

No. 17-71121

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

In re THOMAS E. PRICE,
SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*,
Defendants and Petitioners,

v.

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT
OF CALIFORNIA,
Respondent,

INSTITUTE FOR FISHERIES RESOURCES, *et al.*,
Plaintiffs and Real Parties in Interest.

On Petition from an Order of the United States District Court
For the Northern District of California
Case No. 3:16-cv-01574-VC
The Honorable Vince Chhabria
United States District Judge

**UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF AS *AMICI*
CURIAE IN OPPOSITION TO PETITION FOR WRIT OF
MANDAMUS**

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Unopposed Motion for Leave to File Brief of *Amici Curiae*

Pursuant to Federal Rules of Appellate Procedure 27 and 29 and Circuit Rule 29, the undersigned law professors respectfully request that the Court grant them leave to file an amicus brief in this matter, in opposition to petitioners Thomas E. Price, Secretary of Health and Human Services, et al.'s (hereinafter collectively referred to as "FDA") Petition for a Writ of Mandamus to the United States District Court for the Northern District of California.

Amici have written about and taught administrative, environmental, and open government law for years, and in some cases for decades, and have a strong interest in the proper implementation of the Administrative Procedure Act ("APA") and in the correct application of the "deliberative process privilege" that the FDA has invoked here. Moreover, *amici* have engaged in the teaching, research, writing, and practice of law under the judicial review provisions of the APA, which compel the review of agency action on the basis of "the whole record or those parts of it cited by a party[.]" 5 U.S.C. § 706. Several of the *amici* have written and published

articles on the scope and application of the deliberative process privilege or Exemption 5 of the Freedom of Information Act (which encompasses the deliberative process privilege) and the process by which agencies compile and submit administrative records in judicial review actions under the APA.

The issue before this Court is the application of the “deliberative process privilege,” a long-recognized evidentiary privilege that has its origins in the common law and which has been ably handled by courts for decades under a traditional privilege analysis, but which FDA now seeks to convert into an ironclad rule it can use to keep documents of its own choosing out of the administrative record—and away from public and judicial scrutiny. In the accompanying brief, *amici* present two main arguments: First, that the origins and evolution of the deliberative process privilege, as reflected in the cases relied upon by FDA, do not support the agency’s request for a black-letter rule that deliberative documents may be unilaterally excluded from an administrative record. And second, that several strong public policy implications compel the rejection of the rule FDA seeks here.

Pursuant to Federal Rule of Appellate Procedure 29 and Circuit Rule 29-3, *amici* have obtained the consent of all parties before moving to file their amicus brief. Based upon communications with the parties' counsel, Respondents Institute for Fisheries Resources, et al. (plaintiffs below) consent to the filing of this *amicus* brief. Petitioner FDA consents to the filing of this *amicus* brief, provided that it is filed on the same date that Respondents' brief is filed, and *amici* are filing this motion and their attached brief on the same day as Respondents' brief is filed. The Circuit Advisory Committee Note to Circuit Rule 29-3 states that a motion for leave to file is not necessary when all parties consent, as is the case here. However because Circuit Rule 29-3 arguably does not apply to an *amici* filing related to a petition for a writ of mandamus, *amici*, in an abundance of caution, have filed this unopposed motion for leave to file their attached brief.

Dated: August 15, 2017.

Respectfully submitted,

s/ James N. Saul

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing Unopposed Motion for Leave to File Brief as Amici Curiae in Opposition to Petition for Writ of Mandamus with the Clerk of the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on August 15, 2017. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: August 15, 2017

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**BRIEF OF *AMICI CURIAE* LAW PROFESSORS IN OPPOSITION
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STATEMENT OF INTEREST OF AMICI CURIAE¹

Amici Curiae are 34 law professors. These professors are teachers and students of administrative law, open government law, environmental and natural resources law, and related areas, and have a longstanding interest in the effective review of agency decisions (environmental and otherwise) under the Administrative Procedure Act (“APA”), 5 U.S.C. §§ 701-706.

Amici oppose the petition for writ of mandamus filed by petitioners Thomas E. Price, *et al.* (hereinafter collectively referred to as “FDA”). The intent of this brief is to (1) draw the Court’s attention to the logical fallacies that have led some courts to expand the deliberative process *privilege* into a per se rule of *exclusion* as applied to the production of administrative records in APA cases; and (2) bring to the Court’s attention the myriad negative policy implications that would result were the Court to adopt the standard proposed by FDA in its petition.

¹ Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), the *amici* state that no party or counsel in this case and no person except counsel of record for *amici* authored or contributed money to fund the preparation of this brief.

This brief is submitted on behalf of the following law professors

(affiliations herein are for identification purpose only):

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INTRODUCTION

In its petition, FDA requests the extraordinary remedy of mandamus in an effort to hide from its obligation under the APA to produce a complete administrative record in this case. The relief FDA seeks would require this Court to expand the deliberative process privilege far beyond its origins and establish a new rule of law in this Circuit that “deliberative materials are outside the scope of APA review and thus are not part of the administrative record.” Petition for a Writ of Mandamus (hereinafter, “Pet.”) at 14. Although *amici* have serious concerns regarding the government’s misuse of the deliberative process privilege, their objective

with this brief is not to challenge the validity of the privilege generally. Rather, they write in order to counter the ongoing “doctrinal creep”² that has caused some courts around the country to contort the doctrine beyond recognition. There is no basis in law or policy to support FDA’s petition, and it should be denied.

ARGUMENT

As *amici* argue below, neither case law nor public policy supports FDA’s proposed expansion of what was originally conceived as a narrowly drawn, rebuttable *privilege* into an inviolable *rule* to be used by agencies to shield their decisionmaking processes from public and judicial scrutiny. Instead, as this Circuit’s prior decisions make clear, agencies must affirmatively assert the deliberative process privilege, justify its application, and explain why it is not overcome by competing policy interests. FDA’s petition for writ of mandamus should be denied.

² See Edward J. Imwinkelried, *The Government’s Increasing Reliance on—and Abuse of—the Deliberative Process Evidentiary Privilege: “[T]he Last Will be First,”* 83 Miss. L.J. 509, 524 (2014) (lamenting the ongoing “doctrinal creep” in which “courts have construed the [deliberative process] privilege broadly and enlarged it far beyond its modest original scope”).

A. FDA’s Petition is Based Upon a Misreading of Supreme Court and D.C. Circuit Precedents that Do Not Support, Let Alone Compel, the Black-Letter Rule FDA Seeks Here

There is no precedent in this or most other circuits for the argument FDA posits to this Court; thus, FDA’s petition relies heavily upon a pair of D.C. Circuit decisions concerning the scope of administrative review under APA Section 706. *See* Pet. at 14-15 (citing *San Luis Obispo Mothers for Peace v. Nuclear Regulatory Comm’n*, 789 F.2d 26, 44-45 (D.C. Cir. 1986) and *In re Subpoena Duces Tecum Served on Office of Comptroller of Currency*, 156 F.3d 1279, 1279-80 (D.C. Cir. 1998) (denial of reh’g en banc). Those D.C. Circuit decisions, in turn, misconstrue several Supreme Court opinions arising under the APA, and ultimately provide no legal basis for converting that privilege into the expansive black-letter rule FDA would have the Court adopt now.

The deliberative process privilege has its roots in a line of “now discredited” decisions by the British House of Lords concerning the scope

of the “Crown privilege.”³ Michael R. Harris, *Standing in the Way of Judicial Review: Assertion of the Deliberative Process Privilege in APA Cases*, 53 St. Louis U. L.J. 349, 359-60 (2009). First invoked in the United States by President Eisenhower⁴, the common justification for the privilege is that for those working within the Executive Branch, “secrecy is necessary to candor, . . . candor is necessary to effective decisionmaking by the executive, and . . . enhancing the effectiveness of executive decisionmaking serves the public interest.” Gerald Wetlaufer, *Justifying Secrecy: An Objection to the General Deliberative Privilege*, 65 Ind. L. J. 845, 849 (1990).

³ The Crown privilege has been sharply curtailed in Britain. As Lord Upjohn remarked in *Conway v. Rimmer*: “I cannot believe that any Minister or any high level military or civil servant would feel in the least degree inhibited in expressing his honest views in the course of his duty on some subject . . . by the thought that his observations might one day see the light of day.” [1968] UKHL 2, [1968] All ER 874, 915.

⁴ Eisenhower urged during the Army-McCarthy proceedings that certain executive materials be exempt from public disclosure, contending that “it is essential to efficient and effective administration that employees of the Executive Branch be in a position to be completely candid in advising with each other on official matters[.]” *Letter to the Secretary of Defense Directing Him To Withhold Certain Information from the Senate Committee on Government Operations*, PUB. PAPERS 483–84 (May 17, 1954).

The deliberative process privilege was first recognized as a litigation privilege in *Kaiser Aluminum & Chemical Corp. v. United States*, 157 F. Supp. 939 (Ct. Cl. 1958), a breach of contract case, but it has its roots in an earlier decision from the Supreme Court, *Morgan v. United States*, 304 U.S. 1, 58 S. Ct. 773 (1938) (“*Morgan I*”). See *Kaiser*, 157 F. Supp. at 946 (citing *Morgan I* for the proposition that courts ordinarily should not “probe the mental processes of the [agency decisionmaker] in reaching his conclusions”). In *Morgan*, the plaintiffs were challenging a decision made personally by the Secretary of Agriculture, fixing the maximum rates to be charged by dealers at the Kansas City Stock Yards through a process which “had all the essential elements of contested litigation[.]” *Morgan I*, 304 U.S. at 20. The only reason provided by the Court to protect the Secretary’s “mental processes” from discovery was that Congress had expressly charged him with “adjudicatory functions,” and thus, his decision-making process “resemble[d] that of a judicial proceeding.” *United States v. Morgan*, 313 U.S. 409, 421–22 (1941) (“*Morgan II*”). *Morgan*

thus has nothing to say about the content of the administrative record in an APA case.

Similarly, the subsequent Supreme Court precedent relied upon by FDA in its petition about the need to protect the “mental processes” of the decisionmaker (Pet. at 13–14) does not support the absolute exclusion of deliberative documents from the record; each of those cases involved a request by the plaintiff to discover information through unusually invasive means targeted at one or more *specific agency employees*, not the defendant agency as a whole. First, in *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971), the plaintiff had sought to compel “administrative officials who participated in the decision to give testimony explaining their action.” *Id.* at 420. Because no administrative record had been prepared, the Court actually left open the possibility that those officials could be compelled to testify, even though “such inquiry into the mental processes of administrative decisionmakers is usually to be avoided.” *Id.* (citing *Morgan II*, 313 U.S. at 422). Moreover, FDA completely ignores *Overton Park’s* much more relevant admonitions that the required “thorough

probing in depth review” must be based on the “whole record,” which is “the full administrative record that was before the [agency].” 401 U.S. at 419–420 (quoting APA section 706 for “whole record” requirement).

Second, in *Camp v. Pitts*, 411 U.S. 138 (1973), the Court simply held that in applying the APA’s “arbitrary and capricious” standard of review, “the focal point . . . should be the administrative record already in existence, not some new record made initially in the reviewing court.” *Id.* at 142. The plaintiffs had urged the lower court to essentially “put aside the extensive administrative record already made” and engage in “true de novo review” of the agency’s decision, which the Court rejected. *Id.* Nothing in *Camp* suggests that deliberative materials must be excluded from an administrative record.

Contrary to FDA’s contentions, the D.C. Circuit has not adopted anything close to a hard-and-fast rule that “deliberative materials are outside the scope of APA review and thus are not part of the administrative record.” Pet. at 14. In the first D.C. Circuit decision FDA points to, *Mothers for Peace*, plaintiffs sought to supplement the

administrative record with “transcripts of a closed meeting of the Nuclear Regulatory Commission.” 789 F.2d at 44. The court rejected that attempt, finding the transcripts revealed “the frank deliberations of Commission members engaged in the collective mental processes of the agency.” *Id.*

The court was quite clearly concerned with protecting the deliberations of the Commissioners themselves, and it said nothing about the inclusion in the record of potentially deliberative documents from lower level staffers. *See, e.g., id.* (analogizing to the *Morgan II* Court’s discussion of the “deposition of the Secretary” in that case, and remarking upon the lack of evidence of “improper conduct by the Commission” during the course of its hearings).

The second D.C. Circuit opinion relied upon by FDA, *In re Subpoena Duces Tecum*, did not arise under the APA, but rather involved a motion to compel the FDIC to produce certain documents as part of an ongoing state court action. 145 F.3d 1422, 1423 (D.C. Cir. 1998). In its initial decision, the court held that “the common law deliberative process privilege is not appropriately asserted . . . when a plaintiff’s cause of action turns on the

government's intent." *Id.* at 1424. On petition for rehearing, the court first reaffirmed that holding, 156 F.3d at 1279, then stated in dicta that "[a]gency deliberations not part of the record are deemed immaterial." *Id.* The court purported to rely upon *Morgan II*, *Overton Park*, and *Camp*, but engaged in no analysis of the application of the deliberative process privilege to the compilation of administrative records under the APA, because it simply was not an issue in that case.

Here, of course, plaintiffs do not seek to probe the "subjective motivations" of any particular individual through deposition or other invasive discovery; rather, they simply seek to have the "whole record" as required by APA section 706. *Overton Park*, 401 U.S. at 419. The various Supreme Court and D.C. Circuit cases FDA cites regarding the need to protect the "mental processes" of the decisionmaker (Pet. at 13–14) are simply inapposite, and do not compel the adoption of the rule FDA seeks in its petition.

B. The Rule of Law FDA Seeks Would Run Counter to Long-Established Policies Favoring Agency Transparency and Effective Judicial Review

Through its contention that “deliberative materials are outside the scope of APA review and thus are not part of the administrative record” (Pet. at 14), FDA effectively asks this Court to codify public policy that would undermine government transparency and frustrate effective judicial review of agency decisions. To the extent the government’s interests in “maintaining the confidentiality of advisory opinions, recommendations, and deliberations,” *Nat’l Wildlife Fed’n v. U.S. Forest Serv.*, 861 F.2d 1114, 1117 (9th Cir. 1988), are valid,⁵ they can be readily accounted for through the usual process of asserting the privilege and identifying withheld documents on a privilege log. This process appropriately balances competing interests because it allows the agency to rely on the privilege when justified, while providing non-governmental litigants the

⁵ See *Justifying Secrecy*, *supra*, at 886–88 (disputing the contention that disclosure of internal deliberative documents actually “chills future communications” within an agency).

opportunity to challenge—and the courts to rule upon—potential abuses of the privilege.

1. The Rule FDA Seeks Would Incentivize Agencies to Hide Documents That May Undermine Their Decisions

While *amici* are not aware of any impropriety on the part of FDA in this particular case, it is not hard to imagine the potential consequences that could result if an agency were granted unilateral power to control the information presented to a reviewing court in a case arising under the APA. Both internal and external pressures can lead an agency to deviate from the applicable scientific or legal framework for decisionmaking. See Daniel J. Rohlf, *Avoiding the “Bare Record”*: *Safeguarding Meaningful Judicial Review of Federal Agency Actions*, 35 Ohio N.U. L. Rev. 575, 606 (2009) (hereinafter, “*Bare Record*”) (arguing that such pressures “force agencies to make decisions that, while expedient, are not consistent with the underlying facts or scientific findings, are not consistent with statutory authority or legal requirements, or are not serving the public interest”). As

the D.C. Circuit aptly noted, the “asymmetry in information” that occurs when plaintiffs are unaware of an agency document’s very existence

undermines the reliability of a court’s review upon those portions of the record cited by one party or the other. Since there would be no check upon the failure of the agency to disclose information adverse to it, the normal pressures towards inclusion of all relevant material in the record before the court are absent.

Walter O. Boswell Mem’l Hosp. v. Heckler, 749 F.2d 788, 793 (D.C. Cir. 1984); see also *Seabulk Transmarine I, Inc. v. Dole*, 645 F. Supp. 196, 202 (D.D.C. 1986) (remarking that “indiscriminate use of the ‘deliberative process’ privilege to justify expurgation of administrative records may frustrate the process of judicial review of agency action under the APA”).

Unfortunately, federal agencies have a track record of abusing the deliberative process privilege by improperly withholding documents from the administrative record.⁶ Indeed, FDA implicitly admits that it has not

⁶ *Amici* are aware of at least five published opinions from district courts within this Circuit in which an agency defendant was ordered to complete the administrative record with all or portions of documents it had originally excluded on the basis of the deliberative process privilege. See *Nw. Env’tl. Advocates v. EPA*, No. CIV 05-1876-HA, 2009 WL 349732, at *7 (D. Or. Feb. 11, 2009); *Greenpeace v. Nat’l Marine Fisheries Serv.*, 198 F.R.D. 540, 544–45 (W.D. Wash. 2000); *Oregon Natural Desert Ass’n v. Cain*, No.

even reviewed most of the documents encompassed by the district court's order to determine if they are, in fact, deliberative. *See, e.g.*, Pet. at 1 (lamenting that the district court's order "requires FDA to review individually each document in this vast array of predecisional material and produce the documents for the plaintiffs or assert a specific claim of privilege"). Given that there are potentially "more than 400,000 pages" of e-mail correspondence (Pet. at 9) subject to the district court's order but only *five* included in FDA's certified administrative record,⁷ it seems more likely than not that FDA is simply "pretending the protected material wasn't considered" by FDA when it made its decision. Order Granting Mot. to Compel Completion of the Administrative Record, Dkt. #88, at 1.

3:09-CV-00369-PK, 2016 WL 7104845, at *5 (D. Or. Dec. 5, 2016); *People of State of Cal. ex rel. Lockyer v. U.S. Dep't of Agric.*, No. C05-03508 EDL, No. C05-04038 EDL, 2006 WL 708914, at *4 (N.D. Cal. Mar. 16, 2006); and *Ariz. Rehab. Hosp., Inc. v. Shalala*, 185 F.R.D. 263, 271 (D. Ariz. 1998).

⁷ *See* Pls. Mot. to Compel Completion of the Administrative Record, Dkt. #75, at 7 (citing the Index of Record at FDA-017250; FDA-018022; FDA-013982; FDA-014223; FDA-014224).

Holding agencies to the traditional formulation of the deliberative process privilege provides at least some countervailing pressure to check federal agencies' tendencies to withhold potentially damaging information.

2. The Rule FDA Seeks Would Undermine the Authority of the Courts to Assess the Validity of the Deliberative Process Privilege and to Weigh its Application Against Competing Interests

The rule of law FDA seeks would give federal agencies the remarkably broad ability to shield from judicial scrutiny a trove of information they unilaterally deem unfavorable to their litigation position. As one commentator has noted, this would “empower[] the executive precisely by disempowering the judiciary and the public interests it serves.” *Justifying Secrecy*, 65 Ind. L. J. at 891. Such a rule should not be countenanced by this Court.

Courts have “not only the authority, but the responsibility, to resolve . . . conflict[s]” surrounding the applicability of the deliberative process privilege. *Comm. on Oversight & Gov't Reform, United States House of Representatives v. Lynch*, 156 F. Supp. 3d 101, 104 (D.D.C. 2016) (citing

United States v. Nixon, 418 U.S. 683 (1974)). As an initial step, the reviewing court must determine whether the documents are in fact subject to a *prima facie* claim of privilege, i.e., that they are “*both* (1) ‘predecisional’ or ‘antecedent to the adoption of agency policy’ and (2) ‘deliberative,’ meaning . . . [‘]actually [] related to the process by which policies are formulated.’” *Nat’l Wildlife Fed’n*, 861 F.2d at 1117 (emphasis in original; internal citation omitted). But the analysis doesn’t always end there; depending on the context, courts may be called upon to assess:

- **Whether the privilege has been waived**, for example by the disclosure of the documents pursuant to a FOIA request or in the course of civil discovery. *See, e.g., Alpha I, L.P. ex rel. Sands v. United States*, 83 Fed. Cl. 279, 290 (2008) (holding that the government had waived the deliberative process privilege when it produced certain documents to plaintiffs in another case); *In re McKesson Governmental Entities Average Wholesale Price Litig.*, 264 F.R.D. 595, 599–600 (N.D. Cal. 2009) (same);
- **Whether the agency has withheld from the administrative record only those portions of documents that reflect internal agency deliberations.** *See Pac. Fisheries, Inc. v. United States*, 539 F.3d 1143, 1148 (9th Cir. 2008) (“Factual portions of documents covered by the deliberative process privilege must be segregated and disclosed unless they are ‘so interwoven with the deliberative material that [they are] not[segregable]’”) (internal citation omitted); and

- **Whether the plaintiff's competing interest in the disclosure of the documents is sufficient to override the agency's claim of privilege.** See *F.T.C. v. Warner Commc'ns Inc.*, 742 F.2d 1156, 1161 (9th Cir. 1984) (“The deliberative process privilege is a qualified one. A litigant may obtain deliberative materials if his or her need for the materials and the need for accurate fact-finding override the government's interest in non-disclosure.”)

None of the steps described above—which fall squarely within the court's purview—would be possible if the agency were able to exclude purportedly deliberative documents from the record at the outset.

3. Without a Privilege Log, Litigants are Powerless to Contest an Agency's Exclusion of Purportedly Deliberative Documents

It is axiomatic that the party invoking a privilege that would shield otherwise releasable information from disclosure bears the burden of establishing that the privilege applies. See *United States v. Gurtner*, 474 F.2d 297, 298 (9th Cir. 1973); *Maricopa Audubon Soc'y v. U.S. Forest Serv.*, 108 F.3d 1089, 1092 (9th Cir. 1997). As this Court recognized in *Maricopa Audubon*, “[c]ourts must apply [the agency's] burden with an awareness that the plaintiff, who does not have access to the withheld materials, is at

a distinct disadvantage in attempting to controvert the agency's claims.”

Maricopa Audubon, 108 F.3d at 1092.

Of course, the ordinary means of assessing the government's assertion of the deliberative process privilege is through a privilege log. *See, e.g., Hongsermeier v. C.I.R.*, 621 F.3d 890, 904 (9th Cir. 2010).⁸ Requiring production of a privilege log in APA cases also resolves the tension between the government's burden to justify its claim of privilege, and any presumption of regularity that may be afforded the agency when compiling the record; the presumption can be easily overcome—assuming the plaintiff is aware of the documents in the first place—by showing that the excluded documents were in the possession of the agency and relate to the

⁸ Although there is no definitive rule in the Ninth Circuit, district courts within this Circuit routinely require agencies to produce a privilege log in APA cases when they withhold documents from an administrative record on the basis of the deliberative process privilege. *See, e.g., Ctr. for Food Safety v. Vilsack*, No. 15-CV-01590-HSG (KAW), 2017 WL 1709318, at *5 (N.D. Cal. May 3, 2017); *Desert Survivors v. US Dep't of the Interior*, 231 F. Supp. 3d 368, 370 (N.D. Cal. 2017); *Mickelsen Farms, LLC v. Animal & Plant Health Inspection Serv.*, No. 1:15-CV-00143-EJL-CWD, 2017 WL 2172436, at *4 (D. Idaho May 17, 2017); *People of State of Cal. ex rel. Lockyer*, 2006 WL 708914, at *4.

decision at issue. *See, e.g., People of State of Cal. ex rel. Lockyer*, 2006 WL 708914, at *2.

As Professor Rohlf explained, absent a privilege log, as a practical matter “most of the numerous judgment calls agencies make regarding the scope of their records are unreviewable.” *Bare Record*, 35 Ohio N.U. L. Rev. at 604. The privilege log requirement levels the playing field:

If an agency complies with its obligation to provide with its administrative record an index of material falling within the scope of the record but withheld due to a claim of privilege, parties and reviewing courts will at least be aware of the exclusions, and plaintiffs challenging an agency action have an opportunity to contest exclusions that they believe are unwarranted, or, in the case of material excluded on the basis of deliberative process privilege, can attempt to make that case that their need for the material outweighs the government's interest in withholding it.

Id. at 604–05.

What FDA seeks here would turn this well-worn framework on its head, and would place an impossible burden on those seeking to challenge the agency's claim that the documents are deliberative. Thus a privilege

log is an indispensable tool to ensure the proper application of the privilege.

CONCLUSION

For the foregoing reasons, this Court should deny FDA's petition for writ of mandamus.

Respectfully submitted this 15th day of August, 2017.

s/ James N. Saul

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure 29(a)(4)(G) and 32(g)(1), I certify that the foregoing Brief of *Amici Curiae* complies with the type volume limitation and typeface requirements contained in Federal Rules of Appellate Procedure 29(a)(4) and (5) and Circuit Rule 32-3(2), because it is proportionally spaced, has a typeface of 14 points, and contains 4,030 words, excluding tables and cover page.

Dated: August 15, 2017

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing Brief of Amici Curiae Law Professors in Opposition to Petition for Writ of Mandamus with the Clerk of the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on August 15, 2017. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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