addition, Defendants post on their websites demonstrably false and misleading statements to disparage HCQ, extending beyond Defendants' authority and which they cannot justify in court.

Defendant FDA's Actions Have Caused Redressable Injuries

Standing requires "redressability" to remedy an injury. Certitude is not required, but merely a likelihood that a favorable ruling by the court would resolve the injury. Many state regulators and even the FSMB are relying on statements and actions by the FDA in order to impede access to HCQ; it is predictable and likely that state regulators would follow the lead of federal regulators who have greater funding and pretend to be experts on an issue. Within the same ruling the district court both indicated that it would defer to the FDA, and yet found that state regulators would not. It held that state medical boards **could** still decide that such a prescription runs against best practices (as AAPS alleges they have done) and state governments **could** still choose to prohibit assemblies as part of a comprehensive approach towards combating the virus. Yet, the court held, the fact that State regulators "could" act in a manner contrary to federal authorities is not a finding that they "would" or are likely to act so defiantly. Therefore, the district court concluded, "[a]ccordingly, a favorable decision by this Court is unlikely to redress AAPS' complained of injury."³¹ That conclusion by the court did not follow from its analysis.

The district court held that "independent actors making independent decisions have led to the complained of injuries." But those ostensibly "independent" decisions often expressly relied, in fact, on the FDA's falsehoods and interference with access to HCQ for early and prophylactic use against COVID-19.

There are familiar reasons for adopting a narrow view of standing, such as to avoid legislating from the bench, or to ensure that a real "case" or "controversy" is presented in an adversarial manner. But none of the purposes for standing doctrine should immunize the FDA, which insists on being unaccountable. When innocent human life is at stake, shielding agency misconduct is even less justified.

There are two primary purposes of standing doctrine: separation of powers, and the Constitution Article III "case" or "controversy" requirement, neither of which support denial of judicial review in AAPS's lawsuit. The Separation of Powers Doctrine is a reason to deny standing to generalized objections to decisions originally made by Congress. But Congress has not commanded the FDA to waste more than 60 million doses of life-saving medication, nor would Congress ever do that. False statements by agencies to the public, upon which state regulators rely, should be fully reviewable by the judicial branch. This is consistent with, and even required by, Separation of Powers Doctrine, which embodies a check and balance by one branch of government against another.

The "case" or "controversy" rationale for standing doctrine is also fully satisfied by AAPS's lawsuit. FDA actions are in dispute, and there is a real controversy about them in this case. Physicians on the front lines of treating COVID-19 seek to be able to do their job in saving lives without the irrational interference by the FDA. When a federal agency interferes with someone's life-saving professional work, then he has a legitimate "case" or "controversy" to challenge that interference through his professional association, AAPS.

Standing doctrine is not a bulldozer to be ruthlessly driven without consideration of its underlying purposes. No valid purpose is served by an overly narrow view of standing here, or by declaring that the FDA is free of any judicial accountability for causing the loss of innocent life. The checks and balances essential to our form of government should not have a loophole for a subagency to block access to, and waste with impunity, approved life-saving medication, and to make demonstrably false, disparaging comments about it.

No Deference to Defendant FDA Is Appropriate Here

Courts indicate a preference to defer without much scrutiny to FDA's decisions, despite the fact that they undeniably affect life-related issues for millions of Americans.

But no deference is appropriate to an agency that impedes access to approved life-saving medication. Just as the Las Vegas police officers erred in deferring for some time to the owner of a car with a trapped child inside, courts should not defer in any way to irrational conduct by an agency that arguably causes the loss of innocent life.

Multiple reasons for rejecting any deference to the FDA have been presented by AAPS in its lawsuit, ranging from the conflicts of interest by agency workers to their outspoken opposition to the President. Congressional intent is clear, as manifested in its bipartisan Right to Try Act (2018),³² that the FDA should not be interfering with access to potentially life-saving medication. Courts should not defer to such agency misconduct.

The fact that remdesivir was granted full approval based on limited and contradictory data—data far less favorable than the data available for outpatient use of HCQ—demonstrates that the FDA's decision-making has been arbitrary, capricious, and based on factors other than the data. A denial of standing to challenge this agency misconduct allows tyranny by the regulatory state, contrary to the principles of judicial review.

A recent example in the news illustrates the political bias against the President by FDA functionaries. On Aug 28, 2020, the FDA fired a conservative White House appointee as its

chief spokeswoman, after fewer than two weeks on the job. She was reportedly disliked by the FDA staff because she had once written a book supporting gun rights and had also worked for Sen. Ted Cruz (R-Texas), and an unnamed agency official then crudely smeared her in the press by claiming that she could not pronounce a medical term.³³ The FDA has long acted with such arrogance and without any accountability.

Conclusions

AAPS and its members clearly have standing to sue FDA for its unprecedented restriction of their right to prescribe life-saving, long-approved medication.

No deference is warranted to the “Deep State” when it causes loss of innocent human life by blocking access to and disparaging medication, particularly amid demonstrable bias at the agency.

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