Case No. 20-1784

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Association of American Physicians & Surgeons,

Appellant-Plaintiff

v.

Food and Drug Administration, *et al.*,

Appellees-Defendants

From the United States District Court
for the Western District of Michigan, Southern Division
(No. 1:20-cv-00493-RJJ-SJB)

BRIEF OF APPELLANT ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS

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JURISDICTIONAL STATEMENT

This appeal is brought under 28 U.S.C. § 1291 from a final judgment dated August 14, 2020, by the United States District Court, Western District of Michigan. (R. 22, Page ID #834) Plaintiff-Appellant filed a timely Notice of Appeal on the same day. (R. 23, Page ID #835) The district court had jurisdiction over these federal law claims against federal agencies under 28 U.S.C. § 1331.

STATEMENT OF ISSUES

The issues presented are:

1. Whether Defendants can evade judicial review of their arbitrary withholding of an approved life-saving medication, and falsely disparage the medication without any legal accountability to correct their falsehoods.

2. Whether Defendants can impose anti-life policies related to the loss of more than 200,000 lives without any recourse by physicians who work on the front lines.

3. Whether an association of such physicians has standing to object to the foregoing conduct by Defendants.

4. Whether any deference is warranted to Defendants amid their demonstrable conflicts-of-interests and conduct contrary to the positions of the President.

STATEMENT OF THE CASE

In defiance of President Trump and to the detriment of thousands of lives, Defendant Food & Drug Administration ("FDA") has interfered with access to the safe, inexpensive hydroxychloroquine (HCQ) medication for treating COVID-19. Defendants insist on evading judicial review for their conduct, but such review properly exists and it was an error of law for the district court to hold otherwise. Courts should not look the other way amid arbitrary, anti-life conduct by a federal agency. The district court opinion denying standing and indicating its inclination to defer to the federal agency created an unprecedented lack of accountability on a life-or-death issue, which is inconsistent with constitutional checks and balances.

Judicial review would exist if a federal agency withheld grain from farmers, as Josef Stalin did in 1932 in the Soviet Union in causing the deaths of millions of Ukrainians.[1] The issue here is conceptually identical: Defendants withhold from Americans more than 60 million doses of HCQ which were donated for use by the American people against COVID-19.[2] In poorer countries this medication has

[1] One historian estimates that 3.9 million died from the Ukrainian famine or "Holodomor". https://www.history.com/news/ukrainian-famine-stalin (viewed Aug. 17, 2020). That was caused by a government policy and reactions thereto by farmers, and surely a narrow view of legal standing or judicial review should not be an obstacle to challenge an analogous policy that results in many deaths today.

[2] Sheryl Gay Stolberg, "A Mad Scramble to Stock Millions of Malaria Pills, Likely for Nothing," NEW YORK TIMES (June 16, 2020)

successfully kept mortality from COVID-19 far lower, often 90% lower, than the rate in the United States. Despite this, Defendants continue to withhold and even falsely disparaged HCQ, lest President Trump be credited in this presidential election year for its successful use.

Under the district court ruling, the persons most affected by Defendants' actions – physicians and their association – are denied standing, which means no one would have standing to object to Defendants' misconduct here. That is tantamount to an erroneous blanket denial of judicial review for agency conduct affecting millions of Americans. It was an error of law for the district court and the motions panel, which does not bind this merits panel, to deny standing so broadly in a challenge to Defendants' withholding of and false disparaging HCQ.

A. Factual Background

In 1955, Defendant FDA approved HCQ as a safe medication and it has been used successfully for at least 65 years by patients. (Declaration by Jane Orient, M.D., dated June 22, 2020 ("Orient Decl.") ¶ 12, R. 9-1, Page ID # 347) As a long-established "generic" unpatented medication, HCQ costs less than a

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https://www.nytimes.com/2020/06/16/us/politics/trump-hydroxychloroquine-coronavirus.html (viewed Oct. 26, 2020).

dollar a dose and thus has an affordability for every American, contrary to rival medications.[3]

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"). (Orient Decl. ¶¶ 5-7, R. 9-1, PageID # 346)

Off-label use of prescription drugs accounts for a significant percentage of all prescriptions (*id.* ¶ 6), and many off-label uses have become the standard of medical care.[4] 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 approval by the FDA for off-label uses, and such approval is not customarily sought or granted. (Orient Decl. ¶¶ 8-9, 11, R. 9-1, Page ID ## 346-47)

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[3] The State of Ohio reportedly purchased 2,014,400 hydroxychloroquine pills for $602,629, which is a cost of less than 30 cents per dose. Laura Hancock, *Ohio sitting on 4M hydroxychloroquine pills, no longer recommended for coronavirus*, THE PLAIN DEALER (June 19, 2020). In contrast, remdesivir is an intravenous medication which costs thousands of dollars per patient, in addition to the immense cost of a hospital stay to receive it intravenously. https://www.cbsnews.com/news/gilead-coronavirus-treatment-remdesivir-private-insurance-cost/ (viewed Oct. 28, 2020).

[4] David C. Radley; Stan N. Finkelstein; Randall S. Stafford, *Off-label Prescribing Among Office-Based Physicians*, 166 (9) ARCHIVES OF INTERNAL MEDICINE 1021-26 (2006).

Despite this, Defendant FDA has gone beyond its authority by interfering with access to HCQ. Specifically, Defendant FDA has falsely disparaged it and interfered further by withholding and wasting more than 60 million doses of it which it holds in the Strategic National Stockpile ("SNS") ("HCQ Stockpile").[5]

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 Defendants 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 ….[6]

Multiple additional endorsements of HCQ by experts were referenced in the Complaint below (Compl. ¶¶ 4, 46-48, R. 1, Page ID ## 2, 11-12). For example, 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."[7]

See also Orient Decl. ¶¶ 12, 14-17, R. 9-1, Page ID ## 347-48.

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[5] *See supra* n.2.

[6] https://www.myjoyonline.com/news/international/yale-epidemiologist-says-hydroxychloroquine-could-save-up-to-100k-lives-if-used-for-coronavirus/ (viewed Aug. 30, 2020).

[7] https://www.npr.org/sections/health-shots/2020/05/21/859851682/politics-around-hydroxychloroquine-hamper-science (emphasis added, viewed Aug. 30, 2020).

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 121 studies to date is estimated to be [only] 1 in 27 million ($p = 0.000000037$)."[8]

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.

Valerie Richardson, "Hydroxychloroquine 'very safe,' says Dr. Scott Atlas; blasts 'garbage' medical studies" WASHINGTON TIMES (Aug. 29, 2020).[9]

The experts' praise of HCQ is supported by numerous studies, including research on thousands of patients within this Circuit at the Henry Ford Health System in Michigan, where HCQ safely reduced COVID-19 mortality by 50%. Henry Ford Health System, *Treatment with Hydroxychloroquine Cut Death Rate Significantly in COVID-19 Patients, Henry Ford Health System Study Shows* (July 2, 2020).[10] Dozens of additional studies further demonstrate the efficacy of HCQ as preventive

[8] https://hcqmeta.com/ (viewed Oct. 28, 2020).

[9] https://www.washingtontimes.com/news/2020/aug/29/hydroxychloroquine-uproar-shows-objective-science-/ (viewed Aug. 30, 2020).

[10] https://www.henryford.com/news/2020/07/hydro-treatment-study (viewed Aug. 9, 2020).

or early treatment for the disease.[11] Dr. Raja Bhattacharya, MD, *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 SARSCoV-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.

Raja Bhattacharya, MD, et al., Pre exposure Hydroxychloroquine use is associated with reduced COVID19 risk in healthcare workers, MEDRXIV at 1 (June 12, 2020).[12]

The President of El Salvador, Nayib Bukele, announced that he is taking hydroxychloroquine 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. *See* Tatiana Arias, *Salvadoran leader says he takes hydroxychloroquine*, CNN (May 27, 2020).[13] President Trump did not contract COVID-19 until October when the prophylactic effect would have worn off.

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[11] https://c19study.com/ (a scientific collection of 150 studies clearly showing the effectiveness of HCQ as a preventive and early treatment for COVID-19, viewed Oct. 26, 2020).

[12] https://www.medrxiv.org/content/10.1101/2020.06.09.20116806v1.full.pdf (viewed Oct. 28, 2020).

[13] https://www.cnn.com/2020/05/27/americas/salvador-president-coronavirus-hydroxychloroquine-intl/index.html (viewed Oct. 26, 2020).

On May 31, 2020, the United States and Brazil issued a joint statement regarding health cooperation, which is posted on the White House's website and provides in part the following:

> The American and Brazilian people stand in solidarity in the fight against the coronavirus. Today, as a demonstration of that solidarity, we are announcing the United States Government has delivered two million doses of hydroxychloroquine (HCQ) to the people of Brazil. ...
>
> HCQ will be used 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.

Joint Statement From the United States of America and the Federative Republic of Brazil Regarding Health Cooperation (May 31, 2020).[14] Subsequently the President of Brazil, Jair Bolsonaro, took HCQ as early treatment when he contracted COVID-19, and credits his rapid, full recovery to the inexpensive medication.[15]

Despite this proven track record of success for HCQ, Defendants have 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

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[14] https://www.whitehouse.gov/briefings-statements/joint-statement-united-states-america-federative-republic-brazil-regarding-health-cooperation/ (viewed Oct. 26, 2020).

[15] Andrea Morris, "Brazil's President Bolsonaro Credits Hydroxychloroquine with Helping Him Beat His COVID-19 Infection," *CBN News* (July 29, 2020) https://www1.cbn.com/cbnnews/world/2020/july/brazils-president-bolsonaro-credits-hydroxychloroquine-with-helping-him-beat-his-covid-19-infection (viewed Oct. 21, 2020).

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, Defendants have control over the HCQ Stockpile containing more than 60 million doses of HCQ, to which they have withheld and arbitrarily restricted access while it wastes away. [16]

As to the wrongful disparagement, Defendant FDA falsely posts on its website that HCQ is not efficacious against COVID-19 generally. *See* Frequently Asked Questions on the Revocation of the Emergency Use Authorization for Hydroxychloroquine Sulfate and Chloroquine Phosphate, at 2 (June 16, 2020) (R. 9-7, Page ID # 484) ("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."). 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.") (ASPR's Portfolio of Investigational Medical Countermeasures being used to treat COVID-19, R. 9-8, Page ID # 487). Defendants lack any credible support for their disparaging statements against HCQ's efficacy, particularly for prophylactic and early-treatment uses. (Orient Decl. ¶¶ 15-20, R. 9-1, Page ID ## 347-48)

[16] Medication deteriorates over time, just as food does, which Defendants cannot dispute. (Declaration by Jane Orient, M.D. ¶ 31, R. 9-1, Page ID # 350) The HCQ Stockpile will be discarded if not timely distributed.

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 oseltamivir (Tamiflu®) is recommended 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.[17]

The FDA's above-quoted "can only be used" is also false. HCQ as been approved as safe for 65 years, and Defendants lack the authority to limit off-label prescriptions by posting such a false statement on their website. (Orient Decl. ¶¶ 5-7, R. 9-1, Page ID # 346)

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 Food and Drug Administration (FDA) has announced the removal of Emergency Use Authorizations (EUA) for chloroquine (CQ) and hydroxychloroquine (HCQ) to treat COVID-19. The announcement follows the FDA's determination that CQ and HCQ are unlikely effective treatments for COVID-19. In addition, the FDA further indicated the potential benefit does not outweigh the potential serious cardiovascular events and other adverse effects that can be caused by CQ and HCQ.
>
> Based on this information, the Arkansas Department of Health has updated its guidance related to hydroxychloroquine and chloroquine.

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[17] https://www.webmd.com/drugs/2/drug-17765-5294/tamiflu-oral/oseltamivir-oral/details (emphasis added, viewed June 22, 2020); *accord* Orient Decl. ¶¶ 16, 25, 26, R. 9-1, Page ID ## 347, 349 (antivirals must be taken early in a disease progression to be most effective).

> The utilization of CQ and HCQ for treatment of COVID-19 should be avoided in both outpatient and hospitalized settings. HCQ that has been distributed through the Strategic National Stockpile is no longer authorized under the EUA to treat hospitalized patients for COVID-19, unless they had already started treatments.

Arkansas Dep't of Health, COVID-19 Guidance About Chloroquine (undated);[18] *see also* Oregon Board of Pharmacy, Temporary Administrative Order Including Statement of Need & Justification, at 1 (June 15, 2020) (limiting, at that time, HCQ prescriptions to clinical studies, based on Defendant FDA's actions) (R. 9-10, Page ID # 493).

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 Defendant 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*.

[18] https://www.healthy.arkansas.gov/programs-services/topics/covid-19-guidance-about-chloroquine (R. 9-9, Page ID # 490)

Joint Statement of FSMB, NABP, NCSBN on Inappropriate Prescribing and Dispensing of Medications During the COVID-19 Pandemic (R. 9-11, Page ID # 496).

Background about the Parties.

Plaintiff Association of American Physicians & Surgeons ("AAPS") is a non-profit association of physicians founded in 1943, whose motto is "omnia pro aegroto" (meaning "all for the patient"). (Complaint ¶ 11, R. 1, Page ID #3; Declaration by Jeremy Snavely dated June 22, 2020 ("Snavely Decl.") ¶ 3, R. 9-2, Page ID # 355) Over its 77-year history, AAPS has brought several precedent-setting lawsuits, including *AAPS v. Hillary Clinton*, 997 F.2d 898 (D.C. Cir. 1993), and *AAPS v. Weinberger*, 395 F. Supp. 125 (N.D. Ill.), *aff'd sub nom., AAPS v. Mathews*, 423 U.S. 975 (1975), and amicus briefs by AAPS have been cited by Supreme Court Justices and multiple U.S. Courts of Appeals. *See, e.g.*, *Stenberg v. Carhart*, 530 U.S. 914, 933 (2000); *id.* at 959, 963 (Kennedy, J., dissenting); *District of Columbia v. Heller*, 554 U.S. 570, 704 (2008) (Breyer, J., dissenting); *Texas v. United States*, 945 F.3d 355, 369 (5th Cir. 2019); *Springer v. Henry*, 435 F.3d 268, 271 (3d Cir. 2006).

Defendant FDA is a subagency, also called a constituent agency, which lacks a Cabinet-level Secretary. Instead, the director of the FDA holds the title of "Commissioner", who lacks express deference in applicable statutes. Other agency

Defendants are the Department of Health & Human Services ("HHS") and the Biomedical Advanced Research & Development Authority ("BARDA"). Like the FDA, BARDA is also a constituent agency within HHS. The individual defendants, who are being sued in their official capacity only, are Dr. Stephen M. Hahn, Commissioner of Food & Drugs, Gary L. Disbrow, Ph.D., Acting Director, Biomedical Advanced Research & Development Authority, in his official capacity; and Alex Azar, Secretary of Health & Human Services.

The Defendant agencies have conflicts of interest, and have employed officials who have been publicly defiant of the President. For example, Rick Bright, Ph.D., was the Director at Defendant BARDA as appointed by President Barack Obama, and Bright has been publicly critical of President Trump. Bright has at all relevant times unjustifiably opposed making HCQ widely available for physicians to prescribe to patients in connection with COVID-19. Nicholas Florko, *Why was an obscure federal bureaucrat involved in Trump's emergency hydroxychloroquine authorization?*, STAT (Apr. 24, 2020).[19]

Bright and his allies at Defendant FDA have favored remdesivir, despite how a large study conducted by the World Health Organization concluded is mostly ineffective against COVID-19. Addendum to the Complaint of Prohibited Personnel Practice and Other Prohibited Activity by the Department of Health and

[19] https://www.statnews.com/2020/04/24/why-rick-bright-involved-hydroxychloroquine/ (viewed Oct. 26, 2020).

Human Services Submitted by Dr. Rick Bright, at 22-23 (2020) (R. 9-5, Page ID ## 431-32).[20]

Plagued with conflicts of interest and no accountability, Defendant 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.

Eric Sagonowsky, "Gilead scored a full FDA approval for COVID-19 drug Veklury, but experts aren't convinced," FIERCE Pharma (Oct. 23, 2020).[21] Meanwhile, more than 10% 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.

According to a whistleblower complaint against the Trump Administration submitted by Bright, the FDA Director of the Center for Drug Evaluation and

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20 *See* Compl. ¶ 59 & n.17 (Page ID # 14).

21 https://www.fiercepharma.com/pharma/gilead-scores-full-fda-approval-for-covid-19-drug-veklury-as-cases-spike-again (viewed 10/24/20).

22 https://www.covid19treatmentguidelines.nih.gov/panel-financial-disclosure/ (viewed Oct. 28, 2020).

Research Janet Woodcock also played a pivotal role in pushing for restrictions on HCQ access. (Bright's Whistleblower Complaint Addendum at 43, R. 9-5, Page ID # 452) Woodcock occupied a top position in a public-private operation designed to approve new vaccines for COVID-19. *See* Natalie Grover, *Covid-19 roundup: Hit with new conflict accusations, Janet Woodcock steps out of the agency's Covid-19 chain of command*, ENDPOINT NEWS (May 20, 2020).[23] Prophylactic use of HCQ is a rival approach to vaccination, but Woodcock did not recuse herself from the decision-making at the FDA concerning the restrictions on access to HCQ. After an advocacy group objected to a conflict of interest by Woodcock in her various roles, she recused herself from the review process for vaccination but remains non-recused from decision-making that sharply and unjustifiably limits access to HCQ. *Id.* Woodcock is on the editorial board of the *New England Journal of Medicine*,[24] which broke with its 208-year history by publishing an editorial urging the public to vote against reelecting President Trump.[25]

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[23] https://endpts.com/covid-19-roundup-hit-with-new-conflict-accusations-janet-woodcock-steps-out-of-the-agencys-covid-19-chain-of-command/ (viewed June __, 2020).

[24] https://www.nejm.org/about-nejm/editors-and-publishers (viewed Oct. 21, 2020).

[25] https://www.npr.org/sections/coronavirus-live-updates/2020/10/08/921609669/in-rare-step-esteemed-medical-journal-urges-americans-to-vote-trump-out-of-offic (viewed Oct. 15, 2020).

The Emergency Use Authorization.

Pharmaceutical companies donated up to 100 million doses of HCQ – enough to fully treat more than 15 million people – 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." PhRMA, Member Company Efforts to Combat Coronavirus Outbreak.[26] Then, at the improper insistence of Bright before he was relieved of his HCQ-related duties by the Trump Administration, on March 28, 2020 the FDA arbitrarily and sharply limited use of this HCQ by issuing an Emergency Use Authorization ("EUA"). The form of this EUA was as a Letter from Denise M. Hinton, Chief Scientist, Food & Drug Admin., to Rick Bright, Ph.D., Director, Biomedical Advanced Research & Development Authority, 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 were as follows:

> 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*.

EUA, at 4 (emphasis added) (R. 9-6, Page ID # 477).

[26] https://phrma.org/en/Coronavirus/PhRMA-Member-Efforts (viewed Oct. 28, 2020).

These restrictions arbitrarily denied patients the use of HCQ for its prophylactic effect (*i.e.*, the "with COVID-19" limit requires that the patient *have* COVID-19, usually requiring a positive test result which can take time-critical days to obtain). These restrictions also denied access to HCQ by non-hospitalized patients (such as nursing home residents and patients who visit physicians' offices), and even prohibited access by hospitalized patients for whom clinical trials are available. These restrictions prevented nursing home residents from receiving HCQ, where more than half of the COVID-19 mortalities have reportedly occurred. Jessica Glenza, *Covid-19: nursing homes account for 'staggering' share of US deaths, data show*, THE GUARDIAN (May 11, 2020).[27] Never before has an EUA been used to restrict access to medication as Defendants have done.

COVID-19 Casualties

In the absence of access to HCQ for prophylactic and early treatment for COVID-19, more than 200,000 Americans have reportedly died from the disease this year.[28] Yet multiple foreign governments, including China, India,[29] South

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[27] https://www.theguardian.com/us-news/2020/may/11/nursing-homes-us-data-coronavirus (viewed Oct. 28, 2020).

[28] https://www.worldometers.info/coronavirus/country/us (viewed Oct. 25, 2020).

[29] Himani Chandna, *HCQ breakthrough: ICMR finds it's effective in preventing coronavirus, expands its use*, THE PRINT (May 22, 2020) (available at https://theprint.in/health/hcq-breakthro...se/427583/) (viewed Oct. 28, 2020).

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.[30] In addition, numerous studies confirm the effectiveness of HCQ as an early treatment of COVID-19.[31]

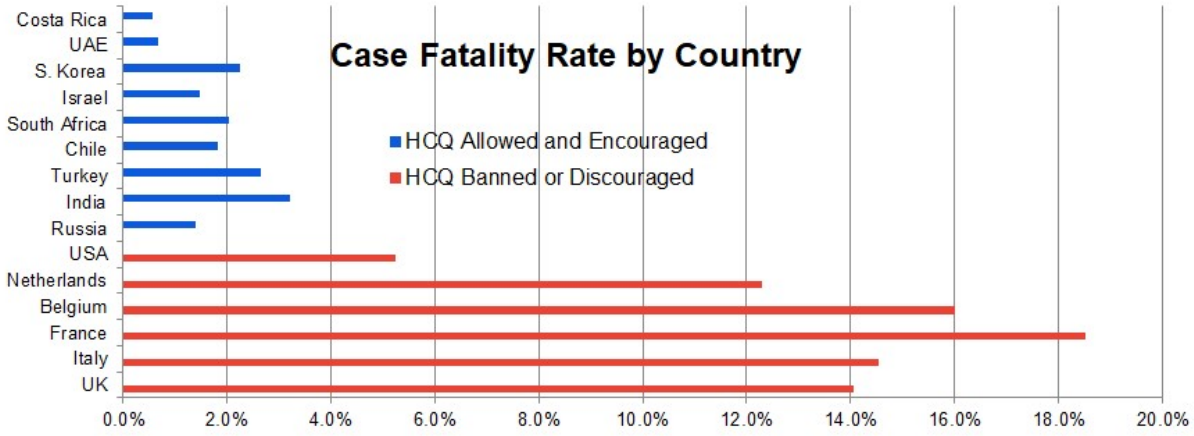
There is a stark and tragic difference in saved lives by countries allowing early and prophylactic use of HCQ compared with the United States, which was already observable as of the third week in May 2020:

Country	HCQ Policy	Mortality rate per COVID-19 case	COVID-19 deaths per 1M population
U.K.	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
Russia	HCQ is encouraged	1.4%	56
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

[30] *See* the worldometers website, cited *supra* n.28.

[31] https://c19study.com/, cited *supra* n.11.

(Snavely Decl. ¶ 28, R. 9-2, Page ID # 359) The following chart graphically shows HCQ's beneficial impact in reducing mortality from COVID-19:



(*Id.* ¶ 29)

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. (*Id.* ¶ 30)

Injury to Plaintiff

Defendant FDA's wrongful conduct has caused injury to a physician member of Plaintiff AAPS ("Dr. John Doe"). (Snavely Decl. ¶ 7, R. 9-2, Page ID # 355) Physician Dr. John Doe has 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. *Id.* Patients of Dr. John Doe have been additionally harmed by being denied access to a full regimen of the potentially lifesaving HCQ. (*Id.* ¶ 9, R. 9-2, Page ID # 356) Dr. John Doe practices within the Western District of

Michigan, where this lawsuit was filed. (*Id.* ¶ 7, R. 9-2, Page ID # 355). Another physician member of AAPS was prevented from successfully prophylactically treating his nursing home patients with HCQ by virtue of Defendants' arbitrary restrictions on HCQ. (*Id.* ¶ 10, R. 9-2, Page ID # 356)

Moreover, numerous physician members of AAPS, including Dr. John Doe, reasonably fear retaliation against them by state medical boards based on Defendants' irrational restrictions on and false disparagement of HCQ. (*Id.* ¶ 8, R. 9-2, Page ID #355)

Disparate Impact of Defendants' Conduct on Gatherings.

Access to affordable prophylactic and early treatment of COVID-19 is particularly important to reopening religious services without a chilling effect which denial of timely access to treatment causes. (Orient Decl. ¶ 21, R. 9-1, PageID # 348) About a quarter (25%) of weekly attendees of all kinds of religious services are over 65 years old, Pew Research Center, *Attendance at religious services*,[32] who are thereby at higher risk from COVID-19 than other demographic groups, such as young and healthy adults.

The AAPS annual meeting, scheduled for September 30 through October 3, 2020, was adversely impacted (and ultimately canceled) due to the inability of members and potential attendees to have access to prophylactic and early treatment

[32] https://www.pewforum.org/religious-landscape-study/attendance-at-religious-services/ (viewed Oct. 26, 2020).

of COVID-19. (Snavely Decl. ¶¶ 24-27, R. 9-2, PageID ##358-59) Restricting and denying access to prophylactic and early treatment by HCQ has a negative effect on attendance at gatherings, in which AAPS members and their patients have a constitutional right to participate.

Statutory and Regulatory Background

Congress enacted the Pure Food and Drugs Act, ch. 3915, 34 Stat. 768 (1906), under its Commerce Power. In 1938, Congress amended and replaced that Act with the Federal Food, Drug and Cosmetic Act ("FFDCA"). PUB. L. NO. 75-717, 52 Stat. 1040 (1938) (codified, as amended, at 21 U.S.C. §§ 301-399i). In enacting the FFDCA, Congress was clear that the FFDCA ***does not*** define the practice of medicine. *See* S. REP. NO. 74-361, at 3 (1935) (FFDCA is "not intended as a medical practices act and [would] not interfere with the practice of the healing art[s]"). Defendant FDA has expressly recognized the freedom that physicians have 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." 59 Fed. Reg. 59,820, 59,821-22 (Nov. 18, 1994) (internal quotation marks omitted, alterations in original).

Section 4(a) of the Project Bioshield Act of 2004, PUB. L. NO. 108-276, §4(a), 118 Stat. 835, 853-859, added Section 564 to the FFDCA, codified as 21

U.S.C. § 360bbb-3. Under that section, the Secretary of HHS can authorize the emergency use of either or both unapproved medical products and/or unapproved uses of approved medical products, 21 U.S.C. § 360bbb-3(a)(1)-(4), upon recognizing or declaring an emergency under the criteria outlined in 21 U.S.C. § 360bbb-3(b)(1)(A)-(D). In such an emergency, the statutory criteria for granting an emergency use application are that the Secretary of HHS concludes the following:

> (1) that an agent referred to in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;
>
> (2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that–
>
> (A) the product may be effective in diagnosing, treating, or preventing–
>
> (i) such disease or condition; or
>
> (ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this chapter, or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262], for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and
>
> (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable;

> (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition;
>
> (4) in the case of a determination described in subsection (b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and
>
> (5) that such other criteria as the Secretary may by regulation prescribe are satisfied.

21 U.S.C. § 360bbb-3(c)(1)-(5). Neither FDA nor HHS nor any other federal agency has promulgated a regulation pursuant to 21 U.S.C. § 360bbb-3(c)(5) to establish criteria that Defendants may consider in granting or revoking an EUA under 21 U.S.C. § 360bbb-3(c).

The judicial review provisions of the Administrative Procedure Act ("APA") proscribe agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The APA further bars agency action that is "in excess of statutory jurisdiction, authority, or limitations," *id.* at § 706(2)(C), and commands courts to "hold unlawful and set aside agency action, findings, and conclusions found to be … contrary to constitutional right, power, privilege or immunity." 5 U.S.C. § 706(2)(B).

B. Relevant Procedural History

AAPS filed this lawsuit on June 2, 2020 (Complaint, R. 1, Page ID #1), and on June 22 AAPS filed a motion for a preliminary injunction to compel Defendants to stop interfering with access to HCQ and to release its HCQ Stockpile. (Motion

for PI, R. 8, Page ID # 66) Defendants opposed AAPS's motion and moved to dismiss on July 10. (Motion to Dismiss and Combined Memorandum, R. 10-11, Page ID ## 502, 550) The district court ruled against AAPS on August 14 by granting Defendants' motion to dismiss on standing grounds, without reaching the merits of AAPS's claims. (Opinion, R. 21, Page ID # 813) The district court indicated that it was inclined to defer to Defendants if standing were found to exist. (Opinion 10 n.6, R. 21, Page ID # 822)

AAPS immediately filed a Notice of Appeal (R. 23, Page ID # 835), and six days later filed in this Court its Emergency Motion for Injunctive Relief (Docs. 7, 8), which was denied by a motions panel on standing grounds on September 24. (Doc. 18-2)

C. Rulings Presented for Review

The district court ruled against AAPS on standing grounds, under FED. R. CIV. P. 12(b)(1). (Opinion at 9-20, R. 21, Page ID ## 821-32) The court did not hold that other persons or groups have stronger standing than AAPS to bring this action, but rather that essentially no one has standing to challenge the Defendant FDA on this issue due to a lack of traceability and redressability. (Opinion at 11-13, 18, R. 21, Page ID ## 823-25, 830) The district court also found a lack of injury to any member of AAPS. (Opinion 16-18, R.21, Page ID ## 828-30) The

district court further indicated that it would have deferred to the Defendant FDA even if standing did exist. (Opinion 10 n.6, R. 21, Page ID # 822)

A motions panel of this Court subsequently denied the Emergency Motion for Injunctive Relief by AAPS, which sought release of the HCQ Stockpile. (Doc. 18-2) (The false disparagement by the FDA of HCQ was not an issue presented or decided by the motions panel.) Like the district court, the motions panel declined to reach the substance of the claims against Defendants, and did not substantively review any of Defendants' conduct. Instead, the panel denied the motion after holding that there is a lack of standing by AAPS, and also indicated its view that Defendants' withholding of the HCQ Stockpile is "exempt" from any judicial review. (*Id.* at 6)

Without addressing the pivotal distinction between supply, which may be plentiful, and access, which may be sharply limited, the motions panel held that "AAPS members' alleged difficulty in accessing HCQ ***cannot be due*** to scarcity caused by the stockpile; as AAPS itself asserted, HCQ is in plentiful supply, and easy to make." (*Id.* at 4, emphasis added) The motions panel then added that even if Defendants' withholding of more than 60 million doses of HCQ "was having a significant effect on commercial access to the drug, an injunction would not solve the problem because state medical boards—not Defendants—control how physicians can prescribe or use drugs." (*Id.*) Without reference to the record,

which contained multiple examples of state medical boards expressly relying on Defendants' policy against HCQ, the motions panel held that "AAPS fails to show that state medical boards are likely to change the way they regulate HCQ because of an injunction forcing Defendants to release doses from the stockpile." (*Id.*) The motions panel then characterized the Defendants' blocking of access to HCQ as "their better judgement." (*Id.*)

While Defendants waste the HCQ Stockpile such that its more than 60 million doses go stale and expire, the motions panel held that "intervening to force Defendants to distribute HCQ would substantially injure Defendants' ability to manage the national strategic stockpile." (*Id.* at 6) The motions panel further doubted that there was irreparable harm that is traceable to Defendants' conduct. (*Id.*) The motions panel did not cite any of the evidence submitted by AAPS, or any of the publicly available data and studies showing how the inexpensive HCQ has helped overcome COVID-19, particularly in foreign countries outside the jurisdiction of Defendants.

SUMMARY OF ARGUMENT

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 conduct by an agency which 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.

No valid purpose or precedent exists for failing to substantively review Defendants' conduct. Nothing good is advanced by giving Defendants a pass on their conduct while hundreds of thousands of Americans reportedly die from COVID-19. The same arguments presented by Defendants here to evade all legal accountability for their 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.[33] 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.

There should be broad standing to object to the withholding of the HCQ Stockpile by Defendants, and to their false disparagement of the medication. Such irrational and potentially wanton conduct, primarily by Defendant FDA which is entitled to no statutory deference here, is not exempt from judicial review. This Court should reverse the district court on standing and then order release of the HCQ Stockpile in a manner that enables physicians to have their prescriptions

[33] "The participants ultimately had to resort to the court for compensation and a public admonishment of the study." Barbara L. Bernier, "Class, Race, and Poverty: Medical Technologies and Socio-Political Choices," 11 HARV. BLACKLETTER J. 115, 125 (1994).

filled for their patients exposed to COVID-19. This Court should also order Defendant FDA to correct its misrepresentations.

ARGUMENT

When unchecked by another branch of government, the entrenched administrative state sometimes engages in anti-life conduct, as in the long-running, widely criticized Tuskegee study. Federal agencies are not churches or synagogues. When agency workers are hostile to the President during an election year and also have conflicts of interest, then there is no basis for presuming that the agency will put the preservation of life first in making decisions that affect the entire country.

But Anglo-American law requires that government sides with innocent life, as expressed in the Declaration of Independence and embodied in centuries of the common law.[34] 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,

[34] For example, private property rights were nearly absolute in the common law, but trespass by necessity to preserve life took priority. *See, e.g.*, *Campbell v. Race*, 61 Mass. 408, 410, 411 (1851) (recognizing this "well settled" rule in the common law, or else "life itself would be endangered").

Defendants post on their websites demonstrably false and misleading statements to disparage HCQ, extending beyond Defendants' authority and which they cannot justify substantively in court. These are not complex or non-justiciable issues, and straightforward adjudication of them on the merits is warranted.

Neither the district court nor the motions panel of this court have held in favor of Defendants' conduct. Instead, both cut off substantive review of Defendants' conduct by holding that AAPS somehow lacked standing, despite how AAPS is a 77-year-old association including as members physicians on the front lines of treating patients for COVID-19. Neither the district court nor the motions panel indicated who they felt would have standing to challenge the wrongful conduct by Defendants, or why a denial of standing here would be consistent with the underlying purposes of standing doctrine. The motions panel does not bind the merits panel.

Simply put, this is a pro-life case of a different color, which requires judicial review and legal accountability for agency conduct that has been wrongly contributing to the ongoing deaths of many thousands of innocent Americans.[35]

[35] The term "pro-life" broadly includes issues related to the preservation of innocent life, including euthanasia at nursing homes and the withholding of lifesaving treatment or medication. The roots of this principle extend as far back as the Magna Carta, which has often been cited in pro-life briefs. *See, e.g.*, Mary Ziegler, "The Conservative Magna Carta," 94 NORTH CAROLINA L. REV. 1653, 1653 (2016) ("For much of American history, Magna Carta has enjoyed almost as much popularity as the Constitution. Starting in the 1980s, socially conservative

I. Standard of Review.

The review by this Court is *de novo* here. "We review *de novo* the district court's decision to dismiss this case for lack of subject matter jurisdiction under Rule 12(b)(1)." *Cartwright v. Garner*, 751 F.3d 752, 760 (6th Cir. 2014). *See Tackett v. M&G Polymers, USA, LLC*, 561 F.3d 478, 481 (6th Cir. 2009).

II. Standing Doctrine Does Not Insulate Anti-Life Actions by an Agency from Judicial Review.

It is settled law that AAPS, as an association of physicians, has standing to challenge conduct by medical boards which arguably interfere with the practice of medicine. *See AAPS v. Texas Medical Board (TMB)*, 627 F.3d 547 (5th Cir. 2010). Having a member physician within the district below who is harmed by Defendants' actions (Snavely Decl. ¶¶ 6-9, R. 9-2, Page ID ## 355-56), AAPS has standing to challenge wrongful conduct by a federal agency which interferes with physicians' care of COVID-19 patients. Access to HCQ in the United States requires a prescription by a physician, and thus physicians have the strongest standing to challenge interference with access to this medication.

Although couched in standing doctrine, the district court and merits panel essentially precluded any and all judicial review of Defendants' conduct in wasting

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movements have increasingly made Magna Carta the centerpiece of their constitutional discourse.") (footnotes omitted). https://scholarship.law.unc.edu/cgi/viewcontent.cgi?article=4873&context=nclr (viewed Oct. 22, 2020).

life-saving medication and in making false statements about it. If standing is precluded for an association of physicians who prescribe HCQ to challenge the interference by Defendants with access to the medication, then standing is denied to everyone to challenge the wrongdoing by the agency. In essence, the district court grants Defendants carte blanche free of any legal accountability for their conduct. Not even the President enjoys such unfettered authority, and the President is further subject to political accountability which Defendants lack.

Concurring with the district court's denial of substantive review, the motions panel even added that Defendants are exempt from judicial review with respect to the HCQ Stockpile. Defendants could dump the entire stockpile into the Potomac River, or simply store it in a hot warehouse until the medication loses its efficacy entirely, without any check or balance on their misconduct, under that decision by the motions panel. The implications of the ruling illustrate its deficiency.

These holdings against judicial review of agency misconduct are reversible errors, particularly when many innocent lives are snuffed out on an ongoing basis due in part to unjustified agency conduct. Checks and balances against Defendant FDA should exist, as they do on virtually every other issue. Defendant FDA does not properly have carte blanche to cause the ongoing deaths of hundreds of thousands of people without being accountable in court. Someone has standing to object to agency conduct which contributes to the deaths of hundreds of thousands

of innocent lives, and AAPS physicians on the front lines in treating COVID-19 have as much standing as anyone. These AAPS members suffer interference in their practices due to Defendants and this easily suffices for standing purposes, particularly when hundreds of thousands of innocent lives are at stake.

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 a child locked inside.[36] Respectful of property rights, they asked the owner of the car for his permission to smash a window to save the child. 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 child died. Not even the slightest delay was required by law, or consistent with it.

Likewise, the 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. While precedents on standing can often be found on both sides, what was missing from the decisions by the district court and

[36] https://www.nydailynews.com/news/crime/ny-daughter-dies-20201007-m7q2kuqshbde5gn5r3vgt4pkta-story.html (viewed Oct. 26, 2020).

motions panel is recognition of the need for checks and balances on anti-life conduct by a federal agency. For centuries, legal doctrines of private property, trespass, and free speech have not been construed to allow or conduct contrary to innocent life.

Standing doctrine does not eliminate judicial review of an agency which blocks life-saving medication from millions of people, and which makes false and misleading disparagement of the medication to interfere with life-saving work by a plaintiff's members. None of the purposes of standing doctrine exists in this case to preclude review, nor were any such purposes cited by the district below or the motions panel. This case is a far cry from cases which have been dismissed for lack of standing, such as lawsuits by taxpayers. Linda Simard, "Standing Alone: Do We Still Need the Political Question Doctrine?," 100 DICK. L. REV. 303, 310-20 (1996) (hereinafter, "*Simard, Standing Alone*").

A prescription is needed to obtain HCQ, and thus Americans necessarily rely on physicians to write them prescriptions for this medication in order to obtain it. Physicians are thereby intrinsically at the forefront of this issue. Withholding and disparaging the medication interferes with the ability of physicians to do their job in treating COVID-19. One physician alone could sue or, with even stronger standing, an association of such physicians could sue. That is what Plaintiff AAPS has done here.

Simply put, there is nothing conservative about narrowing standing in order to avoid judicial review of anti-life actions by federal agencies. Denying standing here is tantamount to making the subagency Defendant FDA above the law, unaccountable for its actions which can contribute to the death of hundreds of thousands of Americans. The motions panel avoided reference to AAPS's argument about the withholding of grain from Ukrainian farmers in 1932, which AAPS pointed out caused millions of deaths and yet could evade judicial review under the same narrow approach to standing adopted here. AAPS members are akin to the farmers, and the HCQ Stockpile is akin to the grain. Judicial review is essential to scrutinize such a potentially deadly withholding of a medication that is promotive of life.

A. All the Elements of Standing Exist Here.

Membership entities like AAPS can assert their own standing (*i.e.*, injury to the entity) in addition to associational and third-party standing. *Harkless v. Brunner*, 545 F.3d 445, 458-59 (6th Cir. 2008). As a corporation, AAPS of course also has rights under the First Amendment. *Mich. State AFL-CIO v. Schuette*, 847 F.3d 800, 805 (6th Cir. 2017).

Plaintiff AAPS has associational standing because its members have standing, the issues raised here are germane to AAPS's mission, and nothing requires individual members' participation as plaintiffs. (Snavely Decl. ¶¶ 3, 31,

R. 9-2, PageID ## 355, 361) AAPS additionally has third-party standing on behalf of physicians. AAPS further has standing as an entity because it has been harmed by Defendants' interference with early treatment for COVID-19. (Compl. at 23 ¶ 116, R. 1, Page ID # 23) AAPS has a member within the district below who has suffered interference in his practice of medicine due to Defendants' actions. (Snavely Decl. ¶¶ 6-9, R. 9-2, Page ID ## 355-56)

1. AAPS Has Associational Standing.

An entity has associational standing to assert claims on behalf of its members. *Hunt v. Washington Apple Advertising Comm'n,* 432 U.S. 333, 343 (1977). Here, AAPS's members have standing and nothing requires their individual participation. *Int'l Union v. Brock*, 477 U.S. 274, 284, 287 (1986) (purely legal actions for injunctive and declaratory relief do not require the participation of individual members.). In addition, protecting the rights of physicians and patients is germane to AAPS's mission. (Snavely Decl. ¶ 3, R. 9-2, PageID #355).

The U.S. Court of Appeals for the Fifth Circuit fully established associational standing by AAPS in an analogous case brought by it against the Texas Medical Board. *AAPS v. TMB*, 627 F.3d 547 (5th Cir. 2010). There the Fifth Circuit walked through the elements of associational standing based on actions by a state medical board against members of AAPS and held that AAPS

has associational standing to sue the medical board for its conduct. *Id.* at 550-53. The situation is conceptually similar here, where AAPS sues Defendants for interfering with the practice of medicine by its members, namely their ability to treat their patients with a full regimen of HCQ for COVID-19. Defendants' false statements about HCQ and withholding of the HCQ Stockpile have misled state authorities to impede the ability of physicians to prescribe HCQ, or face disciplinary retaliation if they do. The sort of discipline faced by physician members of AAPS on this issue is analogous to the discipline they faced when they had standing to sue the Texas Medical Board, as held by the Fifth Circuit in the above-cited case.

The district court erred in rejecting associational standing, by finding that this case is "nothing like" the *Texas Medical Board* case. (Opinion 18, R. 21, Page ID # 830) But there, as here, the issue was the possibility of retaliation and interference with physicians as they provided care to patients. Due to Defendants' conduct, state regulators are relying on Defendants' statements to deter and restrict the practice of life-saving medicine for COVID-19 patients. Defendants brag about their expertise and influence on the one hand, but then in court suddenly Defendants are somehow without influence over state regulators. In fact, of course, Defendants' influence is intentionally enormous over the state regulators, and has caused the impediments to access to HCQ to the injury of AAPS members.

2. Defendant FDA's Actions Have Caused Redressable Injuries.

The district court erred in finding a lack of redressability both for AAPS and its members. (Opinion 13, R. 21, Page ID # 825) The necessary element of redressability does not require certitude that a court ruling will remedy an injury, but merely a likelihood of such an effect. The district recognized the proper standard, but did not apply it. *See Friends of the Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 181 (2000) (noting the standard for redressability is whether "it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision") (quoted by Opinion 13, R. 21, Page ID # 825).

As set forth in AAPS's Complaint and as cited in multiple public documents, many state regulators and even the Federation of State Medical Boards are relying on statements and actions by Defendant FDA in order to impede access to HCQ. It is predicable and likely that state regulators would follow the lead of federal regulators who have greater funding and pretend to be experts on an issue, as Defendants do. Indeed, in this lawsuit Defendants have demanded and received deference by the court. In the same ruling the district court both indicated that it would defer to Defendants, 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 here) and state governments ***could***

still choose to prohibit assemblies as part of a comprehensive approach towards combating the virus" even if Defendants lost here. (*Id.*, emphasis added) State regulators "could" act in a manner contrary to federal authorities, but that is not a finding that they "would" or are likely to act so defiantly. Yet the district court concluded, "[a]ccordingly, a favorable decision by this Court is unlikely to redress AAPS' complained of injury." (*Id.*) That conclusion by the court below was a non sequitur to what the court wrote before it.

False, disparaging statements by Defendants against HCQ constitute substantial motivating factors for states to block access to HCQ. This Court could redress Plaintiff AAPS's injuries by compelling a withdrawal of those statements. *See Tozzi v. HHS,* 271 F.3d 301, 310 (D.C. Cir. 2002).

3. The Injuries Are Traceable to Defendants' Conduct.

The district court also denied standing based on a lack of traceability to Defendants' conduct. (Opinion 11-13, R. 21, Page ID ## 823-25) But the district court overlooked the interference by Defendants with access to HCQ for prophylactic use. If an American plans to travel to Africa, then he can easily obtain access to HCQ in the United States on a prophylactic basis before he leaves, to protect against malaria. But if the same American wants to attend a religious service, political rally, or an AAPS conference, he cannot obtain access to HCQ for prophylactic use to enable him to attend those gatherings. Defendant FDA's false

statements and withholding of the HCQ Stockpile have the effect of impeding that prophylactic access.

The district court points out that some (not all) state regulators impose restrictions of their own on gatherings, and on HCQ use. But they have done so often in reliance in the actions by Defendants, as it is typical that state regulators follow the lead of federal regulators. Indeed, state regulators and the FSMB expressly cite the (irrational) position of the FDA in imposing restrictions. Traceability is no more tenuous than simply reading what the state regulators themselves expressly base their restrictions on.

Hence the district court erred when it held that "independent actors making independent decisions have led to the complained of injuries." (Opinion 12, R. 21, Page ID # 824). Those "independent" decisions often expressly rely on Defendant FDA's falsehoods and interference with access to HCQ for early and prophylactic use against COVID-19. That easily satisfies the requirement of traceability.

4. AAPS Has Third-Party Standing.

Standing is "transitive" through membership organizations: a potential plaintiff with standing who belongs to a membership group gives the large group standing to assert the standing that the member could assert. *See N.Y. State Club Ass'n, Inc. v. New York,* 487 U.S. 1, 9 (1988). Because AAPS's physician

members have standing on behalf of themselves and their patients, so too does AAPS.

By rejecting any form of standing by AAPS, the district court essentially held that no physician – and thus no one – can have standing to challenge Defendants' actions against HCQ, which requires a prescription to obtain. Defendants are thereby given complete immunity from any accountability in court, and from any check-and-balance on their conduct. This result is hardly consistent with well-established norms of judicial review.

B. The Purposes of Standing Doctrine Are Undermined, Not Advanced, by Denying Standing Here.

There are familiar reasons for adopting a narrow view of standing, in order 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 exist here, where an agency seeks to avoid accountability entirely for its misconduct. Moreover, it is a misuse of standing doctrine to preclude all possible challenges to agency conduct that endangers innocent human life.

The history of standing doctrine is thoroughly described in the above-cited law review article. *Simard, Standing Alone*, cited *supra*, 100 DICK. L. REV. at 308-23. That article, with numerous citations to Supreme Court decisions, explains the two primary purposes of standing doctrine: separation of powers, and the Article III "case" or "controversy" requirement. *Id.* at 318-23.

Neither of these goals of standing doctrine are advanced by denying standing here, and in fact both goals are undermined by the ruling below.

Separation of powers doctrine is a reason to deny standing to challenges to taxation or spending decisions originally made by Congress, not unauthorized wrongdoing by an agency. Congress has not commanded Defendants 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. *Id.* at 319-21.

The "case" or "controversy" rationale for standing doctrine is also fully satisfied here. Actions by Defendants 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 Defendants. 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.

There is no suggestion that AAPS seeks merely an advisory opinion here, which would be precluded by the requirements of Article III standing. There is no suggestion that the Plaintiff and Defendants here are somehow not adversarial,

which could also be a reason to invoke standing doctrine. There is no suggestion of anyone else having greater standing than AAPS to challenge the senseless conduct by Defendant which is costing innocent lives on an ongoing basis. Congress has expressly prohibited federal agencies from acting in an arbitrary manner, and Plaintiff AAPS has standing to enforce that prohibition in order to enjoin Defendants' wrongful conduct.

In sum, standing doctrine is not a bulldozer to be ruthlessly driven without consideration of its underlying purposes. No such purpose is served by an overly narrow view of standing here, or by declaring that Defendants are free of any judicial accountability for causing the loss of innocent life. The checks and balances essential to our form of government do 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.

C. No Deference to Defendant FDA Is Appropriate Here.

The district court and, to a lesser extent, the motions panel indicated a preference to defer without much scrutiny Defendants' decisions which undeniably affect life-related issues for millions of Americans. (Opinion 10 n.6, RE 21, Page ID # 822; Doc. 18-2, at 4 – referring to "better judgement" by agencies)

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 in side, courts should not defer in any way to irrational conduct by an agency which arguably causes the loss of innocent life.

Multiple reasons for rejecting any deference to Defendants have been presented in this case, ranging from the conflicts-of-interest to outspoken opposition by agency workers to the President. Congressional intent is clear, as manifested in its bipartisan Right to Try Act (2018), that Defendant FDA should not be interfering with access to potentially life-saving medication. PUB. L. NO. 115-176. The conduct by Defendants as set forth in this case is demonstrably unjustified and improper in withholding medication and making falsely disparaging statements about it. Courts do not properly defer to such falsehoods or improper agency conduct.

Under the district court decision, conflicts of interest among Defendants go unchecked, to the detriment of millions of Americans. 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 is arbitrary, capricious, and based on factors other than the data. But the district court ruling and the decision by the motions panel deny anyone standing to object to object, even when the result is the loss of thousands of

lives. This amounts to tyranny by the administrate state contrary to the principles of judicial review.

A recent example in the news illustrates how politically biased against the President some workers at Defendants are. On August 28, 2020, the entrenched FDA bureaucracy fired a conservative White House appointee as its chief spokeswoman, after less than merely 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, and an unnamed agency official then crudely smeared her in the press by claiming that she could not pronounce a medical term.[37] The FDA is a subagency that abuses its power without accountability in court for its conduct.

President Trump's longtime trade advisor in the White House, Peter Navarro, Ph.D., explained in an interview on June 15, as reported in the *New York Times*, that the interference by Defendant FDA "is a Deep State blindside by bureaucrats who hate the administration they work for more than they're concerned about saving American lives." Sheryl Gay Stolberg, *A Mad Scramble to Stock Millions of Malaria Pills, Likely for Nothing*, N.Y. TIMES (June 16, 2020).[38] The

[37] https://www.politico.com/news/2020/08/28/fda-top-spokesperson-leaves-404422 (viewed Aug. 29, 2020).

[38] https://www.nytimes.com/2020/06/16/us/politics/trump-hydroxychloroquine-coronavirus.html (viewed Oct. 28, 2020).

Hon. Navarro could have also highlighted the lack of accountability for the irrational actions by Defendant FDA.[39]

No deference is warranted by a reviewing court to agency decision-making that arguably causes the loss of innocent human life by blocking access to medication, particularly amid demonstrable bias at the agency.

III. A Motions Panel Decision Does Not Bind a Merits Panel.

For multiple reasons as explained by the Ninth Circuit in litigation against President Trump, a decision by a motions panel does not bind a merits panel in the same case. "At least four other circuits have agreed that later panels may review the merits of a case 'uninhibited' by a motions panel's earlier decision in the same case." *E. Bay Sanctuary Covenant v. Trump*, 950 F.3d 1242, 1262 (9th Cir. 2020). Decisions by motions panels are typically without the full briefing and rights of petitioning for reconsideration which are attendant to a merits panel, which further weighs against allowing a motions panel to bind a merits panel. *See id.* at 1263-64. Much shorter word-count limits on the submissions to a motions panel, and the lack of any oral argument, also militate against any binding effect by its decision on a merits panel.

[39] The term "Deep State" is a popular variant, recognized by dictionaries, on longstanding criticism of an unaccountable "administrative state." *See, e.g.*, *Gundy v. United States*, 139 S. Ct. 2116, 2140 (2019) (Gorsuch, J., dissenting) ("Even Justice Douglas, one of the fathers of the administrative state, came to criticize excessive congressional delegations ….").

Here, the motions panel merely decided a procedural issue with respect to only one part of the claims by AAPS here: the release of the HCQ Stockpile. The motions panel expressly acknowledged that AAPS did not move for injunctive relief before that panel on the falsely disparaging statements by the FDA about HCQ. (Doc. 18-2, at 3) The motions panel therefore did not decide whether AAPS has standing to seek correction of the falsely disparaging statements by the FDA of medication which AAPS members seek to prescribe but are limited in doing so because of the FDA's statements.

The decision by the motions panel has no binding effect on this merits panel.

IV. Defendants' Conduct Is Not Exempt from the APA.

The non-binding motions panel decision tersely held that Defendants' withholding and wasting of the HCQ Stockpile is nonreviewable under the Administrative Procedure Act ("APA"). (Doc.18-2, at 6) The district court opinion below did not so hold.

The motions panel cited 5 U.S.C. § 701(a)(2) (APA applies "except to the extent that … agency action is committed to agency discretion by law") and 21 U.S.C. § 360bbb-3(i) ("Actions under the authority of this section by the Secretary, by the Secretary of Defense, or by the Secretary of Homeland Security are committed to agency discretion"). But Defendant FDA is merely a subagency and

lacks a "Secretary", so this exemption statute should not apply to the complained-of conduct here.

Moreover, States have acted based on FDA's unauthorized statements disparaging HCQ, and thus the false statements by the FDA would be reviewable even if FDA's EUA-related actions were not. *See Tozzi,* 271 F.3d at 310; *Block v. Meese,* 793 F.2d 1303, 1309 (D.C. Cir. 1986) (government statements reviewable if they *de facto* cause third-party action).

In addition, Defendant FDA's EUA-related actions are reviewable because the APA waives sovereign immunity for judicial review of final agency action for which the plaintiff has no other adequate remedy in a court. 5 U.S.C. §§ 702-704. That review applies both to Defendants' EUA and to their subsequent revocation of the EUA because both actions constituted "final agency action."

Presumably no one would doubt that a hypothetical decision by a federal agency to withhold silos of grain from starving farmers would be reviewable in federal court. Likewise, Defendant FDA is not exempt from judicial review for its withholding of and interference with access to HCQ, by virtue of a limited exemption granted to certain decisions made by the Secretary.

CONCLUSION

This Court should reverse the decision below and summarily grant the requested relief of release of the HCQ Stockpile by Defendants, and require their correction of their false disparagement of the medication.

Dated: October 28, 2020

Respectfully Submitted,

s/ Andrew L. Schlafly

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Dated: October 28, 2020

s/ Andrew L. Schlafly

Attorney for Appellant

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I hereby certify that on October 28, 2020, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/ Andrew L. Schlafly

Attorney for Appellant

ADDENDUM

Designation of originating court documents

Complaint, R. 1, Page ID ## 1-24

Motion for Preliminary Injunction, R. 8, Page ID ## 66-68

Declaration by Jane Orient, M.D., dated June 22, 2020, R. 9-1, Page ID ## 346-52

Declaration by Jeremy Snavely dated June 22, 2020, R. 9-2, Page ID ## 354-61

Addendum to the Complaint of Prohibited Personnel Practice and Other Prohibited Activity by the Department of Health and Human Services Submitted by Dr. Rick Bright, R. 9-5, Page ID ## 410-72

Emergency Use Authorization, R. 9-6, Page ID ## 477-81

Frequently Asked Questions on the Revocation of the Emergency Use Authorization for Hydroxychloroquine Sulfate and Chloroquine Phosphate (June 16, 2020), R. 9-7, Page ID # 483-85

ASPR's Portfolio of Investigational Medical Countermeasures being used to treat COVID-19, R. 9-8, Page ID # 487

Arkansas Dep't of Health, COVID-19 Guidance About Chloroquine, R. 9-9, Page ID ## 489-91

Oregon Board of Pharmacy, Temporary Administrative Order Including Statement of Need & Justification, at 1 (June 15, 2020), R. 9-10, Page ID ## 493-94

Joint Statement of FSMB, NABP, NCSBN on Inappropriate Prescribing and Dispensing of Medications During the COVID-19 Pandemic, R. 9-11, Page ID ## 496-98

Motion to Dismiss, R. 10, Page ID # 502

Combined Memorandum in Support of Defendants' Motion to Dismiss and in Opposition to Plaintiff's Motion for a Preliminary Injunction, R. 11, Page ID ## 550-593

Opinion dated August 14, 2020, R. 21, Page ID ## 813-33

Final judgment dated August 14, 2020, R. 22, Page ID # 834

Notice of Appeal dated August 14, 2020, R. 23, Page ID # 835