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)

REPLY IN SUPPORT OF 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 replies in support of its emergency motion for injunctive relief (Doc. 8) to compel Appellees-Defendants to release the hydroxychloroquine ("HCQ") that they withhold and waste in the Strategic National Stockpile (the "HCQ Stockpile").

Introduction

Defendants have it backwards. They care more about their power over the HCQ Stockpile than the lives being lost daily without access to it: "the injunction plaintiff seeks would irreversibly overturn the status quo, by compelling the government to disburse the hydroxychloroquine in the Stockpile—a step that, once taken, cannot be undone." (Defs. Opp. 12) It is the loss of life that "cannot be undone," while pills in a stockpile can be easily replenished by Defendants.

Defendants tacitly concede the following in their opposition brief:

(1) Defendants withhold and block access to the HCQ Stockpile of more than 60 million doses, which was donated to treat COVID-19;

(2) Experts, including Yale Professor Dr. Harvey Risch, observe that release of the HCQ Stockpile could save 50,000-100,000 American lives;

(3) HCQ has been approved as safe by the FDA and used safely since 1955, and the CDC officially declares HCQ to be safe today;

(4) President Trump safely used HCQ as a prophylactic against COVID-19, but AAPS members and their patients are obstructed in prophylactic and early access to HCQ;

(5) Foreign countries have kept their mortality rates far lower – sometimes

90% lower – than the United States' rate, by encouraging use of HCQ;

(6) Treating COVID-19, like treating the flu, requires taking medication as early as possible in the exposure to or progression of the disease; and

(7) Defendants defiantly refuse to concede authority even to President Trump to release the HCQ Stockpile.

Under Defendants' arguments, they can withhold more than 60 million doses of HCQ while Americans die without early treatment, and there is absolutely nothing a U.S. Court of Appeals can do about such an atrocity. That is not the law.

Reply to Defendants' Misleading Factual Assertions

Defendants mislead this Court as they have misled the public:

Defendants' Misleading Statement:

- "Hydroxychloroquine is FDA approved to treat certain diseases, but not to treat or prevent COVID-19." (Defs. Opp. 6)

Correction:

The FDA almost ***never*** approves medication for additional treatments once it is approved, as HCQ was in 1955. Today many prescriptions are for uses never approved by the FDA, because once a medication is approved for one use there is no reason to incur expense to obtain approval for another use. (Declaration by Jane Orient, M.D., dated June 22, 2020 ("Orient Decl.") ¶¶ 6-11, R. 9-1, PageID ##346-47). Additional uses are for physicians, not the FDA, to decide.

Defendants' Misleading Statement:

- "FDA carefully reviewed the available scientific data and determined that

> hydroxychloroquine is unlikely to be effective in treating COVID-19 patients and that the use of the drug for that purpose has potentially serious adverse side effects." (Defs. Opp. 24)

Correction:

Hydroxychloroquine cannot be dangerous as a prophylactic for COVID-19 while the CDC officially declares it as safe and promotes its use as a prophylactic for malaria. (Mot. 20 & n.17, which Defendants do not contest) The side effects would be the same whether HCQ is used prophylactically for malaria, which is encouraged by the CDC, or for COVID-19, which Defendants irrationally block.

HCQ requires a prescription by a physician who, as with any prescribed medication, makes a determination of whether the benefits outweigh the risks. That is not for the FDA to block after it approves a medication. If an American wants to take HCQ in order to attend a religious service, football game, AAPS conference, or political gathering, then that is a decision for each American to make in consultation with his physician without FDA interference. Americans have a right to access the same medication, which is recommended by the CDC if they travel to Africa, in order to assemble or vote in-person in an election.

As former Stanford University Medical Center Professor Dr. Scott Atlas recently observed:

> "***Hydroxychloroquine is super safe***. … It's been used for 65 or 70 years …. ***Very safe drug***."

Valerie Richardson, "Hydroxychloroquine 'very safe,' says Dr. Scott Atlas; blasts 'garbage' medical studies" WASHINGTON TIMES (Aug. 29, 2020) (emphasis added).[1] AAPS's requested relief would open up much-needed access to the HCQ Stockpile for prescription-based access. (Declaration of Jeremy Snavely dated June 22, 2020, ¶ 16, R. 9-2, PageID #357)

Reply Argument

In this time-sensitive matter affecting 100,000 lives, Defendants' reliance on hyper-technical procedural objections are misplaced and unjustified. During the ten days that Defendants took to file their mostly non-substantive opposition brief, roughly another 10,000 Americans died without timely access to HCQ.

Defendants rely on a chambers opinion by then-Justice Rehnquist based on Supreme Court Rules, which of course do not apply here in the Sixth Circuit. *Compare Communist Party of Ind. v. Whitcomb*, 409 U.S. 1235, 1235 (1972) (Rehnquist, J., in chambers) *with A. Philip Randolph Inst. v. Husted*, 907 F.3d 913, 918 (6th Cir. 2018) ("Rules of the Supreme Court, which of course do not bind this Court"). *See also S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613 (2020) (Roberts, C.J., concurring in denial of application without any other justice joining his concurrence) (quoted by Defs. Opp. 25) Notably, the latter

[1] https://www.washingtontimes.com/news/2020/aug/29/hydroxychloroquine-uproar-shows-objective-science-/ (viewed Sept. 1, 2020).

concurrence by Chief Justice Roberts expressly depends on "politically accountable officials." *Id.* Here, Defendants are defying President Trump, so the argument for political accountability supports the relief sought by AAPS to overcome the ***lack*** of political accountability by Defendants.

I. AAPS Has Standing.

Instead of trying to defend the indefensible, Defendants seek to dodge review here. Defendants argue that AAPS as an association of physicians somehow lacks standing to obtain judicial review about access to HCQ. But AAPS's requested relief, if granted, would open up immediate access to HCQ at pharmacies by virtue of the requested release from the HCQ Stockpile. Currently AAPS members cannot successfully prescribe HCQ, as those prescriptions are not filled for preventive or early treatment of COVID-19. (Mot. 7, citing two declarations)[2] But if this Court orders Defendants to release the HCQ Stockpile to pharmacies which promise to fill those prescriptions, as AAPS seeks, then those prescriptions by AAPS members will be filled. Millions of Americans could then choose to take HCQ as preventive medication to attend religious services, AAPS

[2] Defendants argue that nine out of eleven ***manufacturers*** have HCQ on hand (Defs. Opp. 17), but AAPS members and the public need availability of HCQ by ***retail pharmacists*** for prophylactic and early treatment of COVID-19 as sought by AAPS's motion and supported by two declarations referenced therein (Mot. 7), which describes the inability of the patients of a member of AAPS to obtain a full regimen of the potentially life-saving HCQ for COVID-19. *See also* Orient Decl. ¶ 32, R. 9-1, PageID #350.

conferences, political gatherings, football games, and vote in-person in the election. Standing exists to obtain what is currently denied, particularly when it means saving lives and securing constitutional rights. *United States v. Students Challenging Regulatory Agency Procedures*, 412 U.S. 669, 689 n.14 (1973) ("an identifiable trifle is enough for standing to fight out a question of principle") (inner quotations omitted).

Defendants further argue against standing by saying that it is too speculative to expect State authorities to respect and follow a decision to release the HCQ Stockpile. (Defs. Opp. 15-16) But the requested relief does not require cooperation by all State authorities, many of whom have expressly abided by FDA positions. The requested relief is for Defendants to release the HCQ Stockpile to pharmacies which promise to fill prescriptions without delay or restrictions, and if some States block their resident pharmacies from doing that, then the HCQ Stockpile simply would not be released to them. It is necessary only that at least one State not get in the way, and it is hardly speculative to expect that. Many States are supportive of President Trump on this and other issues.

Defendants implicitly concede that everyone might have an argument for standing about lack of access to HCQ amid the COVID-19 pandemic, yet then argue that such universal injury would negate standing by AAPS. (Defs. Opp. 14 n.2, quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992)). But *Lujan* was

a case about environmental harm and the preclusion there was for universal standing based on a general aesthetic value. *Id.* at 562-63, 575. Standing is not negated by the pervasiveness in loss of life due to obstruction by an agency.

II. AAPS Complied with FED R. APP. P. 8, which Does Not Strictly Apply Here Anyway.

The emergency motion by AAPS explains that the district court denied on standing grounds its request to enjoin Defendants, and AAPS's motion even expressly referenced 11 times the lower court opinion and order denying the relief. This satisfies the requirements of FED. R. APP. P. 8. As an authority relied on by Defendants themselves explained, "After the district court denied their motion to enjoin Defendant, they rightly filed this motion with the appellate court …." *A. Philip Randolph Inst.*, 907 F.3d at 917 (accepting and deciding an emergency motion that sought an injunction, as sought here, after such motion was filed in this Sixth Circuit) (cited by Defs. Opp. 12).

Moreover, this Court's power to issue injunctive relief is not limited by FED. R. APP. P. 8. "This Court has the power to grant an injunction pending appeal to prevent irreparable harm to the party requesting such relief during the pendency of the appeal." *Overstreet v. Lexington-Fayette Urban Cty. Gov't*, 305 F.3d 566, 572 (6th Cir. 2002) (citing *Eastern Greyhound Lines v. Fusco*, 310 F.2d 632, 634 (6th Cir. 1962)). AAPS seeks to preserve the status quo of American lives, but not the

stay of any ruling below, so FED. R. APP. P. 8 limitations do not apply here.[3]

Defendants rely on a 2-1 decision in *Baker v. Adams Cty./Ohio Valley Sch. Bd.*, which was over the dissent by Judge Cornelia Kennedy, but that decision is no barrier to the relief sought by AAPS here because AAPS ***did*** initially seek the same relief in the district court but was denied on standing grounds, which blocked any hope of obtaining further relief there. 310 F.3d 927 (6th Cir. 2002) (cited by Defs. Opp. 11-12).

Finally, the procedure suggested by Defendants would have been "impracticable" under Rule 8(a)(2)(A)(i), and even silly, for AAPS to bring any additional motion for injunctive relief in the district court after it ruled against AAPS for a lack of standing and thereby precluded any relief there. Defendants are incorrect in arguing that granting AAPS relief here this would "swallow the rule," because most dismissals in district court are not on standing grounds as the one below was. (Defs. Opp. 12 n.1)

III. Defendants' Conduct is Fully Reviewable by This Court.

Defendants brazenly argue that their decisions are non-reviewable by federal

[3] After consultation with a clerk of this Court, the undersigned counsel initially filed his emergency motion here under the CM/ECF category of "motion for miscellaneous relief," with a description that it was for emergency injunctive relief. (Doc. 7) The following day the clerk's office requested that the motion be refiled under the CM/ECF category "motion injunction pending appeal," which the undersigned counsel then did. (Doc. 8)

courts. Under Defendants' view they could dump the entire HCQ Stockpile into the Potomac River and there would be no legal accountability.

Fortunately, no federal agency is above the law or above judicial review for such an abuse of discretion causing the loss of life. The lack of any relevant authorities for Defendants' desperate argument is glaring. They cite to *Norfolk S. Ry. Co. v. Perez*, but there this Court engaged in *de novo* review of an agency decision and that does not help Defendants here. 778 F.3d 507, 511 (6th Cir. 2015) (quoted by Defs. Opp. 21).

As the Supreme Court has explained, the exception to judicial review of agency decision-making is very narrow, and thus inapplicable here:

> The general exception to reviewability provided by § 701(a)(2) for action "committed to agency discretion" ***remains a narrow one***, see *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402 (1971) ….

Heckler v. Chaney, 470 U.S. 821, 838 (1985) (emphasis added). *See also* 5 U. S. C. § 706(2)(A) (quoted by Mot. 16 but oddly missing from Defendants' opposition); *Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 140 (1967) (judicial review is not blocked "unless there is persuasive reason to believe that such was the purpose of Congress"). No purpose of Congress allows Defendants to waste life-saving medication during a pandemic.

IV. Defendants Fail to Rebut the Multiple Reasons Why This Court Should Not Defer to Them in This Case.

AAPS presented four compelling reasons why Defendants are not worthy of

any deference on this issue. (Mot. 17-20) Defendants do not rebut any of them, but instead try to disparage them as policy arguments. (Defs. Opp. 21) But deference is statutorily to the president and his appointed Secretary, not to an insubordinate agency staff who defy the president to try to defeat him in an election. Defendants cite no statute requiring deference to a subagency bureaucracy that insists on wasting more than 60 million doses of life-saving medication, and the statutes instead speak in terms of deferring only to the president-appointed "Secretary," as Defendants acknowledge. (Defs Opp. 21-22)

Defendants misplace reliance on *Berry v. DOL*, as that decision rejected an agency's broad argument for non-reviewability of a decision not to reopen a claim for benefits if there is new evidence. 832 F.3d 627, 630 (6th Cir. 2016). Where there is new evidence, such a decision by an agency "is not the type of decision the Supreme Court has recognized as being 'committed to agency discretion by law.'" *Id.* (quoting 5 U.S.C. § 701(a)(2)). The Supreme Court has never recognized an agency's withholding of life-saving medication as being beyond judicial review.

Notably, Defendant FDA does not even have a "Secretary" or cabinet-level official, and accountability for the FDA bureaucracy is badly needed. The Fifth Circuit had to rule against the FDA ***twice*** on another high-profile issue where the FDA sought to interfere with patient access to compounded medication. *See Med. Ctr. Pharm. v. Holder*, 634 F.3d 830, 832 (5th Cir. 2011) (ruling, for the second

time, against the FDA's attempt to interfere with compounding pharmacies).

V. This Dispute Is Not Moot, as Thousands Continue to Die Weekly.

Defendants' argument of mootness is particularly misplaced, as many deaths mount daily from COVID-19. AAPS's Complaint and arguments below sought the same relief as AAPS seeks here: early access to COVID-19 patients to help save their lives.

Nothing has been mooted by Defendants' revocation of the Emergency Use Authorization, by which Defendants limited access further. Defendants argue that plaintiff's complaint challenged only Defendants' limitation in its since-revoked Emergency Use Authorization (Defs. Opp. 22), but AAPS's Complaint expressly sought the following in its prayer for relief:

> All Defendants are enjoined to make available and distribute promptly, and for the benefit of the public holding valid prescriptions, the HCQ being stored in the SNS [Strategic National Stockpile]

(Complaint ¶118(C)(ii), R. 1, PageID ##23-24) Nothing is moot here.[4]

[4] Defendants say HCQ has a shelf life of 3 years, but omit how much of that was used up prior to the donations to the HCQ Stockpile. Moreover, withholding the HCQ Stockpile until after the COVID-19 pandemic passes is akin to simply dumping the medication in the Potomac River now.

Conclusion

AAPS requests that this Court grant its motion to order release of the HCQ Stockpile.

Dated: September 1, 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 reply complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because:

> this reply contains 2,599 words excluding the parts of the petition exempted by Fed. R. App. P. 32(f).

2. This reply 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:

> this reply has been prepared in a proportionally spaced typeface using Microsoft Office Word in 14-point Times New Roman font.

Dated: September 1, 2020

s/ Andrew L. Schlafly
Attorney for Appellant

CERTIFICATE OF SERVICE

I hereby certify that on September 1, 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