UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

INSTITUTE FOR FISHERIES RESOURCES, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

Case No. 16-cv-01574-VC

ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT; GRANTING IN PART AND DENYING IN PART DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

Re: Dkt. Nos. 244, 254

This case involves a challenge to a decision by the Food and Drug Administration to allow a company to create and farm genetically engineered salmon. As part of the approval process, the FDA assessed the likelihood that the engineered salmon would escape from captivity and adversely affect normal salmon—including salmon species that are endangered. The agency concluded that the engineered salmon were highly unlikely to escape from the two facilities where the company initially planned to raise them, and that even if the salmon found a way to escape they were unlikely to survive or establish themselves as a population in the wild.

The FDA did not, however, meaningfully analyze what might happen to normal salmon in the event the engineered salmon *did* survive and establish themselves in the wild. Even if this scenario was unlikely, the FDA was still required to assess the consequences of it coming to pass. This is especially true because the FDA knew that the company's salmon operations would likely grow, with additional facilities being used for farming. Obviously, as the company's operations grow, so too does the risk of engineered salmon escaping. Thus, it was particularly

important at the outset for the agency to conduct a complete assessment of the risks posed by the company's genetic engineering project, including an assessment of the consequences for normal salmon if the engineered salmon established themselves in the wild.

Indeed, we now know that the FDA has subsequently given the company permission to operate a third facility. In approving this facility, the agency relied heavily on the analysis it conducted for the first two facilities, even though that analysis had not meaningfully explained what might happen if the engineered salmon were to establish themselves in the wild. Before starting the country down a road that could well lead to commercial production of genetically engineered fish on a large scale, the FDA should have developed a full understanding—and provided a full explanation—of the potential environmental consequences. The agency is ordered to go back and complete the analysis.

I

In 2015, the FDA approved an application to create and farm genetically engineered salmon submitted by a company called AquaBounty. The salmon, which the company has named "AquAdvantage," can grow to full size in roughly half the time it takes for normal salmon to mature. In approving the application, the FDA authorized AquaBounty to produce eggs at a facility on Prince Edward Island in Canada and to grow the eggs into mature fish at a facility in Panama, with the understanding that the fish would be sold as food in the United States. The approval was conditioned on the adoption of several measures designed to minimize the risk that the AquAdvantage salmon would escape into the wild, where it might mix with normal salmon. Most prominently, the FDA specified that the salmon must be created and farmed in landlocked facilities; they may not be farmed in "net pens" that connect to the ocean.

After the approval, AquaBounty got its operations up and running in Canada and Panama. Since then, AquaBounty shut down the Panama facility and submitted a supplemental application to grow the salmon at a facility in Indiana. The FDA granted this application, again with conditions designed to minimize the risk that the genetically engineered fish would escape. In approving the supplemental application, the FDA relied on and incorporated the original

approval.

The plaintiffs in this case are a coalition of advocacy and industry groups concerned with the environmental implications of the decision to approve the AquAdvantage salmon. AquaBounty has intervened to defend the approval alongside the FDA and the other government defendants. At a high level, the plaintiffs contend: (i) the FDA's authority over "drugs" does not give it the power to regulate genetically engineered animals; and (ii) even if the FDA can regulate genetically engineered animals pursuant to its drug authority, the agency unlawfully abused that authority when it approved the AquAdvantage salmon.

The Court addressed the plaintiffs' broader contention regarding the FDA's authority in a prior ruling, and the current ruling assumes the reader is familiar with the prior one. But in a nutshell, the prior ruling held that although it might initially sound strange to hear that genetically engineered animals come within the FDA's authority to regulate "drugs," it turns out that the relevant statutory definition of a "drug" is much broader than its colloquial meaning, and the process of creating and farming genetically engineered animals indeed falls squarely within the agency's authority. The claims relating to the plaintiffs' broader attack on the FDA's authority were thus resolved in favor of the defendants as a matter of law. *Institute for Fisheries v. Hahn*, 424 F.Supp.3d 740 (N.D. Cal. 2019).

What remain are the claims by which the plaintiffs challenge the FDA's particular decision to approve the AquAdvantage salmon. Although these claims are numerous, and brought under different statutes, they are all based on the assertion that the FDA failed to adequately assess the risk that the salmon would escape and survive in the wild, and the consequences that would result for the environment if this risk materialized. Technically speaking, the plaintiffs have challenged only the FDA's approval of the original application relating to the facilities on Prince Edward Island and in Panama; they have not challenged the FDA's supplemental approval for the Indiana facility. Thus, because the Panama facility has been shut down, the primary focus of this case is the Prince Edward Island facility. Nonetheless, the FDA's approval of the supplemental application relating to the Indiana facility is relevant,

because that approval builds on the original one.

At this stage, eight claims remain. Six of those claims come under the National Environmental Policy Act ("NEPA"), which requires agencies to consider the potential effect of their actions on the environment, and the Administrative Procedures Act, which instructs federal courts to set aside the actions of federal agencies that fail to comply with statutory requirements. Most prominently, Claim 2 asserts that the FDA violated NEPA by failing to take a sufficiently "hard look" at the environmental consequences of its decision to approve the AquAdvantage application. That claim is closely related to Claim 6, which alleges that in considering the application the FDA was required to prepare a more thorough environmental impact statement, rather than stopping at the less-comprehensive environmental assessment. The other four NEPA claims are simply more specific arguments about the ways in which the FDA's NEPA analysis was inadequate: that it failed to consider connected, cumulative, and interdependent actions (Claim 3); failed to adequately evaluate cumulative effects (Claim 4); failed to adequately analyze alternatives (Claim 5); and improperly relied on mitigation measures (Claim 7).

As for the two non-NEPA claims, Claim 10 alleges that the FDA violated the Endangered Species Act by failing to properly consult with two other agencies, the National Marine Fisheries Service ("NMFS") and the Fish and Wildlife Service ("FWS"), before taking an action that "may affect" a listed or endangered species—in this case, the population of wild Atlantic Salmon that lives in the Gulf of Maine. Claim 12 alleges that, aside from the environmental statutes, the Food, Drug, and Cosmetic Act ("FDCA") itself requires the FDA to consider potential environmental impacts when determining whether a drug is "safe for use" within the meaning of that statute.

II

Before turning to the individual claims, it's worth discussing a conceptual issue that runs through many of them. The plaintiffs believe that the FDA should have rejected the new drug application based on environmental concerns. But the parties have a fundamental dispute about

the extent to which the FDA even has the authority (much less the obligation) to act on those concerns. This dispute is primarily about the scope of the FDCA, which is the statute that authorizes the FDA to exercise regulatory authority over drugs. But it's also about the interplay between that statute and NEPA.

The FDCA instructs the Secretary of Health and Human Services (whose umbrella of authority includes the FDA) to approve a new animal drug application if the drug is "safe for use." 21 U.S.C. § 360b. The statute gives the word "safe" some context by stating that it "has reference to the health of man or animal." 21 U.S.C. § 321(u). When the Secretary makes a safety determination, the FDCA requires him to consider:

> among other relevant factors, (A) the probable consumption of such drug and of any substance formed in or on food because of the use of such drug, (B) the cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substance, (C) safety factors which in the opinion of experts, qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data, and (D) whether the conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably certain to be followed in practice.

21 U.S.C. § 360b(d)(2). This language suggests that the safety determination focuses singularly on the health of humans and animals, perhaps with a particular focus on those who will, by design, come directly into contact with the drug.

For its part, NEPA requires federal agencies undertaking any major action to first consider the impact that action will have on the environment. The statute serves two related purposes. First, it promotes public awareness of the environmental impacts of the actions being contemplated by agencies. Second—and more importantly—it forces the agencies themselves to consider the environmental impact of their actions, giving the agencies an opportunity to change course upon discovering that the impact would be significant. *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349 (1989).

In this litigation, the FDA has taken the narrow position that its decision whether to approve a new animal drug application must be guided by the terms of the FDCA alone. The

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