IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HIV AND HEPATITIS POLICY INSTITUTE *et al.*,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES *et al.*,

Defendants.

Civil Action No. 1:22-cv-02604-JDB

DEFENDANTS' MOTION TO DISMISS FOR LACK OF STANDING

Pursuant to Federal Rule of Civil Procedure 12(b)(1), Defendants move to dismiss this action for lack of standing. The reasons for this motion are set forth in the Memorandum in Support of Defendants' Motion to Dismiss for Lack of Standing.

Dated: October 28, 2022

Respectfully submitted,

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MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FOR LACK OF STANDING

INTRODUCTION

Plaintiffs, three healthcare advocacy organizations, challenge a rule promulgated by the Centers for Medicare & Medicaid Services ("CMS") addressing the effect of manufacturer financial assistance for prescription drugs (through coupons, discount cards, or otherwise) on the cost-sharing limitations applicable under the Affordable Care Act for an individual enrolled in a covered plan. The challenged rule provides that amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs, whether or not generic equivalents are available and subject to state law, "may be, but are not required to be, counted toward the annual limitation on cost sharing" applicable to that enrollee's insurance plan. 45 C.F.R. § 156.130(h). Plaintiffs claim that this rule is contrary to statute, inconsistent with existing regulations, and arbitrary and capricious in violation of the Administrative Procedure Act ("APA").

Plaintiffs' claims should be dismissed for lack of subject-matter jurisdiction. Plaintiffs have not credibly alleged—as it is their burden to do—that they have the requisite Article III standing. Specifically, plaintiffs have not alleged that the new rule causes any concrete, nonspeculative injury to their organizational activities sufficient to give them standing to bring suit on their own behalf. And, while two of the plaintiffs, Diabetes Patient Advocacy Coalition ("DPAC") and Diabetes Leadership Council ("DLC"), suggest they may also claim standing to bring suit on behalf of their members, they fail to identify a single member who is detrimentally injured by the challenged rule and whose injuries would be remedied by the relief plaintiffs seek. Accordingly, they have not met their burden to establish standing on this basis. Therefore, this case should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(1).

BACKGROUND

I. STATUTORY BACKGROUND

In 2010 Congress enacted the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (the "Affordable Care Act"), which, among other things, generally required employer-sponsored group health plans and health insurers to ensure that any annual cost-sharing imposed under their plans does not exceed specified limitations. *See* 42 U.S.C. §§ 300gg-6(b), 18022(c)(1). Cost-sharing is defined to include "deductibles, coinsurance, copayments, or similar charges; and . . . any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of Title 26) with respect to essential health benefits covered under the plan." *Id*. § 18022(c)(3).

II. THE 2020 RULE

In 2019, CMS proposed changes to the cost-sharing limitations applicable under the Affordable Care Act to address the effect of manufacturer financial assistance for prescription drugs (through coupons, discount cards, or otherwise). *See* Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020, 84 Fed. Reg. 227, 290-91 (proposed Jan. 24, 2019). CMS noted that "[d]rug manufacturers often offer coupons to patients to reduce patient out-of-pocket costs," for example, "[t]o compete with another brand name drug in the same therapeutic class, to compete with a generic equivalent when released, or to assist consumers whose drug costs would otherwise be extremely high due to a rare or costly condition." *Id.* at 290; *see also* Compl. ¶¶ 8, 30. However, CMS found that "the availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. . . . Such coupons

can add significant long-term costs to the health care system that may outweigh the short-term benefits of allowing the coupons, and counter-balance issuers' efforts to point enrollees to more cost-effective drugs." 84 Fed. Reg. at 290.

CMS further noted that the Affordable Care Act "does not speak directly to the accounting and use of drug manufacturer coupons to the annual limitation on cost sharing." 84 Fed. Reg. at 290. And, as CMS later explained, prior to this point, "federal rules did not explicitly state whether issuers and group health plans had the flexibility to determine how to factor in direct drug manufacturer support amounts towards the annual limitation on cost sharing"—though some states had passed laws on the issue. Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans, 85 Fed. Reg. 29,163, 29,232 (May 14, 2020); 84 Fed. Reg. at 290 & n.143. Nevertheless, many insurance companies had already adopted "copay accumulator adjustment programs"—or "copay accumulator programs"—through which amounts paid on behalf of an enrollee through manufacturer assistance were not counted towards the enrollee's annual cost-sharing limit. *See* Compl. ¶¶ 9-10, 33.

Accordingly, CMS proposed a new regulation that would provide that, for plan years beginning on or after January 1, 2020, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to reduce or eliminate out-of-pocket costs for prescription brand drugs with a generic equivalent were not required to be counted toward the annual limitation on cost sharing, subject to state law. 84 Fed. Reg. at 291.

Following receipt and consideration of comments, CMS finalized this new regulation, as modified, "to allow issuers and plans to exclude drug manufacturer coupons from counting toward the annual limitation on cost sharing when a medically appropriate generic drug is

available," subject to applicable state law. Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020, 84 Fed. Reg. 17,454, 17,456 (Apr. 25, 2019) (the "2020 Rule"); *see also id.* at 17,544-46, *codified at* 45 C.F.R. § 156.130(h)(1). As then finalized, 45 C.F.R. § 156.130(h) read as follows:

> § 156.130 Cost-sharing requirements.
>
> . . .
>
> (h) Use of drug manufacturer coupons. For plan years beginning on or after January 1, 2020:
>
> (1) Notwithstanding any other provision of this section, and to the extent consistent with state law, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to enrollees to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have an available and medically appropriate generic equivalent are not required to be counted toward the annual limitation on cost sharing (as defined in paragraph (a) of this section).

84 Fed. Reg. at 17,567-68. Essentially, the 2020 Rule expressly permitted the use of copay accumulator programs by insurers, subject to applicable state law—but only with respect to drugs for which a generic alternative was available and medically appropriate. In the rule's preamble, CMS emphasized that "issuers may, but are not required to, undertake the option to exclude manufacturer coupons from counting towards the annual limitation on cost sharing" in those circumstances. *Id.* at 17,546. CMS also stated that, with respect to drugs for which there was no available and medically appropriate generic equivalent, "amounts paid toward cost sharing using any form of direct support offered by drug manufacturers *must* be counted toward the annual limitation on cost sharing." *Id.* at 17,545 (emphasis supplied).

III. THE 2021 RULE

The next year, CMS again proposed changes to the policy regarding how drug manufacturer financial assistance affects an enrollee's annual limitation on cost sharing. Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans, 85 Fed. Reg. 7,088, 7,090 (proposed Feb. 6, 2020). Specifically, CMS proposed to revise 45 C.F.R. § 156.130(h) "to state that, to the extent consistent with applicable state law, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs," whether or not generic equivalents were available, "may be, but are not required to be, counted toward the annual limitation on cost sharing." *Id.* CMS noted that, since finalizing § 156.130(h)(1), it had received feedback indicating "there was confusion about whether § 156.130(h), as finalized, requires plans and issuers to count the value of drug manufacturers' coupons toward the annual limitation on cost sharing, other than in circumstances in which there is a medically appropriate generic equivalent available." *Id.* at 7,135. CMS further noted that HHS and the Departments of Labor and the Treasury had released FAQs acknowledging this confusion, as well as the possibility that the requirement could create a conflict with certain rules for high-deductible health plans. *Id.* CMS proposed to resolve that conflict by revising § 156.130(h) to give plans and issuers the flexibility, subject to applicable state law, to determine whether to include or exclude amounts of manufacturer support from the annual limitation on cost sharing, regardless of whether a generic equivalent is available. *Id.* at 7,136.

Following receipt and consideration of comments, CMS finalized the revised regulation as proposed, with one minor modification of the title to make it clear it applied not just to drug

manufacturer "coupons" but to any form of "direct support provided by drug manufacturers." 85 Fed. Reg. at 29,230-32 (the "2021 Rule").

The current version of 45 C.F.R. § 156.130(h) now reads as follows:

§ 156.130 Cost-sharing requirements.

. . .

> (h) Use of direct support offered by drug manufacturers. Notwithstanding any other provision of this section, and to the extent consistent with State law, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs may be, but are not required to be, counted toward the annual limitation on cost sharing, as defined in paragraph (a) of this section.

CMS explained that this current regulation would enable issuers and group health plans "to continue longstanding practices with regard to how and whether drug manufacturer coupons accrue towards an enrollee's annual limitation on cost sharing." 85 Fed. Reg. at 29,231. Essentially, the current rule expressly permits insurers to use copay accumulator programs with respect to any drug, whether or not it has a generic equivalent, subject to relevant state law.

Plaintiffs, three healthcare advocacy organizations, have now filed the present suit challenging the 2021 Rule.

LEGAL STANDARDS

Defendants move for dismissal of the Complaint under Federal Rule of Civil Procedure 12(b)(1), on the ground that the plaintiffs lack standing and that the Court accordingly lacks subject-matter jurisdiction. On a motion to dismiss under Rule 12(b)(1), a plaintiff bears the burden of establishing the court's jurisdiction. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). However, a court is obliged to accept "as true all of the factual allegations contained in the complaint and draw[] all inferences in favor of the nonmoving party." *Hemp Indus. Ass'n v.*

Drug Enf't Admin. 36 F.4th 278, 288 (D.C. Cir. 2022) (citation and internal quotation marks omitted).

At the pleading stage, a complaint need only contain "sufficient factual matter, accepted as true, to state a claim [of standing] that is plausible on its face." *Kareem v. Haspel*, 986 F.3d 859, 866 (D.C. Cir. 2021) (internal quotation marks omitted; alteration in original), *cert. denied*, 142 S. Ct. 486 (2021). However, "standing cannot be inferred argumentatively from averments in the pleadings, . . . but rather . . . it is the burden of the party who seeks the exercise of jurisdiction in his favor . . . clearly to allege facts demonstrating that he is a proper party to invoke judicial resolution of the dispute." *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 231 (1990) (citations and internal quotation marks omitted). The court does "not assume the truth of legal conclusions, nor do[es it] accept inferences that are unsupported by the facts set out in the complaint." *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 913 (D.C. Cir. 2015) (quoting *Arpaio v. Obama*, 797 F.3d 11, 19 (D.C. Cir. 2015)) (citations and internal quotation marks omitted).

ARGUMENT

THE CASE SHOULD BE DISMISSED BECAUSE PLAINTIFFS LACK STANDING

The doctrine of constitutional standing, an essential aspect of the Article III case-or-controversy requirement, demands that a plaintiff have "a personal stake in the outcome of the controversy [so] as to warrant his invocation of federal-court jurisdiction." *Warth v. Seldin*, 422 U.S. 490, 498 (1975) (citation and internal quotation marks omitted). At its "irreducible constitutional minimum," the doctrine requires a plaintiff, as the party invoking the Court's jurisdiction, to establish three elements: (1) a concrete and particularized injury-in-fact, either actual or imminent; (2) a causal connection between the injury and defendants' challenged

conduct, such that the injury is fairly traceable to the challenged action of the defendants; and (3) a likelihood that the injury suffered will be redressed by a favorable decision. *Defs. of Wildlife*, 504 U.S. at 561. The party invoking federal jurisdiction bears the burden of establishing these elements. *Id.*

It appears that the three plaintiff organizations claim standing to sue on their own behalf, and that plaintiffs DPAC and DLC also may claim standing on behalf of their members. Compl. ¶¶ 15-17. To bring suit on its own behalf, an organization must itself meet the requirements for standing. *See Havens Realty Corp. v. Coleman*, 455 U.S. 363, 378 (1982). To establish standing to bring suit on behalf of its members (representational or associational standing), an organization must demonstrate that "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Ass'n of Flight Attendants–CWA v. U.S. Dep't of Transp.*, 564 F.3d 462, 464 (D.C. Cir. 2009) (citations and internal quotation marks omitted). As discussed further below, the three plaintiff organizations have not alleged any injury to their organizational interests and thus fail to establish that they have standing to sue on their own behalf. DPAC and DLC also have not alleged a sufficiently concrete and nonspeculative injury-in-fact to any of their members to confer representational standing. Accordingly, none of the plaintiffs has established Article III standing, and the Complaint should be dismissed.

A. Plaintiff Organizations Lack Standing to Sue on Their Own Behalf As They Allege No Injury to Their Organizations

To establish standing to sue on its own behalf, an organizational plaintiff must demonstrate "concrete and demonstrable injury to the organization's activities . . . . [T]he

organization must allege that discrete programmatic concerns are being directly and adversely affected by the challenged action." *Common Cause v. Fed. Election Comm'n*, 108 F.3d 413, 417 (D.C. Cir. 1997) (quoting *Nat'l Taxpayers Union, Inc. v. United States*, 68 F.3d 1428, 1433 (D.C. Cir. 1995)). "To allege an injury to its interest, 'an organization must allege that the defendant's conduct perceptibly impaired the organization's ability to provide services in order to establish injury in fact.'" *Food & Water Watch, Inc*., 808 F.3d at 919.

The Complaint does not contain any such allegations on behalf of any of the three plaintiff organizations. HIV and Hepatitis Policy Institute ("HHPI") states that it is a "national policy and advocacy organization working to promote quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions." Compl. ¶ 15. The Complaint then asserts only that HHPI "has a distinct interest in ensuring that the Affordable Care Act's provision for an annual limit on cost-sharing is fully implemented." *Id.* DPAC states only that it is an "alliance of people with diabetes, caregivers, patient advocates, health professionals, diabetes organizations and companies, working collaboratively to promote and support public policy initiatives to improve the health of all 37 million Americans with diabetes." *Id.* ¶ 16. And DLC merely alleges that it "unites former leaders of national diabetes organizations" and is "dedicated to securing effective, affordable health care and a discrimination-free environment for every person with diabetes." *Id.* ¶ 17.

Thus, the Complaint is noticeably free of any allegations that the three plaintiff organizations have themselves suffered a concrete, demonstrable injury to their organizational activities as a result of the 2021 Rule. At most, the Complaint alleges that they may be suffering injuries to their abstract general interests, *e.g*., in ensuring their preferred implementation of the Affordable Care Act and in securing their preferred healthcare policy for persons with certain

chronic health conditions. But asserted injuries to such abstract interests are not sufficient to confer standing. To establish injury-in-fact, a plaintiff must show that the defendant's action affects him in a "particularized," that is, an "individual" way. *Defs. of Wildlife*, 504 U.S. at 560 & n.1. "[A] plaintiff must have more than 'a general interest common to all members of the public.'" *Lance v. Coffman*, 549 U.S. 437, 440 (2007) (citation omitted). Rather, the question is whether the plaintiff will suffer an individual injury "beyond [a] generalized grievance—an injury that is concrete, particularized, and imminent rather than 'conjectural or hypothetical.'" *Carney v. Adams*, 141 S. Ct. 493, 499 (2020) (citation omitted). Thus, with regard to organizational plaintiffs, "[a]n organization must allege more than a frustration of its purpose because frustration of an organization's objectives 'is the type of abstract concern that does not impart standing.'" *Food & Water Watch, Inc*., 808 F.3d at 919. The Supreme Court has made it clear that "a mere 'interest in a problem,' no matter how longstanding the interest and no matter how qualified the organization is in evaluating the problem, is not sufficient by itself to render the organization 'adversely affected' or 'aggrieved' within the meaning of the APA." *Sierra Club v. Morton*, 405 U.S. 727, 734–35 (1972).

The plaintiff organizations here assert no concrete, particularized injury to their organizational activities but rather rely only on their general organizational purposes as the sole basis for standing. That theory is insufficient to establish Article III standing, and their claims should therefore be dismissed. *See Sierra Club*, 405 U.S. at 736 (holding that the Sierra Club's longstanding concern with and expertise in environmental issues were not sufficient to give it standing to challenge recreational development in Sequoia National Park); *Food & Water Watch*, 808 F.3d at 920-21 & n.9 (holding that advocacy organization's concern that agency's poultry

inspection policy was inconsistent with organization's food safety mission too abstract an injury to support standing).

B. Plaintiffs DPAC and DLC Lack Standing to Sue on Behalf of Their Members As They Allege No Particularized Injury to Specific Members

DPAC and DLC suggest that they may be claiming standing to sue on behalf of their members as well as on their own behalf. *See* Compl. ¶¶ 16-17. To pursue standing on this basis, they must allege that "at least one of [each organization's] members would have standing to sue."[1] *Sierra Club v. EPA*, 754 F.3d 995, 999 (D.C. Cir. 2014). "[I]t is not enough" for the association "to aver that unidentified members have been injured." *Chamber of Com. of U.S. v. EPA*, 642 F.3d 192, 199 (D.C. Cir. 2011). Rather, "an organization bringing a claim based on associational standing must show that at least one specifically-identified member has suffered an injury-in-fact." *Am. Chemistry Council v. Dep't of Transp.,* 468 F.3d 810, 820 (D.C. Cir. 2006). Neither DPAC nor DLC sufficiently allege that they have identifiable members who have suffered a concrete and particularized injury-in-fact from the 2021 Rule and who would have individual standing. In the absence of sufficient allegations of a member with such standing, these organizations have failed to establish that they have standing to sue on behalf of their members.

DLC asserts only that it "is comprised of people with diabetes, parents of children with diabetes," as well as allies and volunteers. Compl. ¶ 16. But DLC completely fails to allege that

[1] Given the brevity of plaintiffs' allegations, defendants cannot at present assess whether they have alleged sufficient "pertinence between litigation subject and organizational purpose." *See Humane Soc'y of the U.S. v. Hodel*, 840 F.2d 45, 58 (D.C. Cir. 1988). Defendants do not contest that DPAC and DLC meet the last requirement for representational standing, that neither the claims asserted nor the relief requested requires the participation of individual members in the lawsuit. *See Ass'n of Flight Attendants–CWA*, 564 F.3d at 464.

any individual members have been adversely affected by the 2021 Rule. It may be, as plaintiffs imply throughout the Complaint, that some diabetes patients are adversely affected by the copay accumulator programs that are now expressly authorized by the 2021 Rule and that this is the theory on which DLC is claiming standing (though DLC fails to allege even this much). However, any such speculation about the "statistical probability that some of [an organization's] members are threatened with concrete injury" is not sufficient to confer standing. *Summers v. Earth Island Inst.*, 555 U.S. 488, 497 (2009). "It is not enough to show . . . that there is a substantial likelihood that at least one member [of the association] may have suffered an injury-in-fact." *Am. Chemistry Council*, 468 F.3d at 820. Rather, the courts "require[] plaintiffs claiming an organizational standing to identify members who have suffered the requisite harm." *Summers*, 555 U.S. at 499. DLC makes no attempt to meet this straightforward standard here and therefore it has failed to show it has standing to assert claims on behalf of its members. *See Pub. Citizen, Inc. v. Trump*, 297 F. Supp. 3d 6, 18 (D.D.C. 2018) (holding that plaintiffs lacked standing to challenge certain actions where "they have made no effort—either in their complaint or in the multiple declarations they have submitted—to identify a specific member who has suffered, or who is likely to suffer, an injury in fact" from those actions).

In contrast to DLC, DPAC does allege that its members include "patients with diabetes who utilize manufacturer assistance and are harmed by copay accumulator programs." Compl. ¶ 16. However, even the latter allegations fail to sufficiently establish that the 2021 Rule itself has injured one of DPAC's members. First, DPAC fails to identify a specific member or members who have been so injured. *See Am. Chemistry Council.,* 468 F.3d at 820 ("[A]n organization bringing a claim based on associational standing must show that at least one specifically-identified member has suffered an injury-in-fact."). Second, DPAC's generalized

allegation of harm *from copay accumulator programs* does not sufficiently plead that at least one of its members has suffered an injury *from the 2021 Rule itself*. This is because (1) the 2021 Rule implemented a change from the 2020 Rule only with regard to manufacturer assistance for drugs without generic equivalents and (2) the members'ultimate experiences depend on actions taken, or not taken, by third parties—their insurers or plan administrators, as well as states. To establish standing, a plaintiff must allege that his injury is "fairly . . . trace[able] to the challenged action of the defendant." *Defs. of Wildlife*, 504 U.S. at 560 (citation and internal quotation marks omitted). However, "[w]hen the plaintiff is not himself the object of the government action or inaction he challenges," but the "asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of *someone else*," as is the case here, this element is "'substantially more difficult' to establish." *Id*. at 562. In such circumstances "it becomes the burden of the plaintiff to adduce facts showing that those choices have been or will be made in such manner as to produce causation and permit redressability of injury." *Id.*

DPAC has not met that burden here. DPAC's allegations do not state that its members who are allegedly harmed by copay accumulator programs are so harmed with regard to a drug which has no generic equivalents, that is, that their insurers or plans have chosen to implement a copay accumulator program in such a situation—much less that the member in fact needed to pay more for drugs or suffered some other particularized injury germane to DPAC's purposes because of that copay accumulator program. In other words, the allegations fall short of establishing that the 2021 Rule has itself adversely impacted a specific member. DPAC's allegations are therefore insufficient to establish that it has at least one member who himself or herself has suffered a concrete, particularized injury from the 2021 Rule and therefore has

standing to sue in his or her own right. Accordingly, DPAC has also failed to meet its burden to establish that it has standing to sue on behalf of its members. *See Am. Chemistry Council*, 468 F.3d at 819 (stating that "[it] is not enough to allege that petitioners' associations comprise the majority of the workers who handle hazardous materials"; rather, the associations must show that "at least one member of the association faces imminent dangers because, for example, he or she has "been or will be working in specific areas with safety concerns"); *Sierra Club v. EPA*, 292 F.3d 895, 901-02 (D.C. Cir. 2002) (holding that allegations that some of plaintiff's members "live, work, and recreate in communities adversely affected by the chemical plants," along with lists of members' addresses, were insufficient to establish the necessary fact that "at least one member of the organization lived at the time of filing and continues to live in a place affected by the Rule").

CONCLUSION

For the foregoing reasons, the Complaint should be dismissed for lack of standing.

Dated: October 28, 2022

Respectfully submitted,

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[PROPOSED] ORDER GRANTING DEFENDANTS' MOTION TO DISMISS FOR LACK OF STANDING

Upon consideration of the Defendants' Motion to Dismiss for Lack of Standing, the response and reply thereto, and the entire record herein, it is hereby

ORDERED that, for the reasons set forth in Defendants' Motion, Defendants' Motion be and hereby is **GRANTED**; and it is further

ORDERED that the case be and hereby is **DISMISSED WITH PREJUDICE**.

So ordered on this _____ day of _____, 2022.

_____
JOHN D. BATES
United States District Judge