

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DR. MARK GEIER, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 05-1749 (RWR)
)	
)	
DEPARTMENT OF HEALTH AND)	
HUMAN SERVICES, <i>et al.</i> ,)	
)	
Defendants.)	

**FEDERAL DEFENDANTS’ REPLY MEMORANDUM
IN SUPPORT OF MOTION TO DISMISS**

This case borders on the frivolous. Four scientists published a scientific article in a peer-reviewed journal, Pediatrics, reviewing and critiquing several other studies (the “Article”). Among the numerous criticisms of the numerous studies, Plaintiffs focus on probably the most innocuous of the criticisms--that the Plaintiffs’ studies did not explain where they obtained data which Defendants understood to be unobtainable from the Centers for Disease Control and Prevention (“CDC”). Plaintiffs cannot bring a defamation action--and even if they could the Article comes nowhere near being considered defamatory. Rather, they are attempting to claim, through claims based on the Administrative Procedure Act (“APA”) and Bivens, that the government is conspiring to ruin their careers by accusing them of fraud. The simple fact is that the Article speaks for itself and the Defendants did nothing improper, much less actionable. Consequently, Plaintiffs’ APA and Bivens claims should be dismissed.

DISCUSSION

I. Plaintiff's Opposition is Untimely and Further Evidence of Failure to Prosecute.

1. As an initial matter, the Plaintiffs have not actively prosecuted this case. As explained at length in the Federal Defendants' Response to Plaintiffs' Motion for an Emergency Stay of Further Proceedings, docket entry no. [34], Plaintiffs moved the Court for a deadline of December 21, 2005, to file any opposition to the federal Defendants' motion to dismiss, no. [10], and the Court granted the motion. Apparently due to a typo in Plaintiffs' motion, no. [11], the Court's minute order dated December 16, 2005, gave a deadline of December 21, 2006, but the 2006 deadline made no sense at all in the context of the case, including for example the fact that the same minute order gave federal Defendants until January 15, 2006, for their reply.

There the matter stood for several weeks, with plaintiffs failing to file anything in response to the federal defendants' motion to dismiss. Undersigned counsel brought the matter to the attention of Plaintiffs' counsel in early March 2006, but still Plaintiffs did nothing. On March 14, 2006, the Court dismissed the American Academy of Pediatrics ("AAP") (publisher of Pediatrics) based on plaintiffs' failure to oppose the AAP's motion to dismiss. On March 16, 2006, undersigned counsel sent an email to plaintiffs counsel, explaining, *inter alia*, that the federal defendants intended to file a motion to dismiss for failure to prosecute. On March 17, 2006, Plaintiffs moved for an emergency stay pending their replacement of their "lead" counsel.

On Monday, March 20, 2006, the federal Defendants filed a response to the motion for an emergency stay, and on March 21, 2006, Plaintiffs filed via ECF an opposition to the federal Defendants motion to dismiss, docket entry no. [33]. This opposition appears to have been signed by the "lead" counsel whose various (and undisputed) problems supported Plaintiffs'

motion for an emergency stay. Nothing in the opposition itself, its ECF entry or the docket sheet indicates whether Plaintiffs sought or obtained leave to file their opposition.

Because the Court already dismissed the AAP based on Plaintiffs' failure to file a timely opposition to the motion to dismiss,¹ the federal Defendants ask for the same treatment of their motion to dismiss. Indeed, Plaintiffs went even longer without responding to the federal Defendants' motion to dismiss than they did for AAP's motion: Plaintiffs were two and a half months overdue in opposing AAP's motion when the Court dismissed AAP, but Plaintiffs waited three months past the deadline to file their opposition to the federal Defendants' motion to dismiss. If anything, the equities favor giving Plaintiffs more latitude in responding to the claims against the AAP because it published the Article and it is not a governmental entity protected by sovereign immunity defenses. Therefore, the federal Defendants respectfully request that the Court strike the Plaintiffs' opposition as either untimely, or inconsistent with their explanations in their motion for an emergency stay, and grant federal Defendants' motion as conceded.

II. Plaintiff's Factual Claims about the Article Are Baseless.

As for the legal arguments, the first point to be made is that the Article speaks for itself and, therefore, the Plaintiffs' counsel's various re-characterizations of the language in the key paragraph therein deserve no deference or assumption of validity by the Court. The language of that paragraph is as follows:

Substantial questions regarding the accuracy of the denominator data for the incidence

¹ See docket entries nos. [17] (motion to dismiss), [27] (Plaintiffs' final motion for extension with respect to AAP), [28] (AAP's request to treat its motion to dismiss as conceded), and [29] (dismissal order).

calculation also exist. . . . The authors indicated the source of these data as the “Biological Surveillance Summaries of the CDC.” However, CDC reports only aggregate doses distributed for DTaP and other vaccines and provides no manufacturer-specific data. [footnote: “Zhou W, Pool V, Iskander JK, et al., Surveillance for safety after immunization: Vaccine Adverse Event Reportign System (VAERS)--United States, 1991-2001, *MMWR Surveill. Summ.* 2003; 52: 1-24.] It is unclear how the authors estimated manufacturer-specific data because, on the basis of agreements with manufacturers, DCD does not release these data. No source is cited in the publication. The authors provided no details on how total DTaP doses distributed were translated into the number of children vaccinated with specific thimerosal-containing or thimerosal-free vaccines, which is particularly problematic for a vaccine administered in a 5-dose schedule over a 4- to 5-year period.

Article at 796. Nowhere does the Article use any of the phrases that Plaintiffs’ counsel uses to describe the language, e.g. “falsified key data,” Plf. Opp. at 23, “committed science fraud,” *id.* at 10, or “scientific misconduct,” *id.* at 33. Instead, the Article merely describes the language of the Geiers’ own articles, and notes that these previous articles do not explain where the Geiers obtained their manufacturer-specific data. If the Geiers contested the accuracy of this description of their prior work, then the Article’s authors may well have come a good deal closer to having done something improper, but the Geiers make no such claim. (In any event, the language of the Geiers’ prior articles speaks for itself also.) Therefore, the Court should flatly reject the attempt by Plaintiffs’ counsel to argue that the Court must assume as true their allegation that the authors of the Article accused Plaintiffs of “fraud” or “misconduct.” Instead, the Court should look to the words of the Article themselves for the factual basis of this case.

Moreover, the Article demonstrates the relatively minor aspect of the paragraph at issue in this case, by explaining the numerous other critiques of the Geiers’ prior studies (and those of other researchers), most of which appear more substantial and fill up far more space in the Article. For one thing, the Article explains that its purpose was to review the literature on the

connection, if any, between autism in children and the use of mercury-containing thimerosal in various vaccinations. The Article explains that the “gold standard” of research is studies done on the basis of clinical trials, using randomized, controlled comparisons between groups with and without the agent at issue. See Article at 794. Such research poses numerous obvious obstacles in the context of an “existing vaccination program,” however, so the link under consideration (i.e. between autism and thimerosal in vaccines) can be evaluated, albeit not as accurately, via epidemiological studies, which are essentially statistical studies that attempt to test many different possible contributing factors by looking for statistically valid correlations. Id. The Article then reviewed several sources of bias, e.g. reporting bias and diagnostic bias, in the twelve studies they considered, of which only about half were done by the Plaintiffs. Id. at 795-99. The vast majority of the Article’s analysis consists of explaining the numerous and weighty reasons why the twelve epidemiological studies contain various flaws that should prevent the scientific community from using those studies to conclude that there is a demonstrable link between autism and thimerosal. It should go without saying that this sort of criticism of other scientific studies is the life-blood of medical research and the advancement of scientific knowledge.

The particular flaw at issue here--the Geiers’ failure to explain the source of the manufacturer-specific data--does not appear to have carried sufficient weight within the Article to have been repeated or referenced anywhere else in the Article, such as the introduction or conclusion. It is also notable that the Geiers do not contest or challenge any of these numerous other criticisms leveled at their prior articles by the authors of the Article.

Thus, within this fuller context, it is easier to understand the minor import of the

paragraph at issue in this case. The paragraph merely does two things: (1) explains what the Geiers themselves wrote or did not write in their prior articles, i.e. how they obtained manufacturer-specific data; and (2) that the authors understood that CDC policy precluded release of manufacturer-specific information. There is no dispute about the factual accuracy of the first part--the Geiers' articles did not explain how they overcame the HHS general prohibition against release of such information.

Therefore, the entire allegation of "misconduct" and "fraud" arises from the sentence explaining the authors' understanding of the CDC policy. To support the sentence, the authors inserted a footnote that cited another privately published article, not the CDC policy itself. The Geiers do not allege that the authors actually knew the CDC policy to be otherwise, only that they should have known how the Geiers obtained the data simply because two of the authors work for the CDC. Indeed, the record is already clear that the authors sent a correction to Pediatrics within a few weeks after the Article, explaining that even though they were correct about that CDC policy, they did not know that the manufacturer-specific data had in fact been released to the Geiers. See Fed. Def. Mot. Dismiss, Ex. 4, no. [10-4]. Thus, the Geiers' entire complaint--that the authors accused them of "fraud"--reduces to the authors explaining that the printed words of the Geiers' prior articles did not explain how the Geiers got data which the authors did not understand to be available, and where the authors did not purport to rely on any inside government information in explaining their understanding of the CDC policy, and where the authors promptly submitted a correction, generously "regret[ting] the error." This is a small claim indeed, one hardly worthy of the federal courts' time to adjudicate.

III. Plaintiffs' APA Claims Fail.

A. There Was No Final Agency Action.

Plaintiffs cannot demonstrate the requisite legal consequences flowing from the actions of the federal Defendants to support the necessary element of “final agency action” under the APA. The dicta from the cases Plaintiffs cite cannot overcome the holdings and facts of those cases. For example, in Invention Submission Corp. v. Rogan, 357 F.3d 452, 457 (4th Cir. 2004), the advertising at issue did not create “legal consequences” for plaintiffs:

If the PTO's advertising made business more difficult for Invention Submission by raising the public's awareness, the decisions of members of the public “are attributable to independent responses and choices of third parties” and cannot be imputed to the PTO for purposes of determining whether its conduct was a final agency action. *See* [Flue-Cured Tobacco, 313 F.3d] at 861.

Id. at 460. This is precisely analogous to this case because the Geiers themselves allege in their complaint that their work as expert witnesses depended on the private parties who actually appear as litigants making the decision to hire them on a contractual basis. See Compl. ¶ 19.

Similarly, in Industrial Safety Equipment Assoc., Inc. v. EPA, 837 F.2d 1115 (D.C. Cir. 1988), the government report at issue recommended use of only a few of the various kinds of government-certified asbestos protection respirators and thus came far closer to constituting the final, official pronouncement of the agency, but the D.C. Circuit still held that it was not final agency action reviewable under the APA.

B. Many of the Decisions Complained of Were Made By Non-governmental Entities or Other Agencies Not Named as Defendants.

In this case, many of the relevant decisions that might conceivably be considered agency action were not made by the federal agency being sued. The decision to publish the Article was

made by the non-federal publisher of Pediatrics, the AAP, as was the decision to publish the correction and how much prominence to give the correction. The decisions by the various litigants not to hire the Geiers as expert witnesses are obviously not made by either the federal Defendants or any part of the federal government. See Compl. ¶ 19. The decisions about how the government defends the civil actions against the CDC and HHS are made by the Department of Justice, pursuant to its litigation authority, see 28 U.S.C. § 516, because the CDC and HHS do not have independent litigating authority.

C. No Agency Action in Actions by Subordinate Officials.

Plaintiffs have no response to the federal Defendants' argument that there can be no final agency action because the federal Defendants were not the heads of their respective agencies but were in fact subordinate officials and nothing in the Article purported that full weight of the CDC or any other federal agency viewed the Article as an official policy statement or anything akin to a precedent letter or legal opinion, or that the Article had gone through any sort of agency decision-making process. Cf. Industrial Safety.

D. No Substantive Standard by which to Judge Agency's Action.

Plaintiffs cannot identify any substantive standard by which to judge whether the agency action (whatever it was) was arbitrary and capricious. First, none of the statutes that authorize HHS officials to write and publish articles contain any substantive limitations or conditions on what sort of articles may be written, or what procedures they must follow prior to going out with a scientific article. See 42 U.S.C. § 241 (Public Health Service Act).

Second, even if it were somehow proper to import the common law of defamation into an APA analysis, the Article cannot be seen as defamatory, as Plaintiffs repeatedly imply, because

such a claim based on the established publication would easily fail to state a claim under D.C.

law. To state a claim of defamation under the law of D.C., a complaint must allege:

- (1) that the defendant made a *false and defamatory* statement concerning the plaintiff;
- (2) that the defendant published the statement without privilege to a third party;
- (3) that the defendant's fault in publishing the statement amounted to at least negligence;
- and
- (4) that either the statement was actionable as a matter of law irrespective of special harm or its publication *caused* the plaintiff special harm.

Benic v. Reuters America, Inc., 357 F. Supp. 2d 216, 220-21 (D.D.C. 2004) (citing Klayman v. Segal, 783 A.2d 607, 613 n.4 (D.C. 2001)) (emphasis added). See also Beeton v. District of Columbia, 779 A.2d 918, 923 (D.C. 2001). To satisfy the first element, Plaintiffs must allege facts sufficient to show that the Article made them appear “odious, infamous, or ridiculous.” Howard Univ. v. Best, 484 A.2d 958, 989 (D.C. 2001). The statements “must be more than unpleasant or offensive” to qualify as defamatory. Id. In Benic, the court rejected an employee’s allegations that his employer’s published statements regarding the employee’s departure would lead some to think that the employee had been fired or had done something wrong, because the employee’s allegations could not be characterized as “odious, infamous, or ridiculous.” 357 F. Supp. 2d at 222-23 & n.4. Here, even assuming for the sake of argument that the Article “accused” the Geiers of doing something wrong, that would not suffice to constitute a “defamatory” statement under D.C. law. See id. (clarifying that a statement implying that the plaintiff employee was guilty of a crime might be considered defamatory).

In addition, Plaintiff’s complaint fails to allege facts sufficient to meet the fourth element of a defamation claim--causation. The alleged harm of being shut out of work as expert witnesses, which Plaintiffs attribute to the work of DOJ lawyers arguing on behalf of HHS, fails

in light of the published decision of the Court of Federal Claims (dated October 9, 2003), which expressly disqualifies Dr. Geier as an expert witness and expressly finds it “doubtful that Dr. Geier fulfills the American Medical Association (AMA) guidelines for expert witnesses.” See Fed. Def. Mot. Dismiss, Ex. 5, docket entry no. [10-5]. This order predated the Article’s publication (September 2004) by over a year.

Nor do Plaintiffs meet the standards for the sort of APA claim permitted in Industrial Safety. First, there is no evidence or factual allegation that the agency was “intent on penalizing” Plaintiffs. Second, the Article was not “demonstrably false” because the literal language is correct. At worst, the language in the key paragraph might arguably be deemed incomplete (though even that label does not square with footnote 49 in the Article which explains the basis of the authors’ knowledge of the CDC policy). The CDC generally does not release manufacturer-specific data, but the authors were unaware, at the time the Article was published, that the Geiers had nonetheless managed to obtain the data from the CDC.

E. There is No Authority in the APA for Plaintiffs’ Requested Remedy.

In addition, Plaintiffs cannot identify any plausible remedy under the APA, which authorizes the courts to set aside agency actions and remand the matters back to the agency for further actions. See, e.g., Florida Power & Light Co. v. Lorion, 470 U.S. 729, 744 (1985); Cellco Partnership v. FCC, 357 F.3d 88, 98 (D.C. Cir. 2004). Of course, Plaintiffs cannot and do not ask the Court to set aside publication of the Article for that would be moot, just as any similar order regarding the correction. Remand to the agency for further consideration begs the question of what the agency is supposed to consider and under what standards. Requiring the agency to take further actions, such as taking different positions in the vaccine litigation runs far beyond

what is authorized by the APA and, in any event, names the wrong agency as defendant since it is DOJ that decides how to defend the HHS in court.

IV. Plaintiffs' Bivens Claims Fail.

A. No Violation of Any Right to Reputation.

Plaintiffs' Bivens claim fares no better than their APA claim. First, the effect, if any, on the Geiers' employability as expert witnesses is far more attenuated here than that in the "reputation plus" cases cited by the Geiers. This is evident both by the facts as alleged in the complaint, and is bolstered by the judicial notice of the Weiss decision and its issuance well before publication of the Article. See Ex. 5 to Fed. Def. Mot. Dismiss (listing numerous cases in which Geiers' testimony has been given no weight).

B. Schwartz and Pickering are Protected by Qualified Immunity.

Moreover, the federal Defendants are clearly entitled to qualified immunity because there is no basis to find that they should have known they were committing either a constitutional violation or even defamation. First, the Article was not defamatory, nor was it even factually incorrect, much less so far beyond the norm of scientific publishing that the federal Defendants should have known they were violating Plaintiffs' constitutional rights. Thus, even if the cases cited by Plaintiffs regarding a liberty interest in "follow[ing] a chosen profession," Plfs. Opp. Fed. Mot. Dismiss at 27, included working on a case-by-case contractual basis as an expert witness, the simple fact remains that the authors did not defame or otherwise interfere with the Geiers' constitutional rights. Plaintiffs also cite various agency debarment cases that simply do not apply here for the evident reason that such proceedings undoubtedly constitute final agency action and so should (and do) provide for due process protections.

Moreover, Plaintiffs do not question that the federal Defendants took the steps they describe in the correction. They merely question whether that was enough. It certainly is enough--more than enough--to qualify them for qualified immunity. If not, the clear implication is that the federal Defendants were constitutionally obliged to consult with the Geiers prior to publishing the Article, in which they correctly state what the Geiers' prior articles contained (and did not contain) and correctly recite their understanding of the CDC policy regarding release of manufacturer-specific data and the basis for that understanding.

C. There is No Constitutional Right to Appear as an Expert Witness.

The Geiers also cannot overcome the simple fact that all of the First Amendment cases they cite regarding the right of access to the courts apply only to potential litigants--that is, the right of access to the courts is the right to sue and have one's rights vindicated. Expert witnesses have no constitutional right under the First Amendment to be called to testify on behalf of other litigants. Alternatively, the Geiers have no standing if, as they now assert, "they are vindicating the rights of the underlying claimants to have the Geiers as expert witnesses," *id.* at 41. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 559-62 (1992).

CONCLUSION

For all of the reasons set forth above, the United States respectfully requests that Plaintiffs' complaint against HHS and the PHS defendants be dismissed for lack of subject matter jurisdiction and/or failure to state a claim.

April 13, 2006

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that I caused a copy of Federal Defendants' Reply in Support of Motion to Dismiss to be served by first class mail on:

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