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22 UNITED STATES DISTRICT COURT
23 NORTHERN DISTRICT OF CALIFORNIA

24 INSTITUTE FOR FISHERIES
25 RESOURCES, *et al.*,
26
27 Plaintiffs,
28
29 v.
30 THOMAS E. PRICE, M.D., *et al.*,
31
32 Defendants, and
33
34 AQUABOUNTY TECHNOLOGIES, INC.,
35
36 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

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

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

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

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

8 This Court should exercise its “inherent power to control the disposition of the causes on
9 its docket [to] promote economy of time and effort for itself, for counsel, and for [the] litigants”
10 by staying the order pending appellate review. *CMAX, Inc. v. Hall*, 300 F.2d 265, 268 (9th Cir.
11 1962); *see also Landis v. North Am. Co.*, 299 U.S. 248, 254 (1936); *Filtrol Corp. v. Kelleher*,
12 467 F.2d 242, 244 (9th Cir. 1972); *Mediterranean Enters., Inc. v. Ssangyong Corp.*, 708 F.2d
13 1458, 1465 (9th Cir. 1983) (noting that a trial court may find it efficient for its own docket and
14 the fairest course for the parties to enter a stay pending resolution of independent proceedings
15 bearing upon the case.). Particularly given the substantial burden imposed by the January 10,
16 2017 Order, it would be most efficient for the Court to await a ruling from the Ninth Circuit on
17 the mandamus petition. The Federal Defendants therefore respectfully request that this Court
18 stay the January 10, 2017 Order and July 11, 2017 compliance deadline until the Court of
19 Appeals rules on the mandamus petition. Plaintiffs oppose this motion. Intervenor-Defendant
20 takes no position on this motion, but does not waive its right to file a reply brief addressing the
21 motion or opposition, as necessary.

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

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

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

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

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

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

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

4 Because the Ninth Circuit has not directly addressed whether agencies may exclude
 5 deliberative documents from administrative records, decisions from courts in this judicial district
 6 have created an opportunity for plaintiffs to forum shop to bog agencies down in document
 7 review and seek what is essentially discovery in an APA case. *See* ECF 88, at 1 (citing *People of*
 8 *State of Cal. ex rel. Lockyer v. U.S. Dep't of Agric.*, No. C05-03508 EDL, 2006 WL 708914, at
 9 *3 (N.D. Cal. Mar. 16, 2006)); *id.* at 2 (citing *Gill v. Dep't of Justice*, No. 14-CV-03120-RS
 10 (KAW), 2015 WL 9258075, at *6 (N.D. Cal. Dec. 18, 2015)). Agencies sued in this district face
 11 a significantly different and more onerous burden to prepare administrative records than they do
 12 elsewhere, even within the Ninth Circuit. *See, e.g., See San Luis & Delta-Mendota Water Auth.*
 13 *v. Jewell*, No. 1:15-cv-01290, 2016 WL 3543203, at *19 (E.D. Cal. June 23, 2016).

14 **2. FDA Will Be Irreparably Harmed Absent a Stay**

15 Orders imposing onerous discovery burdens and significant litigation costs may cause
 16 irreparable harm and justify a stay pending appeal. *See Brown v. Wal-Mart Stores, Inc.*, No. 09-
 17 0339, 2012 WL 5818300, at *4 (N.D. Cal. Nov. 15, 2012) ("Courts evaluate whether litigation
 18 expenses constitute irreparable harm based on the specific circumstances of each case.");
 19 *Richards v. Ernst & Young LLP*, No. 08-4988, 2012 WL 92738, at *4-5 (N.D. Cal. Jan. 11,
 20 2012) (granting stay because serious burden, including discovery, would be avoided if
 21 defendants won on appeal); *see also Pena v. Taylor Farms Pac., Inc.*, No. 13-1282, 2015 WL
 22 5103157, at *4-5 (E.D. Cal. Aug. 27, 2015) (collecting cases). Courts consider whether a stay
 23 would avoid substantial, unrecoverable, and wasteful discovery costs, and whether the costs
 24 would be inevitable regardless of the result of the appeal. *Id.*

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

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

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

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

24 **3. Plaintiffs Will Not Be Prejudiced By a Stay**

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

27
 28 ² An outstanding FOIA request seeks certain related documents, but its scope is significantly narrower than the scope of the Court's order.

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

9 **4. The Public Interest Favors a Stay**

10 Compliance with this Court's order will divert resources from FDA's public health
 11 priorities. Further, public policy favors efficient use of resources, and the public interest is
 12 especially apparent when public resources are at stake. *Burgan v. Nixon*, No. 16-61, 2016 WL
 13 6584478, at *5 (D. Mont. Nov. 7, 2016); *C.B.S. Employees Federal Credit Union v. Donaldson*
 14 *Lufkin & Jenrette Sec. Corp.*, 716 F. Supp. 307, 310 (W.D. Tenn. 1989). FDA estimates that it
 15 would cost over \$2 million dollars for CVM's FOIA reviewers (*i.e.*, not including scientific and
 16 other reviewers brought on to assist) to review the documents of just three of the 17 (or more)
 17 custodians whose records have been collected so far. Garcia-Malene Decl. ¶ 15. Even this
 18 subset is a significant amount of taxpayer money that need not be spent at all if Federal
 19 Defendants prevail on mandamus. Public policy weighs strongly in favor of a stay.

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

25
 26
 27 ³ See AquaBounty Technologies, Inc. Form 10-K (2016 annual report dated Mar. 16, 2017), at 9-
 28 10, available at [http://services.corporate-
 ir.net/SEC.Enhanced/SecCapsule.aspx?c=197553&fid=14896944](http://services.corporate-ir.net/SEC.Enhanced/SecCapsule.aspx?c=197553&fid=14896944) (last visited April 13, 2017).

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Dated: April 14, 2017

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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