**Case No. 20-1784**

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UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

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Association of American Physicians & Surgeons,

*Appellant-Plaintiff*

v.

Food and Drug Administration, *et al.*,

*Appellees-Defendants*

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

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# REPLY BRIEF OF APPELLANT ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS

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## SUMMARY OF ARGUMENT

Appellees-Defendants Food and Drug Administration ("FDA"), *et al.*, demand to avoid entirely any legal accountability for their misrepresentations and anti-life actions. Ignoring the substantive arguments by Appellant-Plaintiff Association of American Physicians & Surgeons ("AAPS"), Defendants essentially insist that no one has standing to obtain judicial review for agency misrepresentations and interference with potentially life-saving care. An association of physicians on the front lines of treating for COVID-19, namely AAPS, is somehow without standing to object to the FDA's irrational, devastating interference with the physicians' attempts to save lives. It is not that Defendants suggest that anyone other than AAPS has standing; rather, Defendants insist they are beyond judicial review of their indefensible conduct.

Defendants cite nothing in the history or foundational basis for standing doctrine to justify misusing it to evade accountability in court for wrongdoing. AAPS does not seek monetary damages, and instead merely seeks equitable relief to correct the FDA's falsehoods and open access to a stockpile of medication which is wasting away. Defendants should be providing this relief on its own initiative, and certainly should be doing so after being alerted to it. Instead, Defendants stretch standing doctrine so far that it would remove any check-and-balance on the administrative state, even on life-or-death matters.

The fallacy in Appellees-Defendants' argument is made clear by realizing that it would enable them to avoid judicial review no matter how false their statements are, or how wrongful their conduct becomes. Appellees-Defendants' position in this court typifies the growing problem of a lack of accountability and check-and-balance on the administrative state as they pursue their own agenda of obstruction and interference with the ability of Americans to preserve life.

Any litigant other than appellee would feel compelled, at a minimum, to defend its conduct that is the subject of this litigation. But not the FDA. It does not defend its conduct at issue here. It does not defend withholding and wasting of more than 60 million doses of HCQ which were donated to the American people by generous pharmaceutical companies. Instead, the FDA asserts for itself the power to do the equivalent of Josef Stalin's withholding grain from starving farmers, as the FDA insists that absolutely no judicial review is available to correct such an injustice.

In their response, Defendants repeatedly conflate the very different attributes of "supply" and "access", ignoring their pivotal distinction. Improper denial of access would never be an issue if supply were synonymous with access. Hunger would not exist if supply meant access. There was plenty of grain in supply in silos for Ukrainian farmers in 1932; they starved to death because they were denied access to what was in supply. Abundant supply does not mean access, and the very

claim in this case is that Defendants are impeding access.

Defendants make several statements in their brief which can easily mislead. For example, Defendants argue that "if the drug [hydroxychloroquine (HCQ)] currently is not available for use to try to prevent or treat COVID-19 despite plaintiff 's allegation that the supply is plentiful, then an order directing defendants to provide access to additional hydroxychloroquine will not solve the problem." (Defs. Br. 23 n.2) Yet Defendants do not deny that they are withholding more than 60 million doses of HCQ, and of course an order against Defendants to provide access to that massive amount of HCQ would alleviate the problem encountered by physicians and their patients in accessing the medication.

Standing doctrine was never intended to completely shield the administrative state from judicial review. Moreover, standing doctrine should not be used to shield anti-life governmental conduct from accountability. Defendants do not substantively defend their actions, and do not deny that their actions are contributing to the widespread loss in American lives. There is no basis for inferring that Defendants' conduct at issue here was with good intentions, rather than the result of conflicts of interest or unauthorized ideological bias. AAPS has alleged that Defendants have acted arbitrarily and improperly, and standing doctrine should not be misused in order to reject such allegations rather than address the merits.

## ARGUMENT

Defendants admit "[t]he FDA regulates the marketing and distribution of drugs by manufacturers, not the practices of physicians in treating patients." *Planned Parenthood Sw. Ohio Region v. DeWine*, 696 F.3d 490, 496 n.4 (6th Cir. 2012) (cited by Defs. Br. 3). So why do Defendants insist on their misrepresentations about HCQ, which do interfere with the practice of physicians in treating patients?

As explained in AAPS's opening brief (AAPS Br. 9) and not contested by Defendants' response, Defendants make the following misrepresentations about hydroxychloroquine:

> (1) "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***." Frequently Asked Questions on the Revocation of the Emergency Use Authorization for Hydroxychloroquine Sulfate and Chloroquine Phosphate, at 2 (June 16, 2020) (R. 9-7, Page ID # 484, emphasis added)
>
> (2) "hydroxychloroquine sulfate … ***can only be used for the treatment of COVID-19 as part of an ongoing clinical trial***." (ASPR's Portfolio of Investigational Medical Countermeasures being used to treat COVID-19, R. 9-8, Page ID # 487, emphasis added)

Both disparaging statements are false, and Defendants lack any support for them, particularly for prophylactic and early-treatment uses of HCQ. (Declaration by Jane Orient, M.D., dated June 22, 2020, ¶¶ 15-20, R. 9-1, Page ID ## 347-48)

In addition, Defendants fail to address the central issue of their continuing to withhold more than 60 million doses of HCQ in a stockpile, such that it wastes

away rather than being made available for prescriptions by physicians to patients. If the FDA does not regulate the practice of medicine by physicians, as it asserts in its response, then it should not be interfering with use of this long-approved medication to fill prescriptions by physicians treating patients with COVID-19.

These issues remain for consideration by the merits panel, as Defendants do not dispute that the prior ruling by the motions panel does not bind a merits panel.

## I. AAPS Has Standing Because There Is Traceability and Redressability.

The FDA argues here that its influence is so small that the interference with access to HCQ cannot be traced to it, and that AAPS's injury is not redressable by any ruling against the FDA. This is ironic, as the FDA asserts that it has some kind of special expertise and influence in its pronouncements, including the ones at issue here which falsely disparage HCQ. The FDA wants and expects its statements to be relied upon by state regulators and others. Yet to avoid judicial review here the FDA pretends instead that virtually no state regulator really listens to it at all.

Of course the interference with access to HCQ is traceable to the FDA's conduct, and redressable by an injunction against it, thereby satisfying the second and third prongs of the *Spokeo* test. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (standing exists whenever "[t]he plaintiff [has] (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is

likely to be redressed by a favorable judicial decision").

Yet Defendants rely on non sequiturs about supply and access to argue against traceability and redressability. Repeatedly Defendants fallaciously argue that if a supply is plentiful, then widespread access must also exist. (Defs. Br. 12, 14, 19, 23 n.2, 26) Defendants' conclusion about access does not follow from its premise about supply. The fundamental distinction between supply and access is essential on many issues, including food, water, medical care, and wealth itself. Monopolies would not be objectionable if supply and access were coterminous with each other. Ample supply does not guarantee adequate access, and that is the current problem with HCQ which is at issue in this case.

Defendants pretend here to have insignificant influence over state medical boards. (Defs. Br. 10, 12) But the very Federation of State Medical Boards, on which state regulators rely, expressly invoked the FDA's position against HCQ. (AAPS Br. 11-12) State regulators have likewise expressly cited the FDA's position against HCQ in propagating the interference with access to HCQ, as demonstrated by AAPS's opening brief and filings below. (AAPS Br. 10-11)

Defendants fail to adequately distinguish the *Association of American Physicians & Surgeons v. Texas Med. Bd*, 627 F.3d 547 (5th Cir. 2010), where standing for AAPS was found by the Fifth Circuit when AAPS complained in Texas about wrongdoing by the Texas Medical Board. (Defs. Br. 19-20)

Defendants admit that the Fifth Circuit found that AAPS had standing in that case. (Defs. Br. 19 – "the Fifth Circuit concluded that plaintiff had associational standing"). But Defendants try to avoid this precedent by saying that the standing of AAPS's members was never in question. (Defs. Br. 19) In fact, the Fifth Circuit held that it was "[b]eyond question" that AAPS members would have standing to sue in their own right. *AAPS v. TMB*, 627 F.3d at 550. Likewise, it is ***beyond question*** that AAPS physician members have standing to challenge interference by the FDA with the ability of AAPS members to have their prescriptions filled of the long-approved medication HCQ for COVID-19 patients.

As to the first prong of the *Spokeo* test, an injury-in-fact from the interference with access to hydroxychloroquine, and filling physicians' prescriptions for it, cannot be seriously doubted. *See, e.g.*, *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). *See also* AAPS Br. 19-20.

Finally, it is worth noting that Defendants include misleading statements in their brief:

- "Hydroxychloroquine is approved by the FDA to treat certain diseases, but has not been approved to treat or prevent COVID-19." (Defs. Br. 5) ***In fact***, approved medications are often used to treat other medical conditions without additional approval, which is known as "off-label" use. The FDA rarely approves the additional uses, because additional approval is neither required nor cost-effective. (AAPS Br. 4, 21)

- The FDA "did not have any impact on physicians' ability to prescribe the drug off-label when deemed appropriate. (Defs. Br. 11). ***In fact***, that is squarely at issue in this case, and AAPS's contrary allegations and evidence must be taken as true at this stage in the litigation.

- If the FDA determines that the evidence of safety and effectiveness is sufficient, and the other requirements for approval are satisfied, ***the agency approves the drug for the conditions of use*** described in the labeling. (Defs. Br. 3, citing 21 U.S.C. § 355(d), emphasis added). ***In fact***, when medications such as hydroxychloroquine are approved as safe, there are rarely limitations as to the purpose of the treatment after the approval. Such medications may be approved only for adults, or not for use during pregnancy, or other such conditions, but limitations are rarely placed on the use of the medication for only some diseases.

In its brief here the FDA also makes statements disparaging the safety of HCQ, which are belied by the fact that HCQ has been approved by the FDA as safe without limitation since 1955. (AAPS Br. 3)

## II. AAPS Did Not Waive Third-Party Standing on Appeal.

AAPS emphasized associational standing as the most straightforward jurisdictional basis for its lawsuit. But by focusing on its strongest argument for standing, AAPS did not waive other bases for standing. In one part of their brief Defendants say that AAPS "focuses on its associational standing and the third-party standing of its member physicians" (Defs. Br. 28, citing AAPS Br. 34-40), while in another part of its brief Defendants argue that "plaintiff has forfeited this Court's review of the third-party standing issue." (Defs. Br. 24)

AAPS did not waive third-party standing, and indeed expressly argued for it

in a section with its own heading. (AAPS Br. 39-40, Point II.A.4 – "AAPS Has Third-Party Standing") It is not waiver of an argument to devote a separate section with its own heading to it. AAPS has third-party standing because it "is entitled to assert those concomitant rights of third parties that would be diluted or adversely affected should her constitutional challenge fail and the statutes remain in force." *Craig v. Boren*, 429 U.S. 190, 195 (1976) (inner quotations omitted).

As to first-party standing, AAPS prefers that the Court focus on the stronger associational and third-party standing bases for jurisdiction here.

## III. There Is No Basis for Assuming that the Decision-Making by Defendants Was Either Rational or Consistent with the Preservation of Life.

Defendants offer no basis for assuming rational, pro-life decision-making by them, and there is none. Defendants do not deny the widely reported conflicts of interest which taint their decisions at issue in this case. Moreover, Defendants do not and cannot deny that ideologies differ when the sanctity of life is at issue. Many look to a cost-benefit analysis when the context is saving lives in nursing homes, where roughly half of the mortalities from COVID-19 have been. That utilitarian approach, however, is without basis in statute or the law, and cannot justify impeding access by physicians and the public to potential life-saving medication, as Defendants have done.

Many States have legalized assisted suicide,[1] and entire countries have legalized euthanasia.[2] Similar negative or utilitarian views about life may be dominant at the FDA. Is that approach authorized by Congress? No. Does it have any basis in Anglo-American law? No. Should there be any judicial deference to decision-making by the FDA without any fact-finding as to what conflicts-of-interest or ideological bias may have motivated its decisions? No.

Accordingly, there should be no presumption that the FDA's actions were done in good faith consistent with our Nation's values and legal norms.

## IV. Defendants Fail to Establish any Exemption from the APA.

Defendants argue that they are exempt from judicial review under the Administrative Procedure Act ("APA"), by stating that Congress expressly provided that "[t]he Secretary, *through the Commissioner [of Food and Drugs]*, shall be responsible for executing [the Federal Food, Drug, and Cosmetic Act]." (Defs. Br. 30, emphasis in original) But that provision does not delegate APA

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[1] "Since Oregon voted to legalize physician assisted suicide in 1994, Washington, Vermont, The District of Columbia, Colorado, Hawaii, and California have passed similar laws." Delaney Blakely, Note: "A Comparative View of the Law, Ethics, and Policies Surrounding Medical Aid in Dying in the United States and Netherlands," 19 Wash. U. Global Stud. L. Rev. 235, 240 (2020). New Jersey has since also legalized assisted suicide.

[2] For example, Belgium has both legal and illegal euthanasia. *See* Toni C. Saad, "Euthanasia in Belgium: Legal, Historical and Political Review, 32 Issues L. & Med. 183 (2017). Not surprisingly, Belgium has by far the highest COVID-19 mortality rate in the world among its overall population. https://www.worldometers.info/coronavirus/#countries (viewed 12/16/20)

immunity from judicial review, and Defendants cite no precedent for non-review extending beyond what the APA expressly allows. Moreover, even if the Secretary of HHS and the FDA Commissioner were to enjoy APA immunity from judicial review for their actions, their subordinates do not and such subordinates and others were the ones who engaged in the conduct at issue in this case. (AAPS Br. 16-17)

The improper withholding of the HCQ Stockpile and the misrepresentations by Defendant FDA about HCQ were not actions taken by its Commissioner, so no exemption from the APA would attach even under Defendants' sweeping argument. Rather, it was staff within the FDA and others who engaged in the challenged conduct, without any apparent blessing by the Secretary of HHS or the Commissioner of the FDA. (AAPS Br. 16) Defendants have simply failed to demonstrate why deference to the Secretary or Commissioner should apply to protect wrongdoing by staff and other government workers. Congress never intended for the APA to exempt all staff conduct from judicial review.

Defendants tacitly concede that the motions panel does not bind the merits panel on this or any other point, and Defendants do not rely on the opinion by the motions panel for this issue. As AAPS argued in its opening brief, Defendants' actions are further reviewable because the APA waives sovereign immunity for judicial review of final agency action for which the plaintiff has no other adequate

remedy in a court. 5 U.S.C. § 704. Defendants do not dispute that their relevant conduct constitutes final agency action.

Defendants say nothing in response to AAPS's argument that no one would doubt that a hypothetical decision by a federal agency to withhold silos of grain from starving farmers would be reviewable in federal court. Yet here we are, with Defendants insisting that their withholding of "silos" of potentially life-saving medication is somehow not reviewable in federal court. This is the "administrative state run amok," causing far more harm than Congress ever authorized. Reuel E. Schiller, "Enlarging the Administrative Polity: Administrative Law and the Changing Definition of Pluralism, 1945-1970," 53 VAND. L. REV. 1389, 1405 (Oct. 2000).

## V. A Lack of Standing Here Would Set a Dire Precedent for Challenging Future Lawless Actions by the Administrative State.

A lack of meaningful accountability for the administrative state – called the "Deep State" in political discourse – has increasingly been viewed as a problem by judges and scholars alike, even before agencies sought to evade judicial review by invoking an expansive view of standing doctrine. As explained by Professor Reuel E. Schiller in a heavily referenced article:

> Thus, when postwar legal thinkers turned their attention to the role of the judiciary in the administrative state, they found themselves pulled in opposite directions. On the one hand, the dictates of process theory suggested that the courts should have a limited role in policing legislatively created entities like administrative agencies. On the other hand, fears

> concerning the absolutist potential of the administrative state demanded the creation of some controls on its power; the most obvious candidates were the courts. Indeed, ***the claim that imposing the rule of law on agency behavior could protect Americans from an administrative state run amok, which prior to World War II had been solely the claim of opponents of the New Deal, was increasingly heard across the political spectrum***.

*Id.* at 1404-05 (emphasis added).

The President is accountable to judicial review, Congress is accountable to judicial review, and state government is accountable to judicial review. The notion of an administrative state being above any meaningful accountability and judicial review, as sought by Defendants' arguments, is inimical to our system of government. This problem has worsened since President Harry Truman observed, "'I thought I was the president, but when it comes to these bureaucrats, I can't do a damn thing,'" and this often-called "headless fourth branch of government" may not quite be "the very definition of tyranny, but the danger posed by the growing power of the administrative state ***cannot be dismissed***." *City of Arlington v. FCC*, 569 U.S. 290, 313-15 (2013) (Roberts, C.J., joined by Kennedy and Alito, JJ.) (quoting R. Nathan, The Administrative Presidency 2 (1983), other inner quotations omitted, emphasis added). *See also United States v. Allegan Metal Finishing Co.*, 696 F. Supp. 275, 295 (W.D. Mich. 1988) ("In an increasingly administrative state … accountability is often difficult to ascertain.").

Agency interference with access to safe, potentially life-saving medication is the issue here, but on the horizon are additional threats of interference by an

emboldened administrative state which would then also evade judicial review without congressional authorization. Banning the traditional automobile as fueled by efficient gasoline, for example, is the goal of supporters of a Biden Administration, and this has already been attempted by executive order in California beginning in 2035. Under the expansive view of standing doctrine urged by Defendants, the public would lack standing to object to such irrational overreach by a federal agency. And if the federal agency cloaks its decision-making in pseudo-scientific assertions,[3] then the administrative abuse of power will extend further so that courts defer to the supposed expertise of the agency, no matter how distorted its process is by conflicts-of-interest and ideological bias.

If standing doctrine is extended to immunize agency action against judicial review, then victims of improper agency action will include more than an association of physicians and their patients. Immunity from judicial review for agencies under standing doctrine amounts to granting the agencies carte blanche to act as irrationally as they like, with the result of depriving Americans access to

[3] Continuing the apt analogy to the withholding of grain by Josef Stalin from Ukrainian farmers in 1932, pseudo-science was used then, too, to justify the irrational, deadly interference. Nikolai Vavilov had data-driven work that was an accurate exposition of agricultural genetics, but pro-Marxist and scientifically wrong views of Trofim Lysenko were adopted by Stalin, and through ideological bias Lysenko was able to marginalize Vavilov's work. Millions then starved, and Vavilov died in prison. Today "Lysenkoism" connotes a deliberate distortion of science for ideological goals – as the FDA has done with respect to HCQ. https://politicsandinsights.org/tag/adam-smith-institute/ (viewed 12/16/20).

affordable, effective medication and other beneficial goods. Actions taken by federal agencies can cause enormous harm, and standing doctrine should not be construed so broadly as to make it nearly impossible for anyone to challenge misconduct by the administrative state.

None of the bases for standing doctrine is to reduce accountability and judicial review of the administrative state. The notion that federal agencies could evade judicial review while acting irrationally and contrary to fundamental needs of ordinary Americans, simply by invoking standing doctrine, is incompatible with the Rule of Law. None of Defendants' precedents supports broadening standing doctrine to the point of allowing an agency to completely evade judicial review, particularly when the agency engages in conduct that is patently indefensible and potentially detrimental to the lives of hundreds of thousands of Americans.

Defendants cite to only 14 decisions in their entire brief, none of which supports denial of standing to an association of professionals whose work is impeded by irrational agency action. The closest precedent cited by Defendants is *Clapper v. Amnesty Int'l USA*, where a 5-4 Supreme Court held that the hypothetical interception of future communications was an insufficient basis for standing by interest groups. 568 U.S. 398, 401-02 (2013). The procedural posture in *Clapper*, however, was on summary judgment when more evidence is expected, not the motion to dismiss granted below. Moreover, this Circuit has emphasized

that *Clapper*, unlike here, was based on a heightened requirement of standing when the challenge is to the constitutionality of an action. *Parsons v. United States DOJ*, 801 F.3d 701, 710 (6th Cir. 2015) ("The standing inquiry is particularly rigorous when reaching the merits of the dispute 'would force [the Court] to decide whether an action taken by one of the other two branches of the Federal Government was unconstitutional.'") (quoting *Clapper*, 133 S. Ct. at 1147, quoting *Raines v. Byrd*, 521 U.S. 811, 819-20 (1997)). Here, AAPS does not primarily assert unconstitutional conduct by Defendants, but irrational actions contrary to administrative law.

Neither *Clapper* nor any other precedent justifies denying judicial review of Defendants' irrational interference with the life-saving care provided by physician members of AAPS to patients. The Supreme Court held in *Clapper* that "[w]hen a plaintiff's alleged injury is the result of 'the independent action of some third party not before the court,'" the injury is not traceable to the defendant and "the plaintiff generally lacks standing to seek its redress." *Crawford v. DOT*, 868 F.3d 438, 455 (6th Cir. 2017) (quoting *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 42 (1976)). Here, the interference with HCQ is directly traceable to and the result of Defendants' misrepresentations and withholding of the HCQ Stockpile.

No valid purpose or precedent exists for failing to substantively review agency conduct in these circumstances. Nothing good is advanced by giving

Defendants a pass while hundreds of thousands of Americans reportedly die from COVID-19. The same arguments presented by Defendants here to evade all legal accountability for their conduct could likewise be used to dodge judicial review of an agency's withholding of grain from farmers, or penicillin from patients as was done in the notorious Tuskegee study by the federal government.[4] Such non-reviewability could allow similar wrongdoing by agencies. It is not a proper exercise of judicial restraint to look away while a federal agency contributes to the deaths of many thousands of innocent Americans.

## CONCLUSION

For the foregoing reasons and those set forth in Appellant's opening brief, this Court should reverse the decision below and summarily grant the requested relief of release of the HCQ Stockpile by Defendants, and require their correction of their false disparagement of the medication.

Dated: December 18, 2020

Respectfully Submitted,

s/ Andrew L. Schlafly

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[4] Barbara L. Bernier, "Class, Race, and Poverty: Medical Technologies and Socio-Political Choices," 11 HARV. BLACKLETTER J. 115, 125 (1994).

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

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Dated: December 18, 2020

s/ Andrew L. Schlafly

Attorney for Appellant

## CERTIFICATE OF SERVICE

I hereby certify that on December 18, 2020, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/ Andrew L. Schlafly

Attorney for Appellant

# ADDENDUM

## Designation of originating court documents

Declaration by Jane Orient, M.D., dated June 22, 2020, R. 9-1, Page ID ## 347-48

Frequently Asked Questions on the Revocation of the Emergency Use Authorization for Hydroxychloroquine Sulfate and Chloroquine Phosphate (June 16, 2020), R. 9-7, Page ID # 484

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