

No. 19-15615

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**In the United States Court of Appeals  
for the Ninth Circuit**

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**GOLDWATER INSTITUTE,**

*Plaintiff-Appellant,*

v.

**UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,**

*Defendant-Appellee.*

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On Appeal from the United States District Court  
for the District of Arizona,  
Case No. 2:15-cv-01055-SRB (Hon. Susan R. Bolton)

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**BRIEF AMICUS CURIAE OF  
THE NEW CIVIL LIBERTIES ALLIANCE  
IN SUPPORT OF PLAINTIFF-APPELLANT AND REVERSAL**

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**CORPORATE DISCLOSURE STATEMENT  
AND FED. R. APP. P. 29(a)(4)(E) STATEMENT**

The New Civil Liberties Alliance is a 501(c)(3) nonprofit organization organized under the laws of the District of Columbia. It has no parent corporation and no publicly held corporation owns ten percent or more of its stock.

All parties were timely notified and consented to the filing of this brief. No counsel for a party authored any part of this brief. No one other than amicus curiae, its members, or its counsel financed the preparation or submission of this brief.

**TABLE OF CONTENTS**

CORPORATE DISCLOSURE STATEMENT AND FED. R. APP. P. 29(a)(4)(E) STATEMENT .....ii

TABLE OF CONTENTS .....iii

TABLE OF AUTHORITIES ..... v

INTEREST OF AMICUS CURIAE..... 1

SUMMARY OF THE ARGUMENT..... 3

ARGUMENT ..... 5

I. THIS COURT SHOULD NOT ENDORSE THE DISTRICT COURT’S ABANDONMENT OF ITS DUTY OF INDEPENDENT JUDGMENT..... 5

II. THIS COURT SHOULD INSTRUCT DISTRICT COURTS TO NOT VIOLATE THE DUE PROCESS CLAUSE BY DISPLAYING BIAS TOWARD ONE OF THE LITIGATING PARTIES..... 7

    A. SHOWING BIAS TOWARD AN AGENCY LITIGANT VIOLATES DUE PROCESS RIGHTS OF THE OTHER LITIGANT(S)..... 7

    B. SHOWING BIAS AGAINST A LITIGANT OPPOSED TO AN AGENCY’S POSITION DENIES DUE PROCESS..... 9

III. THE COURT SHOULD CALL OUT THESE CONSTITUTIONAL PROBLEMS WITH *AUER* DEFERENCE NOTWITHSTANDING THE REQUIREMENTS OF *STARE DECISIS*..... 9

IV. *KISOR* REQUIRES REVERSAL HERE..... 12

    A. THE PLAIN MEANING OF THE WORDS OF THE AGENCY’S REGULATION SHOWS THE AGENCY’S— AND THE DISTRICT COURT’S—ARGUMENT FAILS *AUER* STEP ZERO..... 12

B. AT MINIMUM, <i>KISOR</i> REQUIRES THE COURT TO CONDUCT A RIGOROUS STEP ZERO ANALYSIS TO DETERMINE WHETHER <i>AUER</i> EVEN APPLIES.....	14
CONCLUSION .....	16
CERTIFICATE OF SERVICE .....	17
CERTIFICATE OF COMPLIANCE .....	18

## TABLE OF AUTHORITIES

### Cases

<i>Al-Fayed v. CIA</i> , 254 F.3d 300 (D.C. Cir. 2001).....	15
<i>Auer v. Robbins</i> , 519 U.S. 452 (1997).....	passim
<i>Caperton v. A.T. Massey Coal Co.</i> , 556 U.S. 868 (2009).....	7
<i>Epic Systems Corp. v. Lewis</i> , 138 S. Ct. 1612 (2018).....	14
<i>Food Marketing Institute v. Argus Leader Media</i> , 139 S. Ct. 2356 (2019).....	13
<i>Graves v. New York</i> , 306 U.S. 466 (1939).....	10
<i>Gutierrez-Brizuela v. Lynch</i> , 834 F.3d 1142 (10th Cir. 2016).....	7, 11
<i>Hopkins v. Dep’t of Housing &amp; Urban Dev’t</i> , 929 F.2d 81 (2d Cir. 1991).....	15
<i>King v. Mississippi Military Dep’t</i> , 245 So.3d 404 (Miss. 2018).....	7
<i>Kisor v. Wilkie</i> , 139 S. Ct. 2400 (2019).....	passim
<i>Lessner v. U.S. Dep’t of Commerce</i> , 827 F.2d 1333 (9th Cir. 1987).....	15
<i>Marbury v. Madison</i> , 5 U.S. 137 (1803).....	2, 10
<i>Masterpiece Cakeshop, Ltd. v. Colorado Civil Rights Comm’n</i> , 138 S. Ct. 1719 (2018) .....	8
<i>Tetra Tech. EC, Inc. v. Wisconsin Dep’t of Revenue</i> , 914 N.W.2d 21 (Wis. 2018).....	6, 9
<i>United Student Aid funds, Inc. v. Bible</i> , 136 S. Ct. 1607 (2016).....	9
<i>Utah Animal Rights Coalition v. Salt Lake City Corp.</i> , 371 F.3d 1248 (10th Cir. 2004).....	11
<i>W. Alabama Women’s Ctr. v. Williamson</i> , 900 F.3d 1310 (11th Cir. 2018).....	11
<i>Wilson v. Safelite Group, Inc.</i> , ___ F.3d ___, 2019 WL 3000995 (6th Cir. July 10, 2019).....	11

**Constitutional Provisions**

U.S. Const. art. III .....3, 5, 6, 7  
 U.S. Const. amend. V (Due Process Clause) .....1, 3, 7, 9, 12

**Statutes**

5 U.S.C. § 551(2) ..... 13  
 5 U.S.C. § 552(a) ..... 14  
 5 U.S.C. § 552(a)(4)(B) ..... 15  
 5 U.S.C. § 552(b)(4) (Exemption 4) ..... 13  
 28 U.S.C. § 453..... 4, 8  
 Ariz. Rev. Stat. § 12-910(E)..... 7

**Regulations**

21 C.F.R. § 601.51 .....13, 14, 15

**Rules**

Cir. R. 29-2(c)(2) ..... 18  
 Cir. R. 29-2(c)(3) ..... 18  
 Fed. R. App. P. 29(a)(4)(E).....ii  
 Fed. R. App. P. 29(a)(5) ..... 18  
 Fed. R. App. P. 32(a)(5) ..... 18  
 Fed. R. App. P. 32(a)(6) ..... 18  
 Fed. R. App. P. 32(f) ..... 18

**Other Authorities**

Br. for Pet’r in *Kisor v. Wilkie*, S. Ct. No. 18-15, 2019 WL 338890 (Jan. 24, 2019) ..... 4  
 Edward A. Hartnett, *A Matter of Judgment, Not a Matter of Opinion*, 74 N.Y.U.L. Rev. 123 (1999)..... 11

Judicial Conference of the U.S., Code of Conduct for United States Judges (2014), <a href="https://bit.ly/2VVup3F">https://bit.ly/2VVup3F</a> .....	12
Philip Hamburger, <i>Chevron Bias</i> , 84 Geo. Wash. L. Rev. 1187 (2016).....	7
Philip Hamburger, <i>Law and Judicial Duty</i> (Harvard 2008) .....	5
Thomas W. Merrill, <i>Judicial Opinions as Binding Law and as Explanations of Judgments</i> , 15 Cardozo L. Rev. 43 (1993) .....	11

## INTEREST OF AMICUS CURIAE

The New Civil Liberties Alliance (NCLA) is a nonprofit civil-rights organization devoted to defending civil liberties. As a public-interest law firm, NCLA was founded to challenge multiple constitutional defects in the modern administrative state through original litigation, amicus curiae briefs, and other means.

The “civil liberties” of the organization’s name include rights at least as old as the U.S. Constitution itself, such as jury trial, due process of law, the right to be tried by an impartial and independent judge, and the right to live under laws made by the nation’s elected lawmakers through constitutionally prescribed channels, as opposed to illicit unconstitutional shortcuts. Although these civil rights are as important today as they were when our Republic was founded, they have been trampled, belittled and ignored repeatedly by Congress, administrative agencies, and sometimes even the courts—and are in dire need of renewed vindication.

NCLA views the administrative state as an especially serious threat to civil liberties. No other current development in American law denies more rights to more Americans. NCLA primarily aims to defend civil liberties by asserting constitutional constraints on the administrative state. Although Americans still enjoy the shell of their Republic, a very different sort of government has developed within it—a type that our Constitution was designed to prevent. This unconstitutional “administrative state,” which has been allowed to fester and grow within our government, is the focus of NCLA’s concern.

NCLA is particularly disturbed by the practice of extending judicial deference to a federal agency’s self-created exception from the Freedom of Information Act. The



court below eschewed its fundamental duty to “say what the law is,” *Marbury v. Madison*, 5 U.S. 137, 177 (1803), and deferred to the agency interpretations of its regulations under *Auer v. Robbins*, 519 U.S. 452 (1997). ER.011.<sup>1</sup> In doing so, it departed from its duty to independently interpret statutory and regulatory text without bias toward any litigating party.

Furthermore, this amicus curiae brief highlights the concerns expressed in the U.S. Supreme Court’s recent opinions in *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019). NCLA participated as amicus curiae in *Kisor* and Justice Gorsuch’s concurrence in the judgment adopted its argument that the majority’s decision does not address (let alone resolve) the constitutional defects of deferring under *Auer*. NCLA believes that its litigation experience and administrative law expertise will help the Court to resolve this case.

All parties were timely notified about and consented to the filing of this brief.

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<sup>1</sup> ER.nnn refers to the Excerpt of Record page numbers filed by Plaintiff-Appellant at Ninth Circuit Docket No. 14. The page numbers are those assigned by the Plaintiff-Appellant, and *not* the electronic page numbers generated by the Court’s CM/ECF system.

## SUMMARY OF THE ARGUMENT

The Constitution requires federal judges to exercise independent judgment and refrain from bias when interpreting the law. These are foundational constitutional requirements for having an independent judiciary. Article III gives federal judges life tenure and salary protection to ensure that judicial pronouncements will reflect a court's independent judgment rather than the desires of the political branches. Also, the Due Process Clause forbids judges to display any type of bias in favor of or against a litigant when resolving disputes. These statements of judicial duty are so axiomatic that they are seldom if ever mentioned or relied upon in legal argument—because to even suggest that a court might depart from its duty of independent judgment or display bias toward a litigant would be a scandalous insinuation.

Yet the judiciary ignores these foundational constitutional commands whenever it defers to an agency's interpretation of regulations that the agency wrote. *See Kisor v. Wilkie*, 139 S. Ct. 2400 (2019); *Auer v. Robbins*, 519 U.S. 452 (1997); *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945). This practice violates the Constitution by requiring judges to abandon their duty of independent judgment, in violation of Article III and the judicial oath. Such deference also raises serious due-process and separation-of-powers questions when it instructs courts to construe ambiguities *against* (rather than in favor of) FOIA records requesters.

While the *Auer* deference doctrine has been roundly criticized, the bulk of the criticism has ignored the glaring constitutional problems with this court-created

deference regime.<sup>2</sup> The *Kisor* Petitioner, for example, only made cursory mention of *Auer*'s constitutional problems and limited his objection to the separation of powers problem with deference. There was no five-justice majority on the constitutionality question in *Kisor*. *Kisor* did not foreclose NCLA's two main constitutional objections to *Auer*—independent judgment and judicial bias. The Court should call out these constitutional problems notwithstanding the requirements of *stare decisis*. Indeed, because each member of this Court is bound by oath to support and defend the Constitution of the United States, 28 U.S.C. § 453, he or she has a duty to address and expound *Auer*'s constitutional defects so that the Supreme Court can fulfill its duty to act promptly in confessing error and correcting its own unlawful doctrine. There are two ways of fulfilling this duty: writing an opinion that flags these constitutional defects while entering a judgment that follows the deference regime *or* recusing from the case to avoid explicit bias in favor of the federal-agency litigant.

*Kisor* created an “*Auer* Step Zero,” listing several factors courts should consider in determining whether *Auer* even applies to an agency's interpretation of its regulations. Under *Kisor*'s methodology, the plain meaning of the words of the relevant regulation shows the decision below fails *Auer* Step Zero. That is because, at a minimum, *Kisor* requires the Court to conduct a rigorous analysis employing traditional tools of statutory construction to determine whether *Auer* even applies.

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<sup>2</sup> See Br. for Pet'r in *Kisor v. Wilkie*, S. Ct. No. 18-15, 2019 WL 338890 (Jan. 24, 2019) (devoting only two pages to the constitutional problems with *Auer* deference); *Kisor v. Wilkie*, 139 S. Ct. at 2421–22 (only four Justices concluded—devoting a single paragraph to the discussion—that deferring under *Auer* does not violate the Constitution).

## ARGUMENT

### I. THIS COURT SHOULD NOT ENDORSE THE DISTRICT COURT'S ABANDONMENT OF ITS DUTY OF INDEPENDENT JUDGMENT.

The first constitutional problem with *Auer* is that it compels judges to abandon their duty of independent judgment. The federal judiciary was established as a separate and independent branch of the federal government, and its judges were given life tenure and salary protection to shield their decision-making from outside influences. *See* U.S. Const. art. III.<sup>3</sup> Yet the court below abandoned judicial independence by giving automatic weight to the FDA's opinion that documents generated by the agency are exempt from disclosure under the Freedom of Information Act (FOIA). ER.011. That is, the district court deferred to the FDA's self-serving opinion not on account of its persuasiveness, but on account of the brute fact that this non-judicial entity has weighed in on the interpretive question before the Court. *See Kisor*, 139 S. Ct. at 2414. The constitutional problem is especially acute where, as here, the FDA interpreted its regulation in the process of litigating the case.

Such abandonment of independent judgment would never be tolerated in any other context—even if it were commanded by statute and even if it commanded deference to a uniquely expert body. Imagine if a statute established a committee of expert law professors and instructed the federal judiciary to “defer” to this committee's announced interpretations of federal regulations so long as its pronouncements were “reasonable.” A statute of this sort would be laughed out of court; it would be declared an

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<sup>3</sup> *See also* Philip Hamburger, *Law and Judicial Duty* 507–35 (Harvard 2008).

invasion of the judicial prerogatives of Article III and a perversion of the independent judgment that the Constitution requires from the judiciary.

Yet *Auer* (and now *Kisor*) operate precisely the same way: they allow a non-judicial entity—the Food and Drug Administration or the Department of Health and Human Services—to partake in the powers of judicial interpretation. Further, they command judges to defer to the legal pronouncements of a supposedly expert body external to the judiciary—and worse yet, to do so when that body it is a litigant. It is no different in practice from an instruction that courts assign weight and defer to interpretations of agency regulations announced by a congressional committee, a group of expert legal scholars, the *New York Times* editorial board, or a prominent executive-branch official’s Twitter comments. In each of these scenarios, the courts would be following another entity’s interpretation of an agency rule so long as it were “reasonable”—even if the court’s own judgment would lead it to conclude that the regulation means something else.

To be clear, an agency is entitled to have its views heard and considered by the court, just as any other litigant or amicus party, and a court may and should consider the “unique insights” an agency might bring on account of its expertise and experience. *Tetra Tech. EC, Inc. v. Wisconsin Dep’t of Revenue*, 914 N.W.2d 21, 53 (Wis. 2018). None of this respectful consideration compromises a judge’s duty of independent judgment. But *Auer* requires far more; it commands that courts give weight to these views simply because the agency espouses them, and it instructs courts to subordinate their own judgments to the views expressed by the agency. The duty of independent judgment forbids

a regime in which courts defer or give automatic weight to a non-judicial entity's interpretations of regulatory language, a fact that our states have recognized as well.<sup>4</sup>

## II. THIS COURT SHOULD INSTRUCT DISTRICT COURTS TO NOT VIOLATE THE DUE PROCESS CLAUSE BY DISPLAYING BIAS TOWARD ONE OF THE LITIGATING PARTIES.

A related and even more serious problem is that *Auer* deference removes the judicial blindfold. It requires judges to display “systematic bias” toward agencies—and against their counterparties—when they appear as litigants. *See* Philip Hamburger, *Chevron Bias*, 84 *Geo. Wash. L. Rev.* 1187, 1250 (2016). It is bad enough that a judge would abandon his Article III duty of independent judgment by “deferring” to a non-judicial entity's interpretation of a statute. But for a judge to abandon his independent judgment in a manner that favors an actual *litigant* before the court is an even graver matter.

### A. SHOWING BIAS TOWARD AN AGENCY LITIGANT VIOLATES THE DUE PROCESS RIGHTS OF THE OTHER LITIGANT(S).

The Supreme Court has held that even the *appearance* of potential bias toward a litigant violates the Due Process Clause. *See generally Caperton v. A.T. Massey Coal Co.*, 556 U.S. 868 (2009). Yet *Auer* institutionalizes a regime of systematic judicial bias by

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<sup>4</sup> *See, e.g.*, Ariz. Rev. Stat. § 12-910(E) (“In a proceeding brought by or against the regulated party, the court shall decide all questions of law, including the interpretation of a constitutional or statutory provision or a rule adopted by an agency, without deference to any previous determination that may have been made on the question by the agency.”); *King v. Mississippi Military Dep’t*, 245 So.3d 404, 408 (Miss. 2018) (rejecting judicial deference to agency interpretations of statutes because such deference prevents courts from “fulfill[ing] their duty to exercise their independent judgment about what the law *is*.” (quoting *Gutierrez-Briquetela v. Lynch*, 834 F.3d 1142, 1158 (10th Cir. 2016) (Gorsuch, J., concurring)) (emphasis in original)).

requiring courts to defer to agency litigants whenever the parties dispute the meaning of an agency regulation. Rather than exercise their own judgment about what the law is, judges under *Auer* consciously defer to the judgment of one of the litigants before them. See *Masterpiece Cakeshop, Ltd. v. Colorado Civil Rights Comm’n*, 138 S. Ct. 1719, 1734 (2018) (holding that agency and judicial proceedings are required to provide “neutral and respectful consideration” of a litigant’s views free from hostility or bias); *id.* at 1734 (Kagan, J., concurring) (agreeing that the Constitution forbids agency or judicial proceedings that are “infected by ... bias”).

If a judge were to openly admit that he accepts a plaintiff’s interpretation of agency regulations whenever it is reasonable—and that he automatically rejects any competing and perhaps more reasonable interpretation that might be offered by a defendant—would likely be impeached and kicked off the bench for bias and abuse of power. Yet that is exactly what judges do whenever they apply *Auer* deference in cases where the agency appears as a litigant while the opposing litigant gets no such indulgence from the court and must show that the government’s view is not merely wrong but *unreasonably so*.

All federal judges take an oath to “administer justice without respect to persons” and to “faithfully and impartially discharge and perform all the duties incumbent upon [them].” 28 U.S.C. § 453. And judges are ordinarily extremely scrupulous about living up to these commitments. Nonetheless, under *Auer*, judges who are supposed to administer justice “without respect to persons” peek from behind the judicial blindfold and precommit to favoring the agency litigant’s position.

Whenever *Auer* is applied in a case in which the government is a party, the courts are denying due process by showing “systematic favor” to the government’s interpretation of the law, and thereby “depriv[ing] the non-governmental party of an independent and impartial tribunal.” *Tetra Tech.*, 914 N.W.2d at 50.

**B. SHOWING BIAS AGAINST A LITIGANT OPPOSED TO AN AGENCY’S POSITION DENIES DUE PROCESS.**

Even when the government is not a litigant but appears as an *amicus curiae* (or when the Solicitor General is invited to participate in a case), deferring to the government’s position under *Auer* still denies due process to whichever litigant stands opposed to the government. Rather than having the opportunity to convince an impartial magistrate of the rightness of the litigant’s cause, that litigant is forced to try to overcome the government’s thumb on the scale for her opponent. Such favoritism may happen even when the government’s position is created in the course of that very litigation. *See, e.g., United Student Aid Funds, Inc. v. Bible*, 136 S. Ct. 1607, 1608 (2016) (Thomas, J., dissenting from the denial of certiorari) (criticizing the Seventh Circuit for deferring under *Auer* to an agency’s interpretation of its rules that was set forth in an *amicus* brief).

**III. THE COURT SHOULD CALL OUT THESE CONSTITUTIONAL PROBLEMS WITH *AUER* DEFERENCE NOTWITHSTANDING THE REQUIREMENTS OF *STARE DECISIS*.**

*Auer* never considered or addressed these constitutional objections to a regime of agency deference. A four-justice portion of Justice Kagan’s opinion in *Kisor* devoted a single paragraph to discussing the constitutional objections. *Kisor*, 139 S. Ct. at 2421–22.



*Stare decisis* therefore presents no obstacle to a lower court thoroughly discussing these constitutional issues in its opinion. Such a thorough analysis will enable the Supreme Court to better fulfill its duties as the highest court in the land. In all events, this Court’s ultimate duty is to enforce the Constitution—even if it comes at the expense of pointing out the defects in Supreme Court opinions. *See Graves v. New York*, 306 U.S. 466, 491–92 (1939) (Frankfurter, J., concurring) (“[T]he ultimate touchstone of constitutionality is the Constitution itself and not what we have said about it.”).

Furthermore, courts have traditionally given *stare decisis* effect to specific, narrow holdings that settle the meaning of a specific statute or regulation, or that resolve a particular case. However, giving *stare decisis* effect “to prescribe an interpretive methodology governing every future dispute over the meaning of every regulation” is an altogether different matter. *Kisor*, 139 S. Ct. at 2444 (Gorsuch, J., concurring in the judgment). “In contrast to precedents that fix the meaning of *particular* statutes and generate reliance interests in the process, the *Auer* doctrine is an abstract default rule of interpretive methodology that settles nothing of its own force.” *Id.* at \*31 (emphasis in original). *Auer*—and now *Kisor*—which require adherence to *stare decisis* for methodological choices undermine judicial independence and intrude upon a federal judge’s duty to “say what the law is.” *Marbury v. Madison*, 5 U.S. 137, 177 (1803).

Under *Kisor*, notwithstanding its constitutional defects, this Court has two options:

1. Write an *opinion* that flags these constitutional problems while entering a *judgment* that accords with the status quo deference regime. The obligations of *stare decisis* extend only to the judgment that a court enters. “The operative legal act” that a court

performs, “is the entry of a judgment.” Edward A. Hartnett, *A Matter of Judgment, Not a Matter of Opinion*, 74 N.Y.U.L. Rev. 123, 126–27 (1999). “[J]udicial opinions are simply explanations for judgments—essays written by judges explaining why they rendered the judgment they did.” Thomas W. Merrill, *Judicial Opinions as Binding Law and as Explanations for Judgments*, 15 Cardozo L. Rev. 43, 62 (1993). Lower-court judges have written such opinions many times in response to Supreme Court decisions that they regard as lawless or unconstitutional.<sup>5</sup> Indeed, that is an appropriate and respectful way to provoke reconsideration of a mistaken Supreme Court precedent.

2. Another option is for a judge to recuse himself to avoid participating in a deference regime that exhibits unconstitutional bias and violates the judicial oath. The code of judicial conduct requires a judge to “disqualify himself or herself in a proceeding in which the judge’s impartiality might reasonably be questioned, including but not limited to instances in which ... the judge has a personal bias or prejudice concerning a

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<sup>5</sup> See *Wilson v. Safelite Group, Inc.*, \_\_\_ F.3d \_\_\_, 2019 WL 3000995 (6th Cir. July 10, 2019) (Stranch, J., delivered the opinion of the court in which Rogers, J., joined; Thapar, J., delivered a separate opinion concurring in part and in the judgment; Stranch, J., delivered a separate concurrence); *W. Alabama Women’s Ctr. v. Williamson*, 900 F.3d 1310, 1314 (11th Cir. 2018) (Carnes, C.J., joined by Dubina, J.) (applying and enforcing the Supreme Court’s jurisprudence on a specific subject matter while denouncing it as an “aberration of constitutional law”); *Utah Animal Rights Coalition v. Salt Lake City Corp.*, 371 F.3d 1248, 1262–71 (10th Cir. 2004) (Judge McConnell, who wrote the majority opinion, writing separately to call upon the Supreme Court to overturn or cabin its prior decisions on a point of law); *id.* at 1271–75 (Judge Henry, concurring in the judgment, and writing separately to urge the Supreme Court to strengthen and reaffirm its prior decisions on that point of law); *Gutierrez-Brizuela*, 834 F.3d at 1149 (then-Judge Gorsuch writing the panel’s opinion and entering judgment, but writing a separate concurring opinion calling upon the Supreme Court to “face the behemoth” of deference doctrines).

party.”<sup>6</sup> One can reasonably question the impartiality of *any* judge who systematically prefers an agency’s statutory interpretations over those offered by opposing litigants. And a judge cannot excuse this display of bias by invoking his duty to follow the Supreme Court; there is no “superior-orders defense” available in the code of judicial conduct.

Viewed in this perspective, recusal may be the only acceptable choice for judges who feel caught between the demands of *stare decisis* and their duty to avoid bias. Moreover, principled recusals would provide the added benefit of emphasizing how *Auer* compels judges to betray the core responsibilities of the judicial office. The abandonment of independent judgment and the display of systematic bias in favor of the powerful is the legacy of the deferential regime that the Supreme Court has nurtured and propagated. It is long past time for conscientious judges to call out the ways in which this deference has corrupted the judiciary—and to advocate a return to judicial independence and the due process of law that our Constitution demands.

#### **IV. *KISOR* REQUIRES REVERSAL HERE.**

##### **A. THE PLAIN MEANING OF THE WORDS OF THE AGENCY’S REGULATION SHOWS THE AGENCY’S—AND THE DISTRICT COURT’S—ARGUMENT FAILS *AUER* STEP ZERO.**

In *Kisor*, the Court created a Step Zero that requires courts first to use traditional tools of construction and evaluate other factors to determine whether there is a need to resort to *Auer* deference. If it was not clear before, *Kisor* reiterated that any “reflexive” deference—like the court below gave to the FDA’s litigating position—is a “caricature

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<sup>6</sup> Judicial Conference of the U.S., Code of Conduct for United States Judges (2014), <https://bit.ly/2VVup3F>.

of the [*Auer* deference] doctrine.” 139 S. Ct. at 2415. The plain meaning of the relevant regulation and FOIA Exemption 4 unequivocally point to reversal of the district court’s decision.

Exemption 4 protects “information obtained from a person.” 5 U.S.C. § 552(b)(4); *see also Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356 (2019) (discussing limitations of Exemption 4 by construing the plain words of the statute). The Administrative Procedure Act, of which FOIA is a part, defines “person” as “an individual, partnership, corporation, association, or public or private organization *other than an agency*.” 5 U.S.C. § 551(2) (emphasis added). Therefore, Exemption 4 could not apply to information “obtained from” an agency. Only “information *obtained from* a person” can be subject to nondisclosure under Exemption 4. In other words, Exemption 4 does not touch information or documents generated or created *by* the agency. Try as it might, the FDA cannot expand the scope of Exemption 4 by issuing a regulation. And that is precisely what the agency did when it wrote 21 C.F.R. § 601.51. It was confined to the limits of Exemption 4 as is readily discernible from the text of the regulation.

The relevant regulation here states that “the biological product file includes all data and information *submitted with* or incorporated by reference in any *application for* a biologics license, ... and other related *submissions*.” *Id.* (emphasis added). Neither the statutory language of Exemption 4 nor the plain words of the agency’s regulations exempt from disclosure documents or information *created by* the agency. Yet the agency interpreted its regulations to shield documents, emails, and other information *created by* the agency—and the district court endorsed that interpretation as “reasonable” under

the *Auer* deference doctrine. ER.011. Thus, the agency’s contrived interpretation, on its face, flunks *Auer* Step Zero.

**B. AT MINIMUM, *KISOR* REQUIRES THE COURT TO CONDUCT A RIGOROUS STEP ZERO ANALYSIS TO DETERMINE WHETHER *AUER* EVEN APPLIES.**

*Kisor* plainly instructs courts to “resort[] to all the standard tools of interpretation” to determine if a regulation is “genuinely ambiguous.” 139 S. Ct. at 2414. The possibility of *Auer* deference does not even arise until the court determines the regulation to be genuinely ambiguous. Consequently, this Court “must exhaust all the ‘traditional tools’ of construction,” and “make an independent inquiry into whether the character and context of the agency interpretation entitles it to controlling weight.” *Id.* at 2415–16. The agency’s interpretation must not only be “reasonable” but it also “must be one actually made by the agency.” *Id.* In other words, it must be the agency’s “authoritative” or “official position,” *id.* at 2416, rather than—as here—a declaration by an agency official who sifted through the records and determined that 21 C.F.R. § 601.51 precludes her from releasing records created by the federal agency. ER.006 & ER.010 (citing Sixth Decl. of Nancy Sager, FDA’s DIDP<sup>7</sup> Director ¶¶ 7–13).

Furthermore, the agency’s interpretation “must in some way implicate its substantive expertise.” *Kisor*, 139 S. Ct. at 2417. The Freedom of Information Act, which applies to “[e]ach [federal] agency,” 5 U.S.C. § 552(a), conclusively establishes that neither the FDA nor the HHS has any special “substantive expertise” in FOIA matters.<sup>8</sup>

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<sup>7</sup> DIDP is the Division of Information Disclosure Policy at the FDA. ER.003.

<sup>8</sup> See, e.g., *Epic Systems Corp. v. Lewis*, 138 S. Ct. 1612, 1629 (2018) (When, as “[h]ere, ... the [NLRB] hasn’t just sought to interpret its statute, the NLRA, in isolation; it has sought to interpret this statute in a way that limits the work of a second statute, the

What's more, the fact that the interpretation of 21 C.F.R. § 601.51 was given in an affidavit and memorandum submitted during litigation strongly suggests that the agency's reading of the regulation is not a "fair and considered judgment." *Kisor*, 139 S. Ct. at 2417. Instead, it is precisely the type of "merely convenient litigating position or *post hoc* rationalization advanced to defend agency action against attack" that *does not* get *Auer* deference. *Id.* (cleaned up). The agency's argument finds textual basis neither in its own regulation nor in Exemption 4. Consequently, even if the Court walks through the *Auer* Step Zero analysis, there is no occasion to apply *Auer* in this case.

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Arbitration Act, ... on no account might we agree that Congress implicitly delegated to an agency authority to address the meaning of a second statute it does not administer."); *Al-Fayed v. CIA*, 254 F.3d 300, 306–07 (D.C. Cir. 2001) ("[I]t is precisely because FOIA's terms apply government-wide that" "agency-specific 'expertise' is of no significance."); *Lessner v. U.S. Dep't of Commerce*, 827 F.2d 1333, 1335 (9th Cir. 1987) (Because "a basic policy of FOIA is to ensure that Congress and not administrative agencies determine[] what information is confidential ... , deference appears inappropriate in the FOIA context."); *Hopkins v. Dep't of Housing & Urban Dev't*, 929 F.2d 81, 84 (2d Cir. 1991) ("An agency's decision to withhold records requested under the FOIA is subject to *de novo* judicial review." (citing 5 U.S.C. § 552(a)(4)(B))).

## CONCLUSION

Based on the FDA's *ipse dixit*, the agency withheld "[n]ine volumes," ER.343, of records, most of them generated within the agency, and not exempt from disclosure under FOIA Exemption 4. Therefore, the Court should reverse the decision below with instructions to mandate that the FDA release the records requested by the Plaintiff-Appellant.

Respectfully submitted, on July 17, 2019.

*/s/ Margaret A. Little*

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### **CERTIFICATE OF SERVICE**

I certify that this brief was filed using the Case Management / Electronic Case Filing (CM/ECF) system of the U.S. Court of Appeals for the Ninth Circuit. Counsel for all parties are registered CM/ECF users. Service is accomplished by the CM/ECF system.

/s/ Margaret A. Little  
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Dated: July 17, 2019



### **CERTIFICATE OF COMPLIANCE**

This brief contains 4,242 words, excluding the items exempted by Fed. R. App. P. 32(f). The brief's type style and typeface comply with Fed. R. App. P. 32(a)(5) and (6) because it is proportionally spaced, includes serifs, and is 14-point.

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/s/ Margaret A. Little  
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Dated: July 17, 2019