UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS,

Plaintiff,

v.

FOOD & DRUG ADMINISTRATION, et al.,

Defendants.

_____/

CASE No. 1:20-CV-493

HON. ROBERT J. JONKER

OPINION AND ORDER

INTRODUCTION

In March 2020, as part of the federal government's response to the ongoing COVID-19 pandemic, the United States Food and Drug Administration ("FDA") approved an Emergency Use Authorization ("EUA") for hydroxychloroquine, a drug that has commonly been used in treating diseases like malaria and lupus. The EUA permitted healthcare providers to prescribe hydroxychloroquine that was distributed from the federal government's Strategic National Stockpile for use in combating COVID-19. The scope of the emergency authorization was limited. Distribution of the drug from the stockpile for purposes of treating COVID-19 was authorized only to treat adults and adolescents who had already been hospitalized with COVID-19 and for whom clinical trials were unavailable. Approximately three months later the FDA revoked this authorization, meaning that distribution of hydroxychloroquine from the stockpile to treat COVID-19 was restricted further to use only in clinical trials.

Plaintiff Association of American Physicians & Surgeons ("AAPS") is a nonprofit organization comprised of physician members. Its mission includes protecting its members from arbitrary and unlawful government action.[1] AAPS argues in this lawsuit that its members, including an unidentified physician practicing in the Western District of Michigan, wish to prescribe the drug hydroxychloroquine to their patients as a prophylactic against COVID-19. The drug has been touted by some physicians, commentators and government leaders, including President Trump, as an effective treatment or preventative measure against the disease. Indeed, AAPS contends that the actions of Defendants have "impeded the ability of President Trump to make [hydroxychloroquine] available to the public." (ECF No. 8-2, PageID.80).

The matter before the Court is on the motion for preliminary injunction filed by Plaintiff AAPS, and the Defendants' motion to dismiss under Rules 12(b)(1) and 12(b)(6) for lack of standing and failure to state a claim. After review of the motions, and the respective briefing, the Court finds that oral argument on the motions is unnecessary. Hydroxychloroquine is commercially available, and physicians are free to prescribe the drug for off-label uses absent any direction to the contrary by state medical authorities. Nothing in the EUA, or its revocation, had any direct impact on the availability of hydroxychloroquine in the commercial market. AAPS does not really dispute this. Rather they aver the actions of Defendants have led state medical regulatory entities to restrict physician access to the drug that is available on the commercial market causing harm to the organization itself, its physician members, and those members' patients.

[1] So stated in *Association of American Physicians & Surgeons, Inc. v. Texas Medical Bd.*, 627 F.3d 547, 549 (5th Cir. 2010).

The causal connections between the alleged injuries and the complained of actions by the Defendants are attenuated and general, and for the reasons set out below, the Court agrees with Defendants that AAPS lacks standing in this matter under any of the possible theories articulated by AAPS. Accordingly, the Court grants the defense motion, denies AAPS's motion for a preliminary injunction and dismisses this case.

BACKGROUND

1. Statutory Background -- The Emergency Use Authorization in General

This lawsuit involves the issuance, and eventual revocation, of an EUA by the FDA and the Secretary of the Department of Health & Human Services. The authority to issue an EUA is granted by statute that permits the Secretary of Health & Human Services to "authorize the introduction into interstate commerce . . . of a drug, device, or biological product intended for use in an actual or potential emergency," in a public health crisis. 21 U.S.C. §360bbb-3(a)(1). This includes an emergency use of a product that the FDA has approved as safe and effective in other circumstances. *Id.* at § 360bbb-3(a)(2).

Under the statutory framework, the Secretary must first "make a declaration that the circumstances exist justifying the authorization." *Id.* at 360bbb-3(b)(1). One such circumstance is a determination "that there is a public health emergency . . . that affects, or has a significant potential to affect, national security . . . and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents[.]" *Id.* at § 360bbb-3(b)(1)(C). An EUA relating to a drug may then issue if the Secretary concludes that "based on the totality of scientific evidence available," which includes "data from adequate and well-controlled clinical trials, if available, it is reasonable to believe" that (1) the drug "may be effective in diagnosis, treating, or preventing . . . a serious or life-threatening disease or

condition"; (2) "the known and potential benefits of the product . . . outweigh the known and potential risks" of the drug; and (3) a determination that "there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition[.]" *Id.* at § 360bbb-3(c).

The Secretary may also "establish such conditions on an authorization . . . . as the Secretary finds necessary or appropriate to protect the public health." *Id.* at § 360bbb-3(e)(1)(B). The Secretary is required to "periodically review" the EUA and may revise or revoke the EUA if the justification for the emergency is no longer met, if the criteria for the EUA are no longer met, or "other circumstances make such revision or revocation appropriate to protect the public health or safety." *Id.* at § 360bbb-3(g)(1)-(2). All these determinations are expressly "committed to agency discretion." *Id.* at § 360bbb-3(i).

2. The March 2020 EUA with Respect to HCQ

As the COVID-19 virus spread the Department of Health & Human Services responded by, among other things, issuing an EUA regarding hydroxychloroquine to treat the disease. On February 4, 2020, the Secretary of the department issued a "Determination of Public Health Emergency" that stated COVID-19 "has a significant potential to affect national security or the health and security of United States citizens living abroad." 85 Fed. Reg. 7316, 7317 (Feb. 7, 2020). On March 27, 2020, the Secretary then declared that "circumstances exists justifying the emergency use of drugs and biological products during the COVID-19 pandemic[.]" 85 Fed. Reg. 18250-51 (Mar. 27, 2020).

An EUA for hydroxychloroquine to respond to COVID-19 was issued by the FDA the following day. It concluded the criteria for the issuance of the authorization was met. The authorization specifically noted:

> 1. The [COVID-19 virus] can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans invested by this virus;
>
> 2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that [hydroxychloroquine and a similar drug] may be effective in treating COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of [the drugs] when used to treat COVID-19 outweigh the known and potential risks of such products; and
>
> 3. There is no adequate, approved, and available alternative to the emergency use of [the two drugs] for the treatment of COVID-19.

(ECF No. 9-6, PageID.475-476). The scope of the authorization was limited in several respects. The drug, for example, had to be prescribed by a healthcare provider under a valid prescription. It also was limited for treatment of adult and adolescent patients who were hospitalized with COVID-19 and "for whom a clinical trial is not available, or participation is not feasible." (*Id.* at PageID.477).

The scope was also limited to those supplies of the drug from the federal government's Strategic National Stockpile. *Id.* The Secretary of the Department of Health & Human Services, along with other officials, maintains a Strategic National Stockpile of drugs, vaccines, and other biological products, medical devices, and supplies in order "to provide for and optimize the emergency health security of the United States . . . . in the event of a bioterrorist attack or other public health emergency[.]" 42 U.S.C. § 247d-6b. The EUA did not bear on the supplies of hydroxychloroquine available in the commercial market. AAPS does not dispute this, nor does it aver there is any shortage of the drug in the commercial marketplace.

3. The Revocation of the EUA

The March 28th authorization expressly noted that that clinical trial data results, and other information, would continue to inform the agency's review and the risk benefit assessment of the hydroxychloroquine EUA. The authorization noted that the EUA would be effective until the circumstances justifying the authorization for the emergency use was terminated, or the EUA had been revoked. (ECF No. 9-6, PageID.480). On June 15, 2020, the "ongoing assessment" of the hydroxychloroquine EUA resulted in the revocation of the authorization because "the criteria . . . for the issuance of the EUA . . . are no longer met." (ECF No. 8-6, PageID.153). In a June 16, 2020 document further explaining the rationale for the revocation, the FDA stated that it had "determined that [HCQ is] unlikely to be effective in treating COVID-19 for the authorized uses in the EUA. Additionally, in light of ongoing serious cardiac adverse events and other serious side effects, the known and potential benefits of [the drugs] no longer outweigh the known and potential risks for the authorized issue." (ECF No. 8-9, PageID.268). This conclusion, the FDA determined, warranted revocation. (*Id.*).

4. *AAPS' Allegations*

AAPS is a nonprofit organization made up of physicians across various specialties. Its publicly available website advocates for various policy positions, including those related to the current COVID-19 pandemic. In the past weeks and months, the association has issued press releases questioning government mandates related to mask wearing and social distancing,[2] and

[2] Press Release, AAPS, COVID Masks, Distancing Not-Evidence Based (July 20, 2020), *available at* https://aapsonline.org/covid-masks-distancing-not-evidence-based/ ("We're supposed to follow 'evidence-based medicine' these days, but there is no firm evidence to support the masking and 'social distancing' mandates being imposed throughout the land.")

endorsing hydroxychloroquine as an effective treatment or preventative measure for COVID-19.[3] On June 2, 2020, it filed this action "on behalf of its members and their patients to end the irrational interference by the FDA with timely access to hydroxychloroquine." (Compl. ¶ 1. ECF No. 1, PageID.1). The lawsuit was filed after the EUA was issued, but before the revocation.[4] Plaintiff's motion for preliminary injunction, however, was filed after the revocation and in both the Complaint, and in the motion, Plaintiff argues that the restrictions on the scope of the EUA, and the subsequent recission of the authorization for those narrow uses, irrationally and arbitrarily limited access to hydroxychloroquine.

Citing various articles and comparisons, AAPS further contends these restrictions meant that hydroxychloroquine from the stockpile was not available for its most effective use as a prophylactic against COVID-19 infection. It argues that political animus against the current administration or pecuniary interests in less effective treatments motivated the decisionmakers to impose the EUA's restrictions on the distribution of hydroxychloroquine from the stockpile. AAPS alleges it and its members have been injured by these actions. AAPS says it has had to cancel one of its schedule conferences. (Comp. ¶ 116, ECF No. 1, PageID.23). And it says that its doctors fear retaliation if they prescribe commercially available hydroxychloroquine to their

[3] *See, e.g.,* Press Release, AAPS, Hydroxychloroquine is Not About Trump (Aug. 6, 2020), *available at* https://aapsonline.org/hydroxychloroquine-is-not-about-trump/; Press Release, AAPS, Is COVID Treatment Between a Patient and her Doctor? (Aug. 5, 2020), *available at* https://aapsonline.org/is-covid-treatment-between-a-patient-and-her-doctor/; Press Release, AAPS, COVID-19: Will Doctors Tell You What They Think? (July 31, 2020), *available at* https://aapsonline.org/covid-19-will-doctors-tell-you-what-they-think.

[4] For this reason, Defendants argue that this action is moot, since the relief AAPS has requested has already been accomplished. The defense further contends that any modification in the claims for relief must come in the form of an amended complaint, not by motion. AAPS resists Defendants' mootness argument because it contends that it is still being harmed by Defendants' actions. The Court need not resolve the mootness argument since the Court concludes AAPS lacks standing in this matter.

patients because "state regulatory officials have imitated or relied upon" the FDA's decisions. (Compl. ¶ 80, ECF No. 1, PageID.18). Specifically it alleges that the Federation of State Medical Boards "relied on the EUA" to order that:

> Physicians, nurses, pharmacists, pharmacies and hospitals have an ethical duty to put the needs of patients first, and this includes observing strict prescribing guidelines. On March 28, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for use of oral formulations of chloroquine phosphate and hydroxychloroquine sulfate. The authorization allows these medications to be prescribed by clinicians for hospitalized adult and adolescent patients "for whom a clinical trial is not available, or participation is not feasible." Clinicians should avoid prescribing for themselves or their family members and should be aware that deviating from the standard of care could put their license at risk.

(Compl. ¶ 81, ECF No 1, PageID.18). AAPS contends this directive went to state medical boards, entities that "wield complete authority over licenses to practice medicine." (*Id.*).

Due to the actions of Defendants, AAPS alleges its physician members, including a member practicing in the Western District of Michigan that it identifies as "John Doe," have been unable to successfully prescribe a full regimen of [hydroxychloroquine] for patients in need of it[.]" (Compl. ¶ 86). Similarly, AAPS says patients of members have been unable to receive prescriptions for hydroxychloroquine to protect against COVID-19. If physicians do prescribe hydroxychloroquine, AAPS says their members fear retaliation from their state medical boards.

PROCEDURAL BACKGROUND

Plaintiff's Complaint contains three separate counts, alleging a violation of Equal Protection (Count 1); a violation of the Administrative Procedure Act (Count 2); and a violation of the members' First Amendment rights of association. (Count 3). (ECF No. 1). On June 22, 2020, it filed a motion and brief for preliminary injunction seeking to enjoin Defendants' actions with respect to hydroxychloroquine. (ECF No. 8). Defendants subsequently filed a motion to

dismiss citing Rules 12(b)(1) and 12(b)(6) alleging this matter must be dismissed for lack of standing and for failure to state a claim. (ECF No. 8). Under an agreed to stipulation, which the Court grants here, the parties filed combined responsive briefs on both motions.[5]

LEGAL STANDARD

Article III, § 1, of the Constitution limits the jurisdiction of federal courts to hear only actual cases and controversies. *Spokeo, Inc. v. Robins*, ___ U.S. ___; 136 S. Ct. 1540, 1547 (2016), *Lyshe v. Levy*, 854 F.3d 855, 857 (6th Cir. 2017). "Where, as here, a case is at the pleading stage, the plaintiff must 'clearly . . . allege facts demonstrating' each element" of standing. *Spokeo*, 136 S. Ct. at 1547. Standing is "the threshold question in every federal case." *Warth v. Seldin,* 422 U.S. 490, 498 (1975).

Defendants challenge Plaintiff's standing to bring its claims against them and they assert this action must be dismissed for lack of subject matter jurisdiction under FED. R. CIV. P. 12(b)(1). *See Stalley v. Methodist Healthcare,* 517 F.3d 911, 916 (6th Cir. 2008) (stating that a dismissal of a case for lack of standing is one for lack of subject matter jurisdiction under Rule 12(b)(1)). "For purposes of ruling on a motion to dismiss for want of standing, both the trial and reviewing courts must accept as true all material allegations of the complaint, and must construe the complaint in favor of the complaining party." *Parsons v. United States Department of Justice*, 801 F.3d 701, 710 (6th Cir. 2015) (quoting *Warth v. Seldin*, 422 U.S. 490, 501 (1975)).

DISCUSSION

The defense motion primarily asserts that AAPS lacks standing in this matter. In response, AAPS raises three possible avenues for standing. It contends it has standing to sue in its own right;

[5] On July 30, 2020, a date when the briefing had not yet been completed, Plaintiff filed a motion to expedite (ECF No. 15), which is rendered moot by this Opinion and Order.

to sue on behalf of its members; and to sue on behalf of the third-party patients of its members. A review of the "threshold question" demonstrates that AAPS has not sufficiently alleged it has standing in this matter, for the reasons set out below. Accordingly, the Court's analysis of the pending motions begins and ends with this inquiry. [6]

1. Standing in Its Own Right

In the Complaint, AAPS avers that because of defendants' actions, it has had to cancel one of its scheduled conferences and that its annual conference is in jeopardy. (Compl. ¶ 116, ECF No. 1, PageID.24). On this basis, it claims to have standing to sue in its own right. (ECF No. 14, PageID.679). The Court disagrees.

A plaintiff asserting it has standing under the Constitution's actual cases and controversies requirement to sue in its own right must show that it has "(1) suffered an injury in fact, (2) that is

[6] While the Court does not need to address the defense's alternative argument that AAPS has failed to state a claim under Rule 12(b)(6), the Court observes that AAPS' claims would face stiff headwinds in passing Rule 12 scrutiny. The agency's decisions under the APA would be subject to a deferential standard of review, for example, assuming the Court even had authority to review them. *See* 21 U.S.C. § 360bbb-3(i) (committing agency action on emergency authorization to agency discretion). The Secretary, moreover, is plainly authorized to impose scopes, conditions, and other limitations in an authorization for an EUA. *See* 21 U.S.C. § 360bbb-3(d), (e). With respect to the First Amendment association claims, courts have denied the requested relief against governments that have directly imposed restrictions on gatherings. *See, e.g., CH Royal Oak, LLC v. Whitmer*, No. 1:20-CV-570, 2020 WL 4033315, at *5 (W.D. Mich. July 16, 2020); *Givens v. Newsom*, No. 2:20-cv-00852-JAM-CKD, 2020 WL 2307224 (E.D. Cal. May 8, 2020); *Gish v. Newsom*, No. EDCV 20-755 (JGB (KKx), 2020 WL 1979970 (C.D. Cal. Apr. 23, 2020). Plaintiff's claims against Defendants, who did not impose any restrictions on gatherings, but rather imposed statutorily permitted restrictions on hydroxychloroquine in the federal government's stockpile appear even less likely to succeed. Similarly weak are Plaintiff's equal protection claims, which appear to assert Defendants are discriminating against the elderly, an at-risk population, by failing to make hydroxychloroquine available from the stockpile under an EUA. But the scope of the EUA did not single out the elderly population. Nor did it prohibit medical practitioners from prescribing hydroxychloroquine to the elderly from the commercial market.

fairly traceable to the challenged conduct of the defendant, and (3) that it is likely to be redressed by a favorable judicial decision." *Spokeo, Inc.*, 136 S. Ct. at 1547. Assuming without deciding that Plaintiff has shown an injury-in-fact by having to cancel a scheduled meeting and converting its annual conference from an in-person gathering to a virtual one, the Court concludes AAPS cannot meet either of the remaining two elements necessary to establish Article III standing.[7] Consider the second element of causation, which requires that the injury "fairly can be traced to the challenged action." *Valley Forge Christian Coll. v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 472 (1982) (citation omitted). AAPS contends that its injury is traceable to the Defendants because their actions directed state regulatory entities to issue various directives to the physicians practicing in their states. The result of these directives was that physicians did not prescribe hydroxychloroquine both from the stockpile but also from the commercial market as a prophylactic. This allegation is not supported by the record. As AAPS

[7] With respect to the first of the three standing elements, to demonstrate injury in fact, a plaintiff must show that it has "suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Spokeo*, 136 S. Ct. at 1548 (quoting *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560 (1992)). "For an injury to be particularized, it must affect the plaintiff in a personal and individual way." *Id.* (citations removed). To be concrete, an injury "must be *de facto*; that is, it must actually exist." *Id.* "Conclusory allegations do not satisfy the requirements of Article III." *Binno v. American Bar Ass'n*, 826 F.3d 338, 344 (6th Cir. 2016). Plaintiff's Complaint and its briefing do not specify what events AAPS has had to cancel. A review of its publicly available website indicates a March 2020 conference in St. Louis was cancelled after "St. Louis County issued strict restrictions on gatherings which prohibit the holding of our events." Jeremy Snavely, *Cancelled – March 20, 2020 – Thrive, Not Just Survive XXIX, Restoring the Joy in Medicine by Putting Patients First*, AAPS, https://aapsonline.org/event/march-20-2020-thrive-not-just-survive-xxix-restoring-the-joy-in-medicine/ (last visited Aug. 11, 2020). AAPS' website also reports that it has converted its October 3, 2020 annual meeting from an in-person gathering to a virtual meeting "largely due to government orders severely limiting the ability of members from around the country to gather." *AAPS Annual Meeting – October 3*, AAPS, https://aapsonline.org/event/sept-30-oct-3-2020-aaps-77th-annual-meeting-san-antonio-tx/ (last visited Aug. 11, 2020). While the Court decides the issue of standing based on the allegations contained in the Complaint, the rationale provided by AAPS on its website only underscores the lack of traceability and redressability as discussed below.

admits in its Complaint, the state medical boards "wield complete authority over licenses to practice medicine." (Compl. ¶ 81, ECF No. 1, PageID.19). Plaintiff does not, furthermore, contend that Defendants have any authority over these state regulatory boards.

AAPS does allege that a Federation of State Medical Boards has directed these state entities (*Id.*). But the statement of the federation that AAPS cites is ambiguous at best and hardly states in its plain terms that physicians should not prescribe commercially available hydroxychloroquine to their patients. Moreover AAPS does not allege that Defendants directed the federation or that they have any authority over it. Indeed, in a supporting affidavit to its preliminary injunction motion, AAPS' business manager avers that those states that have issued restrictions on commercially available hydroxychloroquine are only "relying" on those guidelines issued by the federation, which, in turn has "cite[d]" the EUA as a rationale. (Snavely Aff. ¶ 13, ECF No. 8-4, PageID.141). This only serves to bolster the conclusion that independent actors making independent decisions have led to the complained of injuries. But AAPS has not sued these actors.

Furthermore, even accepting all of the above, it does not complete the causal chain between the Defendants' actions and the complained of injury to the association. More is needed, and here AAPS offers only bare speculation to assert that absent the Defendants' actions, physicians across the county would have more widely prescribed hydroxychloroquine; that the COVID-19 pandemic would have been curtailed; and that this would negate any need for government mandated restrictions, including prohibitions on assemblies such as the scheduled AAPS conferences.

Indeed, this argument involves an abundance of conjecture and a plethora of independent intervening actions of third parties that are not in this case. The causation alleged need not be proximate. *Parsons*, 801 F.3d at 713 (citing *Lexmark Intern., Inc. v. Static Control Components, Inc.*, 527 U.S. 118, 134 n.6 (2014). And "the fact that an injury is indirect does not destroy standing

as a matter of course." *Id.* (citation omitted). But "[w]hen a plaintiff's injury is the result of 'the independent action of some third party not before the court,' the plaintiff generally lacks standing to seek its redress." *Crawford v. United States Department of Treasury*, 868 F.3d 438, 455 (6th Cir. 2017) (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 42 (1976). That is the case here.

And for the similar reasons, AAPS cannot establish the third element of redressability. "A plaintiff satisfies the redressability requirement when [it] shows that a favorable decision will relieve a discrete injury to [itself]. [It] need not show that a favorable decision will relieve [its] *every* injury." *Parsons*, 801 F.3d at 715 (quoting *Larson v. Valente*, 456 U.S. 228, 244 n.15 (1982)). Here, even if the Court were to grant AAPS requested relief by ordering the FDA to make hydroxychloroquine in the federal government's stockpile widely available for distribution as a prophylactic against COVID-19, state medical boards could still decide that such a prescription runs against best practices (as AAPS alleges they have done here) and state governments could still choose to prohibit assemblies as part of a comprehensive approach towards combating the virus. Accordingly, a favorable decision by this Court is unlikely to redress AAPS' complained of injury. *See Friends of the Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 181 (2000) (noting the standard for redressability is whether "it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision."). Again AAPS could have sued those state medical authorities and government bodies, but they have not, at least they have not here.

Therefore, the Court finds that AAPS has not satisfied its burden of demonstrating it has standing to sue in its own right.

2. Associational Standing

Next, AAPS contends that it has standing to sue on behalf of its members, that is, it has associational standing (also called representational standing). AAPS argues its members, specifically a John Doe physician residing in the Western District of Michigan, have been injured by the hydroxychloroquine EUA and its subsequent revocation.[8] It alleges that Dr. Doe has been unable to prescribe a full regimen of hydroxychloroquine to his patients (Compl. ¶ 86) and that he fears retaliation against him by state medical boards due to the EUA and the Federation of State Medical Boards' directive to the state entities. (Compl. ¶ 90). In its motion for preliminary injunction, AAPS provides an affidavit of its business manager and director of regulatory affairs, stating as much with respect to Dr. Doe. (ECF No. 8-4, PageID.141). The affidavit further details that other physician members have contacted AAPS complaining that they have been unable to prescribe hydroxychloroquine to treat or prevent COVID-19. (Snavely Aff. ¶ 6, ECF No. 8-4, PageID.140). Mr. Snavely avers there are members in Texas and Maine under investigation by their state boards for recommending and prescribing the drug. (*Id.* at ¶ 11). The Complaint is

[8] Defendants argue that Plaintiff's failure to identify a physician by name, or provide an affidavit from that individual, is fatal on its own to AAPS' associational standing argument. AAPS argues it has provided sufficient specificity without identifying its members by name especially where, as here, it alleges its members fear retaliation by state officials holding supposed political animus. It further argues that even if there was such a requirement, it is not required here, where all of its members have been injured. Typically, under the Federal Rules of Civil Procedure every party must have his or her name stated in the case caption. *See* FED. R. CIV. P. 10(a); *Doe v. Porter*, 370 F.3d 558, 560 (6th Cir. 2004). The John Doe physician is not a party to this case, however, and other courts have found the failure of an association to name a member is not fatal to associational standing. *See, e.g.*, *New York v. United States Dep't of Commerce*, 351 F. Supp. 3d 502, 606 n.48 (S.D.N.Y.), *aff'd in part, rev'd in part and remanded sub nom. Dep't of Commerce v. New York*, 139 S. Ct. 2551, 204 L. Ed. 2d 978 (2019), *and appeal dismissed*, No. 19-212, 2019 WL 7668098 (2d Cir. Aug. 7, 2019). The Court assumes then, without deciding, that it is not necessary to identify a member by name to establish associational standing. The Court finds AAPS' associational standing claim fails for other reasons stated.

silent with respect to any specific action taken by a state medical board, though in its motion for preliminary injunction and subsequent briefing AAPS cites communications from the Arkansas Department of Health and the Oregon Board of Pharmacy. (*See* Memorandum of Law in Support, ECF No. 8-2, PageID.100-101; Combined Reply, ECF No. 13, PageID.606-607). A supporting declaration from Lawrence Joseph, an attorney for Plaintiff, also cites to a document from the Michigan Department of Licensing and Regulatory Affairs issued on March 24, 2020. The document is entitled "Reminder of Appropriate Prescribing and Dispensing." (ECF No. 13-1, PageID.654). The same affidavit also references an undated news release from the department that references the EUA. (*Id.* at PageID.656).

The Court finds AAPS fails to demonstrate it has associational standing here. In order to meet its burden for demonstrating it has associational standing, AAPS must show "(1) the organization's members would otherwise have standing to sue in their own right; (2) the interests it seeks to protect are germane to the organization's purpose, and (3) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Friends of Tims Ford v. Tennessee Valley Auth.*, 585 F.3d 955, 967 (6th Cir. 2009) (quoting *Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977) (quotation marks omitted). "Regarding the first element, it generally suffices for an association to demonstrate 'at least one of [its] members would have standing to sue on his own.'" *Waskul v. Washtenaw Cty. Cmty. Mental Health*, 900 F.3d 250, 255 (6th Cir. 2018) (quoting *United Food and Commercial Workers Union Local 751 v. Brown Group, Inc.*, 517 U.S. 554, 554-55 (1996). So, in order to demonstrate the first element of associational standing, an association must "allege that its members, or any one of them, are suffering immediate or threatened injury as a result of the challenged action of the sort

that would make out a justiciable case had the members themselves brought suit." *Warth*, 422 U.S. at 511.

AAPS's claim fails at the first step. This entails a similar analysis as the above, and requires a showing that one or more of AAPS' members can show an injury in fact, causation, and redressability. Beginning with injury, Dr. Doe complains of two injuries: an inability to prescribe hydroxychloroquine and a fear of retaliation by state medical boards. The first complained of injury is not supported by the record, and actually is belied by the documents AAPS depends on. Plaintiff's Complaint, for example, states that health care physicians, such as Dr. Doe, may prescribe FDA-approved drugs for off-label uses. (Compl. ¶ 27, ECF No. 1, PageID.6). The Snavely affidavit from AAPS also concedes that when the EUA was revoked, the Secretary of Health & Human Services stated that [i]f a doctor wishes to prescribe [hydroxychloroquine] working with a patient, they may prescribe it for any purpose that they wish to do so. And this [revocation] actually removes a potential barrier to that." (Snavely Decl. ¶ 18, ECF No. 8-4, PageID.143).

In other words, Dr. Doe can prescribe hydroxychloroquine from the commercial market to his patients. AAPS' assertions to the contrary, notwithstanding the above statements, fails to allege a concrete and particularized injury in fact that is actual and imminent, rather than conjectural or hypothetical. For example, of the two documents provided in the Joseph Declaration, the first document predates the March 28, 2020 EUA as well as the comments the FDA made in June 2020 as part of the EUA's revocation. Thus even if this "reminder" has somehow injured Dr. Doe, he clearly could not show a causal connection when the injury predated the subsequent complained

of actions.[9] The second document also fails to demonstrate any limitation on Dr. Doe's ability to prescribe hydroxychloroquine from the commercial market. It simply references the hydroxychloroquine EUA and the drugs in the stockpile. (ECF No. 13-1, PageID.656). And other communications surrounding the revocation plainly relate to hydroxychloroquine that is available from the stockpile, not the commercial market. *Chloroquine and Hydroxychloroquine*, Public Health Emergency, https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/hydroxychloroquine.aspx (last visited Aug. 12, 2020) (noting the EUA applied to hydroxychloroquine in the stockpile and that "[t]he revocation of the EUA does not change the existing FDA approvals of these drugs for other conditions."). Thus there is no support for the conclusory contentions in the Snavely declaration regarding conflicting information from Defendants. (Snavely Decl. ¶ 22, ECF No. 8-4, PageID.143).

AAPS' second claimed injury to Dr. Doe—a fear of retaliation by the state medical board also fails. Beyond the above documents in the Joseph declaration, which plainly do not show any disciplinary action is imminent with respect to Dr. Doe, AAPS fails to allege any action, impending or otherwise, from the state authority. In sum, the injuries AAPS ascribes to Dr. Doe, the only member identified in any detail, are speculative and hardly imminent, thus AAPS fails to demonstrate an Article III injury in fact. *See Spokeo, Inc. v. Robins*, 136 S. Ct. at 1548 (noting a

[9] The reminder, furthermore, appears to have been issued in response to reports of physicians who inappropriately stockpiled the drug or prescribed it to "themselves, family, friends and/or coworkers *without a legitimate medical purpose*." (ECF No. 13-1, PageID.654). True, the letter states that hydroxychloroquine "has not been proven scientifically or medically to treat COVID-19." Again, nothing in this reminder demonstrates that the department was directed by or relied on Defendants' actions. Moreover, the letter does not state one way or the other whether physicians are able to prescribe hydroxychloroquine to their patients, including for use against COVID-19, if there is a legitimate medical purpose. Nor does it state that such a prescription would be an illegitimate purpose.

plaintiff must show an injury in fact that is "'concrete and particularized' and 'actual and imminent, not conjectural or hypothetical.'") (quoting *Lujan*, 504 U.S. at 560).

Even if AAPS could show an injury in fact with respect to Dr. Doe (or other members based on similar factual assertions), it fails to show causation and redressability with respect to these injuries. Rather, AAPS' contentions illustrate that its members grievances lie against the state authorities, not the federal defendants here. Any traceability from the potential and speculative complained of injury to the Defendants is too indirect and cut off by independent actors making independent decisions.

This case is nothing like *Association of American Physicians & Surgeons, Inc. v. Texas Medical Board*, 627 F.3d 547 (5th Cir. 2010). In that case members of AAPS alleged that members of the Texas State Board of Medical Examiners, the defendants, used concocted anonymous complaints to retaliate against the member physicians. AAPS alleged the board, among other things, violated its members' privacy by releasing records from their disciplinary cases and subjected those physicians who complained to retaliatory disciplinary proceedings. *Id.* at 549-550. On review, the Fifth Circuit Court of Appeals found that the members had associational standing. But the first element was a foregone conclusion and was established "[b]eyond question." *Id.* at 550. And for good reason. Unlike the facts here, the complained of injuries were concrete, particularized, and were clearly traced to the defendants' actions. The only question in that case was whether the third element—asking whether the participation of the individual members was required—was at issue. This case is not such a case.

Accordingly, for the above reasons, AAPS fails to demonstrate it has associational standing because it has failed to demonstrate one or more of the organization's members would otherwise have standing to sue in their own right.

3. Third-Party Standing

AAPS also contends it has standing to bring claims on behalf of those patients of its members physicians who would like, but have been unable, to receive prescriptions from AAPS' member physicians for a full regimen of hydroxychloroquine to treat or prevent COVID-19. The Court disagrees.

Generally "a plaintiff must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." *Warth*, 422 U.S. at 499; *see also Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004). "The rare 'third-party standing' exception to this requirement allows federal courts to hear cases in which a plaintiff can 'show that (1) it has suffered an injury in fact; (2) it has a close relationship to the third party; and (3) there is some hindrance to the third party's ability to protect his or her own interests.'" *Crawford*, 868 F.3d at 455 (quoting *Mount Elliott Cemetery Ass'n v. City of Troy*, 171 F.3d 398, 404 (6th Cir. 1999).

Assuming, as the Court did above, that AAPS has suffered an injury in fact, AAPS has not alleged any facts regarding a close relation with the third parties or the existence of some hindrance to the ability of these third parties to protect their own rights. "Plaintiff is attempting to assert claims belonging not to third parties with which it has a relationship, but to third parties with whom its members purportedly have relationships." *Association of American Physicians & Surgeons, Inc. v. Brown*, No. 2:16-cv-02441-MCE-EFB, 2018 WL 1535531, at *5 (E.D. Cal. Mar. 29, 2018). And so "[w]hile Plaintiff's members might be able to make the requisite showing that they have relationships with particular third-party patients . . . plaintiff is simply not in a position to allege the same." *Id.* Even if AAPS had alleged a close relationship with the third-party patients, it has not alleged any hindrance to those patients' ability to protect their own interests. "Determining the existence of a hindrance requires examining 'the likelihood and ability of the third parties . . . to

assert their own rights.'" *Moody v. Michigan Gaming Control Bd.*. 847 F.3d 399, 402 (6th Cir. 2017). "Courts have found the following to constitute a hindrance that keeps a third party from protecting his or her own rights: deterrence from filing suit due to privacy concerns, imminent mootness of a case, or systemic practical challenges to pursuing one's own rights." *Id.* at 402-03 (citing cases). None of these circumstances are present here. Nor has AAPS identified any barrier that would keep the patients from asserting their own rights. Accordingly, there is no basis for concluding AAPS has met its Rule 12 burden with respect to third-party standing.

CONCLUSION

AAPS believes that hydroxychloroquine has a better chance at combating the global COVID-19 pandemic than the government mandates and other therapies employed so far. But even if AAPS is correct, it has little, if anything, to do with the claims it is trying to bring against these defendants. Its member physicians remain free to prescribe the drug from the commercial market, if they so choose. To the extent AAPS claims it has had to cancel its conferences, or its members have been limited in their ability to prescribe the drug to their patients, the allegations in AAPS' complaint fail to sufficiently link these injuries to the complained of actions by the defendants AAPS has chosen to sue. Having made this threshold determination that AAPS lacks standing, the Court discerns no basis for proceeding to the merits. This matter, therefore, must be dismissed for lack of standing.

ACCORDINGLY, IT IS ORDERED THAT:

1. The Stipulation to Set Briefing Schedule (ECF No. 7) is **ACCEPTED.**
2. AAPS' Motion for Preliminary Injunction (ECF No. 8) is **DENIED** because it lacks standing to bring this action.

3. Defendants' Motion to Dismiss (ECF No. 10) is **GRANTED** to the extent detailed in this Opinion and Order.
4. AAPS' Motion to Expedite (ECF No. 15) is **DISMISSED AS MOOT.**
5. This action is **DISMISSED** for lack of standing.

A separate Judgment shall issue.

Dated: August 14, 2020

/s/ Robert J. Jonker
ROBERT J. JONKER
CHIEF UNITED STATES DISTRICT JUDGE