UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT *et al.*,		
Plaintiffs,	Civil Action No.:	04-0062 (RMU)
v.	Document No.:	24
MICHAEL O. LEAVITT, Secretary, U.S. Department of Health and Human Services *et al.*,		
Defendants.		

MEMORANDUM OPINION

DENYING THE PLAINTIFFS' MOTION FOR RELIEF FROM JUDGMENT

I. INTRODUCTION

This case comes before the court on the plaintiffs' motion for relief from judgment pursuant to Federal Rule of Civil Procedure 60(b)(2). The plaintiffs' suit challenges the defendants' decision not to regulate the commercialization of a genetically engineered ornamental fish ("GloFish") and the defendants' alleged failure to comply with the National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4321 *et seq.*, and the Endangered Species Act ("ESA"), 16 U.S.C. § 1531 *et seq*. On March 30, 2005, the court granted the defendants' motion to dismiss the case, and on March 8, 2006, the court denied the plaintiffs' motion to alter or amend the judgment pursuant to Federal Rule of Civil Procedure 59(e). The plaintiffs now claim to have newly discovered evidence that undermines the court's previous decisions. Because the plaintiffs lacked diligence in presenting the newly discovered evidence to the court, because some of the evidence is merely cumulative and impeaching, and because the newly discovered evidence is not of such a material and controlling nature that it will probably change the court's decision to dismiss the case, the court denies the motion.

II. BACKGROUND

A. Factual Background

The development and use of genetically engineered animals for food and ornamental purposes has become a fast-growing industry in recent years. Am. Compl. ¶ 31. Genetically engineered animals are subject to a wide array of regulatory authority. Mem. Op. (Mar. 8, 2006) ("Mem. Op.") at 1-2. Under the New Animal Drug Application ("NADA")[1] provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Food and Drug Administration ("FDA") is responsible for approving new animal drug products. 21 U.S.C. § 360b.

At least one manufacturer, Yorktown Technologies, L.P. ("Yorktown"), has developed a line of genetically engineered ornamental or pet fish which bears the trademarked name GloFish. Am. Compl. ¶ 35. The GloFish is a bright red fluorescent zebra fish that contains inserted genetic constructs from a sea coral, which cause the fish to glow under certain kinds of light. *Id*. Although GloFish are intended for use in home aquariums, the plaintiffs allege that they "could be put to other uses and readily enter the animal and human food chains through accidental or intentional releases." *Id.*

In the fall of 2003, Yorktown's CEO, Alan Blake, allegedly contacted one of the defendants, John Matheson, Program Officer at the FDA's Center for Veterinary Medicine, to ask about the FDA's views regarding GloFish. Mem. Op. at 4. In response to this inquiry, the FDA reviewed materials provided by Yorktown on its website and consulted directly with staff at

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[1] "The Food, Drug and Cosmetic Act ('FDCA') provides that any new animal drug is considered unsafe prior to receiving FDA approval for its intended use. 21 U.S.C. § 360b(a)(1)(A). To secure such approval, the FDCA requires the applicant to file a New Animal Drug Application ('NADA') that includes information demonstrating both the safety and the efficacy of the drug. *Id.* § 360b(d)(1)(A)." *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1486 (D.C. Cir. 1995).

the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture. *Id.* After considering the legal, scientific, and policy issues involved in the commercialization of GloFish, the FDA determined that regulation would be inappropriate. *Id.* Accordingly, on December 9, 2003, the FDA issued the following statement (the "GloFish Statement"):

> Because tropical aquarium fish are not used for food purposes, they pose no threat to the food supply. There is no evidence that these genetically engineered zebra danio fish pose any more threat to the environment than their unmodified counterparts which have long been widely sold in the United States. In the absence of a clear risk to the public health, the FDA finds no reason to regulate these particular fish.

Id. at 3.

The plaintiffs dispute the veracity of the GloFish statement. Pls.' Mot. to Set Aside J. Under Rule 60(b) on the Basis of Newly Discovered Evidence ("Pls.' Mot.") at 3. They dispute, in particular, the statement that the FDA's decision not to regulate the GloFish was based on its consideration of the public health and scientific evidence. The plaintiffs contend that 14 items of "newly discovered evidence" demonstrate that the FDA decided not to regulate the GloFish because it mistakenly believed it did not have regulatory jurisdiction over the fish. *Id.*

B. Procedural History

On March 4, 2004, the plaintiffs, seeking declaratory and injunctive relief, filed an amended complaint. The amended complaint makes the claims that the FDA: (1) arbitrarily and capriciously distinguished between food and non-food uses in the GloFish Statement; (2) failed to review Yorktown's request for approval of the GloFish under the statutorily-prescribed standards; (3) failed to prepare an environmental impact statement ("EIS") or an environmental assessment prior to allowing the proposed commercialization of GloFish, in violation of NEPA; (4) failed to prepare an EIS or an environmental assessment with respect to genetically

engineered ornamental fish, and other genetically engineered animals generally, in violation of NEPA; (5) failed to prepare a biological assessment and failed to consult with the Fish and Wildlife Service ("FWS") before allowing the proposed commercialization of GloFish, in violation of the ESA; and (6) violated the ESA through its actions with respect to genetically engineered ornamental fish and other genetically engineered animals generally. Am. Compl. ¶¶ 56-79.

On April 19, 2004, the defendants responded to the complaint by filing a motion to dismiss. On March 30, 2005, the court granted the defendants' motion to dismiss. The court dismissed the first two claims (the "NADA claims") because the plaintiffs failed to establish subject-matter jurisdiction. The court reasoned that the FDA's decision not to regulate GloFish is committed to the agency's discretion and that, absent evidence that this was a case "where the agency refuses to institute proceedings solely based on the belief that it lacked jurisdiction," the FDA's actions were not subject to judicial review. Mem. Op. (Mar. 30, 2005) at 17-25. The court dismissed the third and fourth claims (the "NEPA claims") because the FDA had not taken a major federal action as required by NEPA. *Id.* at 25-29. Finally, the court dismissed the fifth and sixth claims (the "ESA claims") because the FDA had not engaged in agency action as required by the ESA. *Id.* at 29-32.

After the court dismissed the plaintiffs' complaint, the plaintiffs filed a motion to alter or amend the court's judgment pursuant to Rule 59(e). In that motion, the plaintiffs reiterated their arguments that the FDA had failed to regulate the GloFish solely on the mistaken belief that it did not have jurisdiction to regulate the commercialization of the fish. The court denied the motion on March 8, 2006 because the plaintiffs merely reiterated their previous arguments

without presenting any new evidence to undermine the court's conclusion that it lacked subject-matter jurisdiction over the case.

The plaintiffs now move, on the basis of Rule 60(b)(2), for relief from the March 30, 2005 order dismissing their case. The motion for relief from the March 30, 2005 order limits its challenges to the court's decision to dismiss claims 1, 2, 3, and 5. The court now turns to the plaintiffs' motion.

III. ANALYSIS

A. Legal Standard for Relief Under Federal Rule of Civil Procedure 60(b)

In its discretion, the court may relieve a party from an otherwise final judgment pursuant to any one of six reasons set forth in Rule 60(b). FED. R. CIV. P. 60(b); *Lepkowski v. Dep't of Treasury*, 804 F.2d 1310, 1311-12 (D.C. Cir. 1986). First, the court may grant relief from a judgment involving "mistake, inadvertence, surprise, or excusable neglect." FED. R. CIV. P. 60(b). Such relief under Rule 60(b) turns on equitable factors, notably whether any neglect was excusable. *Pioneer Inv. Servs. Co. v. Brunswick Ass'n Ltd. P'ship*, 507 U.S. 380, 392 (1993). Second, the court may grant relief where there is "newly discovered evidence" that the moving party could not have discovered through its exercise of due diligence. FED. R. CIV. P. 60(b). Third, the court may set aside a final judgment for fraud, misrepresentation, or other misconduct by an adverse party. *Id.*; *Mayfair Extension, Inc. v. Magee*, 241 F.2d 453, 454 (D.C. Cir. 1957). Specifically, the movant must show that "such 'fraud' prevented him from fully and fairly presenting his case," and that "the fraud is attributable to the party or, at least, to counsel." *Richardson v. Nat'l R.R. Passenger Corp.*, 150 F.R.D. 1, 7 (D.D.C. 1993) (Sporkin, J.) (citations omitted). Fourth, the court may grant relief where the judgment is "void." FED. R. CIV. P. 60(b).

A judgment may be void if the court lacked personal or subject-matter jurisdiction in the case, acted in a manner inconsistent with due process, or proceeded beyond the powers granted to it by law. *Eberhardt v. Integrated Design & Constr., Inc.,* 167 F.3d 861, 871 (4th Cir. 1999). Fifth, the court may grant relief if the "judgment has been satisfied, released, or discharged, or a prior judgment upon which it is based has been reversed . . . or it is no longer equitable that the judgment should have prospective application." FED. R. CIV. P. 60(b); *Twelve John Does v. District of Columbia*, 841 F.2d 1133, 1138 (D.C. Cir. 1988) (noting that not all judgments having continuing consequences are "prospective" for the purposes of Rule 60(b)). Sixth, the court may grant relief from a judgment for "any . . . reason justifying [such] relief." FED. R. CIV. P. 60(b). Using this final catch-all reason sparingly, courts apply it only in "extraordinary circumstances." *Pioneer Inv. Servs.*, 507 U.S. at 393.

A party proceeding under one of the first three reasons must file his Rule 60(b) motion within one year after the judgment at issue. FED. R. CIV. P. 60(b). A party relying on one of the remaining three reasons may file his Rule 60(b) motion within a reasonable time. *Id*. The party seeking relief from a judgment bears the burden of demonstrating that he satisfies the prerequisites for such relief. *McCurry ex rel. Turner v. Adventist Health Sys./Sunbelt, Inc.*, 298 F.3d 586, 592 (6th Cir. 2002).

B. The Plaintiffs' Rule 60(b) Motion is Timely

As a preliminary matter, the court must determine whether the plaintiffs' Rule 60(b)(2) motion is timely. A motion for relief from judgment on the basis of new evidence must be filed "not more than one year after the judgment, order, or proceeding was entered or taken." FED. R. CIV. P. 60(b). Rule 60(b)'s one-year time limit "is not judicially extendable," *Carr v. District of*

Columbia, 543 F.2d 917, 926 (D.C. Cir. 1976), and a district court does not have jurisdiction to consider an untimely Rule 60(b) motion, *United States v. Deutsch*, 981 F.2d 299, 302 (7th Cir. 1992).

The defendants argue that the plaintiffs' motion is time-barred because the plaintiffs filed it on April 14, 2006, more than one year after the court's March 30, 2005 dismissal of the complaint. Defs.' Opp'n at 3. The plaintiffs argue that the court's March 30, 3005 order dismissing their complaint for lack of subject-matter jurisdiction did not become a final order triggering Rule 60(b)'s one-year time requirement until the court ruled on their Rule 59(e) motion on March 8, 2006. That is, the plaintiffs contend that the one-year time limit for filing a Rule 60(b) motion was "suspended" while the court considered their timely-filed Rule 59(e) motion to alter or amend the judgment. Pls.' Mot. at 9 n.1. The defendants dispute the plaintiffs' analysis of the interplay between Rules 59(e) and 60(b), arguing that "the suspension of finality under Rule 59(e) concerns the running of time for an appeal." Defs.' Opp'n at 4.

The defendant is correct in that cases analyzing the effect of a Rule 59(e) motion on the finality of a judgment generally focus on the effect that such a motion has on the running of the period in which an appeal may be filed. *See*, *e.g.*, *Stone v. INS*, 514 U.S. 386, 402-403 (1995) (explaining that a Rule 59(e) motion "toll[s] the running of the time for appeal); *Miltmore Sales, Inc. v. Int'l Rectifier, Inc.*, 412 F.3d 685, 688 (6th Cir. 2005); *Weyant v. Okst*, 198 F.3d 311, 314-315 (2d Cir. 1999). That said, the Advisory Committee Notes to Rule 59 state that a motion brought under that rule "affect[s] the finality of the judgment." FED. R. CIV. P. 59 Advisory Comm. Notes. The Advisory Committee Notes, however, do not state that a Rule 59 motion only affects the finality of a judgment for purposes of filing an appeal. Additionally, some cases

that discuss the effect of a Rule 59(e) motion on the finality of a judgment do not limit that discussion to the implications of such a motion on the appellate timeline. *See*, *e.g.*, *Derrington-Bey v. D.C. Dep't of Corr.*, 39 F.3d 1224, 1225 (D.C. Cir. 1995) (stating that the time limit for filing a Rule 59(e) motion "is to be kept short presumably because a timely Rule 59(e) motion deprives the judgment of finality"); *Weyant*, 198 F.3d at 315 (stating that the 14-day period established by Rule 54(d)(2)(B) for the filing of a motion for attorneys' fees begins to run after resolution of a Rule 59 motion); *Piper v. Dep't of Justice*, 312 F. Supp. 2d 17, 21 (D.D.C. 2004); 12 FED. PRAC. 3d § 59.12. In other words, the suspension of finality on the basis of a timely-filed Rule 59(e) motion is not only applicable to an appeal. Accordingly, the court concludes that a timely filed Rule 59(e) motion suspends the finality of a judgment not just at the appellate level, but at the district court level as well.

The court dismissed the complaint on March 30, 2005, and ten days later, on April 13, 2005, the plaintiffs filed their Rule 59(e) motion. Because the plaintiffs filed a timely 59(e) motion, the court's March 30, 2005 order was not final. The court's March 30, 2005 order did not become final until March 8, 2006, when the court ruled denied the Rule 59(e) motion. *Weyant*, 198 F.3d at 315 (explaining that "[a] judgment's finality is restored upon the resolution of the last of any postjudgment motions that operated to suspend finality"); *see also Miltmore Sales, Inc.*, 412 F.3d at 688. On April 14, 2006, less than one year after the court's order dismissing the complaint became final, the plaintiffs filed the instant Rule 60(b) motion. Because the Rule 60(b) motion was filed within one year of the order dismissing the case, the motion is not time-barred.

C. The Court Denies the Plaintiffs' Rule 60(b) Motion

Having concluded that the plaintiffs' motion for relief from judgment is not time-barred, the court next turns to the merits of the motion. The plaintiffs seek relief from the order dismissing the first, second, third, and fifth claims of their complaint, alleging that the newly discovered evidence undermines the court's analysis in its March 30, 2005 and March 8, 2006 memorandum opinions. Pls.' Mot. at 4. The first, second, third, and fifth claims allege that the FDA: (1) arbitrarily and capriciously distinguished between food and non-food uses in the GloFish Statement (claim 1); (2) failed to review Yorktown's request for approval of the GloFish under the statutorily-prescribed standards (claim 2); (3) failed to prepare an EIS or an environmental assessment prior to allowing the proposed commercialization of GloFish, in violation of NEPA (claim 3); and (4) failed to prepare a biological assessment and failed to consult with the FWS before allowing the proposed commercialization of GloFish, in violation of the ESA (claim 5).[2] *Id.*

Federal Rule of Civil Procedure 60(b)(2) provides, in relevant part, that a court may relieve a party of a final judgment or order on the basis of "newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial." FED. R. CIV. P. 60(b)(2). For newly discovered evidence to meet the requirements of Rule 60(b)(2), the evidence: (1) must have been in existence at the time of the disputed judgment; (2) "could not by the exercise of due diligence have been discovered in time to present it in the original

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[2] The plaintiffs do not challenge the court's ruling that the FDA failed to prepare an EIS or an environmental assessment with respect to genetically engineered ornamental fish and other genetically engineered animals generally, in violation of NEPA (claim 4) and that the FDA violated the ESA through its actions with respect to genetically engineered ornamental fish and other genetically engineered animals generally (claim 5). Pls.' Mot. at 4.

proceeding;" (3) "must not be merely cumulative or impeaching;" and (4) "must be admissible and credible, and of such a material and controlling nature as will probably change the outcome." *Lans v. Gateway 2000, Inc.*, 110 F. Supp. 2d 1, 4 (D.D.C. 2000). *See also* 12 FED. PRAC. 3d § 60.42[2]. The court analyzes these factors below and concludes that the evidence does not meet the requirements of Rule 60(b)(2).[3]

(1) The Plaintiffs Did Not Exercise Due Diligence

The second prong of the Rule 60(b)(2) requires that the moving party must demonstrate "that the failure to produce the newly discovered evidence did not result from a lack of diligence in his part, and that the evidence could not by the exercise of due diligence have been discovered in time to present it in the original proceeding." *Id.* at 5-6. This inquiry "looks not to what the litigant actually discovered, but to what he or she *could* have discovered." 12 FED. PRAC. 3d § 60.42[5] (emphasis in original); *see also Lans*, 110 F. Supp. 2d 6 (quoting 12 FED. PRAC. 3d § 60.42[5]).

In this case, the plaintiffs introduce 14 new items of evidence (labeled New Records A - N). New Record A and New Record C consist of published articles. Pls.' Mot. at 11. Publicly available information cannot constitute newly discovered evidence. *Scutieri v. Paige*, 808 F.2d 785, 794 (11th Cir. 1987); *Music Research, Inc. v. Vanguard Recording Soc'y, Inc.*, 547 F.2d 192, 196 (2d Cir. 1976). Further, although the plaintiffs argue that the articles' "prior existence is irrelevant to [their] due diligence," the plaintiffs fail to explain why those articles were not presented to the court during the original round of dispositive motions.

With respect to the remaining 12 new pieces of evidence, the plaintiffs make much of the

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[3] The parties do not dispute the first prong of the Rule 60(b)(2) test. Defs.' Opp'n at 5.

fact that they did not have the evidence at their disposal during the court's consideration of the defendants' motion to dismiss. In particular, the plaintiffs argue that they did not have the evidence because of the defendants' failure to process their FOIA request for the documents in an expeditious manner.[4] Pls.' Mot. at 7 (stating that "the FOIA response was not delivered for *two years*") (emphasis in original). The plaintiffs, however, received the defendants' response to the FOIA request on December 5, 2005, yet they neglected to present the information to the court until they filed the instant motion on April 14, 2006.[5] Considering that the FOIA materials consist of only 266 pages, a four and a half month delay in presenting the evidence to the court hardly constitutes due diligence.

(2) The New Evidence is Merely Cumulative and Impeaching

The plaintiffs' new evidence also fails to meet the third prong of the Rule 60(b)(2) test. "[N]ewly-discovered evidence will not support a motion for relief from judgment if it merely tends to impeach the credibility of a witness rather than provide substantive evidence concerning a material issue of fact." 12 FED. PRAC. 3d § 60.42[8]. In the instant case, some of the plaintiffs' new evidence is only used to impeach the credibility of the defendants' affiant, Matheson. Pls.' Mot. at 12-13 (stating that New Records E, H, I, J, and K contradict Matheson's declaration). Additionally, New Records E, H, I, and J do not provide substantive evidence regarding the court's conclusion that it lacked jurisdiction to review the FDA's decision not to regulate the

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[4] The court notes that the plaintiffs have not litigated the status of the defendants' FOIA compliance. Additionally, it is possible that the processing of the plaintiffs' FOIA request may have been delayed because they asked for a fee waiver request. In support of that request, the plaintiffs stated that they were making the FOIA request for the purposes of "education and other public interest activities," not that they needed the documents for an imminent litigation. Defs.' Opp'n at 5.

[5] The plaintiffs state that it would have been inappropriate to present the new evidence while their Rule 59(e) motion was pending. The plaintiffs cite no support for this proposition, nor has the court found any.

GloFish. That is, these records do not demonstrate that this is a case in which the FDA failed to regulate GloFish on the basis of a mistaken belief that it did not have regulatory jurisdiction. At most, these records show that Matheson made a mistake regarding dates in his declaration, and that Yorktown's CEO thought an individual at the FDA told him the FDA did not regulate ornamental fish. None of these records, however, contradict the court's conclusion that the FDA had decided not to regulate GloFish after determining that regulation was inappropriate.

(3) The New Evidence is Not of Such a Material and Controlling Nature as Will Probably Change the Outcome

The court also concludes that the new evidence does not satisfy the fourth prong of the Rule 60(b)(2) test. Namely, the new evidence is not "of such a material and controlling nature as will probably change the outcome." *Lans*, 110 F. Supp. 2d at 4. First, the evidence only relates to the plaintiffs' first claim, and is not relevant to second, third, and fifth claims. The plaintiffs' first claim is that the FDA arbitrarily and capriciously denied regulatory jurisdiction over GloFish. Mem. Op. at 5. The court dismissed the plaintiffs' first claim because an agency's decision not to prosecute or enforce "presumptively lies beyond the reach of the APA." Mem. Op. (Mar. 30, 2005) at 21. Although such a presumption may be overcome when an agency's decision is "based solely on the [mistaken] belief that it lacks jurisdiction," *id.* at 22, the plaintiffs in this case failed to present any evidence that the FDA failed to regulate the sale of GloFish on this basis. Mem. Op. at 6. The plaintiffs now allege that the newly discovered evidence shows that the FDA "refused to institute proceedings based solely on the belief that it lacked jurisdiction." Pl.'s Mot. at 3.

Assuming for the moment that the plaintiffs' interpretation of the new evidence is accurate, the new evidence fails to address the court's reasons for dismissing claims 2, 3, and 5.

The court dismissed the second claim because the plaintiffs failed to show that Yorktown submitted a NADA and because the FDA has the discretion to decline to take any enforcement action once a NADA is approved. Mem. Op. at 7-8. The court dismissed the third and fifth claims because the FDA's refusal to regulate GloFish does not constitute a "major federal action" that triggers NEPA compliance, or an "agency action," triggering ESA compliance. *Id.* at 10, 13. Because the new evidence does not relate to the court's reasoning with respect to claims 2, 3, and 5, it is unlikely to change the court's decision to dismiss those claims.

Second, the new evidence does not alter the court's decision to dismiss claim 1 on the basis that this is not a case where the FDA refused to regulate GloFish based solely on the belief that it lacks jurisdiction over them. None of the new items of evidence shows that the FDA ever claimed to lack jurisdiction to regulate the GloFish. At most, the new evidence shows that the FDA was, for some time, undecided on the issue of whether to regulate GloFish (not on the issue of whether it could regulate GloFish)[6] and that Yorktown (not the FDA) stated that the FDA claimed it lacked regulatory jurisdiction over GloFish.[7] The court therefore concludes that it is unlikely that the new evidence would have changed its decision to grant the defendants' motion to dismiss the first claim due to a lack of subject-matter jurisdiction.

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[6] *See*, *e.g.*, New Record B (stating that there were many opinions on whether to regulate GloFish), New Record D (asking for feedback on how to address industry concerns over regulatory jurisdiction), New Record G (stating, in a December 5, 2003 e-mail, that the FDA had not yet "reached a final decision re how and under what circumstances [it] might regulate transgenic animals"); New Record K (stating "we're working on the FDA position").

[7] *See*, *e.g.*, New Records E and F (indicating that Yorktown was aware that the FDA was considering regulating GloFish); New Record L (noting that the FDA was not aware of having told Yorktown that it lacked regulatory jurisdiction over GloFish); New Record M (stating that a reporter was "shopping for a story" with respect to GloFish).

IV. CONCLUSION

For the foregoing reasons, the court denies the plaintiffs' motion for relief from judgment. An order consistent with this Memorandum Opinion is separately and contemporaneously issued this 8th day of January, 2007.

RICARDO M. URBINA
United States District Judge