UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ANIMAL LEGAL DEFENSE FUND, et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY JR., et al.,

Defendants,

and

ELANCO ANIMAL HEALTH,

Intervenor-Defendant.

Case No. 20-cv-03703-RS

ORDER GRANTING DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

I. INTRODUCTION

Plaintiffs in this action are three advocacy groups: Animal Legal Defense Fund, Food & Water Watch, and Food Animal Concerns Trust. They challenge the decision of defendant Federal Drug Administration ("FDA") to approve the animal drug Experior for use in cattle feedlots. Elanco Health, the manufacturer of Experior, has intervened as an additional defendant.

Experior is touted to reduce the amount of ammonia gas released from the waste of cattle raised for beef. Plaintiffs contend Experior has not been shown to be safe and effective, and that FDA did not adequately consider the drug's environmental impacts. Plaintiffs assert claims under the Administrative Procedures Act ("APA"), 5 U.S.C. § 551, *et seq*. for alleged underlying failures to comply with the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et*

seq., and the National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4321 *et seq*.[1]

The parties bring cross-motions for summary judgment. FDA and Elanco are separately represented and filed separate briefs, but their arguments are substantially similar. For the reasons set out below, the motions of FDA and Elanco will be granted, and plaintiffs' motion will be denied.

II. BACKGROUND

The product in dispute is "Experior," which is a trade name. Its active ingredient is a drug called lubabegron, which was originally researched as a possible treatment for human obesity. It was subsequently investigated as an animal drug to improve feed efficiency in cows –*i.e.*, to promote weight gain with less food. Then it was proposed to reduce ammonia and greenhouse gases from cows. Elanco eventually abandoned any additional claims and now asserts an environmental benefit only from reductions in the amounts of ammonia released from cow manure.[2]

Experior is theorized to function by increasing the percentage of dietary nitrogen that cows utilize, rather than excrete. Nitrogen functions as a form of "crude protein," an important nutrient in cattle feed. Only 10-30% of dietary nitrogen, however, is "utilized" by a cow, *i.e.*, deposited in their tissue as protein; the remainder is excreted through urine and feces, where it converts to ammonia gas—which is a combination of nitrogen and hydrogen. Thus, the theory is that if the cows utilize more, and excrete less, of the nitrogen in their diet, less ammonia will be released from their manure.

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[1] The complaint includes a claim for relief based on the FDA's denial of a stay petition plaintiffs filed under 21 C.F.R. § 10.35. At the hearing on the present motions, the parties agreed that claim need not be reached.

[2] The subtext to plaintiffs' claims is their belief that the negative environmental consequences of large-scale industrial beef production should be addressed by means other than attempting to add drugs to cattle feed. However intuitively persuasive that argument might be, the court's role in assessing claims under the APA does not include making such policy determinations.

Experior is a "β-adrenergic drug." Such drugs act on β-adrenoceptors, which are cell surface receptors widely distributed throughout the body that mediate the activity of cells. There are different types of adrenoceptors. Within the β type, there are at least 3 subtypes: β1, β2, and β3. β-*agonist* drugs "agonize" (*i.e.*, stimulate or activate) β-adrenoceptors. Conversely, β-*antagonist* drugs "antagonize" (*i.e.*, inhibit or block) them.

Plaintiffs contend it is well known that β-adrenergic *agonist* drugs are linked to significantly higher mortality rates in cows due to a host of fatal respiratory, cardiac, and digestive issues, in addition to significant behavioral issues that make animals more likely to be abused and suffer in ways that directly impact food safety and worker health. Thus, plaintiffs contend, Elanco found it "of critical importance" that Experior not be pharmacologically classified as a β-agonist, "to differentiate their product" from other approved β-agonists. After initially warning that additional studies were needed to determine if Experior is an β-agonist or β-antagonist, FDA ultimately recommended it be classified as a "β-agonist/antagonist," meaning it stimulates some β-receptors and suppresses others.

III. LEGAL STANDARDS

Because this is an APA case, it is not an inquiry under Rule 56 of the Federal Rules of Civil Procedure as to whether there are disputed factual issues for trial. Rather, this is a review on the merits under the APA of the validity of FDA's approval of Experior. *See, Klamath Siskiyou Wildlands Ctr.*, 962 F.Supp.2d 1230, 1233; *see also Sierra Club v. Mainella*, 459 F. Supp.2d 76, 89 (D.D.C. 2006) ("[T]he standard set forth in Rule 56(c) does not apply [in an APA case] because of the limited role of a court in reviewing the administrative record."); *McCrary v. Gutierrez*, 495 F.Supp.2d 1038, 1041 (N.D. Cal. 2007) (judicial review of agency action under the APA limited to the administrative record).[3]

[3] Defendants' "renewed" challenge to plaintiffs' standing is governed by Rule 56 standards. As will appear, however, defendants have not presented anything to undermine the declarations previously found to support standing.

"Under the APA, it is the role of the agency to resolve factual issues to arrive at a decision that is supported by the administrative record, whereas 'the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.' " *Sierra Club*, 459 F.Supp.2d at 90 (quoting *Occidental Eng'g Co. v. INS*, 753 F.2d 766, 769–70 (9th Cir. 1985)). In other words, "the district court acts like an appellate court, and the 'entire case' is 'a question of law.' " *Nat'l Law Ctr. on Homelessness & Poverty v. U.S. Dep't of Veterans Affairs*, 842 F.Supp.2d 127, 130 (D.D.C. 2012) (quoting *Amer. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001)). "Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Stuttering Found. of Am. v. Springer*, 498 F.Supp.2d 203, 207 (D.D.C. 2007).

FDA's underlying decision was governed by its obligation under the FDCA to determine that a new animal drug is both safe and effective before approving it. *Rhone-Poulenc, Inc., Hess & Clark Div. v. Food & Drug Admin.*, 636 F.2d 750, 752 (D.C. Cir. 1980). The drug sponsor—here, Elanco—bears the burden of demonstrating that (a) the drug is safe and effective for the target animals; (b) food products from the target animals will be safe for human consumption; and (c) the manufacture and use of the drug will not harm the environment. 21 U.S.C. § 360b(b)(1); 21 C.F.R. § 10.25(a)(1). To demonstrate safety, the drug sponsor must conduct all tests necessary to ensure the drug will be safe for humans, animals, and the environment when used as labeled. *Am. Cyanamid Co. v. Young*, 770 F.2d 1213, 1218 (D.C. Cir. 1985) (citing 21 U.S.C. § 360b(d)(1)(A), (E), (3)). To demonstrate effectiveness, the drug sponsor must conduct "adequate and well-controlled investigations, including field investigation," that provide the evidence necessary for FDA to conclude "the drug has the effect it purports to have." *Id.*; see also 21 C.F.R. § 514.4.

Once the sponsor has put forth its application for approval, FDA "shall" refuse approval where (a) the drug application does not show "whether or not such drug is safe," (b) the evidence shows the drug is actually unsafe, (c) there is insufficient information to support a drug's safety, or (d) the application lacks "substantial evidence" to show that a drug is effective. 21 U.S.C. §

360b(d)(1). "If any one of § 360b(d)'s requirements is not met, FDA's charge is to reject the new animal drug application." *Am. Cyanamid Co.*, 770 F.2d at 1218 (citing *Masti-Kure Prods. Co., Inc. v. Califano*, 587 F.2d 1099, 1104 (D.C. Cir. 1978)).

IV. DISCUSSION

A. Standing

At the outset of this litigation, FDA and Elanco both brought motions to dismiss challenging plaintiffs' standing. The plaintiff organizations disavowed any attempt to claim standing for themselves as entities (so-called "organizational standing"), arguing instead that they have "associational standing" under the rule that an organization may have standing if it can show "that its members, or anyone of them, are suffering immediate or threatened injury as a result of the challenged action of the sort that would make out a justiciable case had the members themselves brought suit. . . ." *Hunt v. Wash. State Apple Growers Ass'n*, 432 U.S. 333, 342 (1977).

The order denying the motions to dismiss rejected defendants' arguments that plaintiffs' individual members have no injury-in-fact and cannot show causation or redressability. In their respective opening briefs for the present motions, FDA and Elanco merely referred to and incorporated their prior arguments about standing. On reply, however, defendants expanded their arguments, insisting that even if plaintiffs' showing on standing was sufficient at the pleading stage, it was incumbent on them to present additional evidence to support their claims of injury-in-fact.

This is not a case, however, where a plaintiff's allegations were presumed to be true at the pleading stage, but fail on summary judgment if not supported by evidence. While plaintiffs certainly could have elected to obtain and submit additional evidence, they were not obligated to do so. Plaintiffs' standing was previously established based on the declarations they submitted in opposition to the motions to dismiss, and nothing has changed since then to undermine those declarations.

The parties submitted supplemental briefing following the Supreme Court's recent decision in *Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367 (2024). In that case, a unanimous court had little trouble concluding several pro-life doctors and associations lacked standing to challenge decisions by the FDA to relax restrictions on mifepristone, a drug used to induce abortions.

The court observed that when a plaintiff challenges the government's "unlawful regulation (or lack of regulation) of someone else," standing can be harder to establish. 602 U.S. at 382. "That is often because unregulated parties may have more difficulty establishing causation—that is, linking their asserted injuries to the government's regulation (or lack of regulation) of someone else." *Id.* The court further explained the causation requirement "precludes speculative links—that is, where it is not sufficiently predictable how third parties would react to government action or cause downstream injury to plaintiffs." *Id.* at 383.

Here, the causation chain is not unduly tenuous or speculative. It is reasonable to assume that Elanco will respond, and has responded, to the approval of Experior by marketing it nationwide, and that it will find a market of buyers, likely expanding over time. It is virtually certain that the purchasers will use the drug once they have purchased it to treat their cattle. Although there is uncertainty regarding how widespread use of Experior will become and when and whether particular members of the plaintiff organizations will encounter it, there is a direct line between the challenged government action and the harms plaintiffs allege their members will suffer. Plaintiffs have made an adequate showing that their members possess "personal stakes" in this matter, thereby satisfying the principles that "courts decide litigants' legal rights in specific cases, as Article III requires, and that courts do not opine on legal issues in response to citizens who might roam the country in search of governmental wrongdoing." 602 U.S. at 379.

B. Materials outside the administrative record

As noted, the role of the court in an APA case is to determine whether the evidence in the administrative record permitted the agency to make the challenged decision. As a result,

"[j]udicial review of an agency decision typically focuses on the administrative record in existence at the time of the decision and does not encompass any part of the record that is made initially in the reviewing court." *Lands Council v. Powell*, 395 F.3d 1019, 1029–30 (9th Cir. 2005) (quoting *Southwest Ctr. for Biological Diversity v. United States Forest Serv.*, 100 F.3d 1443, 1450 (9th Cir. 1996). There are, however, "narrow exceptions to this general rule." *Lands Council*, 395 F.3d at 1030.

Specifically, the court is permitted to admit extra-record evidence: "(1) if admission is necessary to determine whether the agency has considered all relevant factors and has explained its decision, (2) if the agency has relied on documents not in the record, (3) when supplementing the record is necessary to explain technical terms or complex subject matter, or (4) when plaintiffs make a showing of agency bad faith." *Id.* (internal citations and quotation marks omitted). The *Lands Council* court cautioned, "these exceptions are narrowly construed and applied . . . . Were the federal courts routinely or liberally to admit new evidence when reviewing agency decisions, it would be obvious that the federal courts would be proceeding, in effect, de novo rather than with the proper deference to agency processes, expertise, and decision-making." *Id.*

To support their motion for summary judgment, plaintiffs have offered a 43-page declaration of a putative expert witness, Dr. John Tegzes. Plaintiffs contend the declaration may be considered under the *Lands Council* exception for materials "necessary to determine whether the agency has considered all relevant factors" and/or the exception for information "necessary to explain technical terms or complex subject matter,"

Plaintiffs likely could have simply filed the Tegzes declaration with their motion, leaving it to defendants to argue in their oppositions that it should not be considered, in whole or in part. Perhaps in anticipation of a motion to strike, however, plaintiffs filed a prophylactic "motion to consider materials outside the administrative record," noticed to be heard concurrently with the cross-motions for summary judgment.

Defendants' request to have the propriety of the Tegzes declaration decided in advance of the summary judgment motion was denied. Accordingly, defendants moved to strike the

declaration, *and* offered two rebuttal declarations, to be considered if the Tegzes declaration were not stricken. Plaintiffs, in turn, sought to strike the rebuttal declarations, contending they stand on a different footing than the Tegzes declaration, and are not admissible under any *Lands Council* exception.

Upon review, the Tegzes declaration is not admissible, as it is not "necessary" for either of the purposes for which plaintiffs offer it. To the extent the declaration includes legal conclusions and opinions, those would not be appropriate subjects for expert testimony even outside the context of an APA action. To the extent Tegzes' arguments, factual assertions, and conclusions are directed towards having the court substitute its scientific judgment for that of the FDA, they are improper.

That said, plaintiffs are not precluded from raising in attorney argument any or all of the same alleged deficiencies in the FDA's approval process that Tegzes identified, or from using his explanations of any technical terms or complex subjects. Indeed, it does not appear the Tegzes declaration offers much, if any, factual matter that is not in the administrative record. To the extent there are any such facts, plaintiffs have not shown they are admissible under the *Land's Council* exceptions. The declaration primarily consists of arguments that plaintiffs are free to make, but which do not turn on evidence outside the record. *See Southwest Center for Biological Diversity v. U.S. Forest Serv.*, 100 F.3d 1443, 1451 (9th Cir. 1996) ("The information contained in these documents can either be extracted from the [administrative] record or is not necessary to this court's review of the [agency's] action. Although the documents [plaintiff] seeks to include might have supplied a fuller record, they do not address issues not already there." (internal quotations omitted)). Accordingly, the Tegzes declaration and the FDA's rebuttal declarations will not be admitted.

C. Deference

Plaintiffs contend the FDA's determinations in this matter are not entitled to the deference they otherwise would be, because when it approved Experior "based on its environmental effects,"

it was acting outside its special expertise. *See Center for Biological Diversity v. Bernhardt*, 982 F.3d 723, 740 (9th Cir. 2020) ("deference applies only when the agency is making predictions 'within its area of special expertise'") (quoting *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1982)).

FDA insists it *does* have "special expertise in scientifically evaluating the safety, effectiveness, and environmental impact of a new animal drug" and that its determination is entitled to heightened deference. The deference rule is intended to spare courts from "act[ing] as a panel of scientists, instructing the agency, choosing among scientific studies, and ordering the agency to explain every possible scientific uncertainty." *Lands Council v. McNair*, 629 F.3d 1070, 1074 (9th Cir. 2010) (quotation omitted).

If the question before the FDA was whether Experior was effective in reducing the impact of commercial beef operations on the atmosphere, it might implicate the expertise of the EPA more so than that of the FDA. The intended use for which Experior was approved, however, is the "reduction of ammonia gas emissions per pound of live weight and hot carcass weight." While it may be the case that the *reason* beef producers would be interested in reducing ammonia gas emissions is to lower the impact of their operations on the atmosphere, the FDA did not address that issue, so its level of expertise on the point is irrelevant.

Furthermore, it cannot reasonably be disputed that the FDA's responsibility for evaluating the safety of new drugs routinely requires it to consider environmental impacts. For example, in this case the FDA looked at the risks imposed by residual Experior in the environment to soil microorganisms, plants such as corn, radish, perennial ryegrass, soybean, tomato, and wheat, earthworms, algae, water flea, and rainbow trout. AR112747-51, AR112755-56.

Accordingly, the FDA did not act outside its areas of statutory responsibility and expertise, and there is no basis to give it lesser deference in this matter. That said, none of the conclusions in this order rely on any particularly "heightened" deference to the FDA.

D. Efficacy

When evaluating new animal drug applications, the FDA determines whether there is "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling." 21 U.S.C. § 360b(d)(1)(E); *see also* 21 C.F.R. § 514.1(b)(8). The FDCA further defines substantial evidence as "evidence consisting of one or more adequate and well controlled investigations"—e.g., "a study in a target species" or "a study in laboratory animals"—that are conducted by qualified experts and "on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the [purported or represented] effect" under the labeled conditions. 21 U.S.C. § 360b(d)(3); see also 21 C.F.R. § 514.4(a). FDA's regulations clarify that "adequate and well-controlled studies" are those which, "as a matter of sound scientific judgment," are "necessary to establish that a new animal drug will have its intended effect," 21 C.F.R. § 514.4(a), as described extensively at 21 C.F.R. § 514.117.

The FDA found that there was substantial evidence to support approving Experior for the "reduction of ammonia gas emissions per pound of live weight and hot carcass weight in beef steers and heifers fed in confinement for slaughter during the last 14 to 91 days on feed." AR113248; see also AR113298-99. The FDA based its conclusion on five "adequate and wellcontrolled" studies involving 536 total animals. *See* AR113248-58. These studies were conducted at Michigan State University using single-animal chambers, AR113249, AR113254; and the University of California, Davis using cattle pen enclosures "designed to mimic feedlot conditions by housing groups of feedlot cattle together," AR113250. "Given the consistency of response to lubabegron across all five studies, FDA concluded that effectiveness at the minimum duration of 14 days is supported." AR113258.

Plaintiffs insist the record data is inconclusive as to whether Experior even has this effect and devoid of a supported explanation of how it would do so. To the extent that plaintiffs continue to mistake effects on the atmosphere with the claimed effect of "reduction of ammonia gas emissions per pound of live weight and hot carcass weight," it is irrelevant that the FDA did not

require proof that Experior achieved any particular environmental results (other than the requirement that it not cause significant *harm* to the environment).

As mentioned above, Experior is hypothesized to affect cows' nitrogen retention and utilization, but FDA's reviewers state expressly, "[a]lthough this hypothesis is plausible, it has not been supported by evidence." AR112893; see also AR111886-90, AR112339-40. Plaintiffs contend none of the studies in the record actually show what happens to the nitrogen that would have been excreted and ultimately released as ammonia, thereby undermining any claims of effectiveness. As defendants point out, however, Elanco did not intend to claim Experior was effective to increase muscle mass, so there was no occasion to conduct further studies to confirm the hypothesis as to its mode of action. Plaintiffs ultimately acknowledge there is no legal requirement that a drug's mode of action be known and understood.

Plaintiffs also point to FDA's supposed "admission" in the administrative record that Elanco's studies did not demonstrate Experior is effective because they "were not designed to measure or evaluate herd and farm scale emissions." AR113043, Plaintiffs complain that while Experior is marketed for use in feedlot cattle, the effectiveness studies were done in semi-controlled facilities that were not open to the environment and therefore insulated from factors that will impact ammonia gas emissions such as "temperature, pH, microbial community abundance, wind."

Defendants again observe the intended use of Experior is the "reduction of ammonia gas emissions per pound of live weight and hot carcass weight." The FDA had reasonably determined published research "support[ed] [Elanco's] assertion that gas emissions should be based on some unit of animal production," AR37210. Live weight or hot carcass weight was found to be an appropriate unit. *See* AR35087, AR33564. Upon concluding Elanco's studies demonstrated effectiveness on this per-pound basis, the FDA reasonably required the Experior label to disclaim predictions for larger units, which could be affected by other factors: "Ammonia gas emissions were measured for individual animals or small groups of animals held in environmentally controlled facilities. Based on existing information, reliable predictions of the reduction of

ammonia gas emissions cannot be made on a herd, farm, or larger scale." AR113262; *see also* AR113043; AR119009-10 (explaining in Stay Petition Response that Experior's approved use was "not for the reduction of ammonia gas emissions per herd, farm or larger scale").

Apart from contending there were no studies done under feedlot conditions, plaintiffs argue the studies that were done were rife with errors and shortcomings. Plaintiffs identify four main complaints. First, plaintiffs argue that cow feed and water intake were not consistently measured, analyzed, and recorded in studies, such that the results may have been influenced by feed consumption and nutrient variability rather than Experior. Plaintiffs offer specific examples of instances in which there were deviations from the study protocols, and where the FDA acknowledged such deviations presented potential issues.

The administrative record, however, shows the FDA adequately addressed those issues. *See, e.g.*, AR94540 ("the impact on the study results should be minimal" because the lapses occurred with similar frequency across all dosage groups, including the control group) AR98014-18 (explaining day-to-day variability in emissions was significant enough to conclude it was "unlikely that changes in emissions [were] due to lapses in ad libitum feed intake alone" and suggesting temperature fluctuation may have contributed).

Second, plaintiffs argue, measurements of the effectiveness studies did not account for variables that could influence the results. For example, some studies suggested the cows given Experior consumed less feed and gained more weight faster than control cows. Again, the FDA's analysis accounted for the possible effects of Experior on feed efficiency and rate of weight gain. Following three preliminary studies concerning effectiveness, the agency concluded that the data "suggests that [lubabegron] affects gas emissions, particularly [ammonia], independently from body weight or weight gain." AR37207.

Third, plaintiffs contend Elanco's effectiveness studies did not analyze Experior's effects on volatilized ammonia and nitrogen emissions. To the contrary, the effects on volatilized ammonia is exactly what the studies were intended to, and did, measure. The nitrogen study plaintiffs invoke was done to evaluate possible negative environmental consequences of Experior,

and does not bear on the efficacy issue. *See* AR112340*; see also* AR112799-800, AR112807.

Fourth and finally, plaintiffs suggest the FDA allowed Elanco to "manufacture" evidence of effectiveness by accepting data from two studies despite their use of software that was not compliant with FDA regulations for assuring the integrity of electronically captured data. The software allowed data alteration without creating a record. As the FDA explained, it accepted the data because it concluded "data tampering was unlikely." Personnel at the study sites "were masked to treatment assignment," meaning they did not know whether they were in the experimental or control group. AR98001. Without a basis to infer actual data tampering likely occurred, there is no reason to override the FDA's judgment that the study results were scientifically valid.

Accordingly, the FDA reasonably drew conclusions about intended uses and associated conditions of use (or disclaimed them in labeling) based on adequate and well-controlled studies. The FDA's efficacy finding is not subject to being set aside.

E. Safety

When FDA evaluates the "safety" of new animal drugs under the FDCA, its purview includes human food safety, user safety, and target animal safety,. See 21 U.S.C. § 321(u) (indicating "safe" as used in § 360b "has reference to the health of man or animal"). As part of this inquiry, the agency determines whether the evidence "include[s] adequate tests by all methods reasonably applicable to show whether or not [the] drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling." 21 U.S.C. § 360b(d)(1)(A); *see also* 21 C.F.R. § 514.1(8).

In approving Experior, the FDA reasonably evaluated human food safety. Based on pharmacology, toxicology, and residue chemistry studies, the FDA determined that (1) humans could safely consume an acceptable daily intake ("ADI") of food from cattle treated with Experior and that (2) public health would be protected by setting a tolerance for Experior residues in cattle liver tissue. AR113276-98; *see also* 21 C.F.R. § 556.3 (defining ADI as "daily intake which,

during up to an entire life of a human, appears to be without adverse effects").

Plaintiffs claim the "most glaring omission" is the absence of any adequate study in the record addressing the drug's impact on beef consumers. There is little dispute that Experior primarily affects the β3 adrenoceptor. The two human safety studies in the record were conducted in 2002, when lubabegron was being studied for use as a human anti-obesity drug. Those studies only measured β1 antagonist effects in the heart, because no tool had been "validated" for evaluating β3 at that time.

Plaintiffs contend that by the time Elanco sought FDA approval to market the drug for animal use, it was possible to test β3-agonist properties in humans. Specifically, the extent of a drug's β3-adrenoceptor expression can be measured by studying its impacts on bladder control. Thus, plaintiff contends, to assess Experior's effects on β3 receptors accurately, Elanco should have performed bladder function tests and not relied on changes in blood pressure and heart rate as clinical endpoints.

As defendants point out, Experior's safety for beef consumers was evaluated through a panoply of approaches—laboratory animal studies included, *inter alia*, clinical observations, clinical pathology, and urinalysis. Human studies included, *inter alia*, physical examination, clinical chemistry, and urinalysis, as well as responses from test subjects. A safety factor was calculated. The safety factor "reflects uncertainties associated with the extrapolation of data and information," including from "animal data to humans" and due to "variability in sensitivity to the toxicity of the new animal drug among humans."

Plaintiffs' insistence that bladder control testing could and should have been done to evaluate possible effects of the drug as a β3-agonist is unavailing. APA review does not require or permit a court to second-guess an agency's judgment on such an issue. The court's role is to determine whether the record evidence support's the agency decision, not to dictate the details of how the agency evaluates what specific testing is required.

Plaintiffs also argue FDA failed to consider risks to farmworkers who directly handle Experior. The drug's Safety Data Sheet states it "[c]auses eye burns" and "may cause damage to

organs through prolonged or repeated exposure" as well as other symptoms and chronic effects. Experior's label warns that "[i]ndividuals with cardiovascular disease should exercise special caution to avoid exposure," and instructs individuals to "use protective clothing, impervious gloves, protective eyewear, and a NIOSH approved dust mask" when mixing and handling Experior.

The existence of those warnings supports concluding the FDA *did* consider, and appropriately address, risks to farmworkers. Plaintiffs, however, seize on an observation in the record that "feedlot cowboys rarely use impervious gloves, protective clothing, dust masks, and goggles during their normal workday activities in the feed lot setting (especially in really hot weather)." Without more, however, the possibility of injuries arising from misuse does not support a conclusion that the product is so unsafe as to preclude approval.

Finally, plaintiffs contend questions remain as to whether Experior is safe for the cows. Plaintiffs offer a laundry list of potential negative health consequences they contend were not adequately investigated. Defendants again have identified the conclusions and reasoning set out in the record to support the FDA's determination that those concerns did not rise to a level precluding the conclusion that Experior is safe. The FDA's safety finding is not subject to being set aside.

F. NEPA

NEPA requires an agency to prepare an Environmental Impact Statement (EIS) whenever proposing to take "major Federal actions significantly affecting the quality of the human environment." 42 U.S.C. § 4332(2)(C). To determine whether an EIS is required, an agency first prepares an Environmental Assessment (EA), which results in either a decision to prepare a more thorough EIS or a Finding of No Significant Impact (FONSI). 40 C.F.R. §§ 1501.4(b), 1508.9(a)(1).

Judicial review of decisions under NEPA is governed by the APA. *Bark v. U.S. Forest Serv.*, 958 F.3d 865, 869 (9th Cir. 2020). Importantly, "[n]either the statute nor its legislative

history contemplates that a court should substitute its judgment for that of the agency as to the environmental consequences of its actions." *Kleppe v. Sierra Club*, 427 U.S. 390, 410 n.21 (1976). Accordingly, the "only role for a court" is to ensure that the agency "has taken a 'hard look' at environmental consequences." *Id.* "In reviewing an agency's finding that a project has no significant effects," courts ask whether the agency met that "hard look" requirement, "based [its decision] on a consideration of the relevant factors, and provided a convincing statement of reasons to explain why a project's impacts are not significant." *Bark*, 958 F.3d at 869 (internal citation omitted); *see also, Inst. for Fisheries Res.*, 499 F. Supp. 3d 657, 665 (N.D. Cal. 2020) (quoting *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1211 (9th Cir. 1998)).

Congress enacted NEPA to ensure that agencies have detailed information about significant environmental impacts when they make decisions and to ensure that this information will be available to the public. *Robertson v. Methow Valley Citizen's Council*, 490 U.S. 332, 349 (1989). "NEPA does not provide substantive protections, only procedural ones—it exists to ensure a process." *Conservation Cong. v. Finley*, 774 F.3d 611, 615 (9th Cir. 2014) (internal quotation marks omitted).

Here, the EA prepared by FDA resulted in a FONSI. Plaintiffs insist it is absolutely irreconcilable for FDA to approve a drug based on its alleged environmental effects, but then to conclude it will not actually impact the environment. Plaintiffs point to the FONSI itself, which states, ""it is currently not possible to assess the significance of the environmental impacts due to the reduction of ammonia gas emissions from use of Experior" and "the magnitude and effects of ammonia gas reductions cannot be quantified."

Once again, plaintiffs are conflating the issue of whether Experior will function to lower the ammonia gas emissions from commercial beef production with a narrower question, in this instance whether Experior will "significantly affect the quality of the human environment" in other ways.[4] The FONSI reflects a judgment that any reduction of ammonia gas emissions would

[4] Plaintiffs contend if FDA found that lubabegron was "effective" for purposes of the FDCA, then the drug's impacts "necessarily must" also be "significant within the meaning of NEPA." This

not be "significant" because it would, at most, only offset some of the negative environmental consequences of commercial beef productions. The failure of the FONSI to quantify that benefit is not a basis to reject the FDA's conclusion.

Moreover, the FDA carefully evaluated whether a generally beneficial reduction in ammonia gas emissions might nonetheless have negative side effects. AR112405-06. It was ultimately satisfied that lubabegron's mode of action—that nitrogen that otherwise would become ammonia was instead retained as muscle protein— was "plausible" and explained how the drug reduced ammonia emissions without adverse environmental impacts. AR111886-88, AR112339-40.

The EA also reflects FDA's careful consideration of other potential environmental consequences that could flow from use of Experior. The FDA applied a risk quotient approach that involves comparing a substance's predicted environmental concentration ("PEC") with its predicted no-effect concentration for certain surrogate non-target organisms ("PNEC"). The analysis started by calculating the PNEC of the drug in a variety of organisms: soil microorganisms, plants (corn, radish, perennial ryegrass, soybean, tomato, and wheat), earthworms, algae, water flea, and rainbow trout. AR112747-51, AR112755-56. The EA then calculated PEC values for manure, soil, and surface water.

Dividing PEC by PNEC for each organism, the EA found that the risk quotient value for each organism was less than one, indicating Experior was not expected to have an environmental impact. AR112756-57. The risk quotient values "for the most sensitive species in the terrestrial and aquatic ecosystems were 0.09 (soil microorganisms) and 0.10 (algae)." AR113042. Based on this analysis, the FDA ultimately was able to conclude there was "little or no potential for

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argument ignores the plain text of the FDCA and NEPA, which set out different standards for "effectiveness" of a drug and "significan[ce]" of an environmental impact. Compare 21 U.S.C. § 360b (concerning effectiveness for a drug's "intended use"), with 42 U.S.C. § 4332(2)(C) (concerning actions that "significantly affect[ ] the quality of the human environment"); 40 C.F.R. § 1508.27 (defining "significantly").

significant adverse effects on terrestrial and aquatic organisms." AR113042.

Plaintiffs do not claim the FDA's basic approach was unsound, instead they offer a litany of quibbles regarding aspects of the analysis they believe could and should have been done differently. Again, however, a court is not to substitute its judgment for that of the agency as to the environmental consequences of its actions. Defendants have made an adequate showing that the FDA took the requisite "hard look," consideration of the relevant factors, and provided a convincing statement of reasons. There is no basis to remand for further proceedings under NEPA.

G. Sealing motions

Multiple sealing motions have been filed. While the parties devoted substantial efforts to conferring for the purpose of minimizing the amount of material proposed for sealing and narrowing their disputes, the process did not produce either a joint proposed order addressing all of the sealing motions, or a joint proposed order with specified exceptions for items as to which the parties could not agree. As explained in Civil Local Rule 79-5, the public has a right of access to the court's files. The parties must explore all reasonable alternatives to filing documents under seal, minimize the number of documents filed under seal, and avoid wherever possible sealing entire documents (as opposed to merely redacting the truly sensitive information in a document). Only in rare circumstances should a party seek to file portions of a brief under seal.

Here, Elanco is the party seeking to maintain material under seal. It argues, among other things, that much of the material it wants protected was previously treated as non-public, confidential business information during the FDA proceedings. Plaintiffs correctly observe that the standards applied by the FDA are not coextensive with the standards governing what may properly be filed under seal in federal court litigation. That said, Elanco has made a minimally sufficient showing the portions of the administrative record, declarations, and exhibits it seeks to maintain under seal are appropriate for such treatment. Given the stronger policy against sealing briefs, Elanco has not provided a sufficient basis for its requested redactions in the substantive briefing.

Accordingly, the sealing motions are denied with respect to any and all of the briefs submitted in support of or in opposition to the substantive motions. As to the administrative record and the declarations and exhibits submitted in support of the motions, the sealing motions are granted to the extent proposed by Elanco in Dkt. No, 138-2 and Dkt. No. 136-2, and are otherwise denied. The parties' proposed orders suggested that the Clerk of the Court be instructed to file on the public docket any materials as to which sealing has been denied. Under Rule 79-5, the responsibility for doing so rests with the parties.

VI. CONCLUSION

Plaintiffs' motion for summary judgment is denied, and defendants' cross-motions for summary judgment are granted. The motions to consider extra-record materials is denied, and the motions to strike the declarations offering extra-record materials are granted. The sealing motions are granted to the extent specified above, and are otherwise denied. A separate judgment will enter.

IT IS SO ORDERED.

Dated: April 1, 2025

RICHARD SEEBORG
Chief United States District Judge

United States District Court
Northern District of California