No. 17-____

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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

Petitioners.

PETITION FOR A WRIT OF MANDAMUS TO THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

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INTRODUCTION

Pursuant to 28 U.S.C. § 1651 and Rule 21 of the Federal Rules of Appellate Procedure, the Secretary of Health and Human Services, the Acting Commissioner of the Food and Drug Administration (FDA), and the FDA, respectfully petition this Court to issue a writ of mandamus to the United States District Court for the Northern District of California in *Institute for Fisheries Resources v. Price*, No. 3:16-cv-1574 (N.D. Cal.) (Chhabria, J.). In a pending suit for judicial review of agency action under the Administrative Procedure Act (APA), the district court has granted a motion by the plaintiffs to supplement the extensive administrative record with hundreds of thousands of pages of internal, deliberative documents. The 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 through the submission of a privilege log.

The district court's order rests on a fundamental misunderstanding of the scope of an administrative record and the nature of judicial review of agency action. It is a basic tenet of administrative law that review of agency action is based on the agency's stated reasons for its decision and that, barring exceptional circumstances, it is beyond the power of courts to probe the mental processes of the agency. For that reason, the *en banc* D.C. Circuit and other courts have declined to require agencies to include internal, deliberative, and predecisional agency documents in an administrative record. Because documents that reflect predecisional deliberations within the agency

are not part of an administrative record in the first instance, those courts have also not required agencies to review all such documents and create a privilege log describing them. These decisions recognize that internal documents reflecting an agency's predecisional deliberations are not part of the administrative record any more than documents reflecting a trial court's predecisional deliberations, such as bench memos, other communications between judges and their staff, and drafts of decisions, are part of the trial record.

The district court order here is squarely in conflict with these decisions. FDA has already produced a voluminous and comprehensive administrative record covering more than twenty years of agency proceedings and containing approximately 38,000 pages of documents. Plaintiffs have not provided any evidence that FDA conducted the administrative proceeding in bad faith or that any other extraordinary circumstances that might warrant examination of predecisional materials are present. The district court has nonetheless ordered the government to produce all predecisional documents or describe any withheld documents in a privilege log. The order compels FDA to review, by FDA's estimate, significantly more than 400,000 pages of documents, requiring thousands of hours of time and diverting agency personnel away from mission-critical functions.

The governing criteria for mandamus relief articulated in *Bauman v. U.S. District Court*, 557 F.2d 650 (9th Cir. 1977), are satisfied here. The district court has committed a clear error of law and acted beyond its authority to review agency action.

Immediate review is needed to avoid the staggering burden the government will face in complying with the district court's order. No other means are available to obtain the relief the government seeks; the district court's error in this case has been repeated with increasing frequency in district courts within this Circuit, and in particular in the Northern District of California; and this Court itself has yet to address the issue. Petitioners respectfully request that the Court issue the writ and direct the district court to vacate its clearly erroneous order.

STATEMENT OF JURISDICTION

This Court has authority to issue a writ of mandamus pursuant to 28 U.S.C. § 1651 and Rule 21 of the Federal Rules of Appellate Procedure.

STATEMENT OF THE ISSUE

Whether the district court committed clear legal error and exceeded its judicial authority by ruling that hundreds of thousands of pages of internal, deliberative agency documents are part of the administrative record in this case and that the agency must either produce those documents or review and describe withheld material in a privilege log.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in the addendum to this petition.

STATEMENT OF THE CASE

A. Background

This case concerns the regulation of genetically engineered salmon. FDA has been considering this general subject since 1994. Dkt. 82-2 at 2. After many years of consideration, including discussions within FDA, and with other agencies, industry stakeholders and other interested outside parties, the FDA issued draft guidance on the regulation of genetically engineered animals in 2008. *See* 73 Fed. Reg. 54,407 (Sept. 19, 2008). After receiving and reviewing thousands of comments, the guidance was finalized and published on January 16, 2009. 74 Fed. Reg. 3057 (Jan. 16, 2009). The guidance clarifies that a recombinant DNA ('rDNA") construct that is intended to alter the structure or function of an animal meets the definition of a drug under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 321 *et seq.*, and that FDA has authority to regulate such constructs in genetically engineered animals through the "new animal drug approval" provisions of the Act. The guidance sets forth guidelines and recommendations for potential applicants. 74 Fed. Reg. at 3057.

In September 2010, FDA convened a public Veterinary Medicine Advisory Committee ("VMAC") meeting to discuss the new animal drug application of a biotechnology company, AquaBounty Technologies, Inc. ("AquaBounty"), concerning a genetically engineered salmon. *See* 75 Fed. Reg. 52,605 (Aug. 26, 2010) (announcement of VMAC meeting). In association with that meeting, FDA made publicly available AquaBounty's environmental assessment, and established a docket

to accept public comments. The agency received thousands of written comments from various interested groups and individuals on AquaBounty's application.

Subsequently, in December 2012, FDA released its own draft environmental assessment and preliminary Finding of No Significant Impact (draft EA/preliminary FONSI), which analyzed the potential environmental impact of an FDA approval of AquaBounty's new animal drug application, on which the agency received thousands of comments. *See* 77 Fed. Reg. 76,050 (Dec. 26, 2012). On November 19, 2015, following review of the comments, additional review of minor submissions from AquaBounty, and further deliberation, the agency responded to relevant and substantive comments, and approved AquaBounty's application under the conditions of use specified in the approval documents, allowing introduction of the salmon into interstate commerce. 80 Fed. Reg. 73,104 (Nov. 24, 2015).

The Plaintiffs filed suit in the Northern District of California in March 2016. They allege that FDA lacked authority to approve AquaBounty's application and issue Guidance 187 under the FDCA; failed to comply with the National Environmental Policy Act, 42 U.S.C. § 4321 *et seq.*; failed to consult adequately with the Fish and Wildlife Service and the National Marine Fisheries Service under the Endangered Species Act, 16 U.S.C. § 1531 *et seq.*; and failed to adhere to the procedural requirements of the APA, 5 U.S.C. § 706. Dkt. 53 at 65-66.

B. The Administrative Record

Legal challenges to agency action are decided on the basis of the administrative record. After a thorough review, FDA filed an approximately 38,000-page administrative record in this case. Dkt. 82-2 at 2. The administrative record contains documents dating back to December 1994, and includes, among other things:

- Studies and other materials submitted by AquaBounty;
- FDA's analysis of the materials submitted by AquaBounty, and its responses to AquaBounty regarding those submissions;
- Minutes of meetings with AquaBounty
- A transcript of the September 2010 VMAC meeting to discuss AquaBounty's application, the Chair's final report, and FDA's response to that report;
- AquaBounty's environmental assessment;
- FDA's subsequent draft environmental assessment and preliminary FONSI, and FDA's final environmental assessment and FONSI;
- Thousands of pages of public comments on FDA's draft guidance document, the new animal drug application, AquaBounty's environmental assessment as discussed at the VMAC meeting, FDA's

draft environmental assessment and preliminary FONSI, and FDA's responses to those comments;[1]

- The "Freedom of Information Summary" for the AquaBounty approval, a 161-page document describing the data, analysis, and other information considered and FDA's conclusions leading to its decision to approve the application;
- FDA's emails and letters with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service, in which FDA provided information and responded to questions concerning FDA's determination that approval of a new animal drug application by AquaBounty would have no effect on endangered species;
- A detailed FDA memorandum describing the review of AquaBounty's application and providing the reasons for approval; and
- The decision documents approving AquaBounty's application.

See Dkt. 71-2.[2]

[1] Before Plaintiffs filed their motion, the government had agreed to produce more than 70,000 additional public comments to Plaintiffs once a protective order is in place to protect the personal privacy or identifying information and confidential commercial or financial information of commenters. Dkt. 82-2 at 3-4.

[2] The administrative record also included a variety of other materials, such as: FDA inspection reports of AquaBounty facilities; two citizen petitions filed by Plaintiffs requesting preparation of a full environmental impact statement, and FDA's

Plaintiffs filed a motion to "compel completion" of the administrative record on November 15, 2016. Plaintiffs claimed that notwithstanding the voluminous administrative record the agency had produced, which had been prepared in accordance with the agency's protocols, the administrative record must be supplemented to include "internal memoranda, correspondence, notes, drafts, revisions, or prior versions of FDA's decision documents." Dkt. 75 at 5. The government opposed Plaintiffs' motion, invoking the settled rule in the D.C. Circuit (which was approvingly cited by this Court in *Portland Audubon Society v. Endangered Species Committee*, 984 F.2d 1534, 1549 (9th Cir. 1993)) that internal, deliberative materials need not be included in the administrative record. Dkt. 82-2 at 7-8.

In a two-page order issued two days prior to the scheduled hearing, the district court granted Plaintiffs' motion. *See* Dkt. 88. The district court rejected the government's position—and the settled rule in the D.C. Circuit—that separate and apart from any claim of privilege, deliberative and predecisional documents need not be included in an administrative record. *Id.* The district court concluded that internal, deliberative materials may be withheld from the administrative record only on the basis of specific assertions of privilege, and therefore ordered the government to

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denial of those petitions; and more than 400 publications containing relevant data and analysis. *See* Dkt. 71-2.

review all such materials and either produce them or identify them and set forth the basis for withholding them on a privilege log. *Id.*

On the day of the hearing, and in view of the magnitude of this undertaking, the district court extended the 30-day deadline in the original order, giving the government until July 11, 2017, to complete its review, but also directed Plaintiffs to narrow the scope of their demand. Dkt. 90 (minute order). The district court directed the parties to file a status report on March 14, 2017, to provide an update on narrowing efforts. *Id.*

Plaintiffs narrowed the scope of their demand in certain respects, but reserved the right to expand their request in the future. Even as presently agreed, the volume of material covered by the request remains extraordinarily large. The government is to apply 31 broad search terms to the records of 17 different e-mail custodians over a 23-year period. Dkt. 94 at 2; Dkt. 97-2 (Wanke Decl.) ¶ 4.[3] According to FDA's current estimate, based on e-mail searches of just 3 of the 17 custodians, this process will require review of more than 400,000 pages, which, under current staffing levels, will take far in excess of a year. Dkt. 97-1 (Garcia-Malene Decl.) ¶¶ 13-14. FDA does not believe it is possible to complete this process by the current mid-July deadline, and even completing the review by year's end would require the diversion of FDA

[3] The custodians themselves are to conduct a search of their computer hard drives and paper files for additional responsive documents. Dkt. 97-1 (Garcia-Malene Decl.) ¶¶ 11-12.

personnel from mission-critical functions to work on the matter. *Id.* ¶ 21. The government waited to file this petition until after the March 14 status report deadline, in order to engage in good-faith negotiations with Plaintiffs regarding the scope of their request, and to obtain additional clarity regarding the full magnitude of the undertaking that compliance with the district court's order would require.

STANDARD OF REVIEW

The Court considers a petition for a writ of mandamus by applying the five factors identified in *Bauman v. U.S. District Court*, 557 F.2d 650 (9th Cir. 1977):

> (1) whether the petitioner has no other means, such as direct appeal, to obtain the desired relief;
>
> (2) whether the petitioner will be damaged or prejudiced in any way not correctable on appeal;
>
> (3) whether the district court's order is clearly erroneous as a matter of law;
>
> (4) whether the district court's order is an oft repeated error or manifests a persistent disregard of the federal rules; and
>
> (5) whether the district court's order raises new and important problems or issues of first impression.

Perry v. Schwarzenegger, 591 F.3d 1147, 1156 (9th Cir. 2009) (citing *Bauman*, 557 F.2d at 654-55).[4] These factors are guidelines, and the only factor that is a prerequisite for

[4] The three factors the Supreme Court has established for mandamus relief—(1) the party seeking relief has no other adequate means of relief; (2) the right to relief is clear and undisputable; and (3) issuing the writ is appropriate in the circumstances—overlap substantially with the *Bauman* factors and are also satisfied for the reasons discussed. *See Cheney v. U.S. Dist. Ct.*, 542 U.S. 367, 380-81 (2004).

mandamus is the third, clear legal error. *Id.* (citing *Burlington N. & Santa Fe Ry. Co. v. U.S. Dist. Ct.*, 408 F.3d 1142, 1146 (9th Cir. 2005); *Admiral Ins. Co. v. U.S. Dist. Ct.*, 881 F.2d 1486, 1491 (9th Cir. 1989)).

ARGUMENT

An Order Compelling an Agency To Include Predecisional Deliberative Materials in the Administrative Record or Prepare a Privilege Log Exceeds the District Court's Authority and Is Clear Legal Error That Should Be Corrected by Mandamus

The district court's order satisfies each of the five *Bauman* factors for the extraordinary remedy of mandamus. In ruling that the administrative record includes deliberative materials and that FDA must produce such materials or invoke specific privileges to justify their withholding, the district court exercised judicial power it does not have. The court's order is at odds with decisions of the Supreme Court and the *en banc* D.C. Circuit, and it finds no support in the decisions of this Court or the language of the APA. Requiring FDA to comply with this clearly erroneous order will subject it to a grave administrative burden, and there do not appear to be any other means for the agency to obtain relief. The legal error underlying the district court's order is one that district courts within this Circuit have made with increasing frequency in recent years. The legal issue presented by the district court's order has not been directly addressed by this Court, and a growing divide among the district courts within this Circuit regarding this issue has significant implications for administrative litigation. The Supreme Court and this Court have exercised

supervisory mandamus jurisdiction to address comparably important questions of first impression regarding the procedural rights and obligations of parties in litigation, and this Court should do so here as well. *See, e.g.*, *Perry*, 591 F.3d at 1156-57 (issuing writ to address district court's authority to require disclosure of internal campaign communications) (citing, *inter alia*, *Schlagenhauf v. Holder*, 379 U.S. 104, 110-12 (1964)); *City of Las Vegas v. Foley*, 747 F.2d 1294, 1296-97 (9th Cir. 1984) (issuing writ where district court ordered legislators to be deposed to determine their subjective motivations); *see also Mohawk Indust., Inc. v. Carpenter*, 558 U.S. 100, 111 (2009) (collateral order review is generally not available for disclosure orders, but in an appropriate case may provide basis for mandamus) (citing *Cheney v. U.S. Dist. Ct.*, 542 U.S. 367, 390 (2004); *Firestone Tire & Rubber Co. v. Risjord*, 449 U.S. 368, 378-79 n.13 (1981)).[5]

1. The district court's order is clearly erroneous as a matter of law. It conflicts with basic principles regarding judicial review of agency action and the scope of the administrative record on which that review takes place.

As a general matter, "judicial review of agency action is limited to review of the record on which the administrative decision was based." *Thompson v. Dep't of Labor*,

[5] Many of the cited cases involve the doctrinally distinct issues presented by discovery obligations in ordinary civil litigation. Although the issues presented bear some superficial resemblances—in part because the district court's order here blurs the lines between APA review and civil discovery—this case implicates the uniquely important interests of ensuring the proper scope of judicial review of agency action.

885 F.2d 551, 555 (9th Cir. 1989). The administrative record includes "all documents and materials directly or indirectly considered by agency decision-makers." *Id.* (emphasis omitted). But that description refers to materials of the sort considered to be part of a record in an adjudicatory proceeding, e.g., evidentiary materials and submissions by parties. *See* 5 U.S.C. § 556(e) and *infra* pp. 18-19. Contrary to the district court's belief, the bare fact that predecisional, deliberative materials, such as internal memoranda and emails from agency staff, were generated in the agency's decision-making process, does not transform those materials into documents that were before the agency in any relevant sense and therefore part of the administrative record, any more than a bench memorandum becomes part of the trial record when it is prepared for a district judge.

The district court failed to recognize that the scope of the administrative record is bounded by the proper scope of administrative review. It is long settled that agency action should be judged on the basis of the agency's stated reasons for its decision. *See SEC v. Chenery Corp.*, 318 U.S. 80, 88 (1943) ("confining our review to a judgment upon the validity of the grounds upon which the Commission itself based its action"); *see also Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983) ("It is well-established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself."); *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 169 (1962). It is "not the function of the court to probe the mental processes" of the agency. *United States v. Morgan*, 304 U.S. 1, 18 (1938) ("*Morgan I*").

"Just as a judge cannot be subjected to such a scrutiny . . . so the integrity of the administrative process must be equally respected." *United States v. Morgan*, 313 U.S. 409, 422 (1941) ("*Morgan II*"). Accordingly, "[s]uch inquiry into the mental processes of administrative decisionmakers is usually to be avoided." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971). Where, as here, administrative findings are made at the time of the decision and have been included in the administrative record, *Overton Park* provides that "there must be a strong showing of bad faith or improper behavior before such inquiry may be made." *Id.* No such determination of bad faith or improper behavior was made here.[6]

Applying these teachings, the D.C. Circuit, the only court of appeals to have squarely addressed the question, has concluded that deliberative materials are outside the scope of APA review and thus are not part of the administrative record. In *San Luis Obispo Mothers for Peace v. Nuclear Regulatory Commission*, 789 F.2d 26, 44-45 (D.C. Cir. 1986), the *en banc* D.C. Circuit considered a motion to supplement the administrative record with transcripts of a closed-door meeting of the Nuclear

[6] While making no findings regarding bad faith or improper behavior, the district court nevertheless concluded that the presumption of regularity to which agencies are entitled in their preparation of the administrative record was overcome. It did so based only on (1) the tautological conclusion that the omission of the deliberative, internal documents (or a privilege log justifying withholding on a document-by-document basis) was itself a basis for requiring production of those same documents, and (2) the inadvertent omission from the 38,000 page administrative record of a single subsequently discovered document, which Plaintiffs already possessed, reflecting a public comment from an environmental group to the U.S. Fish and Wildlife Service. Dkt. 88 at 2; Dkt. 82-2 at 4.

Regulatory Commission to discuss the license application whose approval the petitioners were challenging. The court rejected that effort, stating that "[j]udicial examination of these transcripts would represent an extraordinary intrusion into the realm of the agency, and that the petitioners must make a "'strong showing of bad faith or improper behavior'" before the court would be "warranted in examining the deliberative proceedings of the agency." *Id.* (quoting *Overton Park*, 401 U.S. at 420). The court analogized an agency's deliberations to the deliberative processes of a court and stated that, "[w]ithout the assurance of secrecy, the court could not fully perform its functions." *Id.* The D.C. Circuit has subsequently reiterated that "the actual subjective motivation of agency decisionmakers is immaterial as a matter of law" to APA review. *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) (citing, *inter alia*, *Overton Park*, 401 U.S. at 420; *Camp v. Pitts*, 411 U.S. 138 (1973); *Morgan II*, 313 U.S. at 409).

District courts within the D.C. Circuit have adhered to that reasoning in subsequent decisions rebuffing efforts by plaintiffs to require preparation of a privilege log specifically identifying withheld deliberative materials. *See, e.g.*, *National Ass'n of Chain Drug Stores v. U.S. Dep't of Health & Hum. Servs.*, 631 F. Supp. 2d 23, 27 (D.D.C. 2009); *Oceana, Inc. v. Locke*, 634 F. Supp. 2d 49, 52-53 (D.D.C. 2009) ("*Oceana I*") (collecting cases), *rev'd on other grounds*, 670 F.3d 1238 (D.C. Cir. 2011); *Stand Up for California! v. Dep't of Interior*, 71 F. Supp. 3d 109, 123 (D.D.C. 2014) ("[P]rivileged and deliberative materials are not part of the administrative record as a matter of law.").

As the District Court for the District of Columbia explained, "[a]s pre-decisional, deliberative documents are immaterial to the court's decision [under the APA], they are not designated part of the administrative record that forms the basis of the court's decision." *National Ass'n of Chain Drug Stores*, 631 F. Supp. 2d at 27; *Oceana, Inc. v. Pritzker*, --- F.Supp.3d ----, 2016 WL 6581169 (D.D.C. Nov. 4, 2016) ("*Oceana II*"), at *7 (summarizing D.C. Circuit precedents and providing extended discussion of rationale for excluding predecisional, deliberative materials from administrative record). And because such materials are outside the scope of the administrative record in the first instance, the agency is not required to produce a privilege log to identify them and explain their exclusion. *Oceana II,* 2016 WL 6581169, at *7 (declining to "requir[e] all predecisional and deliberative documents to be logged in a Vaughn–type index[,] [which] would place a significant burden on agencies whose decisions are challenged as arbitrary and capricious"). The district court order here is in direct conflict with these decisions.

Some district courts within this Circuit have likewise held that internal, deliberative and predecisional materials are outside the scope of administrative review. *See, e.g.*, *Carlsson v. U.S. Citizenship & Immig. Servs.*, 2015 WL 1467174 (C.D. Cal. Mar. 23, 2015), at *7 n.5; *California v. U.S. Dep't of Labor*, 2014 WL 1665290 (E.D. Cal. Apr. 24, 2014), at *13. And although this Court has not squarely addressed the issue, it has strongly suggested that deliberative materials are not properly part of the record for APA review. *Portland Audubon Society v. Endangered Species Committee*, 984 F.2d 1534 (9th

Cir. 1993), involved a request for discovery regarding alleged *ex parte* contacts with the agency charged with granting exemptions from Endangered Species Act requirements. The Court distinguished the purely internal deliberations at issue in the D.C. Circuit's *Mothers for Peace* case (and at issue here) from "allegedly improper *ex parte* contacts between decisionmakers and outside parties." 984 F.2d at 1549. In so doing, the Court approvingly cited *Mothers for Peace* in suggesting that the administrative record includes "neither the internal deliberative processes of the agency nor the mental processes of individual agency members." *Id.* at 1549.[7]

The principle that predecisional, deliberative materials are outside the scope of the administrative record is also reflected in the scope of review of agency action in the courts of appeals. When an agency decision is subject to direct review, the "record to be filed in the court of appeals . . . shall consist of the order sought to be reviewed or enforced, the findings or report upon which it is based, and the pleadings, evidence, and proceedings before the agency, board, commission, or officer concerned." 21 U.S.C. § 2112(b). Rule 16 of the FRAP defines the administrative record in the same terms. The advisory committee that adopted Rule 16 in 1967

[7] In addition, in a 2010 unpublished disposition, the Court denied a motion to supplement the administrative record (and provide an accompanying privilege log) to include various documents, including internal, deliberative and predecisional materials. The Court stated that it will "assume that an 'agency properly designated the Administrative Record absent clear evidence to the contrary,'" and held that the petitioner had made no such showing. *Cook Inletkeeper v. Envtl. Protection Agency*, 400 F. App'x 239, 240 (9th Cir. 2010) (quoting *Bar MK Ranches v. Yuetter*, 994 F.2d 735, 740 (10th Cir. 1993) and *Portland Audubon Society*, 984 F.2d at 1548).

explained in the accompanying note that "[t]he record in agency cases is thus *the same as that in appeals from the district court*—the original papers, transcripts, and exhibits in the proceeding below" (emphasis added). No one would suggest that the record "in appeals from the district court" includes deliberative materials prepared within the court, such as bench memos and recommendations provided to the presiding judge by his staff, or preliminary drafts of opinions and orders. The trial record comprises the materials submitted to the court by the parties, the transcripts of the court's proceedings, and the orders issued by the court, not the internal deliberative work product generated within the court's chambers. As the committee note indicates, the administrative record in agency review cases is subject to the same limitations.

This principle is also reflected in the terms of the APA itself. In formal administrative proceedings, the APA provides that the "exclusive record for decision" consists of "[t]he transcript of testimony and exhibits, together with all papers and requests filed in the proceeding." 5 U.S.C. § 556(e). Thus, the contents of the administrative record are determined by the agency itself as it decides what filings and testimony to admit into the record. The administrative record comprises the materials that are admitted by the agency in the course of the proceeding—and only ("exclusive[ly]") those materials. Materials that are not "filed in the proceeding" pursuant to the agency's procedures, such as internal agency documents memorializing the agency's own deliberations, are categorically outside the scope of the administrative record under section 556(e).

The APA does not contain a parallel provision explicitly prescribing the scope of the administrative record in informal agency proceedings. But there is no reason why deliberative materials should be treated any differently when they are generated in the course of an informal adjudication or rulemaking than when they are created in a formal proceeding. If anything, the informal character of the proceeding gives the agency more, rather than less, latitude in deciding what materials belong in the record. That decision is one for the agency, rather than the court, to make. It is a fundamental principle of administrative law that a court may "not stray beyond the judicial province . . . to impose upon the agency its own notion of which procedures are 'best' . . . ." *Vermont Yankee Nuclear Power Corp. v. Nat. Res. Defense Council*, 435 U.S. 519, 549 (1978). Thus, a court has no authority to compel an agency to place deliberative materials in the administrative record, regardless of whether the agency is proceeding through a formal hearing under 5 U.S.C. § 556 or, as here, an informal rulemaking or adjudication.

2. For the foregoing reasons, the district court's order is clearly erroneous as a matter of law. The order will cause significant prejudice to FDA if immediate appellate relief is not provided.

The resources and effort that will be required for FDA to comply with the district court's order are extraordinary. As explained in declarations submitted below, FDA estimates that its five experienced non-scientific Center for Veterinary Medicine Freedom of Information Act reviewers would require more than three years to

complete review of the hundreds of thousands of pages of material amassed thus far in response to the district court's order. Garcia-Malene Decl. ¶ 14. As a result, completing the review by July 11, 2017, the deadline currently issued by the district court, is a virtual impossibility, and in the absence of a stay of the order, FDA will be compelled to seek additional time to comply. Completing review by the end of this calendar year would require FDA to divert substantial resources away from its mission-critical functions, which include significant public health issues, such as addressing antimicrobial resistance and preparing enforcement actions involving products that violate federal law and that could create dangers to human or animal health. *Id.* ¶ 21.

The Court has previously concluded that the burden imposed by an erroneous document production order is a valid basis for granting mandamus relief. *Medhekar v. U.S. Dist. Ct.*, 99 F.3d 325, 326 (9th Cir. 1996) (per curiam) (burden and cost imposed by district court improperly requiring Rule 26(a)(1) initial disclosures satisfied second *Bauman* factor) (citing *Admiral Ins. Co.*, 881 F.2d at 1491).[8] The enormous undertaking and diversion of resources necessary to comply with the district court's unlawful order here warrants issuance of the writ.

[8] As noted earlier, *see supra* note 5, this case differs from *Medhekar* and others regarding discovery burdens because it does not merely implicate the interests of private parties in ordinary civil litigation, but rather those of the Executive Branch regarding the important question of the proper scope of judicial review of agency action.

The remaining *Bauman* factors are also satisfied. There do not appear to be any other means for obtaining relief from the district court's order. For obvious reasons, the order is not appealable as a final order under 28 U.S.C. § 1291. This Court has generally held that the collateral order doctrine is not available for orders requiring production or disclosure of documents. *See Medhekar*, 99 F.3d at 326. Discretionary review pursuant to 28 U.S.C. § 1292(b) is available only in cases of a "controlling question of law" that would likely resolve the litigation. *See Medhekar*, 99 F.3d at 326 (collateral order review and review pursuant to 28 U.S.C. § 1292(b) are generally not available for orders requiring production or disclosure); *Admiral Ins. Co.*, 881 F.2d at 1490. And the order is highly unlikely to be subject to review on appeal from the final judgment in this case, even assuming that the judgment is adverse to the government. Thus, mandamus appears to be the only mechanism available for timely and effective appellate review.

The district court's error is one that has been repeated with increasing frequency in the Northern District of California. *See, e.g.*, *Gill v. Dep't of Justice*, 2015 WL 9258075 (N.D. Cal. Dec. 18, 2015), at *6-*7; *United Farm Workers v. Envtl. Protection Agency*, 2008 U.S. Dist. LEXIS 79332 (N.D. Cal. Aug. 26, 2008), at *7-*9; *California ex rel. Lockyer v. U.S. Dep't of Agriculture*, 2006 WL 708914 (N.D. Cal. Mar. 16, 2006), at *3-*4. As noted earlier, the Court has yet to squarely address this important question, one that has the potential to substantially affect the course of many administrative lawsuits filed within this Circuit each year. In the absence of clear

guidance from this Court, the lack of uniformity in district courts' approach to this important issue within the Ninth Circuit, *see San Luis & Delta-Mendota Water Auth. v. Jewell*, 2016 WL 3543203 (E.D. Cal. June 23, 2016) (noting difference in N.D. Cal.'s and E.D. Cal.'s jurisprudence on this question), creates significant potential for forum shopping. This Court should therefore exercise its supervisory power to correct the district court's clear error and settle the law in this Circuit on this recurring issue.

CONCLUSION

For the foregoing reasons, this Court should issue a writ of mandamus.

Respectfully submitted,

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s/ Nitin Shah

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Department of Health and Human Services

April 2017

STATEMENT OF RELATED CASES

Pursuant to Ninth Circuit Rule 28-2.6, petitioners state that they know of no related case pending in this Court.

s/ Nitin Shah
Nitin Shah

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 21(d). This brief contains 5,419 words.

s/ Nitin Shah
Nitin Shah

CERTIFICATE OF SERVICE

I hereby certify that on April 19, 2017, I electronically filed the foregoing petition with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. On this date, a notice of filing of this petition, including the petition itself, will be lodged in the district court in the underlying matter, and service in compliance with Federal Rule of Appellate Procedure 21(a)(1) will be accomplished through the district court's CM/ECF system. All counsel in this case are participants in the district court's CM/ECF system.

In addition, a courtesy copy of the foregoing brief has been provided via e-mail to the following counsel:

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s/ Nitin Shah
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ADDENDUM

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

INSTITUTE FOR FISHERIES RESOURCES, et al., Plaintiffs, v. SYLVIA MATHEWS BURWELL, et al., Defendants.	Case No. 16-cv-01574-VC **ORDER GRANTING MOTION TO COMPEL COMPLETION OF THE ADMINISTRATIVE RECORD** Re: Dkt. No. 75

A complete administrative record includes "all documents and materials directly or indirectly considered by agency decision-makers." *Thompson v. U.S. Dep't of Labor*, 885 F.2d 551, 555 (9th Cir. 1989) (emphasis omitted). It is obvious that in many cases internal comments, draft reports, inter- or intra-agency emails, revisions, memoranda, or meeting notes will inform an agency's final decision. Therefore, the 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."

Of course, these types of materials could be protected from disclosure by the deliberative process privilege. *See F.T.C. v. Warner Commc'ns Inc.*, 742 F.2d 1156, 1161 (9th Cir. 1984). But the scope of the 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. *See, e.g., People of State of Cal. ex rel. Lockyer v. U.S. Dep't of Agric.*, No. C05-03508 EDL, 2006 WL 708914, at *3 (N.D. Cal. Mar. 16, 2006). *But see, e.g., Oceana, Inc. v. Pritzker*, No. CV 15-1220 (ESH), 2016 WL 6581169, at *5-7 (D.D.C. Nov. 4, 2016).

Given the government's reliance on an overly narrow understanding of the universe of materials that may need to be included in the administrative record, its failure to produce a full privilege log, and its concession that at least one document was inadvertently omitted from the record, the plaintiffs have met their burden to overcome the presumption that the administrative record is complete. *See, e.g.*, *Gill v. Dep't of Justice*, No. 14-CV-03120-RS (KAW), 2015 WL 9258075, at *6 (N.D. Cal. Dec. 18, 2015). The plaintiffs' motion is therefore granted, and the government is ordered to complete the administrative record and/or produce a log of documents withheld from the record on privilege grounds within 30 days.

The plaintiffs have leave to conduct appropriate third-party discovery on their ESA claim. *See W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 497 (9th Cir. 2011); Order Granting Motion to Dismiss (Dkt. No. 66) at 5 n.1.

IT IS SO ORDERED.

Dated: January 10, 2017

VINCE CHHABRIA
United States District Judge

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

INSTITUTE FOR FISHERIES RESOURCES, *et al.*,

Plaintiffs,

v.

THOMAS E. PRICE, M.D., *et al.*,

Defendants, and

AQUABOUNTY TECHNOLOGIES, INC.,

Intervenor-Defendant.

Case No. 3:16-cv-01574-VC

FEDERAL DEFENDANTS' MOTION TO STAY JANUARY 10, 2017 ORDER PENDING PETITION FOR WRIT OF MANDAMUS

Date: May 25, 2017
Time: 10:00 a.m.
Location: Courtroom 4 - 17th Floor
Judge: Hon. Vince Chhabria

NOTICE OF MOTION AND MOTION TO STAY JANUARY 10, 2017 ORDER PENDING PETITION FOR WRIT OF MANDAMUS

TO THE HONORABLE COURT, ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on May 25, 2017, at 10:00 a.m., or as soon thereafter as counsel may be heard, before the Honorable Vince Chhabria of the United States District Court for the Northern District of California, in Courtroom 4, on the 17th floor of the Philip E. Burton Courthouse and Federal Building, 450 Golden Gate Avenue, San Francisco, California, defendant Thomas E. Price, M.D., et al. (Federal Defendants), will and hereby do move this Court for an Order staying its Order Granting Plaintiffs' Motion to Compel Completion of the Administrative Record (ECF 88), including the July 11, 2017 deadline for compliance with that order, pending resolution of a petition for writ of mandamus to the Ninth Circuit Court of Appeals.

This motion is made pursuant to Civil Local Rules 6-1 and 6-3, which authorize the Court to extend or amend the time for an event or deadline already fixed by Court order upon a motion made by a party, and pursuant to Federal Rule of Appellate Procedure 8, which authorizes the District Court to stay an order pending resolution of an appeal. This motion is based on this notice, the attached memorandum of points and authorities, the Declarations of Gorka Garcia-Malene, and Hilary Wanke, Esq., the files and pleadings on record in this matter, and any other matter that may be properly considered.

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MEMORANDUM OF POINTS AND AUTHORITIES

The United States has been authorized to file a petition for a writ of mandamus in the United States Court of Appeals for the Ninth Circuit requesting that the Court of Appeals direct this Court to vacate its order issued on January 10, 2017, which requires the Food and Drug Administration (FDA) to include in the administrative record "internal comments, draft reports, inter-or intra-agency emails, revisions, memoranda, or meeting notes," or otherwise justify their exclusion on a privilege log. ECF 88.

This Court should exercise its "inherent power to control the disposition of the causes on its docket [to] promote economy of time and effort for itself, for counsel, and for [the] litigants" by staying the order pending appellate review. *CMAX, Inc. v. Hall*, 300 F.2d 265, 268 (9th Cir. 1962); *see also Landis v. North Am. Co.*, 299 U.S. 248, 254 (1936); *Filtrol Corp. v. Kelleher*, 467 F.2d 242, 244 (9th Cir. 1972); *Mediterranean Enters., Inc. v. Ssangyong Corp*, 708 F.2d 1458, 1465 (9th Cir. 1983) (noting that a trial court may find it efficient for its own docket and the fairest course for the parties to enter a stay pending resolution of independent proceedings bearing upon the case.). Particularly given the substantial burden imposed by the January 10, 2017 Order, it would be most efficient for the Court to await a ruling from the Ninth Circuit on the mandamus petition. The Federal Defendants therefore respectfully request that this Court stay the January 10, 2017 Order and July 11, 2017 compliance deadline until the Court of Appeals rules on the mandamus petition. Plaintiffs oppose this motion. Intervenor-Defendant takes no position on this motion, but does not waive its right to file a reply brief addressing the motion or opposition, as necessary.

Whether to issue a stay is "an exercise of judicial discretion . . . to be guided by sound legal principles." *Nken v. Holder*, 556 U.S. 418, 433-34 (2009) (internal citations omitted) based on the following factors: (1) the applicant's likely success on the merits; (2) irreparable injury to the applicant absent a stay; (3) substantial injury to the other parties; and (4) the public interest. *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987); *see also Leiva-Perez v. Holder*, 640 F.3d 962, 970 (9th Cir. 2011) (*Nken* requires a showing of irreparable harm, but applies a balancing test showing "that irreparable harm is probable and either: (a) a strong likelihood of

success on the merits and that the public interest does not weigh heavily against a stay; or (b) a substantial case on the merits and that the balance of hardships tips sharply in the petitioner's favor"). Each of these factors counsels in favor of a stay.

1. FDA Has a Strong Likelihood of Success on the Merits

Federal Defendants are likely to succeed on the merits under either the "likelihood of success" or "substantial case on the merits" standard. *Leiva-Perez*, 640 F.3d at 970. On September 30, 2016, FDA filed a 37,837-page administrative record, which includes, *inter alia*, FDA's scientific reviews, memoranda explaining its decision to approve AquaBounty Technologies Inc.'s (ABT) new animal drug application concerning genetically engineered salmon, and the facts it considered. Plaintiffs moved to compel FDA to "complete" the record with "internal FDA and inter-agency memoranda, e-mails, communications, documents, revisions, and drafts of documents related to FDA's decision." ECF 75. After canceling oral argument, this Court ordered FDA either to include such documents, or justify their exclusion on a privilege log.[1] ECF 88. The order exceeds the Court's limited authority to review cases brought under the Administrative Procedure Act (APA). *See FCC v. Pottsville Broad. Co.*, 309 U.S. 134, 141 (1940) (describing the constitutionally limited scope of judicial power conferred by Congress).

Review under the APA is narrow; the court determines based on the administrative record whether the agency has examined the relevant factors or made a clear error in judgment. *Citizens to Preserve Overton Park Inc. v. Volpe*, 401 U.S. 402, 420 (1971). Judicial inquiry into the deliberative process of agency decision-makers is to be avoided. *Id.* For this reason, the *en banc* D.C. Circuit has held that internal deliberative documents such as those sought by Plaintiffs in this case are not part of the administrative record because the agency's decision must be reviewed on the basis of its stated reasons in the record, not on its predecisional mental processes. *See San Luis Obispo Mothers for Peace v. Nuclear Regulatory Comm'n,* 789 F.2d 26, 45 (D.C. Cir. 1986) (en banc). While the Ninth Circuit is not bound by the D.C. Circuit's

[1] The Court extended its original deadline requiring FDA to complete the record within 30 days to July 11, 2017. ECF 90.

decision in *San Luis Obispo*, the fact that another court of appeals sitting *en banc* has already held that predecisional and deliberative materials are not part of the agency record demonstrates the substantiality of the government's request for appellate relief in this case.

Because the Ninth Circuit has not directly addressed whether agencies may exclude deliberative documents from administrative records, decisions from courts in this judicial district have created an opportunity for plaintiffs to forum shop to bog agencies down in document review and seek what is essentially discovery in an APA case. *See* ECF 88, at 1 (citing *People of State of Cal. ex rel. Lockyer v. U.S. Dep't of Agric.*, No. C05-03508 EDL, 2006 WL 708914, at *3 (N.D. Cal. Mar. 16, 2006)); *id.* at 2 (citing *Gill v. Dep't of Justice*, No. 14-CV-03120-RS (KAW), 2015 WL 9258075, at *6 (N.D. Cal. Dec. 18, 2015)). Agencies sued in this district face a significantly different and more onerous burden to prepare administrative records than they do elsewhere, even within the Ninth Circuit. *See, e.g.*, *See San Luis & Delta-Mendota Water Auth. v. Jewell*, No. 1:15-cv-01290, 2016 WL 3543203, at *19 (E.D. Cal. June 23, 2016).

2. FDA Will Be Irreparably Harmed Absent a Stay

Orders imposing onerous discovery burdens and significant litigation costs may cause irreparable harm and justify a stay pending appeal. *See Brown v. Wal-Mart Stores, Inc.*, No. 09-0339, 2012 WL 5818300, at *4 (N.D. Cal. Nov. 15, 2012) ("Courts evaluate whether litigation expenses constitute irreparable harm based on the specific circumstances of each case."); *Richards v. Ernst & Young LLP*, No. 08-4988, 2012 WL 92738, at *4-5 (N.D. Cal. Jan. 11, 2012) (granting stay because serious burden, including discovery, would be avoided if defendants won on appeal); *see also Pena v. Taylor Farms Pac., Inc.*, No. 13-1282, 2015 WL 5103157, at *4-5 (E.D. Cal. Aug. 27, 2015) (collecting cases). Courts consider whether a stay would avoid substantial, unrecoverable, and wasteful discovery costs, and whether the costs would be inevitable regardless of the result of the appeal. *Id.*

Here, absent a stay, FDA will suffer irreparable harm as a result of the staggering burden that compliance with this Court's order will impose. FDA has considered issues related to ABT's application for over 20 years, and estimates that between 50-100 custodians may have records within the scope of the Court's order. Although the parties have currently agreed that

FDA will search the files of 17 custodians, Plaintiffs reserve the right to expand that number. Even as limited, the order will impose substantial costs to collect and review these documents for relevance, privilege, ABT confidential information, third-party confidential information, and personal privacy information — costs that a stay will avoid.

FDA's Center for Veterinary Medicine's (CVM) Freedom of Information Act (FOIA) Officer estimates that it will take far in excess of a year, and will require assistance from CVM scientific reviewers and other experts outside the FOIA team, to review the 428,610 pages collected so far, and that estimate includes emails from only three of the 17 custodians whose files will be searched. Ex. A (Declaration of Gorka Garcia-Malene (Garcia-Malene Decl.)) ¶¶ 10-14; Ex. B (Declaration of Hilary Wanke, Esq.) ¶ 9. These employees will be diverted from FDA's mission-critical functions, which include significant public health matters such as reviewing new animal drug applications and supporting CVM's other public health priorities, including antimicrobial resistance and enforcement actions involving violative products, which diversion could adversely impact public health and cause further harm. Garcia-Malene Decl. ¶ 21. This review will also significantly and adversely affect CVM's ability to meet statutory obligations to provide documents under the FOIA. *Id.* ¶ 22.

In short, CVM expects that CVM's public health priorities and, by extension, its core mission, will be compromised, and its information disclosure operations will be severely compromised for a substantial period of time to comply with the Court's order. *Id.* ¶ 21. The order has already required significant agency time and resources, and will continue to do so unless it is stayed. None of these costs may be recovered. And this is work that need not be performed at all if Federal Defendants prevail on the petition for mandamus.[2] This harm easily qualifies as irreparable. *See Pena*, 2015 WL 5103157, at *4.

3. Plaintiffs Will Not Be Prejudiced By a Stay

As a result of the meet and confer process and the concomitant expansion of the supplemental materials, FDA currently estimates that, absent a stay, it will take well over a year

[2] An outstanding FOIA request seeks certain related documents, but its scope is significantly narrower than the scope of the Court's order.

to comply with the Court's order. Garcia-Malene Decl. ¶¶ 14, 20. Federal Defendants intend to ask the Ninth Circuit to review the mandamus petition on an expedited basis and, if the Court does so, the legal issue may be resolved in less time than the time it would take Federal Defendants to comply with the order. Rather than prejudicing Plaintiffs, a stay may ultimately advance timely resolution of Plaintiffs' merits claims. Moreover, ABT's salmon is currently subject to an import alert, and ABT is uncertain about when it may be able to begin marketing.[3] Thus, even if a stay were to cause some delay, Plaintiffs may not suffer any of the alleged harm they sought to prevent during that time.

4. The Public Interest Favors a Stay

Compliance with this Court's order will divert resources from FDA's public health priorities. Further, public policy favors efficient use of resources, and the public interest is especially apparent when public resources are at stake. *Burgan v. Nixon*, No. 16-61, 2016 WL 6584478, at *5 (D. Mont. Nov. 7, 2016); *C.B.S. Employees Federal Credit Union v. Donaldson Lufkin & Jenrette Sec. Corp.*, 716 F. Supp. 307, 310 (W.D. Tenn. 1989). FDA estimates that it would cost over $2 million dollars for CVM's FOIA reviewers (*i.e.*, not including scientific and other reviewers brought on to assist) to review the documents of just three of the 17 (or more) custodians whose records have been collected so far. Garcia-Malene Decl. ¶ 15. Even this subset is a significant amount of taxpayer money that need not be spent at all if Federal Defendants prevail on mandamus. Public policy weighs strongly in favor of a stay.

The Court's January 10, 2017 Order presents a substantial legal issue that significantly affects the scope of administrative records and the nature of judicial review. The Federal Defendants respectfully request that this Court stay its January 10, 2017 Order, including the July 11, 2017 deadline for compliance with that order, until the Ninth Circuit rules on the mandamus petition.

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[3] *See* AquaBounty Technologies, Inc. Form 10-K (2016 annual report dated Mar. 16, 2017), at 9-10, *available at* http://services.corporate-ir.net/SEC.Enhanced/SecCapsule.aspx?c=197553&fid=14896944 (last visited April 13, 2017).

Dated: April 14, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 14, 2017, I filed a copy of the foregoing document on the Court's CM-ECF system, which will automatically effect service on counsel for all parties.

/s/ Frederick H. Turner
FREDERICK H. TURNER

EXHIBIT A

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

INSTITUTE FOR FISHERIES RESOURCES, *et al.*, Plaintiffs, v. THOMAS E. PRICE, M.D., *et al.*, Defendants, and AQUABOUNTY TECHNOLOGIES, INC., Intervenor-Defendant.	Case No. 3:16-cv-01574-VC **DECLARATION OF GORKA GARCIA-MALENE IN SUPPORT OF FEDERAL DEFENDANTS' MOTION TO STAY JANUARY 10, 2017 ORDER PENDING PETITION FOR WRIT OF MANDAMUS** Date: Time: Location: Courtroom 4 - 17th Floor Judge: Hon. Vince Chhabria

I, Gorka Garcia-Malene, declare as follows:

1. I am the Freedom of Information Act (FOIA) Officer, in the Office of the Director, Center for Veterinary Medicine (CVM), United States Food and Drug Administration (FDA), in Rockville, Maryland. I have held this position since April 22, 2013.

2. Previously, from January 30, 2012 to April 19, 2013, I was an International Regulatory Policy Analyst in FDA's Office of International Programs (OIP), in Silver Spring, Maryland. My job duties and responsibilities included supervising the initial receipt and processing of FOIA requests assigned to OIP, collecting and reviewing documents, and determining OIP's response to the FOIA requests. Prior to joining OIP, from September 28, 2009 to January 27, 2012, I was a member of the Litigation Team for the Division of Information Disclosure Policy within FDA's Center for Drug Evaluation and Research (CDER), in Silver Spring, Maryland. At CDER, I responded to requests for information from Congress, and I performed detailed analyses and evaluations of records responsive to complex and sensitive FOIA requests in the context of litigation.

3. The statements made in this declaration are based upon my personal knowledge and official records available to me in my capacity as CVM's FOIA Officer. I have personal and first-hand knowledge of the facts set forth in this Declaration, unless otherwise stated, and, if called as a witness, I could and would testify competently thereto.

4. As CVM's FOIA Officer, I oversee CVM's review of documents for confidential and privileged information, primarily for responding to requests for documents under the FOIA. My staff also reviews documents for disclosure in administrative records, although administrative records are not FOIA productions. I am overseeing CVM's review of documents for the administrative record in the above-captioned case.

5. CVM is the center within FDA responsible for approving new animal drug applications. FDA approved the new animal drug application concerning AquaBounty Technologies, Inc.'s (ABT) genetically engineered salmon, AquAdvantage Salmon (AAS), on

November 19, 2015.

6. I supervised the document review of over 25,000 pages of the administrative record that FDA filed on September 30, 2016, in the above-captioned case that challenges FDA's approval of ABT's new animal drug application concerning AAS. I have a staff of 10 reviewers, which includes five experienced, senior reviewers. To prepare the September 30, 2016 record, in addition to leveraging my staff, I recruited and trained 37 scientists from the Office of New Animal Drug Evaluation to identify confidential commercial and trade secret information in these documents. The scientists were able to complete their review in about two months. This was the first time I undertook this type of collaboration, and I did so because records relating to this product discuss extremely complicated scientific concepts. In addition, this was the largest-scale project that I have ever supervised on such a short timeframe.

7. During the time of that review, as a result of the drain on available information disclosure staff, traditional FOIA operations virtually ground to a halt. This was principally due to the fact that the 37 scientists reviewed primarily for novel scientific information that may be confidential commercial or trade secret information, and three experienced reviewers on my staff were responsible for reviewing every page of every record for the remaining information disclosure issues: deliberative process privilege, ABT confidential information, third-party confidential information, attorney-client privilege, and personal privacy information. The fourth experienced reviewer continued to work on an unrelated FOIA litigation and the fifth was on maternity leave.

8. I understand that the Court issued an order on January 10, 2017 that requires FDA to search for, collect, review, and provide documents from custodians related to FDA's approval of ABT's application, or otherwise justify the exclusion or redaction of documents on a privilege and redaction log. This order encompasses internal comments, draft reports, inter-or intra-agency emails, revisions, memoranda, and meeting notes. Because CVM does not include deliberative documents such as drafts and internal memoranda in administrative records, these documents are not stored in a central location, and a search must be conducted across all

custodians of all file types to locate such documents.

9. I understand that there are email, computer, and paper file searches being conducted in response to the Court's order. For the email search, I understand that the parties have initially agreed to apply a list of 31 search terms to the email files of 17 custodians. This collection will encompass the timeframe from at least 1994 to November 19, 2015.

10. I have been informed by others in FDA and the U.S. Department of Justice (DOJ) that the emails for three of the 17 custodians have been gathered and had search terms applied to them. According to DOJ, which has loaded the documents of these three custodians into its Relativity database, application of the search terms yielded 32,536 documents (401,401 pages) after de-duplication. These documents will require disclosure review. Importantly, this is but a subset of the total number of pages that will be collected from all 17 custodians.

11. In addition, CVM has a shared drive that contains documents relating to the AAS approval from which I have been informed by others in FDA and DOJ that 836 documents (11,554 pages) were collected for review in response to the Court's order.

12. Finally, I have been informed by others in FDA and DOJ that there was a guided collection in response to the Court's order whereby the 15 of the 17 custodians who are still at FDA searched their hard copy and computer files for documents related to the matters at issue in this case. The guided collection has produced 810 documents to date (15,655 pages) for review. I have been informed by others in FDA that the two custodians who are no longer at FDA will have their files searched electronically under the supervision of FDA's eDiscovery Manager.

13. In total, 428,610 pages have been collected so far in response to the Court's order, and that number includes emails from only three of the 17 custodians whose emails will be searched. Based on years of reviewing and processing these types of documents, I estimate that it will take an average of five minutes per page to review the documents collected in response to the Court's order. That estimate is conservative here because these documents will need to be reviewed for relevance, deliberative process privilege, ABT confidential information, third-party confidential information, attorney-client privilege, and personal privacy information. Each of the

categories of information will need to be marked and/or treated accordingly, and FDA will then need to determine if any relevant documents have already been produced as part of the 37,837-page administrative record. The documents will need to be bates-stamped and indexed in some manner, and each assertion of deliberative process and attorney-client privilege will need to be justified on a log.

14. Applying the estimate of five minutes per page to the over 400,000 pages retrieved so far, it would take my five experienced reviewers over three years working full-time on this case to complete the production, and doing so would jeopardize my compliance with another court-mandated production. For the present review, I expect to receive assistance from about 50 scientific reviewers to comply with the Court's order. While the scientific reviewers will be trained to review primarily for novel scientific information that may be confidential commercial and trade secret information, my five experienced reviewers will still be responsible for reviewing virtually every page of relevant documents for privileged and protected information.

15. The average cost of an experienced, full-time equivalent (*i.e.*, an employee's time for an entire year, 40 hours per week for 52 weeks) for my team is about $122,285. Thus, the cost to CVM, if just the five experienced FOIA reviewers were to conduct the review of the documents collected so far, is expected to be well over $2 million, and that figure does not factor in the costs of the rest of the FOIA staff and the scientific and other reviewers that would be brought onto the project.

16. I expect this document review to be extremely difficult because of the multiple potential categories for review (relevance, deliberative process privilege, ABT confidential information, third-party confidential information, attorney-client privilege, and personal privacy information), the highly complex nature of the scientific subject matter in the documents, and because the vast majority of the documents are emails. In my experience, emails are more challenging to review than other documents because the reviewer often lacks important context to make determinations about privilege or whether certain information may be confidential,

necessitating research and outreach within the organization to finalize the review of one or a few pages of email.

17. Seven of my 10 reviewers, two of whom are responsible for final review of all the records, are currently working to produce a total of about 450,000 pages of records for a different litigation, and documents in that litigation are being produced at a rate of about 13,000 pages every six weeks. These seven reviewers have been working on this project full time for well over two years, and I do not expect that document production to be completed for another two to three years. This team of seven reviewers includes outside contractors working under two distinct contracts to assist with the document review for that litigation. These two contracts alone have cost CVM over $700,000 per year for the last two years. The plaintiffs in that case have temporarily agreed to forgo the production of emails due to the difficulty involved in reviewing that record type, and the production is thus proceeding much more quickly than I anticipate the AAS review will.

18. The Court's order in the above-captioned case places an extraordinary burden on my staff, and would be the largest and most challenging review project that I have ever undertaken. I do not believe it is possible to meet the current deadline of July 11, 2017, to review the over 400,000 pages collected so far, let alone the total number of documents that will need review once all 17 custodians' records are collected.

19. Nor does my office have the budget to hire outside contractors to assist with this scientifically complex review to any significant extent, which from past experience I anticipate would be very expensive. A contractor costs more than the average full-time equivalent employee. One of the contracts for reviewers currently in place for the other litigation costs CVM over $420,000 per year for three reviewers. Despite their experience and proficiency, their work contains mistakes and necessitates a second review by my more experienced staff members.

20. My team does not have authority to hire additional staff at this time. As noted, seven of my 10 staff members are currently supporting another litigation project, and the

remainder are fully employed with other duties, primarily reviewing documents for FOIA requests. In the face of this overwhelming order, my staff will be forced to substantially curtail FOIA operations. The other mandatory litigation production will lose most of its reviewers and take several more years to complete, and the rest of my staff will be dedicated to the AAS production required by the order. Despite dedicating most of my staff and scores of additional reviewers, CVM will be unable to meet the current deadline imposed by the Court to comply with the order. Even with the assistance of additional reviewers, I expect our review would take far in excess of a year, given the very large estimated number of pages to review even for just the three custodians' records collected thus far for review.

21. Moreover, any attempt to complete the review by the end of this calendar year with the assistance of CVM scientists and others would require FDA to divert substantial resources away from its mission-critical functions, which include significant public health issues, such as addressing antimicrobial resistance and enforcement actions involving violative products, which could adversely impact human or animal health. Reviewers from the Office of New Animal Drug Evaluation, for example, necessarily will have time taken away from reviewing products that protect human and animal health.

22. Finally, the near complete diversion of staff resources from working on FOIA operations will severely and negatively impact CVM's ability to comply with its FOIA statutory obligations, dramatically increasing response times for even simple requests.

Pursuant to 28 U.S.C. §1746, I declare under penalty of perjury that the foregoing is true and correct.

Date: Gorka Garcia-malene -S

Digitally signed by Gorka Garcia-malene -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000370291, cn=Gorka Garcia-malene -S
Date: 2017.04.14 15:19:16 -04'00'

Gorka Garcia-Malene
FOIA Officer, CVM
U.S. Food and Drug Administration

EXHIBIT B

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Attorneys for Defendants

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

INSTITUTE FOR FISHERIES RESOURCES, *et al.*,

Plaintiffs,

v.

THOMAS E. PRICE, M.D., *et al.*,

Defendants, and

AQUABOUNTY TECHNOLOGIES, INC.,

Intervenor-Defendant.

Case No. 3:16-cv-01574-VC

DECLARATION OF HILARY WANKE, ESQ. IN SUPPORT OF FEDERAL DEFENDANTS' MOTION TO STAY JANUARY 10, 2017 ORDER PENDING PETITION FOR WRIT OF MANDAMUS

Date:
Time:
Location: Courtroom 4 - 17th Floor
Judge: Hon. Vince Chhabria

I, Hilary Wanke, Esq., declare as follows:

1. I am FDA's eDiscovery Manager with Records, eDiscovery and Risk Management within the Office of Information Management & Technology (OIMT), United States Food and Drug Administration (FDA), 11601 Landsdown St., North Bethesda, Maryland, 20852. I have held this position since January 2013. Prior to this, I worked as a contract attorney for the Department of Energy (DOE) and private law firms on eDiscovery and Freedom of Information Act (FOIA) cases.

2. I make this declaration in support of the Federal Defendants' Motion to Stay January 10, 2017 Order Pending Petition for Writ of Mandamus in the above-captioned case. I have personal and first-hand knowledge of the facts set forth in this Declaration, unless otherwise stated, and, if called as a witness, I could and would testify competently thereto.

3. As FDA's eDiscovery Manager, I regularly assist components of FDA with the collection and production of electronically stored information (ESI) for litigation. I have overseen the collection and search of documents for the FDA's Center for Veterinary Medicine in the above-captioned case.

4. I understand that the Court's order requires FDA to collect, review, search and produce documents from custodians related to FDA's approval of AquaBounty Technologies, Inc.'s (ABT) new animal drug application concerning genetically engineered salmon, or otherwise justify the exclusion of documents or redactions on a privilege and redaction log. I also understand that the relevant timeframe for documents related to this approval is from at least 1994 through November 2015, and that the parties have currently agreed that FDA will search the email files of 17 custodians, applying the following search terms:

AquaBounty or "Aqua Bounty"
ABT or ABF
AquAdvantage w/5 salmon
AquAdvantage w/5 gene

AAS
GE salmon
Genetically engineered salmon
Genetically modified salmon
Transgenic salmon
"Executive Order" or "EO" & "12114"
A/F Protein
"genetically engineered animal" w/5 guidance
"transgenic animal" w/5 guidance
"Guidance w/5 187" or "GE animal guidance" or "GFI 187"
"Gulf of Maine DPS" or "Gulf of Maine district population segment"
opAFP
"ocean pout" or "eel pout"
("Prince Edward Island" or "PEI") & Fortune Bay
"Boquete" & "Panama"
Panama National Environmental Authority
Ron Stotish or Ronald Stotish
Joe McGonigle or Joe McGonagle
John Fay
Gary Frazer
Richard Sayers
Michael Rubino
Kevin Amos
Angela Somma
James Lecky
Jason Kahn
Anne Kapuscinski

5. Staff in the eDiscovery office are in the process of collecting emails from the 17 custodians, processing, applying the search parameters, and providing the documents to the Department of Justice (DOJ) on a rolling basis. Thereafter, ESI is uploaded into a document management platform hosted by DOJ known as Relativity for further processing, search and review.

6. The agreed-upon terms were converted into the following Boolean search expression for use in the FDA eDiscovery tool:

> AquaBounty OR "Aqua Bounty" OR "ABT" OR "ABF" OR (AquAdvantage NEAR(5) salmon) OR (AquAdvantage NEAR(5) gene) OR "AAS" OR "GE salmon" OR "Genetically engineered salmon" OR "Genetically modified salmon" OR "Transgenic salmon" OR (("Executive Order" OR "EO") AND 12114) OR

"A/F Protein" OR ("genetically engineered animal" NEAR(5) guidance) OR ("transgenic animal" NEAR(5) guidance) OR (Guidance NEAR(5) 187) OR "GE animal guidance" OR "GFI 187" OR "Gulf of Maine DPS" OR "Gulf of Maine distinct population segment" OR opAFP OR "ocean pout" OR "eel pout" OR ("Prince Edward Island" OR PEI AND "Fortune Bay") OR (Boquete AND Panama) OR "Panama National Environmental Authority" OR Stotish OR McGon?gle OR Fay OR Frazer OR Sayers OR Rubino OR Amos OR Somma OR Lecky OR Kahn OR Kapuscinski[1]

7. I conservatively estimate that it takes staff in the eDiscovery office and other OIMT support groups about four hours per custodian to collect ESI, and eight hours per custodian to fully process, search, and transfer documents. For this specific collection, the total hour commitment was initially estimated to reach over 200 hours. This threshold has been exceeded, accumulating approximately 273 hours to date due to additional work required (outlined below) beyond the initial anticipated level of effort.

8. Our office currently employs three staff and is concurrently responsible for other active eDiscovery cases in support of FDA litigation, Congressional, investigative, and Freedom of Information Act requests. Additionally, we are in the midst of a major technology deployment. Finally, we have recently lost a seasoned eDiscovery analyst and we have a small office with limited ability to hire. Given our workload and the limitation on staffing, I estimate it will take 260 additional hours to complete processing, searching and transferring the email files of the remaining custodians to DOJ, and to collect archived email and network share content for the two custodians who are no longer at FDA.

9. As of this date, staff in the eDiscovery office have applied the Boolean search string outlined above (¶ 6) to three key custodians.

10. FDA's collection efforts have been complicated by a problem with email attachments. In certain circumstances, email attachments are stored separately from their parent

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[1] The search expression expanded the agreed-upon scope by searching names using the surname only rather than both "First Last" format. This was done in an effort to capture more potentially responsive documents.

email messages and require "reattachment" prior to application of search terms. Unfortunately, following production it was observed that reattachment did not occur on a large number of the attachments, and as a result my team had to reprocess the data for these three custodians and reproduce the data set in full. Additionally, the software was unable to reattach some files through the automated process, and as a result those attachments require manual recovery from the system. This has taken considerably more time than we originally anticipated. We are continuing to evaluate whether the latest searches have adequately addressed this problem and can then be used to search and process documents for the remaining 14 custodians.

Pursuant to 28 U.S.C. §1746, I declare under penalty of perjury that the foregoing is true and correct.

Hilary B. Wanke -S

Digitally signed by Hilary B. Wanke -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001200468, cn=Hilary B. Wanke -S
Date: 2017.04.14 12:45:00 -04'00'

Date: April 14, 2017

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

INSTITUTE FOR FISHERIES RESOURCES, *et al.*, Plaintiffs, v. THOMAS E. PRICE, M.D., *et al.*, Defendants, and AQUABOUNTY TECHNOLOGIES, INC., Intervenor-Defendant.	Case No. 3:16-cv-01574-VC **[PROPOSED] ORDER** Date: Time: Location: Courtroom 4 - 17th Floor Judge: Hon. Vince Chhabria

Having considered Federal Defendants' Motion to Stay January 10, 2017 Order Pending Petition for Writ of Mandamus, the responses of Plaintiffs and Intervenor-Defendant AquaBounty Technologies, Inc. thereto, and the entire record in this case, it is hereby

ORDERED that the motion is GRANTED and the January 10, 2017 Order, including the July 11, 2017 deadline for compliance with that Order, is stayed pending resolution of the Federal Defendants' Petition for Writ of Mandamus to the United States Court of Appeals for the Ninth Circuit.

_____
Date

_____
HON. VINCE CHHABRIA
United States District Judge