Case No. 20-1784

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Association of American Physicians & Surgeons,

Appellant-Plaintiff

v.

Food & 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)

EMERGENCY MOTION FOR INJUNCTIVE RELIEF BY APPELLANT ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS

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Appellant-Plaintiff Association of American Physicians & Surgeons ("AAPS") hereby seeks emergency injunctive relief to compel Appellees-Defendants to release the hydroxychloroquine ("HCQ") that they withhold and waste in the Strategic National Stockpile (the "HCQ Stockpile"). Appellees-Defendants are the Food & Drug Administration, Dr. Stephen M. Hahn, Commissioner of Food & Drugs, in his official capacity, Biomedical Advanced Research & Development Authority, Gary L. Disbrow, Ph.D., Acting Director, Biomedical Advanced Research & Development Authority ("BARDA"), in his official capacity, Department of Health & Human Services, and Alex Azar, Secretary of Health & Human Services, in his official capacity (collectively, "Defendants"). It is irrational, arbitrary, and capricious for Defendants to waste more than 60 million doses of HCQ that were donated to alleviate the COVID-19 pandemic, and for Defendants to withhold that potentially life-saving medication while many thousands of Americans die from the disease.

AAPS is a non-profit association of physicians founded in 1943, which is devoted to defending the practice of ethical, private medicine against government interference. 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).

Background

In a scenario that future historians might compare to the politically motivated withholding of grain from millions of Ukrainians by Josef Stalin in 1932, or the withholding by the U.S. federal government of penicillin from African American men in the long-running Tuskegee study in the rural South, Defendants withhold and waste more than 60 million doses of potentially life-saving medication for COVID-19.[1] This emergency motion by AAPS seeks to enjoin this waste of this HCQ Stockpile and compel its release while it is still timely to save lives and alleviate injuries from the disease.

Yale School of Public Health epidemiology Professor Harvey Risch, M.D., observed that "75,000 to 100,000 lives will be saved" if the stockpile of HCQ being

[1] Sheryl Gay Stolberg, "A Mad Scramble to Stock Millions of Malaria Pills, Likely for Nothing," NEW YORK TIMES (June 16, 2020) https://www.nytimes.com/2020/06/16/us/politics/trump-hydroxychloroquine-coronavirus.html (viewed Aug. 17, 2020).

wrongly withheld by Defendants were released, as sought by AAPS here, and he 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 ….[2]

Dr. Risch's praise of HCQ is supported by many studies, including research on thousands of patients at the Henry Ford Health System in Michigan. This study demonstrated that HCQ is both very safe and highly effective in treating COVID-19, reducing 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).[3] Dozens of additional studies further demonstrate the efficacy of HCQ as preventive or early treatment for the disease.[4] Similarly, 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

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[2] https://www.myjoyonline.com/news/international/yale-epidemiologist-says-hydroxychloroquine-could-save-up-to-100k-lives-if-used-for-coronavirus/ (viewed Aug. 8, 2020).

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

[4] https://c19study.com/ (a collection of 78 studies clearly showing the effectiveness of HCQ as an early treatment for COIVD-19, viewed Aug. 20, 2020).

> 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).[5] Multiple additional attestations as to the safety of HCQ were quoted by AAPS in its Complaint below (Compl. ¶¶ 4, 46-48, R. 1, Page ID ## 2, 11-12), including how National Public Radio quoted the expert Dr. Jon Giles, an epidemiologist and rheumatologist at Columbia University Department of Medicine, endorsing the safety of HCQ as follows:

> "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."[6]

See also Declaration by Jane Orient, M.D., ¶¶ 12, 14-17, R. 9-1, Page ID ## 347-48.

President Donald Trump has repeatedly praised HCQ and successfully took it himself in May as a prophylactic against HCQ, and retweeted favorably about this pending lawsuit on July 27,[7] which underscores its national urgency. Due to

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[5] https://www.medrxiv.org/content/10.1101/2020.06.09.20116806v1.full.pdf (viewed Aug. 17, 2020).

[6] https://www.npr.org/sections/health-shots/2020/05/21/859851682/politics-around-hydroxychloroquine-hamper-science (emphasis added, viewed Aug. 18, 2020).

[7] https://aapsonline.org/judicial/djt-rt-07-27-2020.png (viewed July 30, 2020).

the upcoming presidential election, President Trump's vocal support of HCQ has triggered opposition to the medication for political reasons.

Even Democratic politicians have praised HCQ for saving their lives, despite the implicit credit that provides to Trump. On August 8, the *New York Post* quoted Democratic Queens Councilman Paul Vallone as saying that HCQ "saved my life" from COVID-19 and quoted his brother, Judge Peter Vallone, as saying that "big money does not want this drug to be used. Always follow the money," while he linked to a study by New York University demonstrating the efficacy of HCQ to treat COVID-19.[8,9]

Yet more than 60 million doses of HCQ are deteriorating in Defendants' warehouses,[10] while many thousands of Americans die each week without early treatment for COVID-19. The lower court never reached this issue, and dismissed this case by finding a lack of standing by AAPS to challenge Defendants' misconduct. (Opinion, R. 21, Page ID ## 821-32)

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[8] https://nypost.com/2020/08/08/nyc-councilman-credits-hydroxychloroquine-for-covid-19-recovery/ (viewed Aug. 20, 2020).

[9] https://www.ny1.com/nyc/all-boroughs/news/2020/05/12/nyu-study-looks-at-hydroxychloroquine-zinc-azithromycin-combo-on-decreasing-covid-19-deaths (viewed Aug. 9, 2020).

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

Argument

I. Standard of Review

AAPS seeks injunctive relief to prevent irreparable harm to its members and itself, and to reduce potentially avoidable deaths caused by the arbitrary and irrational actions by Defendants. This motion is analogous to one for a preliminary injunction, for which this Circuit considers four factors: "'(1) whether the movant has a strong likelihood of success on the merits; (2) whether the movant would suffer irreparable injury without the injunction; (3) whether issuance of the injunction would cause substantial harm to others; and (4) whether the public interest would be served by issuance of the injunction.'" *City of Pontiac Retired Emps. Ass'n v. Schimmel*, 751 F.3d 427, 430 (6th Cir. 2014) (quoting *PACCAR Inc. v. TeleScan Techs., LLC*, 319 F.3d 243, 249 (6th Cir. 2003)); *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008). "[T]he degree of likelihood of success required [for the first factor] may depend on the strength of the other factors." *In re DeLorean Motor Co.*, 755 F.2d 1223, 1229 (6th Cir. 1985).

II. AAPS Has Standing, and Judicial Review Is Essential Here under the Administrative Procedure Act and the Constitution.

AAPS demonstrates that it has standing here, just as the Fifth Circuit held in *AAPS v. Texas Medical Board (TMB)*, discussed *infra*. The court below erred in holding otherwise and declining to reach the merits of this case.

As a preliminary matter, the district court misperceived two underlying issues. First, the district court imprecisely described HCQ as being "commercially available": "Hydroxychloroquine is commercially available, and physicians are free to prescribe the drug for off-label uses absent any direction to the contrary by state medical authorities." (Opinion 2, R. 21, Page ID # 814) The term "commercially available" implies access by any willing buyer, which is simply not true with respect to HCQ. To the contrary, HCQ is often unavailable for prophylactic or early treatment. (Declaration by Jeremy Snavely dated June 22, 2020 ("First Snavely Declaration") ¶¶ 9-11, 27, R. 9-2, Page ID ## 356, 259) The district court's statement is no more correct than saying that enriched uranium is "commercially available" because there are purchases of it somewhere, or that the ultra-secretive National Security Agency is open to the public because visitors sometimes go there. If someone is exposed to COVID-19, he ***cannot*** obtain HCQ as early protection against the disease even though he could obtain HCQ as a prophylactic if he planned to travel to a malaria-infested region of Africa. (Declaration by Jane Orient, M.D., ¶¶ 17-18, 36, 38, 40, R. 9-1, Page ID ## 348, 351-52) There is no rational basis for denying public access to HCQ amid its longtime, safe use as a prophylactic against malaria.

Second, the district court omitted discussion of the wasting of the HCQ Stockpile by Defendants. Conceptually, this is no different from the government

having a special device that could save a patient's life; the patient would have standing to prevent the government from irrationally destroying the device rather than allowing him access to it. Similarly, if the National Archives decided to burn its original copies of the Declaration of Independence, or if the National Park Service decided to tear down the Lincoln Memorial, legal standing would exist for groups having a bona fide interest in those issues, just as AAPS has here.

Defendants' interference with access to HCQ harms AAPS and its members, both as physicians and patients, as does Defendants' wasting of the HCQ Stockpile. AAPS has standing to seek that review, and wrongdoing by governmental officials that needlessly results in the loss of thousands of American lives should not be allowed to evade timely judicial review. The district court suggested a lack of redressability but the release of the HCQ Stockpile would redress the substantial injuries felt by AAPS members and the American public.

A. AAPS Has Standing.

Founded in 1943, AAPS is an association of physicians in all 50 states, some of whom treat COVID-19 and all of whom are potential victims of it. AAPS itself has had to cancel its scheduled conferences due to COVID-19. It is difficult to imagine a plaintiff which would have greater standing than AAPS to challenge interference with early treatment of this disease. Such governmental interference harms members of AAPS and AAPS itself.

Indeed, if there ever were an issue for which standing is nearly universal, it is interference with access to preventive and early treatment for COVID-19. The lives of more than 300 million Americans have been profoundly affected by the fear of contracting and being hospitalized for this disease, rather than having access to preventive and early treatment for it. This widespread fear deters Americans from attending religious services, dining out, participating in political conferences, and traveling to conventions. Rather than doubting whether AAPS has standing, a more challenging question would be to try to identify anyone who would not have standing to object to interference with preventive and early treatment for COVID-19.

In particular, AAPS has standing in at least three different ways: based on its members who are impeded in successfully prescribing for HCQ, based on the inability by AAPS itself to hold conferences without access to a prophylactic for COVID-19, and based on third-party standing by AAPS for its members and patients. Each of these is reviewed in turn below.

1. AAPS Has Associational Standing Based on its Members.

The Fifth Circuit, in *AAPS v. Texas Medical Board*, found associational standing by AAPS in a lawsuit it brought in federal court in Texas about arbitrary discipline against physicians by the Texas Medical Board (TMB) there. 627 F.3d 547 (5th Cir. 2010). There it was an analogous issue of unfair interference with and

retaliation against physicians by a state medical board, similar to what physicians face here if they prescribe HCQ amid the interference with access by Defendants.

After restating the Sixth Circuit standard for associational standing,[11] the district court sought to distinguish the *AAPS v. TMB* precedent for associational standing by AAPS. (Opinion 18, R. 21, Page ID # 830) Individual AAPS members face the same sort of retaliation if they prescribe HCQ as AAPS members faced in *AAPS v. TMB*, where AAPS was found "beyond question" to have associational standing by the Fifth Circuit on a key element relevant here. 627 F.3d at 550-51; First Snavely Declaration ¶¶ 7-8, 11, R. 9-2, Page ID ## 355-56. In addition, the interference with AAPS members' ability to successfully prescribe a full regimen of HCQ to patients, early when they need it most, is "clearly traced to the defendants' actions" of disparaging and blocking access to HCQ. Conversely, once the HCQ Stockpile, which contains more than 60 million doses of the medication, is released, then the interference with access to HCQ, and retaliation against physicians who prescribe it, will mostly cease.

[11] Associational standing exists if "(1) the organization's members would otherwise have standing to sue in their own right; (2) the interests it seeks to protect are germane to the organization's purpose, and (3) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Friends of Tims Ford v. TVA*, 585 F.3d 955, 967 (6th Cir. 2009) (quoting *Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977), inner quotes omitted, as quoted by Opinion 15, R. 21, Page ID # 827).

Furthermore, how could AAPS members, who are on the front lines treating COVID-19 patients, not be injured by impediments to use HCQ as a prophylactic? AAPS has members who inevitably see patients with COVID-19. AAPS members want access to HCQ as a prophylactic to protect themselves and thereby protect their own families, just as health care workers have successfully used HCQ as a prophylactic against COVID-19 in India. *See supra* footnote 5 and accompanying text. By impeding access to HCQ and withholding the HCQ Stockpile from use, Defendants' actions irrationally impede the ability of AAPS's member physicians to practice their profession, and thereby injure them. This gives AAPS members individual standing, and confers associational standing on AAPS under the first prong of the associational standing test. Indeed, no other potential plaintiff would have any greater standing to challenge Defendants' irrational policy.

The other two prongs of the associational standing – requiring that the issue be germane to the organization's purpose and that there be a lack of a need for individual participation – are also plainly satisfied. For 77 years AAPS has stood for the rights of practicing physicians and their patients against irrational governmental conduct and interference (Opinion 2, R. 21, Page ID # 814; Compl. ¶ 11, R. 1, Page ID ## 3-4), and participation by individual physicians is unnecessary to obtain a release of the HCQ Stockpile.

2. AAPS Has Standing in Its Own Right.

AAPS has standing in its own right because Defendants' actions impair AAPS's own First Amendment activity. As many fear attending events without a prophylactic to protect against COVID-19, AAPS has had to cancel its own conferences. (First Snavely Declaration ¶¶ 23-25, R. 9-2, Page ID # 358)

The district court observed that "[t]he causation alleged need not be proximate" and the injury can be merely "indirect," but found a lack of standing because some injury could be caused by parties not before the court. (Opinion 12, R. 21, Page ID # 824) Yet if Defendants released the massive HCQ Stockpile, many physicians and patients would then have unfettered access to it. Interference by a State authority with access to a federally released stockpile is, frankly, implausible. Even if a few State regulators attempted to interfere with a release from the (federal) HCQ Stockpile, the vast majority of States would not interfere further and thus significant relief would result to AAPS amid the availability of HCQ as a prophylactic to prevent against COVID-19. AAPS's interest in dealing with State medical and pharmacy boards, without Defendant FDA's improper interference with HCQ, likewise renders this a first-party injury. *See Columbia Broadcasting System, Inc. v. U.S.*, 316 U.S. 407, 422-23 (1942); *Haitian Refugee Center v. Gracey*, 809 F.2d 794, 811 n.13 (D.C. Cir. 1987) (no "independent need…. [for] third party standing since the legal right … not to be injured by

unauthorized agency action … was their own"); Declaration by Jeremy Snavely dated July 20, 2020 ("Second Snavely Declaration") ¶ 6, R. 13-2, Page ID # 659.

3. AAPS Has Third-Party Standing.

AAPS has third-party standing too, on behalf of its longtime physician members and their patients. AAPS satisfies the three-part test for third-party standing: (1) AAPS has its own constitutional standing, (2) AAPS has a close relationship with its members, including a Dr. John Doe referenced in the Complaint (Compl. ¶¶ 85-90, R. 1, Page ID # 19) and in the First Snavely Declaration ¶¶ 7-9, R. 9-2, Page ID ## 355-56, and (3) the threat of enforcement or harassment hinders the initiating of his own suit by an AAPS member. *See Kowalski v. Tesmer*, 543 U.S. 125, 128-30 (2004). AAPS thus has third-party standing to seek redress for its physician-members' injuries. In addition, AAPS has third-party standing on behalf of the patients who have been exposed to COVID-19 and could not possibly pursue this kind of lawsuit in time to obtain relief.

The district court rejected third-party standing here. (Opinion 19-20, R. 21, Page ID ## 831-32, quoting *Moody v. Michigan Gaming Control Bd.*, 847 F.3d 399, 402-03 (6th Cir. 2017)). But patients infected by COVID-19 have neither the time nor the ability to challenge interference with preventive and early access to HCQ, for which they need a physician's prescription. More than 100,000 victims of COVID-19 have died within days or weeks of contracting the virus, as Herman

Cain fell to the disease in July.[12] Hence "these circumstances" of "privacy concerns," likely "imminent mootness" of an individual case, and "systematic practical challenges," for a COVID-exposed person to pursue a federal lawsuit to obtain early access to HCQ, are all insurmountable obstacles to individuals pursuing claims on this issue. Third-party standing thus exists under the very Sixth Circuit precedent relied on by the district court below.

Physicians have standing to assert their patients' interests under the *Kowalski* test, *supra*; *see also Crossen v. Breckenridge*, 446 F.2d 833, 840 (6th Cir. 1971) (finding "standing of a doctor to assert the alleged rights of his patients in his own behalf"). Because AAPS's physician members are on the front lines of treating for COVID-19 and have standing to assert their patients' interests, so does AAPS. *See N.Y. State Club Ass'n, Inc. v. New York,* 487 U.S. 1, 9 (1988) (holding that 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).

4. Redressability Exists.

The district court found a lack of redressability by suggesting that State regulators might still interfere with access to HCQ even if Defendants released it. (Opinion 13, R. 21, Page ID # 825) But such speculation would negate

[12] https://www.cnbc.com/2020/08/04/herman-cain-was-on-a-ventilator-before-he-died-from-covid-19-top-aide-says.html (viewed Aug. 9, 2020).

redressability in many legitimate cases. In a lawsuit against infringement on First Amendment rights, a court could thereby decline relief based on speculation that another governmental authority might also infringe on those same rights. A plaintiff need not sue everyone who might infringe in order to stop one defendant who is infringing. In practice, States typically follow the lead of the federal government, and a release of the HCQ Stockpile by Defendants would result in all or nearly all States following that lead.

Defendants should release the stockpile to pharmacies that promise to fill prescriptions for HCQ without conditions or delay, and Defendants should provide public notice as to the contact information of those pharmacies. Such relief would greatly alleviate the interference with early access to HCQ and thereby redress the ongoing injury to AAPS, its members, and their patients.

B. Judicial Review Exists under the Administrative Procedure Act and the Constitution.

When agencies act in an arbitrary and capricious manner which contributed to the death of more than 100,000 Americans, and the ongoing deaths of many more, then judicial review exists to scrutinize the agencies' conduct. Placed in historical perspective, if Josef Stalin's policy which starved millions of Ukrainians to death were a policy by an agency of the United States, then judicial review of

such a policy in federal court would presumptively be available.[13] If a federal agency were withholding stockpiled grain that farmers need to avoid starving to death, then judicial review would exist to scrutinize the irrational, deadly conduct by the agency.

The Administrative Procedure Act ("APA") proscribes 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 compels 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).

The decision below sets forth the statutory scheme by which Defendants have acted in promulgating, and then revoking, its Emergency Use Authorization. (Opinion 3-6, R. 21, Page ID ## 815-18, quoting, *inter alia*, 42 U.S.C. § 247d-6b)). But for the purposes of this Motion, it is the action by Defendants in receiving, withholding, and wasting more than 60 million doses of HCQ which are at issue, and which is prohibited by the APA independent of any statutory scheme. *See, e.g.*, *Service v. Dulles*, 354 U.S. 363, 388 (1957) (once an agency acts by regulation, even when not required to, the agency cannot then disregard it). Defendants

[13] 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.

accepted the donations to the HCQ Stockpile, and cannot evade judicial review now while wasting the HCQ.

Defendants insisted on being exempt entirely from judicial review with respect to its Emergency Use Authorization (Defs. Combined Mem. dated July 10, R. 12, Page ID ## 584-85). But even if such an exemption applied, it would be narrowly construed not to preclude judicial review of agency conduct which exacerbates a massive loss of life.

C. Deference to Defendant Agencies Would Be Inappropriate Here for Multiple Reasons.

The district court indicated its inclination to defer to the agencies on this matter as Defendants predictably urge (Opinion 10 n.6, R. 21, Page ID # 822), but such deference is unwarranted in this unique situation.

First, the withholding and wasting of medication by Defendants, while nearly 200,000 Americans die from the disease for which the medication was donated, is senseless and utterly indefensible. HCQ has proven to be very safe with more than a 65-year track record, while studies, experts, and individual recipients praise it as being life-saving. *See* Background, *supra*. No deference was warranted when the federal government withheld penicillin from African American men in

the Tuskegee study in the South,[14] and no deference is warranted here for Defendants' withholding of potentially life-saving medication for COVID-19.

Second, Defendants are acting contrary to the publicly stated position about HCQ by the President, who has retweeted favorably about this lawsuit. *See id.* Defendants' argument for deference here is not for deference to the Executive Branch, as led by the President, but instead for deference to insubordination within the Executive Branch. That is analogous to a sailor asking for deference when he is acting contrary to the captain of his ship.

Third, the issue of access to HCQ has obviously become politicized amid a very contentious presidential election. A Democrat officeholder was even subjected to punishment by her party for merely praising HCQ and Trump's endorsement of it, which she credits as helping her overcome COVID-19. "Detroit Democrats plan to vote to censure and bar any future endorsements of a Democratic lawmaker who credited President Donald Trump with advocating for the drug that she said cured her of COVID-19."[15] Deference to an agency decision tainted by political bias would be inappropriate.

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[14] "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).

[15] Beth LeBlanc, "Democrats plan to censure lawmaker who credited Trump for COVID-19 recovery" THE DETROIT NEWS (Apr. 23, 2020)

Fourth, no deference is warranted amid conflicts-of-interest at agencies. BARDA official Rick Bright, Ph.D., played a pivotal role in Defendants' decisions and he favors an expensive, proprietary medication developed by Gilead Sciences ("Gilead"). (Addendum to Bright's Complaint at 22, 24, R. 9-5, Page ID ## 431, 433) FDA Director of the Center for Drug Evaluation and Research Janet Woodcock pushed for restrictions on HCQ access, yet she occupied a top position in a public-private operation designed to approve a rival approach of vaccination 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).[16]

The Michigan Supreme Court has properly rejected an analogous claim for deference by a misbehaving hospital. Justice Robert Young observed in writing for that *en banc* court, the context of a demand for deference made by hospitals: "This claim overlooks the reality that courts routinely review complex claims of all kinds. Forgoing review of valid legal claims … amounts to a grant of unfettered

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https://www.detroitnews.com/story/news/politics/2020/04/23/democrats-plan-censure-lawmaker-whitsett-credited-trump-covid-19-recovery/3010947001/ (viewed Aug. 17, 2020).

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

discretion ….” *Feyz v. Mercy Mem’l Hosp.*, 475 Mich. 663, 680, 719 N.W.2d 1, 11 (2006).

D. Deference to State Authorities in Banning Some Gatherings Does Not Justify Irrational Interference with Access to a Prophylactic that Would Facilitate Gatherings.

The lower court implied that because several decisions by district courts (not by the Sixth Circuit) authorized government to selectively restrict gatherings, then it must be constitutional for government to interfere with gatherings in other ways too. (Opinion 10 n.6, R. 21, Page ID # 822) But that does not follow. This Circuit ***ordered*** a city to allow religious services to occur when secular gatherings are allowed. *Maryville Baptist Church, Inc. v. Beshear*, 957 F.3d 610, 616 (6th Cir. 2020) (“The breadth of the ban on religious services, together with a haven for numerous secular exceptions, should give pause to anyone who prizes religious freedom.”).

As recognized by the Centers for Disease Control and Prevention (“CDC”), for decades HCQ has been used safely as a prophylactic for people who travel to Africa, in order to protect them against malaria.[17] If Defendants started prohibiting access to HCQ for that purpose, then that arbitrary restriction would be

[17] The Centers for Disease Control and Prevention (“CDC”), Medicines for the Prevention of Malaria While Traveling Hydroxychloroquine (Plaquenil™) (Exh. 12 to Mot. for Prelim. Inj., R. 9-12, Page ID # 501). https://www.cdc.gov/malaria/resources/pdf/fsp/drugs/Hydroxychloroquine.pdf (p. 2, viewed Aug. 18, 2020).

constitutionally suspect for infringing on the right to travel to Africa. Defendants' arbitrary interference with access to HCQ, which deters people from attending religious and political gatherings, is likewise infirm.

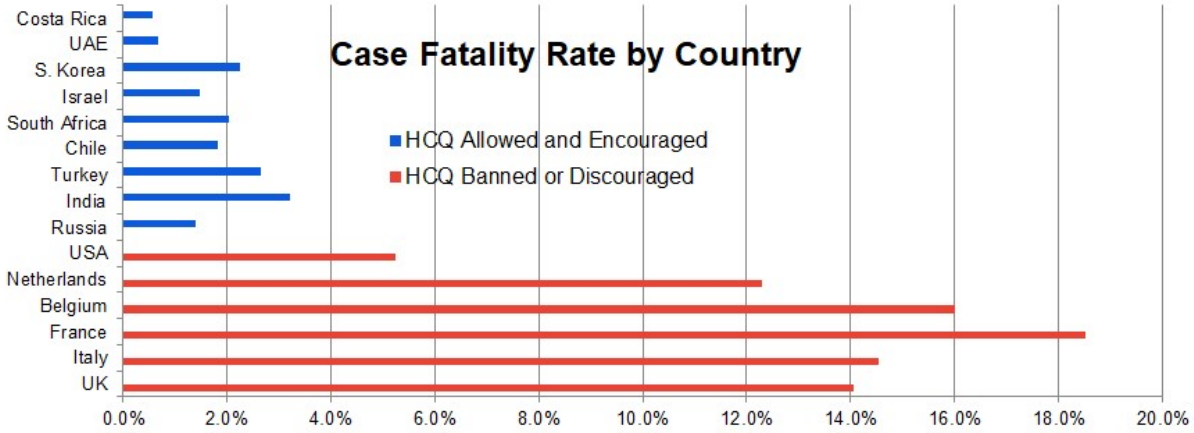
III. Countries Allowing Early Access to HCQ Have Held Mortality Rates from COVID-19 Far Lower than the United States.

Many nations have successfully allowed HCQ for preventive and early treatment of COVID-19, while the United States and secular nations in Western Europe have blocked it with disastrous results as of June 22:

Country	**HCQ Policy**	**Percentage COVID-19 Deaths Per Case**	**COVID-19 Deaths Per Million in Population**
United Kingdom	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
United States	FDA interferes with access to HCQ	5.2%	370 (has risen to 532)
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

First Snavely Declaration ¶ 28, R. 9-2, Page ID # 360 (based on the data posted at the independent, scientific, and widely respected worldometers.info/coronavirus website).

AAPS highlighted below this stark different in success in defeating COVID-19 by countries which allow HCQ access, compared with the more secular countries that have interfered with access:



Id. at ¶ 29.

Attendance at religious services is higher in the cultures where HCQ is allowed, such as Poland, Israel, South Korea, Republic of the Philippines, Turkey, and several nations in South and Central America, but they have much lower mortality rates from COVID-19 as they pursue the more pro-life policy of authorizing HCQ access.[18] Nations in Western Europe having secular views against the sanctity of life and infrequent religious worship have been more likely

[18] https://www.worldometers.info/coronavirus/#countries (viewed Aug. 19, 2020).

to block access to HCQ, and they have higher mortality rates from COVID-19. President Trump was elected on a pro-life position, and respect for his electoral mandate reinforces the need to enjoin the secularized interference by Defendants with the potentially life-saving HCQ.

IV. Relief by this Court Appears to be the Only Way that the HCQ Stockpile Will Be Released Rather than Wasted.

President Trump has made his position clear in support of HCQ, but in this litigation Defendants implicitly take the position that not even he can order them to release the HCQ Stockpile. Apparently under this view of Defendants themselves, only a federal court can command them to distribute the HCQ Stockpile rather than allow it to waste away as Defendants intend.

Many thousands of Americans are dying from COVID-19 each week without access to the HCQ Stockpile for preventive or early treatment of COVID-19. Rule of law does not elevate form over substance at the cost of thousands of lives on an ongoing basis. This Court should order Defendants to end their intransigence, and release the HCQ Stockpile rather than wasting it.

V. All Four Factors for Injunctive Relief Favor Granting It.

All four factors for a preliminary injunction (Point I, *supra*) support granting the requested injunction. First, AAPS has a strong likelihood to prevail on the merits because there is no justification for Defendants to withhold and waste more than 60 million doses of potentially life-saving medication while many thousands

of Americans die each week. Second, the irreparable harm – which includes massive loss of life – is obvious. Third, there would be no harm from a grant of the injunctive relief, because the medication has been proven to be safe for more than 65 years and Defendants are wasting it anyway. Fourth, the public interest, namely the health and confidence of millions of Americans, would be served by the requested injunctive relief.

CONCLUSION

AAPS respectfully requests that this Court order Defendants to expeditiously release the HCQ Stockpile to pharmacies in the United States which promise to fill prescriptions for them without delay or restriction in protecting against COVID-19, and that Defendants publicly post a list of those pharmacies, with their contact information.

Dated: August 20, 2020

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Certificate of Compliance With Type-Volume Limitation, Typeface Requirements, and Type Style Requirements pursuant to Fed. R. App. P. 32(a):

1. This motion complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because:

> this motion contains 5,198 words excluding the parts of the petition exempted by Fed. R. App. P. 32(f).

2. This motion complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because:

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Dated: August 20, 2020

s/ Andrew L. Schlafly
Attorney for Appellant

CERTIFICATE OF SERVICE

I hereby certify that on August 20, 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, thereby providing service on all parties. I certify that all participants in the case are registered CM/ECF users.

s/ Andrew L. Schlafly
Attorney for Appellant