No. 22-40802

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

ROBERT L. APTER, M.D., FACEP; MARY TALLEY BOWDEN, M.D.; and PAUL E. MARIK, MBBCh, M.MED, FCCM, FCCP,

***Plaintiffs - Appellants*,**

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES; FOOD AND DRUG ADMINISTRATION; AND ROBERT M. CALIFF, M.D., MACC, IN HIS OFFICIAL CAPACITY AS COMMISSIONER OF FOOD AND DRUGS,

***Defendants - Appellees*.**

On Appeal from the United States District Court
for the Southern District of Texas, Galveston Division
No. 3:22-CV-184-JVB
The Honorable Jeffrey Vincent Brown, Judge Presiding

AMICUS CURIAE BRIEF OF THE ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS IN SUPPORT OF PLAINTIFFS-APPELLANTS, IN SUPPORT OF REVERSAL

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CERTIFICATE OF INTERESTED PERSONS

The case number here is No. 22-40802, *Apter et al. v. Dep't of Health & Human Services et al.*

Amicus Curiae Association of American Physicians and Surgeons is a non-profit corporation that has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

Pursuant to the fourth sentence of Circuit Rule 28.2.1, the undersigned counsel of record certifies that the parties' list of persons and entities having an interest in the outcome of this case is complete, to the best of the undersigned counsel's knowledge, with the following additions:

Association of American Physicians and Surgeons, *Amicus Curiae*

Andrew L. Schlafly, counsel for *Amicus Curiae*

These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

/s/ Andrew L. Schlafly
Andrew L. Schlafly
Counsel for Association of American Physicians and Surgeons

Dated: February 13, 2023

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IDENTITY, INTEREST AND AUTHORITY TO FILE[1]

Amicus curiae Association of American Physicians and Surgeons ("AAPS") is a national association of physicians. Founded in 1943, AAPS has been dedicated to the highest ethical standards of the Oath of Hippocrates and to preserving the sanctity of the patient-physician relationship. AAPS has been a plaintiff in multiple lawsuits against certain government action, including one concerning the scope of the authority of the United States Food and Drug Administration ("FDA"). *See Ass'n of Am. Physicians & Surgs. v. United States FDA*, 13 F.4th 531, 534 (6th Cir. 2021). *See also Ass'n of Am. Physicians & Surgs. v. Tex. Med. Bd. (TMB)*, 627 F.3d 547 (5th Cir. 2010) (AAPS prevailing on appeal against the Texas Medical Board); *Cheney v. United States Dist. Court*, 542 U.S. 367, 374 (2004) (citing *Ass'n of American Physicians & Surgeons v. Clinton*, 997 F.2d 898 (D.C. Cir. 1993)); *Ass'n of American Physicians & Surgeons v. Mathews*, 423 U.S. 975 (1975). The U.S. Supreme Court has expressly made use of *amicus* briefs submitted by AAPS in high-profile cases. *See, e.g., Stenberg v. Carhart*, 530 U.S. 914, 933 (2000); *id.* at 959, 963 (Kennedy, J., dissenting);

[1] All parties have consented to the filing of this brief by *Amicus*. Pursuant to FED. R. APP. P. 29(a)(4)(E), undersigned counsel certifies that: counsel for the *Amicus* authored this brief in whole; no counsel for a party authored this brief in any respect; and no person or entity – other than *Amicus*, its members, and its counsel – contributed monetarily to this brief's preparation or submission.

District of Columbia v. Heller, 554 U.S. 570, 704 (2008) (Breyer, J., dissenting). U.S. Courts of Appeal have expressly cited an *amicus* brief by AAPS. *See, e.g.*, *Springer v. Henry*, 435 F.3d 268, 271 (3d Cir. 2006).

Amicus AAPS members have treated hundreds of thousands of COVID-19 patients and have direct and vital interests in curtailing interference by the FDA with the practice of medicine, especially in regards to the treatment of COVID-19.[2]

SUMMARY OF ARGUMENT

The denial of judicial review by the court below was reversible error. The FDA's misconduct in interfering with early treatment of COVID-19 by ivermectin was reprehensible, and as harmful as any final agency rule. The courthouse doors must be open for accountability of the FDA when it interferes with life-saving treatment, as it has done with respect to COVID-19. This Court need not determine at this stage how substantively wrong the FDA was, but merely that a cause of action exists against this federal agency for such alleged misconduct that potentially causes the loss of life. Improper interference by a federal agency with life-promoting medical practices of physicians cannot properly be immune from judicial review, and it was an error of law for the lower court to shelter it.

[2] The "FDA" includes all the Defendants-Appellees as defined in the opening brief by Appellants (App'ts Br. 4 n.1), and *Amicus* adopts that same terminology here.

Many state courts expressly relied on the FDA's unfounded and improper disparagement of ivermectin as a legal basis for denying access by dying patients to that long-approved-as-safe medication as prescribed by physicians. FDA's conduct at issue in this case thereby had immense legal consequences. As would have been easily proven below if this case had not been prematurely dismissed, the campaign by the FDA to interfere with the prescribed use of ivermectin to treat COVID-19 patients caused many avoidable deaths. The FDA's invocation of science was pretextual to justify the interference, which was motivated by improper ideological reasons rather than any objective analysis of scientific data. The distortion of science in such a manner is not new, and is not confined to the FDA among federal agencies. There is even a term available to describe the misuse of science in a pretextual way for an undisclosed political agenda.[3] Yet under the reasoning below, federal agencies would be able to evade timely, meaningful judicial review of its false public statements, despite in fact how the agencies may thereby be causing loss in life.

[3] The pro-Marxist and scientifically wrong views of Trofim Lysenko were adopted in the 1930s by Josef Stalin, and "Lysenkoism" connotes a deliberate distortion of science for ideological goals – as the FDA does today without adequate expertise. *See* Point II, *infra.*
https://politicsandinsights.org/tag/adam-smith-institute/ (viewed Feb. 11, 2023).

It is axiomatic that the FDA does not lawfully practice medicine, and lacks any authority to interfere with it. No state medical board licenses the FDA or any Washington, D.C., bureaucrat to practice medicine as the FDA improperly did to the detriment of many. The FDA is fully equipped to defend itself in court below, and discovery should be allowed including depositions properly taken. Slamming shut the courthouse doors prior to allowing this routine progression of litigation, as is ordinarily allowed for plaintiffs in virtually any other case of this magnitude, was contrary to clear precedent of this Court. When a federal agency engages in conduct that allegedly causes the needless loss of life, then courts in this jurisdiction must be open for full judicial review of the agency's misconduct.

Few would doubt that the misconduct by the FDA at issue here was intended to have a substantial impact. The FDA's interference with early treatment of COVID-19 by ivermectin – a long-approved safe medication – was relied upon by state regulators and many courts in denying access by COVID-19 patients to the life-saving medication. Deaths occurred because of the FDA's misconduct, which was beyond the FDA's proper authority and imposed with an agency bias against inexpensive early treatment of COVID-19. The FDA had its own agenda contrary to that of then-President Trump, and the FDA has a history of being anti-life such that Congress itself has tried to rein in the FDA's abuse of power on this issue.

Courts should not shut down all causes of action against the FDA as it improperly imposes its anti-life ideology.

For too long the FDA been able to evade judicial review, in contrast with the rest of government. Viewed objectively, the FDA's misconduct is both defiant and appalling. The more the FDA avoids submitting to discovery procedures that are commonplace for every other defendant, the bigger that the mushrooms grow in the dark at this agency headquartered in an office building near the D.C. Beltway. Reversal is warranted of the premature dismissal of this good-faith lawsuit, which seeks a modicum of judicial scrutiny of the FDA misconduct in interfering with the practice of ethical medicine. The inexplicable actions by the FDA to impede life-saving early treatment with medication approved decades ago by the FDA itself must be reviewable in court.

ARGUMENT

"The 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) (emphasis added). This fundamental principle was more recently reiterated in a decision concerning the FDA's interference with the use of hydroxychloroquine to treat COVID-19. "Although the [Federal Food, Drug, and Cosmetic Act] regulates a manufacturer's distribution of drugs, it does not go further by regulating a

doctor's practice of medicine. … It instead leaves the regulation of doctors to the states." *Ass'n of Am. Physicians & Surgs v. United States FDA*, 13 F.4th 531, 534 (6th Cir. 2021) (citation omitted).

But this widely recognized limitation on the scope of FDA authority becomes meaningless if the FDA can evade judicial review when it violates this standard, as it did with respect to ivermectin in treating COVID-19. The FDA failed to stay in its proverbial lane, and deliberately veered across the double-lined demarcation established by Congress and the courts for keeping the FDA from interfering with the practice of life-saving medicine. Tragically, the equivalent of thousands of head-on collisions resulting in the loss of many lives resulted from the FDA's interference with ivermectin, for which the FDA must have some accountability in court.

On COVID-19, the FDA had an agenda to impede early treatment with inexpensive medication, presumably to push expensive, royalty-generating patented drugs. This bias by the FDA is neither new nor surprising. But by insisting on its own approach to treating COVID-19, the FDA acted unlawfully and harmed many. Legal accountability for the FDA's misconduct must exist.

I. This Court's Recent Precedent in *Data Marketing Partnership* Requires Reversal of the Ruling Below.

The district court repeatedly cited an applicable recent precedent of this Court, but then failed to fully follow it. *See Data Mktg. P'ship, LP v. United States DOL*, 45 F.4th 846 (5th Cir. 2022) (cited below by *Apter v. United States HHS*, No. 3:22-cv-184, 2022 U.S. Dist. LEXIS 225612, at *12, *13, *14, *15 (S.D. Tex. Dec. 6, 2022)). In *Data Mktg.*, this Court rejected an attempt by a federal agency, similar to the one below, to evade judicial review by arguing that its action was not "final" and thus non-reviewable. This Court unanimously and thoroughly rejected that argument, based on reasoning that applies with greater force here.

As this Court explained in *Data Mktg.*, finality exists for the purposes of judicial review even for advisory opinions, and even when an agency may change its mind:

> This argument [of non-reviewability] is squarely foreclosed by numerous Supreme Court decisions. *See, e.g.,* [*Sackett v. EPA*, 566 U.S. 120, 127 (2012)] ("The mere possibility that an agency might reconsider in light of 'informal discussion' and invited contentions of inaccuracy does not suffice to make an otherwise final agency action nonfinal."); *Hawkes*, 578 U.S. at 598 ("The Corps may revise an [action] within the five-year period based on new information. That possibility, however, is a common characteristic of agency action, and does not make an otherwise definitive decision nonfinal." (quotation omitted)). An action is either final or not, and the mere fact that the agency could—or actually does—reverse course in the future does not change that fact. *See Biden v. Texas*, 142 S. Ct. at 2545 ("[B]oth the June 1 Memorandum and the October 29 Memoranda, *when they were issued*, marked the consummation of the agency's decisionmaking process and resulted in rights and obligations being determined." (emphasis added)

> (quotation omitted)). ***Were it otherwise, no agency action would be final because an agency could always revisit it. And that can't be right.***

Id. at 854 (emphasis added).

That reasoning applies fully here, where finality and legal consequences should be measured against the time period of the impact. The context here is measured in days in providing early treatment for COVID-19, not a time horizon of years typical of other agency actions such as the regulation of energy or the environment. Moreover, thousands of lives hung in the immediate balance here, and widespread mortality brought finality to the impact of the FDA's actions. It is irrelevant in this context of the COVID-19 pandemic that the FDA may change its mind months or years later, when mootness sets in.

Despite this obvious immediate effect, the court below held that "the statements here are not final agency action" because:

> [s]ome of the statements at issue here imply a lack of finality, as they include language indicating that they were made based on "[c]urrently available data," "[a]dditional testing [was] needed," "[c]linical trials [were] ongoing," and "initial research [was] underway."

Apter, 2022 U.S. Dist. LEXIS 225612, at *13-14 (citing Dist. Ct. Dkts. 25-1 at 3; 25-2 at 2; 25-29 at 3). The district court further held that "no case law establishes the proposition that fleeting content on social media can mark the consummation of an agency's decisionmaking process." *Id.* But while social media may be "fleeting" in the prioritized visibility of its content, lives were simultaneously

being lost in a "fleeting" way, too. References to time durations are meaningful only when placed in context and compared against other relevant time metrics. Life itself can be "fleeting", as Shakespeare famously observed. *See Macbeth*, Act V, scene 5 ("Life's but a walking shadow, a poor player, that struts and frets his hour upon the stage, and then is heard no more. It is a tale told by an idiot …."). Fleeting conduct by the FDA warrants judicial review when its effects include immediate mortality, as it did during the COVID-19 pandemic.

The district court expressed its opinion of non-finality but ultimately relied on another aspect of that issue. "The court will not reach that question, however, because the [FDA's] statements fail the second prong of the final-agency-action test," the court below found. The ultimate basis of the decision below against finality was that "[n]one of the statements determine rights, obligations, ***or legal consequences***." *Apter*, 2022 U.S. Dist. LEXIS 225612, at *14 (emphasis added).

No legal consequences? More than a dozen reported court decisions have expressly invoked the FDA's improper statements against ivermectin as part of the court's reasoning, typically to deny access by hospitalized patients to the long-approved ivermectin medication. In a case involving a plaintiff here (Dr. Bowden), a Texas appellate court expressly relied on the FDA as follows:

> The [hospital-employed] doctor explained that he had not prescribed Ivermectin while treating Mr. Jones's COVID-19 because the Food and Drug Administration (FDA) had issued a warning that the drug should not be used

> for COVID-19 treatment, and because, likely for the same reason, the drug was not part of Huguley's COVID-19 protocol.

Tex. Health Huguley, Inc. v. Jones, 637 S.W.3d 202, 209 n.12 (Tex. App. 2021). In other words, that hospital and many other hospitals used the FDA's pronouncements at issue here as their basis for denying care to patients hospitalized with COVID-19. The Texas appellate court and many other courts affirmed that denial of care by hospitals based in part on the FDA's statements at issue in this case. That was a deadly legal consequence of the FDA's interference with the practice of physicians, including a plaintiff in this case here, as they attempted to provide life-saving care to COVID-19 patients.

The Texas appellate court began its opinion with its superficial observation that "judges are not doctors." *Id*. at 207. But the same is true about every profession and field involved in other disputes before courts, which courts properly resolve every day. *See, e.g.*, *Feyz v. Mercy Mem'l Hosp.*, 475 Mich. 663, 680, 719 N.W.2d 1, 11 (2006) (that argument "overlooks the reality that courts routinely review complex claims of all kinds" and should not grant "unfettered discretion to private hospitals"). The FDA does not properly practice medicine either, and has no experience or real expertise in how to treat COVID-19 patients. Hospitals are not licensed to practice medicine. The pronouncements by the FDA against ivermectin, as at issue in this case, had a tremendous legal consequence, as

hospitals invoked them to block access by dying hospitalized COVID-19 patients to this inexpensive medication that helped save the lives of thousands of COVID-19 patients under the care of private physicians outside of hospitals.

The *Huguley* decision was one of many appellate court decisions that deferred to hospitals as they imposed the position taken by the FDA against using ivermectin to treat COVID-19. The state appellate cases were wrongly decided, but the point is that they were decided in express reliance on the FDA's proclamations. Thus there were (and continue to be) substantial legal consequences due to the FDA's pronouncements at issue in this case.

For example, on September 9, 2021, David DeMarco sought in-patient medical treatment by Wilmington Hospital in that Delaware city. He had COVID-19 and yet the hospital denied him, against his wishes, to receive treatment by ivermectin. His wife sued in Chancery Court there, which ruled against her and the patient in heavy reliance on the FDA's position and official public statements at issue here:

> The U.S. Centers for Disease Control [("CDC")] and the FDA have issued advisories indicating that ivermectin is not authorized or approved for the prevention or treatment of COVID-19.

DeMarco v. Christiana Care Health Servs., 263 A.3d 423, 432 (Del. Del. Ch. 2021) (inner quotations and citations omitted). In denying access by this hospitalized patient to ivermectin, the Delaware Chancery Court expressly cited

the FDA eight (8) times. For example, that court expressly relied on this testimony by a physician employed by the hospital that was denying the access to ivermectin:

> Q. Doctor, why does the medication management team rely on the FDA recommendations? . . .
> A. And so the FDA, part of their role is to provide an opportunity to review [medical literature] and then provide guidance to the rest of us, as healthcare practitioners, in terms of what may be effective, as well as safe, in the management of a disease. So it's a very high bar, and the United States is known, in terms of the FDA, of having a high bar in terms of safety threshold and then efficacy, approving efficacy for management before recommending something.
> …
> Q. And is ivermectin part of these treatment guidelines that Christiana Care uses?
> A. No.

Id. at 435 n.91 (inner quotations and citations to the transcript omitted).

The above attribution of expertise and authority to the FDA to guide physicians in the practice of medicine was both unjustified and contrary to federal law. *See, e.g.*, 21 U.S.C. § 396 ("Practice of Medicine" is not to be limited by the FDA). But this Court need not even go that far. Rather, the point here is that the FDA proclamations plainly had legal consequences, and thus judicial review must be available to consider how improper, biased, and incorrect the FDA pronouncements were. The district court erred as a matter of law by holding that there were somehow no legal consequences to what the FDA engaged in as its campaign of its false disparagement of ivermectin.

In reliance on the FDA, and on the hospital that relied on the FDA, the Delaware Chancery Court ruled on September 24, 2021, against access by the hospitalized patient to a prescription written by his physician for ivermectin to treat COVID-19. David DeMarco, a former Emmy Award-Winning Editor at NBC Sports Philadelphia, then died from COVID-19-related complications 14 days after that court decision denying him access to ivermectin in reliance on the FDA.[4]

Many similar state appellate decisions were handed down around our country, virtually all in reliance on the FDA's biased and unjustified pronouncements at issue here. One such decision by the Wisconsin appellate court was taken for review by the Wisconsin Supreme Court, which held oral argument in January and a decision is pending. *Gahl v. Aurora Health Care, Inc.*, 403 Wis. 2d 539, 977 N.W.2d 756 (Ct. App.), *pet. for review granted*, No. 2021AP1787-FT, 2022 Wisc. LEXIS 506 (Sep. 14, 2022). The FDA is invoked 11 times by the appellate panel majority there, but only once by the dissenting judge who sided with the hospitalized COVID-19 patient's attempt to have access to ivermectin as prescribed by a physician. There the 2-1 panel majority quoted an Ohio court as holding against "'forcing the hospital to give ivermectin to a patient when the hospital's doctors, the FDA, CDC, and the AMA do not believe ivermectin should

[4] https://www.facebook.com/snbc13/posts/415313936920527 (viewed Feb. 8, 2023).

be a recommended way to treat COVID-19.'" *Gahl*, 403 Wis. 2d at 577 n.30, 977 N.W.2d at 775 (quoting *Smith v. West Chester Hosp., LLC*, No. CV 2021 08 1206, 2021 Ohio Misc. LEXIS 103, at *3, *7-12 (Ohio C.P. Sept. 6, 2021)). Both rulings mistakenly rely on entities that lack any license to practice medicine, as only physicians (many of whom prescribe ivermectin) have the training and authority to do so. But regardless of how wrong these state court decisions are in expressly relying on the FDA, they prove that that FDA's public stance against ivermectin has had enormous legal consequences contrary to the central holding below. *See Apter*, 2022 U.S. Dist. LEXIS 225612, at *14-19.

Similarly, a New York State court has relied heavily on the FDA's unjustified and unauthorized stance against ivermectin to deny patients access to the medication as prescribed by their physicians. "[P]er the FDA, there is no current evidence to justify off-label use of Ivermectin at this time. See *Poter v. Adams*, 104 AD3d 925, 926, 961 NYS2d 556, 558 [2d Dept. 2013] and (Why You Should Not Use Ivermectin to Treat or Prevent COVID-19, U.S. Food & Drug Administration, [citing FDA website]." *D.J.C. v. Staten Island Univ. Hosp.-Northwell Health*, 73 Misc. 3d 840, 846-47, 157 N.Y.S.3d 667, 672-73 (Sup. Ct.). *See also Frey v. Trinity Health-Michigan*, No. 359446, 2021 Mich. App. LEXIS 6988, at *2 n.5 (Ct. App. Dec. 10, 2021) (denying a hospitalized patient access to ivermectin based in part on the FDA's disparagement of it, citing *Why You Should*

Not Use Ivermectin to Treat or Prevent COVID-19, September 3, 2021, as posted by the FDA on its website).

State courts and state medical boards are expected to abide by the Supremacy Clause, which includes conforming to federal law and, by implication, pronouncements of federal agencies. No legal scholar would be surprised by any of the above state court rulings, which were foreseeable legal consequences from the FDA's pronouncements at issue here. Thus judicial review must exist in federal court to challenge the FDA on this.

II. Legal Accountability is Overdue for the FDA, Which Lacks Medical Experience While Imposing an Anti-Life Ideology.

The denial of judicial review of the FDA below has the practical effect of continuing to block any legal accountability for a federal agency that continues to impose its own ideological agenda. As shown below, the FDA's track record is contrary to the will of the American people and is defiant of elected officials. The common theme in the FDA's actions is to aggrandize power for itself, at the expense of access by patients to life-saving treatment.

The FDA has no medical expertise, contrary to unjustified, even fawning deference to it as found in some judicial opinions. FDA employees are not practicing physicians, and no one in its D.C.-area office buildings treated COVID-19 patients in large volume as AAPS member physicians did. For a new and

rapidly changing virus as COVID-19 was, a government agency cannot possibly react with the speed and flexibility that practicing physicians can as they observe and treat the disease in many patients each day. The experts here are the practicing physicians who see what works and what does not on an hourly basis. That was not the FDA during COVID-19. Pretentions of any medical expertise by the FDA employees, who process paper and emails in office buildings rather than treat COVID-19 patients, are simply false with respect to this virus. If there is to be any deference by courts on this issue, the deference should be to practicing physicians who treated many COVID-19 patients as AAPS members did.

Without judicial review, the FDA has been allowed to develop and impose its own ideology, which has long been to interfere with access by dying patients to potentially life-saving treatment. Frustrated and dismayed by the FDA's conduct on this issue, which predates COVID-19, Congress eventually enacted an extraordinary law in 2018 with bipartisan support to end this ongoing interference by the FDA. This Right to Try Act was intended by Congress to ensure that dying patients, as hospitalized COVID-19 patients later became, can access medications their physicians think may help alleviate the illness. PUB. L. NO. 115-176. But even that bipartisan legislation did not rein in the entrenched abuse of power by the FDA. It has thumbed its nose at that new law, and continued to evade judicial review.

For example, the Ninth Circuit allowed the FDA to evade judicial review for its defiance of the Right to Try Act for terminally ill cancer patients, and dismissed a lawsuit against FDA interference, by adopting the same fiction of "not a final decision" that was used by the court below:

> An advice letter recognizing that Congress has not yet made an exception to the [Controlled Substances Act (CSA)] to allow for the legal use of psilocybin for therapeutic purposes is not a final agency decision.
>
> **DISMISSED**.

Advanced Integrative Med. Sci. Inst., PLLC v. Garland, 24 F.4th 1249, 1261-62 (9th Cir. 2022) (footnote omitted, emphasis in original). With that, the FDA is allowed to continue its anti-life approach contrary to the congressional intent in passing the Right to Try Act.

On the issue of potentially life-saving treatments from reuse of one's own adult stem cells, the FDA has likewise interfered and obstructed for 20 years. Many promising life-saving cures, and treatments that might alleviate devastating paralysis, continue to be blocked by the FDA as it abuses its authority. More than two decades ago scientists agreed that adult stem cells could yield marvelous new treatments and cures, yet the FDA impeded this ever since, even for extraction and reinsertion of one's own stem cells back into himself. Federal courts are currently divided over whether the FDA's continued interference with the use of one's own adult stem cells as treatment of the same patient is something the FDA can

properly block. *See United States v. Cal. Stem Cell Treatment Ctr.*, No. EDCV 18-1005 JGB (KKx), 2022 U.S. Dist. LEXIS 156714, at *25 (C.D. Cal. Aug. 30, 2022) (ruling against the FDA's interference with autologous stem cell transplants while observing that "other courts have concluded otherwise") (citing *United States v. U.S. Stem Cell Clinic, LLC*, 403 F. Supp. 3d 1279 (S.D. Fla. 2019)). During the same time period that the FDA has blocked adult stem cell development and use, innovation in unregulated fields such as smart phones has improved lives.

The FDA has likewise interfered with compounding pharmacies as they stepped up to help COVID-19 patients during the pandemic. The FDA disparages this important component that helped enormously during COVID-19:

> Compounded drugs are not FDA-approved. This means they have not undergone premarket review for safety, effectiveness or manufacturing quality. Because they are subject to a lower regulatory standard, compounded drugs should only be used to meet the needs of patients whose medical needs cannot be met by an FDA-approved drug. The agency recommends FDA-approved drugs be used to treat patients whenever possible.

FDA, "Compounding Activities | COVID-19."[5] Ivermectin ***is*** an FDA-approved drug, so prescribing it "whenever possible" should have been supported by the FDA according to its own public position, rather than interfering with the use of ivermectin to treat COVID-19 as at issue here.

[5] https://cacmap.fda.gov/drugs/coronavirus-covid-19-drugs/compounding-activities-covid-19 (viewed Feb. 11, 2023).

This Court itself has had to rein in an abuse of power by the FDA as it attempted to interfere with compounding pharmacies prior to COVID-19 by insisting on surprise inspections of facilities in Texas and elsewhere. The FDA lost on this issue the district court level, and then did not appeal on that point to this Court, yet later the FDA asserted this power for itself anyway. This Court then flatly held against the FDA inspections. *See Med. Ctr. Pharm. v. Holder*, 634 F.3d 830, 836 (5th Cir. 2011).

If the FDA had medical expertise concerning the treatment of COVID-19, then deferring to it might make some sense. But there is no real medical expertise to defer to at the D.C.-area office buildings of the FDA, and its actual record in addressing COVID-19 was the worst in the world despite how the United States spends the most per capita on health care. *See* World Bank Data, "Current health expenditure per capita" (Jan. 30, 2022) (U.S. spends on health care more than double the per capita expenditures in France, Japan, the U.K., and other comparable countries).[6] Mortality from COVID-19 in the U.S. was reportedly far worse than other large countries, even the higher-publicized trouble spots of Brazil, Italy, and the U.K.[7]

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[6] https://data.worldbank.org/indicator/SH.XPD.CHEX.PC.CD?most_recent_value_desc=true (viewed Feb. 11, 2023).

[7] https://www.worldometers.info/coronavirus/ (viewed Feb. 11, 2023).

This higher mortality from COVID-19 under FDA policies should not surprise anyone familiar with the FDA's obsession with expanding its own power at the expense of what actually saves lives. FDA officials lack the training, expertise, and authority of practicing physicians, including the members of AAPS who had far higher success rates with their patients than the overall population did under FDA policies. Deferring to the FDA would be like deferring to General George Custer's military recommendations if discovered after his debacle at the Battle of Little Bighorn. *See* Major Bradford D. Bigler, Book Review: *The Last Stand*, 2011 Army Law. 42, 43 (May, 2011) (the book makes "a strong case that Custer was out for redemption at" Little Bighorn). Whatever credibility the FDA may have had before COVID-19, in light of the results the FDA is entitled to no deference now on anything related to it. The FDA should not be able to evade discovery and judicial review now, and FDA pronouncements should not be deferred to in court as though they were "best judgments." Rather, there should be legal accountability for "biased judgments" uncovered by discovery at the agency.

Other courts have not hesitated to call out and reject anti-life ideology by other federal agencies, hospitals, or courts. "We decline to accept the 'anti-life' principles suggested by [the federal agency] HUD that a pregnancy can never be considered a circumstance beyond a woman's control, and that a woman should have to 'choose' between bearing a child or losing the home in which she and the

child otherwise hope to live." *In re Huderson*, 96 B.R. 541, 552 (Bankr. E.D. Pa. 1989). "It is but another triumph for the forces of secular humanism (modern paganism) which have now succeeded in imposing their anti-life principles at both ends of life's spectrum." *Brophy v. New England Sinai Hosp., Inc.*, 398 Mass. 417, 443, 497 N.E.2d 626, 640 (1986) (Nolan, J., dissenting). Courts can take notice that federal agencies in the D.C. area, including the FDA, are in a political culture that is far out-of-step with the rest of our Nation. The FDA is headquartered near the D.C. "Beltway" in Montgomery County, Maryland, where only 19% of the votes in the last presidential election were reportedly cast for the pro-life Donald Trump,[8] while only 5% of the votes in D.C. were reportedly cast for him.[9] That political echo chamber lacks the breadth and depth of experience of AAPS members nationwide, and no deference to the FDA is warranted.

Indeed, in 2020 the FDA was even openly defiant of President Trump, including the FDA firing a conservative White House appointee in August 2020 as its chief spokeswoman after less than merely two weeks on the job. The FDA apparently disliked her because had worked for Sen. Ted Cruz (R-TX), and an unnamed agency official then smeared her in the press by alleging that she could

[8] https://patch.com/maryland/silverspring/montgomery-county-election-results-19-trump-79-biden (viewed Feb. 11, 2023).

[9] https://electionresults.dcboe.org/election_statistics/2020-General-Election (viewed Feb. 11, 2023).

not pronounce a medical term.[10] The FDA has dodged judicial accountability for so long that it answers to no one at this point, while patients are denied life-saving treatments nationwide on more than ivermectin.

The FDA and HHS wasted or returned the well-intentioned gift to the American people by pharmaceutical companies of 100 million pills of hydroxychloroquine for treating COVID-19, without any accountability for the FDA in a court of law for interfering with that donation. *See Ass'n of Am. Physicians & Surgs v. United States FDA*, 13 F.4th 531 (6th Cir. 2021). This bizarre conduct by the HHS/FDA is reminiscent of Stalin's withholding of grain in 1932, which perhaps could have likewise been allowed by a reviewing court indifferent to life on a theory of non-finality similar to that adopted below, despite how devastating and even fatal these decisions by a centralized government are.

The lack of judicial review of FDA conduct has resulted in an unrelenting abuse of power at that agency against allowing life-saving treatment by others. This results in the avoidable loss of innocent human life, as the agency is accountable to no one while it acts to block access by physicians and patients to beneficial medication, in this case ivermectin. The opposition to judicial review of administrative action should be rejected, as many judges on this Court expressly

[10] https://www.politico.com/news/2020/08/28/fda-top-spokesperson-leaves-404422 (viewed Aug. 29, 2020).

rejected a similar notion in *Cochran v. United States SEC*, 20 F.4th 194, 224 (5th Cir. 2021) (Oldham, J., concurring, joined by Smith, Willett, Duncan, Engelhardt, and Wilson, JJ.), *cert. granted*, 142 S. Ct. 2707 (2022).

III. The Decision Below to Deny Judicial Review of the FDA's Misconduct Would Have Devastating Consequences If Not Reversed.

If not reversed, the ruling below could become a roadmap for artful maneuvering by the FDA and other federal agencies to avoid judicial review. If official statements by federal agencies on social media, the internet, and elsewhere are never actionable, then the impact could be devastating in many fields beyond medicine, from energy to the environment. If federal agencies can hide behind pretenses of non-finality or a purported lack of legal consequences, despite how millions of people and businesses are forced to rely heavily on the directions that federal agencies take, then it might herald the end of judicial review of the administrative state. Pronouncements by agencies on social media would become unreviewable under the ruling below because they are "fleeting"; actions by agencies that are misinterpreted as not having legal consequences would likewise be considered non-final and thus non-reviewable. The decision below has the effect of expanding a loophole for taxpayer-funded, D.C.-based federal agencies to engage in enormous mischief at the expense of the American public, free enterprise, and sometimes (as here) American lives. This Court's recent *en banc*

ruling in *Cochran* stands against this. *See Cochran*, 20 F.4th at 212 (rejecting an approach whereby conduct by a federal agency would "never receive judicial review if district court jurisdiction were precluded").

The possibilities created by the decision below for improper interference by federal agencies with the energy industry comes quickly to mind. Many within the Biden Administration are politically hostile to traditional energy, and could impede energy development without judicial review in a variety of ways under the decision below. An agency's public statements against energy production, distribution, and use could then be cited by state officials and sympathetic courts to interfere with basic rights to access energy. The narrowing of judicial review of the administrative state by the district court could have potentially devastating consequences in Texas and other states, on many substantial issues. Discovery and litigation on the merits should not be prematurely cut off based on how clever a federal agency might be in imposing its own ideological agenda.

The issue of legal accountability for actions taken by the administrative state should be decided in the context of intended or likely consequences, not artful manipulation of administrative procedure by agency employees. When they make public statements they obviously intend for them to have an effect, and that should typically suffice to trigger judicial review. When agency conduct is intended to have consequences, as it usually is, then it should be immediately reviewable

without any obstacle of proving its finality. Otherwise too much harm can be inflicted by a clever federal agency without judicial review to halt its improper behavior.

This case illustrates as much. By merely adding disclaimers that the FDA's position was subject to ongoing review – when discovery below would likely show that there was no such genuine ongoing internal review – the FDA persuaded the district court to look the other way and grant the FDA immunity. The incoherence of this approach is reinforced by how a pandemic is inherently transitory, and the FDA could thereby always evade judicial review for its actions during a pandemic merely by falsely declaring that its position was subject to ongoing review. By the time finality would be clear, the pandemic would be over and the harm caused by the FDA would never be timely reviewed. Mootness would soon arrive such that judicial review would never happen, and discovery would never be allowed to test the veracity of statements made by the agency.

Six members of this Court have expressly rejected the view of Harvard Law Professor James Landis, who became an early Chairman of the Securities Exchange Commission (SEC), to shift power from the courts to the administrative state, which is essentially what the lower court did in this case at bar:

> Landis took particular umbrage at criticisms from the judiciary. Judges who failed to appreciate the SEC's efforts were as ignorant as Americans guided by numerology. And that's why Landis did not trust courts to review the

SEC's work. To the contrary, Landis wanted *agencies* to do *the courts'* work. *Cochran*, 20 F.4th at 221 (Oldham, J., concurring, joined by Smith, Willett, Duncan, Engelhardt, and Wilson, JJ., emphasis in original).

This Court need not rule here against the FDA on the ultimate merits of this case, but merely that this case should proceed to discovery below rather than allow the FDA to prematurely avoid any judicial review of its conduct. If the FDA acted earnestly and with justification, then discovery would prove as much. But if, as appears likely, the FDA had its own ideological agenda that it was promoting through its pronouncements, and may have even been urged to do so by special outside interests, then let that come out in discovery and let the chips fall where they may on a motion for summary judgment or at trial.

CONCLUSION

For the foregoing reasons and those stated in the Appellants' brief, the decision below should be fully reversed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on February 13, 2023, I electronically filed the foregoing brief with the Clerk of the Court for the U.S. Court of Appeals for the Fifth Circuit by using the Appellate CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the CM/ECF system.

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CERTIFICATE OF COMPLIANCE

1. This brief has been prepared using Times New Roman 14-point, proportionately spaced, serif typeface, in Microsoft Word.

2. This brief complies with FED. R. APP. P. 29(a)(5) and 32(a)(7)(B) because it contains a total of 6,209 words, excluding material not counted under Rule 32(f).

Dated: February 13, 2023

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