

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

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GARY NULL, <u>et al.</u> ,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 09-1924 (RBW)
)	
U.S. FOOD AND DRUG)	
ADMINISTRATION, <u>et al.</u> ,)	
)	
Defendants.)	
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ORDER

The plaintiffs, various New York State healthcare professionals and public-interest organizations, bring this action against the defendants, the United States Food and Drug Administration and its Commissioner, and the United States Department of Health and Human Services and its Secretary, alleging that the defendants' actions in approving or licensing various vaccines to combat the 2009 H1N1-A influenza virus were not authorized in the manner required by the law. Complaint for Declaratory and Injunctive Relief ("Compl.") ¶¶ 1-4. The plaintiffs seek declaratory relief, as well as temporary and permanent injunctive relief. Id. ¶¶ 23-24. Currently before the Court are three motions. First, the plaintiffs filed a motion for preliminary injunctive relief, premised on their position that the defendants' actions were the catalyst for mandatory vaccine requirements imposed by the State of New York on most healthcare workers who have patient contact, id. ¶ 9, and that the healthcare professional plaintiffs face immediate irreparable harm because their employers have represented that any refusal by the plaintiffs to receive the 2009 H1N1-A influenza vaccine will result in the immediate

termination of their employment. Plaintiffs' Motion for Injunctive Relief at 30; see also Compl. ¶ 4(a)-(f). The defendants oppose the motion and have moved to dismiss this action based on the plaintiffs' lack of standing.¹ See Defendant's Motion to Dismiss and Defendant's Memorandum of Points and Authorities in Opposition to Plaintiff's Motion for Preliminary Injunction. Responding to the defendants' motion to dismiss, the plaintiffs filed a motion to amend their complaint to add the following: an additional federal executive agency defendant, a claim that the President's "National Emergency Declaration on HINI" was unlawful, and additional minor children plaintiffs who allege that they will be subject to a New Jersey law that mandates children under age five to receive the 2009 H1N1-A influenza vaccine. See Motion to Amend Complaint for Injunctive Relief. The defendants oppose any amendment of the plaintiffs' complaint. See Defendants' Memorandum in Opposition to Plaintiffs' Motion to Amend Complaint. The Court held a hearing on the motions on November 5, 2009. Upon consideration of the parties' written submissions, the applicable legal authority, the oral arguments presented by the plaintiffs, and for the reasons the Court expressed during the hearing on the motions, the Court must deny the plaintiffs' motion to amend their complaint, deny the plaintiffs' motion for injunctive relief, and grant the defendants' motion to dismiss this case for lack of standing.

First, the plaintiffs' motion to amend their complaint must be denied. Federal Rule of Civil Procedure 15 states that a party may amend its pleadings with "the opposing party's written consent or the court's leave," and that "[t]he court should freely give leave

¹ The Court also considered the following documents in ruling on the motions addressed in this Order: The Plaintiffs' Responding Memorandum to Defendants' Motion to Dismiss with Motion to Amend Complaint; the Plaintiffs' Memorandum in Support of Plaintiffs' Standing to Bring Action; and the Defendants' Response to Plaintiffs' Memorandum in Support of Plaintiffs' Standing to Bring Action.

when justice so requires." Fed. R. Civ. P. 15 (a)(2). The proposed amended complaint seeks to add additional plaintiffs that allege direct harm from a completely different state law than the one relied upon by the original plaintiffs. While the amended complaint still identifies the same action of the federal defendants as unlawful, the nature of the injury is different, and any analysis that the Court would have to undertake related to that state law necessarily would be different as well. The plaintiffs seeking to be added to this case may just as easily file a new lawsuit, and have indicated their desire to do so. Their claims therefore are more appropriately heard in that case, if one is filed. As to the additional allegations, for the reasons explained below, the plaintiffs do not have standing, and therefore adding the additional allegations and claims would be futile. Forman v. Davis, 371 U.S. 178, 182 (1962) (noting that the Court may deny leave to amend the complaint when the reason for the denial is "futility of [the] amendment"). Accordingly, principles of justice do not weigh in favor of granting the proposed amendments, and the plaintiffs' motion to amend their complaint is denied.

As to the remaining motions, the Court's analysis must start with a few principles derived from Article III of the United States Constitution. First, "[i]n limiting the judicial power to 'Cases' and 'Controversies,' Article III of the Constitution restricts it to the traditional role of Anglo-American courts, which is to redress or prevent actual or imminently threatened injury to persons caused by private or official violation of law." Summers v. Earth Island Inst., ___ U.S. ___, ___, 129 S. Ct. 1142, 1148 (2009). Accordingly, "except when necessary in the execution of that function, courts have no charter to review and revise legislative and executive action." Id. In order to be entitled to injunctive relief then

a plaintiff must show that he is under threat of suffering 'injury in fact' that is concrete and particularized; the threat must be actual and imminent, not conjectural or hypothetical; it must be fairly traceable to the challenged action of the defendant; and it must be likely that a favorable judicial decision will prevent or redress the injury.

Id. Compliance with these principles of Article III is necessarily demanded by the proscription that "federal courts cannot decide purely abstract or theoretical claims, or render advisory opinions." Ticor Title Ins. Co. v. F.T.C., 814 F.2d 731, 735 (D.C. Cir. 1987). This doctrine of ripeness, one of the fundamental principles of Article III, "requires a court to evaluate 'both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.'" Id. at 736.

Here, the plaintiffs acknowledge that the entire theory of their case is predicated on the allegation that the State of New York has mandated that most healthcare workers in that state who have patient contact must be vaccinated with the 2009 H1N1-A influenza vaccine, Compl. ¶ 9, and that while that mandate was in place, the healthcare professional plaintiffs faced immediate irreparable harm because their employers represented that any refusal by the plaintiffs to receive the 2009 H1N1-A influenza vaccine would result in the immediate termination of the plaintiffs' employment, Plaintiffs' Motion for Injunctive Relief at 30; see also Compl. ¶ 4(a)-(f). However, the plaintiffs now acknowledge that the state law was enjoined from enforcement by a New York state court, and therefore the healthcare professional plaintiffs are not currently subject to a mandate that they receive the vaccination for the 2009 H1N1-A influenza virus under that state law. Based on these representations, the plaintiffs are not now alleging an injury-in-fact, rendering their alleged injury to nothing more than pure

speculation that they may be subject to this mandate if it is revived, or another mandate that might in the future impose the same vaccination requirement. Neither of these possibilities is an actual and imminent reality, and therefore the plaintiffs are not currently threatened with imminent harm.

Further, at the hearing on the parties' motions, the plaintiffs acknowledged that the New York State Department of Health has now initiated rulemaking proceedings to address whether the vaccination of healthcare workers from the 2009 H1N1-A influenza should be required, and that the plaintiffs are not foreclosed from participating and submitting their views in those rulemaking proceedings. Thus, despite the plaintiffs' expressed belief that the outcome of those rulemaking proceedings will result in the issuance of another mandate requiring that they submit to the vaccination, their position is purely speculative. The outcome of that rulemaking proceeding cannot be known, and the Court cannot give the plaintiff any relief from those rulemaking proceedings prior to their completion. Indeed, the Court must have before it final agency action before it can entertain a challenge to such action; doing anything else would put the Court in the position of rendering an advisory opinion, which it cannot do. Ticor Title Ins., 814 F.2d at 735, 739.

One final point worth making is that the plaintiffs have not, in any manner, demonstrated how the actions of the State of New York, or any state for that matter, could be "fairly traceable to the challenged action of the defendant[s]," another predicate for standing. Summers, ___ U.S. at ___; 129 S. Ct. at 1149. What a state legislature or executive agency mandates its residents to do based on health and safety concerns, is first and foremost within the providence of the of the state. See Jacobson v. Commonwealth

of Massachusetts, 197 U.S. 11, 35 (1905) ("Since . . . vaccination, as a means of protecting a community against smallpox, finds strong support in the experience of this and other countries, no court, much less a jury, is justified in disregarding the action of the legislature simply because in its or their opinion that particular method was – perhaps, or possibly – not the best either for children or adults."). But moreover, state action cannot be attributed to the federal government merely because the federal government had some role in authorizing a decision independently taken by the state. Stated more directly, just because the federal government approved a vaccine as safe for human consumption, cannot be said to be the action that is allegedly creating the threat of the actual and imminent harm complained of by the plaintiffs, when it is the State of New York which is actually requiring the plaintiffs to submit to the vaccination. In other words, just because one action had to precede another action cannot be said to be the cause for the subsequent action independently taken by a separate sovereign. But this discussion at this time is itself purely academic, because the State of New York mandate is no longer in effect.

Accordingly, for the reasons expressed during the hearing and as set forth above, it is hereby

ORDERED that the plaintiffs' motion to amend their complaint is **DENIED**. It is further

ORDERED that the plaintiffs' motion for preliminary injunctive relief is **DENIED**. It is further

ORDERED that the defendants' motion to dismiss this case is **GRANTED** and that this case is **DISMISSED** based on the plaintiffs' lack of standing.

SO ORDERED this 10th day of November, 2009.

_____/s/_____
Reggie B. Walton
United States District Judge