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

RESPONSE TO PETITION FOR WRIT OF MANDAMUS

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INTRODUCTION

In this mandamus action, the Food and Drug Administration (FDA or Petitioners) seeks to circumscribe the scope of administrative records, reducing them to a fraction of what circuit courts and the Supreme Court have held is necessary for judicial review of agency action under the Administrative Procedure Act (APA). Long-settled administrative law requires agency records to include everything that was before the agency and considered directly or indirectly in reaching the challenged decision. This "whole record," including material contrary to the agency's decision, is essential to effective judicial review. Agencies can withhold legitimately privileged materials, but in order to do so, they must justify each assertion of privilege for specific documents to enable the parties and the court to evaluate the propriety and scope of the privilege claim.

FDA seeks to upend these bedrock administrative law and privilege principles. The agency here intentionally excluded from its administrative record materials it considered in approving the commercial production of the first-ever genetically engineered animal for human consumption. FDA, categorically and without explanation, omitted tens of thousands of documents—without any review—because it believed them to be to be "deliberative" *per se*, including nearly all internal emails, draft documents, meeting notes, analyses, and informal communications or memoranda addressing issues FDA considered. While there is

no dispute that these materials exist and that FDA considered them when making its decisions, FDA did not identify the materials withheld from the record or justify such withholdings under any privilege. Instead, FDA improperly re-defined "deliberative" to mean "internal," and categorically withheld the information, analyses, and communications that form the basis for its decisions. The agency's far-reaching position is that it can withhold these materials from the record without justifying them under any privilege and without even identifying them to the court and the parties.

There is a fundamental difference between excluding material wholesale from the scope of the administrative record, and applying the deliberative process privilege to withhold specific record material that the agency directly or indirectly considered in its decisions. Contrary to FDA's view, the deliberative process privilege requires that material be more than just "internal" or "pre-decisional" to be applicable, and, even then, an agency cannot apply the privilege presumptively: it must affirmatively assert and specifically support each withholding because the privilege is qualified and can be overcome. FDA's position would transform the application of the qualified (and reviewable) deliberative process privilege from a document-by-document specific justification into a blanket and unchallengeable exemption that would allow an agency to omit all of its "internal" or "pre-decisional" documents from an administrative record at the outset.

The district court correctly rejected FDA's arguments and held that FDA had improperly limited the scope of the record. That decision is well supported by this Court's jurisprudence. FDA has failed to carry its heavy mandamus burden of showing the decision was clearly erroneous. The Court should reject FDA's attempt to create a brand new categorical record exemption for all internal materials an agency unilaterally considers to be "deliberative."

STATEMENT OF THE CASE

FDA's approval of AquaBounty's "AquAdvantage" genetically engineered salmon (GE salmon) is the first time any country has authorized the commercial production of a man-made GE animal to be sold as food. Dkt. 53 at ¶ 4 (Plaintiffs and Real Parties in Interest Appendix (App.) at 65, 66). Accordingly, ensuring FDA's analysis is complete and rigorous is not only critical for evaluating and mitigating the risks from this novel organism, but also important to help ensure that the agency undertakes a full and accurate evaluation of the risks and safety of any future GE animals. Plaintiffs challenged several final agency actions related to FDA's approval of GE salmon, including its November 2015 approval, its evaluation of the environmental risks under the National Environmental Policy Act (NEPA), and its determination (in FDA's "Guidance 187") that the agency has authority to review and approve GE animals under the "new animal drug" provisions of the Federal Food Drug and Cosmetic Act. Dkt. 53 at ¶¶ 156-265

(App. 65, 108-30). FDA reached these challenged decisions after considering GE salmon since at least 1994. Pet. at 4. Ten of Plaintiffs' claims are reviewed based on the administrative record pursuant to the APA. 5 U.S.C. § 702(2)(A); Dkt. 53 at ¶¶ 156-265 (App. 65, 108-30).[1]

Despite beginning work on AquaBounty's GE salmon application more than twenty years ago, FDA produced an administrative record of only 921 documents, and did not produce a privilege log documenting any materials withheld or redacted under any privilege claim. Dkt. 71-2 (App. 132-232). FDA included in its record official documents, studies, some external communications with AquaBounty and other agencies, and summaries of agency conclusions. *Id*. But the record was nearly devoid of any internal memoranda, analysis, emails, other correspondence, meeting notes, or drafts and revisions of FDA's decision documents. *Id*.; Dkt. 75 at 5-10 (App. 233, 243-48).

For example, the two-decade record includes only *five* documents containing internal agency emails. Dkt. 75 at 10 (App. 233, 248). Similarly, FDA produced only *six* documents that preceded the publicly-released versions of the Environmental Assessment (EA) during FDA's five-year NEPA review process; of

[1] Plaintiffs' Endangered Species Act claim is not limited to the record. *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 497 (9th Cir. 2011).

those, one is merely an outline.[2] None of the remaining versions contain edits, revisions, or track changes. The record also contains no drafts of FDA's approval letter for AquaBounty's new animal drug application, nor any earlier versions of the challenged GE animal "guidance" FDA promulgated.

In short, the record consists largely of final, mostly public, documents and omits materials demonstrating how the agency analyzed and considered the evidence to reach its decisions. It lacks the essential materials courts use to evaluate agency decisions.

Plaintiffs filed a motion to complete the record, Dkt. 75 (App. 233), which FDA contested, arguing that all internal material is "deliberative," *per se*, and therefore may be excluded from the administrative record without acknowledging or cataloguing those exclusions. Dkt. 82-2 (App. 255). The district court properly

[2] Those versions include an "investigative EA," dated Dec. 14, 2001 (FDA-001098) (App. 428); AquaBounty's outline for the EA, dated Aug. 30, 2007 (FDA-005063) (App. 659); a draft EA from AquaBounty, dated Jan. 11, 2010 (FDA-009954) (App. 662); a draft EA from AquaBounty "for public display," dated Aug. 26, 2010 (FDA-14129) (App. 862); a revised draft EA "for public display," dated Dec. 7, 2010 (FDA-015686) (App. 947); and a draft EA, dated Mar. 31, 2011 (FDA-016843) (App. 1037) (which is entirely redacted under FOIA exemptions b(4) and b(5)). The few internal review memos contained in the record are all dated 2010 or earlier—well before the FDA released the public draft EA in 2012. There are no documents reflecting the agency's review or considerations between 2010 and 2015, when the FDA finalized the EA. It is hard to imagine that FDA did not send any emails, do any analysis, draft any memos, or revise any drafts or other documents in the last five years of its review, particularly in light of the extensive number of comments it received.

rejected FDA's argument, holding that "the scope of the [deliberative process] privilege doesn't define the scope of the material directly or indirectly considered. If a privilege applies, the proper strategy isn't pretending the protected material wasn't considered, but withholding or redacting the protected material and then logging the privilege." Dkt. 88 at 1 (App. 277, 277) ("[T]he government is wrong to assert that these types of materials, as a categorical matter, should be excluded from the universe of materials 'directly or indirectly considered by agency decision-makers.'" (citing *Thompson v. U.S. Dep't of Labor*, 885 F.2d 551, 555 (9th Cir. 1989))). Because FDA applied an "overly narrow understanding of the universe of materials that may need to be included in the administrative record," the court ordered the agency to complete the record with "internal comments, draft reports, inter- or intra-agency emails, revisions, memoranda, or meeting notes" and to justify any withheld materials in a privilege log. *Id*. at 1-2 (App. 277-78). The court initially ordered FDA to comply within 30 days, but subsequently granted FDA's request for an additional six months. Dkt. 90 (App. 279).

The parties conferred multiple times regarding FDA's production, agreed upon a narrowed scope for the search and production of documents, and submitted to the district court a status report on the ongoing production process. *See* Dkt. 94 (App. 281). FDA never indicated it disagreed with the court's legal conclusions, let alone was considering the extraordinary step of seeking to overturn the Order

through a writ of mandamus. Nor did FDA approach Plaintiffs with a specific request for additional time to comply with the Order, to suggest a more refined set of agency custodians or document search terms, or to indicate anything other than a generalized concern about their ability to fully comply with the deadline to complete the record.

SUMMARY OF ARGUMENT

A complete administrative record is fundamental to effective judicial review. This Circuit has long held that records must contain all material that an agency directly or indirectly considered, including material contrary to the agency's decision. Courts routinely review the same types of materials FDA excluded here when evaluating decisions under the APA. While the deliberative process privilege applies to certain material an agency considers, the scope of this privilege is not the same as the scope of the record. Moreover, the deliberative process privilege is a limited and qualified privilege, and, like other privileges, an agency bears the burden of establishing with particularity its applicability. FDA improperly seeks to transform this limited privilege into a wholesale exclusion.

FDA carries a heavy burden to demonstrate that the extraordinary remedy of mandamus is clear and indisputable. Although there are five factors the Court may consider when evaluating a request for mandamus relief, the requirement that FDA demonstrate clear error as a matter of law is dispositive. FDA cannot show the

district court committed any error—much less the high bar of clear error—when it required FDA to produce all documents the agency directly or indirectly considered and to support any asserted privileges. No Ninth Circuit authority conflicts with the Order; rather, the Order follows and applies well-established precedent defining an administrative record's proper scope, and the requirements for asserting the deliberative process privilege. FDA's attempt to cobble together its own standard from selective citations to other cases falls far short of demonstrating "clear error." Finally, although the absence of clear error alone is dispositive, the other mandamus factors also weigh in favor of denial. FDA's request for a writ should be denied.

STANDARD OF REVIEW

Mandamus is a "drastic and extraordinary remedy reserved for really extraordinary causes . . . [and] only exceptional circumstances amounting to a judicial usurpation of power, or a clear abuse of discretion." *Cheney v. U.S. Dist. Court for the Dist. Of Columbia*, 542 U.S. 367, 380 (2004) (internal quotation marks and citations omitted); *Miller v. Gammie*, 335 F.3d 889, 895 (9th Cir. 2003) (en banc) (explaining that mandamus is "an extraordinary remedy that may be obtained only to confine an inferior court to a lawful exercise of prescribed jurisdiction or to compel it to exercise its authority when it is its duty to do so" (quoting *Cordoza v. Pac. States Steel Corp.*, 320 F.3d 989, 998 (9th Cir. 2003))).

Petitioners must demonstrate a right to the writ that is "clear and indisputable." *In re Orange, S.A.*, 818 F.3d 956, 960 (9th Cir. 2016) (quoting *Confederated Salish v. Simonich,* 29 F.3d 1398, 1404 (9th Cir. 1994)). Demonstrating a "clear and indisputable" right to mandamus is particularly difficult in the evidentiary context, because district courts have broad discretion when reviewing evidentiary disputes and to manage their dockets. *See Perry v. Schwarzenegger*, 591 F.3d 1147, 1157 (9th Cir. 2010) ("[T]he courts of appeals cannot afford to become involved with the daily details of discovery." (citation omitted)); *see also In re Perez*, 749 F.3d 849, 854 (9th Cir. 2014) (holding that this Court "is particularly reluctant to interfere with a district court's day-to-day management of its cases").

To ensure that mandamus is reserved for rare, exceptional situations, this Court reviews five factors: (1) whether there are other means to attain relief, (2) whether the petitioner will be prejudiced in a way not correctable on appeal, (3) whether the district court's ruling is clearly erroneous as a matter of law, (4) whether it is an oft-repeated error, or (5) whether there are issues of first impression. *Bauman v. U.S. Dist. Court*, 557 F.2d 650, 654-55 (9th Cir. 1977). The third *Bauman* factor—whether the court's order is clearly erroneous as a matter of law—is the most important. Its absence is dispositive. *In re United States*, 791 F.3d 945, 955 (9th Cir. 2015) ("[T]he absence of factor three—clear error as a matter of law—will always defeat a petition for mandamus." (quoting

DeGeorge v. U.S. Dist. Court for the Cent. Dist. of Cal., 219 F.3d 930, 934 (9th Cir. 2000))). Clear error is a highly deferential standard of review. *In re Van Dusen*, 654 F.3d 838, 841 (9th Cir. 2011) (requiring a "definite and firm conviction" the district court's order was incorrect (quoting *DeGeorge*, 219 F.3d at 936)). Moreover, "the absence of controlling precedent weighs strongly against a finding of clear error." *In re. Swift Transportation Co.*, 830 F.3d 913, 916-17 (9th Cir. 2016) (without Ninth Circuit precedent prohibiting the district court action, "its ruling is not clearly erroneous." (quoting *In re Morgan*, 506 F.3d 705, 713 (9th Cir. 2007))).

ARGUMENT

I. THE WHOLE RECORD IS ESSENTIAL FOR APA REVIEW.

The APA requires judicial review of an agency decision be based on the "*whole* record." 5 U.S.C. § 706 (emphasis added). The Supreme Court has held that the "the whole record" must include all material that was actually before the agency in order to allow the court to engage in the "thorough, probing, in-depth review" of an agency action required by the APA. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 415 (1971). This review is "a searching and careful inquiry" to allow courts "to comprehend the agency's handling of the evidence cited or relied upon . . . [and] to educate ourselves so that we can properly perform our reviewing function: determining whether the agency's conclusions are

rationally supported." *Nw. Coal. for Alternatives to Pesticides v. EPA*, 544 F.3d 1043, 1052 n.7 (9th Cir. 2008) (quoting *Ctr. for Auto Safety v. Peck*, 751 F.2d 1336, 1373 (D.C. Cir. 1985)).

In APA review, it is crucial that courts have the whole record, in order to determine, among other things, whether "the agency . . . entirely failed to consider an important aspect of the problem," articulated a rational connection between the facts before it and the decisions made, or "offered an explanation for its decision that runs counter to the evidence before the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983). Neither litigants nor courts can properly assess the lawfulness of agency action without the entire record. *Portland Audubon Soc'y v. Endangered Species Comm.,* 984 F.2d 1534, 1548 (9th Cir. 1993) ("If the record is not complete, then the requirement that the agency decision be supported by 'the record' becomes almost meaningless."). For this reason, the Ninth Circuit has long held that the whole record includes all materials "directly or indirectly considered by the agency decision-makers," as the district court correctly cited, and specifically includes "evidence contrary to the agency's position." *Thompson*, 885 F.2d at 555; *see also* Dkt. 88 at 1 (App. 277).

FDA seeks to omit from the record the types of internal documents that go to the heart of APA review and make up the "whole record." FDA cannot construct a post-hoc sanitized narrative of the decision-making process in an attempt to shield

its decisions from the thorough, probing, in-depth review the law requires. *See Portland Audubon Soc'y* , 984 F.2d at 1548 ("An incomplete record must be viewed as a 'fictional account of the actual decision-making process.'").

FDA's attempt to justify this result improperly conflates elements of the deliberative process privilege with the scope of the record. The Ninth Circuit has never limited administrative records in this way, nor allowed the deliberative process privilege to be applied this way.

II. FDA'S POSITION IS CONTRARY TO THE DELIBERATIVE PROCESS PRIVILEGE.

As the district court correctly determined, FDA has confused the narrow and qualified deliberative process privilege with the scope of the record it must produce in the first instance. The gravamen of FDA's argument is that all internal comments, draft reports, inter- or intra-agency emails, revisions, memoranda, or meeting notes are necessarily "deliberative" in their entirety and can *per se* be excluded from the administrative record, even when the agency directly or indirectly considered them, simply because they are "internal" and pre-date the decision. Pet. at 11-19. This argument, however, is not grounded in the actual, *defined* "deliberative process" privilege, but instead merely borrows elements from that privilege to significantly narrow the scope of the record from the *outset*, before documents that it directly or indirectly considered are identified or evaluated for privilege. Although FDA does not directly define the term "deliberative" in its

brief, it routinely conflates this term of art with the terms "internal" and "pre-decisional." *See, e.g.*, Pet. at 1, 3 ("internal, deliberative documents"); 2 ("predecisional deliberations"); 8 ("internal, deliberative materials").

The deliberative process privilege is among those that agencies may legitimately, but narrowly, assert to withhold identified material from the record. The privilege can apply to documents that would expose deliberations and chill candid discussion and development of agency policy. *Nat'l Wildlife Fed'n v. U.S. Forest Serv.*, 861 F.2d 1114, 1117 (9th Cir. 1988) (discussing purposes of and requirements for privilege). It protects specific material that is not only (1) "predecisional" or "antecedent to the adoption of agency policy," but also (2) "deliberative," meaning "it must actually be related to the process by which policies are formulated." *Id*. Only material which "would expose an agency's decision-making process in such a way as to discourage candid discussion within the agency and thereby undermine the agency's ability to perform its functions" may be withheld. *Carter v. U.S. Dep't of Commerce*, 307 F.3d 1084, 1090 (9th Cir. 2002) (quoting *Assembly of the State of Cal. v. U.S. Dep't of Commerce*, 968 F.2d 916, 921 (9th Cir. 1992); *see also Kowack v. U.S. Forest Serv.*, 766 F.3d 1130, 1135 (9th Cir. 2014).[3]

[3] Cases applying the deliberative process privilege in the FOIA context are relevant to APA record review; it "is a common law privilege, … but '[f]ederal courts regularly apply FOIA precedent when interpreting the deliberative process

Although all truly "deliberative" material that may qualify for the privilege must necessarily be both "internal" and "pre-decisional," the reverse is not true: all "internal" and "pre-decisional" documents are not *automatically* deliberative and covered by the privilege. The determination of whether the privilege applies to a given document is by its nature a case-by-case, fact-based determination, that as such cannot be presumed categorically. Indeed, that is why this Court has a context-specific or "functional" approach to determining whether material may be shielded as deliberative which "focus[es] on whether the document in question is a part of the deliberative process." *Nat'l Wildlife Fed'n*, 861 F.2d at 1118-19 (emphasis omitted).

Moreover, the privilege itself is not absolute, even for those documents that qualify. This is because the privilege is both narrow (it does not cloak entire documents) and qualified (it can be overcome for any individual document based on a showing of need). "Private parties and reviewing courts alike have a strong interest in fully knowing the basis and circumstances of an agency's decision." *Nat'l Courier Ass'n v. Bd. of Governors of Fed. Reserve Sys.*, 516 F.2d 1229, 1241 (D.C. Cir. 1975). So, for example, purely factual material severable from the development of policy is not protected by the privilege. *Kowack*, 766 F.3d at 1135

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privilege' because that privilege has been incorporated into FOIA in Exemption 5." *Desert Survivors v. U.S. Dep't of the Interior*, 231 F. Supp. 3d 368, 379 (N.D. Cal. 2017) (citations omitted).

(rejecting broad claim of deliberative process privilege where agency did not even "tr[y] to segregate" factual aspects of documents or explain how they would "expose the agency's decision-making process").[4] And, even when the privilege is properly invoked and justified, the identified documents are *still* subject to disclosure if a litigant's need for the materials and the need for accurate fact-finding override the government's interest in non-disclosure. *FTC v. Warner Commc'ns Inc.*, 742 F.2d 1156, 1161 (9th Cir. 1984).

To enable the parties and the courts to conduct this review, agencies invoking the deliberative process, or any other, privilege must disclose and justify its application in a privilege log or other means. *See, e.g.*, *Nw. Envt'l Advocates v. EPA*, No. 05-1876-HA, 2008 WL 111054, at *4 (D. Or. Jan. 7, 2008) ("Because the agencies bear the burden of establishing that a privilege applies, they must reveal, through a detailed log, the documents excluded from the record. Absent such a log, plaintiff has no way to challenge assertion of the privilege, and [a] court has no way to evaluate the claim."). *Accord Maricopa Audubon Soc. v. U.S. Forest Serv.,* 108 F.3d 1089, 1092 (9th Cir. 1997); *Coastal States Gas Corp. v. U.S. Dep't of Energy*, 617 F.2d 854, 868 (D.C. Cir. 1980) ("[T]he agency has the

[4] FDA cannot certify that the withheld material here does not contain severable factual elements because, as the agency admits, it has not yet reviewed those documents.

burden of establishing what deliberative process is involved, and the role played by the documents in issue in the course of the process.").

FDA's assertion that *all* internal and pre-decisional documents are presumptively "deliberative" and may be unilaterally withheld flies in the face of these well-established privilege principles. FDA's blanket exclusion of this material without even disclosing its existence robs the parties and the court of the ability to make any of the determinations essential to understanding whether the privilege is properly and narrowly invoked. Indeed, it would effectively eliminate the need for any justifications in privilege logs or elsewhere if agencies could make such wholesale, preliminary, and presumptive record exclusions.[5] Rather than carry its burden to establish the privilege, FDA would shift the burden to other parties to demonstrate that the privilege was improperly asserted. Particularly where FDA does not even acknowledge the existence of the material, it is difficult to understand how it believes a party could satisfy that burden.

Taken to its logical conclusion, FDA's position would ultimately result in only the final decision document itself as the administrative record, since everything else is "predecisional." This Court should reject FDA's effort to twist the narrow, qualified deliberative process privilege into an indiscriminate exemption that allows it to omit communications, emails, memoranda, analyses,

[5] Indeed, in this case, FDA did not even produce a privilege log that describes or justifies its redaction of specific material from the documents it did produce.

drafts and other material that it directly and indirectly considered in making its decisions.

III. THE DISTRICT COURT DID NOT COMMIT CLEAR ERROR.

A. FDA Mischaracterizes the Proceedings Below.

In its Order, the district court followed the well-established APA and privilege principals outlined above. FDA implies that the Order requires it either (1) to produce material that reflect "deliberations within the agency," or that "probe the mental process of the agency," or (2) to review and log that material. Pet. at 1-2, 11. The Order does not set up this false choice. Rather, the district court simply ordered FDA to complete the record with all materials it considered as part of its decision. Dkt. 88 at 1 (App. 277) (citing *Thompson* 885 F.2d at 555). While much of this material is unlikely to qualify for the deliberative process privilege, as that term is actually defined, the Order recognized that some of these materials may be protected and directed FDA to justify any specific redaction or withholding in a privilege log. *Id*. at 1-2 (App. 277-78). FDA's characterization of the Order as a choice between producing privileged material and merely documenting it incorrectly presumes that all of the withheld material is privileged before FDA's review even begins. Indeed, because FDA omitted most material from the record and failed to justify *any* privilege withholdings, the district court

has yet to rule on any FDA application of the deliberative process or any other privilege.

FDA also mischaracterizes the district court's Order as one to "supplement" the record (*e.g.*, Pet. at 1, 8), but it is not: it is an order to *complete* the record. There is a significant difference between whether a record should be supplemented with extra-record materials and whether a record is complete to begin with, as here. *See Wildearth Guardians v. U.S. Forest Serv.,* 713 F. Supp. 2d 1243, 1253 & n.5 (D. Colo. 2010) (explaining difference between supplementation and completion and how "confusion [between the two] has significant consequences for courts and litigants"). When seeking to *complete* a record, "[p]laintiffs need not show bad faith or improper motive to rebut the presumption" of regularity that may otherwise attach to an agency record. *People of State of Cal. ex rel. Lockyer v. U.S. Dept. of Agric.,* No. C05-03508 EDL, 2006 WL 708914, at *2 (N.D. Cal. Mar. 16, 2006). Rather, plaintiffs must demonstrate only that materials exist which were directly or indirectly considered in the agency's decision, or that the agency applied an improper standard when compiling the record. *Id.* at *3; *Thompson*, 885 F.2d at 555. FDA admits that this material exists—indeed, it emphasizes that there are thousands of such documents. *See* Pet., Add. at 19-20 (summarizing results of preliminary search that has identified over 34,000 documents). FDA does not dispute that the agency directly or indirectly considered these documents.

Here, the only question is whether FDA is legally justified in omitting existing documents that it considered from the record and Plaintiffs have easily satisfied their burden to rebut the presumption of regularity.

B. The District Court's Order is Fully Consistent with Ninth Circuit Precedent.

In addition to mischaracterizing the proceedings below, FDA fails to cite any binding precedent that establishes that the district court's Order was improper. Indeed, the most FDA tentatively hazards is that "this Court has not squarely addressed the issue" of whether all internal documents are outside the scope of an administrative record in APA review. Pet. at 3, 16. Yet such peeking over the precedential parapet is not nearly enough to establish "clear error" and fatally undermines FDA's extraordinary writ request: without clear precedent prohibiting the district court's action, FDA cannot demonstrate that the Order is clearly erroneous as a matter of law. *In re. Swift Transp. Co.*, 830 F.3d at 916-17. Lack of clear error is dispositive, *In re United States*, 791 F.3d at 955, and the Court should deny the writ on this basis alone.

But, more importantly, FDA is wrong that it has raised even a close question: as explained above, FDA's theory runs contrary to well-established tributaries of this Court's jurisprudence on the scope of the record and the application of the deliberative process privilege. *See supra.* Indeed, Ninth Circuit decisions demonstrate that internal, pre-decisional documents are regularly part of

the administrative record. The Ninth Circuit routinely relies on internal documents when reviewing agency decisions, including draft or revised decisions, internal emails, correspondence, memoranda, and meeting notes. *See, e.g.*, *Native Vill. of Point Hope v. Jewell*, 740 F.3d 489, 499-505 (9th Cir. 2014) (relying heavily on "internal [agency] emails" and "draft scenario[s]" to find agency violated NEPA under APA review); *Earth Island Inst. v. Hogarth*, 484 F.3d 1123, 1134-35 (9th Cir. 2007) (citing agency "internal memoranda," including "briefing packet" and "talking points" to determine an agency's finding was arbitrary and capricious under the APA), *aff'd as modified*, 494 F.3d 757 (9th Cir. 2007); *'Īlio'ulaokalani Coal. v. Rumsfeld,* 464 F.3d 1083, 1096-1101 (9th Cir. 2006) (relying on minutes and comments in draft environmental impact statement (EIS) to find the EIS was inadequate); *Reno-Sparks Indian Colony v. EPA*, 336 F.3d 899, 906 (9th Cir. 2003) (on direct review, upholding agency rule and relying on, *inter alia*, "internal agency memorandum"). These "pre-decisional deliberative communications may go to the heart of the question of whether an agency action was arbitrary and capricious, an abuse of discretion or otherwise inconsistent with the law under Section 706(2) of the APA." *Desert Survivors v. U.S. Dep't of the Interior*, 231 F. Supp. 3d 368, 382 (N.D. Cal. 2017) (citing cases where these documents included "the equivalent of a 'smoking gun' in an environmental case," where agencies had

erred by ignoring advice from in-house experts, or where senior officials interfered with scientific analyses).

FDA mischaracterizes this Court's decision in *Portland Audubon Society*, 984 F.2d at 1549. Pet. at 16-17. The language FDA cites is merely the Court's summary of a D.C. Circuit decision, *San Luis Obispo*, which the Court distinguished before ordering an evidentiary hearing to obtain testimony from the agency decision-makers. 984 F. 2d at 1549. Importantly, this Court did not hold, as FDA argues, that internal, pre-decisional materials should be universally excluded from the record, nor even that all deliberative materials should necessarily be excluded from review. To the contrary, this Court found that "a record that does not include all matters on which [an agency] relied does not constitute the 'whole record' required for judicial review and that the failure to include all materials in the record violates the [APA]." 984 F. 2d at 1536-37. The Court further held that the "'[t]he whole record' includes everything that was before the agency pertaining to the merits of its decision." *Id*. at 1548.[6]

[6] Petitioners cite *Cook Inletkeeper v. EPA*, 400 F. App'x 239, 240 (9th Cir. 2010), but in addition to being non-precedential, Circuit Rule 36-3(a), it is inapposite. The Court declined to supplement the record because the agency demonstrated that it did not directly or indirectly consider the documents at issue. In contrast here, FDA does not deny consideration of the materials it has withheld, nor do Plaintiffs seek materials not considered by the agency.

Lacking the required Ninth Circuit precedent, FDA instead selectively mischaracterizes several cases from the D.C. Circuit and Supreme Court. Yet neither the D.C. Circuit nor the Supreme Court has held in support of FDA's far-reaching theory that an agency can exclude whole categories of internal materials from the record at the outset.

C. The Supreme Court Decisions FDA Cites Support the District Court's Order.

FDA first cites several of Supreme Court decisions, implying they are at odds with the district court's Order. Pet. at 13-14. To the contrary, those decisions are either addressing a different question or merely reiterate the fundamental principles of APA review that support the court's Order. FDA primarily invokes cases that admonish against probing an agency official's "mental processes." Pet. at 13-14 (citing *U.S. v. Morgan*, 304 U.S. 1, 18 (1938) and *U.S. v. Morgan*, 313 U.S. 409, 422 (1941), which predate the APA). But that is not at issue here; as explained above, the district court did not order that FDA produce or disclose any materials that might implicate the "mental processes" or subjective motivations of agency personnel such as personal notes. *See, e.g., N. Pacifica, LLC v. City of Pacifica*, 274 F. Supp. 2d 1118, 1122 (N.D. Cal. 2003) (summarizing the qualified mental process privilege that may apply to an individual decision-maker's "uncommunicated motivations for a policy or decision"). Most likely, the types of personal materials that might be protected by the mental process privilege would

not be among the materials FDA considered directly or indirectly when making its decisions, which *are* subject to the court's Order. And, even if FDA's search revealed them, the proper course is to identify them and justify their withholding in a privilege log; it is not to use their potential existence to justify categorically withholding reams of other material that informed the agency's decisions.[7]

D. The D.C. Circuit Does Not Support FDA's Position.

FDA next stretches imprecise language in two D.C. Circuit decisions to argue that all "deliberative materials" are outside the scope of the record. Pet. at 14. Contrary to FDA's assertion, the only time the D.C. Circuit has directly addressed an argument by an agency that it could unilaterally exclude from a record whole categories of material it considered, like internal memoranda, it *rejected* the argument. *Nat'l Courier Ass'n*, 516 F.2d at 1241 (noting that "[t]he process by which [an agency] decision has been reached is often mysterious enough without the agency's maintaining unnecessary secrecy" and holding "[t]he proper approach, therefore, would appear to be to consider any document that might have influenced the agency's decision to be 'evidence' . . . but subject to any

[7] Moreover, FDA's claim that mandamus is somehow warranted because "the district court exercised judicial power it does not have," Pet. at 11, is contrary to well-established caselaw on administrative record scope, as explained above. More fundamentally FDA's argument would extend the availability of mandamus to any case in which the district court makes a legal decision with which a litigant disagrees. That is not the same as lacking authority.

privilege that the agency properly claims as protecting its interests in non-disclosure").

In re Subpoena Duces Tecum, 156 F.3d 1279, 1279-80 (D.C. Cir. 1998), Pet. at 15, does not instruct otherwise. That case merely reaffirms that the deliberative process privilege is available in APA cases. *Id*. at 1279-80 (finding that the deliberative process privilege may be invoked in APA cases because, in contrast to the direct challenge to FDIC's motives in that case, the agency's underlying motives in APA cases are not directly at issue). The court observed that in cases where the agency's motivations were not at issue, "agency deliberations not part of the record are deemed immaterial." *Id*. at 1279. Contrary to the interpretation by a handful of district courts, the D.C. Circuit did *not* state that "agency deliberations [*are*] not part of the record."[8] This is a fine, but critical distinction. In fact, consistent with the mental process privilege, the D.C. Circuit clarified that documents it considered immaterial are specifically those that reveal mental

[8] While it is true that some D.C. district courts have mistakenly read the language in *In re Subpoena Duces Tecum* to support a broader exemption for all deliberative materials, *see* Pet. at 15-16 (citing cases), these cases are inconsistent with this Circuit's case law considering these materials in APA cases. As FDA admits, *see* Pet. at 21, many other district courts have rejected this approach, including in this circuit. *See Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.,* No. CV01-640-RE, 2005 U.S. Dist. LEXIS 16655, *10 (D. Or. Mar. 3, 2005) (rejecting agency's argument that it may omit documents because they did not "form the basis" for the agency's decision and ordering competition of the record); *Lockyer*, 2006 WL 708914, at *4 (ordering production of internal communication, drafts, and analyses).

processes of the decisionmaker, not *all* deliberative material. *See id*. at 1279-80 (restating *Overton Park*'s caution that "the actual subjective motivation of agency decisionmakers is immaterial as a matter of law"). Again, in this case, the district court did not order—and Plaintiffs do not seek—material revealing the subjective motivations of an individual decision-maker, but rather the analyses, memoranda, communications and emails, drafts, and meeting notes that the agency considered when reaching its decisions.

Moreover, *In re Subpoena Duces Tecum* did not make any findings as to whether the privilege would shield any particular materials from disclosure in any APA case; nor could it have—the agency action it was reviewing was not challenged under the APA. As *Overton Park* held—along with hundreds of APA cases since—courts must perform a "thorough, probing, in-depth review" of agency action based on the "whole record" before the agency. 401 U.S. at 415, 419. Courts cannot do so unless the record contains the material the agency directly or indirectly considered.

FDA's characterization of *San Luis Obispo Mothers for Peace v. U.S. Nuclear Reg. Comm'n*, 789 F.2d 26, 45 (D.C. Cir. 1986) (en banc), fails for the same reasons. The specific question there was not whether all deliberative material may be excluded, but whether to allow petitioners to add to the completed record with specific transcripts of a closed meeting among the decision-makers in an

adjudicative proceeding. 789 F.2d at 44-45 (seeking to add material regarding whether the agency had illegitimately excluded earthquakes from emergency planning).

Because the transcripts would reveal the subjective mental processes of individual decision-makers, the court addressed the narrow issue of whether the petitioners had made a threshold showing of bad faith sufficient to justify supplementing the record with that material. The court refused to consider the transcripts themselves to show bad faith, reasoning that "Petitioners must make the requisite showing before we will look at the transcripts. We will not examine the transcripts to determine if we may examine the transcripts." *Id*. at 45. That is a different question than what is at issue here: whether the agency can categorically withhold tens of thousands of documents that the agency considered in reaching its decision.[9]

[9] Even in this more restrictive context, the court stated that it was *not* establishing a blanket rule that such material may always be excluded, and recognized that "there may be cases where a court is warranted in examining the deliberative proceedings of the agency." 789 F.2d at 45. *See also Deukmejian v. Nuclear Reg. Comm'n*, 751 F.2d 1287, 1324 n.229 (D.C. Cir. 1984) (original panel decision recognizing the principle that internal pre-decisional agency analyses are "presumptively" part of the administrative record but may be shielded from disclosure by the application of privileges like the deliberative process privilege).

E. Judicial Review of Agency Action in Other Contexts Does Not Support FDA's Arguments.

FDA also argues that the APA's provisions governing formal administrative hearings, 5 U.S.C. § 556(e), and the appellate rules governing a record for direct appellate review of specific agency actions, Fed. R. App. P. 16, analogously support its production of a limited record. Pet. at 17-19; 13. It is wrong.

FDA incorrectly insists that the scope of "formal" adjudicative rulemaking is limited to documents the agency chooses to include, and so any materials the agency does not file, like internal documents, are "categorically excluded." Pet. at 18. To the contrary, the record created during a formal rulemaking is not controlled exclusively by the agency, but includes all testimony submitted or sought by all parties to the hearing, including depositions, subpoenas, and cross-examination. 5 U.S.C. § 556(b)-(d) (procedures for a trial-like hearing presided over by an agency hearing body or an administrative law judge, for which subpoenas, offers of evidentiary proof, and depositions can be taken, and the parties are permitted to conduct cross-examination of agency officials and witnesses "as may be required for a full and true disclosure of the facts"). If the agency refused to include certain information at the hearing, the denial of that "request" would be subject to judicial review as well. There is nothing in Section 556 that supports FDA's position that such proceedings "categorically exclude" internal agency documents, or that such a decision would be categorically shielded

from judicial review. Rather, formal rulemaking is more structured and inclusive than informal rulemaking (like that at issue here), which requires only that the agency compile a record of what it considered and a privilege log for any privileged documents.[10]

FDA's analogies to direct appellate review also fail. 28 U.S.C. § 2112 specifically provides that the agency record "shall" include "*all* of the evidence before the agency," *id.* § 2112(b) (emphasis added), and expressly provides for parties to supplement that record if it omits "any portion of the proceedings before the agency" that the "court subsequently determines to be proper for it to consider to enable it to review or enforce the order in question," *id.* Fed. R. App. P. 16 is similarly broad, explaining that the record on review of an agency order must include "any findings or reports on which it is based," all evidence, and "other parts of the proceedings before the agency," Fed. R. App. P. 16(a)(2-3), and similarly allows for supplementation for omissions from the record, Fed. R. App. P. 16(b). Contrary to FDA's characterization, Pet. at 18, the Fed. R. App. P. 16 advisory notes stand only for the unremarkable proposition that the agency record for direct review or enforcement of an agency's adjudicative order (*i.e.*, not

[10] Hence the overwhelming shift by agencies to informal rulemaking in modern administrative law. Aram A. Gavoor, *Public Participation in Nonlegislative Rulemaking*, 61 Vill. L. Rev. 759, 769 (2016) (describing formal rulemaking as "rarely used and largely defunct"); Peter L. Strauss, *The Rulemaking Continuum*, 41 Duke L.J. 1463, 1468 (1992) ("[F]ormal rulemaking is the least frequent, the most stylized, and the most demanding of resources at the agency's head.").

rulemaking or other actions) is the same as what was reviewed in formulating the agency order being reviewed. Indeed, the committee notes make clear Fed. R. App. P. 16(a) is "based upon 28 U.S.C. § 2112(b)."

Moreover, it is false that agency appellate records are simply devoid of internal agency documents such as emails or drafts. *See, e.g.*, *Reno-Sparks Indian Colony*, 336 F.3d at 906 (direct appellate review case under Clean Air Act relying on an "internal agency memorandum"). Regardless, the scope of review and the scope of the record in this case are governed exclusively by the APA, 5 U.S.C. § 706, which provides jurisdiction in the district court. Cases brought on direct review to the Court of Appeals under more specific statutory vehicles might have different requirements, but do not address the APA's language that such review is based on the "whole record" before the agency.

Finally, FDA compares internal agency drafts and emails relied upon by agency decision-makers to bench memoranda that are prepared for a district judge. Pet. at 18. This comparison defeats itself. Executive agencies are subjected to the requirements of the APA, whereas the judicial branch is not, 5 U.S.C. § 701(b)(1)(B), and with good reason: these two different branches of government perform very different functions in enforcing laws and reviewing their legality, respectively.

In sum, there is no authority or precedent that clearly conflicts with the district court's Order. Rather, the Order merely enforces the mandates of the APA and is supported by both Supreme Court and Ninth Circuit authority. FDA has failed to show clear error and the Court should deny the writ.

IV. OTHER MANDAMUS FACTORS WEIGH AGAINST THE WRIT.

Though failure to find clear error is dispositive, *Burlington*, 408 F.3d at 1146, other *Bauman* factors also weigh against granting the extraordinary writ requested here.

A. FDA Can Raise the Scope of the Record on Appeal.

The first *Bauman* factor is whether there are any other adequate means, such as direct appeal, to attain the relief sought. *Bauman*, 557 F.2d at 654; *In re Ozenne*, 841 F.3d 810, 816 (9th Cir. 2016) (en banc). The legal issue here can be addressed on appeal after final judgment. FDA does not meaningfully dispute this, protesting only that the record scope is "highly unlikely to be subject to review on appeal from the final judgment." Pet. at 21. Yet FDA will have discretion to determine for itself what issues and orders it appeals. Fed. R. App. P. 3(c)(1)(B) (notice of appeal to contain orders, or parts thereof being appealed); *McElmurry v. U.S. Bank Nat. Ass'n*, 495 F.3d 1136, 1141-42 (9th Cir. 2007) (rejecting mandamus writ alleging the district court erred by considering evidence that went towards the merits because such a decision "is reviewable in an appeal from a final

judgment"); *see also In re Ozenne*, 841 F.3d at 816 ("The first [mandamus] condition is 'designed to ensure that the writ will not be used as a substitute for the regular appeals process.'" (quoting *Cheney*, 542 U.S. at 380-81).[11]

B. Completing the Record Will Not Prejudice Petitioners.

The second *Bauman* factor is whether FDA will be prejudiced in a way not correctable on appeal. 557 F.2d at 654. Because the question of law can be addressed later on appeal, FDA is left only with its assertions that the staff time and expense it will take to complete the record is an uncorrectable prejudice. Pet. at 19-20. FDA argues such document production burdens cannot be repaired, Pet. at 20-21, but this Court has repeatedly held such litigation costs and delays are "regrettable, yet normal, features of our imperfect legal system" and are not cognizable mandamus grounds. *Calderon v. U.S. Dist. Court for the Cent. Dist. of Cal.*, 163 F.3d 530, 535 (9th Cir. 1998) (en banc), *overruled on other grounds by Woodford v. Garceau,* 538 U.S. 202, 205 (2003) ("The mere annoyance and cost of having to litigate will not support mandamus."); *DeGeorge*, 219 F.3d at 936. Well beyond the burden of preparing and lodging a complete administrative record, in denying mandamus, this Court has "consistently rejected the position

[11] For the same reason, FDA's writ also fails the fifth *Bauman* factor—whether the court's Order raises new and important problems or issues of first impression. *Bauman*, 557 F.2d at 655. The district court's decision followed this Court's well-established precedent, *see supra*, but to the extent it did raise any new legal issues, those again could be appealed by FDA as part of a final judgment appeal. *See, e.g.*, *In re Ozenne*, 841 F.3d at 816.

that the costs of trying massive civil actions render review after final judgement inadequate." *In re Orange*, 818 F.3d at 964 (internal citations omitted).

That preparation of the administrative record is a significant undertaking is not surprising in light of the context of this case: approval of a novel genetically engineered animal that FDA took years to review. Nor is it an extraordinary burden or proper grounds for a mandamus writ. If they have any significance, these precedential regulatory circumstances militate even more in favor of ensuring the court and parties have a complete record on which to adjudicate this matter.

FDA relies on *Medhekar v. U.S. District Ct.*, 99 F.3d 325 (9th Cir. 1996), but there the lower court interpreted specific language in securities statutes regarding whether all discovery must be stayed during a motion to dismiss. Unlike here, the Court held the harm of the district court ordering discovery disclosures to proceed was irreparable, since it was the "precise harm intended to be avoided by the stay provision of the [securities] Act." *Id.* at 327.

The bureaucratic burdens FDA raises are not uniquely prejudicial, or statutorily-enshrined, as in *Medhekar*. The opposite is true: they are normal for agencies during APA record-review litigation. Indeed, other federal agencies have guidance instructing officials to include internal, pre-decisional documents in the record, identify any material they wish to shield from disclosure, and justify withholdings through a privilege log. National Oceanic and Atmospheric

Administration Guidelines for Compiling an Agency Admin. Record (2012) (App. 1197, 1205) ("[I]nternal communications are considered to be part of the Administrative Record because they are directly or indirectly considered by agency decision-makers. . . . All such documents must be identified for inclusion in the Administrative Record but flagged for potential listing, in whole or in part, on the agency's Privilege Log."); Department of Interior Standardized Guidance on Compiling an Admin. Record (2006) (App. 1215, 1222-4, 1227) (similar).

Agencies, including FDA, also have this same duty to pursuant to FOIA. *See EPA v. Mink*, 410 U.S. 73, 89 (1973) (distinguishing internal materials that reflect "deliberative or policy-making processes on the one hand, and purely factual, investigative matters on the other" for purposes of defining the deliberative process privilege); *Nat'l Wildlife Fed'n*, 861 F.2d at 1118-19. Indeed, since 2010 several Plaintiffs have had broad Freedom of Information Act (FOIA) requests lodged with FDA on its GE salmon approval. Dkt. 105 (App. 290, 305-06); Dkt. 106 (App. 311); Dkt. 107 (App. 357). Thus, by the time this case was filed, FDA had already had over six years to comply with its independent duty under FOIA to review and prepare most of the material and/or a privilege log that should have been produced as FDA's administrative record. Several of these FOIA requests are still outstanding. *Id.*; Pet. Add. 11 n.2.

Petitioners' delay also belies its argument regarding prejudice. *McDaniel v. U.S. Dist. Court for the Dist. of Nevada*, 127 F.3d 886, 889 (9th Cir. 1997). Petitioners complied with the Order for three full months, giving no indication that they intended to appeal. Such unreasonable delays, partial compliance, and implicit consent undermine Petitioners' claim that their injury is not correctable. *Id.*; *In re Telular Corp.*, 319 F. App'x 909, 911 (Fed. Cir. 2009) (describing several cases in which delays of three to five months before filing a petition weighed against the need for a writ of mandamus).

Finally, while mandamus is not an appropriate remedy, Petitioners certainly have the ability to mitigate their burden and costs, by working further with Plaintiffs to narrow the scope of documents FDA needs to produce, or seek more time to comply. FDA sought mandamus before making any attempts to negotiate for a reasonable extension, explain delays or problems, or discuss modification or further narrowing of the search parameters, as Plaintiffs have repeatedly indicated that they are willing to do. *See, e.g.,* Dkt. 94 (App. 281, 282-83, 286). Petitioners' costs and resources carry little weight compared with the important needs of litigants and the court to undertake the full, thorough, and probing review of FDA's action that the APA requires.

CONCLUSION

FDA improperly seeks to withhold a massive number of documents, which it admittedly considered when reviewing AquaBounty's application to grow and sell GE salmon, and without asserting any particularized evidentiary privilege. FDA's novel interpretation of the scope of an administrative record has no basis in Ninth Circuit precedent, and is contrary to this Court's frequent reliance on internal agency documents in APA review. FDA has failed to establish that the district court committed clear error. The district court correctly followed the well-established principle that a complete administrative record must include all documents the agency directly or indirectly considered.

For the foregoing reasons, this Court should deny the petition for a writ of mandamus.

Respectfully submitted this 15th day of August, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on August 15, 2017, I electronically filed the foregoing RESPONSE TO WRIT OF MANDAMUS and APPENDICES PARTS 1 AND 2 with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the appellate CM/ECF system.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

Respectfully submitted this 15th day of August, 2017.

/s/ George Kimbrell

CERTIFICATE OF COMPLIANCE

Pursuant to Ninth Circuit Rules 21-1(c) and 32-3(2), this Response to Petition for Mandamus contains 8,388 words, excluding the documents listed at Fed. R. App. P. 32(f). In accordance with the formula in Ninth Circuit Rule 32-3, (8,388/280), the Response does not exceed the designated 30-page limit in Ninth Circuit Rule 21-2(c). The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

DATED: August 15, 2017

/s/ George Kimbrell