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THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

INSTITUTE FOR FISHERIES RESOURCES, *et al.*, *Plaintiffs*, v. THE HONORABLE THOMAS E. PRICE, *et al.*, *Defendants*, and AQUABOUNTY TECHNOLOGIES, INC., *Intervenor-Defendants*.	Case No. 3:16-cv-01574-VC **OPPOSITION TO FEDERAL DEFENDANTS' MOTION TO STAY JANUARY 10, 2017 ORDER PENDING PETITION FOR WRIT OF MANDAMUS** Date: May 4, 2017 Time: 2:00 p.m. Location: Courtroom 4 - 17th Floor Judge: Hon. Vince Chhabria

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INTRODUCTION AND SUMMARY OF ARGUMENT

More than three months after this Court granted Plaintiffs' motion to complete the record and provided an extended timeframe for the agency to comply, the Food and Drug Administration (FDA or Defendants) has returned with a request to halt all work on producing that record until the Ninth Circuit Court of Appeals can consider its extraordinary petition for a writ of mandamus to overturn this Court's January 10, 2017 Order Granting Motion to Compel Completion of the Administrative Record (Order). FDA has failed, however, to meet its heavy burden to support the issuance of a stay.

First, Defendants have not made the required strong showing that their mandamus petition, itself an extraordinary, rarely-granted remedy, is likely to succeed on the merits. Mandamus requires a showing of clear error, a high bar that FDA cannot clear. This Court's Order is fully supported by and consistent with existing precedent in the Ninth Circuit, and the extra-circuit caselaw FDA cites does not support its argument. Further, FDA's radical position that it can unilaterally cull from the administrative record any documents considered in making its decision without acknowledging their existence or in any way justifying asserted privileges to the Court or Plaintiffs is contrary to the foundational principles of Administrative Procedure Act (APA) review and the deliberative process privilege on which the agency purports to rely. As this Court correctly held, FDA was wrong that its "internal comments, draft reports, inter- or intra-agency emails, revisions, memoranda, or meeting notes . . . as a categorical matter, should be excluded from the universe of materials directly or indirectly considered by agency decision-makers." Order at 1, ECF No. 88 (concluding that the scope of any "privilege doesn't define the scope of the material directly or indirectly considered."). All documents that were considered directly or indirectly by an agency are part of the administrative record for judicial review under the APA. A limited number of documents may be withheld under legitimate claims of privilege, but such claims must be documented, substantiated, and challengeable. Otherwise litigants are precluded from documents that informed agency decisions, and courts are denied access to agency considerations fundamental to judicial review.

Second, Defendants have not shown irreparable harm absent a stay while their petition

for a writ of mandamus is pending. The harms FDA claims from re-shuffling agency priorities and staff to compile a complete record are merely the consequence of having to follow the law, and such duties are not cognizable as irreparable harm. Moreover, FDA has substantially the same production and review burden under the Freedom of Information Act (FOIA), even without this litigation or the Court's Order, because several Plaintiffs have lodged broad genetically engineered (GE) salmon FOIA requests with FDA, since at least 2010.

Third, Defendants have failed to show a stay would not injure Plaintiffs or other interested parties. Contrary to Defendants' claims, a stay will delay resolution, stall judicial review, and increase the risks to the environment from AquaBounty's production of GE fish. FDA's speculation regarding the pace of AquaBounty's GE salmon production does not meet its burden.

Finally, the public interest supports having agencies comply with the law, protecting the environment, and having timely judicial review of agency actions. It does not support allowing agencies to unilaterally withhold materials that might be vital to judicial review. The Court should deny FDA's untimely stay motion and require the agency to continue to work with Plaintiffs to produce the documents necessary to complete the record.

BACKGROUND

This Court ordered Defendants to complete the administrative record on January 10, 2017. *See* Order, ECF No. 88. The Court held that Defendants had relied on an "overly narrow understanding of the universe of materials that may need to be included in the administrative record," and also had failed to provide a privilege log of withheld documents. *Id.* at 2. The Court recognized that a complete administrative record includes "all documents and materials directly or indirectly considered by agency decision-makers" and that these internal materials (like "comments, draft reports, inter- or intra-agency emails, revisions, memoranda, or meeting notes") logically inform the agency's decision, and thus cannot be categorically excluded from the record. *Id.* at 1 (*citing Thompson v. U.S. Dep't of Labor*, 885 F.2d 551, 555 (9th Cir. 1989)). The Court ordered Defendants to complete the record and produce a privilege log within thirty days. *Id.* at 2.

On January 12, 2017, the Court held a case management conference at Defendants' request. Min. Order, ECF No. 90. Defendants requested an additional five months to comply with the Court's Order. While Defendants noted the possibility that they might seek limited reconsideration of the Court's Order with respect to the third party discovery, notably they did not indicate any intention to seek reconsideration of (let alone appeal) the Court's decision that FDA must complete the administrative record with the excluded materials. *See* January 12, 2017 CMC Audio Recording, at 17:43-19:45.

The Court subsequently extended the deadline, granting FDA six more months, until July 11, 2017. Min. Order, ECF No. 90. The Court also directed Plaintiffs to consider ways "to narrow" the scope of the documents FDA is to produce, and the Court allowed Plaintiffs to request a shortened deadline, "if after narrowing the scope they find that the deadline seems too long." *Id*.

Thereafter the Parties met and conferred regarding Defendants' production, agreed upon a compromised scope for the search, and submitted to the Court a status report on that ongoing production process, as of March 14, 2017. *See* Joint Status Report, ECF No. 94. While Defendants have raised concerns after the fact regarding the search parameters they agreed to in early February, at no time during this process have Defendants approached Plaintiffs with a specific request for additional time to comply with the Court's order, to suggest a more refined set of custodians or search terms, or to indicate anything other than a generalized concern about their ability to fully comply with the July 11, 2017, deadline to complete the record. Nor, despite their agreement to produce documents on a rolling basis, have Defendants produced more than a handful of documents in response to the Court's Order, the production of which would allow Plaintiffs to evaluate ways to further focus the search effort. *Id.* at 2 (detailing FDA's production of seventy-one non-substantive documents).

ARGUMENT

I. STANDARD OF REVIEW.

A stay "is an extraordinary remedy that should be granted sparingly." *Addington v. U.S. Airline Pilots Ass'n*, Nos. CV08-1633-PHX-NVW, CV08-1728-PHX-NVW, 2009 WL 2761928,

at *1 (D. Ariz. Aug. 28, 2009). FDA "bears the burden of showing that the circumstances justify an exercise of that discretion." *Nken v. Holder*, 556 U.S. 418, 433-34 (2009). The burden for a stay is substantially similar to that of an injunction; courts consider "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Id.* at 434; *Haller v. Wells Fargo Bank NA*, No. CV11-01381-PHX-FJM, 2011 U.S. Dist. LEXIS 139285, at *4 (D. Ariz. Dec. 1, 2011)(denying motion for a stay, holding that where party fails to make any showing that a stay is justified, it necessarily falls far short of the "'clear showing' that the Supreme Court demands before the 'extraordinary remedy' of injunctive relief is granted")(quoting *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008)).

The first two factors are "the most critical." *Nken*, 556 U.S. at 434. As to the first, "at a minimum," the movant "must show that there is a substantial case for relief on the merits." *Lair v. Bullock*, 697 F.3d 1200, 1204 (9th Cir. 2012). Further, "simply showing some possibility of irreparable injury fails to satisfy the second factor." *Nken*, 556 U.S. at 434 (internal quotation marks and citation omitted).

II. FDA HAS NOT SHOWN A STRONG LIKELIHOOD OF SUCCESS ON THE MERITS OF ITS MANDAMUS MOTION.

FDA has not met its burden to show how it is likely to succeed on the merits of its mandamus motion, let alone the "strong showing," *Nken*, 556 U.S. at 434, and "substantial case," *Lair*, 697 F.3d at 1204, required to satisfy the first stay factor.

A. Mandamus is a Drastic and Extraordinary Remedy.

It is not an ordinary appeal for which FDA must make its "strong showing" of success; rather it is a mandamus writ, codified at 28 U.S.C. § 1651(a), which is a "drastic and extraordinary" remedy, that is "reserved for really extraordinary causes." *Cheney v. U.S. Dist. Ct. Dist. of Columbia*, 542 U.S. 367, 380 (2004). As the Supreme Court explained, "only exceptional circumstances amounting to a judicial usurpation of power," or a "clear abuse of discretion," justifies the "invocation of this extraordinary remedy." *Id.* (internal quotation marks

and citation omitted); *United States v. McCandless*, 841 F.3d 819, 822 (9th Cir. 2016).

Moreover, FDA has the "burden of showing that [the agency's] right to the issuance of the writ is clear and indisputable." *United States v. Guerrero*, 693 F.3d 990, 999 (9th Cir. 2012)(quoting *Bauman v. U.S. Dist. Court*, 557 F.2d 650, 656 (9th Cir. 1977)). The Ninth Circuit has five mandamus factors it considers in deciding if that "clear and indisputable" burden is met, including whether the district court's order is clearly erroneous as a matter of law. *Guerrero*, 693 F.3d at 999.[1] Regardless of the other factors, the absence of a clear error finding is "dispositive." *Id.*; *Perry v. Schwarzenegger*, 591 F.3d 1147, 1156 (9th Cir. 2010).

Clear error is a very high standard. *Ocean Garden, Inc. v. Marktrade Co., Inc.*, 953 F.2d 500, 502 (9th Cir. 1991)("[T]o be clearly erroneous, a decision must . . . strike us as wrong with the force of a five-week old, unrefrigerated dead fish.")(internal quotation marks and citation omitted). Thus, in order to grant the writ, the Ninth Circuit must be "firmly convinced" that the district court committed clear error, and cannot grant the writ even if "the district court's interpretation might be overruled later on direct appeal." *Guerrero*, 693 F.3d at 999 (quoting *DeGeorge v. U.S. D. Ct. Cent. D. Cal.*, 219 F.3d 930, 936 (9th Cir. 2000)).

B. FDA's Position Is Contrary to Ninth Circuit Caselaw.

FDA cannot meet this steep judicial burden, because the agency's extremely constrained view of what an administrative record constitutes is wrong (and dangerous). This Court rejected FDA's arguments that, as a matter of law, the agency's internal documents are outside the scope of an administrative record and the agency has no duty to prepare a privilege log to identify the documents it is withholding. *See* Order, ECF No. 88. FDA cannot show that decision was

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[1] The factors are:

> (1) whether the petitioner has no other means 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.

Guerrero, 693 F.3d at 999.

clearly erroneous. In its motion, FDA cannot point to a single Ninth Circuit decision with which this Court's decision allegedly conflicts, let alone clearly erred in not following. At the same time, FDA ignores *Thompson*, 885 F.2d at 555, which, as the Court explained, ECF. No. 88, holds that a complete administrative record "consists of all documents and materials directly or indirectly considered by agency decision-makers and includes evidence contrary to the agency's position." *Id.*

While ignoring *Thompson*'s admonition on the proper scope of a record, FDA claims there are no Ninth Circuit cases on point. However, Ninth Circuit APA record review cases have long relied on the very same kinds of materials that FDA seeks to withhold here—draft or revised decisions, internal emails, memoranda, meeting notes—in deciding cases. *See, e.g.*, *Great Basin Res. Watch v. BLM*, 844 F.3d 1095, 1103 (9th Cir. 2016)(quoting email); *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 National Environmental Policy Act (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"), *aff'd as modified*, 494 F.3d 757 (9th Cir. 2007); *Ilioulaokalani Coal. v. Rumsfeld*, 464 F.3d 1083, 1096-97, 1098-99, 1101 (9th Cir. 2006)(relying on minutes and comments in draft environmental impact statement (EIS) to find the EIS was inadequate); *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 402 F.3d 846, 862-63 & n.4 (9th Cir. 2005)(citing U.S. Army Corps staff emails); *Reno-Sparks Indian Colony v. EPA*, 336 F.3d 899, 906 (9th Cir. 2003)(upholding agency decision under NEPA challenge, relying on, *inter alia*, an "internal agency memorandum"); *Sw. Ctr. for Biological Diversity v. U.S. Bureau of Reclamation*, 143 F.3d 515, 522-3 (9th Cir. 1998)(reviewing drafts included in administrative record in ruling on summary judgment). FDA's far-reaching argument runs contrary to this longstanding circuit precedent.[2]

[2] FDA also erroneously claims the decisions rejecting its hyper-constrained interpretation of record review are limited to the Ninth Circuit, and specifically the Northern District of California. *See, e.g., Suffolk County v. Sec. of Int.*, 562 F.2d 1368, 1384 (2d Cir. 1977)(upholding district court review of internal agency document and holding that despite the deliberative process privilege, the court may review deliberative memoranda); *Miami Nation of Indians of Indiana v. Babbitt*, 979 F. Supp. 771, 775-779 (N.D. Ind. 1996)(ordering completion

Having a record sanitized of anything but "final" public documents, as here, does not demonstrate how the agency actually analyzed the evidence and factors, to determine whether the agency "articulated a rational connection between the facts found and the choice[s] made," *Pac. Coast Fed'n of Fishermen's Ass'ns v. NMFS*, 265 F.3d 1028, 1034 (9th Cir. 2001), or fully illustrate whether the agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency," *Motor Veh. Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). That is why often, as in the above cases, internal material like that excluded by FDA here is the *sine qua non* of courts' evaluations of the process and substance of agency decisions.

C. The Extra-Circuit Precedent FDA Relies upon Does Not Support Its Position.

Rather than address Ninth Circuit cases, FDA relies on *San Luis Obispo Mothers for Peace v. Nuclear Regulatory Comm'n*, 789 F.2d 26, 45 (D.C. Cir. 1986) to support its argument that this Court committed clear error. FDA did not cite *San Luis Obispo* in its brief opposing Plaintiffs' motion to complete the record, *see* Opp'n Mot. Compel, ECF No. 82, but now argues that the D.C. Circuit's decision supports its view that an agency can categorically withhold all internal documents from a record. The case says nothing of the sort.[3] *San Luis Obispo* does not address the issue raised by FDA's writ—whether an agency must assert and defend a privilege to exclude material it identifies as deliberative.

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to include draft reports, notes); *Wild Earth Guardians v. U.S. Forest Service*, 713 F.Supp. 2d 1243, 1260 (D. Colo. 2010)(ordering competition of the record with internal deliberations and recommendations); *Coastal Conservation Ass'n v. Gutierrez*, No. H-05-1214, 2006 U.S. Dist. Lexis 96704, at *9 (S.D. Tex. Feb. 17, 2006)(granting plaintiffs' motion to compel completion of the record and requiring defendants to compile a privilege log); *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, No. CV01-640-RE, 2005 U.S. Dist. LEXIS 16655, at *10 (D. Or. March 3, 2005)(compelling agency to complete record with internal drafts of memoranda or decision documents and communications); *Wash. Toxics Coal. v. U.S. Dep't of Interior*, No. C04-1998C, 2005 U.S. Dist. LEXIS 45566 (W.D. Wash. June 14, 2005)(compelling completion of record with internal agency documents because such evidence is relevant to whether the agency failed to consider an important aspect of the problem).

[3] Even if *San Luis Obispo* did support FDA's new position, it is not binding on this Court, and thus cannot be used to show the Court clearly erred in not following it. Especially where, as detailed in Section II(B) *supra*, there is Ninth Circuit case law directly contrary to the FDA's reading of the case.

Instead, *San Luis Obispo* addressed only the narrow issue of whether the petitioners had made a threshold showing of bad faith sufficient to justify supplementing the record with transcripts of a closed meeting among the ultimate decision-makers in an adjudicative proceeding.[4] *San Luis Obispo*, 789 F.2d at 44. The court refused to consider the transcripts to show bad faith, reasoning that "[p]etitioners 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. This limited holding is a far cry from a determination that an agency may categorically exclude all internal documents from the administrative record in the first place. Indeed, in refusing to supplement the record with the transcript, the court in *San Luis Obispo* specifically noted that it was not establishing a blanket rule that deliberative material may be excluded, and recognized that "[t]here may be cases where a court is warranted in examining the deliberative proceedings of the agency." *Id.* In fact, 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 v. Bd. of Governors of Fed. Reserve Sys.*, 516 F.2d 1229, 1241 (D.C. Cir. 1975). The Court's Order that FDA produce a complete record does not implicate or require revelation of the ultimate decision-maker's individual subjective mindset, it merely requires the agency to produce all of the documents that were before the agency and directly or indirectly considered by

[4] *San Luis Obispo* was also about supplementation of the record, not completion of the record. That distinction is crucial because it dictates who bears the burden (the agency bears burden of completion once a plaintiff rebuts the presumption of regularity, while the burden of supplementation lies with a plaintiff) and what is required to meet that burden (greater for supplementation than for completion). *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) ("Plaintiffs need not show bad faith or improper motive to rebut the presumption [of regularity]" when moving to complete the record); *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"). Contrary to a motion to complete the record, where "Plaintiffs need not show bad faith or improper motive," *Lockyer*, 2006 WL 708914, at *2, a showing of bad faith like that required in *San Luis Obispo*, "applies only to instances where the method of supplementation involves testimony inquiring into the mental processes of administrative decisionmakers." *Ad Hoc Metals Coal. v. Whitman*, 227 F. Supp. 2d 134, 140 n.5 (D.D.C. 2002)(citing *Citizens to Preserve Overton Park Inc. v. Volpe*, 401 U.S. 402, 420 (1971)).

the agency in making its decision. Order at 1, ECF No. 88 (citing *Thompson* 885 F.2d at 555).

D. FDA's Position is Contrary to Bedrock Principles of Administrative Law.

Production of the whole administrative record is integral to the APA's requirement that the Court conduct a "thorough, probing, in-depth review" of an agency's decision that is "searching and careful." *Citizens to Preserve Overton Park*, 401 U.S. at 415-16. As the Ninth Circuit emphasized in *Portland Audubon Soc'y v. Endangered Species Comm.*, 984 F.2d 1534, 1548 (9th Cir. 1993), "[a]n incomplete record must be viewed as a fictional account of the actual decisionmaking process . . . . If the record is not complete, then the requirement that the agency decision be supported by the record becomes almost meaningless.")(internal quotation marks and citation omitted). FDA's argument that agencies can unilaterally exclude from an administrative record documents that they relied upon in making their decision and can do so without the need to acknowledge the existence of those documents, or in any way justify the asserted privileges to the Court or Plaintiffs, does not square with the APA. All documents that were considered directly or indirectly by an agency are part of the record for judicial review under the APA. *Thompson*, 885 F.2d at 555.

Some documents can of course be withheld in whole or part under a claim of privilege, but such claims must be documented, substantiated, and challengeable. *Maricopa Audubon Soc'y v. U.S. Forest Serv.*, 108 F.3d 1089, 1092 (9th Cir. 1997)(whether a federal agency has met is burden to justify a claim of privilege is a question of law the court reviews *de novo*). The deliberative process privilege is not automatic: it is narrow and qualified, meaning it must be affirmatively asserted and justified, and can be challenged and overcome in a balancing test determination. *F.T.C. v. Warner Commc'ns, Inc.*, 742 F.2d 1156, 1161 (9th Cir. 1984)("The deliberative process privilege is a qualified one. A litigant may obtain deliberative materials if his or her need for the materials and the need for accurate fact-finding override the government's interest in non-disclosure."). If FDA's position was correct, there would be no logging of deliberative materials in APA cases, and thus no way to challenge the privilege, transforming it from a qualified and judicially reviewable legal standard to iron-clad, non-reviewable agency fiat.

III. FDA HAS FAILED TO SHOW IRREPARABLE HARM ABSENT A STAY.

FDA has also failed to show irreparable injury absent a stay, the second "critical" stay factor. *Nken*, 556 U.S. at 434. FDA's alleged injury is the "substantial costs" of continuing to comply with the Court's order while the Ninth Circuit considers its petition for a writ. FDA alleges that completing the record will take them more than twice the time that they told the Court was sufficient in January, and take FDA staff from other agency tasks. Mot. Stay at 4, ECF No. 97. These arguments fail both legally and factually.

First, it is important to distinguish temporally between the harm FDA alleges here, and that alleged in the mandamus writ. Whereas, for the mandamus motion, FDA's alleged harm is having to complete the record in full, for the stay motion, the only harm or prejudice FDA can claim is that *increment* of record completion work that may result from continuing to comply with the Court's Order while the Ninth Circuit considers their writ. Yet, FDA waited ninety-two days to bring their stay motion: any alleged short-term consequences arising from Defendants' belated request to stay are a product of Defendants' own actions and delay in bringing the stay motion.

Second, regardless of the length of time in question, complying with the Court's Order is simply the natural consequence of the agency's unlawful action—it does not qualify as irreparable harm. *See, e.g.*, *Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin. (NRDC)*, 884 F. Supp. 2d 108, 123-25 (S.D.N.Y. 2012)(rejecting government's motion for stay pending appeal; holding "the argument 'that potentially wasted and diverted agency staff resources constitutes irreparable harm' has been held 'meritless'")(quoting *Shays v. Fed. Election Comm'n*, 340 F. Supp. 2d 39, 48 (D.D.C. 2004)); *Graphic Commc'ns Union v. Chi. Tribune Co.*, 779 F.2d 13, 15 (7th Cir. 1985)(holding that costs incurred as consequence of compliance with court order do not show irreparable harm). As the court in *NRDC* stated: "This is a sensible rule . . . [A]ccepting the [g]overnment's argument would almost always result in a finding of irreparable harm whenever an agency was required to comply with a court order." 884 F. Supp. 2d at 124. FDA cites no case to support its claim that having to assign a limited number of agency staff or to "reshuffle" its priorities to complete the record here on a court-ordered

timeline is a cognizable irreparable injury. *See, e.g.*, *Ctr. for Food Safety v. Hamburg*, No. 4:12-cv-4529-PJH, 2013 WL 5718339, at *2 (N.D. Cal. Oct. 21, 2013)(rejecting similar arguments that alleged interference with "other agency priorities" constitutes an irreparable injury).

Moreover irreparable injury is defined as injury that cannot be "adequately remedied by money damages and is often permanent or at least of long duration," such as environmental pollution. *Amoco Prod. Co. v. Village of Gambell, Alaska*, 480 U.S. 531, 545 (1987). A temporary call on the agency's resources to compile a complete administrative record is not a permanent or long-lasting injury, and it is one that adequately can be solved with the agency's existing agency resources. Moreover, as noted *supra*, the injury alleged in this stay context is even more temporary, since it is only the time increment before the Ninth Circuit rules on FDA's motion.

FDA's argument also lacks merit factually. FDA claims the Court's Order created a new burden for them, and that "this is work that need not be performed at all" if FDA prevailed on its mandamus motion. Mot. Stay at 4, ECF. No. 97. But, even outside the context of this case, the agency already had the same ongoing and outstanding duty generally, and specifically for GE salmon, pursuant to FOIA. FDA admits there are outstanding FOIA requests related to GE salmon, but claims their scope is "significantly narrower" than the issues here. *Id.* at 4 n.2. Contrary to FDA's assertions, several of the Plaintiffs have submitted broad FOIA requests that required FDA to conduct searches it now claims will "impose substantial costs" and a "staggering burden." In 2011, one of the Plaintiffs submitted a broad FOIA request to FDA seeking "all documents, records, and materials" related to the Aqua Bounty salmon, including specifically "inter-agency studies, memoranda, and correspondence." *See* Declaration of Khushi Desai (Desai Decl.) and Desai Decl. Ex. A (FOIA request). Another Plaintiff organization filed a similar but separate FOIA in 2010, and related FOIAs later. *See* Declaration of Zachary B. Corrigan (Corrigan Decl.) (explaining that Plaintiff Food & Water Watch submitted a FOIA request for "all information and records related to the safety and effectiveness of AquaBounty Technology's (ABT) AquAdvantage Salmon") and Corrigan Decl. Ex. A. Thus, *even absent the*

Court's Order FDA should have been undertaking identical or substantially similar searches to respond to the FOIA requests on GE salmon. Indeed, as to the agency's claim of time-constraints, given that the FOIA requests were filed in 2010-11, FDA has had over six years to review and prepare most of this material and/or a privilege log by the time this litigation was filed. A stay here would not obviate that duty.

Finally, it is noteworthy that Plaintiffs first learned the details of Defendants' alleged irreparable "hardships" from the Court's Order upon reading their stay motion and the declarations filed with it. Defendants did not meet and confer on these issues, nor did they raise the issues discussed in the declarations in the March status report to the Court, filed a month before the stay motion, or later to Plaintiffs. Joint Status Report at 3-4, ECF No. 94 (summarizing ongoing work to collect and review documents). Plaintiffs continue to be willing to work with Defendants, including by expeditiously reviewing documents culled to date to narrow further the scope of custodians or search terms, but thus far, Defendants have produced only seventy-one non-substantive documents. Plaintiffs have no basis on which to evaluate FDA's process, and so far, no basis to further narrow the scope of production. Rather than categorizing the harm as irreparable when it is not, FDA should instead address any alleged burden by continuing to work with Plaintiffs to further narrow the scope of production. Should more time be necessary to accomplish that task, Plaintiffs have already indicated to FDA their willingness to consider a reasonable request for an extension, provided that it would not prejudice Plaintiffs. *See infra* at Section IV.

IV. FDA HAS FAILED TO SHOW THE STAY WILL NOT SUBSTANTIALLY INJURE PLAINTIFFS AND THE PUBLIC.

FDA has failed to show that the requested stay will not "substantially injure the other parties interested in the proceeding." *Nken*, 556 U.S. at 434. FDA claims Plaintiffs will not be injured because a stay will "advance timely resolution" of the case. Mot. Stay at 5, ECF. No. 97. Arguing that a *stay*—a legal and practical halting of FDA's production of the record—will somehow speed things up is nonsensical. FDA gets there by claiming now that it will take the agency "well over a year" to comply with the Court's Order, and that the Ninth Circuit might

grant their writ for mandamus before then. This assumption is based on speculation that the Ninth Circuit will grant their extraordinary request for a writ, which is unlikely considering the arguments addressed above. In contrast, if the Court granted the stay and the Ninth Circuit denies the writ for mandamus, this case will have been further delayed, when FDA could instead have been continuing to complete the record during that time. FDA cannot get around the fact that further delaying its record production will further delay this case and the relief Plaintiffs seek.

FDA also argues Plaintiffs will not be injured because AquaBounty is "uncertain about when it may be able to begin marketing" their GE salmon. Mot. Stay at 5, ECF No. 97. AquaBounty itself, however, has been notably silent on the pace of its production efforts. As far as Plaintiffs are aware, AquaBounty's production of GE salmon is underway. Moreover, the environmental harms central to this case come to fruition from, among other things, the production of GE salmon eggs, and do not require the later step of marketing the fully-grown fish. Absent a commitment by AquaBounty itself to halt production, Plaintiffs are prejudiced by additional delay. FDA's bare speculation about AquaBounty's commercial development schedule does not meet their burden to show Plaintiffs will not be injured by further unnecessary delay.

V. THE PUBLIC INTEREST SUPPORTS DENYING THE STAY.

FDA has failed to show how the public interest supports a stay. *Nken*, 556 U.S. at 434. Rather, the public interest fully supports having FDA comply with the law. *Native Ecosystems Council v. U.S. Forest Serv.*, 866 F. Supp. 2d 1209, 1234 (D. Idaho 2012)("[E]nsuring that government agencies comply with the law is a public interest of the highest order.")(internal quotation marks and citation omitted); *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 235 F. Supp. 2d 1143, 1162 (W.D. Wash. 2002)(same). The public interest supports protecting the environment and public health, and allowing for full and timely judicial review of FDA's unprecedented approval of a novel, first-of-its-kind genetically engineered animal. Completing the record, as lawfully required, is a proper use of agency resources, *Native Ecosystems Council*, 866 F. Supp. 2d at 1234, and FDA already has an independent duty to prepare the same materials

even absent this litigation, *see supra*. FDA's underlying mandamus position is equally contrary to the public interest: FDA is not entitled to withhold what it has now identified as thousands of documents relevant to its decisions, without ever identifying the material is seeks to withhold, by unilaterally describing it as deliberative. *Nat'l Wildlife Fed'n v. U.S. Forest Serv.*, 861 F.2d 1114, 1124 (9th Cir. 1988)(Pregerson, J. concurring)("We should all bear in mind that secret government is abhorrent to democratic values.").

As to the time and money allegedly needed to comply with the Court's order, FDA's administrative record struggles are likely related to the nature of its decision. It has undertaken a lengthy, first-ever approval of a highly-controversial GE animal, using a regulatory pathway it created in guidance (not regulations) generated as it went along, under a 1938 statute for which this use was never intended—and it evidently failed to compile and maintain an organized record as it so acted. *See* 21 C.F.R. § 10.3 (FDA regulations define "Administrative file" as "the file or files containing all documents pertaining to a particular administrative action, including internal working memoranda, and recommendations."); Jan. 12, 2017 CMC Audio Recording, at 2:15-5:22 (Defendants stating that FDA never compiled internal documents over 20-year approval). In short: this is a novel endeavor for the agency, and it either does not have proper protocols in place or did not follow them. However, that makes it all the more important and valuable for FDA to get its internal processes in line with its statutory duties, for this judicial proceeding and any future GE animal approvals, and as such in the public interest to deny the stay.[5]

[5] It appears FDA is having similar issues in modernizing its record production generally. The Declaration of Gorka Garcia-Malene discusses how the agency is now producing another record of 450,000 pages that has taken them several years of staff time and expenses, undercutting their claims that this case is singular. *See* Decl. Garcia-Malene at 6, ECF No. 97-1. And the Declaration of Hilary Wanke indicates that some of the problem with producing emails has to do with FDA's software disconnecting emails from their attachments. *See* Decl. Wanke, ECF No. 97-2 at 4-5. Forcing FDA to correct its approach to compiling an administrative record will serve the public interest by ensuring that FDA complies with the law when producing records in the future.

CONCLUSION

For the above reasons, Defendants cannot satisfy the substantial burden warranting the extraordinary relief of a stay. FDA's interpretation of what must be included in the record is contrary to bedrock administrative law and long-established Ninth Circuit APA jurisprudence. The Court's Order that FDA include these materials in the administrative record is neither unusual or overbroad, and critical to meaningful APA review.

Plaintiffs acknowledge that the length of time FDA considered the GE salmon approval was significant, the approval and regulatory pathway both unprecedented, and as such the record will be voluminous. Despite FDA's failure to begin work on this process seven years ago when Plaintiffs first submitted FOIA requests, or even one year ago when this case was filed, the solution is to continue working with Plaintiffs to facilitate production of the record in as expeditious and efficient a manner as possible, even if that may require some additional time, not to halt that record process and file a meritless mandamus petition.

For the forgoing reasons, Plaintiffs respectfully request this Court DENY Defendants' Motion to Stay January 10, 2017 Order Pending Petition for Writ of Mandamus.

Respectfully submitted this 27th day of April, 2017 in San Francisco, California.

/s/ George Kimbrell

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