IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, Plaintiff, v. 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, in his official capacity; DEPARTMENT OF HEALTH & HUMAN SERVICES; and ALEX AZAR, Secretary of Health & Human Services, in his official capacity, Defendants.	No. 1:20-cv-00493-RJJ-SJB Hon. Robert J. Jonker Mag. Sally J. Berens **Oral Argument Requested**

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

Amid the national coronavirus pandemic, Defendants have impeded the ability of President Donald Trump to make available to the public the same safe medication that he and other world leaders have successfully taken for themselves: hydroxychloroquine (HCQ). They have remained healthy by taking this harmless medication as a prophylaxis, but Defendants have interfered with public access to it for physicians and nurses on the front lines of the pandemic, and for ordinary Americans seeking security against COVID-19. Celebrities and others with connections have been able to obtain immediate access to this medication for their own early treatment of the virus, but the less connected have gone on ventilators and died without access to HCQ. Without access to early treatment or prophylaxis, people are impeded from exercising their First Amendment right to attend political rallies and conventions, and religious services.

A "perfect storm" of politics in this presidential election year, along with conflicts of interest at the Defendant federal agencies, has resulted in unjustified obstacles to access to HCQ, an inexpensive medication having a track record of more than 75 years of safety. 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 this interference by FDA officials "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).[1]

A federal bureaucrat who is an outspoken critic of President Trump, Rick Bright, masterminded inserting insurmountable obstacles to public access to HCQ during this crisis. Specifically, he and others at the FDA inserted an arbitrary set of conditions on public access to this medication: a patient must be first be hospitalized with COVID-19 *and* a clinical trial must be unavailable to him. These irrational impediments are indefensible and can only be understood as the result of political opposition to Trump amid improper conflicts of interest by bureaucrats at Defendant federal agencies.

After Plaintiff filed and served its lawsuit here, Defendants then abruptly revoked its initial Emergency Use Authorization without notice or public input, in an analysis compromised by falsehoods in a discredited *Lancet* article that was subsequently retracted and in reliance on studies that waited too late – and average of 16.6 days into COVID-19 – before providing HCQ (*i.e.*, studies that did not test for prophylaxis or early treatment).[2] This revocation letter by the FDA dated June

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[1] https://www.nytimes.com/2020/06/16/us/politics/trump-hydroxychloroquine-coronavirus.html (viewed June 22, 2020).

[2] Wei Tang, *et al.*, *Hydroxychloroquine in patients with mainly mild to moderate coronavirus disease 2019: open label, randomised controlled trial*, __ THE

15, 2020 unjustifiably prohibits *all* new uses of HCQ for COVID-19 from the federal Strategic National Stockpile (SNS) under any circumstances, and falsely implies that all uses of HCQ for COVID-19 should stop. (Exh. 4) This interference by the FDA with access by the public to donated HCQ, and the false statements by the FDA implying that all use of HCQ for COVID-19 should end, are arbitrary and irrational, and this Court should enjoin Defendants accordingly.

Pharmaceutical companies donated nearly 100 million doses of HCQ to the SNS, but Defendants have improperly withheld most of these doses from public access such that much of them will eventually need to be thrown away as they degrade over time. This colossal waste, to the detriment of Plaintiff, its members, their patients, and the public, is the epitome of arbitrary agency action which must be enjoined by this court.

Recognition of two indisputable facts suffices to invalidate Defendants' interference with HCQ. First, this medication is extremely safe, as proven by a successful track record of more than 75 years. Defendants do not and cannot deny this. HCQ is safer than many medications which are directly available to the public without even the requirement of a prescription, such as Tylenol and bronchodilators.

BMJ __ (May 6, 2020) (forthcoming 2020). The revocation also cites the joint U.K. National Institute for Health Research and Oxford University RECOVERY study, which similarly focuses on hospitalized patients for whom a prophylactic or early treatment is too late.

As quoted by National Public Radio, the expert Dr. Jon Giles, an epidemiologist and rheumatologist at Columbia University Department of Medicine, emphasized the safety of HCQ:

> "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."[3]

Many other experts have stated likewise, and the federal Centers for Disease Prevention and Cure (CDC) even implies as much on its official website.[4]

Second, in treating viruses such as COVID-19, it is clearly more effective to treat them *early* or prophylactically. This fundamental principle is true for the flu and other viruses. As explained by experts in a recent article published by the *New York Times*:

> *Acting before or very soon after an infection is the best way to handle most acute viral diseases*. Why aren't we focusing on that with Covid-19? … [W]e believe that trials of prophylactic and therapeutic drugs for asymptomatic and mild cases of Covid-19 have a greater chance of success than does administering drugs to critically ill patients – as well as greater long-term potential to benefit more people overall.

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[3] Will Stone, *Politics Around Hydroxychloroquine Hamper Science*, National Public Radio (May 21, 2020); *see also* Compl. ¶ 46 & n.10 (PageID.11-12) (linking to same).

[4] CDC, Medicines for the Prevention of Malaria While Traveling Hydroxychloroquine (Plaquenil™) (Exh. 12); *see also* Compl. ¶ 48 (PageID.12) (linking to same).

Richard Malley and Marc Lipsitch, *Acting before or very soon after an infection is the best way to handle most acute viral diseases. Why aren't we focusing on that with Covid-19?* N.Y. TIMES (May 23, 2020) (emphasis added). Similarly, an eminent Professor of Epidemiology in the Department of Epidemiology and Public Health at the Yale School of Public Health and Yale School of Medicine, Harvey A. Risch, recently stated likewise in a peer-reviewed medical journal:

> An outpatient treatment that prevents hospitalization is desperately needed [for COVID-19]. … *These medications need to be widely available and promoted immediately for physicians*.

Harvey A Risch, Early Outpatient Treatment of Symptomatic, High-Risk Covid-19 Patients That Should Be Ramped-Up Immediately as Key to the Pandemic Crisis, __ AM. J. EPIDEMIOLOGY __ (May 27, 2020) (forthcoming 2020) (emphasis added);[5] *see also* Lee DeVito, Henry Ford Health System still moving forward with hydroxychloroquine study, DETROIT METRO TIMES (Jun 16, 2020) ("'We have analyzed our data and have seen a significantly improved outcome in a group of COVID-19 patients who received hydroxychloroquine,' Dr. Steven Kalkanis, CEO of the Henry Ford Medical Group, told Metro Times in a statement on [June 15].").[6]

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[5] https://academic.oup.com/aje/advance-article/doi/10.1093/aje/kwaa093/5847586 (viewed June 22, 2020); Compl. ¶ 44 & n.8 (PageID.11) (linking to same).

[6] As Dr. Steven Kalkanis explained, his "'ongoing WHIP COVID-19 study is an FDA-approved study looking at hydroxychloroquine as a *potential preventative medication for healthy, pre-screened individuals*.'" *Id.* (emphasis added).

The British Broadcasting Corporation (BBC) reported on the success of Turkey in keeping its mortality low from COVID-19:

> Chief doctor Nurettin Yiyit … says *it's key to use hydroxychloroquine early*. "Other countries are using this drug too late," he says, "especially the United States. We only use it at the beginning. We have no hesitation about this drug. We believe it's effective because we get the results."

Orla Guerin, Coronavirus: How Turkey took control of Covid-19 emergency, BBC News (May 29, 2020) (emphasis added).[7]

When someone is possibly exposed to the flu, then he may obtain the anti-viral medication Tamiflu which is to be taken *within the first 24 or 48 hours of exposure* or contracting the virus:

> Take this medication as soon as flu symptoms appear or as soon as possible after you have been exposed to the flu. Oseltamivir works best if you start taking it within 2 days of either of these events.[8]

But when an American is potentially exposed to COVID-19, he has been forced to wait until he is hospitalized and even then cannot obtain the anti-viral medication HCQ unless a clinical trial is unavailable to him. (In clinical trials, half of the

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[7] https://www.bbc.com/news/world-europe-52831017# (viewed June 22, 2020); Compl. ¶ 45 & n.9 (PageID.11) (linking to same).

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

participants receive a placebo and thus do not receive the desired medication.)

The infringement on constitutional rights by Defendants' irrational interference with access to a safe medication is breathtaking. Tens of thousands of elderly in nursing homes have died without ever receiving HCQ. Denied timely access to medication, Americans are afraid to attend gatherings, including AAPS's annual conference and political gatherings, lest they contract COVID-19 without protection by prophylaxis or early treatment. The lack of equal access to this medication, which world leaders are taking as a prophylaxis while most members of the public have been denied access to it, is unconstitutional. In addition, Defendants' arbitrary actions violated the Administrative Procedure Act.

Just as many lawsuits have challenged federal agency actions for allegedly being unjustified in *implementing* a new policy by President Trump, a plaintiff may also challenge an agency action for being unjustified in *interfering with* a policy position taken by President Trump. Plaintiff seeks a preliminary injunction here against Defendants for obstructing access to HCQ in an arbitrary, irrational, and unjustified way, to the detriment of Plaintiff, its members, and the American public.

THE PARTIES

Plaintiff AAPS was founded in 1943 and is a nonprofit membership organization of physicians in virtually all specialties. AAPS is incorporated under the laws of Indiana and headquartered at 1601 N. Tucson Blvd., Suite 9, in Tucson,

Arizona. AAPS membership includes physicians practicing in this Western District of Michigan. Members of AAPS, including at least one in this district, have been and continue to be harmed irreparably by the FDA's restrictions on HCQ. 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. Declaration of Jeremy Snavely ("Snavely Decl.") ¶¶ 3, 31 (Exh. 2).

Defendant Department of Health & Human Services (HHS) is a federal executive agency. Defendants Food and Drug Administration (FDA) and Biomedical Advanced Research & Development Authority (BARDA) are constituent agencies within HHS.

Defendant Stephen M. Hahn is the Commissioner of Food & Drugs, who is the lead officer within the FDA.

Defendant Gary L. Disbrow is BARDA's Acting Director, who is the lead officer within BARDA.

Defendant Alex Azar is the Secretary of Health & Human Services, who is the lead officer within HHS.

STANDARD OF REVIEW

Plaintiff seeks preliminary injunctive relief to prevent irreparable harm to it and its members, and to reduce potentially avoidable deaths caused by the arbitrary

and irrational actions by Defendants. A court must consider four factors in deciding a motion for a preliminary injunction: "'(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) (collectively, the "*Schimmel-Winter* factors"). "[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).

Although some circuits distinguish between "mandatory preliminary injunctive relief that requires the non-moving party to undertake affirmative action [and] prohibitory injunctive relief that simply preserves the status quo," this Circuit rejects that division. *United Food & Commer. Workers Union, Local 1099 v. Sw. Ohio Reg'l Transit Auth.*, 163 F.3d 341, 348 (6th Cir. 1998). Accordingly, courts in this Circuit evaluate both types of interim relief under the same analysis:

> [W]e reject the Tenth Circuit's "heavy and compelling" standard and hold that the traditional preliminary injunctive standard – the balancing of equities – applies to motions for mandatory preliminary injunctive relief as well as motions for prohibitory preliminary injunctive relief.

Id. As shown below, all four factors point strongly in favor of granting a preliminary injunction here.

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]"). FDA has expressly recognized the freedom that physicians possess to prescribe approved drugs off-label: "[O]nce 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).

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, 10 (Exh. 1). Off-label use of prescription drugs accounts for a significant percentage of all prescriptions. *Id.* ¶ 6. Many off-label uses

have become the standard of medical care.[9] For generic medication such as HCQ, on which any patent rights have long since expired, 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 (Exh. 1).

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

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[9] 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).

> 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 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).

Section 1557 of the Affordable Care Act prohibits discrimination in health

programs and activities by not only recipients of federal funds but also federal agencies:

> [A]n individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 …, the Age Discrimination Act of 1975 …, or section 504 of the Rehabilitation Act of 1973 …, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title[.]

42 U.S.C. § 18116(a). The entity Defendants – HHS, FDA, and BARDA – are "Executive Agencies" within the meaning of Section 1557 of the Affordable Care Act, and the SNS is a "health program or activity" within the meaning of that section.

As relevant here, 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 directs 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).

STATEMENT OF FACTS

Today federal bureaucrats working within the Trump Administration have

brazenly criticized him, and arbitrarily interfered with his policies. When obstructionist individuals within a federal agency violate the constitutional and statutory rights of Americans, then there is a valid cause of action in federal court to stop the violations.

Rick Bright, Ph.D., is a bureaucrat in Washington, D.C., who has outspokenly criticized our president in connection with the coronavirus. Bright publicly takes credit for inserting debilitating impediments to public access to hydroxychloroquine (HCQ) after this medication was praised by President Trump. Bright and his ideological allies employed by Defendant agencies inserted these arbitrary and unconstitutional obstacles to public access as follows.

Defiance of President Trump by Defendants.

Bright was the Director at BARDA as appointed by the president, Barack Obama. Bright strongly favors vaccination for COVID-19, even though no such vaccine is available, and some experts doubt the feasibility of developing a timely vaccine for this novel virus. C.J. Robles, *HIV Scientist Doubts Coronavirus Vaccine; Claims Social Distancing is Better to Fight COVID-19*, TECH TIMES (May 20, 2020).[10] Bright has at all relevant times unjustifiably opposed making HCQ widely

[10] https://www.techtimes.com/articles/249779/20200520/hiv-scientist-doubts-coronavirus-vaccine-claims-social-distancing-is-better-to-fight-covid-19.htm (viewed June 22, 2020).

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).[11]

Bright and agency officials working with him have been biased by their opposition to President Trump and their support of rival treatments other than HCQ, such as remdesivir as advocated by Bright and vaccination as sought by others. Specifically, Bright favors an expensive, proprietary antiviral medication developed by Gilead Sciences ("Gilead"). Bright formed the following pre-conceived opinion in favor of Gilead which should have caused his recusal from the decision-making process about HCQ:

> Gilead's supply of the drug [*i.e.*, remdesivir] was low – it had only a few thousand doses of the drug on hand and the timeline to manufacture more was lengthy. *[Bright] repeatedly advised Dr. Kadlec and other HHS officials of the urgent need to acquire the existing doses and to secure future doses as they were produced*. He also strongly recommended that HHS work with Gilead to "on-shore" all steps of the Remdesivir supply chain to ensure an uninterrupted supply in the United States.

Addendum to the Complaint of Prohibited Personnel Practice and Other Prohibited Activity by the Department of Health and Human Services Submitted by Dr. Rick

[11] https://www.statnews.com/2020/04/24/why-rick-bright-involved-hydroxychloroquine/ (viewed June 22, 2020).

Bright, at 22-23 (2020) (Exh. 5).[12]

According to a whistleblower complaint against the Trump Administration submitted by Bright, FDA Director of the Center for Drug Evaluation and Research Janet Woodcock also played a pivotal role in pushing for restrictions on HCQ access. *Id.* at 43. 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).[13] 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.*

The Emergency Use Authorization.

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

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[12] *See* Compl. ¶ 59 & n.17 (PageID.14) (emphasis added) (Bright's complaint is attached as Exh. 5 hereto); the source of this and the other documentary exhibits are attested to by Exh. 3.

[13] 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 22, 2020).

limited use of HCQ from the SNS 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 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) (Exh. 6).

These restrictions 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 days to receive). These restrictions also denied access to HCQ by non-hospitalized patients (such as nursing home residents and patients who visit physicians' offices), and even denied or restricted access to hospitalized patients for whom clinical trials are available.

The EUA indicated that its statutory criteria were met with respect to the existence of an emergency for the COVID-19 pandemic under 21 U.S.C. § 360bbb-3(b), that the COVID-19 virus can cause serious or life-threatening diseases or conditions under § 360bbb-3(c)(1), that HCQ is or may be effective in treating or

preventing the COVID-19 virus under § 360bbb-3(c)(2)(A)(i), and that there is no adequate, approved, and available alternative to HCQ under § 360bbb-3(c)(3).[14]

Defendants cannot credibly invoke any perceived scarcity of HCQ as a basis for rationing access to HCQ, given how the SNS could be readily replenished if the stockpile were actually used. *See infra* note 20. Moreover, the donated nearly 100 million doses of HCQ are degrading and losing their effectiveness, particularly amid the summer heat such that they will need to be discarded if not used. Orient Decl. ¶ 31 (Exh. 1).

Defendants' limitations prevent the use of HCQ as a prophylaxis, as President Trump and other world leaders have been using it. Defendants have also prevented nursing home residents from receiving it, 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).[15]

In dispute is whether the debilitating restrictions in the EUA's "Scope of

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[14] The Secretary of Defense did not request the EUA and thus the criteria of 21 U.S.C. § 360bbb-3(c)(4) are not germane here. Defendants have not promulgated additional regulatory criteria pursuant to 21 U.S.C. § 360bbb-3(c)(5), and thus it adds no additional criteria for the issuance or revocation of an EUA.

[15] https://www.theguardian.com/us-news/2020/may/11/nursing-homes-us-data-coronavirus (viewed June 22, 2020).

Authorization" are necessary under § 360bbb-3(c)(2)(A) by prohibiting access to HCQ by patients who are not "hospitalized with COVID-19 for whom a clinical trial is not available." Defendants gave two rationales for these restrictions in the EUA: (1) "The safety profile of these drugs has only been studied for FDA approved indications, not COVID-19;" and (2) "FDA encourages the conduct and participation in randomized controlled clinical trials that may produce evidence concerning the effectiveness of these products in treating COVID-19." EUA, at 2 (Exh. 6).

Never in the history of the United States has an "emergency *use* authorization" been issued to *restrict the use* of a long-established, safe medication, and Defendants have no rational basis for so restricting HCQ. Defendants' limitations on the use of the long-approved medications are outside the scope of any statutory authorization.

Multiple studies suggest that HCQ is more effective if used early in the progression of COVID-19, *see* Jane Orient, M.D., Declaration ("Orient Decl.") ¶¶ 15-20 (Exh. 1), as other antiviral medication like oseltamivir (Tamiflu®) is, and Defendants' blanket federal limitations on HCQ use and access are arbitrary, irrational, and unjustified in interfering with early treatment by HCQ.

Defendants' Expansion of the Restrictions by Revoking the EUA

Without advance notice or public comment, on June 15, 2020 Defendants abruptly revoked the EUA and improperly expanded its restrictions on HCQ to

prohibit virtually all use of HCQ from the SNS for treating COVID-19. (Exh. 4) Whereas this lawsuit initially challenged the legality of the restrictions in the EUA concerning the use of HCQ for COVID-19, Defendants' surprising reversal of themselves – their revocation of the EUA – *expanded* those restrictions on access to HCQ. Defendants even published statements purporting to ban virtually all use of HCQ for COVID-19, which are unjustified and subject to review in this case.

Although Defendants' revocation ostensibly applies only to revoking use of stockpiled HCQ to treat hospitalized COVID-19 patients, Defendants' supporting materials include blanket statements that HCQ is not efficacious against COVID-19 generally (i.e., including for prophylactic and early-treatment uses). *See* Frequently Asked Questions on the Revocation of the Emergency Use Authorization for Hydroxychloroquine Sulfate and Chloroquine Phosphate, at 2 (June 16, 2020) ("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.") (Exh. 7); ASPR's Portfolio of Investigational Medical Countermeasures being used to treat COVID-19 (as Issued by Defendant HHS on June 16, 2020) ("Now, hydroxychloroquine sulfate and chloroquine phosphate can only be used for the treatment of COVID-19 as part of an ongoing clinical trial.") (Exh. 8).

Defendants lack credible support for their disparaging statements against HCQ's efficacy for prophylactic and early-treatment uses. Orient Decl. ¶¶ 15-20

(Exh. 1).

Reliance on the FDA Restrictions by State Officials

As is customary, state regulatory officials have imitated or relied upon the unjustified FDA policy. 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. 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);[16] *see also* Oregon Board of Pharmacy, Temporary Administrative Order Including Statement of Need & Justification, at 1 (June 15, 2020) (limiting HCQ prescriptions

[16] https://www.healthy.arkansas.gov/programs-services/topics/covid-19-guidance-about-chloroquine (Exh. 9).

to clinical studies, based on FDA's EUA actions) (Exh. 10). The Arkansas Department of Health's warning includes links to FDA's revocation and its "frequently-asked-questions" document quoted above. (Exh. 9, pp. 2-3) Defendants' false and disparaging statements about HCQ's efficacy are influential government documents that constitute substantial motivating factors for states to act against HCQ, and this Court could redress Plaintiff's injuries by vacating or compelling a withdrawal of those statements. *Tozzi v. HHS,* 271 F.3d 301, 310 (D.C. Cir. 2002).

The Federation of State Medical Boards ("FSMB") – which directs state medical boards that wield complete authority over licenses to practice medicine – relied on the EUA 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*.

Joint Statement of FSMB, NABP, NCSBN on Inappropriate Prescribing and Dispensing of Medications During the COVID-19 Pandemic (Exh. 11).

COVID-19

COVID-19 has reportedly caused the death of more than 120,000 Americans in merely a few months this year,[17] roughly half of whom have contracted and died from this disease in nursing homes. COVID-19 disproportionately impacts the elderly and those with pre-existing medical problems such as chronic lung disease, serious heart conditions, severe obesity, or chronic kidney disease undergoing dialysis. *See* CDC, Coronavirus Disease 2019 (COVID-19): Older Adults ("8 out of 10 deaths reported in the U.S. have been in adults 65 years old and older");[18] CDC, Coronavirus Disease 2019 (COVID-19): People Who Are at Higher Risk for Severe Illness;[19] *see also* note 15, *supra*. By denying elderly nursing-home patients access to HCQ when COVID-19 affects those patients more severely than younger patients, the Defendants' restrictions disparately impact the elderly.

Pharmaceutical companies donated up to 100 million doses of hydroxychloroquine (HCQ) – enough to fully treat more than 10 million people – to the federal government for immediate use in treating COVID-19, and as part of their

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[17] https://www.worldometers.info/coronavirus/country/us (viewed June 21, 2020).

[18] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html (viewed June 22, 2020).

[19] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html (viewed June 22, 2020).

efforts for the "prevention and treatment of the coronavirus outbreak." PhRMA, Member Company Efforts to Combat Coronavirus Outbreak.[20] Most of these donated doses of HCQ have not been distributed to the public and are in danger of being wasted as time and the opportunity to use them passes.

Multiple foreign governments, including China, India,[21] South Korea, Costa Rica, United Arab Emirates, and Turkey, successfully recommend use of HCQ for effective early treatment of COVID-19, and for use as a prophylaxis for the disease. Studies confirm the effectiveness of HCQ as an early treatment of COVID-19. Orient Decl. ¶¶ 15-20 (Exh. 1). There are no proper peer-reviewed or meritorious studies showing a lack of HCQ safety for COVID-19 patients. *Lancet*, a once-prestigious British medical journal, misled the public by publishing a study disparaging HCQ; after receiving criticism *Lancet* then embarrassingly retracted the study because it relied on unsound data. Other retrospective studies cited in the media to the contrary are too flawed to inform rational decision-making because they compare outcomes without involving similar patient populations (e.g., the HCQ patients may have been more sick than the non-HCQ patients or may have come

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[20] https://phrma.org/en/Coronavirus/PhRMA-Member-Efforts (viewed June 22, 2020).

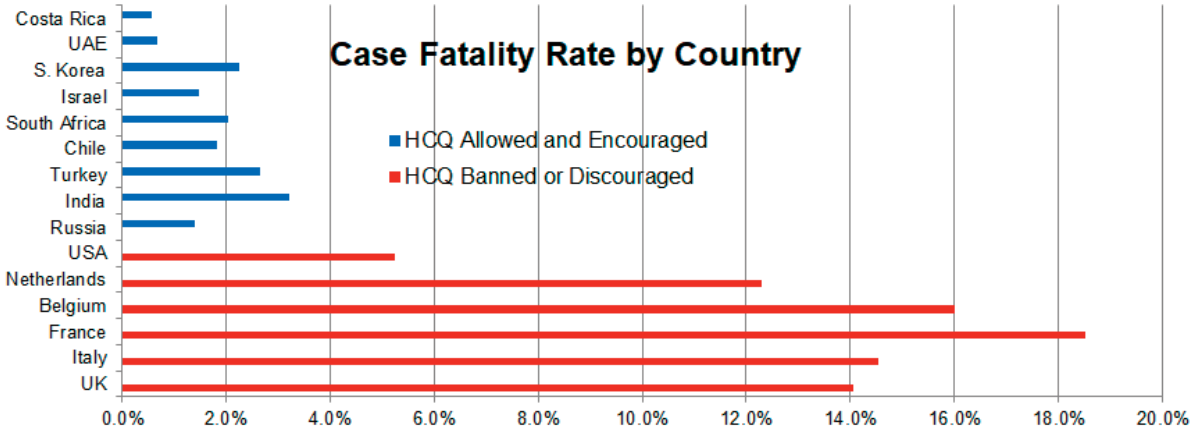
[21] Himani Chandna, *HCQ breakthrough: ICMR finds it's effective in preventing coronavirus, expands its use*, THE PRINT (May 22, 2020) (available at https://theprint.in/health/hcq-breakthro...se/427583/) (viewed June 22, 2020).

from geographic areas with more acute exposures, which would explain higher rates of negative outcomes without showing in any way that HCQ caused or contributed to those outcomes).

There is a dramatic difference in saving lives in countries allowing early and prophylactic use of hydroxychloroquine compared with the United States:

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%	370
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

Snavely Decl. ¶ 28 (Exh. 2). The following chart graphically shows HCQ's beneficial impact in reducing mortality from COVID-19:



Id. ¶ 29.

In addition, more than 25 articles since 1982 published 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.

The President of El Salvador, Nayib Bukele, announced that he is taking hydroxychloroquine as a prophylaxis 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).[22]

On May 31, 2020, the United States and Brazil issued a joint statement

[22] https://www.cnn.com/2020/05/27/americas/salvador-president-coronavirus-hydroxychloroquine-intl/index.html (viewed June 22, 2020).

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).[23] Thus, for an American citizen to obtain HCQ as a prophylaxis, he would need to travel to Brazil where it is using doses of HCQ from the federal SNS as a prophylaxis there. Defendants' arbitrary actions prevent Plaintiff and Americans from obtaining the same HCQ from the federal SNS to which Brazilians have been granted access by the White House.

HCQ's Early Effectiveness Repeatedly Demonstrated.

Almost daily a new study is reported which demonstrates the effectiveness of HCQ for treating COVID-19 *if used early*, as other anti-viral medications are. Yet

[23] https://www.whitehouse.gov/briefings-statements/joint-statement-united-states-america-federative-republic-brazil-regarding-health-cooperation/ (viewed June 22, 2020).

Defendants' statements and restrictions continue to interfere with early use.

In an article dated June 12, 2020, Dr. Raja Bhattacharya, MD, *et al.* explain that HCQ is effective as a prophylaxis 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. 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).[24]

Similarly, on June 13, the Indian Ministry of Health stated as part of its clinical management protocol for COVID-19 to use hydroxychloroquine early:

> As is the case with other antivirals, this drug should be used as early in the disease course as possible to achieve any meaningful effects and should be avoided in patients with severe disease.

Government of India, Ministry of Health and Family Welfare, Directorate General of Health Services, Clinical Management Protocol: COVID-19, at 18 (Version 3 June 13, 2020).[25]

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[24] https://www.medrxiv.org/content/10.1101/2020.06.09.20116806v1.full.pdf (viewed June 22, 2020).

[25] https://www.mohfw.gov.in/pdf/ClinicalManagementProtocolforCOVID19.pdf (viewed June 22, 2020).

Injury to Plaintiff

Defendant FDA's unlawful action has caused injury to a physician member of Plaintiff AAPS ("Dr. John Doe"). Snavely Decl. ¶ 7 (Exh. 2). 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.

Dr. John Doe practices within the Western District of Michigan. *Id.* ¶ 7. 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.

Numerous physician members of AAPS, including Dr. John Doe, reasonably fear retaliation against them by state medical boards based on Defendants' irrational restrictions on HCQ along with their incorporation into the directive made to state medical boards by the FSMB. *Id.* ¶ 8.

Disparate Impact of FDA Policy on Gatherings.

Access to 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 (Exh. 1)

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*,[26] 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, has been adversely impacted by the inability of members and potential attendees to have access to prophylactic and early treatment of COVID-19. Snavely Decl. ¶¶ 24-27 (Exh. 2). Restricting and denying access to prophylactic and early treatment by HCQ has a negative effect on attendance at gatherings, which AAPS members and their patients have a constitutional right to attend.

ARGUMENT

The Due Process Clause of the Fifth Amendment includes an equal-protection component that is coextensive with the equal-protection guarantees of the Equal Protection Clause of the Fourteenth Amendment. *Buckley v. Valeo,* 424 U.S. 1, 93 (1976); *Bolling v. Sharpe,* 347 U.S. 497, 499 (1954). At a minimum, under those equal protection guarantees, the government cannot treat similarly situated groups or persons differently without a rational basis for doing so. Associative rights are also at stake here, as access to a prophylaxis has the effect of preventing people from congregating at the AAPS annual meeting, national political conventions, and even

[26] https://www.pewforum.org/religious-landscape-study/attendance-at-religious-services/ (viewed June 22, 2020).

religious services.

I. PLAINTIFF HAS A STRONG LIKELIHOOD OF SUCCESS ON THE MERITS.

The first – and most important – *Schimmel-Winter* factor is the likelihood of movants' prevailing. *Winter,* 555 U.S. at 20. The following three subsections discuss Plaintiff's strong likelihood of prevailing on each of the complaint's three counts (namely, the APA, the equal protection component of the Due Process Clause, and the First Amendment).

This Court's consideration of constitutional issues is necessary here because a common APA remedy is *vacatur*: "If an appellant … prevails on its APA claim, it is entitled to relief under that statute, which normally will be a vacatur of the agency's order." *American Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001). By contrast, for equal-protection violations, the Court has more flexibility. *Heckler v. Mathews,* 465 U.S. 728, 740 (1984) (either "withdrawal of benefits from the favored class" or "extension of benefits to the excluded class" will remedy equal-protection violations). Plaintiff respectfully submits that this Court should expand access to those unconstitutionally denied access to HCQ rather than allow Defendants to unjustifiably restrict access by everyone to a demonstrably safe, inexpensive medication.

A. Plaintiff is likely to prevail on its APA claim.

As Plaintiff argues in the subsections I.A.2-I.A.4, *infra*, Plaintiff is likely to

prevail on the APA merits on three distinct bases: (1) Defendants acted arbitrarily, (2) Defendants exceeded their authority, and (3) Defendants acted unconstitutionally. Because the relief sought here is urgent – literally, life or death, in some instances – a preliminary injunction is necessary immediately.

Defendants issued their restrictive EUA based on a mixture of improper motives, including a desire to thwart efforts by President Trump to respond to the COVID-19 pandemic and a preference for a rival treatment – remdesivir – that involved financial and other conflicts of interest. When faced with this lawsuit challenging their EUA action and this Complaint that extensively documents the benefits of HCQ as both a prophylaxis and an early treatment for COVID-19, *see* Compl. ¶¶ 39-50 (PageID.9-15), Defendants abruptly revoked their EUA for hospitalized patients without considering the issues that the complaint raises on the need to *expand* access for prophylactic and early-treatment uses of HCQ. In both the initial EUA and its revocation, Defendants acted improperly without good faith.

In APA actions, the reviewing court generally focuses on the administrative record before the agency, *Camp v. Pitts*, 411 U.S. 138, 142 (1973), but courts can go outside that record – even allowing depositions – on a showing of bad faith or improper behavior by the agency. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420 (1971). In deciding when to supplement the agency's proposed record, a court is "not required to exhibit a naiveté from which ordinary citizens are free."

Dep't of Commerce v. New York, 139 S.Ct. 2551, 2575 (2019) (internal quotations omitted). Given the series of irrational actions compounded by conflicts of interest, Plaintiff will challenge the record that Defendants certify unless that record is complete.

1. Judicial review of Defendants' actions falls within the APA's waiver of sovereign immunity.

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 revocation of the EUA because both actions were "final agency action." As such, both actions are reviewable.

Finality has two prongs: (1) a consummated decision-making process, and (2) the agency action is "one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear,* 520 U.S. 154, 177-78 (1997) (interior quotations omitted). Both actions were consummated decisions, first to issue the EUA, then to revoke it. Moreover, legal consequences flowed from both actions. The EUA *allowed* access to stockpiled HCQ for hospitalized COVID-19 patients without access to clinical trials and denied access to all others. Revoking the EUA *denied* access to those patients and failed to consider expanding access to other types of uses (*i.e.*, prophylactic and early-treatment uses).

An agency's revocation of its own informal action is reviewable APA action

if the agency fails to consider relevant issues, *U.S. Dep't of Homeland Sec. v. Regents, Univ. of California*, 591 U.S. __ (June 18, 2020) (No. 18-587, Slip Op. at 2), and final agency action to revoke a prior final agency action is clearly reviewable. *See Greater Detroit Res. Recovery Auth. v. United States EPA*, 916 F.2d 317, 322 (6th Cir. 1990); *cf. Air Brake Sys. v. Mineta*, 357 F.3d 632, 644-45 (6th Cir. 2004). Because an agency's revocation of its own prior action is reviewable, revocation cannot moot review of the initial action in the way that a vacated judicial decision can terminate ongoing appeals. To the contrary, this Court could vacate the revocation if the Court finds that Defendants either acted on an arbitrary or improper basis or failed to consider alternate action.

2. Defendants' actions are arbitrary and capricious.

The APA authorizes a reviewing court to hold unlawful and set aside "agency action … arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Leaving aside the possibility that APA arbitrary-and-capricious review poses a *lower* bar to invalidate an agency action, it certainly does not pose a *higher* bar: "we can discern in the Commission's opinion a rational basis for its treatment of the evidence, and the 'arbitrary and capricious' test does not require more." *Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S.

281, 290 (1974).[27] So, while "[t]he standard of review – rational basis or arbitrary and capricious – is determined by statute," *Chemung Cty. v. Dole*, 781 F.2d 963, 971 (2d Cir. 1986) (*citing Overton Park*, 401 U.S. at 413), remarkably little hangs on which test applies. APA arbitrariness and capriciousness mirrors the lack of a rational basis under constitutional equal-protection analysis. *See* Section I.B, *infra*. For the reasons set forth in I.B, *infra*, Defendants' actions were "arbitrary, capricious, an abuse of discretion" within the meaning of the APA. *See* 5 U.S.C. § 706(2)(A).

In addition to the arbitrary and capricious nature of the EUA's restrictions and the revocation's preservation of those restrictions *vis-à-vis* access to stockpiled HCQ, Defendants' restrictions also violate Section 1557 of the Affordable Care Act ("ACA") by discriminating against the elderly in nursing homes. *See* 42 U.S.C. § 18116(a). In doing so, Defendants acted "not in accordance with law" within the meaning of the APA. *See* 5 U.S.C. § 706(2)(A). Specifically, ACA's Section 1557 allows disparate-impact claims to the same extent as the underlying statutory provision that a plaintiff invokes, *Doe v. BlueCross BlueShield of Tenn., Inc.*, 926 F.3d 235, 238-44 (6th Cir. 2019), and the Age Discrimination Act of 1975 allows

[27] Congress ratified this view by amending the APA in 1976, while leaving that issue unchanged. *Lorillard v. Pons*, 434 U.S. 575, 580 (1978) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change").

disparate-impact claims. *Smith v. City of Jackson*, 544 U.S. 228, 240 (2005). As relevant here, the denial of HCQ to non-hospitalized patients disparately impacts the elderly in nursing homes, who are at higher risk from COVID-19 than are other non-hospitalized patients. *See* notes 18-19, *supra*, and accompanying text. Accordingly, the EUA's restrictions violated Section 1557 and were not, therefore, in accordance with the law within the meaning of the APA. *See* 5 U.S.C. § 706(2)(A).

3. Defendants' actions exceed their statutory authority.

The APA authorizes a reviewing court to hold unlawful and set aside "agency action … in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). As explained in this section, Defendants lacked the statutory authority to condition use of HCQ on the unavailability of a controlled HCQ study.

As explained above, the Project Bioshield Act of 2004 added Section 564 to the FFDCA, which authorizes Defendants to issue EUAs. *See* 21 U.S.C. § 360bbb-3. Nothing in the Project Bioshield Act or Section 564 directly authorizes Defendants to limit access to stockpiled drugs based on the availability of a controlled study. A patient's need for the drug in an emergency should be the only relevant criterion under the laws that Congress enacted. While Section 564(c)(5) authorizes adoption of "such other criteria as the Secretary may by regulation prescribe," 21 U.S.C. § 360bbb-3(c)(5), the Secretary has not prescribed a

controlled-study criterion.

This Court will likely hold that the EUA's controlled-study criterion exceeded Defendants' statutory authority. That APA violation, moreover, is not trivial. For patients with access to controlled studies, the EUA's controlled-study criterion means that the patient may not get HCQ, because a controlled study involves dosing some patients with placebos. *See* Orient Decl. ¶ 27 (Exh. 1). Moreover, for treating physicians during a pandemic, Defendants' imposition of the need to check for a controlled study wastes medical resources on an unauthorized administrative requirement. For all these reasons, Defendants acted "in excess of statutory jurisdiction, authority, or limitations" within the meaning of the APA. *See* 5 U.S.C. § 706(2)(C).

4. Defendants' actions violate the Constitution.

The APA authorizes a reviewing court to hold unlawful and set aside "agency action … contrary to constitutional right [or] power." 5 U.S.C. § 706(2)(B). As explained in the next two subsections, the agency actions here violated not only the equal-protection component of the Fifth Amendment's Due Process Clause but also the First Amendment. "The power to interpret the Constitution … remains in the Judiciary," *City of Boerne v. Flores*, 521 U.S. 507, 524 (1997), and nothing in the APA protects federal defendants from judicial relief for constitutional violations. Accordingly, this Court need not await Defendants' certifying of an administrative

record and Plaintiff's dispute of that record before ruling on the constitutional issues.

B. Plaintiff is likely to prevail on its equal-protection claim.

Defendants' arbitrary restrictions on access to HCQ violate equal-protection rights guaranteed by the Fifth Amendment's Due Process Clause by discriminating based on a patient's hospitalization status, illness status, and access to a clinical trial, without a rational basis for that discrimination. The lack of a rational basis for the restrictions in the EUA, the continuation of those restrictions for distributed HCQ after the revocation of the EUA on June 15, and the continued hoarding of HCQ in the federal SNS, all add up to an equal protection violation. Physicians and patients are unable to obtain HCQ for prophylactic and early treatment purposes due to Defendants' actions, while world leaders and the celebrities enjoy immediate access to HCQ for those purposes. Defendants' interference with access thereby violate the Equal Protection Clause of the Constitution.

As indicated, Defendants gave two rationales for the EUA restrictions: HCQ's safety profile *vis-à-vis* COVID-19 and the FDA goal to encourage clinical trials. EUA, at 2 (Exh. 6). Both rationales are meritless under equal-protection analysis.

Defendants' first rationale is a strawman, because safety is determined with respect to patients, not diseases. HCQ has been proven to be safe for more than 65 years and has been fully approved by the FDA as safe since 1955. The EUA misled the public with its first rationale by falsely pretending that a medication approved as

safe for treating one disease can somehow not be safe for treating another disease. The EUA further misled the public with its first rationale by falsely implying that medication approved as safe for one use requires time-consuming additional studies of safety before it may properly be used to treat a new disease. In fact, the "safety profile" with respect to new uses of a medication previously approved by the FDA is virtually never studied, and there is no rational basis for delaying new uses of previously approved medication by requiring such studies.

With respect to patients with COVID-19 who are not hospitalized, the FFDCA, the Constitution's federalist structure, and the presumption against preemption all suggest that Congress did not intend Defendants to supersede a prescribing medical professional's judgment for off-label uses of FDA-approved drugs for patients. With respect to patients not infected with COVID-19 for whom HCQ is prescribed or sought for HCQ's prophylactic effect, EUA's stated safety concern about HCQ's effect on patients *infected with* COVID-19 never made any sense with respect to patients *not infected with* COVID-19.

As to the EUA's seeking to push patients into clinical trials in lieu of having their medical professional prescribe the drug, Defendants lack the authority to limit access that way and the restriction is absurd and irrational. Significantly, many who participate in a "randomized controlled clinical trial" do not even receive the drug in question. The very essence of a clinical trial is to give half the participants a

placebo, as a control group against which to compare the performance of the other half who receive the medication. Requiring people to participate in a clinical trial for the 50% chance they may receive HCQ is to deny half of the patients access to HCQ. There are ample doses of HCQ in the SNS, so this limitation cannot be justified based on any shortage of it. HCQ was approved as safe 65 years ago, so this restriction cannot be based on any safety concern. The medication is inexpensive, costing less than $1 per dose,[28] so this limitation cannot be based on cost. Like the hospitalization requirement, the restriction prohibiting use if a clinical trial is available is wholly irrational and unjustified. The EUA irrationally discriminated against those who would receive only a placebo, and not HCQ, in a clinical study arbitrarily required by the EUA.

The EUA discriminated against everyone who is outside of a hospital: residents of nursing homes, physicians who care for nursing home patients, physicians having office practices, and patients who are treated in connection with office visits. The discrimination against these millions of people threatens to cause the unnecessary death and unnecessary illness and thereby injures AAPS members and their patients.

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[28] 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).

There never was any rational basis for prohibiting the use of an anti-viral medication, such as HCQ, until *after* hospitalization as required by the EUA which continues to govern millions of doses distributed under the EUA. Defendants' restriction is contrary to fundamental principles of medical practice, whereby *early* treatment of viruses is most effective. Waiting until after someone is hospitalized before making medication available is akin to waiting until a jury is deliberating before hiring a good attorney. Such delay is illogical and irrational. Defendants thereby violate the Equal Protection Clause by imposing such an absurdity.

Indeed, hospitals even plan to return some of the HCQ they have received,[29] because the value of the medication is to keep patients out of hospitals, not to treat patients late in the course of the virus after they were hospitalized. Tamiflu, an anti-viral medication for the ordinary flu, is to be administered within the first 24 or 48 hours of exposure, which is outside of a hospital in most situations. Restricting Tamiflu to use by only hospitalized patients would be an absurdity. So is the restriction by Defendants that HCQ can be used from the SNS only for hospitalized patients.

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[29] D. Beasley, *Trump critical of FDA decision to revoke emergency use of drug he has promoted for COVID-19*, REUTERS (June 15, 2020), available at: https://www.reuters.com/article/us-health-coronavirus-hydroxychloroquine/u-s-fda-revokes-emergency-use-status-of-drug-touted-by-trump-for-covid-19-idUSKBN23M283 (viewed June 21, 2020).

These restrictions by Defendants on the use of HCQ are irrational and completely indefensible. Hence, they fail scrutiny under the Equal Protection Clause, and Plaintiff is likely to prevail on the merits.

C. Plaintiff is likely to prevail on its First Amendment claim.

Defendants' arbitrary restrictions on access to HCQ violate First Amendment associative rights by allowing such injuries to continue unnecessarily. Moreover, because Defendants intended to cause those injuries to continue, Defendants have caused the continued harms, even if Defendant did not cause the underlying pandemic.

The right to gather at political rallies, conferences, political conventions, and even religious services has been sharply limited by the unavailability to most Americans of a prophylactic against COVID-19. Whether this interference with gatherings is intentional or not, the effect of withholding a potential prophylaxis or early treatment against COVID-19 certainly has this chilling effect on gatherings, an undeniable First Amendment right. An arbitrary action which has a disparate impact on associative rights is unconstitutional, and thus Plaintiff is likely to prevail on the merits.

Here within the Sixth Circuit, there is a robust First Amendment right of association which requires strict scrutiny for neutral laws which infringe on that right. *See, e.g.*, *Johnson v. City of Cincinnati*, 310 F.3d 484, 487, 505-06 (6th Cir.

2002) (affirming the invalidation of a City of Cincinnati drug-exclusion ordinance in part because it infringed on First Amendment rights of association).

Participating in political rallies and conventions, holding national conferences, and attending religious services are unquestionably expressive associative activities which are fully protected by the First Amendment. As the Supreme Court held in explaining the constitutional right to freedom of association:

> An individual's freedom to speak, to worship, and to petition the government for the redress of grievances could not be vigorously protected from interference by the State unless a correlative freedom to engage in group effort toward those ends were not also guaranteed. According protection to collective effort on behalf of shared goals is especially important in preserving political and cultural diversity and in shielding dissident expression from suppression by the majority. Consequently, we have long understood as implicit in the right to engage in activities protected by the First Amendment a corresponding right to associate with others in pursuit of a wide variety of political, social, economic, educational, religious, and cultural ends.

Roberts v. United States Jaycees, 468 U.S. 609, 622 (1984) (citations omitted).

By denying the public access to an inexpensive, safe prophylaxis against a highly contagious virus, COVID-19, Defendants impede the ability of the public to congregate for political or religious reasons. Opponents of the reelection of President Trump have an incentive to obstruct wide distribution of HCQ, thereby thwarting Trump's campaign rallies.

If there is a compelling reason to deny people a medication they want before

congregating, then a government policy can still infringe on the right of association. But Defendants' withholding of HCQ in the SNS lacks a compelling basis, or even a rational one. The medication is degrading in the SNS and will need to be discarded due to the passage of time. If some tablets are stored in warm temperatures, which would not be surprising in summer months, then the degradation of that stockpile of HCQ is even quicker. Stated simply, Defendants do not have a compelling interest in hoarding the HCQ until it degrades or becomes untimely to distribute after the COVID-19 crisis eventually passes and many people have died.

Note that proof of effectiveness of HCQ as a prophylaxis is unnecessary to this freedom of association rights. A mere perception of effectiveness suffices to increase or decrease the confidence of people to congregate as before. Orient Decl. ¶¶ 15, 21, 40 (Exh. 1). It is not necessary to quantify the prophylactic effect of HCQ any more than it is necessary to quantify a chilling effect on another First Amendment right, that of free speech. At any rate, studies have shown effectiveness of HCQ as a prophylaxis, and President Trump and other world leaders have successfully taken the medication for that purpose. (Compl. ¶ 49, Compl. (PageID.12) citing *CNN*). HCQ has been used successfully as a prophylaxis for travelers to areas where malaria is prevalent. Orient Decl. ¶ 18 (Exh. 1).

For lack of a prophylaxis, AAPS had to cancel its spring meeting in St. Louis, and participation in its annual meeting in San Antonio is being severely hindered.

Snavely Decl. ¶¶ 22-27 (Exh. 2) The chilling effect on freedom of association imposed by Defendants' arbitrary withholding of HCQ is unconstitutional, and Plaintiff is likely to prevail on the merits of this claim.

Defendants cannot constitutionally infringe on the right of the people to gather for political, religious, or other purposes by denying public access to a safe medication which may be a prophylaxis against COVID-19. Plaintiff is likely to prevail on the merits to remove this arbitrary restriction on their access to HCQ.

II. THE REMAINING *SCHIMMEL-WINTER* FACTORS FAVOR PLAINTIFF.

Having established a likelihood of prevailing on the merits, Plaintiff now establishes that the remaining *Schimmel-Winter* factors point toward this Court's granting interim relief while this case proceeds to the merits. A preliminary injunction is needed – in the interim – because of the extreme risk that the COVID-19 pandemic poses to the public as well as to Plaintiff's members and their patients.

A. Plaintiff will suffer irreparable harm without an injunction.

The second *Schimmel-Winter* factor concerns the irreparable harm that a plaintiff would suffer, absent interim relied. *Winter,* 555 U.S. at 20. Plaintiff, its members, and their patients suffer infringements on their constitutional rights of equal protection and the First Amendment associative rights due to Defendants' arbitrary actions. Plaintiff is arbitrarily being denied access to HCQ as a prophylactic and early treatment against COVID-19, despite how this medication is available as

a prophylaxis to world leaders and as early treatment to those having connections to obtain it immediately.

"The Supreme Court has unequivocally admonished that even minimal infringement upon First Amendment values constitutes irreparable injury sufficient to justify injunctive relief." *Newsom v. Norris*, 888 F.2d 371, 378 (6th Cir. 1989) "[T]o the extent that [Plaintiff] can establish a substantial likelihood of success on the merits of its First Amendment claim, it also has established the possibility of irreparable harm as a result of the deprivation of the claimed [First Amendment] rights." *Connection Distrib. Co. v. Reno*, 154 F.3d 281, 288 (6th Cir. 1998).

B. <u>The balance of the equities tip in favor of an injunction.</u>

The third *Schimmel-Winter* factor – the balance of equities, *Winter,* 555 U.S. at 20 – tips in the Government's favor for two reasons. Under this factor, the harm to Plaintiff "should the preliminary injunction not be issued must be weighed against the harm to others from the granting of the injunction." *United Food & Commercial Workers Union*, 163 F.3d at 363. This balancing of the harm tilts strongly in favor of Plaintiff.

Defendants are currently wasting many millions of doses of HCQ, and Defendants will not suffer any harm if this Court orders them to stop wasting the donated stockpile. Plaintiff also suffers enormously from the continuation of the arbitrary restrictions by Defendants on access to HCQ. Plaintiff's physician

members are prevented from successfully prescribing HCQ as a prophylaxis or as early treatment for COVID-19, and Plaintiff's annual meeting is disrupted by the inability of its attendees to receive HCQ as a prophylaxis. The early access by President Trump, other world leaders, celebrities, and others having connections is denied to ordinary Americans to their detriment.[30] The requested preliminary injunction would reduce the harm while not causing any harm to Defendants.

C. The public interest favors an injunction.

The last *Schimmel-Winter* factor – the public interest, *Winter,* 555 U.S. at 20 – also favors Plaintiff: "it is always in the public interest to prevent the violation of a party's constitutional rights." *G & V Lounge, Inc. v. Michigan Liquor Control Comm'n,* 23 F.3d 1071, 1079 (6th Cir. 1994); *Washington v. Reno*, 35 F.3d 1093, 1103 (6th Cir. 1994) (recognizing the "greater public interest in having governmental agencies abide by the federal laws that govern their existence and operations"). Removing arbitrary restrictions on public access to safe, potentially life-saving medication is also in the public interest. More than 120,000 Americans have reportedly died from COVID-19, as cited above. Enjoining interference by

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[30] *See*, *e.g.*, P. Sblendorio, *Daniel Dae Kim believes malaria drug was the 'secret weapon' in his coronavirus recovery*, N.Y. DAILY NEWS (Mar. 22, 2020) (describing how a famous television actor obtained early treatment by HCQ and attributes his recovery to it) (available at: https://www.nydailynews.com/coronavirus/ny-coronavirus-daniel-dae-kim-20200322-m3twpzcgvbgitnyww66uhokwtq-story.html (viewed June 22, 2020)).

Defendants to early access to an inexpensive anti-viral medication, which reportedly has been successful if used early, advances the interest of the public.

Finally, it is hardly in the public interest for Defendants to waste nearly 100 million doses of donated HCQ, which will occur if the injunctive relief is denied. The effectiveness of medication declines over time to the point where eventually the medication must be discarded. In addition, the pandemic will ultimately pass before these doses are used, in the absence of a preliminary injunction, and untimely access to the many millions of HCQ tablets would be as arbitrary and wasteful as simply throwing them out now.

CONCLUSION

For the foregoing reasons, this Court should enter the preliminary injunction against Defendants as requested by Plaintiff to broaden meaningful public access to HCQ pending the final resolution of this litigation.

Dated: June 22, 2020

Respectfully submitted,

/s/ Lawrence J. Joseph

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CERTIFICATE OF COMPLIANCE

This memorandum complies with the word limit of Local Civil Rule 7.2(b)(i) because – excluding the parts exempted by that rule – the memorandum contains 10,676 words. The word count was generated using Microsoft Word 2016.

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CERTIFICATE OF CONCURRENCE

Pursuant to Local Civil Rule 7.1(d), the parties' counsel conferred by telephone on June 19, 2020, and the defendants will oppose the plaintiff's motion for interim relief and cross move to dismiss.

Dated: June 22, 2020

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