UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

BRIAN WARD,
Plaintiff,

vs. Case No.: 3:25cv930/TKW/ZCB

DEPARTMENT OF HEALTH & HUMAN SERVICES, et al.,
Defendants.
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REPORT AND RECOMMENDATION

Plaintiff, proceeding *pro se*, commenced this action by filing a complaint against the Department of Health and Human Services, Robert Kennedy, Jr., the Food and Drug Administration, and Martin Makary. (Doc. 1). He paid the filing fee. (*Id.*). In his complaint, Plaintiff seeks to invalidate 21 C.F.R. § 50.22, which he claims authorizes the government to conduct secret "biomedical experimental studies" on unsuspecting Americans. (*Id.* at 1, 48-68). Having reviewed the complaint, the Court believes dismissal is warranted for lack of standing.

"[A]n essential and unchanging part of the case-or-controversy requirement of Article III" is that the plaintiff must have standing. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). Standing requires a

personal stake in the case. A plaintiff "must make three showings to enjoy standing to sue in federal court: (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that [the defendants] likely caused his injury; and (iii) that a favorable judicial decision can likely redress his injury." *Polelle v. Florida Sec'y of State*, 131 F.4th 1201, 1208 (11th Cir. 2025) (cleaned up). Because standing involves this Court's Article III jurisdiction, the Court "must raise *sua sponte* any issues related to standing that [it] spot[s]." *Id.* at 1207; *see also Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 180 (2000) (recognizing courts have "an obligation to assure ourselves that [the plaintiff] had Article III standing at the outset of the litigation").

"The type of relief sought also bears on whether the plaintiff has standing." *Attala Cnty., Miss. Branch of NAACP v. Evans*, 37 F.4th 1038, 1042 (5th Cir. 2022). "[W]hen plaintiffs seek prospective relief to prevent future injuries, they must prove that their threatened injuries are 'certainly impending.'" *Jacobson v. Florida Sec'y of State*, 974 F.3d 1236, 1245 (11th Cir. 2020). In other words, the plaintiff must establish "a material risk" of future harm. *Muransky v. Godiva Chocolatier, Inc.*, 979

F.3d 917, 928 (11th Cir. 2020). Federal courts cannot "adjudicate hypothetical or abstract disputes," or "exercise general legal oversight of the Legislative and Executive Branches." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423-24 (2021).

Here, Plaintiff has failed to sufficiently allege that he has suffered a "concrete, particularized, and actual or imminent" injury. *Polelle*, 131 F.4th at 1208. Plaintiff alleges that he fears he will unknowingly be the subject of "biomedical experimental studies" by the government. (Doc. 1 at 1). Plaintiff, however, has not plausibly alleged that he faces a "certainly impending injury." For instance, he has not identified any current clinical investigations ongoing under 21 C.F.R. § 50.22, nor has he alleged sufficient facts to show that he personally is at a "material risk" of being selected to be a subject in such a study. Instead, he alleges that 21 C.F.R. § 50.22 has left "him vulnerable to grave physical, psychological, and constitutional injuries" and that Defendants "may conduct clinical investigations on him under the Regulation without his knowledge." (Doc. 1 at 44). Plaintiff's allegations are "conjectural and hypothetical." *Lujan*, 504 U.S. at 560; *see also Clapper v. Amnesty Int'l*, 568 U.S. 398, 411 (2013) (dismissing for lack of standing when plaintiffs

alleged that their communications with individuals in foreign countries *might* be intercepted, noting that "it is speculative whether the Government will imminently target communications to which [plaintiffs] are parties").

The Court provided Plaintiff with an opportunity to show cause why his case should not be dismissed for lack of standing. (Doc. 5). But Plaintiff's response (Doc. 6) has not alleviated the Court's concerns regarding his failure to establish standing. Plaintiff admits that it is unknown if and when he could be subject to a study under 21 C.F.R. § 50.22. (*Id.* at 3). These "[a]llegations of possible future injury are not sufficient." *Clapper*, 568 U.S. at 409. Moreover, under Plaintiff's view of standing, every American would have standing to challenge 21 C.F.R. § 50.22 because they *could be* subject to a secret clinical investigation. This is the exact type of generalized grievance the standing requirement is intended to prevent. *See Lujan*, 504 U.S. at 575-76 (describing the prohibition on "generalized grievances").[1]

[1] Plaintiff claims this Court is "impermissibly invert[ing] the burden" by requiring allegations of a more concrete, particularized, and imminent injury. (Doc. 6 at 3). But caselaw is clear that it is Plaintiff's burden to allege that he has suffered a "concrete, particularized, and actual or

Plaintiff argues that he has standing because he satisfies the "zone-of-interests" test. (Doc. 6 at 7-10). The "zone of interests" test is a prudential standing principle. *Valley Forge Christian Coll. v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 474-75 (1982). Prudential standing principles constitute additional barriers to standing; they are not an alternative route to establish Article III standing. *See id.* ("Beyond the constitutional requirements, the federal judiciary has also adhered to a set of prudential principles that bear on the question of standing."); *see also* Erwin Chemerinsky, *Federal Jurisdiction* 106-112 (7th ed. 2016) (describing that the "zone of interests" test is a prudential standing requirement that is applied "[a]ssuming that the constitutional standing requirements are met"); *Movimiento Democracia, Inc. v. Johnson*, 193 F. Supp. 3d 1353, 1368 (S.D. Fla. 2016) (recognizing that the "zone of interests" test is an "additional test" to be applied in some situations after the plaintiff has established Article III standing). Because Plaintiff has not met the constitutional standing requirements of Article III, the "zone of interests"

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imminent" injury. *TransUnion LLC*, 594 U.S. at 423-24. He has not done so.

standing doctrine is inapplicable and in no way saves Plaintiff's case from dismissal.

Accordingly, for the reasons above, it is respectfully **RECOMMENDED** that Plaintiff's case be **DISMISSED without prejudice** for lack of standing.

At Pensacola, Florida this 8th day of September 2025.

/s/ Zachary C. Bolitho
Zachary C. Bolitho
United States Magistrate Judge

Notice to the Parties

Objections to these proposed findings and recommendations must be filed within fourteen days of the date of the Report and Recommendation. Any different deadline that may appear on the electronic docket is for the Court's internal use only and does not control. An objecting party must serve a copy of the objections on all other parties. A party who fails to object to the magistrate judge's findings or recommendations contained in a report and recommendation waives the right to challenge on appeal the district court's order based on unobjected-to factual and legal conclusions. *See* 11th Cir. Rule 3-1; 28 U.S.C. § 636.