UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PAUL G. KING, *et al.*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 06-1357 (EGS)
MICHAEL O. LEAVITT, Secretary of Health and Human Services, *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION

Plaintiffs, several individuals and one advocacy organization, the Coalition For Mercury-Free Drugs, filed a citizen petition with the Food and Drug Administration ("FDA"), requesting that FDA take numerous measures relating to the use of thimerosal and other mercury compounds in vaccines and other products regulated by FDA, including revoking the license and/or approval of all such products that contain mercury. FDA responded to the citizen petition, concluding that the scientific evidence did not support plaintiffs' contention that all products containing thimerosal and other mercury compounds are unsafe. FDA therefore had no grounds on which to revoke the license or withdraw the approval of any product containing thimerosal or mercury and denied the petition. Following this FDA response, plaintiffs submitted a petition for a "stay of action" to FDA,

asking FDA to reconsider and modify its response to the citizen petition. That request currently remains pending before the agency. Plaintiffs' amended complaint challenges the substance of the FDA's initial response under the Administrative Procedure Act ("APA").

Plaintiffs have filed a motion for a preliminary injunction, arguing that the FDA response was inadequate and seeking various forms of mandatory relief against the FDA with respect to products that contain mercury or thimerosal. Defendants oppose the motion on the merits. Defendants have also filed a motion to dismiss the amended complaint on the grounds that plaintiffs are not challenging a final agency action. These two motions are currently pending before the Court. Upon consideration of the motions and supporting memoranda, the responses and replies thereto, the applicable law, and the entire record, the Court concludes that plaintiffs are not challenging a final agency action. Therefore, for the reasons stated herein, plaintiffs' motion for a preliminary injunction is **DENIED**, defendants' motion to dismiss is **GRANTED**, and plaintiffs' amended complaint is **DISMISSED without prejudice.**

BACKGROUND

Plaintiffs submitted a citizen petition to FDA on July 30, 2004. Am. Compl. Ex. A. In their petition, plaintiffs requested that FDA prohibit the use of certain vaccines, revoke the

approval of certain drugs, recall certain vaccines and drugs, and issue "black box" warnings for certain products because the drugs or vaccines contain mercury or thimerosal. *Id.* at 1-6. Plaintiffs filed their initial complaint on August 1, 2006, claiming that FDA had unreasonably delayed acting on their petition. Compl. ¶ 1.

FDA responded to the citizen petition on September 26, 2006, explaining that all licensed and approved products containing thimerosal are safe, and that the studies submitted with the petition do not support the petitioners' contention that all products containing thimerosal are unsafe. *See* Defs.' Ex. A, Letter from Jeffrey Shuren to Dr. Paul G. King, September 26, 2006, at 1, 3-21 (hereinafter "FDA Response"). The response specifically analyzed the studies and other materials on which plaintiffs based their contentions concerning the harmful effects of mercury in FDA-regulated products, and found that the cited materials did not support the petitioners' arguments. *See id.* at 11-21. FDA also concluded that it had "no grounds to revoke the licenses and withdraw the approvals of thimerosal-containing products" or to seek any of the other remedies sought in the petition. *Id.* at 22-23.

Defendants moved to dismiss the case on October 16, 2006, on the ground that plaintiffs' unreasonable delay claim was moot because FDA had responded to the citizen petition. Plaintiffs

filed an opposition to defendants' motion to dismiss on October 25, 2006 and, on the following day, a motion for leave to amend their complaint, together with a proposed amended complaint. Plaintiffs' amended complaint challenges the FDA Response under the APA, claiming that it was unreasonably delayed and not in accordance with the law. Am. Compl. ¶¶ 8-10, 41-44. The Court granted the motion for leave to amend the complaint as unopposed, and denied defendants' initial motion to dismiss as moot. Order, Nov. 21, 2006.

Also on October 25, 2006, plaintiffs submitted to FDA a petition for a "stay of action." Am. Compl. ¶ 24 & Ex. E. Though styled as a request for a stay, the new petition essentially asked FDA to reconsider and modify its denial of the initial petition. Specifically, petitioners argued that the FDA Response reached conclusions that were not supported by scientific evidence, and that the response failed to properly respond to the initial petition's legal and scientific arguments. *Id.* at 3. The new petition asked for a stay of the FDA response until the FDA properly responded to petitioners' arguments and agreed to ban the use of all "[t]himerosal or any other mercury-based compound . . . from all of medicine." *Id.* at 1-2. Plaintiffs included as evidence with the stay petition numerous attachments that had not been submitted with the initial petition. *See, e.g.*, Am. Compl. Ex. E, References 12, 18, 20.

The petition for a stay remains pending before FDA.

On November 20, 2006, plaintiffs filed a motion for a preliminary injunction. In their motion, plaintiffs argue that the FDA Response "completely failed to respond to the issues raised in the Plaintiffs' Citizen Petition." Pls.' P.I. Mem. at 3. Like their petition for a stay filed with FDA, plaintiffs' motion for preliminary relief cited to and included materials that were not submitted to FDA during its consideration of plaintiffs' initial citizen petition. *See, e.g.*, Pls.' P.I. Mem. at 1 n.1, at 2 nn. 2-10, and Exs. 1-10. The motion seeks a preliminary injunction enjoining the FDA from licensing any influenza vaccination for use in pregnant women or children that contains thimerosal and from recommending that pregnant women receive any vaccine that has a Pregnancy C designation. Pls.' P.I. Mot. at 1. Additionally, the motion requests that the Court direct FDA to require all vaccine manufacturers to place a "black box" warning on any influenza vaccine product that contains thimerosal. *Id.* On December 22, 2006, defendants filed an opposition to the motion for a preliminary injunction. Defendants also filed a motion to dismiss the amended complaint on the grounds that there is no final agency action for this Court to review, and that plaintiffs have failed to exhaust the administrative process they initiated.

STANDARD OF REVIEW

A motion to dismiss for failure to state a claim should be granted when it appears "beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Sparrow v. United Air Lines*, Inc., 216 F.3d 1111, 1114 (D.C. Cir. 2000) (citations omitted). Moreover, a complaint will be liberally construed on Rule 12(b)(6) motions. *Warren v. District of Columbia*, 353 F.3d 36, 37 (D.C. Cir. 2004). The Court will accept as true all factual allegations in the complaint, and give plaintiff the benefit of all inferences that can be drawn from the facts alleged. *See Atchinson v. District of Columbia*, 73 F.3d 418, 422 (D.C. Cir. 1996).

To obtain a preliminary injunction, a party must demonstrate that: (1) it has a substantial likelihood of success on the merits; (2) it will suffer irreparable injury in the absence of preliminary relief; (3) other interested parties will not be substantially injured if the requested relief is granted; and (4) granting such relief would serve the public interest. *See Katz v. Georgetown Univ.*, 246 F.3d 685, 687-88 (D.C. Cir. 2001). The likelihood of success requirement is the most important of these factors. *See id.* The D.C. Circuit has further explained that "[t]hese factors interrelate on a sliding scale and must be balanced against each other." *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1318 (D.C. Cir. 1998). Furthermore, the injunctive

relief plaintiffs seek is not merely to preserve the status quo, but to obtain mandatory, affirmative injunctive relief. This type of relief presents "an additional hurdle" and the power to issue such an injunction "should be sparingly exercised." *See Mylan Pharmaceuticals, Inc. v. Shalala*, 81 F. Supp. 2d 30, 36 (D.D.C. 2000).

ANALYSIS

The APA authorizes review only with respect to a "final agency action." 5 U.S.C. § 704; *see Reliable Automatic Sprinkler Co. v. CPSC*, 324 F.3d 726, 731 (D.C. Cir. 2003) ("The District Court's authority to review the conduct of an administrative agency is limited to cases challenging 'final agency action.'"). FDA's regulations provide: "A request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition . . . before any legal action is filed in a court complaining of the action or failure to act." 21 C.F.R. § 10.45(b).

It is well-established that a party may not seek judicial review of an agency decision while simultaneously asking the agency to reconsider its decision because a "request for administrative reconsideration renders an agency's otherwise final action non-final with respect to the requesting party." *Clifton Power Corp. v. FERC*, 294 F.3d 108, 110 (D.C. Cir. 2002);

City of New Orleans v. SEC, 137 F.3d 638, 639 (D.C. Cir. 1998). In *ICC v. Brotherhood of Locomotive Engineers*, 482 U.S. 270 (1987), the Supreme Court held that, while 5 U.S.C. § 704 might "relieve parties from the requirement of petitioning for rehearing before seeking judicial review," it does not "prevent petitions for reconsideration that are actually filed from rendering the orders under reconsideration nonfinal." *Id.* at 284-85; *see also Stone v. INS*, 514 U.S. 386, 392 (1995) (holding that under the APA, the "timely filing of a motion to reconsider renders the underlying order nonfinal for purposes of judicial review.").

This is the case even if the petition for reconsideration is filed after the party has filed for judicial review. *Wade v. FCC*, 986 F.2d 1433, 1434 (D.C. Cir. 1993) ("The danger of wasted judicial effort that attends the simultaneous exercise of judicial and agency jurisdiction . . . arises whether a party seeks agency reconsideration before, simultaneous with, or after filing an appeal or petition for judicial review." (citations omitted)). The court in Wade further held that "[s]o long as a request for agency reconsideration remains pending, therefore, [the] attempt to seek judicial review must be dismissed as 'incurably premature.'" *Id.*[1]

[1] Earlier D.C. Circuit precedent held that this type of dismissal should be for lack of jurisdiction. *See City of New Orleans*, 137 F.3d at 639. Later precedent indicates, however,

Plaintiffs cannot evade the limits of the APA by attempting to characterize their second petition as one for a "stay" rather than reconsideration. Regardless of whether their petition is called a petition for stay or for reconsideration, petitioners are in fact seeking reconsideration and modification of the FDA Response, which renders that decision non-final. Plaintiffs' second petition challenges the FDA Response on its merits, submits evidence in an attempt to refute the findings in the FDA Response, and essentially seeks the same relief as the initial petition. Therefore, the second petition is in substance a petition for reconsideration, not a stay.[2]

Plaintiffs cannot simultaneously seek administrative reconsideration and judicial review of the same order. *See Clifton Power*, 294 F.3d at 110. This is especially apparent because petitioners' second petition included new information that FDA has not previously considered and petitioners' claims in this Court are predicated on that same information. *See Wade*, 986 F.2d at 1434. Therefore, because plaintiffs' claims do not

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that the "final agency action" requirement of the APA is not jurisdictional. *See Reliable Automatic Sprinkler*, 324 F.3d at 731. That being so, the dismissal is for failure to state a claim rather than for lack of jurisdiction. *See id.*

[2] Although plaintiffs' second petition is styled as a petition for a "stay," because plaintiffs' initial petition requested that FDA take various types of mandatory action, and FDA declined to do so, there is no agency action to "stay" in any event.

challenge a final agency action, plaintiffs' amended complaint is dismissed for failure to state a claim upon which relief can be granted. Because plaintiffs can abandon their second petition to FDA and properly challenge the FDA Response under the APA,[3] however, plaintiffs' amended complaint is dismissed without prejudice.

Because the amended complaint must be dismissed for failure to state a claim, the pending motion for a preliminary injunction must be denied as well. *See Trudeau v. FTC*, 384 F. Supp. 2d 281, 296 (D.D.C. 2005). Plaintiffs do not have a substantial likelihood of success on claims that have not survived a motion to dismiss. *See id.* Nor can plaintiffs make the showing necessary for the Court to grant affirmative, injunctive relief as opposed to an injunction maintaining the status quo. *See Mylan Pharmaceuticals*, 81 F. Supp. 2d at 36.

CONCLUSION

Because plaintiffs have effectively filed a petition for reconsideration with FDA, the challenged FDA Response in this

[3] In fact, plaintiffs have stated that they are willing to do so, but have not yet withdrawn their second petition. *See* Pls.' Reply at 15. The Court notes that if plaintiffs renew their APA claims against an FDA action, such claims must be based on the proper administrative record. *See Commercial Drapery Contractors, Inc. v. United States*, 133 F.3d 1, 7 (D.C. Cir. 1998) (holding that discovery is not permitted for APA claims, and that they must be decided upon the administrative record); 21 C.F.R. § 10.3(a) (defining administrative record for FDA decisions).

case is not a final agency action, and plaintiffs have thus failed to state a valid claim under the APA. Accordingly, defendants' motion to dismiss the amended complaint is **GRANTED** and plaintiffs' motion for a preliminary injunction is **DENIED.** Because plaintiffs can render the FDA Response a final agency action by simply withdrawing their second citizen petition, plaintiffs' amended complaint is **DISMISSED without prejudice.** An appropriate Order accompanies this Memorandum Opinion.

Signed: Emmet G. Sullivan
United States District Judge
March 1, 2007