

Case No. _____

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

In re Association of American Physicians & Surgeons,

Petitioner-Plaintiff

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

PETITION FOR WRIT OF MANDAMUS

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PETITION FOR WRIT OF MANDAMUS

Petitioner Association of American Physicians & Surgeons (“AAPS”) hereby petitions for a writ of mandamus pursuant to the All Writs Act, 28 U.S.C. § 1651(a), and FED. R. APP. P. 21(a), to compel the United States District Court for the Western District of Michigan, Southern Division, the Honorable Robert J. Jonker, to rule on AAPS’s pending motion for a preliminary injunction in an emergency matter concerning access to medication for COVID-19. Respondents are the Food & Drug Administration, Dr. Stephen M. Hahn, Commissioner of Food & Drugs, in his official capacity, Biomedical Advanced Research & Development Authority, Gary L. Disbrow, Ph.D., Acting Director, Biomedical Advanced Research & Development Authority, in his official capacity, Department of Health & Human Services, and Alex Azar, Secretary of Health & Human Services, in his official capacity (collectively, “Respondents”). The underlying litigation concerns Respondents’ unlawful impediments to safe, affordable medication for COVID-19 and thus affects the lives and comfort level of millions of Americans on an urgent basis amid the ongoing coronavirus pandemic. This Petition seeks mandamus to compel the district court to act on AAPS’s motion for a preliminary injunction.

“The All Writs Act empowers the federal courts to issue all writs necessary or appropriate in aid of their respective jurisdictions ... and extends to the potential

jurisdiction of the appellate court where an appeal is not then pending but may be later perfected.” *FTC v. Dean Foods Co.*, 384 U.S. 597, 603 (1966) (interior quotation marks and citations omitted) This Court has held that mandamus is appropriate to address “‘questions of unusual importance necessary to the economical and efficient administration of justice’ or ‘important issues of first impression.’” *John B. v. Goetz*, 531 F.3d 448, 457 (6th Cir. 2008) (citation omitted). In the absence of a ruling by the district court either to grant the preliminary injunction or to deny it to allow appeal to this Court, many Americans will face unnecessary death or illness because Respondents deny access to a potentially life-saving and health-preserving drug stockpiled for this very purpose. This easily satisfies the standard for mandamus relief.

There has been no action by the district court in this time-sensitive case since it was filed on June 2, 2020 (Doc. 1 below), or since the briefing was completed on AAPS’s pending motion for a preliminary injunction (Doc. 8) on July 20 (Doc. 13), or since AAPS filed a motion for an expedited hearing or ruling on July 30 (Doc. 15). In the meantime, many thousands of Americans have reportedly died from COVID-19 while being denied access to hydroxychloroquine (HCQ), despite its immense success in studies and in poorer countries that make it widely available.

Respondents have unlawfully interfered with patient access to HCQ for COVID-19 in three ways. First, Respondents accepted donations of nearly 100 million doses of HCQ to the Strategic National Stockpile for COVID-19, but have since refused to distribute the vast majority of that medication and instead is allowing it to deteriorate such that it will be wastefully discarded rather than helping save lives. Second, Respondents have posted false, disparaging statements about HCQ, upon which other regulators have relied in blocking access to it. Third, Respondents imposed arbitrary restrictions on HCQ use as part of an Emergency Use Authorization (EUA) and, after the filing of this lawsuit, Respondents rescinded the EUA in a manner that improperly extended their wrongful restrictions and disparagement to continue to block access to HCQ for early treatment of COVID-19.

President Donald Trump, who has repeatedly praised HCQ and successfully took it himself in May as a prophylaxis against HCQ, retweeted favorably about this pending lawsuit on July 27, which underscores the national significance of this litigation. Due to the upcoming presidential election, President Trump's support of HCQ has caused some of his opponents to block access to it for political reasons.

On July 28, 2020, Yale School of Public Health epidemiology Professor Harvey Risch, M.D., stated on national television that "75,000 to 100,000 lives will be saved" if the stockpile of HCQ being wrongly withheld by Respondents were

released, as sought by AAPS in its pending motion for a preliminary injunction.

Professor Risch observed further in frustration at the politically motivated interference with access to HCQ:

It's a political drug now, not a medical drug And I think we're basically fighting a propaganda war against the medical facts¹

As presented to the district court in a sworn declaration in support of AAPS's pending motion for a preliminary injunction, countries that are allowing access to HCQ to treat COVID-19 early and prophylactically are doing far better in conquering the disease than the wealthier United States is:

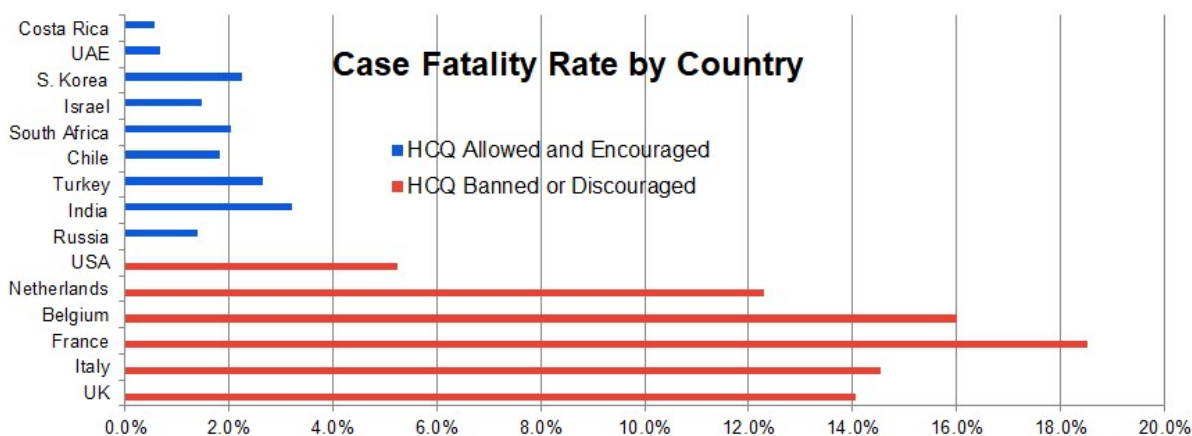
Country	HCQ Policy	Percentage COVID-19 Deaths Per Case	COVID-19 Deaths Per Million in Population
United Kingdom	HCQ is discouraged and mostly unavailable	14%	628
Italy	HCQ's value was not known for the many initial casualties	14.5%	573
France	HCQ is officially disfavored	18.5%	454
United States	FDA interferes with access to HCQ	5.2%	370
Russia	HCQ is encouraged	1.4%	56
India	HCQ is used prophylactically	3.2%	10

¹ <https://www.myjoyonline.com/news/international/yale-epidemiologist-says-hydroxychloroquine-could-save-up-to-100k-lives-if-used-for-coronavirus/> (viewed August 8, 2020).

Country	HCQ Policy	Percentage COVID-19 Deaths Per Case	COVID-19 Deaths Per Million in Population
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

Declaration of Jeremy Snavely dated June 22, 2020, at ¶ 28 (Exh. 2 to AAPS Mot. for a Preliminary Injunction, Doc. 8-4).

AAPS additionally provided this information graphically to the district court, thereby highlighting the stark contrast between the success in defeating COVID-19 by countries, typically poorer, which allow HCQ access, compared with the wealthier, more liberal countries that have interfered with access:



Id. at ¶ 29.

As explained to the district court, a recent study of thousands of patients at the Henry Ford Health System in Michigan demonstrated that HCQ is both very

safe and highly effective in treating COVID-19, reducing mortality by 50%.

Henry Ford Health System, *Treatment with Hydroxychloroquine Cut Death Rate Significantly in COVID-19 Patients, Henry Ford Health System Study Shows* (July 2, 2020).² Dozens of additional studies further demonstrate the efficacy of HCQ as preventive or early treatment for the disease.³ A petition by AAPS at <https://hcqpetition.com/> supporting Henry Ford Health System's request to the FDA to allow outpatient use attracted 8,568 signatures by August 8.

As also explained to the district court in support of AAPS's pending motion for a preliminary injunction, there is a striking correlation between countries having policies which recognize the sanctity of life and those which are allowing access to HCQ for early and prophylactic treatment of COVID-19. The more religiously affiliated countries of Poland, Israel, South Korea, Republic of the Philippines, Turkey, and several in South and Central America have much lower mortality rates from COVID-19 as they pursue the more pro-life policy of authorizing HCQ access.⁴ In contrast, nations in Western Europe having secular views against the sanctity of life have been more likely to block access to HCQ,

² <https://www.henryford.com/news/2020/07/hydro-treatment-study> (viewed August 9, 2020).

³ <https://c19study.com/> (a collection of 70 studies clearly showing the effectiveness of HCQ as an early treatment for COVID-19, viewed August 9, 2020).

⁴ <https://www.worldometers.info/coronavirus/#countries> (viewed August 8, 2020).

and they have higher mortality rates from COVID-19. President Trump holds and was elected on a pro-life position, and respect for his electoral mandate reinforces the need to enjoin the anti-life interference with HCQ by Respondents.

On July 30, former presidential candidate and Trump supporter Herman Cain died from COVID-19, within mere weeks of contracting it, and many hundreds or thousands of other Americans are tragically dying daily from this disease in the absence of access to early, effective treatment. The beloved Herman Cain died in Georgia⁵ which, in reliance on false anti-HCQ statements and arbitrary actions by Respondents, generally denies access to HCQ.⁶ Ironically, like President Trump, Cain himself had repeatedly advocated in favor of access to this potentially life-saving medication.⁷

Even Democratic politicians have praised HCQ for saving their lives, despite the implicit credit that provides to Trump. On August 8, the *New York Post* quoted Democratic Queens Councilman Paul Vallone as saying that HCQ “saved my life”

⁵ <https://www.cnbc.com/2020/08/04/herman-cain-was-on-a-ventilator-before-he-died-from-covid-19-top-aide-says.html> (viewed August 9, 2020).

⁶ <https://gbp.georgia.gov/document/document/rule480-10-038-22medicationlimitationseffective032720pdf/download>
<https://gbp.georgia.gov/press-releases/2020-04-08/covid-19-coronavirus-response-georgia-board-pharmacy> (both viewed August 9, 2020).

⁷ <https://heavy.com/news/2020/07/herman-cain-hydroxychloroquine/> (viewed August 9, 2020).

from COVID-19 and quoted his brother Judge Peter Vallone as saying that “big money does not want this drug to be used. Always follow the money,” while he linked to a study by New York University demonstrating the efficacy of HCQ to treat COVID-19.^{8,9}

In the district court proceeding, Respondents raised issues of standing and reviewability, but both are easily resolved in favor of AAPS as it argued below. AAPS has standing in its own right because FDA’s actions impair AAPS’s own First Amendment activity (Doc. 13, at 11-12), and FDA’s actions irrationally impede the ability of AAPS’s member physicians to practice their profession (*id.* at 12-21). As to reviewability, FDA’s rescission of its EUA included further arbitrary action, and thus is reviewable (*id.* at 21-22).

Timely consideration and resolution of AAPS’s motion for a preliminary injunction is essential to stem the ongoing irreparable harm from Respondents’ arbitrary actions, false disparagement, and hoarding of HCQ in the Strategic National Stockpile, where it deteriorates rather than being used as intended.

⁸ https://nypost.com/2020/08/08/nyc-councilman-credits-hydroxychloroquine-for-covid-19-recovery/?utm_source=email_sitebuttons&utm_medium=site%20buttons&utm_campaign=site%20buttons (viewed August 9, 2020).

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

CONCLUSION

AAPS respectfully requests that this Court order the district court to promptly rule on the pending motion for a preliminary injunction, and that this Court enjoin Respondents from taking any action in the meantime contrary to the relief sought in the pending motion.

Dated: August 10, 2020

Respectfully submitted,

/s/ Andrew L. Schlafly

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CERTIFICATE OF SERVICE

I hereby certify that on August 10, 2020, I electronically filed the foregoing with the Clerk of the Court for the United States District Court for the Western District of Michigan by using the CM/ECF system, thereby providing service on all parties and providing notice to the court itself. I certify that all participants in the case are registered CM/ECF users.

s/ Andrew L. Schlafly

Attorney for Petitioner